



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

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September 26, 2003

Docket No. 03002945
Control No. 133602

License No. 37-00245-02

Jerry Rosen
Radiation Safety Officer
University of Pittsburgh
Radiation Safety Office
Room G-7, Parran Hall/SPH
130 DeSoto Street
Pittsburgh, PA 15261

SUBJECT: UNIVERSITY OF PITTSBURGH, ISSUANCE OF LICENSE AMENDMENT,
CONTROL NO. 133602

Dear Mr. Rosen:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that your license was written in a format compatible with the revised 10 CFR Part 35, dated April 24, 2002 (enclosed).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. Please note the last condition on your license indicates that, "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary. That said, the safety procedures and periodic spot check procedures previously submitted for use with your (remote after loading unit, teletherapy unit, gamma stereotactic radiosurgery unit) are considered part of the license until such time as you submit safety and spot check procedures in accordance with the requirements of 10 CFR 35.610, 35.642, 35.643, or 35.645, as applicable. 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).

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

6/34

J. Rosen
University of Pittsburgh

2

Thank you for your cooperation.

Sincerely,

Original signed by Michelle Beardsley

Michelle Beardsley
Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosures:

1. Amendment No. 95
2. 10 CFR Part 35

cc:

Niel Wald, M.D., Chairman, Radiation Safety Committee

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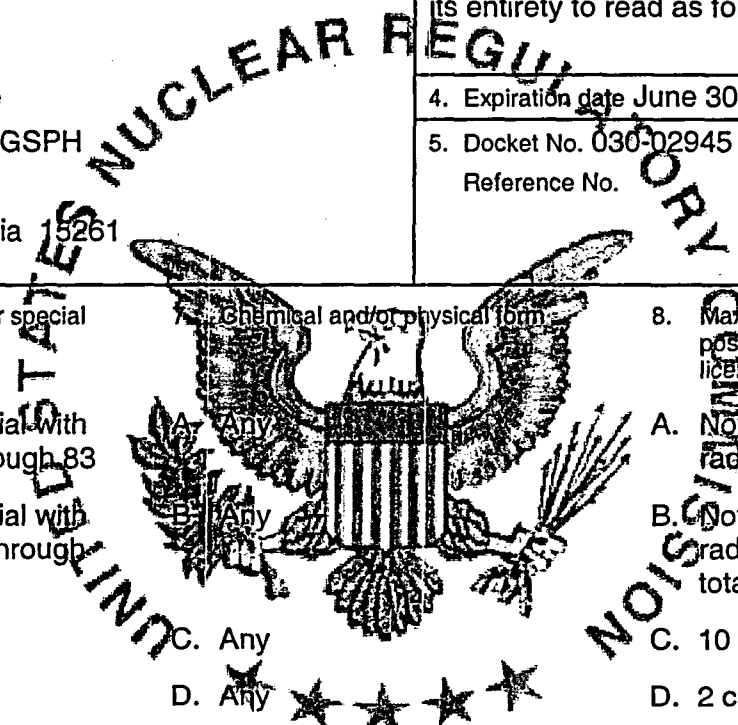
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MATERIALS LICENSE

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.

Licensee	In accordance with the letters dated August 28 and September 12, 2003,
1. University of Pittsburgh	3. License number 37-00245-02 is amended in its entirety to read as follows:
2. Radiation Safety Office Room G-7 Parran Hall/GSPH 130 DeSoto Street Pittsburgh, Pennsylvania 15261	4. Expiration date June 30, 2012
	5. Docket No. 030-02945 Reference No.

6. Byproduct, source, and/or special nuclear material	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 number 3 through 83	A. Any	A. Not to exceed 1 curie per radionuclide and 10 curies total
B. Any byproduct material with atomic numbers 84 through 103	B. Any	B. Not to exceed 1 millicurie per radionuclide and 10 millicuries total
C. Americium 241	C. Any	C. 10 millicuries
D. Hydrogen 3	D. Any	D. 2 curies
E. Cesium 137	E. Sealed Sources (3M Company Series 6500)	E. 5 curies
F. Iodine 125	F. Any	F. 2 curies
G. Iodine 131	G. Any	G. 2 curies
H. Molybdenum 99	H. Any	H. 10 curies
I. Phosphorus 32	I. Any	I. 2.5 curies
J. Technetium 99m	J. Any	J. 10 curies
K. Xenon 133	K. Any	K. 10 curies
L. Yttrium 90	L. Glass microspheres (MDS Nordion, Inc. Model TheraSphere)	L. 3 curies



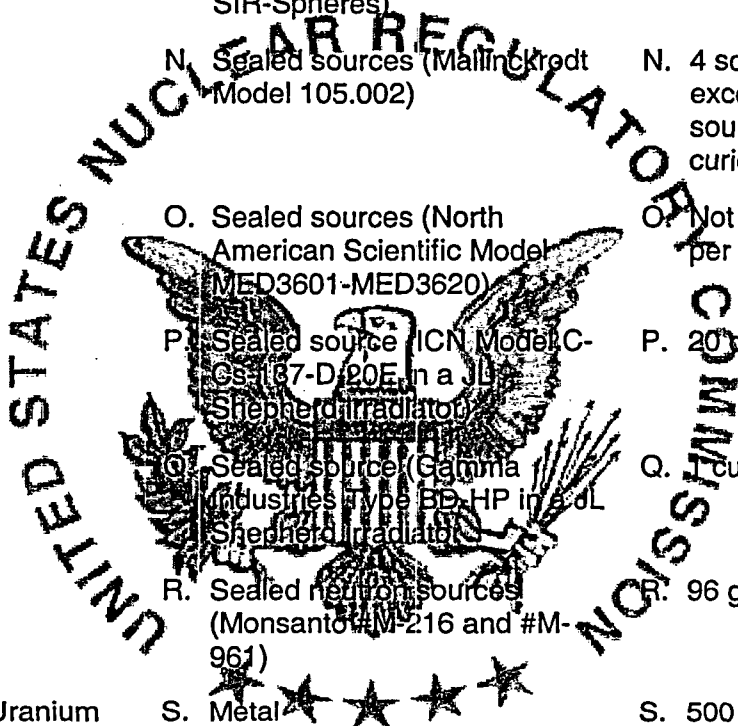
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
37-00245-02

Docket or Reference Number
030-02945

Amendment No. 95

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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 |
| M. Yttrium 90 | M. Resin microspheres (AEA Technology QSA, Inc. Model SIR-Spheres) | M. 3 curies |
| N. Iridium 192 | N. Sealed sources (Mallinckrodt Model 105.002) | N. 4 sources, two sources not to exceed 12 curies each and two sources not to exceed 13 curies each |
| O. Gadolinium 153 | O. Sealed sources (North American Scientific Model MED3601-MED3620) | O. Not to exceed 300 millicuries per source and 2.4 curies total |
| P. Cesium 137 | P. Sealed source (ICN Model C-Cs-137-D/20E in a J.L. Shepherd irradiator) | P. 20 curies |
| Q. Cobalt 60 | Q. Sealed source (Gamma Industries type ED-HP in a J.L. Shepherd irradiator) | Q. 1 curie |
| R. Plutonium 239 | R. Sealed neutron sources (Monsanto M-216 and #M-961) | R. 96 grams |
| S. Uranium depleted in Uranium 235 | S. Metal | S. 500 kilograms |



9. Authorized use:

- A. through M. Medical diagnosis, therapy and research in humans in accordance with any applicable U.S. Food and Drug Administration (FDA) requirements. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; and student instruction.
- N. One source for medical use permitted by 10 CFR 35.600, in each of two Nucletron Corporation microSelectron remote afterloader units. The source activity may not exceed 12 curies at the time of installation. Two sources in their shipping containers as necessary for replacement of the source in the remote afterloader units.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
37-00245-02

Docket or Reference Number
030-02945

Amendment No. 95

- O. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- P. through R. Research and development as defined in 10 CFR 30.4; student instruction; and instrument calibration.
- S. Shielding in linear accelerators.

CONDITIONS

10. Licensed material shall be used or stored only at the licensee's facilities located: on the main campus of the University of Pittsburgh in Pittsburgh, PA; at the University of Pittsburgh Center for Biotechnology & Engineering, 300 Technology Drive, Pittsburgh, PA; at the Bellefield Professional Building, 4th Floor, 130 North Bellefield Avenue, Pittsburgh, PA; at the Bellefield Towers, 100 North Bellefield Avenue, Pittsburgh, PA; at 260 Kappa Drive, Pittsburgh, PA; at Children's Hospital of Pittsburgh, One Children's Place, at 125 DeSoto Street and 3705 Fifth Avenue at DeSoto Street, Pittsburgh, PA; at the Hill Building, 3434 Fifth Avenue, Pittsburgh, PA; at the Ironbriar Building, 3600 Forbes Street, Pittsburgh, PA; at the Keystone Building, 3520 Fifth Avenue, Pittsburgh, PA; at the Lillian Kaufman Building, 3471 Fifth Avenue, Pittsburgh, PA; at Magee-Womens Hospital, Forbes and Halket Streets, Pittsburgh, PA; at Magee-Womens Research Institute, 204 Craft Avenue, Pittsburgh, PA; at the Medical Center Building, 3515 Fifth Avenue, Pittsburgh, PA; at UPMC Montefiore, 3459 Fifth Avenue, Pittsburgh, PA; at UPMC Presbyterian-Shadyside, 200 Lothrop Street, Pittsburgh, PA; at the Rangos Research Center, 3460 Fifth Avenue, Pittsburgh, PA; at the Western Psychiatric Institute and Clinic, 3811 O'Hara Street, Pittsburgh, PA; at 3343 Forbes Avenue, Pittsburgh, PA; at 3635 Boulevard of the Allies, Pittsburgh, PA; at the Hillman Cancer Center, 5115 Center Avenue, Pittsburgh, PA; at the McGowan Institute for Regenerative Medicine, 3025 East Carson Street, Pittsburgh, PA; at the Cellomics Building, 100 Technology Drive, Pittsburgh, PA; at the University Primate Research Laboratory, 109 New Texas Road, in Plumboro, PA; at the University of Pittsburgh Pymatuning Laboratory of Ecology, 13142 Hartstown Road, in Linesville, PA; at University of Pittsburgh Branch Campuses in Johnstown, Bradford, Titusville and Greensburg, PA; at the Mon Valley Community Health Center, Eastgate No. 8, Monesson, PA; and at the Laurel Ridge Observatory, Laurel Ridge Road, Ligonier, PA.
11. A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- B. 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 recency of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
- D. The Radiation Safety Officer for this license is Jerry C. Rosen.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
37-00245-02

Docket or Reference Number
030-02945

Amendment No. 95

12. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- 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.
 - 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.
 - 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.
 - 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.
 - 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.
 - 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
37-00245-02

Docket or Reference Number
030-02945

Amendment No. 95

- G. 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.
- H. 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. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer, name and model numbers, and the date of the inventory.
18. Pursuant to 10 CFR 20.2002, and through December 31, 2002 only, the licensee may dispose of incinerator ash containing radioactive materials with atomic numbers 1 through 83, except as identified below, as ordinary waste in a landfill, provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies. The total volume of incinerator ash disposed of to the landfill shall not exceed 550 cubic meters in calendar year 2002.
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:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
37-00245-02Docket or Reference Number
030-02945

Amendment No. 95

- C. A record of each such disposal permitted under this license condition shall be retained for 3 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.
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. 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.



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
37-00245-02Docket or Reference Number
030-02945

Amendment No. 95

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. 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. Letter dated August 8, 2000
- B. Application dated April 27, 2001
- C. Letter dated March 19, 2002
- D. Letter dated May 6, 2002
- E. Electronic mail letter dated May 14, 2002
- F. Letter dated September 24, 2003



For the U.S. Nuclear Regulatory Commission

Date September 26, 2003

By

Original signed by Michelle Beardsley

Michelle Beardsley
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406