DCD/DCB

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May 25, 1994

William L. Axelson
United States Nuclear Regulatory Commission
801 Warrenville Rd.
Lisle, IL, 60632-4351

RE: License No. 24-00513-32
Docket No. 030-02278

Subject: Additional Information Submitted in support of Reply to the Notice of Violation and Proposed Civil Penalty (NRC Inspection Report No. 030-02278/94001(DRSS))

Dear Sir:

This letter and attachments are being sent to you in response to your May 6, 1994 letter which required the University to submit an additional response addressing NRC's specific concerns with the April 7, 1994 Reply to Notice of Violation and to submit a safety performance improvement program.

The enclosed "Supplemental Information to an April 7, 1994 Reply to a Notice of Violation" addresses each of the specific concerns listed in your May 6, 1994 enclosure.

Also enclosed is the "Safety Performance Improvement Program -- Action Plan for the University of Missouri-Columbia Radiation Safety Program." This plan, developed in conjunction with our consultant, addresses the root causes of the compliance problems at the University of Missouri-Columbia. The action plan describes how the University is going to achieve sustained control over the radiation safety program. Some of the issues addressed are:

- Radiation Safety Officer responsibilities.
- Radiation safety staffing.
- Training for radiation safety personnel which includes making performance-based assessments.
- Training for the authorized users and their staff.
- Radiation Safety Committee and University Administration communication and responsibilities.
- Enforcement protocol.
- Computer management system.
- Self-assessment program.

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We hope that you find the enclosed information satisfactory. We are confident the safety performance improvement program provides the University an action plan that will achieve an exemplary Radiation Safety Program.

Sincerely,

Jacquelyn K. Jones
Associate Vice Chancellor
Administrative Business Services

Enclosure Safety Performance Improvement Program
Supplemental Information

cc: James Lieberman, Director
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Office of Enforcement
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Chancellor Kiesler
Provost Brouder
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SUPPLEMENTAL INFORMATION TO AN APRIL 7, 1994 REPLY TO A NOTICE OF VIOLATION

Violation 1. *Surveys not performed in accordance with 10 CFR 20.201(b) to assure radiation levels were limited in unrestricted areas.*

NRC concern: *The reply does not: (1) fully identify the reasons for the violation; and (2) include the corrective steps taken to address each causal factor.*

(1) The initial response by the authorized user was correct. The user cleaned and addressed the spill correctly so as to mitigate the spill and prevent the spread of contamination. However, due to the following problem areas, the spill and resulting contamination were not handled properly.

- The authorized user did not know what follow-up actions and documentation should have been made, and did not realize the importance of notifying the Radiation Safety Office. This was due to inadequate training and failure of the authorized user to follow procedures contained within the radiation safety manual.

- The authorized user did not recognize that fixed contamination remained on the floor following the cleanup of removable contamination. This was due to lack of training in proper surveying techniques designed to recognize the limitations of the laboratory survey instrument, and due to failure to know what steps should be taken with regard to spill cleanup, follow up survey procedures, and proper documentation.

- The Radiation Safety Staff did not follow good laboratory survey techniques in their inspection to identify fixed contamination. The lack of discussion with laboratory personnel at the time of inspection did not allow an opportunity to learn of the spill and contamination cleanup.

- The Radiation Safety Staff did not institute immediate and effective corrective action and instruction for the authorized user and laboratory personnel. This was due to inadequate Radiation Safety Office operating practices designed to help authorized users identify and address problems.

(2) The specific corrective steps that have been taken in regard to this authorized user and contamination event are as follows.

- The RSO met with the authorized user on March 30, 1994 and reviewed the proper procedure to respond to a spill of radioactive material. The RSO emphasized the requirement to notify the Radiation Safety Office of a contamination event, especially when contamination of the floor or personnel occurs. The authorized user had also attended the March 28, 1994 mandatory meeting where contamination control procedures were reviewed and the requirement to notify the Radiation Safety Office of a contamination event was discussed.

- The authorized user obtained new survey instrumentation on April 20, 1994. A two hour training session was conducted by a Health Physicist for the authorized user and laboratory personnel which included use of the instrument, proper survey technique, and contamination control procedures. A performance-based evaluation was made for each individual to determine their understanding.

- The RSO has reviewed with the Radiation Safety Staff proper survey techniques and the importance of interacting with the laboratory personnel. Since the NRC inspection there have been over eight follow up inspections or additional visits with this authorized user by the Radiation Safety Staff.

- Changes to the Radiation Safety Office operating practices to improve the Radiation Safety Staff's performance in identifying problems and instituting timely and effective corrective actions are described in the University's action plan.

The safety performance improvement program included with this supplemental information describes the long-term corrective steps that are being taken to avoid further violations of this type. Those long-term corrective steps will address each of the causal factors listed above in the following ways:

- The training of authorized users will be strengthened by the establishment of more formalized lines of communication with an assigned Health Physicist and an assigned Radiation Safety Committee (RSC) representative. This interaction will emphasize the need of an authorized user to know what follow-up actions and documentation are required in the case of contamination, and the importance of notifying the Radiation Safety Office of such an event.

- Procedures contained in the radiation safety manual are being revised to be more clear and concise. An evaluation of the adequacy of instrumentation necessary to support authorized users survey procedures is being made and upgraded, as necessary, to provide proper contamination control. Included with this instrumentation review is performance-based training and evaluation for laboratory personnel in proper surveying procedures.

- The Radiation Safety Staff responsible for surveying and inspection of laboratories is being upgraded to full-time technicians with experience and/or training in health physics. Inspections are being modified to require performance-based evaluation of laboratory personnel performance of surveys, contamination control and documentation, and notification requirements; discussion of the inspection results with the authorized user or laboratory personnel will address the problems identified and speedup the process of determining and implementing corrective actions. Evaluation of the technicians' performance will be made periodically by a Health Physicist and/or by the RSO.

- The assigned Health Physicist or the RSC representative can be called in to assist the authorized user in the development and implementation of corrective actions, and to make sure the process continues in a timely fashion. The authorized users will be expected to be active participants in the University's radiation safety program. The heightened awareness of the Radiation Safety professional staff and the RSC members in the day-to-day operation of the overall program will be used to identify problem trends and needs for global corrective actions.

Violation 2A. RSO authorized an increase in possession limits and the Radiation Safety Committee did not review or approve the authorization at their next meeting, as required by Condition 30 of the License.

NRC Concern: The date when corrective actions will be implemented is not identified.

As stated in the University's April 7, 1994 reply to this violation, full compliance was achieved on March 31, 1994 and the RSO is ensuring that future interim authorizations issued are reviewed at the next Committee meeting. However, because the University is evaluating the program as a whole to identify needed improvement, the process of issuing interim authorizations will be addressed as part of Phase Two of the University's action plan.

Violation 2C. Basic instruction and general information training not presented by the Authorized User before radiation workers under their control were involved with working with radioactive materials, as required by Condition 30 of the License.

NRC Concern: The reply does not adequately address the corrective steps that will be taken to avoid further violations.

As described in the safety performance improvement program accompanying this supplemental information, the long-term corrective steps that are being taken to avoid further violations of this type are as follows:

- New authorized users and authorized users requesting renewal will be interviewed by a Health Physicist as part of the authorization approval process; the Health Physicist will make sure that authorized users understand the scope of their authorization and associated responsibilities.

- Authorized users will have a laboratory-specific review by their assigned Health Physicist as part of the authorization approval process; discussion of the responsibility for training of personnel and scope of that training is part of this review.

- As part of inspections done by the Radiation Safety Staff, a list of the authorized user's staff (radiation workers) will be verified and their needed level of training reviewed.

Violation 2E. Food and drink being consumed, stored or prepared in radioactive work areas, contrary to the requirements established in Condition 30 of the License.

NRC Concern: The reply : (1) incorrectly identifies the reasons for the violation; (2) does not describe the corrective action taken to avoid further violations; (3) does not identify the date for full compliance; and (4) is not consistent with previous immediate corrective action described in the teleconference February 1, 1994.

(1) Reasons for the violation: The authorized users were not aware of the terms and conditions of the license. There was inadequate health physics oversight of this aspect of the radiation safety program.

(2) Corrective action: Authorized users and administrative personnel have been reminded that no consumption, storage, or preparation of food or drink shall be allowed in rooms posted as radioactive material use areas. In mandatory meetings conducted on March 28, April 28 and May 19, 1994, the RSO has emphasized the ban on eating and drinking in radioactive use areas and the safety reasons for this good laboratory practice. Additional mandatory meetings are scheduled for May 26 and June 1, 1994.

(3) Additional corrective action and date of full compliance: To assure that compliance is maintained, the University will utilize the enhanced communications and participation by authorized users, Radiation Safety Staff, and Radiation Safety Committee to address this license condition. The University consultant's review of radioactive material use areas will specifically address this issue as part of Phase One of the action plan.

(4) The University believes there have been no inconsistencies in regard to statements made about corrective actions taken or in the April 7, 1994 reply to this violation. In addressing this license condition authorized users, the Radiation Safety Staff, and the Radiation Safety Committee will be working together in Phase Two of the action plan to examine the controls necessary for compliance and to ensure the health and safety of individuals working around radioactive materials.

Violation 2F. Fume hood not tested for air flow measurements on a semi-annual basis, contrary to the requirement established in Condition 30 of the License.

NRC Concern: The reply does not fully explain the steps taken to avoid further violations.

The steps which have been taken in regard to this violation include placing this hood on the regular schedule to measure the flow rate semi-annually, and reminding the Radiation Safety Staff to verify during laboratory inspection that hood flow rate measurements are in compliance. The steps which are being taken to prevent further violations of this type are addressed in Phase Two of the University's action plan. Specifically, authorized users are being expected to be more knowledgeable of their laboratory requirements, technician performance will be periodically evaluated by a Health Physicist and/or by the RSO, and all inspection reports will be reviewed by the assigned Health Physicist.

Violation 3F. The Licensee failed to make a record of each survey of the patient and the area of use immediately after implanting the source, contrary to the requirement of 10 CFR 35.406(c).

NRC Concern: The reply does not consider the use of the surveys to effectively identify misplaced sources as denoted in 10 CFR 35.406(c).

While the occurrence of this violation was and continues to be denied, the University has and will continue to perform a radiation survey of the patient and area of use in accordance with 10 CFR 35.406(c) and Regulatory Guide 10.8, Appendix Q. The University performs this survey to confirm that no sources have been misplaced and to minimize worker and public dose during implant therapy.

SAFETY PERFORMANCE IMPROVEMENT PROGRAM -- ACTION PLAN FOR THE UNIVERSITY OF MISSOURI-COLUMBIA RADIATION SAFETY PROGRAM

INTRODUCTION

The United States Nuclear Regulatory Commission has directed the University of Missouri-Columbia (University) to develop and implement a corrective action plan. The purpose of the University's review of the radiation safety program and implementation of this action plan is to: (a) foster thorough knowledge of license conditions and NRC regulations by the Radiation Safety Staff and radioactive material users; (b) instill a sense of accountability regarding compliance with safety requirements in the Radiation Safety Staff and radioactive material users; and (c) establish an effective and ongoing self-assessment program.

PHASE ONE: (Time line--In Process)

- Hire a qualified Health Physics consultant to review the entire radiation safety program and make corrective action recommendations.

  This is being done in a two-step process. The first step occurred from May 11, 1994 through May 20, 1994, when Susan J. Engelhardt, President of Engelhardt & Associates, Inc. came to the University to review the health physics portion of the radiation safety program. She met with the Radiation Safety Staff, the Radiation Safety Committee and the University administration to begin determination of what the deficiencies are and how best to correct them. The second step of this process will be carried out from June 6, 1994 through July 15, 1994, by Susan J. Engelhardt, President of Engelhardt & Associates, Inc. and her associate, Dr. Ralph Grunewald, Radiation Safety Officer, Medical College of Wisconsin. This second step will entail reviewing the academic use and medical use portions of the University's licensed activities. The review will include examining a minimum of 100 laboratories and examining the authorized user's records, training, laboratory procedures and facilities. Material control, area radiation and contamination control, and the use of safety equipment will be reviewed. The review of the medical use portion will also include a thorough assessment of both compliance with the requirements of 10 CFR 35 and Regulatory Guide 10.8. A written report of the findings will be provided to the University. A closeout meeting will be held at the

University to present findings to the RSO, Radiation Safety Committee, and University administration.

PHASE TWO: (Time line--Completion by end of December 1994)

RADIATION SAFETY PROGRAM IMPROVEMENT

- STAFFING NEEDS: When working to achieve an improved compliance status, additional staff is often necessary; therefore, the University will hire 3 technicians (position title: Environmental Health Technician) who will have experience and/or training in health physics. These technicians will be responsible for doing the radiation safety surveys/inspections of laboratories on campus and will assist the Radiation Safety professional staff (Health Physicists) in day-to-day work. NOTE: These technicians will replace the graduate student FTE listed for the program in the University's February 28, 1992 license renewal application. In addition, the University will hire one additional Health Physicist to assist with the program.

- UNIVERSITY ADMINISTRATION: The Radiation Safety Committee (RSC) members will be appointed to 3 year terms; candidates for membership will be gathered from the RSO, the RSC Chair, and other appropriate sources (e.g., Deans and authorized users). Members of the Committee should be representative of the disciplines that use radioactive materials on campus. The University administration will include a letter of appointment and support for each faculty and staff appointment to the Committee. The RSO and RSC will, at least quarterly, provide the Provost and the Vice Chancellor for Administrative Services with a status report of the radiation safety program so that senior management is kept cognizant of pertinent activities.

- MU RADIATION SAFETY COMMITTEE (RSC): As part of this action plan, the following will be done with respect to the RSC.

  a. The RSC membership should reflect the authorized user disciplines on campus.

  b. Senior management will re-affirm its support of the RSC to ensure that Committee members know corrective actions taken by the RSC will be supported.

  c. Members of the RSC will be assigned specific groups of authorized users for which they will act as a primary representative. The RSO and the RSC Chair will decide how authorized user assignments are made. The RSC

representative will be familiar with the research activities and work conducted by their assigned authorized users. This Committee member will assist the Radiation Safety Staff with compliance problems associated with their assigned authorized users.

- RADIATION SAFETY OFFICER (RSO): The RSO is responsible for the following:

  a. Assign health physics responsibilities so that each Health Physicist can focus on a particular aspect of the radiation safety program and help ensure that it is in compliance with license conditions and NRC regulations.

  b. Assign each Health Physicist a group of authorized users for which the Health Physicist will act as a primary contact with the Radiation Safety Staff and will provide the first review of applications for use.

  c. Meet with deans, chairs, and faculty groups to explain changes in the radiation safety program, and describe their responsibilities to support and sustain the radiation safety program.

  d. Act as the liaison between the administration, RSC, radiation safety staff and authorized users to establish and facilitate the channels of communication. In this role, the RSO will be kept cognizant of activities occurring in the radiation safety program and act as the major link which ensures that these interactions in identifying and correcting problems occur and progress at reasonable rates.

  e. Hire new staff as necessary to implement the action plan.

  f. Conduct random inspections of various aspects of the radiation safety program to review performance of the radiation safety staff.

  g. Provide the second review of applications for use of the radioactive materials and requests for special conditions.

  h. Establish the process to assign the application review to a RSC member, to issue interim authorizations as necessary, and to schedule the application for Committee approval at the next RSC meeting.

  i. Take corrective action where there are violations of the regulations set forth by the University. If appropriate, these actions may be taken in conjunction with an assigned RSC member, the Committee Chair, or by Committee action.

Corrective action may include the immediate stoppage or modification to individual uses of radioactive materials in the event of imminent threat to health and safety.

- RADIATION SAFETY PROFESSIONAL STAFF (Health Physicists): As part of this action plan, the Health Physicists will do the following:

  a. Each Health Physicist will be assigned a segment of the radiation safety program to review and develop a thorough knowledge of that segment, and to ensure that all aspects of that segment are in compliance with license conditions and NRC regulations.

  b. Each Health Physicist will draft procedures and associated documentation forms for the assigned segment of the program. These procedures and forms will be reviewed by the RSO and the RSC, and will be tested over a period of time to confirm that the procedures do meet all the requirements.

  c. Each Health Physicist may also work with a technician assigned by the RSO, and act as a liaison between the technician and authorized users.

  d. Each Health Physicist will review applications for use of radioactive materials and requests for special conditions received from their assigned authorized users. These applications will be forwarded to the RSO for a second review.

  e. Each Health Physicist will review inspection reports of their assigned group of authorized users, and recommend corrective actions for violations of University regulations to the RSO, as necessary.

  f. Each Health Physicist will conduct periodic inspections to evaluate performance of technicians.

- RADIATION SAFETY STAFF TECHNICIANS: As part of this action plan, the technicians will be responsible for the following areas:

  a. Surveying and inspecting laboratories for compliance utilizing performance-based evaluations.

  b. Meet with authorized user or laboratory representative to discuss the findings of the inspection.

c. Report problems to the authorized user's assigned Health Physicist for subsequent follow up.

d. Route all written inspection reports to the assigned Health Physicist for review.

e. Provide a written inspection report to the authorized user.

- AUTHORIZED USERS: As part of this action plan to heighten authorized user's awareness of individual responsibilities and provide direction as to what they must do to assure compliance with the University's license, the following will be done:

  a. New applicants will be interviewed by the RSO so that the radiation safety program can be explained, and RSC member and Health Physicist introduced. In addition, once the application is approved, a Health Physicist will visit the laboratory before radioactivity is used and conduct a performance based evaluation for readiness.

  b. Each authorized user will be assigned an RSC representative as a primary contact with the Committee.

  c. Each authorized user will be assigned a Health Physicist as a primary contact with the Radiation Safety Staff.

  d. The authorized users will become active participants in implementing and sustaining the radiation safety program. Verification of their awareness and completion of responsibilities will be done through the use of performance-based training and evaluation.

  e. The radiation safety manual will be updated to reflect the procedural changes made for the radiation safety program to provide clear, concise, and effective instructions and forms in support of users meeting their authorization responsibilities.

ENFORCEMENT

In order to assure compliance with radiation safety rules and regulations, the following enforcement protocol will be instituted:

- If an authorized user is found to be in noncompliance with some aspect of MU's radiation safety program regulations, the authorized user will be visited by a Health Physicist; the problem will be reviewed and corrective action plans discussed.

- If an authorized user does not come into compliance, or if either the Health Physicist or the authorized user is not satisfied with the outcome of the visit, the RSO, in conjunction with the RSC representative, will decide what corrective action should transpire. This may include another visit to the authorized user's laboratory.

- When an RSC representative or the Committee Chairman make a site laboratory visit and verify non-compliance, the authorized user will be required to submit a written corrective action plan to the RSO and the RSC.

- If compliance is not achieved, the authorized user will be issued a suspension or modification order from the RSO or the RSC, and may be required to attend a Committee meeting to present corrective actions before reinstatement of authorization can be considered by the RSC.

- Cessation of operations can be individually instituted by the RSO at any time in the event of a threat to health and safety.

TRAINING

- The following areas will be modified to emphasize use of performance-based training techniques:

  a. Instrumentation use
  b. Surveying a laboratory for contamination
  c. Emergency response
  d. Reporting requirements
  e. Lab-specific training
  f. Required records and record-keeping

- A complete review of the formal training program will be done and guidelines set up for authorized users to implement the required lab-specific training for their laboratory personnel.

COMPUTER MANAGEMENT SYSTEM

- The RSO, in conjunction with the computer project manager, will obtain input from the Radiation Safety Staff to identify enhancements to fully utilize the computer management system.

- Most data entry for the program will be done by clerical personnel. Data entry will be periodically reviewed by a Health Physicist for quality control.

EQUIPMENT

- The radiation safety staff will complete an evaluation of the adequacy of radiation detection equipment on campus.

- The radiation safety staff will make an assessment of additional special equipment or supply needs for the radiation safety program.

PHASE THREE: (Time Line--Completion by end of December 1995)

- All of the above items will continue to be evaluated on a continuing basis. As the program develops, additional areas will be addressed.

- Staffing needs will be specifically re-evaluated to assure that the program needs are being met.

- A qualified Health Physics consultant will be hired to review the entire program by evaluating the status of the program, assessing the implementation of the action plan, identifying new or continuing problems, and making corrective action recommendations.

- Each of the Health Physicists will begin cross-training the other Health Physicists on their specific assigned license areas to assure that the professional staff has a complete and thorough understanding of the University's license.

- The annual review of the radiation safety program content and implementation will consist of two audits:

a. The RSO will develop a comprehensive audit form to assure that all of the radiation safety records are reviewed each year and that discrepancies are identified; that corrective actions are being initiated; that trends of noncompliance are noted; and program level corrective action prescribed.

b. The RSC will review the RSO audit findings as part of the Committee's annual audit of the radiation safety program. The RSC audit team may choose to focus on specific areas of concern that have been identified.

- The RSC will submit an annual report to the Chancellor, the Provost, and the Vice Chancellor for Administrative Services. The report will summarize findings of the RSO and RSC audits, corrective actions identified and recommend identified needs for continued maintenance of the operational radiation safety program.

PHASE FOUR : (Time Line--On-going)

When the radiation safety program reaches the end of the first year, all of the root requirements for the program will be in place. As an ongoing phase of development, the radiation safety program will be continually fine-tuned to stay in compliance with the ever-changing regulations and demands in the regulatory milieu.