UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

May 10, 2007

Department of Health & Human Services
National Institutes of Health
National Institute of Diabetes and
Digestive and Kidney Diseases
ATTN: David M. Mott, Ph.D.
Radiation Safety Officer
4212 North 16th Street, Room 541
Phoenix, Arizona 85016

SUBJECT: LICENSE AMENDMENT **CORRECTED COPY**

Please find enclosed a corrected copy of Amendment No. 33 to NRC License No. 02-13990-01, **correcting authorized use and authorized users for in vitro studies.**

NRC's Regulatory Issue Summary (RIS) 2005-31, provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS. The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/. Additionally, the link for frequently asked questions may be located at: http://www.nrc.gov/reading-rm/faqlist.html, then select "Withholding of Sensitive Information." Pursuant to NRC's RIS 2005-31, the enclosed materials license will be made publicly available.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(v). You should review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or if you have any questions, please contact me at 925-673-9646.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements.

However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room"; choose "Collections"; choose "NUREG-Series Pubs"; and select "Publications Prepared by the NRC Staff". Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

\RA

James L. Montgomery, Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-01211
License: 02-13990-01
Control: 471283

Enclosures: As stated

Amendment No. 33

MATERIALS LICENSE

CORRECTED COPY

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 letter dated February 22, 2007
1. Department of Health & Human Services National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases	3. License number 02-13990-01 is amended in its entirety to read as follows:
2. 4212 North 16th Street, Room 541 Phoenix, Arizona 85016	4. Expiration date May 31, 2014
	5. Docket No. 030-01211 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. Calcium-45	A. Any	A. 0.5 millicuries
B. Nickel-63	B. Any	B. 0.5 millicuries
C. Sulfur-35	C. Any	C. 4 millicuries
D. Phosphorus-33	D. Any	D. 5 millicuries
E. Carbon-14	E. Any	E. 60 millicuries
F. Hydrogen-3	F. Any	F. 250 millicuries

9. Authorized use:

A. through F. In vitro studies.

E. and F. Research in humans in accordance with any applicable U.S. Food and Drug Administration (FDA) requirements. (Any uptake, dilution and excretion study permitted by 10 CFR 35.100.)

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SUPPLEMENTARY SHEET

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at:

- 4212 North 16th Street (Phoenix Indian Medical Center, 5th Floor), Phoenix, Arizona.
- 445 North 5th Street (Building #2, 2nd Floor), Phoenix, Arizona.
- 1550 East Indian School Road (Building #1), Phoenix, Arizona (In vitro studies only).

11. The Radiation Safety Officer for this license is David M. Mott, Ph.D.

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Leslie J. Baier, Ph.D.	In vitro studies using materials in Items 6.A. through 6.F.
Joy C. Bunt, M.D., Ph.D.	In vitro studies using materials in Items 6.A. through 6.F. Research studies in humans using materials in Items 6.E and 6.F.
Clifton Bogardus, M.D.	In vitro studies using materials in Items 6.A. through 6.F. Research studies in humans using materials in Items 6.E and 6.F.
David M. Mott, Ph.D.	In vitro studies using materials in Items 6.A through 6.F.
Shannon Parrington	In vitro studies using materials in Items 6.A. through 6.F.

13. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.2.

14. 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 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.

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15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

16. The licensee shall conduct a physical inventory every 6 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 included the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

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

18. A. Sealed sources shall be tested from leakage an/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 leak tested if the contain only hydrogen-3; or they contain only radioactive gas; or thee half-life of the isotope is 30 days or less; or they contain no more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material.

    D. Sealed sources need not by 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.

    E. The leak test shall be capable of detecting the presence of 0.005 microcuries (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. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

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F. Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by the licensee or by other person specifically licensed by the U.S. Nuclear Regulatory or an Agreement State to perform such services.

G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.

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 the 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, representation, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated November 19, 2003
    B. Letter dated April 5, 2004
    C. September 29, 2005
    D. Letter Dated December 28, 2005

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

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Date: May 10, 2007

By: _____

James L. Montgomery, Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011