



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 5, 2006

Docket No. 03034011  
Control No. 139274

License No. 29-30262-01

Michael Tweedle, Ph.D.  
President & CEO  
Bracco Research USA  
305 College Road East  
Princeton, NJ 08540

SUBJECT: BRACCO RESEARCH USA, LICENSE AMENDMENT, CONTROL NO. 139274

Dear Dr. Tweedle:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

***Original signed by Dennis R. Lawyer***

Dennis R. Lawyer  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 11

cc:  
Scott Dennerlein, Radiation Safety Officer

M. Tweedle  
Bracco Research USA

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**SUNSI Review Complete: DLawyer**

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NAME	DLawyer/DRL							
DATE	09/05/2006							

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**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. Bracco Research USA</p> <p>2. 305 College Road East Princeton, New Jersey 08540</p>	<p>In accordance with the letter dated August 14, 2006,</p> <p>3. License number 29-30262-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date May 31, 2011</p> <hr/> <p>5. Docket No. 030-34011 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen-3</p> <p>B. Carbon-14</p> <p>C. Phosphorus-32</p> <p>D. Sulfur-35</p> <p>E. Iron-59</p> <p>F. Rubidium 86</p> <p>G. Yttrium-90</p> <p>H. Molybdenum-99</p> <p>I. Technetium-99</p> <p>J. Technetium-99m</p> <p>K. Iodine-125</p> <p>L. Gadolinium-153</p> <p>M. Holmium-166</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. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any</p> <p>J. Any</p> <p>K. Any</p> <p>L. Any</p> <p>M. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 10 millicuries</p> <p>B. 25 millicuries</p> <p>C. 1 millicurie</p> <p>D. 25 millicuries</p> <p>E. 0.1 millicurie</p> <p>F. 10 millicuries</p> <p>G. 25 millicuries</p> <p>H. 4 curies</p> <p>I. 5 millicuries</p> <p>J. 4 curies</p> <p>K. 100 millicuries</p> <p>L. 2 millicuries</p> <p>M. 25 millicuries</p>
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# **MATERIALS LICENSE SUPPLEMENTARY SHEET**

License Number

29-30262-01

Docket or Reference Number

030-34011

Amendment No. 11

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
N. Lutetium-177	N. Any	N. 2 curie
O. Rhenium-186	O. Any	O. 25 millicuries
P. Rhenium-188	P. Any	P. 250 millicuries
Q. Cesium-137	Q. Sealed vial sources (NEN Model 076047)	Q. Not to exceed 35 microcuries per source and 100 microcuries total
R. Lutetium-176m	R. Any	R. 4 millicurie
S. Lutetium-177m	S. Any	S. 4 millicurie
T. Tungsten-188	T. Any	T. 1 millicurie
U. Iridium-192	U. Any	U. 500 microcuries
V. Osmium-191	V. Any	V. 1 millicurie
W. Silver-110m	W. Any	W. 25 microcuries
X. Cobalt-60	X. Any	X. 25 microcuries
Y. Strontium-90	Y. Any	Y. 5 microcuries
Z. Indium-114m	Z. Any	Z. 25 microcuries
AA Zinc-65	AA Any	AA 10 microcuries

## 9. Authorized use:

A. through P.	Research and development as defined in 10 CFR 30.4; animal studies.
Q.	Calibration reference standards.
R. through T.	Contaminant in Lu-177 samples
U. through X.	Contaminant in Re-188 samples
Y.	Contaminant in Y-90 samples
Z. through AA.	Contaminant in In-111 samples

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**CONDITIONS**

10. Licensed material may be used only at the licensee's facilities located at 305 College Road East, Princeton, New Jersey.
11. Licensed material shall be used by, or under the supervision of, Scott Dennerlein, Stephen Eaton, Aldo Cagnolini, Karen Linder, Adrian D. Nunn, or Nannan Wang.
12. The Radiation Safety Officer for this license is Scott Dennerlein.
13. Licensed material shall not be used in or on human beings.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
16.
  - 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. 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.
  - C. 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.
  - D. 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.

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- E. 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.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
20. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
  - B. 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.
  - C. A record of each such disposal permitted under this License Condition shall be retained for three 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.
21. 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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22. 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 January 16, 2001 (ML010230505)
- B. Facsimile dated April 6, 2001 (ML011000159)
- C. Letter dated April 17, 2001 (ML011080066)
- D. Letter dated May 2, 2001 (ML011230494)



For the U.S. Nuclear Regulatory Commission

Date September 5, 2006

By

***Original signed by Dennis R. Lawyer***

Dennis R. Lawyer  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406