UNITED STATES
NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555-0001

ERRATA

November 3, 2005

Report Numbers: NUREG-1556, Volume 9, Revision 1

Report Title:
Consolidated Guidance About Materials Licenses
Program-Specific Guidance About Medical Use Licenses
Final Report

Prepared By:
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Date Published:
May 2005

Instructions:
1. Please replace Appendix F, page F-1 with the enclosed Appendix F, page F-1 which includes a description of a Medical Broad Scope License.

Publishing Services Branch
Office of Administration

UNITED STATES
NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555-0001

2. Please add Appendix F, pages F-24 through F-28 (Sample Medical Broad Scope License).

Enclosures:
1. NUREG-1556, Volume 9, Revision 1, Appendix F, page F-1
2. NUREG-1556, Volume 9, Revision 1, Appendix F, pages F-24 through F-28

Publishing Services Branch
Office of Administration

Sample Licenses

The license conditions listed in the example licenses come from the standard conditions in NUREG 1556 Volume 20, "Guidance About Administrative Licensing Procedures," with some modifications to reflect provisions of 10 CFR Part 35. The modified conditions are as follows:

- Standard tie-down condition (standard condition 38) modified to reflect 10 CFR 35.26
- Decay-in-storage condition (standard condition 140) modified to reflect 10 CFR 35.92
- Sealed sources leak test condition (standard condition 165) modified to reflect 10 CFR 35.67

When preparing licenses, please refer to the latest revision of NUREG 1556, Volume 20 for the most current versions of the license conditions.

Broad Scope License

In accordance with 10 CFR 35.12(e), an applicant that satisfies the requirements specified in 10 CFR 33.13 may apply for a Type A specific license of broad scope. Because NRC grants significant decision making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license generally authorizes the possession and use of a wide range of byproduct radioactive materials. NUREG 1556, Volume 11, "Program-Specific Guidance About Broad Scope Licenses" provides additional guidance to assist the experienced limited scope licensees in preparing an application for a broad scope license.

Sealed Sources and Devices For Broad Scope Licensees

10 CFR 35.15(g) exempts broad scope licensees from the provisions of 10 CFR 35.49(a). 10 CFR 35.49(a) requires that, for medical use, a licensee may only use sealed sources or devices manufactured and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State. 10 CFR 32.74 requires manufacturers and distributors of sources or devices containing byproduct material for medical use to submit information to NRC for review, used for registration of the sealed source or device. This exemption, therefore, grants broad scope licensees the authority to use sealed sources and/or devices that they have fabricated or obtained from vendors without prior NRC or Agreement State review and registration. However, these licensees have the responsibility for conducting the necessary evaluations and using such devices safely. Pursuant to 10 CFR 33.13(c)(3)(iii), the licensee's radiation safety committee is required to assure that radiation safety evaluations commensurate with the intended use of the sources and/or devices have been performed. If the source and/or device is presently listed in NRC's Registry of Sealed Sources and Devices as approved for the licensee's intended use, no radiation safety evaluation by the licensee is required. If the source and/or device has not been registered, or the source and/or device has not been approved for the licensee's intended use, then the licensee must perform a safety evaluation as required by 10 CFR 33.13(c)(3)(ii).

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. Sample Medical Broad Scope	3. License number 99-02110-01
2. 300 Main Street Anytown, Pennsylvania 02110	4. Expiration date March 31, 2013
	5. Docket No. 030-02110 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 with atomic numbers 1 through 83	A. Any	A. 200 millicuries per radionuclide and 15 curies total
B. Any byproduct material with atomic numbers 3 through 83	B. Sealed Sources	B. 1.5 curies per radionuclide and 15 curies total
C. Hydrogen 3	C. Any	C. 2 curies
D. Carbon 14	D. Any	D. 1 curie
E. Phosphorus 32	E. Any	E. 2 curies
F. Sulfur 35	F. Any	F. 2 curies
G. Chromium 51	G. Any	G. 500 millicuries
H. Molybdenum 99	H. Any	H. 10 curies
I. Technetium 99m	I. Any	I. 10 curies
J. Iridium 192	J. Sealed Sources (US Atomic Model IR-192HDR)	J. 12 curies per source and 24 curies total

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-02210-01

Docket or Reference Number
030-02210

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
K. Cobalt 60	K. Sealed Sources (US Atomic Model US CO-60 STER)	K. 33 curies per source and 10,000 curies total

9. Authorized use:

A. through I. Medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in-vitro studies.

J. One source in a US Atomic Model IR-192 THER remote afterloader unit for medical therapy and research in humans. The source activity may not exceed 10 curies at the time of use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

K. Sources in a US Atomic Model STEREO gamma stereotactic radiosurgery unit for medical therapy and research in humans. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery unit.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 300 Main Street, Anytown, Pennsylvania.

11. A. The Radiation Safety Officer for this license is Patty Melt, Ph.D.

B. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.

C. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-02210-01

Docket or Reference Number
030-02210

D. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

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

13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

14. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

15. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

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. 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-02210-01

Docket or Reference Number
030-02210

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.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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.

18. 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 that prevents the foil temperature from exceeding that specified in the certificate of registration issued by NRC pursuant to 10 CFR 32.210 or the equivalent regulations from an Agreement State.

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

19. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, 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 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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-02210-01

Docket or Reference Number
030-02210

C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the 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.

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

21. 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 20, 2002
B. Letter dated February 15, 2003

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS