



U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4352
Attn: Nuclear Materials Safety and Safeguards Division
Materials Licensing Branch

February 21, 2011

**Re: License No.: 24-13383-01
Christian Hospital
11133 Dunn Road
St. Louis, Mo 63136**

To Whom It May Concern:

In accordance with NRC Regulations 10 CFR 35.13 (License Amendments), we wish to amend NRC license 24-13383-01 as follows:

- 1) Add Jeff M. Michalski, M.D. as an Authorized user 10CFR35.400. Dr. Michalski is authorized on NRC license no. 24-00167-11. His authorization letter for the license is attached.
- 2) Add Joseph R. Simpson, M.D., Ph.D. as an Authorized user 10CFR35.400. Dr. Simpson is authorized on NRC license no. 24-00167-11. His authorization letter for the license is attached.
- 3) Add Marie A. Taylor, M.D. as an Authorized user 10CFR35.400. Dr. Taylor is authorized on NRC license no. 24-00167-11. Her authorization letter for the license is attached.
- 4) Please change the mailing address to the Department of Nuclear Medicine rather than the Department of Radiation Oncology as it appears now.

Should there be any further needed information or clarification, please direct questions to Lisa Tincher, RSO at 314-653-4350 or via email at ldt8892@bjc.org.

Sincerely,

Lisa D. Tincher, R.T. (R), (N), (M), CNMT
Radiation Safety Officer
Christian Hospital

RECEIVED APR 18 2011

 **Washington University in St. Louis**

Environmental Health and Safety

Radiation Safety Office

December 3, 2009

TO: Dr. Joseph R. Simpson, M.D., Ph.D.
BJ RO-Radiation Oncology, Dept.
Campus Box 8224

FROM: Susan M. Langhorst, Ph.D., CHP  for SML, RSO
Radiation Safety Officer
Executive Secretary, Radiation Safety Committee

SUBJECT: Authorization for Medical Use of Radioactive Materials

I am pleased to inform you that the Radiation Safety Committee - Authorizations Subcommittee granted approval for you to become a Co-Authorized User for one or more 10 CFR 35 medical uses. Your medical use authorization includes the following functional authorizations:

- I-131 CNS Intracavitary Brain Therapy Authorization [10 CFR 35.300]
Requires AU Prescription
- General Brachytherapy Authorization (Cs-137, I-125, Ir-192, Pd-103, Sr-90)(10CFR35.400)
Requires AU Prescription
- Perfexion Gamma Knife Radiosurgery Authorization (Co-60) [10 CFR 35.1000] Requires
AU Prescription and AU & AMP Presence
- HDR Remote Afterloader Authorization (Ir-192) (10 CFR 35.600)
Requires AU Prescription and AU & AMP Presence
- I-131 Thyroid Carcinoma Therapy Authorization (10 CFR 35.300) Requires AU
Prescription
- General Radiopharmaceutical Therapy Authorization (P-32, Sm-153, Sr-89) (10CFR35.300)
Requires AU Prescription and Presence
- I-131 MIBG Authorization [10CFR35.300]
Requires AU Prescription & Presence

Your use of radioactive materials is governed by the Washington University and Medical Center NRC License No. 24-00167-11.

Please note that you may act as a Washington University Authorized User only for those functional authorizations listed above. Each functional authorization has specific requirements for training and experience, and some have requirements for periodic retraining. It is your responsibility to obtain the required experience and retraining. If you want to seek medical use authorization for any other functional authorization or check your retraining status, please contact Dr. Robert Drzymala.

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December 3, 2009

Please call me at (314) 362-2988 if you have any questions concerning this approval of your medical use authorization.

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Washington University in St. Louis, Campus Box 8053, 660 S. Euclid Avenue, St. Louis, Missouri 63110-1093
(314) 362-3476, Fax (314) 362-4776, radsafety@wustl.edu, <http://radsafety.wustl.edu>



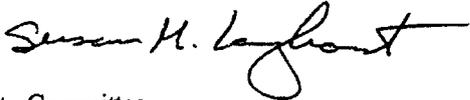
Washington University in St. Louis

SCHOOL OF MEDICINE

RADIATION SAFETY OFFICE

October 23, 2001

TO: Marie A. Taylor, M.D.
Radiation Oncology
Campus Box 8224

FROM: Susan M. Langhorst, Ph.D., CHP 
Radiation Safety Officer and
Executive Secretary, Radiation Safety Committee

SUBJECT: Authorization for Medical Use of Radioactive Materials

As part of our review of Medical Use Authorizations, the Radiation Safety Committee for Washington University and Medical Center reviewed your authorization as an Authorized Medical User. Your complete authorization as currently approved by the RSC is listed below:

- Low Dose-Rate brachytherapy (including remote afterloaders) and I-131 thyroid carcinoma therapy
- All other therapeutic radiopharmaceuticals
- High Dose-Rate remote afterloading brachytherapy

Your use of byproduct materials is authorized under the Washington University and Medical Center NRC License No. 24-00167-11. All other radioactive materials are authorized under Missouri State Registration No. 2793.

Attached is a list of all medical use authorization categories for Radiation Oncology physicians that require separate approval by the Radiation Safety Committee. Please note that you are only authorized for those categories listed above. Each category has specific requirements for training and experience, and some have requirements for periodic retraining. It is your responsibility to obtain the required retraining. If you want to seek authorization for any of the other categories or check your retraining status, please contact Eric Klein.

This listing of your current authorization is being provided to clarify your current medical use approvals and update your medical use authorization documentation. Please call me at (314) 362-2988 if you have any questions concerning your authorization as an Authorized Medical User.

Enclosure

Cc: Carlos A. Perez, M.D.
James A. Purdy, Ph.D.
Eric E. Klein, M.S.

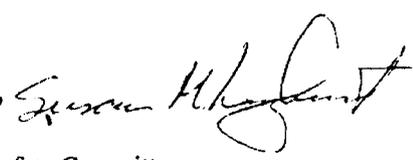
Department (314) 362-3476 Radiation Safety Officer (314) 362-2988 Business Office (314) 362-3333
Facsimile (314) 362-4776 ★ Website: www.radiationsafety.org ★ Facsimile (314) 362-6666
WUSM Campus Box 8053 or 724 South Euclid Avenue [Rooms 2225, 2235, 2240 - 2247] St. Louis, Missouri 63110

Environmental Health & Safety

Radiation Safety Office

September 15, 2005

TO: Jeff M. Michalski, M.D.
Radiation Oncology
Campus Box 8224

FROM: Susan M. Langhorst, Ph.D., CHP 
Radiation Safety Officer and
Executive Secretary, Radiation Safety Committee

SUBJECT: Physician's Authorization for Medical Use of Radioactive Materials

I am pleased to inform you that on September 13, 2005, the Radiation Safety Committee for Washington University and Medical Center granted final approval for you to be an Authorized User for Y-90 SIR-Spheres Therapy. Approval was granted based on the attached written request by Eric E. Klein (dated July 19, 2005). This replaces the interim approval I granted you effective July 20, 2005. With this approval, your medical use authorization includes the following categories, with the change noted in **bold**:

- General Brachytherapy (Cs-137, I-125, Ir-192, Pd-103, Sr-90) [10 CFR 35.400]
- Low Dose-Rate Remote Afterloading Brachytherapy (Cs-137) [10 CFR 35.600]
- I-131 Thyroid Carcinoma Therapy [10 CFR 35.300]
- General Radiopharmaceutical Therapy (P-32, Sm-153, Sr-89) [10 CFR 35.300]
- **Y-90 SIR-Spheres Therapy [10 CFR 35.1000]**
- High Dose-Rate Remote Afterloading Brachytherapy (Ir-192) [10 CFR 35.600]

You are responsible to abide by the requirements and procedures established for each of these functional authorizations. Your use of byproduct materials is authorized under the Washington University and Medical Center NRC License No. 24-00167-11. All other radioactive materials are authorized under Missouri State Registration No. 2793.

Please note that you are only authorized for those functional authorizations listed above. Each functional authorization has specific requirements for training and experience, and some have requirements for periodic retraining. It is your responsibility to obtain the required retraining. If you want to seek authorization for any other functional authorization or check your retraining status, please contact Eric Klein.

Please call me at (314) 362-2988 if you have any questions concerning your medical use authorization.

Cc: Robert J. Myerson, M.D.,
Simon N. Powell, M.D.

Barry A. Siegel, M.D.
Perry W. Grigsby, M.D.
Eric E. Klein, M.S.

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, 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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p style="text-align: center;">Licensee</p> <p>1. Washington University in St. Louis</p> <p>2. Campus Box 8053 660 S. Euclid Avenue St. Louis, MO 63110-1093</p> | <p>In accordance with letter dated September 30, 2009,</p> <hr/> <p>3. License number 24-00167-11 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2013</p> <hr/> <p>5. Docket No. 030-02271 Reference No.</p> |
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Numbers 1-83</p> <p>B. Any byproduct material with Atomic Numbers 1-83</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Sealed sources</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 3 curies per radionuclide. Total possession limit not to exceed 30 curies except as specifically listed below:</p> <table style="margin-left: 20px;"> <tr><td>Hydrogen-3</td><td>40 curies</td></tr> <tr><td>Sulfur-35</td><td>10 curies</td></tr> <tr><td>Phosphorus-32</td><td>10 curies</td></tr> <tr><td>Carbon-14</td><td>10 curies</td></tr> <tr><td>Iodine-131</td><td>5 curies</td></tr> <tr><td>Molybdenum-99</td><td>40 curies</td></tr> <tr><td>Technetium-99m</td><td>40 curies</td></tr> <tr><td>Carbon-11</td><td>20 curies</td></tr> <tr><td>Copper-64</td><td>5 curies</td></tr> <tr><td>Fluorine-18</td><td>50 curies</td></tr> <tr><td>Oxygen-15</td><td>10 curies</td></tr> </table> <p>B. Not to exceed 1 curie per radionuclide. Total possession limit not to exceed 10 curies except as specifically listed below:</p> <table style="margin-left: 20px;"> <tr><td>Cesium-137</td><td>5 curies</td></tr> <tr><td>Iodine-125</td><td>3 curies</td></tr> <tr><td>Iridium-192</td><td>10 curies</td></tr> </table> | Hydrogen-3 | 40 curies | Sulfur-35 | 10 curies | Phosphorus-32 | 10 curies | Carbon-14 | 10 curies | Iodine-131 | 5 curies | Molybdenum-99 | 40 curies | Technetium-99m | 40 curies | Carbon-11 | 20 curies | Copper-64 | 5 curies | Fluorine-18 | 50 curies | Oxygen-15 | 10 curies | Cesium-137 | 5 curies | Iodine-125 | 3 curies | Iridium-192 | 10 curies |
| Hydrogen-3 | 40 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sulfur-35 | 10 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phosphorus-32 | 10 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Carbon-14 | 10 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Iodine-131 | 5 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Molybdenum-99 | 40 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Technetium-99m | 40 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Carbon-11 | 20 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Copper-64 | 5 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fluorine-18 | 50 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oxygen-15 | 10 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cesium-137 | 5 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Iodine-125 | 3 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Iridium-192 | 10 curies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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SUPPLEMENTARY SHEET

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030-02271

Amendment No. 75

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|-------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license Phosphorus-32 3 curies Strontium-90 3 curies |
| C. Any byproduct material, source material and/or special nuclear material with Atomic Numbers 84-103, inclusive. | C. Any | C. Not to exceed 20 millicuries total. |
| D. Any byproduct material | D. Activated Rock Samples | D. Not to exceed 50 millicuries each and 200 millicuries total for radionuclides with atomic numbers less than 84 and not to exceed 2 millicuries total for radionuclides with atomic numbers greater than 83. |
| E. Cesium-137 | E. [REDACTED] | E. [REDACTED] |
| F. Cesium-137 | F. [REDACTED] | F. [REDACTED] |
| G. Cesium-137 | G. [REDACTED] | G. [REDACTED] |
| H. Cobalt-60 | H. [REDACTED] | H. [REDACTED] |
| I. Depleted uranium | I. [REDACTED] | I. [REDACTED] |
| J. Cesium-137 | J. [REDACTED] | J. [REDACTED] |
| K. Iridium-192 | K. [REDACTED] | K. [REDACTED] |

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6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

L. Cobalt-60, as permitted by 10 CFR 35.1000

L.

L.

9. Authorized Use:

A. through C. Medical diagnosis, therapy and research in humans, and research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction and in-vitro studies.

D. Research and Development as defined in Section 30.4 of 10 CFR Part 30 including student instruction.

E.

F.

G.

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H.



I.



J.



K.



L.



CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities located in St. Louis, Missouri, Green Park, Missouri and Creve Coeur Missouri.
- 11.
 - A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
 - B. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, letter dated December 13, 2007, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
 - C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
 - D. The Radiation Safety Officer for this license is Susan Langhorst, Ph.D.



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12. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license
13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
 - D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
 - H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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- 15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
- 17. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism that prevents the foil temperature from exceeding that specified in the certificate of registration issued by NRC pursuant to 10 CFR 32.210 or the equivalent regulations from an Agreement State.
B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
- 18. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- 19. For radioactive material held for decay-in-storage other than that held in accordance with 10 CFR 35.92, the licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

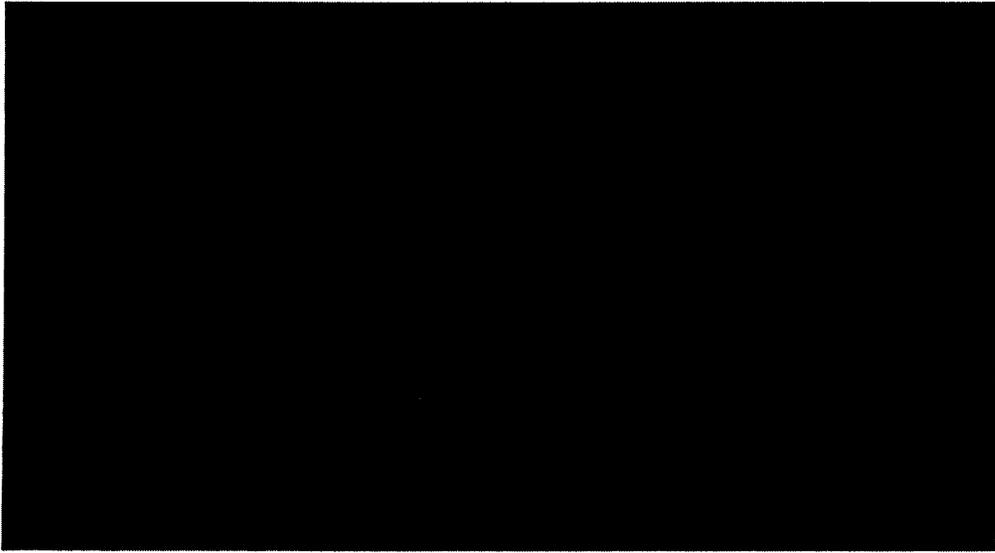
21. 

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22.



23.



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24. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registry Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
25. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
26. Notwithstanding the requirements of License Condition 28, the licensee is authorized to make program changes and changes to procedures specifically identified in the application dated September 30, 2002, and letter dated January 22, 2003, which were previously approved by the Commission and incorporated into the license without prior Commission approval as long as:
- A. the proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;
 - B. the revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
 - C. the licensee's staff is trained in the revised procedures prior to implementation; and
 - D. the licensee's audit program evaluates the effectiveness of the change and its implementation.
27. A. The licensee shall comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (Accession No. ML053130364) as Attachment B to the "Order Imposing Increased Controls" (ADAMS Accession No. ML053130218) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (Fingerprinting Order) (ADAMS Accession No. ML073230831) published in the Federal Register on December 13, 2007 (72 FR 70901).
- B. The licensee shall complete implementation of the said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Fingerprinting Order (ADAMS Accession No. ML080160582).
- C. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to these Orders shall be maintained until the Commission orders otherwise or until the Commission explicitly modifies its regulations to reflect the increased controls and fingerprinting requirements, and states in modifying its regulations that the revisions are to supercede these Orders.

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- D. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. NRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Security-Related Information - Withhold Under 10 CFR 2.390."
28. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated September 30, 2002; and
- B. Letters dated January 22, 2003, March 28, 2003, December 29, 2003, March 9, 2004, September 1, 2004, April 4, 2005, September 2, 2005, November 28, 2005, November 30, 2005, March 27, 2006, December 13, 2007, January 4, 2008, October 16, 2008, December 5, 2008, March 27, 2009, and **September 30, 2009.**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date NOV 23 2009By 
James R. Mullaer, M.H.S.
Materials Licensing Branch
Region III

**NUCLEAR MEDICINE
DEPARTMENT
11133 Dunn Road
St. Louis, Missouri 63136**

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04/12/2011

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**USNRC, Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
Attn: Nuclear Licensing Branch**

60532
CMFZNM1
Apr 12, 2011

