

Myco Pharmaceuticals Inc.

Building 300 • One Kendall Square • Cambridge, MA 02139

June 9, 1994

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

REPLY TO NOTICE OF VIOLATION

ROUTINE INSPECTION NO. 030-33140/94-001

NRC LICENSE NO. 20-30035-01

Dear U.S. Nuclear Regulatory Commission:

This letter responds to your letter of May 16, 1994, concerning the above-cited routine inspection, and the Notice of Violation included as Appendix A to your letter. Myco Pharmaceuticals Inc. ("Myco") appreciates the opportunity to respond to the NRC's observations and to reaffirm its commitment to providing its staff a safe working environment.

Your letter follows a routine safety inspection conducted on April 11, 1994 by Kathleen Dolce of your office of Myco's research and development facility, located in Building 300, One Kendall Square, Cambridge, MA 02139-1562. At the conclusion of the inspection, Ms. Dolce reviewed her findings with Drs. William E. Timberlake, T. Vance Morgan and Christine Bulawa. We were pleased to be informed that Myco was in substantial compliance with NRC regulations and provided a safe work place for its employees. We appreciated the very constructive recommendations made by Ms. Dolce to help us address the items noted and began to do so immediately following her exit interview. The points she raised were restated in Appendix A of your May 16, 1994 letter. I am pleased to inform you that we have addressed the items listed in Appendix A, and believe we meet or exceed NRC regulations for the safe handling of the radioactive materials present in our facility. The specific actions we have taken are given below.

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- Violation A:** At the time we filed our original NRC license application our research facility had not been completed and we had no staff engaged in research in Myco laboratories. Dr. William E. Timberlake, Vice President for Research, was RSO at the time the application was made because he is highly experienced in the handling of radioactive materials. As our labs opened, two senior scientists highly experienced in the safe handling of radioactive materials, Dr. T. Vance Morgan and Dr. Christine Bulawa, began assuming the duties of RSO to assure that the use of radioactive materials was overseen directly and on a day-to-day basis. The duties of RSO were conscientiously and effectively carried out at all times. (All NRC and related communications were directed to Dr. Morgan.) It was our oversight not to amend the original license to reflect this change in responsibilities. We wish to emphasize, however, that an active RSO was continuously in place from the time we opened our facility and began research. We are remedying this situation by amending our license to show Dr. T. Vance Morgan, Senior Scientist, Operations Manager as RSO. The amendment will be submitted no later than June 30, 1994.
- Violation B:** Myco Pharmaceuticals Inc. is committed to providing safety training to all of its staff, including training in the safe handling of radioactive materials. All individuals working with radioactive materials at Myco had received radiation safety training at outstanding universities and were highly experienced in the safe use of radioisotopes. We now understand that certain ancillary staff who occasionally must enter radiation restricted areas also need such training. We conducted a training course on June 8, 1994, presented by Mitch Galanek of the MIT Radiation Protection Office. We have been informed that Mitch is a RSO at MIT, has worked with MIT Radiation Protection for 18 years, and is certified by the American Board of Health Physics. Attendance was required of all Myco laboratory staff. New personnel hired after this course will receive training directly from the RSO prior to beginning work.
- Violation C:** The survey meters used by Myco Pharmaceuticals require calibration only annually. We stated incorrectly in our license application that the survey meters would be calibrated twice annually. We will amend our license to reflect yearly calibrations of survey meters, as suggested by Ms. Dolce. Yearly calibrations will be performed under contract by Mitch Galanek of the MIT Radiation Protection Office. The survey meters in use at Myco from the time our research and development facility opened have been maintained in good operating condition and function appropriately.
- Violation D:** In drafting our original application for an NRC license we anticipated the use of radioisotopes that would require wipe tests for detection. In our initial activities we had very low usage of radioisotopes, predominantly ^{32}P , which can be readily detected by our survey monitors. Therefore, surveys were performed by monitor, not wipe tests. This practice assured that in the event of any contamination, detection and decontamination would occur immediately. In response to Ms. Dolce's comments, we initiated wipe tests on April 8, 1994. These will be supplemented by independent tests conducted under contract by Mitch Galanek of the MIT Radiation Protection Office.
- Violation E:** All of the shipments we have received have been below the threshold requirements for monitoring. We have now implemented monitoring and record keeping for all shipments of radioactive materials received. The monitoring is carried out by Ms. Julie Clifford under the supervision of Dr. Morgan.

- **Violation F:** At the time of the inspection, signs were in place with the universal radioactive symbol displayed and stating "Authorized Personnel Only". All personnel were aware of the meaning of the universal symbol. We have now posted prominent signs stating "CAUTION RADIOACTIVE MATERIALS."
- **Violation G:** Film badges were not in use initially, because the amounts of radioisotopes in use were in the microcurie range. In response to Ms. Dolce's comments, we implemented a film badge program with Landauer Inc. beginning April 15, 1994.

It is the policy of Myco Pharmaceuticals to provide a safe working place for all of its employees and to protect the public. We responded immediately to the observations noted during our initial NRC inspection. We look forward to continued good relations with the NRC in the future and regret any deficiencies or misunderstandings that arose during our start up phase of operations.

Sincerely yours,



Barry A. Berkowitz, Ph.D.
President and CEO

cc: W. E. Timberlake, V.P. Research
T.V. Morgan, Operations Manager
NRC Regional Administrator, Region I
M.M. Shanbaky, Chief, R&D Section