APPENDIX A

NOTICE OF VIOLATION

Myco Pharmaceuticals, Inc.
Cambridge, Massachusetts 02139-1562

Docket No. 030-33140
License No. 20-30035-01

During an NRC inspection conducted on April 11, 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. Condition 11C of License No. 20-30035-01 identifies the Vice President of Research as the Radiation Safety Officer (RSO) for this license.

Contrary to the above, from September 8, 1993 to April 11, 1994, the Vice President of Research was not the RSO for this license. Specifically, the RSO transferred responsibility for the radiation safety program activities to a Senior Scientist and the Operations Manager. This resulted in an inadequate program oversight and numerous violations of the NRC requirements.

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

B. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, from September 8, 1993 to April 11, 1994, all individuals working in or frequenting a restricted area were not instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses. Specifically, radioactive material users, housekeeping, and other ancillary personnel who frequented the isotope laboratory, dark room and radioactive waste room, restricted areas, were not provided training in radiation safety.

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

IE-07

C. Condition 15 of License No. 20-30035-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application submitted with letter dated April 6, 1993 and letter dated May 27, 1993.

Item 3 of letter dated May 27, 1993 requires survey meters to be calibrated every six months by a qualified contractor.

Contrary to the above, as of April 11, 1994, survey meters were not calibrated every six months by a qualified contractor. Specifically, the licensee's survey meters were last calibrated on June 14, 1993 and have not been re-calibrated. The uncalibrated survey meters were used by personnel to perform radiological surveys.

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

D. Condition 15 of License No. 20-30035-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application submitted with letter dated April 6, 1993 and letter dated May 27, 1993.

Appendix 4 of letter dated April 6, 1993 entitled "Monthly Laboratory Survey Procedure" requires, in part, that monthly laboratory surveys be performed by wipes.

Contrary to the above, as of April 11, 1994, monthly laboratory surveys were not performed by wipes. Specifically, the licensee has not performed wipe surveys of all the laboratories posted for the use and storage of radioactive materials.

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

E. 10 CFR 20.2103(a) requires that each licensee maintain records of the results of surveys required by 10 CFR 20.1906(b). 10 CFR 20.1906(b) requires, in part, the licensee to perform a survey of incoming labelled radioactive material packages. The licensee shall retain these records for three years after the record is made.

Contrary to the above, as of April 11, 1994, the licensee did not maintain records of the results of receipt surveys performed between September 8, 1993 and April 11, 1994 and these surveys were required by 10 CFR 20.1906(b). Specifically, only one receipt record was available at the time of inspection. No other receipt records have been maintained by the licensee. The first shipment of radioactive material arrived at the licensee's facility on September 8, 1993.

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

F. 10 CFR 20.1902(e) requires that the licensee post each area or room in which certain amounts of licensed material, specified in §20.1902(e), are used or stored, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Contrary to the above, on April 11, 1994, the licensee did not post each area or room in which certain amounts of licensed material, specified in §20.1902(e), are used or stored, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)." Specifically, the isotope laboratory, an area or room in which source vials of phosphorous-32 (250 microcuries per source vial) are used and stored, was posted with an "Authorized Personnel Only " sign.

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

G. Condition 15 of License No. 20-30035-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application submitted with letter dated April 6, 1993 and letter dated May 27, 1993.

Page 19 of the licensee's Radiation Safety Guide requires all personnel using or routinely exposed to radioisotopes to wear film badges.

Contrary to the above, between September 8, 1993 and April 11, 1994, personnel using or routinely exposed to radioisotopes were not wearing film badges. Specifically, radioactive material workers handled radioactivity without wearing a film badge. Film badges were not available at the time of inspection.

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

Pursuant to the provisions of 10 CFR 2.201, Myco Pharmaceuticals, 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 I, 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.