NRC FORM 374



U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 67

# 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. QC02240 373544

| Licensee | In accordance with letter dated **June 24, 2010,** |
|---|---|
| 1. QHG of Indiana, Inc. | 3. License number 13-01535-01 is amended in its entirety to read as follows: |
| 2. 7950 West Jefferson Blvd.<br>Fort Wayne, IN 46804-1677 | 4. Expiration date June 30, 2015 |
| | 5. Docket No. 030-01594<br>Reference No. |

| 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 |
|---|---|---|
| A. Any byproduct material permitted by 10 CFR 35.100 | A. Any | A. As needed |
| B. Any byproduct material permitted by 10 CFR 35.200 | B. Any | B. As needed |
| C. Any byproduct material permitted by 10 CFR 35.300 | C. Any | C. As needed, not to exceed **one curie of iodine-131**. |
| D. Any byproduct material permitted by 10 CFR 35.400 | D. Sealed Sources (North American Scientific, Inc., Model MED 3631, MED 3633; Draximage, Inc., Brachyseed Model LS-1; Best Industries, Model 2301; Implant Sciences Corp., I-Plant, Model 3500; IsoAid, LLC, Model IAI-125A; Mills Biopharmaceuticals, Inc., Models SL-125, SH-125; Bard Model STM1251; Best Medical International Inc., Model 2335 and Theragenics Corp. Theraseed, Model 200; IsoRay Medical Inc. Model # CS-1 ) | D. **One curie**. |

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| | | |
|---|---|---|
| E. Any byproduct material permitted by 10 CFR 35.500 | E. Sealed sources (North American Scientific, Inc., Models MED 3601 and Du Pont Merck Pharmaceutical Company NES-8412) | E. 300 millicuries per source and 1200 millicuries total |
| F. Any byproduct material permitted by 10 CFR 31.11 | F. Prepackaged Kits | F. 1 millicurie |
| G. Yttrium-90 permitted by 10 CFR 35.1000 | G. Sealed sources (MDS Nordion, Model TheraSphere) | G. 2 curies, not to exceed 540 millicuries per source. |
| **H. Yttrium-90 permitted by 10 CFR 35.1000** | **H. Sealed sources as SIR-Spheres (AEA Technology QSA , Inc.)** | **H. 2 curies** |

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.

D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

F. In vitro studies.

G. Medical use permitted by 10 CFR 35.1000.

H. **Medical use permitted by 10 CFR 35.1000 in a Sirtex Medical Limited brachytherapy afterloader delivery system.**

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 7950 West Jefferson Boulevard, Fort Wayne, Indiana and 7916 W. Jefferson Blvd, Fort Wayne, Indiana.

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11. The Radiation Safety Officer for this license is Randall J. Phillips, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for medical use as indicated:

| Authorized Users | Material and Use |
|---|---|
| Brett A. Hagedorn, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| John Rock, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| Rik Stephens, M.D | 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11. |
| James C. Wehrenberg, M.D | 10 CFR 35.100, 35.200, 35.500 and 31.11. |
| James A. Arata, M.D | 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11. |
| David B. Janizek, M.D. | 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11. |
| Christine Anne Tremper, M.D. | 10 CFR 35.100, 35.200, 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities equal to or less than 33 millicuries) and 35.500. |
| Randall J. Phillips, M.D. | 10 CFR 35.100, 35.200, 35.300, 35.500, 31.11 and **yttrium-90, limited to TheraSpheres, permitted by 35.1000 and yttrium-90 SIR-spheres in a Sirtex Medical Limited brachytherapy afterloader delivery system**. |
| John Pasalich, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Stephen R. Phillip, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Marc Thomas, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Diane D. Daly, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| John L. Bormann, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Michael E. Parker, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Pamela Lee Strange, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Michael W. Tanksley, M.D. | 10 CFR 35.100, 35.200, 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities equal to or less than 33 millicuries) and 35.500. |

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| Authorized Users | Material and Use |
|---|---|
| Joseph R. Decamp, M.D. | 10 CFR 35.100, 35.200, 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities equal to or less than 33 millicuries) and 35.500. |
| John R. Kim, M.D. | 10 CFR 35.100, 35.200, 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities equal to or less than 33 millicuries) and 35.500. |
| Frederick N. Vandeman, M.D. | 10 CFR 35.100, 35.200, 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities equal to or less than 33 millicuries) and 35.500. |
| Andre Byard Stovall, M.D. | 10 CFR 35.100, 35.200, 35.300, 35.500 and yttrium-90, limited to TheraSpheres, permitted by 35.1000. |
| Christopher Michael Kowalski, M.D. | 10 CFR 35.100, 35.200 and 35.500. |
| Richard W. Sibley, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Dakshesh S. Patel, M.D. | 10 CFR 35.100, 35.200 and 35.500. |
| Eric V. Heatwole, M.D. | 10 CFR 35.100, 35.200 and 35.500. |
| Shilpa Kashyap, M.D. | 10 CFR 35.100, 35.200 and 35.500. |
| Deepchand Bajpai, M.D. | 10 CFR 35.300 and 35.400. |
| Rao V. P. Mantravadi, M.D. | 10 CFR 35.300 and 35.400. |
| Marc Apple, M.D | 10 CFR 35.400. |
| Stephen Beyer, M.D | 10 CFR 35.300. |
| Brian Kim, M.D. | 10 CFR 35.100 and 35.200. |
| Shawn Johnson, M.D | 10 CFR 35.100, 35.200, 35.300. |
| Sandeep S. Ahluwalia, M.D | 10 CFR 35.100 and 35.200 and 35.300 (limited to the oral administration of sodium iodide-131). |
| John C. Lacunza, M.D | 10 CFR 35.100 and 35.200. |
| Linda Gould Hippenhammer, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| Daniel Branam, M.D. | 10 CFR 35.100, 35.200 and 35.300 (limited to the oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). |
| Steven Hossler, M.D. | 10 CFR 35.100 and 35.200. |

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| Authorized Users | Material and Use |
|---|---|
| Jonathon Berger, M.D. | 10 CFR 35.100 and 35.200. |
| Eugene Shih, M.D. | 10 CFR 35.100 and 35.200. |
| John H. Arnett, M.D. | 10 CFR 35.100, 35.200 and 35.500. |
| Peter C. Hanley, M.D. | 10 CFR 35.100 and 35.200. |
| Ravi No. Bathina, M.D. | 10 CFR 35.100 and 35.200. |
| Sanjiv G. Aggarwal, M.D. | 10 CFR 35.100 and 35.200. |
| Scott E. Mattson, D.O. | 10 CFR 35.100 and 35.200. |
| Revati J. Ghatnekar, M.D. | 10 CFR 35.100 and 35.200. |
| Krishnan Ramani, M.D. | 10 CFR 35.200. |
| Mark A. Meier, M.D. | 10 CFR 35.200. |
| Venkata Rama Prasad Nalamolu, M.D. | 10 CFR 35.200. |
| Sabeena Ramrakhiani, M.D. | 10 CFR 35.100 and 35.200. |
| Thomas S. Chung, M.D. | 10 CFR 35.300 and 35.400. |
| **Jeffery J. Freeman, M.D.** | **10 CFR 100, 200 and 300 (limited to the oral administration of iodine-131).** |

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. The manufacturer's training for TheraSpheres shall include operation of the delivery system, safety procedures, and clinical use of TheraSpheres.

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16. 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 November 16, 2004;

B. Facsimiles dated May 10, 2005, and September 20, 2007; and,

**C.** Letters dated June 26, 2007, July 14, 2009, October 23, 2009, **April 27, 2010, and September 2, 2010.**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date DEC 16 2010

By Colleen Carol Casey
Colleen Carol Casey
Materials Licensing Branch
Region III