

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>Licensee</p> <p>1. Somascan, Inc.</p> <p>2. Calle José Martí #56 Hato Rey, Puerto Rico 00918</p>	<p>In accordance with the letter dated September 23, 2008,</p> <p>3. License number 52-25617-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2013</p> <hr/> <p>5. Docket No. 030-36194 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.500</p> <p>E. Any Byproduct material permitted by 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Prepackaged Kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 500 millicuries</p> <p>D. 80 millicuries</p> <p>E. 50 millicuries</p>
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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. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
 - E. In vitro studies.

CONDITIONS

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
52-25617-01

Docket or Reference Number
030-36194

Amendment No. 4

- 10. Licensed material may be used or stored only at the licensee's facilities located at Calle José Martí #56, Floral Park, Hato Rey, Puerto Rico and Cardiovascular Hospital, Esq. Ave. Americo Miranda, Centro Medico Edif. Cardiovascular, Sontano, San Juan, Puerto Rico. Licensed material listed in Item 6.D. may also be used or stored at the licensee's facilities located at Torre Plaza, Suite 405, Plaza las Americas, San Juan, Puerto Rico and Somascan Condado, 1409 Ashford Avenue, Condado, Puerto Rico.
- 11. The Radiation Safety Officer for this license is Jorge Toro, 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:

<u>Authorized Users</u>	<u>Material and Use</u>
Jorge Toro, M. D.	35.100, 35.200, 35.300, 35.500, in vitro studies
- 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."

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15. 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 December 23, 2002 [ML030070471]
 - B. Letter dated January 8, 2003 [ML031080393]
 - C. Letter dated March 18, 2003 [ML031080375]
 - D. Letter dated April 9, 2003 [ML031080367]
 - E. Letter dated April 10, 2003 [ML031080337]
 - F. Letter dated December 10, 2008 [ML083450645]



For the U.S. Nuclear Regulatory Commission

Date December 17, 2008

By

Original signed by Elizabeth Ullrich

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406