



www.southeastmissourihospital.com

June 11, 2008

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Reader:

Re: Amendment Request; NRC License Number 24-00128-03

We request amendment of our license as follows:

Item 1

We would like to remove Condition 19, requiring compliance with the Order for Increased Controls. To this end, we would like to modify our possession limits as follows to quantities that are below "Quantities of Concern".

Byproduct, source, and/or special nuclear material	Maximum amount that licensee may possess at any one time
D. Any byproduct material permitted by 10 CFR 35.400	1 curie
E. Any byproduct material permitted by 10 CFR 35.500	1 curie
F. Iridium-192, as permitted by 10 CFR 35.600	Two sources not to exceed 20 curies total*

*Authorized use to remain the same:

- F. *"One source for medical use, as permitted by 10 CFR 35.600, in a Varian Medical Systems High Dose Rate remote afterloading brachytherapy device. The source activity may not exceed 10 curies at the time of medical use. One source in its shipping container for source replacement."*

1701 Lacey Street • Cape Girardeau, MO 63701 • 1-800-455-4636
Radiation Oncology 573/651-5544 • Outpatient Chemotherapy 573/651-5550

RECEIVED JUN 17 2008

Item 2

We would like to modify a condition of our license, included in our license by reference to our letter dated August 5, 2003, regarding survey of patients treated with I-125 Iotrex in the Cytoc Surgical Products GliaSite® Radiotherapy System.

Previous condition

“Upon completing the Iotrex afterloading and during radiotherapy, radiation exposure rate measurements will be used to monitor for unexpected leakage of radioactive material from the GliaSite catheter. Radiation measurements will be performed at the injection site surface, 1 meter from the injection site, and over the patient’s bladder. These measurements will be repeated daily until the radioactive material is retrieved. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates concomitant with large increases in bladder exposure rates) will be documented and evaluated for further action as appropriate. The licensee will use a Model 36100 Keithley Exposure Rate Survey Meter to perform the ambient radiation level surveys.”

New condition

One method of assessing GliaSite integrity during brachytherapy that we may use (not exclusively though) is via radiation survey measurements. Upon completing the Iotrex afterloading and during brachytherapy, radiation exposure rate measurements will be used to monitor for unexpected leakage of radioactive material from the GliaSite catheter. Radiation measurements will be performed over the injection site surface (at 20 to 30 centimeters from the injection site), at 1 meter from the injection site, and perhaps over the patient’s bladder. These measurements will be repeated periodically until the radioactive material is retrieved. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates concomitant with large increases in bladder exposure rates) will be documented and evaluated for further action as appropriate.

The requested new condition is based on a model license application provided by the GliaSite vendor, which they have informed us has met with NRC approval. We wish to make this change to alleviate the difficulties encountered with performing daily surveys on patients that have been released, especially on weekends when our radiation therapy facility is closed. It is our understanding from the GliaSite vendor that the collective experience with GliaSite has shown that daily surveys are not normally necessary to ensure the safety of the patient and others.

Item 3

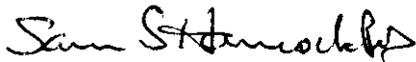
We wish to inform you, in accordance with 10 CFR 35.14, that William Johnson, M.D. has begun work as an authorized user under our license for use of Iridium-192 as permitted by

10 CFR 35.600 in a Varian Medical Systems High Dose Rate remote afterloading brachytherapy device.

Dr. William Johnson is an authorized user on California Radioactive Material License Number 5570-50 at OnCURE Medical Corp. (Copy Attached). He is authorized on this license for brachytherapy treatments utilizing sealed sources to be used in various models of HDR afterloaders.

If you have any questions regarding this matter, please feel free to contact Sam Hancock, PhD, Radiation Safety Officer, or Nick Schupp, Authorized Medical Physicist, at 573-651-5544.

Sincerely,

A handwritten signature in black ink that reads "Sam S. Hancock". The signature is written in a cursive style with a large, stylized initial "S".

Sam S. Hancock, Ph.D.
Radiation Safety Officer

cc: Pat Bira, Vice President

Enclosure: State of California Radioactive Material License Number 5570-50

**RECEIVED**

7/17/06

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the places(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee: OnCURE Medical Corp. dba Prigge Radiation Oncology Center of Modesto	3. License Number: 5570-50 Amendment Number: 30
2. Address: 1316 Nelson Avenue Modesto, CA 95350	4. Expiration date: February 14, 2009 (2)
Attention: J.B. Yu Zhang, Ph.D. Radiation Safety Officer	5. Inspection agency: Radiologic Health Branch North

In response to the letter dated April 27, 2006, signed by J.B. Yu Zhang, Ph.D., DABR, Radiation Safety Officer, License Number 5570-50 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Group 4 as specified in Item 9. 1. Strontium-89	A. Any	A. Total not to exceed 10 mCi.
B. Group 6 as specified in Item 9. 1. Iridium-192 2. Iridium-192 3. Strontium-90	B. 1. Sealed source (Nucletron Corporation Model 105.002) 2. Sealed source (CIS-US, Inc. Models 772 or 774 or Varian Medical Systems, Inc., Model Gammamed 212) 3. Applicator (Amersham SLA-20)	B. *1. Total not to exceed 20 Ci. No single source to exceed 13 Ci. *2. Total not to exceed 20 Ci. No single source to exceed 12 Ci. 3. Total 165 mCi in 3 sources, no single source to exceed 55 mCi. * Total possession limits for Items 1 and 2 not to exceed 20 Ci.
C. Group 9 as specified in Item 9. 1. Any radionuclide with atomic numbers 3-83, inclusive, except: Strontium-90 and Lead-210.	C. 1. Sealed or solid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State.	C. 1. Total not to exceed 10 mCi. Each source not to exceed 10 mCi.

RADIOACTIVE MATERIAL LICENSELicense Number: 5570-50Amendment Number: 30**9. Authorized Use**

To be used for nuclear medicine procedures as specified in groups below:

- A. Group 4 1. Palliative treatment.
- B. Group 6 Brachytherapy and Ophthalmic treatments utilizing sealed or solid sources manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Title 10, Code of Federal Regulations, Part 32.74, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent state regulations (except for sources manufactured prior to August 16, 1974).
1. To be used in a Nucletron Corporation Model 105.999 HDR Afterloader for brachytherapy treatments (12 Ci maximum source installed in device).
 2. To be used in a MDS Nordion, Inc. GammaMed 12it transportable HDR Afterloader for brachytherapy treatments.
 3. Applicator
- C. Group 9 Marker and calibration sources.

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following locations:
- (a) 1051 East Tuolumne, Turlock, CA.
 - (b) 1316 Nelson Avenue, Modesto, CA.
11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.
12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8, and 9 of this license as follows:
- | | |
|------------------------------|--------------------------------------|
| (a) Georg A. Weidlich, Ph.D. | Group 9 (physical measurements only) |
| (b) Vitune Vongtama, M.D. | Group 6 |
| (c) Peter K. Sien, M.D. | Group 6 |
| (d) J.B. Yu Zhang, Ph.D. | Group 9 (physical measurements only) |
| (e) Gary S. Young, M.D. | Groups 4 and 6 |
| (f) Amber E. Arlington, M.D. | Groups 4, 6 and 9 |
| (g) William Johnson, M.D. | Group 6 |
13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements,

RADIOACTIVE MATERIAL LICENSELicense Number: 5570-50Amendment Number: 30

representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- (a) The renewal application cover letter dated March 1, 1999 signed by Georg Weidlich, Ph.D., Radiation Safety Officer, with the attached renewal application and attachments, dated February 25, 1999, signed by John J. Fuery, M.D., Executive Medical Director, as supplemented by letter, with attachment, dated March 12, 1999, letter dated March 15, 1999, and letter, with attachments, dated March 16, 1999, all signed by Georg A. Weidlich, Ph.D., Radiation Safety Officer.
 - (b) The letters dated March 8, 2000, and May 1, 2000; and the letter, with attachments, dated April 20, 2000, all signed by Georg A. Weidlich, Ph.D., Radiation Safety Officer, regarding the replacement of the HDR transportable service with a fixed HDR.
 - (c) The letter, with attachments dated August 21, 2000, by Georg A. Weidlich, Ph.D., Radiation Safety Officer, regarding the removal of physical measurements from two sites.
 - (d) The duties, responsibilities and authority of the Radiation Safety Officer, with attachment, dated August 7, 2001, signed by Jerry Boyajian, Executive Director of Operations, and Robert J. Baker, Ph.D., DABR.
 - (e) The letter, with attachments, dated October 23, 2001, signed by Robert J. Baker, Ph.D., DABR, prior Radiation Safety Officer; the letter, with attached duties, responsibilities and statement of authority for the Radiation Safety Officer, dated December 18, 2001, the letter, with attached calibration certificate, dated December 18, 2001, the letter dated January 21, 2002, and the letter, with attached leak test certificate, dated March 2, 2002, all signed by Georg A. Weidlich, Ph.D., Radiation Safety Officer, regarding the removal of a use location and HDR for human use.
 - (f) The letter, with attachments, received September 19, 2002, regarding the duties, responsibilities and statement of authority of the Radiation Safety Officer and updated policies and procedures.
 - (g) The letter, with attachments, dated April 1, 2004, signed by Ramin Daryabary, Director of West Coast Operations, as modified by the letter dated May 11, 2004, signed by Ramin Daryabry, Director of West Coast Operations and J.B. Yu Zhang, Ph.D., Radiation Safety Officer, regarding the duties and responsibilities of and delegation of authority to the new Radiation Safety Officer.
 - (h) The letter, with attachments, dated September 1, 2004, signed by J.B. Yu Zhang, Ph.D., Radiation Safety Officer, regarding a name change.
 - (i) The letters, all with attachments, dated October 24, 2005, November 30, 2005, and March 1, 2006, all signed by J.B. Yu Zhang, Ph.D., Radiation Safety Officer, regarding the free release for unrestricted use of the 1 South Forest Road, Sonora, use location, the addition of the MDS Nordion, Inc. GammaMed 12it transportable HDR Afterloader, and a name change.
14.
 - (a) The Radiation Safety Officer in this program shall be J.B. Yu Zhang, Ph.D.
 - (b) The Chairperson of the Radiation Safety Committee shall be J.B. Yu Zhang, Ph.D.
 - (c) The Custodian of sealed sources shall be J.B. Yu Zhang, Ph.D.
 - (d) The Alternate Radiation Safety Officer in this program shall be Rui He, M.S.
 15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).

RADIOACTIVE MATERIAL LICENSELicense Number: 5570-50Amendment Number: 30

16. In lieu of the leak test intervals required by California Code of Regulations, Title 17, Section 30275 (c), sealed sources can be tested for leakage and/or contamination at longer intervals when they are specified in a certificate of registration issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. When a longer interval stipulated in a certificate of registration is used, the certificate must be maintained on file and available for inspection for as long as the associated leak test records are retained.
17. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:
 - (a) The Radiation Safety Officer
 - (b) Qualified individuals designated in writing by the Radiation Safety Officer
18. Except for alpha sources, the periodic leak test required by Condition 15 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.
19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.
20. The licensee may use one constancy source for the dose calibrator constancy test provided that the dose calibrator manual indicates that only one constancy source is needed for proper Quality Control.
21. The licensee may use any commercially available device, acceptable to the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, for doing linearity tests of its dose calibrator provided the procedures described by the manufacturer of the linearity device are followed.
22. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to Title 17, California Code of Regulations, Subchapter 4.6. Such procedures shall be performed under the supervision of authorized user physicians on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.
23. Notwithstanding the definition of "Misadministration" in title 17, 30100(j), and the requirements listed in title 17, section 30322, the Licensee shall notify and submit reports regarding "Medical Events," as defined in title 10, Code of Federal Regulations, Part 35, section 35.2, to the Department in accordance with title 10, Code of Federal Regulations, Part 35, section 35.3045.
24. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with the guidance from any of the following:
 - (a) Chapter 4, "Release from Hospital of Patients Containing Radioactive Material" National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).
 - (b) Appendix M in the "Guide for the Preparation of Applications for Medical Programs", State of California, Department of Health Services, Radiological Health Branch.
 - (c) Documented rationale or patient-specific calculations demonstrating that members of the general public will be limited to 500 mrem total effective dose equivalent from patients who have been released containing therapeutic quantities of radiopharmaceuticals.

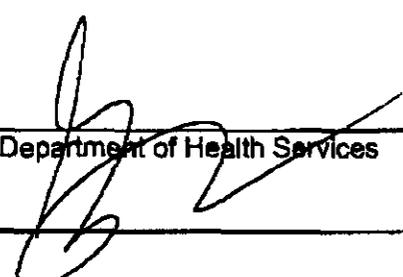
RADIOACTIVE MATERIAL LICENSELicense Number: 5570-50Amendment Number: 30

25. Treatment and management of patients undergoing brachytherapy shall be in accordance with the guidance from any of the following:
- Chapter 5, "Safety Precautions in Clinical Application", National Council on Radiation Protection and Measurements (NCRP) Report No. 40, "Protection Against Radiation From Brachytherapy Sources" (NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).
 - Appendix N in the "Guide for the Preparation of Applications for Medical Programs", State of California, Department of Health Services, Radiological Health Branch.
 - Documented rationale or patient-specific calculations demonstrating that members of the general public will be limited to 500 mrem total effective dose equivalent from patients who have been released containing therapeutic quantities of radionuclides.
26. Remote afterloading device facilities shall be so constructed as to permit continuous observation of patients from outside the treatment room(s).
27. Written emergency instructions shall be posted conspicuously at the remote afterloading device control(s). Instructions shall include directions for manually turning off the remote afterloading device(s), removing the patient, securing the room(s) against unauthorized entry, and notifying the responsible authorized user or the Radiation Safety Officer.
28. Electrical interlock(s) on entrance door(s) to the remote afterloading device room(s) shall be tested for proper operation at least once every month or prior to use (if used less frequently). Records of test results shall be maintained available for inspection.
29. If there is a reason to suspect that the source position indicator or entrance door(s) interlock(s) is/are not functioning properly, use of the remote afterloading device(s) shall be discontinued until the condition has been corrected. A record of any such malfunction shall be made and maintained available for inspection.
30. Special Requirements for Remote Afterloading Device Spot Checks and Calibration:
- At intervals not to exceed daily or prior to use (if used less frequently), the following tests shall be performed:
 - Source position indicator(s).
 - Source positioning reproducibility, to within ± 1 mm.
 - Inspection of guide tubes for kinks and other imperfections.
 - Timing device accuracy shall be performed at intervals not to exceed monthly or prior to each use (if used less frequently).
 - Source travel time error shall be performed at each source loading.
 - At each source loading and then at intervals not to exceed three months, one month for Ir-192, or prior to use (if used less frequently), the licensee shall determine the dose accuracy to within ± 5 percent.
31. Remote afterloading devices authorized by this license shall not be operated unless the licensee has in his possession detailed written instructions specific for the make and model of the remote afterloading device.
32. Each remote afterloading device shall be inspected and serviced in accordance with the manufacturer's recommendations.

RADIOACTIVE MATERIAL LICENSELicense Number: 5570-50Amendment Number: 30

33. For remote afterloading devices, specifically authorized personnel shall:
- (a) Install, relocate, maintain and repair devices containing radioactive material.
 - (b) Leak test, replace and dispose of sealed sources containing radioactive material used in devices.
34. Subsequent to each source loading, radiation surveys shall be performed prior to human use as follows:
- (a) A radiation survey shall be made of the unit source housing, with the source(s) in the shielded position. The maximum radiation levels at 20 centimeters from the surface of the source housing shall not exceed 3 milliroentgens per hour.
 - (b) Records of survey results shall be maintained for inspection.
35. Immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of each survey shall be maintained.
36. Treatment time calculations and data entry for remote afterloaders shall be individually verified by the responsible authorized user physician immediately prior to treatment.
37. Production or processing of radiopharmaceuticals for the purpose of commercial distribution to other licensees is not authorized by this license.
38. At least 30 days prior to vacating any address of use listed in Condition 10 of this license, the licensee shall provide written notification thereof to the Department of Health Services, in accordance with Title 17, California Code of Regulations, Section 30256.
39. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 1316 Nelson Avenue, Modesto, CA.

Issued for the State Department of Health Services

Date: June 3, 2006By: 

Gonzalo Perez
Radiologic Health Branch
MS 7610, P.O. Box 997414
Sacramento, CA 95899-7414

