

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>Licensee</p> <p>1. Biocompatibles, Inc.</p> <p>2. 115 Hurley Road, Building 3 Oxford, Connecticut 06478</p>	<p>In accordance with the application dated November 1, 2012,</p> <p>3. License number 06-30764-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2023</p> <hr/> <p>5. Docket No. 030-36099 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cobalt 57</p> <p>B. Technetium 99m</p> <p>C. Palladium 103</p> <p>D. Iodine 125</p> <p>E. Cesium 131</p> <p>F. Cesium 137</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed Sources (Isotope Product Laboratories Model RV-057)</p> <p>B. Any</p> <p>C. Sealed Source (as specified in Condition 11)</p> <p>D. Sealed sources (as specified in Condition 12)</p> <p>E. Sealed sources (IsoRay Model Cs-1)</p> <p>F. Sealed Sources (Isotope Products Laboratories Model RV-137)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 10 millicuries per source and 25 millicuries total</p> <p>B. 40 millicuries</p> <p>C. 20,000 millicuries</p> <p>D. 20,000 millicuries</p> <p>E. 65 millicuries (internal) per source and 130 curies total</p> <p>F. 0.5 millicuries</p>
<p>9. Authorized use:</p> <p>C., D. and E. Possession, storage, and packaging of sealed sources into a stranded or loose configuration for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.</p> <p>A., B. and F. Calibration and checking of the licensee's instruments.</p>		

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
06-30764-01Docket or Reference Number
030-36099

Amendment No. 16

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 115 Hurley Road, Building 3, Oxford, Connecticut.
11. The following products are authorized, provided the amount of palladium-103 contained in the source/device does not exceed the amounts specified in the following table:

<u>Device/Series Model</u>	<u>Maximum Quantity per Source</u>
Iso Aid IAPd-103A	10 millicuries internal activity
Theragenics Model 200	10 millicuries internal activity

12. The following products are authorized, provided the amount of iodine-125 contained in the source/device does not exceed the amounts specified in the following table:

<u>Device/Series Model</u>	<u>Maximum Quantity per Source</u>
Medi-Physics Inc. 6711	270 millicuries
Medi-Physics Inc. 6733 (EchoSeed)	71.2 millicuries
Best Medical International 2300 Series	110 millicuries
Bebig 125-S06	40 millicuries
Mills Biopharmaceuticals Inc. 125SL	1 millicurie
Mills Biopharmaceuticals Inc. 125 SH	150 millicuries
IsoAid Inc. IAI-125A	10 millicuries
Source Tech Medical LLC STM125	15 millicuries
Theragenics 125-S06	100 millicuries
Theragenics AgX100	20 millicuries

13. Licensed material shall be used by, or under the supervision of Timothy Delaney and Warren Rice.
14. The Radiation Safety Officer for this license is Wayne Richardson.
15. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.14 through

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
06-30764-01Docket or Reference Number
030-36099

Amendment No. 16

30.21, inclusive, or equivalent regulations of any Agreement State.



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
06-30764-01Docket or Reference Number
030-36099

Amendment No. 16

16. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at 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. 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.
- D. 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.
- E. 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.
- F. 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.
- G. 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.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
17. 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. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers,

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
06-30764-01Docket or Reference Number
030-36099

Amendment No. 16

and the date of the inventory.

18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
20. 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. 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 1, 2012 (ML12319A194)
 - B. Letter dated January 30, 2013 (ML13044A431)

For the U.S. Nuclear Regulatory Commission

Original signed by Thomas K. Thompson

Date May 1, 2013

By

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406