U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No.	030-02764/94001(DRSS)	Dockets No.	030-02764
	No. 030-11334/94001(DRSS)		No. 030-11334
	No. 030-18949/94001(DRSS)		No. 030-18949
	No. 030-20526/94001(DRSS)		No. 030-20526
	No. 040-02678/94001(DRSS)		No. 040-02678
	No. 070-00539/94001(DRSS)		No. 070-00539

Licenses No.	34-06903-05	Category G(1)	Priority I
	No. 34-06903-09	Category E	Priority III
	No. 34-06903-11	Category E	Priority III
	No. 34-06903-13	Category E	Priority III
	No. SUD-265	Category E	Priority III
	No. SNM-490	Category E(2)	Priority V

Licensee: University of Cincinnati
Cincinnati, Ohio

Inspections Conducted: January 16-17, 1994 and February 7 - 11, 1994

Project Manager: BJ Holt for — 3/10/94
James L. Cameron — Date
Radiation Specialist

Inspectors: K — G. Nall — 3/10/94
Kevin Nall — Date
Senior Health Physicist

Toye Simmons — 3/10/94
Toye Simmons — Date
Radiation Specialist

BJ Holt for — 3/10/94
Robert Gattone — Date
Radiation Specialist

Reviewed By: BJ Holt — 3/10/94
B. J. Holt, Chief — Date
Nuclear Materials Inspection
Section 1

Approved By: Roy J Caniano — 3/10/94
Roy J. Caniano, Chief — Date
Nuclear Materials Safety Branch

Inspection Summary

Inspections on January 16-17, 1994 and February 7 - 11, 1994 (Reports No. 030-02764/94001(DRSS); No. 030-11334/94001(DRSS); No. 030-18949/94001(DRSS); No. 030-20526/94001(DRSS); No. 040-02678/94001(DRSS); and No. 070-00539/94001(DRSS))

Areas Inspected: This was a routine, announced safety inspection conducted to assess the adequacy of the licensee's overall NRC-licensed operations authorized under six NRC licenses. The inspection of broad scope licensed activities included a review of the licensee's implementation of its quality management program (QMP) and three licensee incident notifications regarding: (1) a lost strontium-90 eye applicator; (2) a leaking nickel-63 sealed source; and (3) a misadministration involving a ruptured iodine-125 implant seed. Areas reviewed during the inspection of each NRC-licensed activity are described in this report.

Results: Of the areas inspected, several apparent violations were identified for License Nos. 34-06903-05 (Broad Scope) and 34-06903-13 (Teletherapy Irradiator). No apparent violations were identified with regard to License Nos. 34-06903-09, 34-06903-11, SUD-265, and SNM-490. Apparent violations identified for License No. 34-06903-05 consist of failure to: (1) secure licensed material in storage in an unrestricted area from unauthorized removal from the place of storage (Section 7); (2) adequately perform dose calibrator geometry dependence testing (Section 6); (3) ensure that all nuclear medicine personnel monitor their hands for radioactive contamination at the completion of each study (Section 6); (4) monitor packages of radioactive material for external radiation and contamination levels prior to shipment (Section 6); (5) provide instruction to all ancillary personnel who enter areas where licensed material is stored or used (Section 7); and (6) maintain the integrity of a sealed source containing licensed material (Section 7). In addition, the inspectors identified four regulatory concerns regarding the licensee's broad scope activities pertaining to: (1) poor housekeeping practices in one laboratory that could contribute to radioactive contamination and/or lost licensed material (Section 6); (2) the delay in issuing the Radiation Safety Committee's 1992 annual report to the University president until December 1993 (Section 4); (3) the licensee's practice of using two licensee employees to identify patients undergoing radiopharmaceutical therapy, brachytherapy or being administered a dosage of sodium iodide iodine-131 or iodine-125 in excess of 30 microcuries (Section 8); and (4) the inappropriate response of a housekeeping supervisor to radiation warning signs (Section 7). Apparent violations identified for License No. 34-06903-13 consist of failure to: (1) have an audible alarm to alert people in the radiation room that the sources will be moved from their shielded position (Section 6); (2) have a control in the radiation room that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed w thin a preset time after activation of the control (Section 6); (3) have an independent backup access control to the radiation room to detect personnel entry while the sources are exposed (Section 6); (4) limit the radiation levels at five centimeters from the shield of the irradiator (Section 6); (5) have heat and smoke detectors in the radiation room (Section 6); (6) attach the key, which operates the mechanism that moves the sources, to a portable radiation survey meter by a chain or cable (Section 6); (7) have a

source position indicator that indicates when the sources are in transit (Section 6); and (8) post the radiation room as a very high radiation area (Section 6). In addition, the inspectors identified a regulatory concern with regard to the licensee's lack of a routine, periodic inspection and maintenance program for its teletherapy-type irradiator (Section 6).

DETAILS

1. Persons Contacted

*Victoria Morris, Radiation Safety Officer
*Mike Burba, Assistant Radiation Safety Officer
*C. W. Kupferberg, Radiation Safety Committee and Associate Senior Vice President, Medical Center
*Ronald Millard, Ph.D., Chair, Radiation Safety Committee
*Michael Gelfand, M.D., Radiation Safety Committee and Division Chair, Nuclear Medicine, Children's Hospital and Medical Center
*Howard Elson, Ph.D., Radiation Safety Committee and Chief Medical Physicist, Radiation Oncology
*John Breneman, M.D., Radiation Safety Committee
*Henry Spitz, Ph.D., Professor, Department of Mechanical, Industrial and Nuclear Engineering
*C. Castello, Director, Environmental Services, University Hospitals
*Pam Masters, Chief Nuclear Medicine Technologist, Children's Hospital and Medical Center
*John Christenson, Ph.D., Radiation Safety Committee and Professor, Department of Mechanical, Industrial and Nuclear Engineering
*Michelle Harrell, R.N., Radiation Safety Committee and Assistant Administrator, Patient Care Services
Howard Boeing, Research Associate

In addition, the inspectors contacted numerous other licensee employees, including nuclear medicine technologists, radiation therapy technologists, authorized user physicians, environmental services personnel and management, patient care personnel, radiation safety office staff, and graduate students.

*Denotes those individuals present at the exit meeting conducted on February 11, 1994.

2. Purpose and Scope of Inspection

Two onsite inspections were conducted at the University of Cincinnati. The first was a special, announced inspection conducted in response to the licensee's initial notification of a misadministration involving a leaking iodine-125 seed. The second was a routine, announced safety inspection conducted to review the adequacy of the overall implementation of the licensee's radiation safety program. The inspections included reviews of licensed activities authorized by six NRC Material Licenses issued to the University. The inspection of the licensee's broad scope license (34-06903-05) was limited to a review of routine medical use activities and to three incidents reported by the licensee. In addition, the inspectors reviewed the licensee's implementation of 10 CFR Part 20, Revised, "Standards for Protection Against Radiation," which became effective on January 1, 1994, for each of its six NRC licenses. Furthermore, the inspectors reviewed the applicability and licensee implementation of 10 CFR Part 36, "Licenses

and Radiation Safety Requirements for Irradiators," which became effective on July 1, 1993, for the licensee's pool and teletherapy-type irradiator licenses (34-06903-09 and 34-06903-13).

3. Summary of Licensed Programs

The University of Cincinnati is authorized pursuant to its medical and academic broad scope licensee, NRC Material License No. 34-06903-05, to possess: (1) radiopharmaceuticals and brachytherapy sources in quantities as needed for medical diagnosis and therapy, for use at several medical centers and hospitals affiliated with the University; and (2) millicurie to curie quantities of any byproduct, source, or special nuclear material, in any form, for medical research, research and development (R&D) pursuant to 10 CFR 30.4, student instruction, animal studies, and calibration of instruments and dosimeters.

Diagnostic nuclear medicine studies are performed primarily at three facilities: (1) University Medical Center and Hospitals; (2) Children's Hospital and Medical Center; and (3) the Medical Arts Building. Radiopharmaceutical therapy procedures are performed at the University Medical Center and Hospital and, to a limited extent, at Children's Hospital and Medical Center. Brachytherapy procedures are performed only at University Medical Center and Hospitals.

The University also possesses separate NRC licenses for nonhuman use in a teletherapy-type unit (License No. 34-06903-13), a 10,000 curie pool irradiator for irradiation of materials (License No. 34-06903-09), one 1650 curie and one 3048 curie self-contained irradiators for blood irradiation (License No. 34-06903-11), plutonium:beryllium neutron sources for experiments and student instruction (License No. SNM-490), and 2500 kilograms of natural uranium in a subcritical assembly for laboratory instruction (License No. SUD-265).

4. Organization and Management Controls

The responsibility for the oversight and control of all NRC-licensed activities is vested in the University President, the Senior Vice President and Provost for Health Affairs, and the Associate Senior Vice President, Medical Center. The Chair of the Radiation Safety Committee reports directly to the Senior Vice President. The Radiation Safety Officer reports to the Associate Senior Vice President, Medical Center, with a reporting path to the Senior Vice President. Direct program management and oversight is provided, as required, by the Radiation Safety Committee (RSC) and the Radiation Safety Office (RSOF).

The University's RSC provides program direction through establishment of procedures and other administrative controls. The current committee is actively involved in the oversight and implementation of the radiation safety program and continues to be dedicated to operating a quality radiation protection program.

Item B, "Radiation Safety Committee," of Appendix 10, "Radiation Safety Program," of the licensee's application received on September 20, 1990, requires that the RSC review the operations of the Radiation Safety Office and the radiation safety program at least annually. Item B further requires that the RSC submit a report to the University President, at least annually, summarizing the functions, activities and achievements of the radiation safety program. Inspector interviews of Radiation Safety Office staff and RSC members and review of RSC meeting minutes indicated that the committee conducted its review of the radiation safety program and the Radiation Safety Office for calendar year 1992 in January and February 1993; however, the report of those reviews was not submitted to the University President until December 1, 1993. Although the report contained good suggestions for improvements in the licensee's radiation safety program, NRC staff expressed concern for the apparent delay in the submission of the report to the University President. The Chair of the RSC accepted responsibility for the delay in submission of the report and assured NRC staff that the report of the audit currently being performed would be submitted in a more timely manner.

One regulatory concern was identified.

5. Inspection History

The NRC last inspected the University's broad scope license on March 8 through 10, 1993. That special inspection was prompted by concerns received by the NRC regarding certain radiation safety activities associated with the University's research uses of radioactive material. The inspection identified two violations. One violation was cited for the failure of an authorized user to maintain records of training provided to a laboratory radiation worker. The second violation pertained to the educational qualifications of the recently appointed Assistant Radiation Safety Officer. The violation was not cited because it was identified by the licensee and the licensee initiated corrective actions to address the violation.

From September 20, 1992 through October 9, 1992, NRC conducted a routine inspection of the licensee's broad scope activities. That inspection identified one violation for an authorized user's possession and use of licensed material that was not approved by the RSC. The effectiveness of the licensee's corrective actions to address that violation was not reviewed during this inspection. Therefore, the violation remains an unresolved item, to be reviewed during a future inspection.

Each of the University's other five NRC licenses were inspected from November 26 through December 14, 1990. During those inspections, no violations were identified for Licenses No. 34-06903-09, No. 34-06903-11, and No. SNM-490. Violations were identified for Licenses No. 34-06903-13 and No. SUD-265. In addition, the inspection identified concerns regarding certain aspects of Licenses No. 34-06903-09 and No. SUD-265. The inspectors reviewed the licensee's

actions in response to each of the previously identified violations and concerns and determined that the licensee has adequately addressed each item.

6. Summary of Routine Inspection Activities

The inspection included a review of routine activities conducted under each of the University's six NRC licenses. The review of routine broad scope activities was limited to the medical use aspects of the license. Specific areas reviewed for each licensed activity are described below.

License No. 34-06903-05 (Broad Scope)

The inspection of the University's broad scope license included a review of licensed medical activities conducted at the University Hospital Radioisotope Laboratory (RIL), the Medical Arts Building (MAB), and Children's Hospital and Medical Center (CHMC).

Condition 27 of License No. 34-06903-05 requires that the licensee conduct its program in accordance with statements, representations and procedures contained in an application received September 20, 1990, a letter dated February 26, 1992, and other referenced documents.

Item 11, "Administrative Procedures," of the referenced February 26, 1992 letter, requires, in part, that personnel wash and monitor their hands when a procedure is completed, and prior to leaving the laboratory. Inspector interviews of nuclear medicine personnel at Children's Hospital and Medical Center (CHMC) indicated that although they washed their hands numerous times each day, they routinely do not monitor their hands when nuclear medicine procedures are completed and prior to leaving the laboratory. Interviews also indicated that they were not aware of the requirement to monitor their hands. Once the inspector brought the requirement to the attention of CHMC personnel, they indicated that they would begin monitoring their hands following completion of nuclear medicine procedures immediately. Since CHMC personnel routinely washed their hands upon completion of nuclear medicine procedures, the likelihood of personnel hand contamination is minimal. The failure of licensee nuclear medicine personnel at CHMC to monitor their hands following each procedure and prior to leaving the laboratory constitutes an apparent violation of License Condition 27.

10 CFR 35.50(b)(4) requires that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. Appendix 13.C., "Dose Calibrators," of the referenced application received September 20, 1990, requires that the licensee perform dose calibrator geometry dependence testing in accordance with the model procedure for calibrating dose calibrators published in Appendix C to Regulatory Guide 10.8, Revision 2. Items 6.b. through 6.f. of the model procedure require that geometry dependence testing be performed for the type of syringe that is normally used for injections. The licensee installed its dose calibrators at each of its medical use facilities on the following

dates: (1) on March 5, 1992 for the dose calibrator used at the RIL; (2) in July 1992 for the dose calibrator used at CHMC; and (3) on April 3, 1989 for the dose calibrator used at the MAB. Interviews of nuclear medicine personnel associated with each facility and a review of records of geometry dependence testing indicated that geometry dependence had not been determined at installation for any of the licensee's dose calibrators for any syringes used for injections. The licensee's failure to properly perform geometry dependence testing on its dose calibrators at installation constitutes an apparent violation of 10 CFR 35.50 and License Condition 27.

Item 11, "Administrative Procedures," of the referenced February 26, 1992 letter, states, in part, that laboratories should be kept clean and orderly. During tours of the areas near the Radioisotope Laboratory (RIL), the inspectors observed the "J" basement hot chemistry laboratory, an area where millicurie quantities of radioactive material are used, to be in a general state of disarray and clutter. Although surveys conducted by the inspectors did not identify any removable contamination in excess of background levels, the inspectors expressed concern for the laboratory's general state. Failure to maintain laboratories in a generally clean and orderly condition may lead to radioactive contamination and/or loss of licensed material. The licensee agreed to monitor general laboratory housekeeping practices more closely.

10 CFR 71.5(a) requires, in part, that a licensee who delivers licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189. 49 CFR 173.475 requires, in part, that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate test that the external radiation and contamination levels are within the allowable limits specified in 49 CFR Parts 171 - 177. Inspector interview of licensee personnel at the Radioisotope Laboratory (RIL) indicated that they routinely do not monitor packages containing unused radiopharmaceutical dosages and/or radiopharmaceutical residues for external radiation and contamination levels prior to offering the packages for return shipment to the nuclear pharmacy. Licensee personnel responsible for performing package monitoring appeared to be unaware of the requirement. The licensee committed to performing the required monitoring beginning with the next radioactive material package shipped. The licensee's failure to monitor radioactive material packages offered for shipment from the RIL for external radiation and contamination levels constitutes an apparent violation of 10 CFR 71.5 and 49 CFR 173.475.

In addition to the above, the inspection included a review of the following program areas: training, retraining and instructions to workers; facilities and equipment; radiological protection procedures; materials; receipt and transfer of radioactive material; area surveys; radiopharmaceutical therapy; brachytherapy; personnel radiation exposures - internal and external; radioactive effluents, waste

management and disposal; notifications and reporting; posting and labeling; independent measurements; and recordkeeping for decommissioning. Except as otherwise noted in this section, no problems were identified for other areas inspected.

Three apparent violations of NRC regulatory requirements and one regulatory concern were identified.

License No. 34-06903-09 (Pool Irradiator)

The inspectors reviewed the licensee's activities conducted under NRC License No. 34-06903-09. That license authorizes possession and use of cobalt-60 sealed source pins, up to 10,000 curies (37 E4 GBq) total activity, for use in a pool irradiator for material irradiation.

The licensee's current inventory of cobalt-60 possessed under this license totals approximately 2000 curies (74 E3 GBq), contained in 54 source pins. Eighteen high activity pins are contained in one array. The remaining 36 lower activity pins are arranged in a second array. The licensee irradiates insects, polymers, and components for detector development. All irradiations are conducted underwater and may last from a few minutes up to a week. Source movement is infrequent and the licensee maintains adequate source handling equipment to conduct those operations.

10 CFR 36.1(b) states that irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by 10 CFR Part 36. Direct measurements performed by the licensee during initial source loading (approximately 10,000 curies) indicated that the maximum radiation level, at one meter from the source array, underwater, was 87.5 rads per hour (cGy/hr). Therefore, the requirements in 10 CFR Part 36 do not apply to this license.

In addition to the above, the inspection included a review of the following program areas: training, retraining, and instructions to workers; facilities and equipment; radiological protection procedures; materials; personnel radiation exposures - external; notifications and reports; posting and labeling; recordkeeping for decommissioning; and independent measurements. No problems were identified in any areas inspected for this licensed activity.

No apparent violations or concerns were identified.

License No. 34-06903-11 (Self-contained Irradiator)

The inspectors reviewed the licensee's activities conducted under NRC License No. 34-06903-11. That license authorizes the use of 2 Nordion International, Inc. blood irradiators (Models Gammacell 3000 and Gammacell 1000) for the irradiation of blood and blood products. The Gammacell 3000 is located in the Hoxworth Blood Center, and the Gammacell 1000 is located in the Children's Hospital Medical Center.

Each facility is a blood bank and operates 24 hours per day, 365 days per year. Two RSC approved users supervise the use of licensed material under this NRC license.

The inspection of activities conducted under this license included a review of: training, retraining, and supervision; sealed source leak testing and inventory; facilities; security; and posting. No problems were identified in any areas inspected for this licensed activity.

No apparent violations or concerns were identified.

License No. 34-06903-13 (Teletherapy-type Irradiator)

The inspectors reviewed the licensee's activities conducted under NRC License No. 34-06903-13. That license authorizes the possession and use of up to 1800 curies of cobalt-60 in an AECL Model C-II teletherapy unit for irradiation of animals and biological specimens (excluding flammable and/or explosive materials), and for the performance of measurements.

The source in this device was last replaced in August 1990. Source activity at the time of replacement was 1710 curies. 10 CFR 36.1(b) states that irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by 10 CFR Part 36. This regulation became effective on July 1, 1993. Inspector calculations indicate that the maximum radiation dose rate at 1 meter from the teletherapy source, accounting for decay, is approximately 1500 rads per hour (cGy/hr). Therefore, the requirements in 10 CFR Part 36 apply to activities conducted under this license.

10 CFR 36.17(b) states that any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of 10 CFR Part 36. The Commission will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public. In November 1993, the licensee submitted a request to the NRC that it be exempted from all requirements contained in 10 CFR Part 36. According to the licensee, it was not aware of the applicability of 10 CFR Part 36 to its teletherapy-type irradiator prior to that time. The licensee's request did not provide any proposed alternatives to the requirements of 10 CFR Part 36 and, as such, the Commission requested that the licensee provide this information. During the inspection, the licensee was in the process of developing its proposed alternative procedures, when it received NRC Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses for Non-Self-Contained Irradiators." The licensee requested that it be given an additional 60 days in order to review the draft guidance and prepare its proposed alternative procedures based on the suggestions contained in the draft guide. Region III approved the licensee's request to extend its response deadline. Notwithstanding the licensee's exemption requests, the

inspectors identified several apparent violations with regard to licensed activities conducted under NRC License No. 34-06903-13.

10 CFR 36.23(b) requires, in part, that each entrance to a radiation room at a panoramic irradiator have an independent backup access control to detect personnel entry while the source is exposed. Detection of entry while the source is exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. Inspector interview of licensee personnel and observation of the irradiator environs indicated that the licensee does not have an independent backup access control that detects personnel entry while the source is exposed and which activates an alarm. The licensee's operating procedures require that an operator be physically present during all irradiations. In addition, if the door to the radiation room were to be opened during treatment, the source would return to the shielded position, but no alarm would be activated. The licensee was not required to have the independent backup access control or the alarm prior to 10 CFR Part 36 becoming effective on July 1, 1993. The licensee's failure to have an independent backup access control that detects personnel entry while the source is exposed and which activates an alarm constitutes an apparent violation of 10 CFR 36.23(b).

10 CFR 36.23(d) requires, in part, that before the sources move from their shielded position, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. Inspector interview of licensee personnel and observation of the irradiator environs indicated that the licensee does not have either the visible or audible alarms. Licensee personnel stated that audible alarms would frighten animals being treated on the unit. The licensee was not required to have these alarms prior to 10 CFR Part 36 becoming effective on July 1, 1993. The licensee's failure to have visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position constitutes an apparent violation of 10 CFR 36.23(d).

10 CFR 36.23(f) requires, in part, that each radiation room of a panoramic irradiator contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control. Inspector interview of licensee personnel and observation of irradiator environs indicated that the licensee does not have the indicated control. The licensee was not required to have the indicated control prior to 10 CFR Part 36 becoming effective on July 1, 1993. The licensee's failure to have a control in the radiation room that prevents the source from moving from the shielded position unless the control has been activated constitutes an apparent violation of 10 CFR 36.23(f).

10 CFR 36.25(c) requires that the radiation dose at 5 centimeters from the shield of a dry-source-storage panoramic irradiator when the source

is shielded not exceed 20 millirems per hour (0.2 millisievert per hour). Inspector surveys with the source in the fully shielded position indicated maximum radiation levels of approximately 70 millirems per hour (0.7 millisievert per hour) at contact with and 40 millirems per hour (0.4 millisievert per hour) at 5 centimeters from the head of the teletherapy-type irradiator. Those elevated radiation levels would normally be authorized for a teletherapy unit licensed under 10 CFR Part 35, "Medical Use of Byproduct Material," and were authorized for this licensee prior to 10 CFR Part 36 becoming effective on July 1, 1993. The licensee's failure to limit the radiation levels at 5 centimeters from the shield of its teletherapy-type irradiator constitutes an apparent violation of 10 CFR 36.25(c).

10 CFR 36.27(a) requires that the radiation room at a panoramic irradiator have heat and smoke detectors. The detectors must activate an audible alarm. Inspector interviews of licensee personnel and observation of irradiator environs indicated that the radiation room does not have heat and smoke detectors. A smoke detector is installed, however, outside the radiation room. The licensee was not required to have heat and smoke detectors in the radiation room prior to 10 CFR Part 36 becoming effective on July 1, 1993. The licensee's failure to have heat and smoke detectors in the radiation room constitutes an apparent violation of 10 CFR 36.27(a).

10 CFR 36.31(a) requires, in part, that the key which actuates the source movement mechanism of a panoramic irradiator be attached to a portable radiation survey meter by a chain or cable. Inspector interview of licensee personnel and observation of irradiator environs indicated that the key which actuates the source movement mechanism was not attached to a portable radiation survey meter. Licensee compliance with this requirement would prevent it from using the source-to-surface distance indicator on the unit or would require the use of a cable or chain of sufficient length that would allow the key to remain in the control console and allow the portable radiation survey meter to be taken into the radiation room for post-irradiation surveys. The licensee was not required to attach the key which actuates the source movement mechanism to a portable radiation survey meter prior to 10 CFR Part 36 becoming effective on July 1, 1993. The licensee's failure to attach the key which actuates the source movement mechanism to a portable radiation survey meter constitutes an apparent violation of 10 CFR 36.31(a).

10 CFR 36.31(b) requires, in part, that the console of a panoramic irradiator have a source position indicator that indicates when the sources are in transit. Inspector interview of licensee personnel and observation of the unit console indicated that the licensee does not have a source position indicator that indicates when the sources are in transit. The licensee was not required to have such a source position indicator prior to 10 CFR Part 36 becoming effective on July 1, 1993. The console does have indicators that indicate when the source is

exposed and when the source is shielded. The licensee's failure to have an indicator on the console to indicate when the source is in transit constitutes an apparent violation of 10 CFR 36.31(b).

10 CFR 36.61(a)(12) requires, in part, that the licensee perform inspection and maintenance checks that include the functioning and wear of the system and mechanism used to expose the sources. The inspection and maintenance checks must be performed at the frequency specified in the license or license condition. Condition 21 of License No. 34-06903-13 requires that the licensee have the teletherapy unit fully inspected and serviced during teletherapy source replacement to assure proper functioning of the source exposure mechanism. The required servicing and inspection was last conducted following the last source replacement on August 14, 1990 and the licensee does not plan to have any servicing and inspection conducted until the next source replacement, expected to occur in 1995 or 1996. The licensee does not have routine preventative maintenance performed on the teletherapy-type irradiator. Due to the age of the unit, and based on NRC experience with older teletherapy units, the licensee should implement routine preventative maintenance checks on the unit in order to check, as a minimum, for functioning and wear of the source movement mechanism. The licensee agreed to consider the inspectors' concern.

10 CFR 20.1902(c) requires that the licensee post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "GRAVE DANGER, VERY HIGH RADIATION AREA." Inspector observation of the irradiator environs indicated that the licensee had not posted the radiation room as a very high radiation area. The licensee was required to post the area as a very high radiation area following the implementation of 10 CFR Part 20, Revised, on January 1, 1994. The licensee's failure to post the radiation room as a very high radiation area constitutes an apparent violation of 10 CFR 20.1902(c).

In addition to the above, the inspection of activities conducted under the license included a review of the following program areas: training, retraining, and instructions to workers; facilities and equipment; radiological protection procedures; materials; notification and reports; posting and labeling; recordkeeping for decommissioning; and independent measurements. Except as noted above, no problems were identified in those additional program areas inspected.

Eight apparent violations of NRC regulatory requirements and one regulatory concern were identified.

License No. SUD-265 (Subcritical Assembly)

The inspectors reviewed the licensee's activities conducted under NRC License No. SUD-265. That license authorizes the possession and use of up to 2500 kilograms of natural uranium in the form of cylindrical slugs for use in a light water moderated subcritical assembly. The assembly is used in graduate level nuclear engineering courses. Labs are

conducted with students under the supervision of RSC authorized users. A plutonium-beryllium (PuBe) source possessed under NRC License No. SNM-490 is used as a neutron source and placed in the assembly as part of the student experiments. The PuBe sources and uranium slugs are not handled by the students.

As a result of the last inspection, the licensee has implemented an annual inventory of the uranium slugs. The last inventory was conducted on January 3, 1994. That inventory confirmed 1302 slugs in the assembly, and 125 slugs in storage.

The inspection of activities conducted under the license included a review of the following program areas: training, retraining, and instructions to workers; facilities and equipment; radiological protection procedures; materials; personnel radiation exposures - external; notifications and reports; posting and labeling; recordkeeping for decommissioning; and independent measurements. No problems were identified in any areas inspected for this licensed activity.

No apparent violations or concerns were identified.

License No. SNM-490 (Sealed Neutron Sources)

The inspectors reviewed the licensee's activities conducted under NRC License No. SNM-490. That license authorizes the possession and use of plutonium-239:beryllium in an amount not to exceed 160 grams. The licensee is authorized for one source each of 16, 32, 48 and 64 grams in the form of encapsulated plutonium-beryllium. The sources are used for the following purposes: 1) as a neutron source in a subcritical assembly; 2) for student experiments in neutron activation of foil, and; 3) for measurement of neutron flux.

Licensed material possessed under the license is used infrequently. Typically, the sources are used only two to three times per year in graduate level nuclear engineering courses.

The inspection of activities conducted under the license included a review of the following program areas: training, retraining, and instructions to workers; facilities and equipment; radiological protection procedures; materials; personnel radiation exposures - external; notifications and reports; posting and labeling; recordkeeping for decommissioning; and independent measurements. No problems were identified in any areas inspected for this licensed activity.

No apparent violations or concerns were identified.

7. Summary of Special Inspection Activities

In addition to the routine inspection of each of the University's six NRC licenses, the inspectors reviewed three incidents reported by the licensee. The incidents included: (1) a lost strontium-90 eye applicator in October 1993; (2) a leaking nickel-63 gas chromatography

source in December 1993; and (3) a misadministration involving a leaking iodine-125 temporary implant seed in January 1994. The inspectors' followup of each incident is described below.

Misadministration Review

On January 7, 1994, the licensee implanted sixteen iodine-125 seeds ranging in activity from 10 to 30 millicuries (370 MBq to 1.11 GBq) in the brain of a 30 year old male patient. In addition, prior to source implantation, the patient underwent a nuclear medicine brain scan which utilized technetium-99m and thallium-201. During the patient's hospital stay, radiation detection surveys of his bed linens indicated the presence of low level radioactive contamination. The licensee believed the contamination to be thallium-201. Prior to explant, on January 14, 1994, the patient underwent a second nuclear medicine brain scan utilizing technetium-99m and thallium-201. Following the explant procedure on January 14, 1994, the Radiation Safety Office placed the iodine-125 seeds into a pan containing water in an effort to determine whether one or more of the seeds was leaking. Analysis of the water indicated the presence of iodine-125. The licensee then notified the NRC Operations Center that it had identified a misadministration. 10 CFR 35.2 defines a misadministration, in part, as a brachytherapy radiation dose involving a sealed source that is leaking.

Licensee surveys of the surgical suite used for seed explantation identified contamination levels ranging from a maximum of 73000 dpm/100 square centimeters on the pan containing the explanted seeds to an average of 700 dpm/100 square centimeters on the floor. Surveys in the patient's hospital room indicated maximum contamination levels of 13000 dpm/100 square centimeters in the bathroom.

NRC Region III dispatched two inspectors to the University on January 16-17, 1994 to monitor the licensee's decontamination efforts and to obtain more details on the misadministration. Based on radiation detection surveys performed by the licensee and confirmed by NRC inspectors, contamination was limited to a surgical suite and two bathrooms used by the patient. The surgical suite had been decontaminated prior to the arrival of the inspectors and the licensee was in the process of decontaminating the remaining areas. Direct radiation surveys of hallways adjacent to the surgical suite and the rooms occupied by the patient during the implant period, a CAT scanning room where the patient underwent diagnostic procedures, and a visitor lounge, did not identify anything above background levels.

The licensee monitored the thyroid of 30 university and university hospital personnel who worked around or provided care to the patient during the implant period and who participated in the licensee's incident followup. One of those individuals, a licensee employee, exhibited a thyroid burden of iodine-125 on January 27, 1994. The licensee's conservative assumptions (i.e. intake on January 14, 1994 and 25 percent uptake to the thyroid) determined that the committed dose equivalent to the individual's thyroid was 5 millirem

(0.05 millisievert). NRC's annual exposure limit for occupational employees is 50000 millirems (500 millisieverts) committed dose equivalent to an organ.

In addition, the licensee monitored the thyroid of one patient visitor and determined that the individual received a committed dose equivalent to the thyroid of 54 millirems (0.54 millisievert) which would give a total effective dose equivalent of 1.6 millirems (0.016 millisievert). NRC annual limit for members of the general public is 100 millirems total effective dose equivalent.

Because of the proximity of photon energies for thallium-201 and iodine-125, the licensee decided to release the patient and have him return one week to ten days later for thyroid monitoring in an effort to allow the shorter half-lived thallium-201 (3 days versus the effective half-life of 36 days for iodine-125) to decay. On January 26, 1994, the licensee monitored the thyroid of the patient and determined that the total uptake in the thyroid was approximately 100 microcuries. That uptake would result in a committed dose equivalent to the patient's thyroid of approximately 300 rads. The licensee does not expect any clinically significant effects to the patient due to the misadministration.

An NRC medical consultant, Melvin Griem, M.D., evaluated the medical aspects of the misadministration. His report dated March 4, 1994 is attached. Dr. Griem concluded that the non-radioactive iodinated contrast agent imaging procedure performed on the patient prior to the implant blocked the absorption of the I-125. He also infers that there is a small risk that the patient could develop thyroid tumors after many years, but this carcinogenic effect can be blocked by the administration of thyroid.

The licensee notified the patient, the patient's family, and the referring physician of the misadministration in accordance with 10 CFR 35.33. The licensee submitted its written report to the NRC Region III office in a letter dated January 27, 1994. A copy of the written report was also provided to the patient.

Condition 20 of License No. 34-06903-05 requires, in part, that sealed sources containing licensed material not be opened by the licensee. The licensee determined that the leaking seed initially contained 20.5 millicuries (760 MBq). Further analysis determined that the seed leaked approximately 2.0 to 2.1 millicuries (74 to 76 MBq). The seed apparently leaked after being inadvertently crushed by a surgical clip used by the physician to secure the catheters containing the seeds during the implant procedure. <u>The licensee's opening of a sealed source containing licensed material, although inadvertent, constitutes an apparent violation of License Condition 20.</u>

One apparent violation of NRC regulatory requirements was identified.

Leaking Nickel-63 Sealed Source Incident Review

Condition 13.E. of License No. 34-06903-05 requires, in part, that if the result of a sealed source leak test analysis reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, a report will be filed with NRC Region III within 5 days of the date of the leak test result.

On December 10, 1993, the licensee received a 15 millicurie (555 MBq) nickel-63 foil source from Varian Chromatography Systems, Walnut Creek, California. The source had been returned to Varian on approximately December 3, 1993 for refoiling. A routine leak test on the source in August 1993 indicated the presence of contamination, but not an indication of leakage (i.e. less than 0.005 microcurie of contamination). The licensee interpreted that result as an indicator of possible future leakage and decided to return the source for refoiling. Varian refoiled the source, performed an initial leak test, placed the source into the original source tower and shipped it to the University. Upon receipt, the licensee performed another leak test and identified approximately 0.06 microcuries (2220 Bq) of removable contamination. The source was then returned to Varian for further analysis. The licensee submitted its written report of the incident on December 13, 1993 to Region III.

Analysis by Varian indicated that the inside of the tower contained approximately 0.330 microcurie (0.122 MBq) of contamination. The licensee and Varian determined that the most likely source of the contamination was the original foil source. The original source, distributed on January 18, 1971, most likely leaked inside the tower, but the contamination only partially migrated outside the tower and was then picked up on the licensee's leak test sample. The licensee did not identify any other similarly contaminated sources in its possession.

No apparent violations or concerns were identified.

Lost Strontium-90 Eye Applicator Incident Review

On October 6, 1993, the licensee notified the NRC Operations Center and NRC Region III of the loss of a strontium-90 eye applicator. The source initially contained 50 millicuries (1.85 GBq) of strontium-90 on February 1, 1957 and contained approximately 20 millicuries (0.74 GBq) at the time it was lost The source had been in permanent storage and had never been used.

The licensee possessed two strontium-90 eye applicators and stored them side-by-side in a fume hood in an adjoining room to Old Operating Pavilion Room 4 (Old Op 4). Until October 15, 1992, Old Op 4 was jointly used by the Radiation Safety Office and University Radiation Oncology. In mid-September 1992, Radiation Safety moved to new facilities and notified University Facilities Management on, or about,

October 15, 1992 that it had vacated Old Op 4. That notification was made so that Radiation Safety would no longer be charged rent for the room. Radiation Oncology continued to occupy Old Op 4.

In February 1993, Radiation Oncology determined that security personnel had provided unauthorized personnel access to Old Op 4. To correct the problem, Radiation Oncology had the area re-keyed with a key which was off all master keys and was available only to Radiation Oncology personnel.

On, or about, June 21, 1993, Hospital Environmental Services (housekeeping) requested that Facilities Management reassign Old Op 4 to them for extra storage space. Facilities Management, thinking that the radiation safety office had released Old Op 4 for unrestricted use, and not knowing that Radiation Oncology was a separate unit that still occupied the room, released Old Op 4 to housekeeping. Housekeeping personnel, unable to access the room from the main door, since the key to the lock had been changed to exclusive Radiation Oncology control, gained access through a side door that Radiation Oncology had not had re-keyed. On June 22, 1993, Radiation Safety Office staff observed housekeeping personnel moving into Old Op 4 and informed them that they were not authorized to be in that room. At that time, Radiation Safety staff determined that the side door had been erroneously left on a master key available to housekeeping personnel. On June 23, 1993, Radiation Safety staff again observed housekeeping personnel in Old Op 4, requested that they vacate the room, and immediately submitted an emergency work order to have the side door re-keyed off the master key. This was completed at 4:00 p.m. the same day.

Radiation Oncology performed a formal inventory of all brachytherapy sources, including both eye applicators, on June 3, 1993. Radiation Oncology performed a second, informal inventory of all brachytherapy sources after initially observing housekeeping personnel in the area on June 22, 1993. That informal inventory accounted for both eye applicators.

On August 4, 1993, Radiation Safety staff attempted to perform a routine leak test of the eye applicators, but could only locate one source in the storage location. Assuming that the second source was in use by Radiation Oncology, the staff member continued to leak test other sources due at that time, with the intention of returning at a later date to perform the leak test on the eye applicator. However, the staff member failed to return in order to perform the leak test and failed to notify anyone that the source could not be located.

On October 5, 1993, Radiation Oncology performed an inventory of all brachytherapy sources and determined that only one eye applicator was present in the storage location. Personnel performing the inventory believed that the source was in use by someone else in the department. The following morning, on October 6, 1993, Radiation Oncology determined that the source was not in use and was missing and notified the Radiation Safety Office.

10 CFR 20.207 requires that licensed material in storage be secured from unauthorized removal from the place of storage. The licensee does not know the final disposition of the source, but believes that the source may have been stolen or inadvertently disposed of. In either case, the source was probably removed from its storage location on June 23, 1993, since the source was positively accounted for on June 22, 1993 and the lock on the side door was changed in the afternoon of June 23, 1993. The licensee's failure to secure licensed material in storage from unauthorized removal from the place of storage constitutes an apparent violation of 10 CFR 20.207. If the source was disposed of to the sanitary landfill, the potential hazard to members of the general public would be minimal. However, if the source was stolen and mishandled, it can produce a localized skin burn after extended contact with the skin.

Radiation Safety Office staff, with assistance from University Police, conducted an investigation of the loss. Pictures of the source and source box were shown to various university, hospital and contractual personnel. Interviews of licensee personnel, including housekeeping personnel observed in Old Op 4 on June 22 and 23, 1993, did not reveal any additional information. Other efforts by the licensee to locate the source were not successful.

Inspector interviews of the housekeeping personnel observed in Old Op 4 on June 22 and 23, 1993 did not provide any additional information which would contribute to recovery of the source. However, the interviews did indicate that the housekeeping supervisor who directed personnel in the room ignored postings in Old Op 4 indicating the presence of radioactive materials and attempted to get housekeeping personnel to remove a brachytherapy storage safe from the area. The safe contained approximately 1 curie (37 GBq) of cesium-137 brachytherapy sources and was labeled as containing radioactive material. Due to the weight of the safe and the presence of the warning labels, housekeeping personnel who had previously received basic radiation safety training, and who recognized the postings, refused to move the safe. Inspector interview of the housekeeping supervisor indicated that although he acknowledges the presence of warning postings throughout the room, he chose to believe that the postings were erroneous and proceeded to occupy Old Op 4. Licensee personnel indicated that the supervisor had been verbally reprimanded; however, during inspector interviews, the supervisor continued to indicate that he did not believe that he had done anything wrong and since other licensee personnel (Facilities Management) had informed him of the availability of the room, he was justified in ignoring the warnings and in assuming that the postings were erroneous. The housekeeping supervisor's inappropriate response to radiation warning signs and the licensee's failure to take corrective actions to preclude similar inappropriate responses by the supervisor or other licensee personnel is of concern to NRC staff. 10 CFR 19.12 requires, in part, that all individuals who work in or frequent any portion of a restricted area be informed and instructed in the topics delineated. Inspector interview of housekeeping personnel indicated that an individual who entered Old Op 4 on June 22 and 23, 1993 had not been informed and instructed in any of the topics delineated in

10 CFR 19.12. The licensee's failure to inform and instruct an individual who worked in Old Op 4, a restricted area, in the topics delineated in 10 CFR 19.12 constitutes an apparent violation of 10 CFR 19.12. No other problems were identified with regard to the licensee's radiation safety training program.

Two apparent violations of NRC regulatory requirements and one regulatory concern were identified.

8. Implementation of the Licensee's Quality Management Program (QMP)

The inspection included a review of the licensee's implementation of its QMP with regard to each modality used by the licensee. The modalities employed by the University include: (1) administrations of sodium iodide iodine-131 in quantities in excess of 30 microcuries (1.11 MBq); (2) therapeutic administrations of radiopharmaceuticals other than sodium iodide iodine 125 or iodine-131; and (3) brachytherapy.

The licensee submitted its written QMP to the NRC with a letter dated January 22, 1992, and provided a statement that the program had been implemented in accordance with 10 CFR 35.32(f). The program, as submitted, appears to meet the requirements in 10 CFR 35.32, with one apparent exception.

10 CFR 35.32(a)(2) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the objective that, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive. Item 3 of the licensee's January 22, 1992 QMP states that patient identification may include identification of the patient by two employees (i.e. physicians, technologist, nurses or other staff member) who can positively identify the patient. Other identification methods are also described. Inspector review of licensee records which contained documentation of the method employed to identify each patient indicated that, in the majority of the cases reviewed, the licensee utilized two employees to positively identify the patient. That method of patient identification does not provide high confidence that byproduct material will be administered as directed by the authorized user. Although licensee employees may be able to recognize the patient, that recognition is not sufficient to ensure that the patient is the same individual named in the written directive. The licensee's method of utilizing two licensee employees to verify the identity of a patient is of concern to NRC staff. The licensee agreed to terminate its use of two licensee employees to verify the identity of a patient and to use other methods for patient verification.

One regulatory concern was identified.

9. Exit Summary

On February 11, 1994, the inspectors and Region III inspection supervisory staff conducted an exit summary with those individuals denoted in Section 1 of this report. The exit summary included a review of the preliminary inspection findings, including the identified apparent violations and concerns, the licensee's corrective actions, and the NRC Enforcement Policy. The licensee did not identify any of the information provided during the inspection and proposed for inclusion in this report as proprietary in nature.

Attachment: Report from Melvin Griem, M.D.
dated March 4, 1994

NRC REGION III, License #34-06903-05, Docket #030-002764 page 1
Univ.of Cincinnati Med. Ctr. I-125 leaking seed. Glioma Implant

To: Mr. John B. Martin, Regional Administrator
Ms. B.J.Holt ph 708-829-9836
Mr. Roy J. Caniano ph 708-829-9804
NRC Region III FAX 708-515-1259

From: Melvin L. Griem, MD, MS, (physics)
University of Chicago, ACMUI, NRC
Phone Discussion Weekend Jan 14-16, 1994

Final Report: March 4, 1994

Signed: Mel L Griem

Re: University of Cincinnati Medical Center(UCMC) I-125 implant leaking seed.

Patient with temporary brachytherapy implant using 20 mc seeds inserted into a recurrent High Grade Glioma of the cerebral cortex. Seeds anchored by metal clips. One seed leaked 10% of its radioactivity. Problem discovered upon removal of implant.

People contacted:
Victoria Morris, MS CHP Radiation safety officer UCMC
John Breneman, MD Radiation oncologist UCMC
Howard Elson, Chief Medical Physicist UCMC

Concerning Dosimetry: (unsealed liquid I-125 systemic
I consulted: absorption and dose of organs)

Paul V. Harper MD Univ. of Chicago
Kurt Hofer, PhD Florida State Univ.

1. Description of the Incident:

I Have reviewed the preliminary notification of unusual occurrence PRO III-94-02. I have discussed the details of the management with Dr. John Breneman and the efforts of Victoria Morris in clean up and survey of potentially exposed individuals. nitially it was thought that the patient's girl friend was exposed to I-125 however the patient had a cyclotron produced isotope administered for an imaging before the implant and it was determined that the radioactivity as determined by spectral analysis was from the cyclotron produced imaging agent and not I-125. No other personnel showed radioactivity and the contamination was contained and properly handled according to your phone reports. The patient had some non-radioactive iodinated contrast agent imaging procedure (x-rey CAT scan)prior to the brachytherapy implant. It was determined that 10% of the I-125 leaked from the seed suggesting that 2 mc was absorbed by the patient. Because of the previous iodinated contrast agent, the thyroid was

flooded with non-radioactive iodine. Without that iodine approximately 33% of an administered dose would be taken up by the thyroid.
However it was determined that the uptake of radioactive I-125 was about 5% in the thyroid.

There was no mis-administration of the treatment dose to the tumor since this was a multiple seed implant.

I also reviewed the 2 x-ray pictures made at right angles showing the position of the seeds just after the implant which were used to determine the tissue dose of the brachytherapy implant. By using a very bright light, I can see the close proximity of a seed and a clip on one view but not on the other. I don't belive this is sufficient evidence to detect the problem just after the procedure. Since the procedure is in the brain thru a small hole, placing the clip on the implant may be difficult to visualize.

Medical Consequence of Exposure:

The only person exposed in the above situation is the patient. If the total dose of 2 mc of I-125 were taken up by the thyroid, the dose would be 60 Gy (6000 rads). This dose is NOT uniformly distributed in the thyroid but the radiation is mainly in the colloid. Because of the Auger decay the nucleus of a cell, the DNA, would receive essentially no dose. It is believed that the critical target for carcinogenic effects is in the chromosomal DNA in the nucleus of the cell out of the range of the Auger dose.

The fact that the patient had non-radioactive iodine before the brachytherapy procedure essentially blocked the absorption of the I-125. Iodine (I-125) would have been excreted by the kidney, the salivary glands and the gut and cleared rapidly from the systemic circulation. No other organs are at risk.

With 5% absorption, a dose in the thyroid of approximately 3 Gy (300 rads) most of which would be in the colloid would be a reasonable estimate.

At 6 Gy in the Michael Reese thyroid exposure study about 15% developed thyroid tumors after many years. Some of this carcinogenic effect can be blocked by the administration of thyroid.

Given that the patient has a recurrent High-grade glioma the prognosis for the patient is very guarded.

Recommendations for follow-up.

The patient could be placed on thyroid to place the exposed gland at rest, thus suppressing TSH production. Long term follow-up of the thyroid by various imaging procedures on a regular basis could be done if the primary brain tumor has been controlled.

Accuracy of data and licensee's evaluation:
The dose calculations the UCMC has provided and my information from Drs. Hofer and Harper agree. Dr. Harper used MIRD 5 estimates. Dr. Hofer did some classic work on I-125 dosimetry in cells in culture and is an authority on the micro-dosimetry.

DOE - Oak Ridge - life-time morbidity study might be notified if the patient is a long term survivor of his primary disease.