



Terrance G. Alexander, Executive Director

March 16, 2007

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

RE: **Amendment to Byproduct Material License No. 21-00215-04**
(Docket No. 030-01988)

Materials Licensing:

The University of Michigan (U-M) is requesting amendments to the U-M Byproduct Material (Broad Scope) License No. 21-00215-04.

Manufacture & Distribution of Radioactive Drugs for Medical Use (mIBG and NP-59)

The University of Michigan (U-M) has elected to terminate all production and commercial distribution activities of radiopharmaceuticals currently authorized, pursuant to 10 CFR Part 32, under its Byproduct Materials license. The license authorizes the University to produce and commercially distribute two radiopharmaceuticals known as mIBG and NP-59. The University requests the license be amended to delete those sections of the Broad Scope License that relate to the preparation and commercial distribution of iodine-131 mIBG (NP-292), iodine-125 mIBG (NP-392), and iodine-131 NP-59. Specifically, please delete Sections 6.S, 7.S, 8.S, 6.T, 7.T, 8.T, 9.S and T, and Appendix D of the license application dated September 27, 2000. The University also requests termination of the associated fee assessments for these activities under the Materials Annual Fee Category 3B.

NOTE – please note that the U-M is requesting an expeditious review and approval of this amendment request in order to capitalize on the financial savings resulting from the pro-rating of the NRC FY 2007 annual materials fee of \$9,400 for the manufacturing and commercial distribution of mIBG and NP-59 [Invoice #AM1507-07 / Code AA905 (ANN) / Materials Annual Fee Category '3B'] for Materials License No. 21-00215-04. Brenda Brown / NRC Headquarters [(301) 415-7554] noted that the annual fee could be pro-rated if a license amendment was submitted before the end of March 2007.

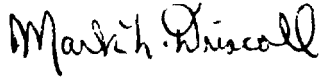
Decay-in-Storage Provisions for the Storage of Radioactive Waste

In accordance with NRC Regulatory Issue Summary 2004-17, Revision 1 ('Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material'), the U-M is requesting that Condition 18 of the Broad Scope License (Amendment No. 92) be amended to allow for the decay-in-storage and processing of both medical and non-medical radioactive waste in a manner similar with the current performance-based requirements specified in 10 CFR 35.92 ('Decay-in-Storage'). Specifically, the U-M requests that Condition 18 of the License be amended to allow decay-in-storage of radioactive materials with half-lives of less than or equal to 120 days and to eliminate the requirement for a specific holding period (currently ten half-lives).

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Thank you for time and consideration in the expeditious review of this amendment request. Please do not hesitate to contact me at Radiation Safety Service / OSEH [(734) 647-2251] should you have any questions or comments regarding this license amendment.

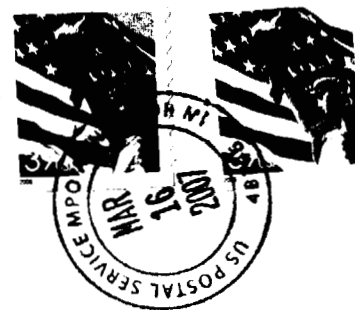
Sincerely,

A handwritten signature in black ink, appearing to read "Mark L. Driscoll". The signature is fluid and cursive, with the first name "Mark" being more prominent.

Mark L. Driscoll
Director / Radiation Safety Officer
Radiation Safety Service / OSEH

MLD/mld
NRCLicenseAmend031607.doc

cc: Terry Alexander, Director, Occupational Safety & Environmental Health
Ruthann Nichols, Ph.D., Chair, Radiation Policy Committee
Darrel Wiedeman, Senior Health Physicist, Nuclear Regulatory Commission (Region III)



THE UNIVERSITY OF MICHIGAN

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