UNIVERSITY OF MISSOURI-COLUMBIA

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April 7, 1994

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

RE: License No. 24-00513-32
Docket No. 030-02278
EA 94-031

Subject: Reply to a Notice of Violation

Dear Sir:

On March 9, 1994 the NRC Region III issued a Notice of Violation (NOV) to The Curators of the University of Missouri (Licensee) in regard to License No. 24-00513-32. The enclosed Reply to a Notice of Violation is the Licensee's written statement as required pursuant to the provisions of 10 CFR 2.201.

The Licensee has taken several actions to immediately address the concerns expressed by the NRC in both the Enforcement Conference (February 28, 1994) and the written Notice of Violation (March 9, 1994). The Licensee desires to address these concerns in a timely manner but also to address these concerns comprehensively. The most significant action taken by the Licensee was the decision to replace the Radiation Safety Officer (RSO) for this License. Dr. Susan M. Langhorst was named RSO for this License and assumed her responsibilities on March 3, 1994. While Dr. Langhorst has been a University employee since 1980, her radiation safety responsibilities were with the Missouri University Research Reactor and not with the broad scope license. Additionally, Dr. Langhorst has been on developmental leave in Washington D.C. for the past 14 months. Consequently, it will take time for her to evaluate the

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radiation safety program fully and comprehensively. The Licensee considers development of the Safety Performance Improvement Program to be a tool that will assist the RSO in accurately assessing the status and needs of the radiation safety program and to correct identified problems. Other immediate actions include: Three meetings by the Radiation Safety Committee to assess violations and review progress on compliance; communications to the authorized users from the Provost, the Vice Chancellor of Administrative Services and the RSO; implementation of computer software for inventory records; and changes in record keeping procedures by the RSO. Additionally, compliance with transportation regulations has been addressed internally by the Department of Environmental Health and Safety.

The Regional Administrator of Region III, in his cover letter to the NOV, requested that the Licensee provide to his office a Safety Performance Improvement Program (SPIP). The Licensee will honor this request and proposes the following plan. The Licensee recognizes the specific components of the SPIP which include: (1) a complete and thorough evaluation of the radiation safety practices and program by qualified persons to determine how the licensee is currently complying with NRC regulations, the conditions of the license, and prudent health physics practices; (2) a compilation of radiation safety deficiencies from that effort; (3) a complete root cause analysis of those deficiencies; and (4) a description of corrective actions to accomplish the improvements necessary for lasting correction of the deficiencies.

At the heart of the SPIP is a complete and thorough evaluation of the radiation safety program. It is crucial that the data used for this evaluation be accurate, complete and timely. If the data is flawed, then the evaluation and analysis that follows likewise will be flawed. For that reason, the Licensee, through the leadership of the RSO, is planning to secure data that represents the program comprehensively, utilizing a variety of resources. These resources will include outside consultants, site visits to other similarly operated Universities and the Radiation Safety Committee assessment of the radiation safety program. Taken together, these resources will provide data that is objective, accurate and timely; data that will be useful in evaluating the current status of our program, and data that can be used to develop and implement corrective measures. These three resources are described in greater detail below.

The first resource planned requires the Licensee to secure the professional services of external consultants. Use of the external consultants will provide an objective evaluation quickly without greatly impacting other aspects of the on-going radiation safety program. Specifically, the services of the consultant will include gathering data on the status and deficiencies of the radiation safety program. It is anticipated that one or more different consulting firms will be involved in evaluating the Licensee's

program, both in the medical use portion and in the academic use portion for at least 100 laboratories on campus. Currently the Licensee has contacted and is negotiating with three consulting firms.

The second resource the Licensee plans to use is the information gained from visiting other similarly operated Universities. The Licensee is currently in contact with three other Universities to schedule site visits and discuss their radiation safety programs with their RSOs. These three Universities were identified by the NRC during a management conference held with the Licensee on February 24, 1994. By visiting these other Universities, the Licensee hopes to become familiar with their radiation safety programs, and learn from their successes and problems. Additionally, these contacts may be useful to the Licensee's RSO by providing a resource for future reference, and exchange of ideas and expertise.

The third resource will be the active involvement of the Radiation Safety Committee in assessing the radiation safety program. The Radiation Safety Committee established two sub-committees on March 8, 1994 to examine specific portions of the radiation safety program. The first sub-committee is currently focused on developing a formalized compliance program which will include an escalated enforcement plan. In addition, the sub-committee is reviewing approval criteria for authorized users. The second sub-committee is examining the requirements of 10 CFR 35 and Regulatory Guide 10.8 in evaluating medical use procedures.

As deficiencies are analyzed by the Licensee's RSO, Radiation Safety Committee and Administration, root causes will be determined and corrective measures will be developed and scheduled for implementation. These combined analyses will specifically address the three categories identified by the current violations. These categories include: provide the radiation safety staff and the authorized users sufficient knowledge of license conditions and NRC requirements; instill the radiation safety staff and authorized users with an adequate sense of accountability regarding compliance with safety requirements; and, development and implementation of an effective self-assessment mechanism designed to look critically at the various aspects of the radiation safety program, to assess the cause of identified deficiencies and to develop corrective measures.

The Licensee takes seriously its responsibility to protect the public health and safety by ensuring that all requirements of the NRC license are met. The SPIP is a tool that the Licensee desires to use to help achieve this goal. The Licensee considers the SPIP to be a living document. That is, it can grow and change as needs develop and are identified. The SPIP will assess the program comprehensively. The foundation of the SPIP is the complete and accurate information from which a viable analysis for effective and

lasting change can be built. The Licensee requests until August 1, 1994 to develop and provide NRC with a copy of the Safety Performance Improvement Program.

Sincerely,

Jacquelyn K. Jones
Associate Vice Chancellor
Administrative Business Services

Brenda Dennis
Notary Public - Brenda Dennis
State of Missouri, County of Boone
My commission expires: 11/20/94

Enclosure Reply to a NOV

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
Region III

Chancellor Kiesler
Provost Brouder
Vice Chancellor Groshong
RSO Langhorst

REPLY TO A NOTICE OF VIOLATION

The following written statement is submitted by the University of Missouri-Columbia on behalf of The Curators of the University of Missouri (Licensee). This statement is submitted in response to the Notice of Violation and Proposed Imposition of Civil Penalty issued on March 9, 1994 (EA 94-031). Included for each alleged violation is: (1) admission or denial of the alleged violation; (2) the reasons for the violation if admitted, and if denied, the reasons why; (3) the corrective steps that have been taken and the results achieved; (4) the corrective steps that will be taken to avoid further violations; and (5) the date when full compliance will be achieved. The format for each consists of a brief summary of the alleged violation followed by the Licensee's response. The response is given in its entirety for each alleged violation and, thus, descriptions of the Licensee's actions taken or planned may be repeated.

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

(1) The University does not dispute the violation.

(2) The spill identified in this violation occurred on December 18, 1993 when a graduate student was cleaning up a radioactive material work area and was placing waste into a waste container. A tube which had contained a P-32 solution, but was essentially empty, dropped on the floor. The Authorized User was also in the laboratory at the time and was immediately made aware of the dropped tube by the student. The student was instructed to remain in the same spot by the Authorized User, and they both began assessing the potential for contamination of the floor and the student's shoes. Direct readings with the laboratory survey instrument by the graduate student and the Authorized User indicated that a small area of the floor and the top of the student's shoe were contaminated. They initiated cleanup of the area, and were careful not to spread the contamination. An attempt was made to clean the student's shoe, but when they were unable to completely decontaminate the shoe, the Authorized User assisted the student in changing shoes and bagging up the contaminated shoe. The Authorized User and the student continued decontamination of the floor area until no removable contamination was evident and no contamination was evident from a direct reading with their laboratory survey instrument. Based on the follow up investigation of the contamination event by the Radiation Safety Staff (RSS), it is believed that the laboratory survey instrument may have become saturated when the fixed contamination area was surveyed, and that the laboratory personnel did not use an appropriate survey technique to recognize the existence of remaining fixed contamination.

The Authorized User did not notify the Radiation Safety Office that the contamination event had occurred, because in her mind it did not constitute a "spill" since she believed the activity was no more than a small fraction of a microcurie and the

decontamination was complete. If a spill involves between 100 and 10,000 pCi/100cm^2 of removable contamination, the Licensee's procedures state that the procedure for "cleaning minor radioactive spills" will be used. Item 9 of this procedure states that the Radiation Safety Office is to be notified. Many of the Authorized User's radiation workers were in the laboratory at the time of this contamination event, and so were aware that it had occurred. A small note was placed in the margin of the laboratory record book that the graduate student had a "hot shoe," but no documentation of the levels of contamination or decontamination efforts and cleanup results were recorded in the book. Each of the laboratory personnel recorded in the laboratory notebook that they surveyed hands and feet before leaving the laboratory on this date.

The Radiation Safety Staff conducted a survey and inspection of the Authorized User's laboratory on December 30, 1993. Occurrence of the contamination event was not evident upon inspection of the laboratory record book by the RSS. None of the individuals from the laboratory were available during the inspection and survey to possibly mention that the contamination had occurred. The RSS survey of the floor area that had been contaminated consisted only of a swipe for removable contamination, but a direct reading of the floor by the more sensitive survey instrument used by RSS was not made. No removable contamination was observed from that area of the floor.

The reasons contributing to this violation are: (a) the Authorized User's failure to notify the Radiation Safety Office that the contamination event had occurred; (b) the failure of the laboratory survey instrument to detect the residual fixed contamination that remained on the floor, most probably due to the inability of the Authorized User or other laboratory personnel to recognize detector saturation because of poor survey technique; (c) the lack of direct discussion between the RSS and Authorized User or other laboratory personnel during the survey and inspection that occurred on December 30, 1993; and (d) the failure of the RSS to make direct contamination readings of the floor area near a radioactive materials work area. However, the Authorized User and student were immediately aware of the possibility of contamination from the dropped tube and worked effectively to prevent the spread of contamination from beyond the area of the spill.

(3) The immediate corrective steps taken by the graduate student and Authorized User were to assess the level of contamination, contain the spread of the contamination, decontaminate the floor, and impound the contaminated shoe. As a result, the spread of contamination was effectively controlled and was not allowed to reach any unrestricted areas. The discovery of the fixed contamination on the floor in this laboratory was made by the NRC during inspection. The date of discovery of this contamination was January 27, 1994. This date was verified by the dated computer report of the removable contamination measurements made by the health physicist accompanying the NRC inspector when the discovery was made. The health physicist immediately decontaminated the area, verified removal of the fixed contamination, and took swipe samples, which verified that the area had

no significant removable contamination remaining. A survey for removable and fixed contamination was conducted by the health physicist of the entire laboratory, including the hallway floor leading to the laboratory on January 28 and 31, 1994. No indication of contamination was found to remain on the floor at the original contamination area, and no additional floor contamination from the original event was identified by the follow up survey. An area indicating evidence of slight contamination from another isotope was identified, and the laboratory personnel instructed to clean the area. In addition, the health physicist surveyed the automobiles belonging to the four individuals who were in the laboratory at the time of the contamination event on December 18, 1993. None of the automobiles were found to be contaminated.

The RSS have performed subsequent inspections and surveys of this laboratory on February 7 and on March 21, 1994. The March survey identified one floor area having 170 pCi/100 cm^2 of removable contamination, which was immediately cleaned by the laboratory personnel and verified as being decontaminated by RSS the next day. These corrective actions and follow up survey information were documented. On March 30, 1994, the RSO visited the laboratory, and discussed the circumstances of the contamination event with the Authorized User. The RSO reviewed the informational and training materials contained within the Authorized User's copy of the Radiation Safety Manual with the Authorized User, and explained the importance of notifying the Radiation Safety Office of contamination events, especially when contamination of the floor or personnel clothing occurs. At this visit, the RSO also discussed with the Authorized User and the graduate student how the December 18 decontamination was accomplished.

The RSS instituted as of February 1, 1994 increased inspection frequencies for Authorized Users who are required to take corrective action on a deficiency identified by the RSS inspection.

In order to address this issue in its global sense for the whole campus, Provost Gerald Brouder and Mr. Kee Groshong,Vice Chancellor for Administrative Services, sent a letter, dated March 11, 1994, to all Authorized Users. This letter stressed the severity of the problems identified by this NRC inspection, the appointment of a new RSO, and MU's commitment to safety. They stated that a change in attitude is absolutely necessary and that it is imperative for MU's Authorized Users to accept their responsibilities in the use of radioactive materials and to personally commit to full compliance with MU policy and NRC regulations.

In addition, Chancellor Charles A. Kiesler sent a letter, dated March 28, 1994, to the Chancellor's Staff, Deans, Directors and Department Chairs in which he noted that today's environment requires quality and accountability to succeed, especially in regard to important Federal regulations. The Chancellor expressed his hope that MU's leaders would use a strategic planning process that included identifying strengths, setting goals,

establishing benchmarks, examining processes, seeking linkages among processes, and involving faculty and staff in a significant way.

The RSO called a mandatory meeting of all Authorized Users on March 28, 1994 where discussion of contamination events which had been identified at MU were discussed, along with cases of the inadvertent spread of contamination to unrestricted areas which had occurred at other universities and medical facilities (NRC Notice 94-16). At this meeting the Authorized Users were reminded of the requirement to notify the Radiation Safety Office of contamination events and the need to be diligent in the control of radioactive materials. The Authorized User discussed in this specific violation attended this mandatory meeting.

(4) This Authorized User will be required to obtain a new survey instrument which is better suited to measuring fixed contamination and area dose rate levels. At the time of delivery of the instrument, a training session will be conducted with the assistance of the Authorized User for the radiation workers in that laboratory. The training will include: instruction on the proper use, maintenance and calibration requirements of the instruments; review of proper survey techniques for personnel, work areas, and packages; and a performance-based check on the instrument's use for each individual in the training session. Limitations of the survey instrument to detect contamination, either by shielding effects or detector saturation, will be emphasized. During this training session, a survey of the laboratory floor will also be performed by the laboratory personnel. The performance-based check for each individual will include their demonstration of the proper use of the survey instrument, the ability to detect contamination, the knowledge of what types of surveys need to be conducted and recorded, and the understanding of responsibility to notify the Radiation Safety Office of radioactive material spills. Materials for the instrument, survey training, and performance-based assessment will be left with the Authorized User so that they can perform the training for any additional radiation workers.

Other Authorized Users are being identified and will be required to obtain the new standardized survey instrument. Currently, twenty Authorized Users have been identified to receive the new instruments. The same training program will be conducted for those Authorized Users and their radiation workers. Additional Authorized Users will be identified from further evaluation of their current survey instruments. The first delivery of the new survey instruments was received on April 5, 1994.

The Radiation Safety Committee will be requiring this Authorized User and the other Authorized Users identified in the NRC inspection report to provide the Committee with a written assessment of their contamination event, causes, corrective actions taken, and their recommendations for assuring that proper surveys are performed. The annual audit by the RSC of the radiation safety program is scheduled for May. The review of contamination

problems like those identified in this violation will be emphasized in that audit, and any recommendations on assuring compliance provided to the full Committee and the RSO.

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with 10 CFR 20.201(b). The results of the reviews, reports and audits discussed in this section will be used in the development of this improvement program.

(5) Compliance for this Authorized User will be achieved by April 22, 1994, when the new survey instrument will be received by and training conducted for this Authorized User and radiation workers.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

2.A. 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.

(1) The Licensee does not dispute the violation.

(2) This violation occurred because the RSO failed to meet the license condition concerning interim authorizations, as stated in item 7.B.1.j . of the License Renewal Application dated February 28, 1992. The RSO did not complete documentation when granting interim authorization and did not present the interim authorization at the next Radiation Safety Committee/Quorum Meeting for review and approval.

(3) The Radiation Safety Committee (RSC) was notified of the interim authorizations which had been issued during 1993 and 1994 at its meeting on March 4, 1994. After an opportunity to review the circumstances of these authorizations, the Committee approved the issuance of those interim authorizations at a meeting on March 31, 1994, with the understanding that the interim increases in authorization limits were no longer in effect. In addition, the Licensee appointed a new RSO, effective March 3, 1994.

(4) The new RSO and a special subcommittee of the RSC will review the process of granting interim authorizations. This subcommittee will recommend to the full Committee a procedure on issuing interim authorizations and presenting these RSO actions at the next RSC/Quorum meeting.

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with Condition 30 of License No. 24-00513-32 in regard to the issuance of interim authorizations. The results of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on March 31, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

2.B. Authorization and receipt records were not properly checked to insure delivered materials are within the authorized levels, as required by Condition 30 of the License.

(1) The Licensee does not dispute the violation.

(2) The Licensee's purchasing and delivery procedures have been designed to serve as a check and balance system to ensure that Authorized Users do not receive radioactive materials in excess of their authorized limits. These procedures underwent a major change more than two years ago when all purchase orders for radioactive materials were required to be approved by Environmental Health & Safety (EH&S). Each purchase was required to be reported to EH&S, and all deliveries (except for specifically approved exceptions) were required to be made to EH&S. This violation occurred because of a failure by the Authorized Users to recognize they were ordering and subsequently receiving radioactive materials in excess of their authorized limits, and failure by EH&S to verify that the Authorized Users were ordering and subsequently receiving radioactive materials in excess of their authorized limits.

(3) Multiple check points have been in place to ensure that Authorized Users are not ordering and subsequently receiving radioactive materials in excess of their authorized limits. The first check point is the Authorized User's responsibility to know their authorized limit for a radioactive isotope and the amount that they currently possess so that their authorization will not be exceeded. The second checkpoint of check occurs when EH&S staff record the report of order from the Authorized User. The EH&S staff reviews a copy of the Authorized User authorization to verify that the amount of the order is not in excess of the authorized limit. At the time of initial delivery of the package to EH&S, the Radiation Safety Staff (RSS) check that a report of the order was made to EH&S. The RSS reviews a copy of the Authorized User's authorization to verify that the amount of the radioactive material to be received is not in excess of the authorized limit. When the package is

delivered to the Authorized User and the final steps of the package receipt and opening procedures are completed in accordance with 10 CFR 20.1906, the Authorized User verifies that the amount of radioactive material received is not in excess of their authorized limit.

The RSS have been reinstructed on the proper check-in procedure required to be performed on each package to verify that the radioactive material received by an Authorized User does not exceed their authorized limit.

(4) In order to ensure that the checks listed above are being made and to strengthen their effectiveness, the following corrective actions are being planned for implementation. To assist the Authorized User in making a check of their authorization limit and amount of material on hand, the Authorized Users will be required to report their authorized limit and amount they currently possess when they report their order of radioactive material to EH&S. To assist the EH&S staff in verifying the Authorized User's authorization limit and amount of material on hand at the time of reporting the order, a central management computer data base has been developed to record the phoned in orders, and to verify that the order is within authorized limits, taking into account the amount of material the Authorized User has on hand. This same data base will be available to the RSS at the time of initial delivery of the package to EH&S where first steps of the Licensee's package receipt procedure are performed. The computer management system will be used to record the amount of material, as described by the accompanying manufacturer's shipping papers, received by the Authorized User, and to verify that this amount, plus the amount they currently possess, is within their authorized limits. When the package is delivered to the Authorized User and the final steps of the package receipt and opening procedures are completed in accordance with 10 CFR 20.1906, the Authorized User will verify: that the amount of radioactive material actually received is as described by the manufacturer's shipping papers; that the authorized limit and amount of material on hand as described by the receipt report generated by the computer management system is correct; and that the receipt of the radioactive material is not in excess of the Authorized User's authorized limit, taking into account the amount of material the Authorized User has on hand.

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with Condition 30 of License No. 24-00513-32 in assuring that Authorized Users do not receive radioactive material in excess of their approved authorization limits. The results of the corrective actions discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on March 29, 1994 when retraining of the RSS on the proper check-in procedure was completed.

Change of ordering procedure to require Authorized Users report their authorized limit and possession amount to EH&S and the instruction on this change will be accomplished by May 1, 1994.

The computer management computer system for verification of order and receipt of radioactive materials is available and training for its use will be completed by June 1, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

2.C. 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.

(1) The Licensee does not dispute the violation.

(2) In the Licensee's investigation of the radiation training for the individuals identified in this violation, it was determined that the radiation worker assigned to 107 Dalton did work with radioactive materials before basic instruction and general information on radiation safety and responsibilities were given. This violation occurred because the Authorized User supervising this individual and in charge of this laboratory assumed the individual's education and training already included knowledge in the proper precautions for use of radioactive materials. The Authorized User failed to verify the individual's knowledge, and did not instruct this individual in the procedures specific to responsibilities for the use of radioactive materials at MU.

Prior to working with radioactive materials, the radiation worker assigned to M609 Health Science Center did receive basic instruction and general information on radiation safety and responsibilities by the Authorized User in that laboratory. Documentation of the training provided by the Authorized User was not recorded on this radiation worker's training form. The Authorized User has normally sent her radiation workers to the Environmental Health & Safety (EH&S) Radioisotope Review training program. While EH&S does conduct formal training programs for radiation workers and Authorized Users, radiation workers are not required to attend these training programs. In establishing their own training scheme, many of the Authorized Users require that their radiation workers attend one or more of the formal radiation safety training programs presented by EH&S.

(3) The radiation worker assigned to 107 Dalton had attended the EH&S Radioisotope Review training program on February 2, 1993, and again on January 27, 1994.

The radiation worker assigned to M609 Health Science Center attended the EH&S Radioisotope Review training program on February 3, 1994.

In order to address this issue in its global sense for the whole campus, Provost Gerald Brouder and Mr. Kee Groshong,Vice Chancellor for Administrative Services, sent a letter, dated March 11, 1994, to all Authorized Users. This letter stressed the severity of the problems identified by this NRC inspection, the appointment of a new RSO, and MU's commitment to safety. They stated that a change in attitude is absolutely necessary and that it is imperative for MU's Authorized Users to accept their responsibilities in the use of radioactive materials and to personally commit to full compliance with MU policy and NRC regulations.

In addition. Chancellor Charles A. Kiesler sent a letter, dated March 28, 1994, to the Chancellor's Staff, Deans, Directors and Department Chairs in which he noted that today's environment requires quality and accountability to succeed, especially in regard to important Federal regulations. The Chancellor expressed his hope that MU's leaders would use a strategic planning process that included identifying strengths, setting goals, establishing benchmarks, examining processes, seeking linkages among processes, and involving faculty and staff in a significant way.

The RSO called a mandatory meeting of all Authorized Users on March 28, 1994 where discussion of contamination events which had been identified at MU were discussed, along with cases of the inadvertent spread of contamination to unrestricted areas which had occurred at other universities and medical facilities (NRC Notice 94-16). At this meeting the Authorized Users were reminded of the requirement to provide basic instruction and general information on radiation safety and responsibilities to their radiation workers and to other individuals frequenting their area of use. The RSO emphasized the importance that each Authorized User establish a level of knowledge and associated training that each radiation worker must have. She explained that the training needed to be specific to the Authorized User's authorized use, and that the Authorized User is required to provide for and document such training. She discussed that the level of training needs to be commensurate to the types of work the Authorized User assigns to the radiation worker, and she reminded the Authorized Users of the resource of training materials available in the Radiation Safety Manual and in the Radiation Safety Handbook. Emphasis was made on developing performance-based evaluations so that a radiation worker's knowledge and ability to perform a procedure can be validated and documented. She stressed that the Authorized Users need to consider the formal training programs conducted by EH&S as a supplement to the laboratory radiation safety training and not a substitute that relieves the Authorized User from providing any radiation safety training for their workers.

(4) The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation

safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with Condition 30 of License No. 24-00513-32 to provide radiation workers basic instruction and general information on radiation safety and responsibilities. The results of the corrective actions discussed in this section will be used in the development of this improvement program.

(5) Both radiation workers identified completed documented training on February 3, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

2.D. Current record of accumulated inventory not available for inspection by NRC, as required by Condition 30 of the License.

(1) The Licensee does not dispute the violation.

(2) The violation occurred because the Licensee did not have a running inventory immediately available for NRC inspection. The Licensee maintained at Environmental Health & Safety an inventory of radioactive material receipts, an inventory of waste pickups, a running total of all radioisotopes received by each Authorized User and their sum, and a record of the authorized limits for each Authorized User. These records are regularly reviewed to assure that the cumulative institutional possession was not in excess of license limits. These records did not include calculation for decay, and therefore provided a high estimate of each isotope and the total possession amount.

At the time of the NRC Inspection, the Licensee was in the process of receiving the Fourth Quarter 1993 quarterly inventory reports from the Authorized Users. Because the inventory records maintained by Environmental Health & Safety (EH&S) were not set up to automatically integrate the information and calculate the actual totals for each Authorized User, a manual calculation, taking into account decay, was required to determine possession amounts from the EH&S inventory records. The Licensee relied on the quarterly inventory information provided by the Authorized Users to monitor the amounts in their possession.

The computerized inventory system being developed for the Licensee to perform the calculations necessary for EH&S to maintain a running inventory was near completion. The Licensee was receiving, on a near daily basis, information from its contracted software vendor that the program was going to be ready to use. As a result, the Licensee was not dedicating personnel resources to completing the inventory manually.

(3) The Licensee had made repeated attempts with its software vendor to solve the software problems associated with maintaining a running inventory. On January 19, 1994, prior to the NRC inspection, the Licensee again discussed these problems with the software vendor, and emphasized the absolute necessity of getting a completed inventory program in place. During that conversation, the software vendor committed to provide and scheduled a professional from their staff to travel to Columbia, MO on February 7, 1994. The vendor's personnel worked intensively with the Licensee during the week of February 7, 1994. The newly integrated computerized inventory system was operational as of April 1, 1994.

(4) Completion of the overall computer management system is continuing. Evaluation of the input data entered into the computerized inventory system is being completed, and the first verification of the system's tracking capabilities will be conducted with data provided from the Authorized Users' First Quarter 1994 Inventory Reports.

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program for License No. 24-00513-32. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with Condition 30 of License No. 24-00513-32 to maintain and make available for inspection a current record of accumulated inventory. The results of the computer management system evaluation discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved when accumulated inventory data was calculated by the computer inventory system for 1994 on April 1, 1994.

Authorized User First Quarter 1994 Inventory Reports are due to be submitted to EH&S by April 29, 1994.

Verification of the computerized inventory system with Authorized User reports will be completed by May 13, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

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

(1) The Licensee does not dispute the violation.

(2) The violation occurred because the Licensee failed to clearly define areas of use for radioactive materials and to strictly enforce the rules prohibiting workers from having and consuming food and drink in these radioactive material use areas.

(3) On January 31, 1994 the RSO sent a letter to all Authorized Users relating to, among other things, the rules prohibiting eating and drinking in radioactive work areas.

In order to address this issue in its global sense for the whole campus, Provost Gerald Brouder and Mr. Kee Groshong,Vice Chancellor for Administrative Services, sent a letter, dated March 11, 1994, to all Authorized Users. This letter stressed the severity of the problems identified by this NRC inspection, the appointment of a new RSO, and MU's commitment to safety. They stated that a change in attitude is absolutely necessary and that it is imperative for MU's Authorized Users to accept their responsibilities in the use of radioactive materials and to personally commit to full compliance with MU policy and NRC regulations.

In addition, Chancellor Charles A. Kiesler sent a letter, dated March 28, 1994, to the Chancellor's Staff, Deans, Directors and Department Chairs in which he noted that today's environment requires quality and accountability to succeed, especially in regard to important Federal regulations. The Chancellor expressed his hope that MU's leaders would use a strategic planning process that included identifying strengths, setting goals, establishing benchmarks, examining processes, seeking linkages among processes, and involving faculty and staff in a significant way.

The RSO called a mandatory meeting of all Authorized Users on March 28, 1994 where discussion of contamination events which had been identified at MU were discussed, along with cases of the inadvertent spread of contamination to unrestricted areas which had occurred at other universities and medical facilities (NRC Notice 94-16). At this meeting, the RSO discussed with the Authorized Users the safety reasons for the prohibition of eating and drinking in radioactive material use areas and the plans to evaluate each laboratory area to reinforce this good laboratory practice.

(4) The Department of Environmental Health & Safety is currently drafting a policy and associated procedures aimed at assisting Authorized Users in defining and posting their restricted areas and radioactive material use areas. The procedures for posting, material control, and prevention of spread of contamination will be reviewed for each laboratory working with uncontained radioactive materials. Included with this review of procedures will be the training emphasis that the prohibition of eating and drinking in these areas exists to ensure that workers do not ingest radioactive materials.

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation

safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with Condition 30 to prohibit eating and drinking in radioactive material use areas. The result of the policy and procedure development and implementation discussed in this section will be used in the development of this improvement program.

(5) Complete implementation requires individual evaluation of each laboratory. This evaluation will occur during the data gathering process used to develop the Safety Performance Improvement Program. Full compliance will be achieved by August 1, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

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

(1) The Licensee does not dispute the violation.

(2) The Licensee has a program in place to measure fume hood flow rates on a semi-annual basis. The hood located in the University Hospital Nuclear Medicine hot laboratory had been erroneously omitted from the Licensee's list of hoods to be measured by the Industrial Hygienist. The December 1992 flow rate measurements of this hood had been made by an outside firm. Subsequent surveys of the laboratory conducted by Radiation Safety Staff (RSS) had failed to identify that the date of the hood flow rate measurement was out of compliance with the requirement of the current license condition.

(3) Flow rate in this hood was measured on January 25, 1994. Test results indicated the fume hood is operating with acceptable flow rate for its design. This hood was placed on the Licensee's regular schedule to measure the flow rate semi-annually. The RSS were reminded of the license condition concerning the measurement of hood flow rates on a semi-annual basis and recording of this information on the Laboratory Inspection Check List.

(4) The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with Condition 30 of License No. 24-00513-32 to test all fume hoods for air flow measurements on a semi-annual basis. Development of this portion of the improvement program will address the current industry

recommendations established for hood flow rate measurements, and the periodic review by Authorized Users and Environmental Health & Safety (EH&S) staff to verify that semi-annual measurements are performed and are within the established limits.

(5) Compliance with the requirement to measure hood flow rates was achieved for this hood on January 25, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

3.A. The Licensee's retained records of leak test results did not contain the measured activity of each test sample expressed in microcuries, or the signature of the RSO, contrary to the requirement of 10 CFR 35.59(d).

(1) The Licensee does not dispute the violation.

(2) This violation occurred because the Licensee failed to document the measured activity results from leak tests in the manner required by 10 CFR 35.59(d). The Licensee has performed all required leak tests and no evidence of leakage has been observed for any of the sealed sources. The Licensee had been recording the results as less than the removable activity level, established in Condition 14.E. of the License, which would require removal of the source from use and notification of NRC. The records of leak test results were signed by the Licensee's health physicist assigned the responsibility to perform these leak tests. The RSO had delegated his responsibility of signing the leak test results to this health physicist in a memo dated April 7, 1993.

(3) This practice was changed and compliance with this item was achieved by January 31, 1994. The new RSO is aware of the responsibility of reviewing and signing the leak test results. The results of future leak tests will record the measured activity in microcuries and will be signed by the RSO, in accordance with 10 CFR 35.59(d).

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation

safety program for License No. 24-00513-32. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with 10 CFR 35.59(d). The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on January 31, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

3.B. The Licensee's retained records of physical inventories of sealed and brachytherapy sources did not contain the signature of the RSO, contrary to the requirement of 10 CFR 35.59(g).

(1) The Licensee does not dispute the violation.

(2) In a memo dated April 7, 1993, the RSO had delegated his responsibility of reviewing and signing the records of physical inventories for sealed and brachytherapy sources to the Licensee's health physicist assigned the responsibility to perform the physical inventories of sealed and brachytherapy sources.

(3) This practice was changed and compliance with this item was achieved on January 31, 1994. The new RSO is aware of the responsibility of reviewing and signing the records of physical inventories of sealed and brachytherapy sources. The records of future physical inventories of sealed and brachytherapy sources will be signed by the RSO, in accordance with 10 CFR 35.59(g).

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with 10 CFR 35.59(g). The result

of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on January 31, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

3.C. The records of the quarterly ambient dose rate survey of areas where brachytherapy sources are stored did not contain the signature of the RSO, contrary to the requirement of 10 CFR 35.59(i).

(1) The Licensee does not dispute the violation.

(2) In a memo dated April 7, 1993, the RSO had delegated his responsibility of reviewing and signing the records of the quarterly ambient dose rate survey of areas where brachytherapy sources are stored to the Licensee's health physicist assigned the responsibility to perform these surveys.

(3) This practice was changed and compliance with this item was achieved on February 16, 1994. The new RSO is aware of the responsibility of reviewing and signing the records of the quarterly ambient dose rate survey of areas where brachytherapy sources are stored. The records of these future surveys will be signed by the RSO, in accordance with 10 CFR 35.59(i).

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with 10 CFR 35.59(i). The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on February 16, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

3.D. The Licensee did not survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored, contrary to the requirement of 10 CFR 35.70(b).

(1) The Licensee does not dispute the violation.

(2) License No. 24-00513-32 is a Type A License of Broad Scope and consists of two major components. One is the medical use program of byproduct material which covers the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings. The other is the academic use program of byproduct material which covers the use of byproduct material in research and development, instrument calibration and student instruction. Only the medical use component of the license is regulated by 10 CFR 35 requirements. The storage area identified in this violation, Room 7Y Health Science Center, is described in Item 11 C. of the License Renewal Application dated February 28, 1992. In that description, the Licensee states that the room will be surveyed monthly when it is in use.

(3) The use of Room 7Y has historically been for the storage of waste resulting from the Licensee's medical use program. Access to this room is under the exclusive control of the Radiation Safety Staff (RSS), and waste is moved into and out of this room only under the direction of the RSS. As soon as the Licensee became aware that the NRC did not consider that the license condition for survey frequency of this room, as approved in the renewal of the License, took precedence over the survey frequency requirement of 10 CFR 35.70(b), the survey frequency was increased to weekly. The Licensee's other radioactive waste facilities are governed by the academic use program, and are thus not governed by the requirement 10 CFR 35.70(b).

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program for License No. 24-00513-32. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with 10 CFR 35.70(b). The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on February 16, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

3.E. Records of contamination survey results were being recorded in picocurie/100 cm^2, contrary to the requirement of 10 CFR 35.70(h).

(1) The Licensee does not dispute the violation.

(2) This violation occurred because the Licensee documented the survey results in picocurie/100 cm^2 rather than in dpm/100 cm^2. The Licensee had performed and documented all required surveys.

(3) Survey procedures for activities conducted under 10 CFR 35 were changed to document area contamination results in dpm/100 cm^2, and compliance with this item was achieved on January 31, 1994.

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program for License No. 24-00513-32. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented to assure compliance with 10 CFR 35.70(h). The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on January 31, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

3.F. 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).

(1) The University disputes the alleged violation.

(2) The University of Missouri-Columbia for several years has only performed temporary brachytherapy implants with Cs-137 and Ir-192 sources. All of these procedures have been conducted at the Ellis Fischel Cancer Center. The Licensee has reviewed 10 CFR 35.406(c), which states:

> Immediately after implanting sources in a patient the Licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The Licensee shall make a record of each survey.

In order to meet the requirements stated in 10 CFR 35.406(c), the University of Missouri-Columbia utilizes the guidance given in Regulatory Guide 10.8. In Regulatory Guide 10.8, Appendix Q: "Model Procedure for Radiation Safety During Implant Therapy" states in step 7.:

> Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

The model procedure suggests use of the form in Exhibit 19, "Radiation Safety Checklist for Temporary Implant Therapy," to report the required survey. Exhibit 19 lists the following instruction after insertion of the implant:

> Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.

The form used to document the survey performed for temporary implant therapy at the University of Missouri-Columbia contains all the survey points listed in Regulatory Guide 10.8.

The Licensee has made a thorough review of all temporary implant procedures performed from March 1991 through March 1994 and the accompanying documentation to determine whether information had been left off any of the implant documentation forms. No omissions were found.

The Licensee does not believe that the survey procedure is, or has been, in violation of the requirements of 10 CFR 35.406(c).

(3) No corrective steps are required.

(4) No corrective steps are required.

(5) The Licensee remains in full compliance with 10 CFR 35.406(c).

4.A. The technologist at Ellis Fischel Treatment Center did not monitor his hands for contamination in a low-background area with a crystal probe or camera either after each procedure or before leaving the area, contrary to the requirement established in Condition 30 of the License.

(1) The Licensee does not dispute the violation.

(2) The Licensee submitted the License Renewal Application dated February 28, 1992 containing the following statement in Item 10.6.D.: "With regard to the administration of radioactive materials on or into humans, the University commits to compliance with 10 CFR 35 and to applicable portions of Regulatory Guide 10.8..." The Licensee intended the statement to mean that applicable sections of the regulatory guide would be used as a model. The January 1994 NRC inspection is the first inspection subsequent to the issuance of the renewed License. As a result of the inspection, the Licensee is now aware that NRC interprets the statement to mean Regulatory Guide 10.8 applies in its entirety. Consequently, certain programs and procedures had not been fully developed or implemented in light of NRC's interpretation.

The Nuclear Medicine technologists at the Licensee's hospitals had been instructed to survey their hands and feet after each procedure or before leaving the area, but they had not been instructed to only use a crystal probe or camera.

(3) The requirement for monitoring hands for contamination with a crystal probe or camera was implemented at both the Ellis Fischel and University Hospital locations, and compliance was achieved on February 2, 1994.

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented in regard to the recommendations contained in Regulatory Guide 10.8 (Revision 2, August 1987) and their applicability to the Licensee's medical use program. The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on February 2, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

4.B. The RSO did not review and initial records of survey results at least monthly and also promptly in those cases in which action levels were exceeded, contrary to the requirement established in Condition 30 of the License.

(1) The Licensee does not dispute the violation.

(2) In a memo dated April 7, 1993, the RSO had delegated his responsibility of reviewing and initialing the records of survey results at least monthly and also promptly in those cases in which action levels were exceeded to the Licensee's health physicist assigned the responsibility to perform these surveys.

The Licensee submitted the License Renewal Application dated February 28, 1992 containing the following statement in Item 10.6.D.: "With regard to the administration of radioactive materials on or into humans, the University commits to compliance with 10 CFR 35 and to applicable portions of Regulatory Guide 10.8..." The Licensee intended the statement to mean that applicable sections of the regulatory guide would be used as a model. The January 1994 NRC inspection is the first inspection subsequent to the issuance of the renewed License. As a result of the inspection, the Licensee is now aware that NRC

interprets the statement to mean Regulatory Guide 10.8 applies in its entirety. Consequently, certain programs and procedures had not been fully developed or implemented in light of NRC's interpretation.

(3) This practice was changed and compliance with this item was met on January 31, 1994. The new RSO is aware of the responsibility of reviewing and initialing the records of survey results at least monthly and also promptly in those cases in which action levels were exceeded. The records of these future surveys will be initialed by the RSO, in accordance with the license condition.

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented in regard to the recommendations contained in Regulatory Guide 10.8 (Revision 2, August 1987) and their applicability to the Licensee's medical use program. The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on January 31, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

4.C. Survey records at Ellis Fischel Cancer Center did not include the measured dose rates, contrary to the requirement established in Condition 30 of the License.

(1) The Licensee does not dispute the violation.

(2) The Radiation Safety Staff (RSS) instructed the nuclear medicine laboratory personnel making the daily area dose rate survey to record that measurements were below the designated alert levels, but did not require them to record the actual reading if it was below this level.

The Licensee submitted the License Renewal Application dated February 28, 1992 containing the following statement in Item 10.6.D.: "With regard to the administration of radioactive materials on or into humans, the University commits to compliance with 10 CFR 35 and to applicable portions of Regulatory Guide 10.8..." The Licensee intended the statement to mean that applicable sections of the regulatory guide would be used as a model. The January 1994 NRC inspection is the first inspection subsequent to the issuance of the renewed License. As a result of the inspection, the Licensee is now aware that NRC interprets the statement to mean Regulatory Guide 10.8 applies in its entirety. Consequently, certain programs and procedures had not been fully developed or implemented in light of NRC's interpretation.

(3) All nuclear medicine personnel who are responsible for conducting the daily dose rate surveys have been instructed to record the actual dose rate readings, and compliance was achieved on February 1, 1994.

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented in regard to the recommendations contained in Regulatory Guide 10.8 (Revision 2, August 1987) and their applicability to the Licensee's medical use program. The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on February 1, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.

4.D. A contamination survey indicated an activity of 4E+3 pCi/100 cm^2 and no documentation of actions taken or follow up survey information was recorded, contrary to the requirement established in Condition 30 of the License.

(1) The Licensee does not dispute the violation.

(2) The contamination survey identified in this violation was conducted by a member of the RSS. Upon obtaining the contamination results, the health physicist notified the personnel in the Nuclear Medicine Laboratory of the contamination and directed them to clean the area. The area of contamination was located on absorbent paper behind the radiopharmaceutical preparation shield. The laboratory personnel cleaned the area, and the health physicist verified that the area had been clean on the following work day. The health physicist did not record these actions taken or the follow up survey information. The Licensee has established recommended action levels for radiation monitoring for removable contamination, as submitted in Item 10.6 B. 6. a. i. of the License Renewal Application dated February 28, 1992. For a controlled localized work surface, such as the surface behind the preparation shield, the recommended action limit is 10 times 100 pCi/100 cm^2, or 1000 pCi/100 cm^2. Item 1.e. of the Records section of Appendix N of Regulatory Guide 10.8 states that a record of contamination survey results must include actions taken in the case of "excessive" contamination and follow up information. Table N-1, included with Appendix N, lists recommended action levels specific for surface contamination by radiopharmaceuticals. For Tc-99m, which was the isotope identified on this contamination survey, the recommended level for a restricted area is listed as 20,000 dpm/100 cm^2, or approximately 10,000 pCi/100 cm^2.

(3) The actions concerning the follow up on the identified contamination are described above. Members of the Radiation Safety Staff (RSS) were reinstructed to document the actions taken concerning identified contamination and the follow up survey information. Compliance was achieved on March 1, 1994.

(4) A subcommittee of the Radiation Safety Committee was established on March 18, 1994 and is currently reviewing 10 CFR 35. Membership of this subcommittee consists of two medical physicists at the Licensee's hospitals, the RSO of the VA hospital, and the MU RSO. This subcommittee will advise the full Committee and RSO of its evaluation of the radiation safety program compliance with NRC regulations, license conditions, and prudent health physics practices, including the Licensee's commitment to "applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987)."

The University of Missouri-Columbia has committed to the NRC that the Licensee will conduct a thorough, systematic, and methodical assessment of the radiation safety program. In the evaluation leading to and the development of the requested Safety Performance Improvement Program, additional long-term corrective actions will be considered and may be implemented in regard to the recommendations contained in Regulatory Guide 10.8 (Revision 2, August 1987) and their applicability to the Licensee's medical use program. The result of the review discussed in this section will be used in the development of this improvement program.

(5) Full compliance was achieved on March 1, 1994.

The Licensee proposes to provide the NRC with a copy of the Safety Performance Improvement Program by August 1, 1994.