## Roldan, Lizette

**From:** Roldan, Lizette
**Sent:** Wednesday, March 16, 2011 8:26 AM
**To:** 'jmckee1@regionalhealth.com'
**Subject:** REQUEST FOR ADDITIONAL INFORMATION REGARDING CONTROL 574592

License No: 40-00238-04
Docket No.: 030-03231
Control No.: 574592

Dear Mr. Mckee

This is in reference to letter dated February 21, 2011 requesting an amendment for Nuclear Regulatory Commission License 40-00238-04. In order to continue our review, we need the following information:

1. In order to determine if Dr. Boyer is qualified as a preceptor, please provide a copy of the Texas Agreement State license where Dr. Arthur Boyer is explicitly named on the license for the use of 35.600.

We will continue our review upon receipt of this information. Please reply to my attention at the Region IV Office and refer to Mail Control No. 574592. Please respond to this e-mail by March 18, 2011. You may reply via PDF format, e-mail or by fax to 817-860-8263.

Sincerely,

*Lizette Roldán-Otero, Ph.D.*
Health Physicist
Nuclear Regulatory Commission
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011
Office: 817-276-6596
Fax: 817-860-8263

## Roldan, Lizette

**From:** JMckee1@regionalhealth.com
**Sent:** Wednesday, March 23, 2011 1:15 PM
**To:** Roldan, Lizette
**Subject:** RE: REQUEST FOR ADDITIONAL INFORMATION REGARDING CONTROL 574592
**Attachments:** ABoyerHDRletter.pdf; L00331a86-May2010.pdf

Lizette,

Attached please find the supporting documents for Dr. Arthur Boyer.

Jim Mckee
Medical Physicist
Radiation Safety Officer
John T. Vucurevich Regional Cancer Care Institute
353 Fairmont Blvd
Rapid City, SD 57701
(605) 719-2339
jmckee1@regionalhealth.com

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From: Roldan, Lizette [Lizette.Roldan@nrc.gov]
Sent: Wednesday, March 16, 2011 7:25 AM
To: McKee, James
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING CONTROL 574592

License No: 40-00238-04
Docket No.: 030-03231
Control No.: 574592

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Lizette Roldán-Otero, Ph.D.
Health Physicist
Nuclear Regulatory Commission
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Arlington, TX 76011
Office: 817-276-6596
Fax: 817-860-8263

SCOTT & WHITE
A WORLD OF HEALING™

March 21, 2011

To Whom It May Concern

Dr. Arthur Boyer has been an approved medical physicist (AMP) at Scott & White Healthcare under the broad scope radioactive materials license L00331 since June 2005, including HDR. Should you need additional information, please contact me.

Sincerely,

David M. Jones, MS, DABR, CHP
Radiation Safety Officer
Scott & White Healthcare
2401 S 31st Street
Temple TX, 76513

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, 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. This license is subject to all applicable rules, regulations and orders of the Agency now or hereafter in effect and to any conditions specified below.

| LICENSEE | This license is issued to correct an error |
|---|---|
| 1. Name: SCOTT AND WHITE MEMORIAL HOSPITAL AND SCOTT SHERWOOD AND BRINDLEY FOUNDATION<br>DBA SCOTT AND WHITE MEMORIAL HOSPITAL<br>ATTN DAVID M. JONES | 3. License Number: L00331 — Amendment Number: 86 |
| 2. Address: 2401 SOUTH 31 ST STREET<br>TEMPLE TX 76508 | PREVIOUS AMENDMENTS ARE VOID |
| | 4. Expiration Date: June 30, 2014 |

## RADIOACTIVE MATERIAL AUTHORIZED

| 5. Radioisotope | 6. Form of Material | 7. Maximum Activity | 8. Authorized Use |
|---|---|---|---|
| A. Any radioactive with atomic number less than 84 | A. Any except sealed sources | A. 3 curies of any radioactive material, Total: 9 curies | A. Medical research, diagnosis and therapy. |
| B. Ra-226 | B. Sealed sources (Ser. No. 1-21) | B. 20 millicuries | B. Calibration of radiation therapy instrumentation. |
| C. Mo-99 | C. Tc-99m generators | C. 18 curies | C. Production of technetium-99m. |
| D. Tc-99m | D. Any | D. 18 curies | D. Medical research and diagnosis. |
| E. Gd-153 | E. Sealed sources (Lunar GD Series; IPL 3409, A3411) | E. No single source to exceed 1.5 curies Total: 2.12 curies | E. Medical diagnosis. |
| F. Cs-137 | F. Sealed source (Shepherd 6810; ORNL A-0096) | F. 1500 curies | F. Use in a J.L. Shepherd Model 143-45A blood irradiator. |
| G. Sr-90 | G. Sealed sources (Tech/Ops M-1; Atlantic Research Corp. B-1) | G. No single source to exceed 60 millicuries, Total: 80 millicuries | G. Medical therapy. |
| H. Pd-103 | H. Sealed source (seeds) | H. 1 curie | H. Medical therapy. |
| I. I-125 | I. Sealed source (seeds) | I. 1 curie | I. Medical therapy. |

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L00331 | 86 |

| 5. Radioisotope (continued) | 6. Form of Material (continued) | 7. Maximum Activity (continued) | 8. Authorized Use (continued) |
|---|---|---|---|
| J. Cs-137 | J. Sealed sources (3M 6D6C; A/S CDC.T1) | J. 1 curie | J. Medical therapy. |
| K. Ir-192 | K. Sealed source (seeds in nylon ribbon) | K. 500 millicuries | K. Medical therapy. |
| L. Gd-153 | L. Sealed line sources (NAS MED 3601; DuPont NES-8412; IPL A3410) | L. No single source to exceed 300 millicuries, Total: 1 curie | L. Transmission scanning of patients with an ADAC gamma camera equipped with a Vantage device and source replacement by properly trained personnel. |
| M. Ge-68/ Ga-68 | M. Sealed source (CTI LS Series) | M. No single source to exceed 10 millicuries, Total: 110 millicuries | M. Instrument calibration and transmission scanning of patients with a Siemens Positron Emission Tomography (PET) scanner equipped with a CPS model ECAT EXACT Series device. |
| N. Ge-68/ Ga-68 | N. Sealed source (CTI LS Series) | N. No single source to exceed 10 millicuries Total: 60 millicuries | N. Instrument calibration and transmission scanning of patients with a Siemens Positron Emission Tomography (PET) scanner equipped with a CTI model ECAT ACCEL Series device. |
| O. F-18 | O. sodium fluoride (saline solution) | O. 200 millicuries | O. Instrument calibration and reference source. |
| P. Ge-68/ Ga-68 | P. Sealed source (IPL A3407 Series) | P. No single source to exceed 13 millicuries, Total: 104 millicuries | P. Instrument calibration and transmission scanning of patients with a GE Advance 4.0 PET Imaging System. |
| Q. Ir-192 | Q. Sealed source (MAL/AEA 105.002) | Q. Two sources not to exceed 12 curies and no source to exceed 10 curies at installation, Total: 20 curies | Q. One source for treatment of humans with a Nucletron-HDR Model 105.999 – high dose rate afterloader (HDR) and the other source in its authorized shipping container during periods of source exchange. |
| R. Y-90 | R. Sealed source (microspheres in solution) | R. 1 curie | R. Interstitial treatment of cancer as indicated in 25 TAC §289.256(kk). |

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L00331 | 86 |

9. Radioactive material shall be used only at:

| A. Site Number | Location |
|---|---|
| 000 | Temple - 2401 South 31st Street |
| 001 | College Station - Bryan/College Station Clinic, 1600 University Drive |
| 002 | Temple – 5701 Airport Road |

**B. The authorized place of use for the Scott & White mobile PET coach is at facilities within the Scott & White Healthcare network.**

10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 000, except those required by 25 TAC §201(d) that are directly related to radioactive materials for human-use and unsealed reference sources for instrument calibration, 25 TAC §202(nn), and 25 TAC §202(tt).

11. The licensee shall comply with the provisions (as amended) of 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252, §289.256 and §289.257.

12. A. Radioactive material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee (RSC), Michael L. Nipper, M.D., Chair. Individuals authorized to serve on this committee are:

| | |
|---|---|
| David M. Jones | RSO/Medical Services |
| Alan Y. C. Cheung, M.D. | Radiation Oncology |
| Michael L. Middleton, M.D. | Diagnostic Radiology |
| Michael L. Nipper, M.D., Chair | Radiology |
| E.S. Rappaport, M.D. | Hematology/Clinical Pathology |
| Kathryn Hunnicutt, BSN | Nursing |
| Wayne T. Stockburger, JD | Executive Director, Imaging |

B. For purposes of conducting meetings of the RSC, a quorum shall include but may not necessarily be limited to the Chair of the RSC, the RSO, and the representative from management.

13. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is David M. Jones

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

15. The licensee shall not open or remove sealed sources containing radioactive material from their respective source holders.

16. A. Sealed sources of radioactive material, Ni-63 foil, and/or plated alpha-emitting sources shall be tested for leakage and/or contamination in accordance with the provisions of 25 TAC §289.201(g).

B. Leak test analyses may be performed by, or under the supervision of, David M. Jones.

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L00331 | 86 |

16. (continued)

C. The periodic leak test required by 25 TAC §289.201(g) does not apply to sealed sources that are stored and exempted by that rule. The sources exempted 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.

17. All radioactive material to be used in humans shall either be of radiopharmaceutical grade or shall be in the form of sealed sources, evaluated and approved for use in humans by the United States Nuclear Regulatory Commission (NRC) or the Agreement State in which they are produced.

18. Radioactive material shall not be used in humans until its pharmaceutical quality and assay have been established.

19. Research protocols which use procedures other than those specified in product labeling must be approved by a duly constituted Institutional Review Board.

20. Unless authorized in condition 8 above, installation or replacement of sources resident in an imaging scanner shall be performed by the scanner manufacturer or a service company authorized to perform these services under the auspices of a current State of Texas, U.S. Nuclear Regulatory Commission (NRC), Agreement state or Licensing state radioactive material license. Non-state of Texas licensees shall apply for and receive reciprocal recognition of their license prior to performing activities involving the use of radioactive materials in Texas. Documentation of this authorization shall be maintained by the licensee for Agency review.

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

21. Experimental animals administered radioactive materials or their products shall not be used for human consumption.

23. A current copy of the licensee's radiation safety manual shall be provided to each person who uses radioactive material authorized by this license.

24. Proposed substantive changes in or additions to the licensee's radiation safety manual shall be submitted to the Agency for approval before being incorporated into that document.

25. Proposed new members to the licensee's Radiation Safety Committee shall be identified to the Agency by name and department, and their membership approved prior to their participation as full-voting members in the committee's deliberations. Interim appointments for replacements of departing members may be made by executive management, pending Agency approval, when the interim appointee has been identified to the Agency and represents the same department as did the departing member.

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L00331 | 86 |

26. The licensee shall not open or remove sealed sources containing radioactive material from the blood irradiator.

27. The manufacturer's instruction manual for the Shepherd blood irradiator shall be followed when using the device. A copy of it shall be made available to all persons using the device.

28. In addition to authorizations of Conditions 5, 6, 7, and 8, the licensee is here by authorized the possession and use of reference sources for diagnostic instrument calibration, as described by 25 TAC §289.256 (s).

29. The licensee shall maintain a current copy of the safety evaluation from "The Registry of Radioactive Sealed Sources and Devices" for each sealed source received under authority of this license, in excess of 100 microcuries of beta/gamma-emitting material or 10 microcuries of alpha-emitting material.

30. Written instructions shall be posted at each HDR/IVB unit control panel. The instructions must inform the HDR/IVB operator of procedures to follow if the source(s) fail to return on command to a shielded position. The instructions must further caution individuals to avoid exposure to a source in an unshielded position. The instructions must further caution individuals to avoid exposure to the highest radiation fields when in the treatment room and specifically indicate how to:

    A. Locate and use the device to manually return the HDR/IVB source(s) to a shielded position while taking note of the time.

    B. Remove the patient from the treatment room.

    C. Secure the room against unauthorized entry.

    D. Notify the responsible physician or RSO.

31. All maintenance on the HDR unit which involves the source, source shielding or beam control mechanism, safety circuits, control panel electrical circuits, or other mechanisms that could compromise safety of the unit shall only be performed by the unit's manufacturer or by other persons specifically licensed to perform such services by this Agency, an Agreement State, or by the NRC. Calibration and quality control procedures may be performed by the licensee provided the unit is under the direct control of an individual authorized by the RSC.

32. Prior to initiation of a treatment program, and subsequent to each exchange of a therapy source, radiation surveys and tests shall be performed in accordance with the following requirements.

    A. A radiation survey shall be made of:

        1. The HDR source housing, with the therapy source(s) in the "off" or shielded position. The maximum radiation levels at 20 centimeters from the surface of the source housing shall not exceed 6.25 milliroentgens per hour.

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L00331 | 86 |

32. (continued)

2. All areas adjacent to the treatment room, with the maximum source activity to be used in any treatment in the "on" or therapy position. The survey shall clearly establish:

   a. Radiation levels in restricted areas do not exceed the limits of 25 TAC 289.202(f).
   b. Radiation levels in unrestricted areas do not exceed the limits of 25 TAC 289.202(n).

B. Tests shall be made to determine proper operation of:

1. Electrical interlocks on entrance doors to each therapy room.
2. The therapy source "on-off" indicators, both at the source housing (if present) and on the therapy machine control panel.
3. Electrical or mechanical restraints on machine or source locating during therapy.
4. The therapy machine timing device.

C. A report of the results of the above surveys and tests shall be maintained by the licensee for inspection by the Agency.

33. Any change made in treatment room shielding, location, or use of a HDR which could result in an increase in radiation levels in unrestricted areas outside a therapy treatment room, and made subsequent to the completion of the initial radiation survey performed in accordance with Condition 32, shall be evaluated by a radiation survey performed in accordance with Section A. Item 2. of Condition 32. A report describing the change(s), and giving the results of the survey(s), shall be sent to the Agency, not later than 30 days following completion of such changes.

34. The licensee shall cease treatment of patients when any safety related system of a HDR unit is found inoperative, including the source drive mechanism, treatment timing system, safety interlocks and radiation field alarms. The licensee shall report to the Agency, any malfunction that requires termination of patient treatment for more then 24 hours and submit a written report of the incident and corrective actions within seven calendar days.

35. Technologists working under this license shall have training and experience as described in Agency Regulatory Guide 3.1.

36. The RSO or an authorized physician user (APU) shall review technologist handling of radioactive materials at least once per month to confirm proper radiation safety procedures.

37. The licensee shall comply with the requirements described in U. S. Nuclear Regulatory Commission's (NRC) Order EA-07-305 (the Order), with attachments. The requirements listed in the Order shall be implemented as part of the trustworthiness and reliability program of the Increased Controls requirements.

Department of State Health Services

# RADIOACTIVE MATERIAL LICENSE

| LICENSE NUMBER | AMENDMENT NUMBER |
|---|---|
| L00331 | 86 |

37. (Continued)

A. By May 28, 2008, the licensee shall provide under oath or affirmation, a certification that the Trustworthiness and Reliability Official (TRO) is deemed trustworthy and reliable by the licensee as required in paragraph B.2. of the Order.

B. All fingerprints obtained by the licensee pursuant to this requirement must be submitted to the NRC for transmission to the U.S. Federal Bureau of Investigation (FBI). Additionally, the licensee's submission of fingerprints shall also be accompanied by a certification, under oath and affirmation, of the trustworthiness and reliability of the TRO as required by paragraph B.2. of the Order.

C. The licensee shall complete implementation of the fingerprinting requirements by August 27, 2008. The licensee shall notify DSHS - Radioactive Material Licensing Group, Manager when they have achieved full compliance with the requirements described in the Order. The notification shall be made within thirty (30) days after full compliance has been achieved.

D. The licensee shall notify Manager, Radioactive Material Licensing Group, DSHS at (512) 834-6688, ext. 2207 within 24 hours if the results from a criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Data Base.

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

application dated May 23, 2002,
letters dated May 24, 2002, June 21, 2003 (X2), July 11, 2003, July 17, 2003, November 11, 2003, November 15, 2004, April 28, 2005, February 23, 2005 (X2), April 14, 2005, June 10, 2005, July 1, 2005, October 11, 2007, January 26, 2010 and April 20, 2010

Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

PS:ps

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date May 12, 2010

J. Scott Kee, Program Coordinator
Medical and Academic Licensing Program