U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No.: 030-02764/89002(DRSS)

Docket No.: 030-02764

License No.: 34-06903-05 Category G(1) Priority I

Licensee: University of Cincinnati
Cincinnati, OH 45267

Inspection at: University of Cincinnati
Cincinnati, OH Campus

Inspection Conducted: September 19 through November 1, 1989

Inspectors: W. J. Slawinski — Date: 2-7-90

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Reviewed by: D. J. Kreniawski, Chief — Date: 2/7/90
Nuclear Materials Safety
Section 1

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Nuclear Materials Safety Branch

Inspection Summary

Inspection on August 25, 1989 and during the period September 19 through November 1, 1989 (Report No. 030-02764/89002(DRSS))
Areas Inspected: Two special announced inspections on August 25, 1989 and from September 19 through November 1, 1989. The former inspection was conducted to review a licensee reported laboratory contamination event, and the latter to review numerous allegations concerning the conduct of licensed activities at the University; compliance with a Confirmatory Action Letter issued August 30, 1989; and the licensee's progress in identifying and correcting problems and strengthening self-disclosed program weaknesses.

Results: An apparent breakdown in the control of past licensed activities was noted that collectively represents a significant lack of attention and management control over licensed responsibilities. Many of the allegations were substantiated, several resulted in apparent violations of regulatory requirements. In addition, several other apparent violations and program weaknesses not associated with the specific allegations were also identified. However, these violations and many of the weaknesses were identified by the licensee and their consultant prior to this inspection and the licensee was actively developing and implementing a self-improvement program during the inspection period. Apparent violations are summarized in Attachment I.

DETAILS

1. Persons Contacted

G. Alexander, Administrative Director, Radiation Safety Office
J. Barbro, Senior Health Physics Technician
M. Boyd, Senior Health Physics Technician
+*H. Elson, Ph.D., Interim Radiation Safety Officer
R. Estes, Health Physics Technician
P. Harris, Health Physics Technician
*D. Harrison, M.D., Senior Vice President and Provost for Health Affairs
P. Jason, Deputy Radiation Safety Officer
*C. Kupferberg, Associate Senior Vice President Medical Center and Associate Dean, College of Medicine
L. Lewnard, Associate General Counsel
*J. Wesner, General Counsel
*J. Wiot, M.D., Chairman, Radiation Safety Committee

+R. Burgin, Nuclear Energy Services (Consultant)
*F. Trejo, Nuclear Energy Services (Consultant)

The inspectors also contacted other licensee employees and contractors.

+Denotes those present at the exit meeting held at the conclusion of the site inspection on October 6, 1989 and contacted for additional information through on January 5, 1990.

*Denotes those present at the NRC/licensee management meeting conducted in Region III on November 1, 1989.

2. Background Information

NRC Region III received three sets of allegations from two different allegers concerning NRC licensed activities at the University of Cincinnati. Nine concerns were initially received in December 1, 1988 and January 25, 1989 telecons from an unidentified individual (AMS No. RIII-88-A-0174). Approximately 20 additional concerns were received in a June 15, 1989 telecon from an anonymous source and expanded upon during the individual's visit to the Region III office on July 6, 1989 (AMS No. RIII 89-A-0084). The allegations encompassed several radiation protection program areas including management controls, radiation safety office technical staff qualifications and training, waste disposal, inventory and accountability, contamination controls, radiological survey and measuring instrumentation and also included concerns related to radiation safety office staff harassment, discrimination, and poor communications. Several of the allegations from the two allegers were similar.

On August 22, 1989, university management (Dr. J. Wiot and a consultant representative) visited the Region III office and advised the NRC staff of management control and related concerns associated with their radiation

protection program and of their plans for internal program review. Shortly thereafter, the licensee hired a consultant initially to selectively audit portions of their program, but later expanded to encompass the entire program after significant laboratory contamination problems were identified during early phases of the consultant's audit. Additionally, potential radiation safety office staff integrity issues surfaced and the university placed their Radiation Safety Officer (RSO) and Deputy RSO on administrative leave and appointed an interim RSO. These radiation safety office staff changes were approved by the NRC staff in License Amendment No. 61, dated August 24, 1989.

On August 25, 1989, the NRC dispatched two inspectors to the University, in response to a licensee telecon the previous day reporting the aforementioned laboratory contamination problems identified during the early phases of the consultant's audit. The purpose of the site visit was to assess the significance of the contamination problems, determine the extent of actions necessary to protect the public and workers, and to evaluate the university's ability to handle the problem effectively. The inspection findings and other information obtained during that site visit were used as a basis for issuance of an NRC Confirmatory Action Letter (CAL) dated August 30, 1989. The CAL directed the licensee to:

- Decontaminate certain research laboratories
- Issue notice(s) to researchers concerning protocol adequacy and compliance, including contamination control and survey requirements, radiation safety office organizational changes and the contamination event.
- Prohibit further purchases of material until protocols are re-examined.
- Continue auditing all non-human use research labs.
- Provide radiation safety refresher training to researchers.

From late August through October 1989, the licensee and their consultant performed a comprehensive audit of the university's radiation protection program, focusing on the research activities conducted in the nearly 700 labs located throughout the University complex. The audit consisted of field inspections of all research labs and included the performance of radiological surveys, observation of lab practices and procedures, radiological surveys and protocol and inventory reviews. The consultant's audit report (NES Audit Report), dated October 30, 1989, was submitted to Region III on November 3, 1989, in response to NRC's request during the August 22, 1989 meeting and the November 1, 1989 management meeting described in Section 20. The audit report summarized the scope and findings of the audit, corrective actions taken by the licensee and consultant recommendations for program improvement. The consultant's audit identified approximately 30 apparent violations of regulatory requirements. Many of these licensee-identified violations were also identified during the NRC inspection; however, there were no

NRC-identified violations that had not been identified by the licensee and/or their consultant prior to this inspection. According to the consultant's audit report, approximately 80% of the laboratories inspected during their audit were found to have violated NRC and/or university regulations. The majority of violations were related to the failure to perform or document results of laboratory surveys and licensed material inventories (26% and 23% of labs, respectively). Followup audits were conducted by the consultant to ensure that certain contaminated labs had been properly decontaminated and that corrective actions were taken.

Apparent violations and other problems identified in the consultant's audit report are discussed throughout this inspection report. In addition, this report also describes apparent programmatic weaknesses and other concerns identified by the NRC inspectors.

3. Purpose of Inspection

This inspection was conducted to review: (1) the allegations provided to the NRC concerning licensed activities at the University; (2) the licensee's compliance with the August 30, 1989 CAL; and (3) the licensee's progress in identifying and correcting problems and strengthening their overall licensed program.

The licensee adequately addressed and completed the necessary actions to satisfy the CAL requirements. The licensee's actions with respect to the CAL are summarized in Inspection Report No. 030-02764/89001(DRSS), issued November 30, 1989.

4. Allegation Followup (General)

During this inspection, the inspectors learned that many of the concerns expressed in the allegations to the NRC had also been provided to the licensee's radiation safety committee (RSC) in a series of internal memorandums from the radiation safety office health physics technicians (HPTs) in late December 1988. The HPTs reportedly advised the RSO of their concerns prior to relaying them to the RSC and were not satisfied with the actions taken. According to the HPT's, communications and management control problems existed in the radiation safety office for many years. Special RSC meetings were held in early 1989 to discuss the HPT concerns and the RSC formed a subcommittee to better evaluate them. On March 20, 1989, the RSC issued a memorandum to the technicians addressing each specific concern; the HPTs were generally satisfied with the RSC's response. Meanwhile, it appears that communication and management control problems within the radiation safety office persisted and may have worsened and that the technician and RSO working relationship was unusually strained and adversarial. Consequently, an individual perceiving harassment from the RSO, submitted the technicians' collective concerns to the NRC along with additional individual concerns.

Each of the allegations received by the NRC was reviewed during this inspection and are described in Section 19 of this report. (Allegation

Nos. RIII-88-A-0174 and RIII-89-A-0084 (OPEN)). The consultant's audit report, submitted to NRC Region III as an enclosure to letter dated November 3, 1989, is referenced throughout this report.

5. Scope of Licensed Program

The University of Cincinnati is a medical and academic broad scope licensee authorized under 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; (2) curie quantities of any byproduct material (with atomic numbers 3-83, inclusive) 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 (3) other miscellaneous licensed material for instrument calibration and leak test analysis services for other licenses. The latter activity was authorized in Amendment No. 60, dated May 5, 1989. (These service activities are discussed further in Section 17.)

Medical research and non-human use R&D are conducted in nearly 700 labs located throughout the university complex, using primarily sub-millicurie quantities of licensed material as tracers and tagging agents. The university also possesses separate NRC licenses for both human and non-human use teletherapy, a 10,000 curie pool irradiator for irradiation of materials, a 1600 curie self-shielded irradiator for blood irradiation, Pu-Be neutron sources for experiments and student instruction and 2500 kilograms of natural uranium in a subcritical assembly for experimental research.

6. Organization, Management Controls and Staffing

The inspectors reviewed the licensee's organization and management controls for the radiation protection program, including changes in the organizational structure, staffing, and effectiveness of procedures and other management techniques used to implement these programs.

a. Overview

Licenses of broad scope are issued only to those institutions that (1) have had previous experience operating under a specific institutional license and (2) have an established comprehensive radiation management program. A broad scope license is intended to accommodate those institutions involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. The University of Cincinnati broad scope license authorizes use of nearly any byproduct material by anyone, in accordance with review and approval procedures developed and implemented by the Radiation Safety Committee (RSC). License Condition No. 11(a) requires that material be used by, or under the supervision of, individuals designated by the RSC. Therefore, strong management and RSC controls and oversight are essential to ensure licensed activities are conducted properly.

Ultimate responsibility for the conduct of NRC-licensed activities at the university is vested in the University President, Joseph Steger, Ph.D., followed by the Senior Vice-President and Associate Senior Vice-president. The individuals holding the latter two positions are identified in Section 1. Direct program management and oversight is provided by a radiation safety committee (RSC) and a radiation safety office. The radiation safety officer (RSO) reports to the RSC Chairman who, in turn, reports to the Associate Senior Vice-President. As a result of the numerous violations and weaknesses recently identified by the licensee, their consultant and the NRC, it appears that the university has not exercised the necessary management controls and oversight over their NRC-licensed program. The university's management control and oversight program are discussed in subsections below.

b. Radiation Safety Committee (RSC)

The University's RSC is composed of a chairman, a management representative, several members trained and experienced in the safe use of those radioactive materials authorized by the NRC license, and other members whose expertise complement the primary function of the committee to administer the institution's licensed program. The committee's current composition was reviewed by the inspectors and meets NRC requirements. The duties, responsibilities, and control mechanisms of the RSC and the administrative procedures for implementing these functions are generally discussed in the licensee's referenced license application dated August 13, 1984. This application requires that the committee review and approve/disapprove applications (i.e., protocols) for the use of radioisotopes within the university by unanimous approval from those RSC members present during an RSC quarterly meeting. However, the scope of these protocol reviews is not specified in the licensee's application or otherwise addressed in regulatory requirements. The inspection disclosed that RSC review of proposed protocols has generally been insufficient, lacking the thoroughness necessary to ensure proper radiological controls are in place during licensed material research. Specifically, new or amendments to existing protocols have routinely not been reviewed by each RSC member to evaluate overall radiological controls including, for example, the adequacy of proposed facilities and equipment and survey, waste disposal and contamination control procedures. In the past, most protocols were provisionally approved by the RSO initially (the scope of the RSO's review is unknown because he was unavailable for interview during this inspection) and subsequently approved by the RSC based on the RSO's recommendation and review of the protocol by less than full committee membership. In some instances, protocols were modified by researchers without notifying the radiation safety office and obtaining RSO and/or RSC approval. These apparent protocol review weaknesses were identified by both the NRC inspectors and the licensee's consultant, and significant changes to the RSC and its modus operandi have recently been developed. These changes include RSC reorganization and development of formal written

RSC operating guidelines describing committee structure, charter, protocol review requirements/methods and committee internal program audit requirements. Formal RSC operating guidelines did not exist previously. The actions taken and proposed by the licensee to strengthen this apparent program weakness were reviewed during the inspection and discussed at the November 1, 1989 NRC/licensee management meeting; these actions appear generally adequate. These issues are addressed further in Section 3.A.2 of the consultant's audit report dated October 30, 1989 (hereinafter referred to as NES Audit Report).

c. Radiation Safety Office

The radiation safety office is directly responsible for governing the day-to-day operations of the radiation protection program at the University. The primary responsibility of the office is to ensure proper development and implementation of the radiation protection program approved by the RSC, through training and deployment of various audit and control mechanisms.

Other responsibilities include but are not limited to the following:

- Provide general surveillance over all activities involving radioactive material through auditing, monitoring and performance of radiation surveys.

- Determine compliance with regulatory requirements and conditions of project approvals (protocols) as specified by the RSC.

- Conduct training programs and otherwise instruct personnel in proper radiation protection procedures.

- Maintain licensed material inventory and an accountability system to ensure licensed possession limits are not exceeded.

- Communicate with the RSC and university management and keep them informed of program issues, developments and problems.

The University of Cincinnati radiation safety office staff is comprised of an RSO, Deputy RSO, Administrative Director, secretary and four HPTs. For approximately the last 20 years and until August 1989, the RSO position was filled by the same individual. As discussed in Section 2, the university placed the RSO and deputy RSO on administrative leave and they remain in this status to date. The ultimate status of these individuals is unknown at this time. A new (interim) RSO was appointed by the university and approved by the NRC in license amendment No. 61, dated August 24, 1989.

During this inspection, the inspectors interviewed all members of the radiation safety office staff except the RSO currently on administrative leave. The RSO was unavailable for interview. The majority of those interviewed expressed concerns with the overall

operation and management of the radiation safety office including numerous radiation protection related concerns which are addressed throughout this report. Based on these interviews, it appears that worker-management relations within the safety office were severely strained for several years and the communications were poor. Although the inspectors did not identify any significant indication that the HPTs were prevented from performing their regulatory required duties because of the existing relationship, they appear to have been hampered from improving and strengthening aspects of the program due to lack of direct radiation safety office management support. The morale of the HPTs appears to have been adversely affected by the relationship with their immediate supervisor and could be partially responsible for the apparent high turnover rate of the HPT staff. (Technician staffing and turnover is described in subsection (d) below.) It does not appear that morale problems precluded HPTs from fulfilling their job responsibilities nor prevented the addressing of significant radiological safety issues.

d. Health Physics Technician Staffing and Responsibilities

The HPTs are responsible for implementing the day-to-day operations of the radiation safety office as directed by the RSO and deputy RSO. Technicians perform several tasks including laboratory surveys, source leak tests and material inventories, administer the film badge program, process incoming radioactive material shipments destined for non-human applications, and conduct survey instrument calibrations and certain waste disposal tasks. The HPTs have little involvement in the nuclear medicine program apart from decontaminating and surveying radiotherapeutic patient rooms, calibrating survey instruments, and performing sealed source inventories and leak tests.

The technical staff of the radiation safety office, excluding the RSO, currently consists of a deputy RSO, two senior HPTs and two HPTs. This technical staff is smaller than that of other universities with similar size/scope programs; therefore, it appears desirable for the licensee to evaluate the necessity for an increased radiation safety office staff.

Since 1985, three radiation safety office HPTs terminated employment and, reportedly, two other HPTs terminated between 1983 and 1985. The loss from the HPT staff over this 6-year period constitutes about 50% turnover. Two hirings in the last 3 years have expanded the HPT staff to its current complement of four. The reasons for the terminations were not determined nor is it known if the apparent poor technician-management relationship in the safety office contributed to this turnover. While this turnover rate may not be excessive, it appears somewhat high and generally is detrimental to the conduct of radiation protection programs due to stability and experience level degradation.

No violations were identified; however, RSC operation and protocol review weaknesses were noted.

7. Internal Audits and Inspections

The inspectors reviewed the research laboratory internal audit and inspection program developed by the licensee and discussed its implementation with the HPT staff. Relevant Inspector findings are discussed below.

Research activities are conducted using licensed material in nearly 700 labs located throughout the University complex. These activities are required to be conducted pursuant to RSC approved protocols, which should define the radiological controls necessary to ensure safety and compliance with regulatory requirements. The licensee's referenced application dated August 13, 1984, states that the minimum protocol specified lab survey frequency is monthly during active use periods. It is normally the responsibility of the lab researcher to conduct these protocol required surveys. The radiation safety office staff verifies effectiveness of research laboratory contamination controls and practices through the performance of periodic independent radiation surveys in these labs. The radiation safety office staff is required, pursuant to referenced letter dated April 11, 1986, to perform surveys in lab use and storage areas at least twice per year and more frequently in those labs using larger quantities of unsealed material; however, as described in Section 11, this requirement has not always been met. Although the radiation safety office conducts periodic radiation surveys in research labs, no lab audits/inspections are routinely conducted by the licensee, or independent group, to determine overall adequacy of lab operations and compliance with protocol and regulatory requirements. For example, labs are not routinely audited to verify adequacy of: (1) waste disposal practices; (2) external and internal exposure controls including use of personnel monitoring devices; (3) lab facilities, equipment and instrumentation; (4) worker training and qualifications; and (5) material control and accountability methods. Additionally, the RSC has not conducted independent audits of the radiation protection program apart from review of exposure reports completed by the RSO. Specifically and as described in Section 3.A.2 of the NES Audit Report, the RSC has failed to conduct "formal annual reviews" of the radiation safety program to include operating procedures, inspections and consultations with the radiation protection staff. According to the NES Audit Report, the RSC has only cursorily reviewed procedures and inspections. The RSC's failure to conduct formal program reviews appears to be a violation of License Condition No. 20, which references the licensee's August 13, 1984 application. The overall lack of an internal audit and inspection program is considered a significant program weakness. Actions to correct the apparent violation and strengthen this program weakness are described in the NES Audit Report; these actions appear adequate.

One apparent violation was identified by the licensee/consultant.

8. Qualifications, Training and Instruction to Workers

The inspectors reviewed the qualification and experience of selected radiation safety office staff members, and the radiation safety training

and supervision provided to research lab workers and certain members of the ancillary staff. Inspector findings are discussed below.

a. Qualification, Experience and Worker Supervision

As previously discussed, the technical staff of the radiation safety office is composed of four HPTs, a deputy RSO and an RSO. The HPT experience at the university radiation safety office ranges from 1½ to 5 years. One technician has an additional 6 years direct reactor health physics experience at nuclear power plants; the additional health physics experience of the other technicians is not significant. Although no regulatory qualification requirements exist for university HPTs, the experience and qualifications of the current staff appear adequate to implement the routine radiation protection program. However, as described in Section 6, the licensee should evaluate the adequacy of the current staffing level in the safety office.

The licensee/consultant audit identified apparent violations of regulatory requirements involving (1) licensed material research conducted by unsupervised lab workers and (2) failure to review and verify the qualifications of researchers designated as principal investigators. These apparent violations are described in sections 3.A.4 and 3.A.11(b) of the NES Audit Report, respectively. Specifically, contrary to License Condition No. 11, at least five examples were identified in which licensed material research was conducted by lab workers that were neither designated, or working under the supervision of individuals designated, by the RSC. Similarly, contrary to License Condition 20 and referenced application dated August 13, 1984, the licensee failed to verify the qualifications of researchers approved as principal investigators. Specifically, the RSC in most instances did not actually review and verify a perspective principal investigator's qualifications and training, and typically granted principal investigator status based solely on the researcher's request and reputation. Corrective actions for these apparent violations appear adequate and are described in the aforementioned sections of the NES Audit Report.

b. Training/Retraining

The licensee's training and worker instruction program was reviewed as part of an allegation followup and is described in Section 19 (Allegation 88-A-0174, Item 8). Concerns related to the training program are delineated in the discussion of the allegation.

The licensee/consultant audit identified several examples wherein lab workers failed to satisfy training requirements delineated in the licensee's referenced application. This appears to be a violation of License Condition No. 20, which references the licensee's August 13, 1984 application. Specifically, the audit disclosed approximately 220 lab workers (22% of radiation workers) engaged in licensed material research who had not completed the licensee's training

course or radiation safety training at another institution, nor did they receive equivalent training from the lab's principal investigator(s). The licensee's corrective actions included development of a new radiation safety training program and measures to ensure the licensee's training course is completed by all lab workers prior to working with radioactive materials. These corrective actions were reviewed by the inspectors and appear adequate. The licensee's new training program was initiated on October 17, 1989.

c. Instruction to Workers

10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area be informed of the radioactive material use in that area and be instructed in the health protection problems and precautions or procedures to minimize exposure, commensurate with their duties in the area. These requirements apply to ancillary staff members who may only occasionally frequent a restricted area as well as radiation workers that routinely work in the area. In addition, the licensee's referenced application requires that housekeeping and support services supervisors meet with radiation safety personnel as needed, and these supervisors are then required to instruct their employees pursuant to 10 CFR 19. This application further states that nursing staff who attend radiotherapeutic patients receive formal instructions from the radiation safety office staff.

Contrary to the above requirements, the licensee/consultant audit disclosed that several housekeeping and support services personnel (comprised of over 400 workers) were not provided radiation safety training/instruction commensurate with their duties and one instance when a nursing staff attending a radiotherapeutic patient was not provided radiation safety instructions. In addition, the University's approximately 30 maintenance department personnel that maintain potentially contaminated ventilation systems were unaware of safety practices/procedures associated with their work activities in restricted area research labs. These examples are apparent violations of License Condition No. 20, which references the licensee's August 13, 1984 application. The licensee's corrective actions are described in Sections 3.A.11(c) and 11(d) of the NES Audit Report and appear to be adequate.

The inspectors reviewed the training provided to the individual who operates the incinerator where radioactive materials are routinely burned. The training provided was found to meet 10 CFR 19 requirements and those delineated in the licensee's April 11, 1986 referenced letter; no problems were noted.

Four apparent violations were identified by the licensee/consultant, one training violation included three examples.

9. Inventory, Material Control/Accountability and Leak Testing

The inspectors reviewed the University's licensed material inventory and accountability system and selected aspects of their sealed source leak testing program. Inspector findings are discussed below.

a. Licensed Material Inventory/Accountability

The University broad scope license allows possession of a vast array of isotopes, in large quantities, primarily for medical use/research and research and development. For example, the licensee is authorized to possess any radiopharmaceutical identified in 10 CFR 35.100-35.400, in quantities as needed for medical use, and curie quantities of any byproduct material in any form with atomic numbers 3-83, for medical research and research and development. Several other specifically listed sealed sources are also authorized. As previously described, research is conducted in nearly 700 labs located throughout the university complex. These relatively high possession limits and the significant number of areas using licensed material make it imperative that the licensee develop and maintain a strong inventory and accountability system. However, as described below, the licensee's inventory and accountability program is weak and in need of significant improvement.

License-referenced letter dated April 11, 1986 states that in regard to their institutional total inventory system, "we continually examine the potential for possession limits being exceeded by an indirect method; that is, we continuously monitor amounts of radioactive material in possession of the university when we examine and total the amounts of radioactivity released into the sewage, incinerated, and/or shipped in drums for disposal. The large majority of non-human use material is disposed in these manners. Although this method will not provide an exact amount of radioactive material on hand, it does, over a long period of time, enable us to determine if we may be approaching possession limits."

Contrary to the above and as described below, the licensee/consultant audit revealed that the university did not adequately determine quantities of licensed material possessed. The methods employed by the licensee were inadequate in that (1) accurate inventory/disposal records were not maintained by individual researchers and (2) researchers routinely forwarded disposal records to the radiation safety office long after (up to 2 years) the disposals were actually made. Furthermore, it appears that this inventory system was conceptually inadequate, because it was incapable of yielding cumulative institutional quantities possessed at any given time.

Letter dated April 11, 1986, referenced in License Condition No. 20, states that principal investigators are responsible for maintaining a running inventory of material they possess, which is forwarded periodically to the radiation safety office. Contrary to this requirement, the licensee/consultant audit revealed that many principal investigators and/or researchers did not routinely maintain

running inventories of material possessed in their labs. Consultant field audits identified that 23% of the 677 labs audited did not maintain running inventories. This appears to be a violation of License Condition No. 20, which references letter dated April 11, 1986. This problem represents a significant program weakness.

License Condition No. 14 requires the licensee to conduct a physical inventory every 6 months to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory. Contrary to this requirement, the licensee/consultant audit identified 46 sealed sources that had not been physically inventoried since as long ago as 1970; inventory records were not maintained for those sources that decayed to below 100 microcuries (an activity below which leak tests are no longer required); inventories listed the location of 14 sources as "no longer here," "lost," "no longer in possession," etc., or listed no location at all. Failure to physically inventory sealed sources at the required frequency is an apparent violation of License Condition No. 14. This problem also represents a significant program weakness. The radiation safety office maintained university sealed source inventory records on 5x7 file cards (one or more card per source). This system proved difficult to obtain an accurate account of sources possessed and to ensure that all sources were inventoried at the required sixth-month frequency.

According to the NES Audit Report, prior to October 18, 1989, the radiation safety office "tracked" 112 sealed radioactive sources. During the consultant's audit, 46 additional sealed sources were discovered and added to the inventory. Currently, ten NRC-licensed sealed sources cannot be specifically accounted for and their location or disposition is unknown at this time. Accountability appears to have been lost sometime during the last few years. The consultant performed a physical inventory of sealed sources the week of October 16, 1989, including a university-wide search for lost, missing, or otherwise unaccountable sources. The licensee speculates that the unaccountable sources were probably transferred or disposed properly and only record traceability has been lost. These "lost" sources are listed below:

Isotope	Nominal Activity
cesium-137	210 microcuries
gadolinium-153	1 curie
nickel-63	3 sources, each approximately 10-15 millicuries
strontium-90	5.8 millicuries
tin-119	4 sources, each approximately 2-5 millicuries

Contrary to 10 CFR 20.402(a), the licensee failed to report to the Commission, the theft, loss, or otherwise unaccountability of these

sources, which potentially constitute a substantial hazard to persons in unrestricted areas.

The corrective actions taken and planned by the licensee for the above noted violations and program weakness involve installation of a computer system to more readily allow inventory and material accountability to be maintained on a continuous basis. The previously used indirect method has been discontinued. All current and future inventory data will be maintained in the computer system.

These violations and the licensee's corrective actions are described in section 3.A.13 of the NES Audit Report.

b. Sealed Source Leak Testing

Condition 12(c) of the university's broad scope license requires that each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months, except that sources designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months. The leak test requirement does not apply to sealed sources that are stored and not being used.

Contrary to the above, the licensee/consultant audit identified (1) seven americium-241 (alpha emitting) sealed sources that were not leak tested between August 1988 and February 1989 and (2) an americium-241 (gamma emitting) sealed source that was not leak tested between August 1987 and February 1989. These sources exceeded the activities (quantities) for leak test exemption and were being used during the specified time periods. Failure to leak test sealed sources at the required intervals appears to be a violation of License Condition 12(c). To correct this problem, the radiation safety office plans to utilize the computer system previously described in section 9(a) to track sources and their locations (for inventories) and the leak test due-dates for each. The computer program alerts the staff of upcoming tasks at specified frequencies to enable scheduling arrangements and ensure that sources are not omitted because of misplaced index cards (the former method of data retention). These corrective actions appear adequate.

Four apparent violations were identified by the licensee/consultant.

10. Facilities and Equipment

The inspectors toured the radiation safety office's counting room, package receipt/distribution, instrument calibration and basement waste drum storage areas and selected non-human use research labs. Inspectors also toured one of the nuclear medicine department hot lab and scanning areas, the incinerator used for licensed material incineration, and the whole body counting facility. Relevant inspector observations and apparent violations identified by the licensee/consultant are discussed below.

a. Survey and Measuring Instrumentation

The University possesses approximately 250 portable radiation survey instruments to support research activities, the nuclear medicine program and radiation safety office operations. The licensee expects this number to increase as research protocols continue to be reviewed, more carefully scrutinized, and radiological requirements are tightened. Non-medical use survey instruments (research lab instruments) are calibrated on an annual basis and nuclear medicine and most radiation safety office instruments, semiannually. All calibrations are performed by the radiation safety office staff.

Prior to 1989, G-M survey instruments were calibrated using either a 1-milligram radium brachytherapy seed or 25 milligram brachytherapy tube. According to the HPTs, these radium sources are not NBS standards or traceable to NBS standards. To calibrate the instruments, the sources were reportedly placed at specified distances from the instruments and gamma constants used to derive distance to dose rate values; no energy response curves were generated for these energy dependent instruments. Failure to employ NBS traceable standards appears to be contrary to License Condition No. 20, which references the licensees application dated August 9, 1984. The application states that NBS standards or traceable standards are used to calibrate instruments. This apparent violation was identified and corrected by the licensee in early 1989; corrective actions are described below. In addition, although not contrary to regulatory requirements, the calibration method employed by the licensee was inappropriate in that it failed to take into account radiation scatter and instrument energy dependency and electronic response. Ion chamber instruments were calibrated using a Victoreen instrument calibrator containing a nominal 50 millicurie cesium-137 source. The HPTS were unsure if the cesium source was NBS traceable.

To correct the self-identified violation described above and to improve their calibration methods, the licensee purchased a new instrument calibrator housing a cesium-137 NBS-traceable standard and have revised their G-M instrument calibration techniques to include high voltage plateau determinations and pulse generator electronic checks. A formal written procedure for instrument calibration is currently being developed.

In addition to the violation described above, the licensee/consultant audit identified two additional equipment-related violations. These violations involve failures to (1) conduct constancy checks of a dose calibrator on five occasions in 1989 when radiopharmaceuticals were administered to patients and (2) use syringe shields during preparation and injection of radiopharmaceuticals. In the former example, the licensee also failed to reverify (i.e. dose calibrate) the activity of the radiopharmaceuticals administered, to ensure they did not vary from the prescribed dose by more than 10%. According to the licensee's consultant, radiopharmaceuticals were assayed in a dose calibrator when they were prepared by the licensee's central pharmacy earlier in the day, but not reassayed at the licensee's satellite facility prior to patient administration. These examples

constitute apparent violations of License Condition 20, which reference the licensee's April 11, 1986 letter. The April 11, 1986, letter requires the use of syringe shields and performance of dose calibrator constancy checks. These apparent violations and the licensee's corrective actions are described in sections 3.A.6 and 3.A.10 of the NES Audit Report.

b. Whole Body Counter

An allegation related to operation of the licensee's whole body counter is described in Section 19 (Allegation 89-A-0084, Item 14). No other aspects of the licensee's whole body counting system were reviewed during this inspection.

c. Facilities

The license/consultant audit identified three apparent regulatory violations associated with licensed material use and storage in unauthorized areas and failure to properly control access to licensed material used in research labs. Specifically, the audit identified: (1) 50 non-human use research labs that were not specified on protocols as use areas, to be areas actively conducting licensed material research. This appears contrary to License Condition 20, which references the licensee's August 13, 1984, application. The application requires that protocols specify use areas. (2) A nominal 10 millicurie americium-241 sealed source housed in a moisture measuring gauge was stored in an area not authorized by License Condition No. 10 from 1987 to September 1989. (3) Nearly 70 laboratories (approximately 10% of those audited by the consultant) using or storing licensed material that were not controlled for the purpose of protection from exposure to radiation and radioactive material (i.e., unrestricted areas) and the material was not secured from unauthorized removal or tended under constant surveillance and immediate control. This appears contrary to 10 CFR 20.207. These apparent regulatory violations and the licensee's corrective actions are described in sections 3.A.3 and 3.A.17 of the NES Audit Report.

Six apparent violations were identified by the licensee/consultant.

11. External Exposure Controls and Monitoring

The inspectors reviewed selected aspects of the licensee's external exposure control and monitoring program and apparent weaknesses and related violations identified in the licensee/consultant audit. Inspector findings are discussed below.

Personal external radiation exposure is monitored by vendor supplied film and TLD badges exchanged on a monthly basis. Currently, approximately 1600 individuals are issued film badges for whole body exposure monitoring. About 600 TLD extremity monitoring badges are issued to those individuals who routinely handle millicurie quantities of beta/gamma emitting material in the departments of Radiation Oncology, Nuclear

Medicine and Radiation Safety. Selected researchers that use millicurie quantities of high energy beta emitters are also issued TLD extremity monitoring devices.

10 CFR 20.201(b) requires that each licensee make such surveys (evaluations) as (1) may be necessary to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. Contrary to this requirement, the licensee/consultant audit disclosed that evaluations were not made to determine the radiation exposures to numerous individuals that lost, misplaced or otherwise failed to submit their film/TLD badges for processing for periods of up to 18 consecutive months. Specifically, the consultant's selective review of film badge reports for 1987-1989 revealed that approximately 270 film badges were not returned for processing or were otherwise unaccounted for, and no evaluations were made to assess the individual's radiation exposure. 270 film badges represents about 7% of all dosimetry issued during that two year period. Failure to evaluate radiation worker exposures appears contrary to 10 CFR 20.201(b), to show compliance with 10 CFR 20.101. The consultant audit further identified 115 film badges, dating back to 1972, located in the RSO's desk drawer; it is unknown if these badges were worn by personnel. According to the licensee, there currently is no information to suggest that any individual who's exposure was not evaluated, received a significant dose.

Implementation of the licensee's personal external radiation monitoring program appears to be weak. To correct these problems, the licensee has made improvements to their radiation control and management program as described throughout this report and the NES Audit Report. An optional dosimetry vendor notification service was recently purchased and the licensee will be notified should an assigned film or TLD badge not be submitted for processing. The licensee is currently attempting to evaluate and assign appropriate exposures to each individual's exposure history that apparently was not previously determined.

In addition to the above, the licensee/consultant audit identified three apparent regulatory violations for failure to conduct radiological surveys in research lab use and storage areas and in one of the licensee's nuclear medicine departments. Specifically, the audit identified that: (1) at least 25% of the nearly 700 research labs audited did not adhere to protocol specified survey requirements and either failed to conduct area wipe tests or did not conduct them at required frequencies; (2) at least six research laboratory use or storage areas were not wipe tested by the radiation safety office twice a year; and (3) nuclear medicine department preparation and injection areas at one satellite hospital failed to conduct daily surveys on at least five occasions in 1989 when radiopharmaceuticals were administered to patients. These examples appear contrary to License Condition No. 20, which references the licensee's April 11, 1986 letter. This letter requires that: (1) researchers comply with protocol specified survey requirements; (2) the radiation safety office wipe test all lab use and storage areas at least twice a year; and (3) nuclear medicine preparation and injection areas be surveyed daily.

These apparent violations and the licensee's corrective actions are described in section 3.A.5 of the NES Audit Report.

Four apparent violations were identified by the licensee/consultant.

12. Internal Exposure Controls and Monitoring

The inspectors reviewed selected aspects of the licensee's internal exposure control and monitoring program including an apparent violation identified in the licensee/consultant audit. Inspector findings are discussed below.

The use of xenon-133 gas is approved for diagnostic studies at all hospitals specifically named on the University's broad scope NRC license. After use, the xenon-133 is transferred to an activated charcoal xenon trap or vented directly outdoors using an exhaust fan and tubing (the latter method used at Highland Hospital in Hillsboro, Ohio.) License application referenced in License Condition No. 20 and dated August 13, 1984, states in regard to xenon-133 studies, "Calculations are made to show concentration in restricted and unrestricted areas are not exceeded (1×10^{-5} uCi/ml and 3×10^{-7} uCi/ml, respectively). Negative pressure is maintained in . . . imaging rooms during use."

Contrary to this requirement, the licensee/consultant audit disclosed that the required xenon gas concentration calculations and negative pressure determinations were not performed for an active xenon use area in Highland Hospital, which is an authorized location of use on the University NRC license. This appears contrary to the License Condition No. 20. This apparent violation of regulatory requirements and the licensee's corrective actions are described in Section 3.A.7 of the NES Audit Report. It does not appear that airborne concentrations exceeded 10 CFR 20 limits because of the relatively small quantities of xenon used per study and the infrequency of patient studies.

One apparent violation was identified by the licensee/consultant.

13. Contamination Controls

Two allegations related to contamination and contamination controls are discussed in Section 19. Apart from these specific allegations, no other aspects of the licensee's contamination control program were reviewed.

14. Waste Disposal

The inspectors reviewed selected aspects of the licensee's radioactive waste disposal program including apparent violations identified by the licensee/consultant. Relevant information and inspector findings are discussed below.

a. Solid Radwaste

Solid contaminated wastes are collected by researchers in plastic bags and/or steel waste drums and temporarily stored in their respective laboratories until the radiation safety office collects the waste for offsite (commercial) disposal. Individual laboratories are required to segregate their wastes into radioactive and non-radioactive waste containers and label the containers to alert personnel and prevent inadvertent disposal of radioactive waste into the normal "cold" trash. 10 CFR 20.203(f) requires that each container of licensed material bear a durable, clearly visible label identifying the radioactive contents, the radiation caution symbol and the words, "caution (or danger) radioactive material."

Contrary to this requirement, the licensee/consultant audit identified at least three research labs in which radioactive material was discarded into unlabeled waste containers. Similarly, xenon-133 contaminated waste was discovered during the licensee audit in an unlabeled "cold trash" waste can located in the imaging room of Highland Hospital. These examples appear contrary to the requirements delineated in 10 CFR 20.203(f). This apparent regulatory violation and the corrective actions taken by the licensee are described in section 3.A.7 and 3.A.8 of the NES Audit Report.

The licensee/consultant audit also identified an apparent violation of 10 CFR 20.401 requirements at Children's Hospital, for failure to maintain records of surveys to show that waste disposed in the normal "cold" trash had decayed to background levels. Another related violation is discussed in Section 19 (allegation 88-A-0174, Item 4).

b. Liquid Radwaste

10 CFR 20.303 permits licensees to dispose of licensed material in the sanitary sewerage system provided the material is readily soluble or dispersible in water and quantities discharged do not exceed specific regulatory limits and concentrations.

The licensee's referenced application requires each university researcher to maintain records of radioactive material concentrations disposed into the sewer system. Also, records of institutional (cumulative) totals are required to be maintained in the radiation safety office. Prior to 1989, the radiation safety office collected disposal information from individual researchers only on a periodic basis and, typically, when researchers depleted their inventory of a particular isotope and attempted to purchase additional material. This could extend up to approximately 1 year. Consequently, this procedure did not provide timely disposal information and the licensee was unable to determine the quantities disposed into the sewer system at any given time.

10 CFR 20.303(d) requires that the gross quantity of licensed and other radioactive material, excluding hydrogen-3 and carbon-14 released into the sewerage system by the licensee does not exceed one curie per year. The quantities released into the sanitary sewerage system may not exceed five curies per year for hydrogen-3 and one curie per year for carbon-14.

Contrary to this requirement, the licensee/consultant audit disclosed that the gross quantity of licensed material released into the sewer system in 1986 exceeded one curie. Specifically, licensee records showed that the university released 1.146 curies in 1986. This apparent violation of 10 CFR 20.303(d) and the licensee's corrective actions are described in Section 3.A.8 of the NES Audit Report.

c. Gaseous Radwaste (Incineration)

The inspectors reviewed selected aspects of the licensee's radioactive waste incineration program authorized pursuant to license condition No. 19. This review included training provided to the incinerator operator, radiological protection procedures employed by this operator, quantities and materials burned, licensee evaluations to show effluent concentrations were within regulatory limits and the licensee's ash disposal methods. The inspectors' review disclosed that the licensee's incineration program appears to comply with applicable regulatory requirements including the commitments contained in their referenced application dated August 13, 1984 and letter dated April 11, 1986. No significant problems were noted by the inspectors; however, it appears desirable for the licensee to verify that incinerator stack exhaust flow rates have not significantly changed since they were last measured in 1979.

One apparent violation of regulatory requirements was identified during the licensee/consultant audit related to incinerator operations. Specifically, contrary to License Condition 20 and the licensee's August 13, 1984 application, the audit disclosed an instance in 1989 when bagged waste delivered to the incinerator was not properly marked to identify its isotopic contents. This apparent violation and the licensee's corrective actions are described in section 3.A.8 of the NES Audit Report.

Four apparent violations were identified by the licensee/consultant.

15. Shipping and Transportation

The inspectors reviewed those aspects of the licensee's radioactive material shipping and transportation program related to a specific allegation and a researcher's question associated with this program area. The allegation is discussed in Section 19 (Allegation 89-A-0084, Item 18) and the researcher's question below.

In a letter submitted to Region III dated August 30, 1989, a biology department researcher questioned the university's policy regarding the distribution of licensed material from the radiation safety office to researchers located across campus. The researcher contended that it should not be a researcher's responsibility to pick up their material from the radiation safety office and transport it to their lab. The inspectors reviewed the licensee's distribution policy and, although not contrary to regulatory requirements, improvements appear desirable. This was conveyed to the licensee and they reviewed the matter and are considering a modification to their package distribution policy. These facts were subsequently conveyed to the researcher in a letter from the Region III office dated October 30, 1989. The licensee's material distribution and internal transfer and transportation policies will continue to be reviewed during future inspections.

No violations or significant concerns were identified by the inspectors.

16. Notifications and Reports

The inspectors reviewed those notification and reporting requirements delineated in 10 CFR 20 and applicable to the licensee in 1989 to date and a specific allegation related to this program area. The allegation is discussed in Section 19 (Allegation 89-A-0084, Item 22), other relevant inspector findings are discussed below.

On August 24, 1989, the licensee telephoned the NRC Region III office to report the contamination incident in Crosley Building laboratories No. 300 and 309. This notification was made pursuant to 10 CFR 20.403(b)(3). The licensee's initial written report of this event was submitted to Region III pursuant to 10 CFR 20.405, in a letter dated September 22, 1989 and their final report in a letter dated November 13, 1989. The reports disclosed that no researchers involved in the contamination incident or ancillary staff that may have frequented the subject labs received significant internal or external exposure. The licensee continues to provide the Region III office with program improvement status reports.

The licensee appears to have satisfactorily met the 10 CFR 20 reporting requirements for the Crosley Building contamination event. The licensee's compliance with the August 30, 1989 Confirmatory Action Letter was previously described in Inspection Report No. 030-02764/89001(DRSS). An apparent 10 CFR 20 violation for failure to report lost or unaccountable sources is described in Section 9(a).

No violations or significant concerns were identified by the inspectors.

17. Service Operations

Generally, broad scope licensees are allowed to perform instrument calibration, leak testing, waste disposal and other service operations to support their operations; however, conduct of such operations for other NRC licensees, as a service, requires specific NRC authorization. The University of Cincinnati has provided survey instrument calibration services for other NRC licensees for several years. In the last 2 years,

this service was routinely performed for approximately 25-30 licensees that are not an agency or political subdivision of the state and included medical and industrial facilities. These instrument calibration services were authorized in Amendment No. 55 to License No. 34-06903-05, dated May 1986, after the licensee submitted the appropriate licensing fee (fee category 3N) as required by 10 CFR 170.31. The instrument calibration service authorization granted in 1986 continues to date but does not include leak testing and waste disposal/pickup services, which require additional licensing action and fee payments.

The licensee/consultant audit disclosed that the university's radiation safety office routinely provided sealed source leak testing services for several NRC licensees since 1968 and occasional waste brokerage services for at least two other NRC licensees in 1987 and 1988. The above noted service activities were reportedly conducted by radiation safety office staff members, utilizing university resources, and under the auspices of the RSO on a for-profit basis.

In February 1989, the university applied to the Commission for leak test service authorization in addition to the previously approved instrument calibration services. This authorization was granted in Amendment No. 60, dated May 5, 1989. Leak testing services for other licensees was not authorized prior to Amendment No. 60. Waste brokerage services remain unauthorized to date.

Contrary to the above, the licensee/consultant audit disclosed that unauthorized service activities were conducted by the university for other NRC licensees. Specifically, contrary to License Condition 9, leak testing services were provided for at least seven other licensees prior to NRC authorization in May 1989 and waste brokerage/disposal services for two licensees in 1987 and 1988. The latter activities remain unauthorized to date. This apparent regulatory violation and licensee corrective actions are described in sections 3.A.1 and 3.A.16 of the NES Audit Report. On August 23, 1989, the RSC chairman suspended all service activities including those currently authorized by the NRC (i.e., leak testing and instrument calibration). The licensee is currently investigating these matters internally and has also reportedly contracted an outside firm to perform an independent investigation into this matter.

One apparent violation was identified by the licensee/consultant.

18. Procedures

The inspectors reviewed the licensee's radiation safety manual and discussed its implementation with the HPT staff and selected researchers, discussed radiation safety procedures generally, and reviewed an allegation related to this program area. The allegation is discussed in Section 19 (Allegation 89-A-0084, Item 7), other relevant inspector findings are discussed below.

The licensee's radiation safety manual was last revised in April 1987 and is issued to all researchers and other users of radioactive material.

According to the licensee, each user is required to read, understand, and adhere to the requirements/guidelines set forth in the manual. The manual, however, is not part of or incorporated by reference in the university's NRC license. The manual describes the RSC, radiation safety office, principal investigators and research protocols; and includes discussions of material procurement/receipt, storage and disposal requirements, radiation protection, decontamination and emergency procedures, and addresses certain human use applications. The inspectors identified no significant problems with the guidelines delineated in the manual. However, the numerous problems and apparent violations described throughout this report indicate that the manual has not been adequately implemented and its guidelines properly followed.

The licensee's application dated August 13, 1984, referenced in License Condition No. 20, includes an ALARA program that describes the management controls and program oversight to ensure ALARA concepts are practiced. In this ALARA program, licensee management committed to "develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization includes a RSC and a RSO." While the university has maintained its RSC and RSO, the licensee/consultant audit disclosed that no written ALARA policy or procedures were developed. Failure to develop the required policy and procedures appears contrary to License Condition No. 20 and constitutes a violation of regulatory requirements. This apparent violation and the licensee's corrective actions are described in section 3.A.2 of the NES Audit Report. The corrective actions consist of inaugurating a formal "Radiation Control and Safety Program" that includes written "RSC Operating Guidelines and Radiation Control and Safety Procedures." Thus far, the licensee has developed and began implementation of the RSC operating guidelines (Section 6(b)) and has drafted the radiation control and safety procedures. These procedures will supplement a new radiation safety training manual and supersede the old radiation safety manual. According to the licensee, individuals completing the new radiation safety training course will be required to certify that they have read and understood the radiation control/safety procedures.

One apparent violation was identified by the licensee/consultant.

19. Allegation Followup (Specific)

As discussed in Sections 2 and 4, NRC Region III received three sets of allegations from two different allegers concerning the conduct of NRC-licensed activities at the University of Cincinnati. Each allegation was evaluated during this inspection and consisted of interviews with licensee and contractor personnel and review of representative records, reports, and procedures. The specific allegations are dispositioned below. (Allegation numbers are assigned for internal tracking purposes).

Allegation (89-A-0084, Item 15): The alleger and other health physics technicians (HPTs) have informed the university ombudsman of their radiological concerns and nothing has been done to address them.

Discussion: Alleger and health physics technician interviews revealed that this allegation was incorrectly stated by the alleger. The inspectors learned that the HPTs intended to inform the University ombudsman of their radiological concerns but had not done so, to date. According to the alleger, HPTs were prohibited from contacting the ombudsman as a result of the "gag order." (The "gag order" concern is a separate allegation and is described later in this section.)

Finding: The allegation was not substantiated; the University ombudsman was not informed of radiological concerns by the HPTs. Other University officials, including the RSC chairman and university president, were informed of the HPT's concerns as previously discussed in Section 4. These concerns were also provided to the NRC and are addressed as separate allegations throughout this section.

Allegation (88-A-0084, Item 20): HPTs were prohibited by George Alexander (administrative director of the radiation safety office) from speaking at RSC meetings as a result of the "gag order." HPTs met with the RSC chairman in June 1989 and are currently allowed to address the committee but are not voting members.

The "gag order" concerns are separate allegations (88-A-0174, Item 1 and 89-A-0084, Item 2) and are described later in this section.

Discussion: In a series of memorandums issued in late December 1988 and early January 1989, the HPTs collectively presented the RSC with a list of radiological, administrative and management control concerns associated with the conduct of the NRC-licensed program and radiation safety office operations. Among these concerns was lack of HPT participation in quarterly RSC meetings. Although HPT attendance and direct participation in RSC meetings is not addressed in NRC regulations, the RSC decided to allow HPT attendance/participation in each meeting. This participation began in April 1989. However, shortly after this participation commenced, the administrative director of the radiation safety office (George Alexander) informed the HPTs that they could continue to attend the meetings but were not allowed to make comments or otherwise participate. Mr. Alexander contended that HPTs were not official RSC members, attended meetings only as observers, and therefore should not actively participate in the meetings. This matter was later clarified and certain of Mr. Alexander's statements were overruled in a June 12, 1989, memorandum from the RSC Chairman to the HPTs.

Currently, the HPTs are allowed to attend and participate in RSC meetings; however, HPTs remain non-voting members.

Finding: The allegation was substantiated. Although Mr. Alexander informed the HPTs that they were prohibited from speaking at RSC meetings, the issue is not related to regulatory requirements and was resolved internally by the licensee.

Inasmuch as there exist no regulatory requirements for technician involvement in RSC meetings and the issue has since been resolved by the licensee, no further NRC action is warranted at this time.

Allegation (89-A-0084, Item 3) The RSO never fully informed the RSC of all the HPTs' concerns.

Discussion: As discussed in Sections 2 and 4, in late 1988/early 1989, the HPTs presented to the RSC a list of concerns associated with the conduct of the NRC-licensed program and radiation safety office operations. According to the technicians, most of these concerns were previously conveyed to the RSO on more than one occasion and he either failed to act or took inadequate actions to resolve the apparent problems. (The inspectors were unable to discuss these issues with the RSO in question.) Consequently, the technicians presented their concerns directly to the RSC. According to the RSC chairman, the RSC was not cognizant of the HPT concerns until they were presented them by the technicians. Several of the technicians' concerns/allegations provided to the RSC are the same as those provided to the NRC and addressed throughout this report.

Finding: The allegation was substantiated in that several technician concerns reportedly expressed to the RSO were not relayed to the RSC. Inasmuch as there is no regulatory requirement related to this issue, this matter was not confirmed with the RSO and the licensee evaluated these concerns and is implementing remedial actions as necessary (Section 2), no further NRC action is required at this time.

As a result of the licensee's review of the HPT concerns and others subsequently brought to their attention and/or identified by their consultant during the audit of their program, numerous apparent violations and weaknesses were identified. These violations and weaknesses are discussed throughout this report.

Allegation (89-A-0084, Item 8) No quality assurance program exists at the university.

This concern was clarified in an interview with the alleger as applicable to 10 CFR Part 35 with respect to RSO review (and sign off) of brachytherapy source leak test, inventory and storage area survey results.

Discussion: 10 CFR 35.59(d), (g) and (i) require the RSO to review and sign off brachytherapy source leak test, inventory and storage area survey results. Inspector review of brachytherapy source leak test, inventory and storage area survey results for 1989 to date revealed that the RSO failed to sign off on these records; it is unknown if the results were reviewed by the RSO. This appears to constitute a violation of the regulatory requirements delineated in 10 CFR 35.59. This apparent violation was also identified by the licensee prior to this inspection.

Finding: The allegation was substantiated in that the RSO did not sign off on brachytherapy source leak test, inventory and storage area survey records for 1989 to date. However, this apparent violation was identified in the licensee/consultant audit prior to this inspection and adequate corrective actions have been implemented. This matter is discussed further in items 3.A.13 and 3.A.14 of the NES Audit Report.

Allegation (88-A-0174, Item 1): University HPTs were required to sign a memo stating that only management is allowed to talk with anyone about the university's radiation safety program.

Allegation (89-A-0084, Item 2): The RSO forced all radiation safety department employees to sign a memo instructing them not to inform individuals or outside agencies, other than the RSO and his assistant, of radiation safety concerns. The RSC supported this "gag order."

Discussion: These allegations pertain to a June 30, 1988 internal memorandum from the RSO and administrative director of the radiation safety office to radiation safety office personnel regarding "Problem Notification Process." An unsigned copy of this memorandum is provided as Attachment A. The memo states in part that "Under no circumstances should any employees state either policies or problems related to radiation safety to anyone within the University of Cincinnati or outside of the University of Cincinnati unless told to do so by one of the above mentioned supervisors. In the event that there is a discrepancy related to this policy by an employee, disciplinary action will be taken."

Another memo was signed by all HPTs, the deputy RSO, and safety office secretary on June 30, 1988, attesting that they read, comprehend and will comply with the June 30, 1988 "Problem Notification Process." Those that signed the memo, stated to the inspectors that they did not refuse and were not forced or coerced to sign the memo nor did any of them question its intent or seek clarification. HPTs informed the inspectors that they interpreted the memorandum to mean that they were prohibited from discussing or forwarding radiological concerns to individuals or agencies (including the NRC), other than the RSO. HPTs indicated that the memo was issued to dissuade them from contacting the NRC and thereby avoid the situation that existed at the University several years earlier when an HPT repeatedly contacted the NRC with radiological concerns.

Mr. Alexander, one of the authors of the memo, was interviewed and informed the inspectors that the intent of the memo was simply to describe the lines of communication within the radiation safety office. According to Mr. Alexander, the memo was not issued to deter employees from contacting the NRC or other agencies and indicated that prohibiting employees from contacting the NRC is a violation of regulations as specified on Form NRC-3. The other author of the memo, the RSO, was unavailable for comment.

This "gag order" concern was one of the issues brought to the RSC's attention by the HPTs in late 1988/early 1989. According to the RSC chairman, the committee was unaware of the "gag order" memo until it was provided to them by the technicians. The RSC did not endorse the

memo as written and issued an interim position/statement in a memo to the HPTs dated March 20, 1989. The interim statement instructed the radiation safety office personnel on the lines of communication indicating that concerns should be expressed in writing to the RSO and, if not resolved, to the Administrative Director (Mr. Alexander) who will notify the RSC. The interim statement, however, was silent with respect to contacting outside agencies or the NRC. Subsequently, on July 31, 1989, a revised "Problem Notification Process" memo was issued by the RSC chairman stating the RSC sanctioned notification process. This later memo is provided as Attachment B and expresses a position very similar to the interim statement issued by the RSC on March 20, 1989. According to the RSC chairman, the purpose of the revised "problem notification process" was to encourage technicians to present their concerns to management so they could be resolved internally. The RSC chairman further stated that personnel are not discouraged from contacting outside agencies and can do so without repercussion or fear of reprisal.

Finding: Portions of the allegation were substantiated in that radiation safety office personnel were required to sign a memo instructing them not to "state either policies or problems related to radiation safety to anyone within the University of Cincinnati or outside of the university unless told to do so by" the RSO or administrative director. The HPTs interpreted the memo to mean that they were prohibited from contacting the NRC about university radiological problems; however, they indicated that this memo did not deter them from eventually contacting the NRC.

The technicians were not forced to sign the memo nor did the RSC support a 'gag order." The intent of the memo was clarified to the inspectors by one of its authors and a revised "problem notification process" procedure was issued by the RSC. The revised procedure continues to be silent with respect to contacting outside agencies.

Although the memo possibly may have deterred radiation safety office staff from contacting the NRC initially, it did not continue to deter them in view of the contacts made to the NRC in 1988 and 1989.

Allegation (88-A-0174, Item 9): HPTs will not volunteer information concerning the university's radiation safety program in fear of reprisal.

Discussion: Although this allegation is not directly attributed to the HPTs and was provided to the NRC by an unidentified individual, the matter was discussed with them. This concern appears to stem from the previously discussed "gag order" memo which, according to the HPTs, implied that disciplinary action would be taken if personnel discussed information regarding the university radiation protection program with individuals other than the RSO. Similarly, and as discussed below in Allegation No. (89-A-0084,Item 17), the HPTs stated that just prior to a previous NRC inspection, the RSO instructed the technicians to not offer any information to the NRC inspector and only answer those questions posed.

Some of the HPTs stated they formerly were hesitant to contact the NRC about their radiological concerns and/or volunteer information during an NRC inspection because of possible disciplinary actions that might be taken. The technicians indicated that an HPT was fired several years ago partially because he contacted the NRC. This alleged firing was previously reviewed by the U.S. Department of Labor in 1983 and is documented in DOL Case No. 83-ERA07. However, all the HPTs stated that they currently have no reservation with supplying information to, or contacting the NRC.

Finding: Some of the HPTs indicated they were hesitant in the past to contact the NRC or volunteer information and others were not. Nevertheless, none of the HPTs are currently hesitant about voluntarily supplying information. No chilling effects appear to exist at this time; consequently, no further NRC action appears warranted.

Allegation (89-A-0084, Item 5): The alleger has been harassed by the RSO since the restroom contamination concerns (Allegation 89-A-0084, Item 1 (Section 13)) were identified. As an example, the alleger is assigned only menial tasks and is not allowed time to read periodicals or use the office computer.

Discussion: Beginning in about March 1989, HPT tasks were assigned using a monthly assignment sheet generated by the Deputy RSO. Prior to this, tasks were verbally assigned by the RSO/deputy RSO as the need arose. According to the alleger, his tasks for the last few years have been limited primarily to laboratory surveys and occasionally sealed source leak tests. The alleger indicated that he was prohibited by the RSO and administrative director of the radiation safety office from performing many of the tasks that the other HPTs were routinely assigned and rotated through. The alleger stated that the RSO and administrative director informed him that it was a management prerogative to assign whatever tasks they deemed appropriate.

Inspector review of written task assignments for April through August 1989 revealed that the alleger was assigned only laboratory survey or leak testing tasks, whereas other HPTs appeared to rotate through these and various other additional tasks. According to the deputy RSO, although the alleger was not assigned dosimetry tasks which require computer use, the alleger's tasks were not intentionally limited. The alleger's claim that he was not allowed time to read periodicals was not supported by the HPTs or the deputy RSO.

The administrative director of the radiation safety office stated he was not involved in assigning HPT work and had no information to offer on this matter. The individual denied that he prohibited the alleger from performing certain tasks as alleged.

Finding: Although the alleger's tasks appear to have been limited to lab surveys and occasional source leak tests and have not included office

computer (dosimetry) work, the allegation does not appear substantiated. The alleger's assignments do not appear to be menial tasks and are also given to other HPTs. The alleger's examples cannot be correlated to harassment.

Allegation (89-A-0084, Item 16): University telephones were tapped in January or February 1989 and a computerized listing of telephone numbers dialed from university extensions was developed to enable them (radiation safety office management) to determine if a call was placed to the NRC.

Discussion: According to the alleger, in about January 1989, the NRC Region III office contacted the RSO regarding radiological concerns at the university, that were conveyed to the NRC by an anonymous individual. Shortly thereafter, the RSO questioned the HPTs regarding the anonymous call to the NRC and subsequently obtained a computerized listing of calls made from radiation safety office telephones.

Some of the HPTs interviewed recalled that back in late 1988/early 1989, the RSO questioned them regarding an anonymous call reportedly made to the NRC from the university. As described in Section 2, an unidentified individual did contact the NRC on December 1, 1988 and again on January 25, 1989, to express concerns regarding activities at the university. There is, however, no record of the NRC contacting the RSO about this matter.

The RSO was unavailable for comment and the matter was not pursued further due to lack of potential for violation of regulatory requirements. The alleger was informed that any organization or individual can obtain a listing of outgoing telephone calls from the telephone company, without tapping phone lines, and that many businesses do this routinely for budget audit and trending purposes.

Finding: The veracity of the allegation was not determined due to lack of potential for violation of regulatory requirements.

Allegation (89-A-0084, Item 17): The RSO implied to the alleger that he "should be absent" during an NRC inspection in May 1989 and instructed all HPTs to be "on their best behavior during the inspection."

Discussion: According to some of the HPTs, the alleged comments attributed to the RSO were made prior to a previous (1988 or 1986) NRC inspection and the HPTs were also instructed at that time to "not offer any information to the NRC inspector and only answer those questions posed." The inspectors were informed that such comments exemplified the RSO's tactics to intimidate his staff and discourage them from discussing their concerns with NRC inspectors. (An NRC inspection was not conducted in or around May 1989.) The RSO was unavailable for comment.

Finding: While the specific May 1989 inspection date is in error, based on HPT interviews, the general allegation appears to be substantiated. This issue is an example of the apparent poor technician-management

relationship that existed within the radiation safety office (Section 6(c)). This matter was not pursued further due to unavailability of the RSO and is subject to further NRC review in future inspections.

Summary of Those Allegations Discussed Above

Ten allegations are discussed above that relate to management controls and style, and certain radiation safety office operations; six were substantiated in whole or in part and resulted in one apparent violation of regulatory requirements. The other four allegations were either not substantiated or not determined due to lack of potential for regulatory violation or significant concern.

Allegation (89-A-0084, Item 10) The HPT's struggle with management to enforce safety.

Discussion: The alleger and other HPTs were interviewed and indicated this concern pertains to the lack of enforcement or sanctions levied against researchers that repeatedly violate radiation safety requirements.

According to the radiation safety office technical staff (excluding the RSO), the licensee has never developed a formal enforcement policy, procedures, or written guidance as a means to promote and protect radiological health and safety, deter problem researchers from continuing to violate regulatory requirements and operate contrary to good health physics practices. The inspectors were informed by the HPTs that enforcement actions against researchers are infrequent, inconsistent, and levied at the sole discretion of the RSO. The licensee's consultant concurred with the HPTs assessment.

Finding: Based on interviews with the radiation safety office technical staff and confirmed by the licensee's consultant, the allegation appears substantiated. The licensee has not developed a formal enforcement policy. Although not a regulatory requirement, an enforcement policy is desirable to ensure compliance, obtain corrective actions and deter violations and adverse health physics practices.

The licensee agreed that an enforcement policy is necessary and is currently working with their consultant to develop one. The university administration formed a task force which is actively developing and implementing a formal "Radiation Control and Safety Program."

Allegation (88-A-0174, Item 2): The university's assistant radiation safety officer is not qualified and did not follow up on safety problems.

This concern was brought to the NRC's attention by an anonymous individual and refers to the Deputy RSO, Mr. Prince Jason. The NRC was informed in a January 25, 1989 telecon with one of the allegers that Mr. Jason was not qualified to be assistant RSO because his degree is in english and not nuclear physics. The alleger did not

provide examples regarding the concern that Mr. Jason did not follow up on problems.

Discussion: Mr. Prince Jason possesses a B.A. degree in English, about 2 years radiation/chemistry experience at a non-operating nuclear power plant and about 5 years experience as a university HPT. Mr. Jason was promoted to university deputy RSO in May 1989. Generic deputy RSO qualification requirements (without naming a specific individual) are delineated in one of the licensee's referenced letters dated July 2, 1986, and states that a deputy RSO who has a total of 4 years training and experience in a health physics program will be appointed as acting RSO during temporary absences of the RSO. Mr. Jason satisfies these general requirements. No other regulatory requirements exist for the deputy RSO position. Mr. Jason's qualifications were not submitted for NRC review, nor is he specifically named and/or approved on the university license as the deputy RSO. His promotion to deputy RSO was an internal university appointment, not approved by the NRC. The license, however, was amended on August 24, 1989 (Amendment No. 61) to specifically name Edward Silberstein, M.D. as the Assistant Radiation Protection Officer. Dr. Silberstein's qualifications/experience were submitted to the NRC for review and he was approved and designated in the NRC license as the Assistant Radiation Protection Officer. Dr. Silberstein's involvement in specific radiation safety office operations has been limited to date.

The concern that Mr. Jason does not follow up on safety problems was discussed with the HPT staff and they generally agreed with the alleger and provided two examples to the inspectors to support this concern. However, inspector review of these two examples revealed no significant indication that Mr. Jason did not follow up on safety problems. Specifically, for the two examples provided, Mr. Jason stated that he evaluated the issues at least in part, conveyed his preliminary findings to the RSO and was instructed that additional followup was not necessary. According to Mr. Jason, safety issues brought to his attention are evaluated and his findings are presented to the RSO; however, it is not uncommon for the RSO to terminate further evaluation or follow-up.

Finding: Neither part of the allegation was substantiated. The general qualifications for the deputy RSO position, as outlined in one of the licensee's referenced letters, are satisfied for Mr. Jason. No other regulatory requirements exist for the deputy RSO position as is currently designated in the University license. There is no significant indication that Mr. Jason did not follow up on safety problems.

Allegation (88-A-0174, Item 8): Training provided to individuals working with radioactive materials is very poor; also, timeliness of training is not good. The alleger, an unidentified University researcher, stated that he worked 4 or 5 months with radioactive material before being trained and that the training class was useless.

Discussion: The radiation safety office provides formal radiation safety training to research lab workers on a semiannual basis. Therefore an individual could work with radioactive materials for up to 6 months prior to receiving the licensee's training. While awaiting the licensee's training course, lab personnel working with licensed material are required by the licensee's referenced application to receive training from the lab's principal investigator(s). The principal investigators, however, are not provided formal guidelines concerning the scope and extent of this training and it is essentially left to the discretion of the principal investigator. Referenced letter dated April 11, 1986 requires lab workers without previous radiation safety training to complete the university radiation safety course. Those that have received training at another university or institution are not required to complete the licensee's training. However, the consultant audit disclosed that, in many cases, previous radiation worker training reportedly obtained at another institution was not verified by the licensee.

The licensee's radiation safety training course was presented by the (previous) RSO and extended over five 2-hour sessions. Attendance was required at a minimum of three of the five sessions. Discussions with the HPT staff and selected lab workers disclosed that the licensee's training primarily encompassed nuclear physics and survey/measuring instrument theory and only minimal coverage of practical (hands-on) health physics applications. Consequently, the training may not have provided the student with the practical health physics knowledge and material handling techniques necessary to safely conduct daily research activities.

Finding: The allegation was substantiated in that lab workers could work with radioactive material for up to about 6 months prior to completing the licensee's training. The quality of the training is somewhat subjective and was not determined. According to the majority of those interviewed, the licensee's training concentrated on nuclear physics theory rather than practical applications more beneficial to lab workers. An apparent violation related to this subject matter is discussed in Section 8(b).

Allegation (89-A-0084, Item 21): The alleger and HPTs do not get to attend training seminars and conferences in violation of Regulatory Guide 8.29 and university personnel guides No. 2-32-02 and No. 2-31-04.

Discussion: Regulatory guides are issued to assist licensees in the development and operation of their radioactive protection program and their implementation is normally not a regulatory requirement. Should a licensee, however, incorporate a particular guide in their NRC license, the licensee is required to follow the recommendations in the guide. Regulatory Guide 8.29 "Instruction Concerning Risks from Occupational Radiation Exposure" is not referenced in the licensee's current NRC license and, therefore, the university is not bound to follow its guidelines. In addition, this guide does not specifically address attendance at training seminars and conferences but rather describes the

instructions that should be provided to workers concerning biological risks from occupational radiation exposure.

University Personnel Guide No. 2-32-02 cited by the alleger, could not be located by the licensee and reportedly does not exist. However, the following University of Cincinnati "Personnel Policies and Procedures Manual" guides related to the subject allegation were reviewed by the inspectors:

- Guide No. 2-31-04
  Subject: Release Time Off with Pay to Attend Professionally-Related Meetings or Events

- Guide No. 2-33-01
  Subject: Employee Development

- Guide Nos. 2-33-02 and 3-33-02
  Subject: In-House Training Programs

The above guides were reviewed by the inspectors and do not require that university employees attend seminars or conferences; rather, the guides encourage employees to take advantage of educational opportunities including remission of fees for university-level courses, in-service training programs and sponsored seminars. Guides No. 2-33-02 and No. 3-33-02 encourage supervisors to approve employee requests to attend in-house training programs after considering the needs of the workplace and the employee.

Finding: The allegation was not substantiated. The regulatory and university personnel guides cited by the alleger do not require HPT attendance at seminars or conferences.

Allegation (89-A-0084, Item 9): The custodial staff is not instructed in the proper procedures for decontaminating restrooms. This is compounded by the high turnover rate of this staff.

Discussion: This allegation refers to restrooms used by patients undergoing diagnostic nuclear medicine studies at university hospitals. These patients normally receive small quantities of short-lived radiopharmaceuticals (technetium-99m and iodine-125/131) for various diagnostic purposes and subsequently may use the restroom. As a result, the toilet may become contaminated with low levels of these radioisotopes. This contamination, however, does not constitute a significant radiological hazard in view of the small quantity and short half-life.

In early 1989, the custodial staff was instructed through the radiation safety office to clean these restrooms in the early morning prior to patient arrival. This allows much of the short-lived contamination from the previous day's patients to decay to negligible levels. The custodial staff does not "decontaminate" these restrooms; rather, the staff cleans these areas employing standard mopping/washing techniques. Rubber gloves are typically worn during the cleaning process.

Finding: The allegation is not substantiated in that the custodial staff does not "decontaminate" restrooms. The extremely low levels of contamination that may be present in the toilet do not warrant decontamination since it decays to insignificant levels within a short period of time. Although the custodial staff is not instructed in decontamination procedures, this staff does not perform decontamination. The turnover rate of the custodial staff is irrelevant to this concern.

Allegation (89-A-0084, Item 11): Annual inventories are crude; no accurate listing of who has what is maintained.

Discussion: This allegation refers to the inventory and accountability system utilized by the radiation safety office to account for institutional (cumulative) quantities of licensed material possessed by the licensee. This concern is discussed in Section 9(a)

Finding: The allegation was substantiated in that the inventory system previously implemented by the licensee was antiquated, maintained primarily by hand in hard data form and was generally ineffective. The previous system did not yield accurate cumulative inventory information nor the amount possessed by an individual researcher at any given time. The licensee/consultant audit identified three apparent violations of regulatory requirements related to inventory and material accountability. These apparent violations are described in Section 9(a). The corrective actions taken and planned by the licensee to strengthen this significant program weakness appear adequate. Implementation of the licensee's revamped inventory and accountability system will continue to be reviewed during future NRC inspections.

Allegation (88-A-0174, Item 7): The licensee may possess sources that are not authorized on the NRC license.

Discussion: This allegation was provided to the NRC by an unidentified university researcher. The only example of this concern specified by the alleger was a 2.5 microgram plutonium source located in the Engineering Building. HPT interviews did not disclose any additional information regarding the alleger's concern.

The university possesses several NRC licenses. License No. SNM-490 authorizes (1) plutonium-239 encapsulated (as Pu-Be) neutron sources (one source each of 16 grams, 32 grams, 48 grams, and 64 grams) to be used for laboratory experiments and student instruction and for use as neutron sources for a subcritical assembly; and (2) any byproduct material (activation products) incident to the performance of irradiation experiments utilizing the Pu-Be source(s). These sources are used and stored at the university's Old Chemistry Building (i.e., location of Nuclear Engineering Department).

In addition, 10 CFR 70.19 authorizes possession/use of plutonium in the form of calibration or reference sources pursuant to a "general license," provided not more than 5 microcuries of plutonium is

possessed at any one time or location. NRC calculations show that 2.5 micrograms of plutonium-239 (the most commonly used and available isotope of plutonium) constitutes less than 5 microcuries. Although the NRC inspection did not verify that the University had a 2.5 microgram source, the licensee could possess it under the general license.

Finding: The allegation is not substantiated; 2.5 micrograms of plutonium is authorized to be possessed by the licensee under the general license provisions of 10 CFR 70.19. No other examples of this concern were provided by the alleger or those interviewed during this inspection.

Allegation (88-A-0174, Item 5): Survey meters are not properly calibrated, employing a radium needle which is not NBS traceable.

Discussion: The licensee's survey meter calibration methods and procedures are described in Section 10(a).

Finding: The allegation was substantiated in that survey meters were not calibrated using NBS traceable sources; one licensee-identified violation was noted as described in Section 10(a). Adequate corrective actions were taken to address the problem.

Allegation (89-A-0084, Item 14): The university's whole body counter is inaccurate and because of this, the counter is no longer used by the DOE facility in Fernald, Ohio. The thyroid counter is probably just as inaccurate.

Discussion: The licensee's nuclear medicine department at University Hospital maintains a whole body counter used for bioassay of university employees and as a service to other institutions/agencies. The counter is approximately a 25-year old fixed geometry system, consisting of a single 8-inch by 4-inch sodium iodide crystal. According to the licensee, the counter is used to identify the presence of isotopes that range in energy from 88 to 1460 KEV; the counter reportedly is not used for quantification. There are no applicable regulatory requirements that relate to counter operation or accuracy; a whole body counter is not addressed in the university license.

The alleger could provide no specific information regarding the "inaccuracy" concern with the whole body counter or thyroid monitor; however, one of the HPTs indicated that whole body count results do not specify confidence levels normally included in such results. The HPT presumed that the alleger may have construed this as an inaccuracy. The thyroid counter concern was not evaluated further, since the alleger was unable to provide specific examples.

According to the licensee, the DOE facility in Fernald, Ohio discontinued use of the university counter because they installed their own whole body counting system a couple of years ago.

Finding: The allegation was not substantiated in that the DOE facility did not discontinue use of the whole body counting device due to its inaccuracy. The accuracy of the whole body counter was not of concern since the licensee reportedly does not quantify the results. Whole body

count results have not been used to demonstrate compliance with NRC requirements.

Allegation (89-A-0084, Item 13): HPTs are not issued "protective masks" that are needed to work in Dr. Jha's area and to function as members of the Cincinnati area radiological emergency response team. Also, masks are necessary when working with iodine-131 patients.

Discussion: This allegation refers to respiratory protection equipment that the alleger contends is needed when decontaminating certain research laboratories, performing direct surveys of iodine-131 radiotherapeutic patient rooms and decontaminating their rooms after patient discharge. The alleger also contends that the equipment should be available because university hospitals are responsible for treating radioactively contaminated patients and the HPTs may be involved in these emergency response actions.

Respiratory protection equipment usage is not addressed in the university's NRC licenses. 10 CFR 20.103(b)-(d) address respiratory protection equipment usage but do not require that such equipment be utilized if other control measures can be employed to limit airborne activity. Basically, 10 CFR 20 states that licensees shall as a precautionary procedure, use process or other engineering controls, to the extent practical, to limit airborne radioactivity. When it is impractical to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in 10 CFR 20.203(d)(1)(ii), other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material below regulatory limits.

According to the alleger, the licensee performs bioassays (thyroid monitoring or whole body counting) on workers after they decontaminate labs or patient rooms and no significant internal depositions or uptakes have been identified. Should the licensee identify a significant uptake, further bioassay evaluations would be conducted.

Finding: The allegation is substantiated in that HPTs have not been issued respiratory protection equipment; however, this equipment does not appear to be necessary for the licensee's routine program and is not required by NRC regulation. Nevertheless, the licensee recently purchased 16 MSA full facepiece air-purifying respirators for emergency use and has pulmonary and fit tested one HPT thus far. Inasmuch as no regulatory requirements were violated and the licensee appears to have satisfied the alleger's concern, no additional NRC action is warranted.

Allegation (89-A-0084, Item 1): Public restrooms adjacent to nuclear medicine departments at Holmes and University Hospitals are contaminated by patients following treatment. The general public use the restrooms and are unnecessarily exposed to radiation. This problem was brought to the RSO's attention and nothing was done to correct the situation.

Discussion: Patients receive small quantities of short-lived radiopharmaceuticals for diagnostic purposes and may use the public

restrooms referenced in the subject allegation. As a result, isolated areas of the restrooms could become contaminated with low levels of short-lived contamination. This contamination does not pose a significant health or safety problem and decays to negligible levels in a short time. Contamination levels measured by the inspectors in the subject restrooms during this inspection were not significant. Low levels of contamination were measured in and around the toilet bowl only.

The alleger forwarded his concern to the RSO and the restroom doors were subsequently posted "For Nuclear Medicine Patient Use Only." This posting should prevent employees and visitors from using the facilities.

10 CFR 20.303(d) states that excreta from individuals undergoing medical diagnosis or therapy with radioactive material are exempt from waste disposal and other limitations in Part 20.

Finding: The allegation was substantiated in that the subject restrooms may become contaminated by patients following treatment and that the general public use the restrooms. However, the contamination does not pose a health or safety concern and the licensee took action to limit restroom use by individuals other than patients. In addition, the restrooms are cleaned on a daily basis. Since patient excreta is exempt from regulatory requirements and the licensee acted responsively to resolve the concern, no further licensee or NRC action appears warranted.

Allegation (89-A-0084, Item 12): Dr. Jha's area in the physics department has a history of contamination problems resulting from cobalt-57 dust.

Discussion: Dr. Jha reportedly conducts research activities utilizing up to millicurie quantities of cobalt-57 (a state regulated material) to produce plate or foil sources used for Mossbauer effect experiments. The HPTs informed the inspectors that Dr. Jha's contamination control practices are weak and contamination has been identified on floor and counter surfaces within his labs on several occasions in the past. As a result, Dr. Jha's operations were temporarily shutdown by the radiation safety office in early 1988, until the lab(s) were decontaminated and contamination control practices improved. In mid-1989, repeat problems resulted in Dr. Jha's operations being permanently suspended.

Finding: The allegation is substantiated and the licensee took adequate action to correct the problem. It should be noted that use of cobalt-57 is regulated by the State of Ohio and not the NRC.

Allegation (88-A-0174, No Item Number): The licensee recently (about November 27, 1988) reported an inadvertent disposal of approximately 500 microcuries of phosphorus-32 to the ordinary trash. The RSO, assistant RSO or someone in management recorded 15 microcuries in their report generated for this incident.

Discussion: On November 22, 1988, a university researcher discovered that miscellaneous solid waste (paper, gloves, pipette tips) contaminated with phosphorus-32 and located in a research lab within a plexiglass waste container was mistakenly discarded into the normal "cold" trash. The plexiglass waste container was not labeled to indicate the presence of

radioactive material and the waste (contained within a plastic bag) reportedly was discarded by the housekeeping staff assuming it was normal trash. The researcher reported the matter to the RSO on November 23, 1988 and the RSO informed (telecon) the NRC that about 500 microcuries was discarded. This activity (500 microcuries) was the quantity initially reported by the researcher to the RSO. After the NRC was contacted, the researcher informed the RSO that the quantity they initially reported to him was incorrect and the correct quantity was 15 microcuries and not 500 microcuries. These facts were documented in a memo from the researcher to the RSO dated November 29, 1988. A written incident report was submitted to the NRC on December 5, 1988 and indicated the correct amount (15 microcuries) discarded.

Adequate corrective actions were taken by the licensee to prevent recurrence of similar incidents. Licensee records reflect the correct quantity discarded and the event appears to have been properly handled by the licensee.

Finding: The allegation was substantiated in that phosphorus-32 was inadvertently disposed in the normal trash. The amount initially reported was 500 microcuries but subsequently changed to reflect the correct amount. As discussed above, the incident was properly handled and related licensee records are accurate.

Allegation (88-A-0174, Item 4): The licensee is improperly disposing of small quantities of iodine-125.

Discussion: Although this allegation was submitted to the NRC by an unidentified researcher, the matter was discussed with the HPT staff. The inspectors learned that one of the licensee's clinical lab researchers routinely (about once/week) disposed of miscellaneous solid waste contaminated with small quantities of iodine-125 into the normal "cold" trash. The clinical lab researcher informed the inspectors that it was his understanding that up to 0.2 microcuries could be disposed into the normal trash without regard to radioactivity. The researcher acknowledged that he apparently misinterpreted information previously conveyed to him by the RSO, who reportedly explained proper disposal methods to the researcher.

Finding: The allegation is substantiated, a researcher was disposing of up to 0.2 microcuries of iodine-125 contaminated waste into the normal "cold" trash. This unauthorized disposal method appears contrary to 10 CFR 20.301 and was also identified by the licensee and consultant. Actions to strengthen this program area are described in Section 14.

Allegation (89-A-0084, Item 4): The university reached its limit for drum disposal and the RSO informed researchers that all liquid radwaste could be poured into the sinks. The licensee had not evaluated this disposal method to ensure compliance with NRC regulations. Many compounds cannot be poured into the sewer because of EPA regulations. Additionally, an inventory program or record of sink disposal did not exist until the alleger initiated a program to do so.

Discussion: During alleger and HPT interviews, concerns were expressed that the radiation safety office does not verify (by sampling) the concentrations released into the sewer system and they rely solely on the records provided by the researchers. Concerns were also expressed that the licensee (the RSO) had not evaluated this disposal method to assure that dilution flow was adequate and solubility/dispersibility requirements were met.

In early 1989 and again in mid-1989, a memorandum was issued by the RSO to all researchers regarding sewer disposal and use of water soluble scintillation cocktails. The memo indicated that drum disposal of toluene and xylene based scintillation cocktails was becoming more expensive and recommended that biodegradable, water soluble cocktails be used whenever possible. Biodegradable soluble cocktails could be disposed into the sewer system instead of collecting cocktails and packaging them into waste drums, thereby eliminating costly drum shipment and burial fees. The alleger apparently misinterpreted this memo to indicate that any and all liquid radwaste, regardless of solubility and concentration, could be released into the sewer system. As described earlier in this section, the licensee had evaluated sewer disposals pursuant to 10 CFR 20 requirements; however, the evaluation method used by the licensee was unable to yield current disposal information at any given time. It does not appear that 10 CFR 20.303(b) daily and monthly disposal limits would be exceeded by the licensee because their radiation safety manual included a table of (10 CFR 20, Appendix B) isotopic concentration limits for sewer disposal (without considering dilution) and researchers were instructed to not exceed the limits in the table. Additionally, the dilution provided by university water usage is significant and would further reduce isotopic concentrations disposed in laboratory sinks. The inspectors did not pursue when or who developed the licensee's sink disposal evaluation and recording methods due to lack of potential for violation of regulatory requirements.

Finding: The allegation is not substantiated. The licensee does not have drum disposal limits but attempts to reduce drum disposal to save costs. Although it appears desirable for the licensee to improve their sewer disposal evaluation methods, no NRC regulatory violations were identified with their surveys/evaluations. One violation, however, was identified by the licensee for exceeding annual (1986) sewer disposal limits. This apparent violation is discussed in Section 14(b).

The alleger's EPA concern will be forwarded to the appropriate regulatory agency.

Allegation (89-A-0084, Item 18): The university improperly transports up to several millicuries of "technetium-99m, iodine-131, gallium and thallium" to their Hillsboro, Ohio clinic without surveying or placarding the transport vehicle.

Discussion: Highland District Hospital, Hillsboro, Ohio, an authorized location of use under the university's broad scope license, employs nuclear medicine technologists to transport diagnostic quantities of radiopharmaceuticals from university campus hospitals to Highland Hospital for nuclear medicine patient applications. The technologists transport

radiopharmaceutical packages which are labeled as Radioactive White I or Yellow II as determined by surveys performed pursuant to 49 CFR 172.403. Vehicles transporting radioactive material packages labeled as other than Radioactive Yellow III are not required to be placarded pursuant to 49 CFR 172.504. Vehicles transporting radioactive material packages whose radiation levels exceed the limits specified in 49 CFR 173.441 are required to conduct vehicle surveys; otherwise, vehicle surveys are not required. The radiation levels measured by the licensee on the radiopharmaceutical packages transported to Highland Hospital do not approach 49 CFR 173.441 limits. In addition, 10 CFR 71.9 exempts physicians licensed pursuant to 10 CFR 35 with respect to transport of licensed material for use in the practice of medicine.

Finding: The allegation was not substantiated. The university's transportation of radiopharmaceuticals to Highland District Hospital was reviewed and found to comply with applicable regulatory requirements delineated in 10 CFR 71 and 49 CFR 172 and 173. The university's nuclear medicine program at Highland District Hospital was discontinued in September 1989 for reasons unrelated to this matter.

Allegation (89-A-0084, Item 22): The NRC was not informed of lost sources in accordance with 10 CFR 20.402 and 20.403.

Discussion: According to the alleger, at least one sealed source was discovered missing by the licensee when its leak test or physical inventory was due in about September 1988. The missing source is a 10 millicurie nickel-63 gas chromatograph foil. The HPTs added that two or three other nickel-63 foil sources have been missing for the last year or two and were also not reported to the Commission. The inspectors were informed by the HPTs and deputy RSO that the RSO was aware of these "missing" sources but did not report the matter to the NRC. The RSO was unavailable for comment.

Review of NRC files did not identify any written reports concerning the subject nickel-63 sources, submitted within the last 2 years. As described in Section 9(a), the licensee/consultant audit disclosed that ten NRC-licensed sources remain lost, missing or otherwise unaccounted for and the losses were not reported to the Commission. These missing sources include three, 10-15 millicurie, nickel-63 foils.

Finding: Based on HPT and deputy RSO statements and licensee/consultant audit findings, the allegation appears substantiated. One apparent violation with multiple examples was identified. This violation and licensee corrective actions are described in Section 9 of this report and Section 3.A.13 of the NES Audit Report.

Allegation (88-A-0174, Item 3): The RSO provides instrument calibration and leak test services for other licensees and the individual does not possess a service license.

Allegation (89-A-0084, Item 19): University employees, including the RSO, are using university facilities and equipment for commercial activities not associated with the university.

Discussion: These allegations were among the list of concerns brought to the RSC's attention by the HPTs in late 1988/early 1989. Prior to this, the RSC was apparently unaware that service operations for other licensees required specific NRC authorization. As described in Section 17, instrument calibration services were granted in 1986 and leak test service authorization requested in February and granted in May 1989. Waste brokerage/disposal service authorization has never been sought by the licensee and remain unauthorized to date.

Finding: The allegation(s) is substantiated in that the university provided unauthorized leak test and waste brokerage services to other licensees, utilizing University facilities/equipment and personnel, prior to NRC authorization/license approval. This apparent violation and licensee corrective actions are described in Section 17. The licensee obtained a license amendment authorizing leak test services in May 1989; however, the RSC suspended all services operations in August 1989. An individual service license is not required unless university administration objects to the conduct of such activities under the university license.

Allegation (89-A-0084, Item 7): No radiation safety program exists under the current RSO (Ken Fritz).

Discussion: This concern was clarified by the alleger to pertain to a lack of standard operating procedures (SOPs) for radiation safety office operations. According to the alleger and other HPTs, the radiation safety office operates without SOPs or other written guidelines governing the performance of routine tasks. HPT interviews revealed that various tasks routinely performed by the radiation safety office staff (i.e., instrument calibrations, lab surveys, air sampling, etc.) may be conducted differently by each technician.

Finding: The allegation is substantiated in that no SOPs exist for routine radiation safety office operations. Although not required by regulatory requirements, SOPs or their equivalent are necessary to ensure uniformity of task completion and application of acceptance criteria. Failure to develop SOPs appears to be a weakness. This matter was discussed with the licensee and their consultant during the inspection, and they indicated that SOPs for radiation safety office operations were under development. These procedures and their implementation will be reviewed during a future NRC inspection.

Allegation Summary

Thirty allegations were reviewed during this inspection; nineteen were substantiated in whole or in part and resulted in nine apparent violations of regulatory requirements. The remaining allegations were either not substantiated or their veracity not determined due to lack of potential for regulatory concern. The apparent violations are discussed throughout this report, as outlined in Attachments I and II.

20. NRC/Licensee Meetings

The inspectors met with licensee representatives (denoted in Section 1) at the conclusion of the site inspection on October 6, 1989 and further discussed inspection findings and information contained in the NES Audit Report in telecons with licensee representatives between November 29 and January 5, 1990. During the October 6, 1989 meeting, the inspectors summarized the scope and general findings of the inspection and discussed the likely informational content of the inspection report with regard to documents and processes reviewed during the inspection. Specific inspection findings were not discussed with the licensee at that time. The licensee did not identify any documents or processes as proprietary.

A licensee/NRC management meeting was held in the NRC Region III office on November 1, 1989. The purpose of this meeting was to discuss the licensee's progress in identifying/correcting problems associated with their licensed program and NRC concerns related to the conduct of licensed activities. In general, the NRC concerns were that the University management lost control of its entire radiation safety program. A report of this meeting was transmitted to the licensee on November 30, 1989 (Inspection Report No. 030-02764/89001(DRSS)).

Attachments:
1. Attachment I, Table of Licensee/ Consultant Identified Violations
2. Attachment A, June 30, 1988 Problem Notification Process for Radiation Safety Office Personnel
3. Attachment B, July 31, 1989 Problem Notification Process

ATTACHMENT I

Table of Licensee/Consultant

Identified Violations

Requirement Violated	Description of Violation	Report Location
License Condition 20, referencing August 13, 1984 application	RSC failed to conduct formal reviews of the radiation protection program	Section 7
License Condition 11(a)	Licensed material research conducted by unsupervised lab workers	Section 8(a)
License Condition 20, referencing August 13, 1984 application	RSC failed to confirm the qualifications of researchers designated as principal investigators	Section 8(a)
License Condition 20, referencing August 13, 1984 application	Licensed material research conducted by untrained lab workers	Sections 8(b) and 19
License Condition 20, referencing August 13, 1984 application	Failure to train/instruct housekeeping and support services personnel	Section 8(c)
License Condition 20, referencing August 13, 1984 application	Failure to instruct maintenance department personnel	Section 8(c)
License Condition 20, referencing August 13, 1984 application	Failure to instruct nursing staff attending to radiotherapeutic patients	Section 8(c)
License Condition 20, referencing April 11, 1986 letter	Failure to maintain running inventories of licensed material possessed in labs	Sections 9(a) and 19
License Condition 12(c)	Failure to leak test sealed sources at required intervals	Section 9(b)
License Condition 20, referencing April 11, 1984 letter	Failure to perform daily dose calibrator constancy checks and dose calibrate radiopharmaceuticals administered to patients	Section 10(a)

Requirement Violated	Description of Violation	Report Location
License Condition 20, referencing August 13, 1984 application	Failure to use syringe shields during preparation and injection of radiopharmaceuticals	Section 10(a)
License Condition 20, referencing August 13, 1984 application	Licensed material research conducted in unauthorized locations of use	Section 10(c)
License Condition 10(d)	Moisture measuring gauge stored in unauthorized location	Section 10(c)
10 CFR 20.207	Licensed material stored and/or used in areas not properly controlled for radiation protection purposes	Section 10(c)
10 CFR 20.201(b) to show compliance with 20.101	Failure to evaluate external (occupational) radiation exposure to lab workers	Section 11
License Condition 20, referencing April 11, 1986 letter	Failure to survey research labs at protocol specified intervals	Section 11
License Condition 20, referencing April 11, 1986 letter	Failure to wipe test use and storage areas at required intervals	Section 11
License Condition 20, referencing April 11, 1986 letter	Failure to survey nuclear medicine preparation and injection areas at required intervals	Section 11
License Condition 20, referencing August 13, 1984 application	Failure to evaluate Xenon gas effluent concentrations	Section 12
10 CFR 20.203(f)	Failure to label waste receptacles containing licensed material	Section 14(a)
10 CFR 20.401	Failure to maintain waste disposal survey records	Section 14(a)

Requirement Violated	Description of Violation	Report Location
License Condition 20, referencing August 13, 1984 application	Failure to label and properly identify waste delivered for incineration	Section 14(c)
License Condition 20, referencing August 13, 1984 application	Failure to develop written ALARA policies and procedures	Section 18
10 CFR 35.59(d)(g) and (i)[1]	RSO failed to review/approve brachytherapy source leak test, inventory and storage area survey results	Section 19
License Condition 14[1]	Failure to physically inventory sealed sources at required intervals	Sections 9(a) and 19
10 CFR 20.402(a)[1]	Failure to report the loss of sealed sources	Sections 9(a) and 19
License Condition 20[1], referencing August 13, 1984 application	Failure to employ NBS traceable standards for survey instrument calibrations	Sections 10(a) and 19
10 CFR 20.301[1]	Disposal of licensed material in normal "cold" trash	Section 19
10 CFR 20.303(d)[1]	Sanitary sewer disposal limits exceeded in 1986	Sections 14(b) and 19
License Condition 9[1]	Unauthorized service activities conducted for other licensees	Sections 17 and 19

[1]Those violations also identified by the NRC inspectors

Attachment A

University of Cincinnati
Radiation Safety Committee

234 Goodman Street
Cincinnati, Ohio 45267-0591

Mail Location #591
Telephones:
Radiation Safety Office 558-4110
Administration 558-9081

June 30, 1988

TO: Radiation Safety Personnel
Univ. of Cincinnati

FROM: George W. Alexander, Jr., B.S. G.W.A.
Kenneth M. Fritz, M.S. KMF

SUBJECT: Problem Notification Process for
Radiation Safety Office Personnel

In the event that there are any problems related to Radiation Safety Office programs, Radiation Health Technicians must notify either the Deputy Radiation Safety Officer, Radiation Safety Officer or Administrative Director of Radiation Safety immediately. Under no circumstances should any employee state either policies or problems related to radiation safety to anyone within the University of Cincinnati or outside of the University of Cincinnati unless told to do so by one of the above mentioned supervisors. Please be reminded that the Radiation Safety Committee makes radiation safety policies for the University, and we act upon the provisions of our NRC Broad License. Your specific jobs are to comply with assigned duties from the supervisors. In the event that there is a discrepancy related to this policy by an employee, disciplinary action will be taken.

NAME DATE

Attachment B

University of Cincinnati
Radiation Safety Committee

234 Goodman Street
Cincinnati, Ohio 45267-0591

Mail Location #591
Telephones:
Radiation Safety Office 558-4110
Administration 558-9081

July 31, 1989

TO: Radiation Health Physics Technicians
Radiation Safety Office

FROM: Jerome F. Wiot, M.D.
Chairman
Radiation Safety Committee

SUBJECT: Problem Notification Process

The following problem notification process was approved by the Radiation Safety Committee of the University of Cincinnati at its July 25, 1989 meeting:

> "If, in the opinion of any of the Health Physics Technicians a significant breach of safety has occurred or a significant potential hazard exists in relation to radiation or radioactive materials both in their use and their disposal within the University, this concern should be submitted in writing to the Radiation Safety Officer (and in his absence the Deputy Radiation Safety Officer), with a copy to the Chairman of the Radiation Safety Committee. It will be the responsibility of the Radiation Safety Officer to adress this concern, take appropriate action and report in writing to the Chairman of the Radiation Safety Committee within thirty days of the filing of the initial concern as to the disposition of the concern.
>
> All such reports will be brought to the next scheduled Radiation Safety Committee meeting as an information issue, and for discussion and action as indicated."

To further clarify this process, the route of complaints which the technicians should follow is: complaints are first presented in writing to the Radiation Safety Officer, Mr. Fritz, (and in his absence the Deputy Radiation Safety Officer, Mr. Jason), and copied to the Chairman of the Radiation Safety Committee, Dr. Wiot. Mr. Fritz is to respond, taking appropriate action and reporting in writing to the Chairman of the Committee within 30 days of the initial complaint. All such actions are to be reported to the Committee at the next regularly scheduled meeting; it should be noted, however, that an emergency meeting may be called at the discretion of the Chairman.

JFW/sk

cc: Mr. Kenneth M. Fritz
Mr. George Alexander