

APPENDIX
NOTICE OF VIOLATION

The McLaughlin Research Institute
for Biomedical Sciences, Inc.
Great Falls, Montana 59405

Docket: 030-30962
License: 25-26973-01

During an NRC inspection conducted on February 10, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. License Condition 14 of License 25-26973-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated April 27, 1989.

Section 10.4 of the application states that the licensee will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

Item No. 8 of Appendix I states that personnel will wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

Contrary to the above, as of February 10, 1994, the licensee did not supply finger exposure monitors to any personnel responsible for the preparation, assay, and application of radiolabelled compounds.

This is a Severity Level IV violation (Supplement IV).

- B. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, as of February 10, 1994, the licensee did not make surveys to assure compliance with 10 CFR 20.2003(a) which limits the disposal of licensed material by release into a sanitary sewerage system. Specifically, the licensee failed to determine the amount of material, in accordance with their water usage, which may be released to the sanitary sewerage system without exceeding concentration limits for their new facility.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, The McLaughlin Research Institute for Biomedical Sciences, Inc., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas
this 1st day of March 1994

bcc:
DMB - Original (IE-07)
LJCallan
DDChamberlain
LWCamper
RAScarano, DRSS/RIV
MMessier, OC/LFDCB (4503)
*WLFisher
*CLCain
*WHRadcliffe
*GLGuerra
*NMIB
*MIS System
*RIV Files (2)

*W/IFS Form

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|---------------------|-----------------|-------------------|---------------------|--|
| RIV:NMIB <i>GLG</i> | NMIB <i>GLG</i> | C:NMIB <i>CLC</i> | AD:DRSS <i>DRSS</i> | |
| WHRadcliffe:nh | GLGuerra | CLCain | DDChamberlain | |
| 2/22/94 | 2/22/94 | 2/23/94 | 3/1/94 | |