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U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 34

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.

Licensee	
1. Department of Health and Human Services Public Health Service, FDA Winchester Engineering and Analytical Center 2. 109 Holton Street Winchester, MA 01890-1197	In accordance with the letter dated October 13, 2009, 3. License number 20-08361-01 is amended in its entirety to read as follows: 4. Expiration date June 30, 2016 5. Docket No. 03004675 Reference No. 04-09759-01, 04-09763-01, 05-09749-01, 10-09754-01, 19-09760-01, 31-09753-02, 31-28300-01, 46-09750-01

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 with atomic numbers 1 through 83	A. Any	A. 50 millicuries per radionuclide and 10 curies total
B. Hydrogen 3	B. Any	B. 80 curies
C. Phosphorus 32	C. Any	C. 300 millicuries
D. Chromium 51	D. Any	D. 300 millicuries
E. Cobalt 60	E. Any	E. 1 curie
F. Nickel 63	F. Any	F. 3 curies
G. Selenium 75	G. Any	G. 300 millicuries
H. Strontium 89	H. Any	H. 1 curie
I. Yttrium 90	I. Any	I. 1 curie
J. Molybdenum 99/Technetium 99m	J. Any	J. 50 curies
K. Technetium 99m	K. Any	K. 500 millicuries
L. Indium 114	L. Any	L. 300 millicuries
M. Iodine 131	M. Any	M. 3 curies
N. Xenon 133	N. Any	N. 1.5 curies
O. Cesium 137	O. Any	O. 1 curie
P. Samarium 153	P. Any	P. 2 curies
Q. Radium 226	Q. Any	Q. 10 microcuries
R. Radium 228	R. Any	R. 500 microcuries

License Number
20-08361-01

Docket or Reference Number
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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
S. Thorium 228	S. Any	S. 500 microcuries
T. Thorium 229	T. Any	T. 10 microcuries
U. Thorium 230	U. Any	U. 500 microcuries
V. Thorium 232	V. Any	V. 500 microcuries
W. Uranium 232	W. Any	W. 5.0 micrograms
X. Uranium 233	X. Any	X. 25 milligrams
Y. Uranium 235	Y. Any	Y. 10 grams
Z. Uranium 236	Z. Any	Z. 400 milligrams
AA. Uranium 237	AA. Any	AA. 0.03 nanograms
BB. Natural Thorium	BB. Any	BB. 20,000 grams
CC. Natural Uranium	CC. Any	CC. 20,000 grams
DD. Depleted Uranium	DD. Any	DD. 10 grams
EE. Neptunium 237	EE. Any	EE. 10 microcuries
FF. Neptunium 239	FF. Any	FF. 100 microcuries
GG. Polonium (any radionuclide)	GG. Any	GG. 200 microcuries per radionuclide and 800 microcuries total
HH. Plutonium (any radionuclide)	HH. Any	HH. 20 milligrams except not more than 5 milligrams of Plutonium 238
II. Americium (any radionuclide)	II. Any	II. 200 microcuries
JJ. Actinium (any radionuclide)	JJ. Any	JJ. 200 microcuries
KK. Curium (any radionuclide)	KK. Any	KK. 200 microcuries per radionuclide and 800 microcuries total
LL. Nickel 63	LL. Plated Foils (U.S. Radium Model No. LAB-784, New England Nuclear Model No. NER-004, Amersham/Searle Model No. NBC, NRD, Inc. Model No. N1001, Isotope Products Laboratories Custom Plated Source, AEA Tech. Custom Plated Source)	LL. 2.5 curies total and no single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

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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
MM. Cadmium 109	MM. Sealed Sources (Amersham Corp. Model No. CUCP.1 and CUC.D1, Isotope Products Laboratories Model No. XFB Series 3204 and 3205, North American Scientific Model No. IND 1602, and New England Nuclear Model No. NER-467 and NER-465)	MM. 100 millicuries total and no single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State.
NN. Americium 241	NN. Sealed Sources (Amersham Corporation Model No. AMC 2084)	NN. 1 millicurie and no single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State.
OO. Americium 241	OO. Sealed Sources (AEA Technologies Model No. AMCL and Amersham Corp. Model No. AMC.P4)	OO. 5 millicuries total and no single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

9. Authorized use:

A. through AA, DD through KK Research and development as defined in 10 CFR 30.4; animal studies; teaching and training of students; and calibration and checking of the licensee's instruments.

LL. To be used for sample analysis in Agilent Technologies, Inc. (formerly Hewlett-Packard) Model No. 19235 or 19303 or Tracor or Thermo Finnigan LLC (formerly ThermoQuest/CE Instruments, formerly Tremetrics Chromatography Group Finnigan Corporation) Model No. 115500 gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

BB, CC and NN. For storage as waste.

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MM. and OO. To be used for multi-element analysis in NITON Corporation Model XL Series x-ray fluorescence analyzer devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at Winchester Engineering and Analytical Center, Winchester, Massachusetts and licensed material in the form of sealed sources may be used at temporary job sites of the licensee anywhere in the United States. Additionally, the following locations are authorized for use of licensed material specified for each location:

Location	Material authorized for use
158-15 Liberty Avenue, Jamaica, New York	Phosphorus 32, Nickel 63 (foils)
60 8th Street, N.E., Atlanta, Georgia	Phosphorus 32, Phosphorus 33, Sulfur 35, Nickel 63 (foils)
Building 20 – Denver Federal Center, Denver, Colorado	Phosphorus 32
1431 Harbor Bay Parkway, Alameda, California	Nickel 63 (foils), Cadmium 109 (sealed), Americium 241 (sealed)
22201 23rd Drive, S.E., Bothell, Washington	Phosphorus 32, Nickel 63 (foils)
19701 Fairchild, Irvine, California	Phosphorus 32, Nickel 63 (foils)

11. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.

12. The Radiation Safety Officer for this license is James J. Cherniak.

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13. The licensee shall not use licensed material in or on human beings.

14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

15. 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.

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H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee. The licensee is authorized to perform cleaning of detector cells containing nickel 63 sources, in accordance with the procedures submitted with the application dated January 20, 2006.

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, and the date of the inventory.

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. 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 which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

20. 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.

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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."

22. Notwithstanding the requirements of License Condition 24, the licensee is authorized to make program changes and changes to procedures specifically identified in the condition, which were previously approved by the U.S. Nuclear Regulatory 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.

    D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

23. 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 20, 2006, except Waste Management Plan, Radiological Status Report, and Preliminary Decommissioning Plan (ML060300421)
    B. Letter dated May 4, 2006 (ML061280461)
    C. Letter dated May 30, 2006 (ML061510222)

For the U.S. Nuclear Regulatory Commission

Date February 18, 2010

By ***Original signed by James P. Dwyer***

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406