U.S. NUCLEAR REGULATORY COMMISSION

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Licenses No. 34-00293-02 and No. 34-00293-14

Reports No. 030-02640/96003(DNMS) and No. 030-31605/96001(DNMS)

Licensee: The Ohio State University

Location: The Ohio State University
Columbus, Ohio Campus

Dates of Inspection: (1) Inspection on June 24-28 and July 10-12, 1996;
(2) Followup inspection to review corrective actions on December 3-5, 1996

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EXECUTIVE SUMMARY

Ohio State University
NRC Inspection Reports No. 030-02640/96003(DNMS)
and No. 030-31605/96001(DNMS)

This routine, unannounced safety inspection was conducted to assess the overall adequacy of the university's NRC-licensed operations authorized under two NRC licenses, including a medical/academic and research broadscope license. The inspection focused on the use and control of radioactive material for research purposes and included a review of four licensee reported incidents that occurred since the last inspection and consisted of a: (1) phosphorus-32 skin contamination incident on March 6, 1996; (2) loss of four cesium-137 brachytherapy sealed sources reported on April 5, 1996; (3) radioiodine patient room lavatory plumbing incident on September 12, 1995; and (4) leaking americium-241 sealed source identified on February 29, 1996. Additionally, the inspectors reviewed implementation of the Radiation Oncology Department's Quality Management Program, use of a High Dose Rate Remote Afterloader device for patient treatments and other incidents selected from the radiation safety office's incident file.

Several apparent violations and other concerns were identified in the overall implementation of the university's radiation safety program, including a continued programmatic weakness with radioactive material inventory, accountability and characterization of stored radwaste. Five apparent violations, including a repeat violation, related to radioactive material inventory/accountability and waste storage were identified. According to the licensee, compliance could not be achieved in all areas of its radiation safety program because of insufficient manpower within the radiation safety office. As a result of these resource limitations, the licensee indicated that it prioritized the completion of tasks, initially focusing on issues of greatest safety significance. In other instances, the licensee misinterpreted or was unaware of certain inventory and NRC reporting requirements.

Eight other apparent violations were identified including repetitive radioactive material security problems, failure to adhere to radiation safety procedures, laboratory protocols and Department of Transportation requirements, and failure to evaluate discharges to the sanitary sewerage system to prevent release of insoluble radioactive material. The root and contributing causes for these other apparent violations varied and included weaknesses in program oversight due to inadequate utilization of staff, training deficiencies, isolated human error and lack of comprehensive self-assessments in all areas of the radiation safety program.

In addition to the apparent violations, concerns were raised with the: (1) adequacy of radiation safety office involvement and oversight of pool irradiator operations; (2) security and contamination controls incident to radioactive package receipt and distribution; and (3) adequacy of research laboratory surveys.

A Confirmatory Action Letter (CAL) was issued to the licensee on August 22, 1996, to confirm the corrective actions the licensee had taken, or planned to take, to address the problems identified during the inspection. A followup inspection on December 3 through 5 1996, found that although corrective actions were implemented for most of the problems

identified during the inspection conducted in June and July 1996, there were exceptions noted. Specifically, training was not provided to all applicable staff in radioactive material transport requirements and waste characterization and disposal was incomplete.

REPORT DETAILS

1. Summary of Licensed Programs

The Ohio State University (OSU) operates a medical/academic and research broadscope program under the authority of NRC Byproduct Material License No. 34-00293-02. The broadscope license authorizes, in part, the possession of: (1) radiopharmaceutical and brachytherapy sources in quantities as needed and up to ten curies (370 GBq), respectively, for medical diagnosis and therapy; (2) twelve curies (444 GBq) of iridium-192 in a remote afterloading brachytherapy device for therapeutic treatments; (3) curie quantities of any byproduct material with atomic numbers 1 to 83, in any form, for research and development (R&D) pursuant to 10 CFR 30.4, student instruction and calibration of instruments; (4) curie quantities of any byproduct material with atomic numbers 3 to 83, in the form of irradiated metals for R&D; and (5) millicurie to curie quantities of specifically listed sealed and unsealed byproduct materials for use in analytical instruments, gauging devices, and for instrument calibration, student instruction and R&D.

Diagnostic nuclear medicine studies are performed at the University Hospital complex. Therapeutic medical procedures are conducted at University Hospital and at the Arthur James Cancer Hospital and Research Institute. Both facilities are located on the main OSU campus in Columbus, Ohio.

Research and development activities are conducted under the supervision of approximately 270 individuals (Approved Supervisors) that have been approved by the University's Radiation Safety Committee (RSC). Research and development activities are conducted in about 600 laboratories located in 30 different buildings throughout the university campus, utilizing primarily sub-millicurie quantities of licensed material at any given time for tagging and labeling experiments.

Research involving human subjects is conducted occasionally and limited to the use of byproduct material which the Food and Drug Administration has accepted a Notice of Claimed Investigational Exemption for a New Drug (IND) or approved a New Drug Application (NDA). This research is funded, supported and/or regulated by another federal agency which has implemented The Federal Policy for Protection of Human Subjects pursuant to 10 CFR 35.6.

In addition to the broadscope medical/academic and research license, the university possesses seven other NRC licenses including License No. 34-00293-14, authorizing use of kilocurie quantities of cobalt-60 sealed sources in a wet storage irradiator for in-water irradiation studies. Pool irradiator activities are described further in Section 12.

2. Inspection History and Purpose

2.1 Inspection History

Three routine inspections of selected OSU licensed programs were conducted between 1991 and 1995, as follows:

1991 An inspection of the activities authorized under five of OSU's NRC licenses was conducted in October and November 1991. Eight violations related to activities conducted under the broadscope program were identified. One violation of License No. SUD-846, authorizing a sub-critical assembly, was also identified. Moreover, the 1991 inspection identified three areas of concern for: (1) weaknesses in the licensed material accountability and control program; (2) long term storage and stockpiling of unusable radioactive materials and waste in the licensee's two principal storage areas; and (3) incompleteness of sealed source and radioactive waste inventories.

1993 An inspection of the activities authorized under three of OSU's NRC licenses was conducted in September and October 1993. Thirty-two violations and several other concerns were identified. Significant problems identified in 1993 included a continued weakness in the licensed material inventory and accountability program and failure to characterize unknown wastes held in long term storage. Twenty eight of the violations collectively represented a significant breakdown in the management of the radiation safety program. The significance of the findings was exacerbated since many of the violations were known or suspected to exist by those responsible, yet continued uncorrected. These 28 violations were categorized in the aggregate as a Severity Level II problem. The remaining four violations were related to the control of licensed material and classified in the aggregate as a Severity Level III problem. A civil penalty was assessed and the licensee was required to submit a Radiation Safety Improvement Plan, which was incorporated into the OSU licenses by Confirmatory Order.

1995 An inspection of the activities authorized under all eight of OSU's NRC licenses was conducted in March 1995. Seven violations of broadscope license requirements were identified including repeat violations for failure to conduct physical inventories of brachytherapy sources in storage and for security of licensed materials.

2.2 Purpose of Inspection

This routine inspection was conducted to assess the overall adequacy of the university's NRC-licensed operations authorized under two NRC licenses, including the medical/academic and research broadscope program. The inspection also included a review of four licensee reported incidents which occurred since the 1995 inspection and consisted of: (1) a phosphorus-32 skin contamination incident on

March 6, 1996; (2) four missing cesium-137 brachytherapy sealed sources reported on April 5, 1996; (3) a radioiodine patient room lavatory plumbing problem on September 12, 1995; and (4) a leaking americium-241 sealed source identified on February 29, 1996. NRC assessment of the broadscope program focused on research activities, particularly in the areas of management and radiation safety committee involvement and oversight; the radiation safety office's ability to oversee daily licensed activities; licensed material control and accountability; waste management and effluents; security of licensed material; and radioactive package ordering, receipt and distribution activities.

3. Organization, Management Control & Staffing

3.1 Inspection Scope

The inspectors reviewed the licensee's organization and management controls for the radiation protection program, including the organizational structure, management and Radiation Safety Committee (RSC) involvement and oversight, radiation safety office staffing, and effectiveness of procedures and management practices in implementing the program.

3.2 Observations and Findings

a. Program Management

In 1994, the organization and reporting structure of the radiation safety program was realigned in an effort to improve weaknesses in management oversight and control identified during the 1993 inspection. Specifically, the Office of Radiation Safety (RSOF) was consolidated with the Office of Environmental and Occupational Health & Safety, which reports to the Assistant Vice President of Environmental and Occupational Health & Safety. The Assistant Vice President of Environmental and Occupational Health & Safety reports to the Vice President of Business and Administration through the Associate Vice President for Physical Facilities. The Vice President for Business and Administration reports to the University President, who in turn, reports to a Board of Trustees.

The Office for Business and Administration has administrative and fiscal responsibility for overall business and administration of the university, including those activities of the Offices of Physical Facilities, Environmental and Occupational Health & Safety, and the Radiation Safety Office. Notwithstanding these organizational responsibilities, based on inspector interviews of licensee management, it appears that the Vice President of Business and Administration is not directly involved in the radiation safety program. Although the Vice President of Business and Administration receives radiation safety committee meeting minutes and meets bimonthly with the Assistant Vice President for Environmental and Occupational Health

& Safety, direct management oversight of the NRC-licensed program has been delegated to the Assistant Vice President of Environmental and Occupational Health & Safety (AVPH&S).

The AVPH&S has been directly involved in radiation safety program oversight since responsibility for the program was realigned. This individual has also served as the management representative of the RSC. A RSC and radiation safety office implement and manage the day-to-day program, as discussed below.

b. Radiation Safety Committee(RSC)

The RSC approves all users and uses of licensed material and provides program direction and oversight through establishment of procedures, deliberations at quarterly meetings and other administrative controls. The committee also audits selected program areas on an annual basis.
The inspectors evaluated the current mechanisms and criteria used by the RSC to approve users and uses of licensed material. Committee membership and meeting minutes for 1995 and 1996 to the date of the inspection were also reviewed and the recently appointed new committee chairman was interviewed. The inspectors found that the RSC had an active role in approving users and uses, as required. However, the inspectors identified a concern with the committee's criteria for approving individuals to use radioactive material for non-medical uses. Specifically, the committee had not established minimum acceptable training and experience criteria as part of its evaluation process for proposed users of radioactive material for non-medical use. The inspectors identified three examples between April 1995 and June 1996 when researchers were approved by the RSC as "Authorized Supervisors" despite having little to no previous radioactive material experience documented on their application form. Draft Regulatory Guide DG-0005, October 1994, recommends that the training and experience of individuals authorized by an RSC to independently use or supervise the use of byproduct material be at least equivalent to that specified in 10 CFR 33.15 (b)(1) and (2), and include 40-hours of training and experience in the safe handling and characteristics of radioactive material.

The RSC conducts an annual audit of the radiation safety program as required. The results of the audit are provided to the Vice President of Business and Administration in a written report. The report serves as an overall status report to senior management on the state of the radiation safety program. However, problems or potential problems revealed during RSC audits appear to have not, in all instances, been pursued and fully assessed for regulatory compliance, nor has the committee ensured that timely and effective corrective actions were taken or planned. This concern is discussed further in section 6.

c. Radiation Safety Office (RSOF)

The RSOF is directly responsible for daily implementation and oversight of the radiation safety program. The principal responsibility of the office is to ensure proper development and implementation of the radiation protection program approved by the RSC, through training and various audit, control and service mechanisms.

As discussed in Inspection Report No. 030-02640/93001(DRSS), the RSOF was staffed by an RSO, three health physicists, one of which served as the Assistant RSO (ARSO), six technicians, two administrative support persons and a part time student technician for a total staff of approximately 12.5 full time equivalent persons. In January 1994, the RSO retired and the RSO position was assumed by the ARSO. In mid-1995, the licensee augmented the RSOF staff with two additional health physicists; however, in early 1996, the RSO terminated employment and the vacated position was filled by one of the newly hired health physicists. Over the last couple of years, two RSOF technicians were promoted to health physicist positions.

As of July 1996, the RSOF staff was composed of an RSO, five health physicists, five technicians, one administrative support person and three part time student technicians for a total full time equivalent staff of approximately 13.5. As discussed in Inspection Report No. 030-02640/93001(DRSS), in 1991, a licensee self-assessment concluded that fifteen full time equivalent positions were needed for the RSOF. Nevertheless, licensee management indicated during this inspection that the current number of RSOF staff should be sufficient to implement the program.

Since 1993, the licensee has had three different RSO's. Also, during the 1.5 year period between January 1994 thru mid-1995, the RSOF was three full time health physicist positions short of the staff level currently deemed appropriate by the licensee.

3.3 Conclusions

While the Vice President of Business and Administration receives RSC audit reports and meeting minutes and consults periodically with the Assistant Vice President for Environmental and Occupational Health & Safety, this degree of involvement may not be sufficient based on the continued weaknesses identified regarding radioactive material inventory, accountability and waste characterization. Additionally, as discussed in Section 5, the licensee claims that radiation safety office staff shortages precluded them from meeting all physical inventory requirements and timely resolving known waste characterization problems. Since the health physicist staffing level was insufficient for the one and one-half year period through mid-1995, the licensee's claim appears to have merit. Although the current staff of the RSOF may be sufficient in number to implement the radiation

safety program, the lack of continuity in the RSO position coupled with the staff shortages that existed over the last several years, appear to have decreased the effectiveness of the overall program. Consequently, the apparent failure to adequately fund the radiation safety program and employ and retain a fully staffed RSOF appears to be a principal contributor to some of the problems identified during the inspection.

The RSC has been properly established and chartered, and it includes an appropriate mix of qualified members. Committee meetings have been conducted regularly, as required, and include discussions of relevance to the radiation safety program. The committee has also displayed an active role in approving users and uses of radioactive material and in program oversight. However, the committee does not appear to have sufficiently examined suspected problems in the implementation of its radiation safety program to determine their veracity and extent, nor taken the steps necessary to ensure known problems are promptly addressed. For example, as discussed in section 6, a RSC audit report documented possible missing sealed sources and that orphaned sources may have been in storage for many years and not inventoried; nevertheless, the committee did not take or otherwise recommend the actions necessary to expeditiously address these potentially significant problems.

4. Qualifications, Training & Instruction to Workers

4.1 Inspection Scope

The inspectors reviewed the qualifications and experience of selected RSOF staff, and the radiation safety training provided to Approved Supervisors, other laboratory researchers and the ancillary staff.

4.2 Observations and Findings

a. RSOF Staff

The majority of the technical staff of the radiation safety office are degreed in health physics or biological sciences and possess several years of health physics or related experience. The staff appears to have an adequate mix of technical expertise and relevant experience. In mid-1995, the RSOF hired two experienced medical specialist health physicists, one of which was promoted to the RSO position in early 1996.

b. Approved Supervisors & Radiation Workers

Each laboratory worker who uses radioactive materials is required to attend a three-hour radiation safety short course provided by the RSOF. The course includes discussion of regulatory requirements, and various generic radiation protection procedures and practices. Completion of the course is required at five year intervals. Approved Supervisors (AS) also attend a one-on-one

Supervisor's Evaluation Conference with the RSOF's senior health physicist, as part of the process to be approved as a radioactive material user by the RSC.

c. Ancillary Staff

The RSOF periodically provides training in varying degrees to maintenance, housekeeping, security and other members of the ancillary staff. For example, all patient care and patient service personnel receive annual radiation safety in-service instruction from the RSOF. Training of non-patient care staffs is likewise provided by the RSOF; however, the training is typically provided to the ancillary staff department supervisors rather than to the line employees directly. Supervisors are required, in turn, to instruct their respective staffs based on what they learned from the RSOF staff. Although the success of this pyramidal training concept for non-patient care ancillary staff is highly dependent on the individual department supervisors, no significant problems were identified in its effectiveness. Nevertheless, the inspectors expressed concern that the licensee had not developed a mechanism to confirm that ancillary staff supervisors instructed their employees appropriately.

A RSOF self-audit completed in early 1996 found that training provided to a large segment of Physical Facilities Supervisors was not always timely. To correct this self-identified problem, a tickler file was established to remind the RSOF staff of training deadlines. Also, several training sessions were provided to housekeeping and other physical facilities supervisors by the RSOF staff throughout 1996.

4.3 Conclusions

The radiation safety training program established for Approved Supervisors and other radiation workers appears properly implemented and generally effective. While no significant problems were identified by the inspectors with ancillary staff training, improvements in the timeliness of training for ancillary staff supervisors and development of a system to confirm proper training of line staff appears warranted.

5. Radioactive Material Inventory, Control/Accountability and Radwaste Characterization

Overview - Radwaste Storage

The licensee stored long-lived radioactive waste primarily in two facilities, the Bulk Chemical Warehouse (BCW) and the Corrosive Storage Bunkers (CB). The BCW, a large warehouse-type building, housed both radioactive and non-radioactive hazardous wastes in drums, large bins, boxes, and plastic trash bags. The CB, a

small concrete block structure comprised of six individual and physically separated cubicles, housed smaller volumes of waste in plastic trash bags and boxes. Various types of unwanted sealed sources were also stored in both facilities.

Dating back to at least the early 1980's and continuing into the 1990s, the RSOF collected radioactive wastes and unusable/unwanted sealed and unsealed sources from its researchers and placed them within the BCW and CB. Some of the wastes and sources were stored in research labs for many years and historical records did not exist or were inadequate to identify the material or its origin. Over time, a large volume of unwanted and unidentified radioactive waste accumulated within the storage facilities. The licensee made little effort to characterize the unidentified, stockpiled materials and allowed the problem to worsen, despite concerns expressed during NRC inspections in 1991 and 1993. Moreover, radioactive material inventory and accountability concerns were also identified during previous inspections and brought to the licensee's attention. Specifically, concerns identified during the 1991 inspection and documented in correspondence to the licensee included: (1) unusable radioactive material that was held in storage indefinitely at multiple campus locations; (2) an incomplete inventory of sealed sources; and (3) failure to inventory radioactive material within the CB. The licensee's response to these concerns indicated that additional financial resources and RSOF technical staff would be acquired to identify, quantify, process, package, and dispose of uncharacterized wastes. Additionally, a commitment was made to update the sealed source inventory by December 31, 1992.

In 1993, a routine inspection identified continued concerns about uncharacterized waste within the BCW and CB, and weaknesses with the inventory and accountability program. The 1993 inspection found that the waste accumulation and characterization problems were not significantly improved since brought to the licensee's attention in 1991. Also, sealed sources in storage were not being inventoried at required intervals, nor did the licensee develop an appropriate inventory and accountability system that could provide cumulative campus-wide inventory information at any given time. Escalated enforcement action was taken for the 1993 inspection findings, in part, because the licensee failed to correct known or suspected problems with its licensed material inventory/accountability program and did not characterize and dispose of the waste in its storage areas.

5.1 Inspection Scope

The inspectors reviewed the university's licensed material inventory/accountability program, and efforts made to address previous problems in this area and with waste characterization in the BCW and CB.

5.2 Observations and Findings

a. Radwaste Characterization

As of July 1996, the BCW housed about ten 30-55 gallon drums of unchacterized solid radwaste, two pallets stacked with boxes and bags of solid wastes, an approximate 75 cubic foot container filled with boxes and bags of wastes and over 100 cubic feet of other boxes, bags and bottles of radwaste. The CB housed five sealed sources of known identity, several reportedly empty containers (lead pigs),and about fifteen 30-40 gallon size bags and 10-15 cubic feet of other miscellaneous containers housing uncharacterized solid and liquid radwastes.

Despite the aforementioned historical problems with radioactive material inventory and waste characterization, this inspection disclosed that radioactive waste characterization in the BCW and CB continued to be a problematic area and a significant weakness in the licensee's program. The licensee had expended little effort to address the radioactive waste characterization problem brought to their attention in 1991. Although the radiation safety office reorganized a small room within the BCW in 1993 where several sealed sources were stored, characterized a small fraction of the accumulated wastes and improved the housekeeping in both the CB and BCW, these efforts were not adequate to significantly improve the overall problem. The licensee indicated that it lacked the staff and equipment to characterize the stored waste, and therefore directed its available resources to other radiation protection program priorities.

In 1996, the licensee sought bids from contractors to characterize its stockpiled wastes and arrange for disposal, concurrent with decommissioning of a low level radioactive waste burial site on the Columbus campus. The licensee planned to secure a contract and initiate the characterization work in late 1996. However, the contract agreement was expedited as a result of inspector concerns expressed to the licensee during the early phases of this inspection. As a result, characterization work was initiated by the contractor in July 1996.

In examining the waste stockpiling problem, the inspectors learned that waste within the BCW and to a lesser extent the CB physically limited the licensee's ability to access all areas of these storage buildings and conduct physical inventories. The licensee also questioned whether sources unknown to them may be located amidst the bags, boxes and other containers of stored waste. This finding will be discussed further in the inventory/accountability section below.

Condition 20 of License No. 34-00293-02, Amendment No. 71 dated June 29, 1992, requires that radioactive waste awaiting disposal via shipment to a final disposal site not be stored for a period greater than 2 years. Condition 21, Amendment No. 71, requires that waste currently possessed exceeding the storage provisions of Condition 20 be disposed of within one year of the issuance of this license. (The license was amended in its entirety and issued on June 29, 1992.)

During a radiation safety program audit conducted by a health physics staff member in December 1995, a violation of License Condition 20 was identified. Specifically, licensed material awaiting disposal via shipment to a final disposal site was stored within the BCW and CB for well over two years. The licensee determined that the cause of the violation was insufficient RSOF staff resources to characterize and process unknown wastes within the BCW and CB. Although the apoarent violation of License Condition No. 20 was licensee identified, corrective actions were not prompt. **Storage of licensed material awaiting disposal via shipment to a final disposal site since at least 1991, is an apparent violation of License Conditions No. 20 and 21.**

The followup inspection in December 1996 revealed that about 750 cubic feet of partially compacted waste was characterized by the licensee's contractor in July and August 1996. Most of this waste was transferred for disposal to the Barnwell Low Level Waste facility in South Carolina through shipments made in November and December 1996. However, certain contractor characterized or otherwise known wastes stored in the BCW and CB were not disposed because of restrictions over transuranic materials and mixed wastes. Moreover, subsequent to contractor waste characterization activities, the licensee discovered additional wastes stored in its BCW and CB, which were apparently overlooked and not characterized by the contractor. Consequently, both characterized and unidentified radwastes remain stored in the BCW and CB. Specifically, approximately 23 gallons of liquid, 3200 scintillation vials and numerous small pieces of contaminated metal remain uncharacterized. Characterized wastes which remain in storage include seven americium-241 sealed sources, 56 gallons of liquid, about 300 small stock vials with liquid residue, a krypton-85 sealed source decayed to about 250 millicuries and about four curies of tritium contaminated tubing.

The licensee plans to complete its waste characterization work and dispose of all remaining wastes stored in the BCW and CB by February 1997, excluding short-lived wastes held for decay in storage and transuranic and mixed wastes that require special disposal authorizations from the State of South Carolina.

b. Licensed Material Inventory and Control/Accountability

The RSOF tracks and maintains inventory records for all radioactive materials possessed by the university under its NRC licenses. The licensee possesses approximately 300 sealed sources under its broadscope license and about 25 under its other NRC licenses. About 60 of these sealed sources are brachytherapy sources used periodically for medical applications at the University Hospital complex. Other sealed sources are possessed by researchers throughout the campus or are maintained in storage by the RSOF.

As reported in Inspection Report No. 030-02640/93001(DRSS), in 1991 and 1992, the licensee expended considerable effort to locate, identify and log all sealed sources possessed at the university. During the 1993 inspection, the licensee indicated that all sealed sources possessed by the university had been physically inventoried and all were accountable. Notwithstanding these previous findings, this inspection disclosed at least five sealed sources whose location or disposition could not be determined to date. These sources and the circumstances surrounding their disappearance are described below.

Source Set A	Four Amersham Model CDC-H1 brachytherapy sources (i.e., Serial Nos. 1051, 1052, 1053 and 1054) each containing an average activity of 15.83 millicuries of cesium-137 as of September 19, 1968

Source set A had been in storage within room 30 of the BCW since 1979. The sources were last physically inventoried in October 1993. On April 4, 1994, a health physicist (HP) attempted to leak test the four sources but was unable to locate them or the storage containers in which they resided. The HP did not report the sources as missing at that time because the sources were presumed to be somewhere within the BCW, possibly having been relocated by another RSOF staff member who also had keys to room 30. The health physicist was unaware of the reporting requirements of 10 CFR 20.2201 at that time. Between April 1994 and March 1996, the health physicist unsuccessfully attempted to locate the missing sources by periodically performing radiation surveys of various containers located within the BCW. In March 1996, the health physicist concluded that the sources were likely not in the BCW as expected, after reorganizing radwaste and other sources stored within room 30 as part of a larger effort to improve its overall housekeeping. On April 4, 1996, the health physicist informed the RSO that the four sources were missing. Additional search efforts conducted on April 4, 1996 within both the BCW and CB were also unsuccessful. The licensee notified the NRC Operations Center about the missing sources on April 5, 1996, and submitted a written report dated April 26, 1996, pursuant to 10 CFR 20.2201.

Based on transfer record review, the licensee believed that the missing sources were probably shipped to Chem Nuclear in Barnwell, South Carolina with a shipment of other radioactive waste on June 8, 1994. However, the inspectors determined that the licensee was unable to correlate the radioactive content of the four sources with that documented on the waste manifest form. Additionally, the waste handler (i.e., Bionomics) disposed of its records of the transfer. Therefore, the licensee was unable to confirm the location of the missing sources.

Source B 100 millicurie americium-241/beryllium sealed source

During a search in 1991 incident to preparation for disposal of radium sources, a HP identified a leak test record that indicated that source B was located in a particular research lab. The health physicist questioned the whereabouts of the source because the last leak test entry, dated July 1976, contained conflicting information. The leak test record indicated that the source was both returned to the manufacturer and in storage at the CB. The health physicist, however, perceived the situation as a paperwork problem and did not consider the source missing. Little effort was made by the health physicist at the time to locate the source or resolve the discrepancy. It is unknown if this problem was reported to the RSO.

In April 1993, a consultant hired by the licensee to audit the radiation safety program noted the discrepancy in the leak test record and alerted the licensee to the potential missing source. The same health physicist that discovered the problem in 1991 was tasked by the RSO with locating the source and/or resolving the discrepancy. The health physicist physically searched for the source periodically during intervals of time between other tasks from April 1993 to April 1995. The search efforts were unsuccessful. The licensee was unable to confirm the source's return to the manufacturer because the manufacturer was unknown.

The health physicist issued a memorandum to the RSO dated April 28, 1995, outlining the actions taken to locate the source. The licensee speculated that the source could be located amongst radioactive wastes and other unwanted sources within the CB. No report was made to the NRC regarding this missing source.

Source C Nuclear Chicago Model 850233 (Serial No. B-7) sealed source containing 22.5 millicuries of cesium-137 as of June 1966

Source C was physically inventoried and transferred by a health physicist from the CB to the BCW in June 1993. In June 1994, the source could not be located within the BCW when a physical search was made incident to its

planned disposal. No further efforts were made to locate the source at that time. The source, however, was apparently returned to the CB sometime after June 1993, because it was unexpectedly discovered there on April 4, 1996, during the licensee's search for missing source set A. No report was made to the NRC regarding this source while it was missing between June 1994 and April 1996.

10 CFR 20.2201 requires, in part, that each licensee report by telephone to the NRC, immediately after its occurrence becomes known any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to 10 CFR 20, under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas. The Appendix C quantities for cesium-137 and americium-241 are 10 and .001 microcuries, respectively.

Failure to immediately report by telephone to the NRC that licensed material in aggregate quantity greater than 1000 times the quantity specified in Appendix C to 10 CFR 20 was identified as missing on three separate occasions, is an apparent violation of 10 CFR 20.2201. Specifically, the licensee failed to immediately report that source set A, source B and source C were identified as missing on April 4, 1994, April 1993 and June 1994, respectively.

The inspectors toured the BCW and CB and questioned the licensee regarding its sealed source inventory within those areas. The tour confirmed that the long term storage of unwanted sealed sources and uncharacterized waste and other materials cluttering the storage areas contributed to source inventory and accountability problems because it physically restricted the licensee's access to all regions of the storage buildings. Therefore, it is possible that sealed sources may be located in inaccessible areas of the BCW and CB or stored in containers, boxes or bags, unbeknownst to the licensee.

In addition to the sealed source control and accountability problems, the inspection identified compliance problems with physically inventorying both sealed and unsealed sources at required intervals.

10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession. Moreover, License Condition No. 15, Amendment No. 74 dated July 2, 1993, requires that the licensee conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 35.400 and 35.500, and every six months for all other sealed and unsealed sources and/or devices.

Due to the health physicist's misinterpretation of the inventory requirements for brachytherapy sources, source set A was not physically inventoried on a quarterly basis. Specifically source set A was not physically inventoried from October 8, 1993, until an attempt was made to leak test these sources on April 4, 1994.

Failure to conduct a quarterly physical inventory of brachytherapy sources is an apparent violation of 10 CFR 35.59 and License Condition No. 15. A similar problem was identified during the inspections in 1993 and 1995. The problem in 1993 was also attributed to the licensee's misunderstanding of the requirements.

The licensee indicated it was aware of the six month inventory requirement of License Condition No. 15 for non-medical use sealed sources; however, compliance could not be fully achieved due to inadequate manpower in the RSOF. The licensee indicated that it prioritized compliance with the inventory requirement by focusing resources on actively used sources. The licensee planned to inventory those sealed sources in storage and not used, as resources allowed. As a result, several non-medical use sealed sources that were in storage were not inventoried as required. These examples are provided below.

Source C was transferred from the CB to the BCW in June 1993, at which time it was inventoried; however, further attempts to inventory the source were not made until June 8, 1994, at which time the source could not be located.

Source Set D	Four sources including: (1) Interatom (Serial No. 147-03-1) containing 100 millicuries of cobalt-60 as of February 15, 1965; (2) Interatom (Serial No. 147-03-2) containing 100 millicuries of cobalt-60 as of February 15, 1965; (3) cobalt-60 source (manufacturer unknown) containing 20 millicuries in November 1964; and (4) cobalt-60 source (manufacturer unknown) (Serial No. 81) containing 20 millicuries in November 1964

Source set D was stored in the CB and not inventoried from June 29, 1992 until April 3, 1996.

Source E	A sealed source containing 8 millicuries of americium-241 as of March 13, 1967, (Serial No. MRC A-SS-P-Am-205)

Source E was stored in room # 502 of the RSOF since March 1991 and not physically inventoried from June 29, 1992 to April 21, 1994, and from December 23, 1994 to March 29, 1996.

Failure to conduct physical inventories of non-medical use sealed sources every six months is an apparent violation of License Condition No. 15.

In 1993, all authorized supervisors (AS) performed a physical inventory of unsealed radioactive materials in their possession and reported the results to the RSOF. The information formed the basis for the initial cumulative inventory of unsealed material on campus. Beginning in 1994 and every six-months thereafter, the inventory information was updated by the RSOF, based on radioactive material inventory summary data and sanitary sewer disposal information supplied by the individual AS. The information provided by the AS on a six-month basis, however, was not a physical accountability of material but based rather on receipt and transfer records maintained by each AS. Consequently, a physical inventory of unsealed radioactive material was not conducted since 1993.

In late May 1996, the licensee realized that License Condition No. 15 also required physical inventories of unsealed materials. To correct this self-identified problem, the licensee developed a procedure for Authorized Supervisors to physically inventory materials in their possession and for reporting the results to the RSOF. Implementation of the procedure commenced in July 1996. Although this apparent violation was identified by the licensee, the problem existed approximately three years before it was identified and corrected.

The failure to conduct a physical inventory of unsealed sources every six-months is an apparent violation of License Condition No. 15.

5.3 Conclusions

a. Waste Characterization

While the licensee was aware of the radwaste accumulation and characterization problem for several years, the problem was not timely corrected due primarily to resource limitations. As a result, one apparent violation was identified for storage of radwaste greater than two years.

b. Material Inventory and Control/Accountability

The licensee has made improvements in its overall radioactive material inventory and accountability systems through the ongoing development of a computerized data base system. Nevertheless, the improvements were protracted over several years and continue to date. As a result, the delays

in fully implementing the improvements allowed problems to persist. As the program slowly evolved and improved, certain long standing inventory and accountability problems resurfaced and problems previously unknown to exist were identified.

Over the last several years, sources suspected to be missing were not searched for aggressively or reported as missing to the NRC due to several reasons including poor communications within the RSOF, failure to recognize the potential significance of the problem and inappropriate prioritization of tasks. Physical inventories were not conducted as required and attributed to several causes including the misinterpretation of requirements, the prioritization of tasks due to staffing shortages and physical restrictions posed by stockpiled wastes. Two apparent violations were identified for failure to immediately report missing sources, and to conduct physical inventories of sealed and unsealed sources at required intervals.

The licensee claims that the size of the RSOF staff was not sufficient to satisfy all known inventory requirements, necessitating a prioritized compliance approach. Also, until recently, significant resources were not devoted to rectify the waste characterization problem. Consequently, the licensee's failure to provide appropriate resources and staff and ensure long term waste characterization and inventory problems were appropriately addressed appear to be, in part, the cause of the apparent violations identified in this program area.

6. Internal Audits and Appraisals

6.1 Inspection Scope

The inspectors reviewed the internal audit program implemented by the licensee in 1995 to date in 1996, focusing on the licensee's ability to self-identify and correct problems.

Program audits were regularly performed by the RSC and the RSOF. Program reviews were also performed by outside consultants hired by the licensee. The licensee, however, does not plan to contract consultants or other external parties to perform additional program review at this time. The last consultant audit was performed by Engelhardt and Associates in July 1994.

6.2 Observations and Findings

a. RSOF Audits

The RSOF has developed two principal mechanisms for auditing its NRC-licensed program. These mechanisms consist of: (1) routine audits and surveillances of each lab that uses or stores radioactive material; and (2) health physicist assessments of selected program areas.

The RSOF regularly conducts audits of all laboratories using and/or storing radioactive materials. Audits are conducted in all labs on at least a quarterly basis, with the exception of its two "Type A" labs, which are audited monthly.

The laboratory audit and surveillance program consists of a visit to each lab to interview workers, observe practices including security, evaluate procedures, equipment and posting, conduct surveys and review records of receipt, transfer and disposal. Researchers are promptly informed of problems found in their labs and corrective actions appear to be taken as necessary.

The inspectors reviewed laboratory audit records and discussed program implementation with involved RSOF staff. The staff appeared generally knowledgeable, thorough and conscientious in their efforts. No significant problems were identified with the laboratory audit and surveillance program; however, the inspectors noted that lab visits were typically conducted during normal work hours, when laboratories were occupied and security problems were less likely to exist. As described in section 11, security problems were identified by the inspectors when laboratory visits were made during off-hours.

In December 1995, the licensee initiated a new self-assessment program developed to expand the involvement of the RSOF health physicists in program reviews. Each of the health physicists conducted an in-depth evaluation and compliance review of one or more program areas within their area of expertise, Findings were summarized in individual reports and submitted to the RSO, who further evaluated the findings and forwarded the reports to the RSC. The audit findings were in turn used by the RSC Audit Subcommittee to better focus its efforts in conducting the annual program review. The inspectors found the health physicist audits to be generally comprehensive and well documented. The licensee plans to continue the health physicist annual audits.

b. RSC Audit

A multi-member Audit Subcommittee of the RSC conducted annual reviews of the overall radiation safety program as required. The audit program was launched in 1993. The audit represents an overall assessment of radiation safety program performance. The audit process is initiated during the first quarter of each calendar year, encompassing the previous years activities, and culminates about mid-year with the issuance of the audit report to senior university management. The audit report is a principal mechanism used to inform senior management of overall program status.

The RSC audit conducted for calendar year 1994 identified several problems or potential problems with implementation of the radiation safety program, including ongoing problems identified during the previous audit which had not been fully corrected. The audit report was forwarded to the Vice President of Business and Administration by letter dated July 12, 1995. The audit report documented that there may be sources in storage that were not physically inventoried, and orphaned sources in the CB stored greater than 10 years. The report also documented that the location of source B, described previously in section 5, remained unknown and that other unaccounted for sources may exist. The audit report indicated that funding for the radiation safety program was an issue that required further resolution.

The RSC audit report for calendar year 1995, provided to the Vice President of Business and Administration via letter dated July 9, 1996, did not document significant emergent problems. However, the audit report underscored the RSC's continued concern with the number of staff allocated to the RSOF. The report also indicated that a more vigorous attempt must be made to account for and document all radioactive sources on campus.

6.3 Conclusions

While no regulatory compliance issues were identified with implementation of the licensee's audit and appraisal program, the inspection disclosed that problems or potential problems identified in RSC audits were not always addressed by the licensee in a timely and effective manner. For example, neither the RSC nor licensee management aggressively examined suspected problems associated with the sealed source inventory program and with the long term storage of orphaned sources and uncharacterized waste. Similarly, a sealed source known to be missing and others suspected to be missing were likewise not adequately pursued or otherwise addressed to ensure compliance.

The licensee's failure to promptly address self-identified or otherwise known or suspected weaknesses in its program is a continuing problem. The failure to correct known or suspected problems in a timely manner was considered a serious weakness in the licensee's program and formed the basis for escalated enforcement action in 1993. Consequently, this continued negative trend is of particular concern to the NRC.

7. Purchase, Receipt & Distribution of Licensed Materials

7.1 Inspection Scope

The inspectors evaluated the licensee's program for the ordering, receipt and distribution of those licensed materials used for other than medical diagnostic and therapeutic purposes. The evaluation included a visit to the main receiving department where shipments of radioactive material are delivered, and interviews of receiving department and other involved staff.

7.2 Observations & Findings

Requisitions for radioactive materials are approved by the RSOF to ensure the requestor is authorized for the quantity and type of radioactive material ordered. Purchase orders are placed by either the Purchasing Department or Research Foundation after RSOF approval. Radioactive material packages are delivered to the main receiving dock on Kenney Road and subsequently distributed to the requestor by two different means.

Packages labeled to satisfy DOT criteria prescribed by 49 CFR 172.403, are segregated and secured at the main receiving dock where they await daily pickup by an RSOF technician. The technician loads the packages into a transport vehicle, and performs direct and/or contamination smear surveys of the packages while within the vehicle. Packages are delivered to the requestor by the RSOF technician, provided the survey results satisfy prescribed limits.

Unlabeled packages such as those containing limited quantities of radioactive material pursuant to 49 CFR 173.421, are delivered directly to the end user by receiving department personnel, similar to non-hazardous material packages. Unlabeled packages are not normally surveyed for radioactivity by the licensee.

Inspector review of radioactive material package receipt and distribution practices disclosed two apparent violations and other concerns related to package security and contamination control, as described below. The inspectors' review also disclosed that the RSOF staff, other than the technician that processes packages, seldom frequent the receiving dock or audit practices of receiving dock personnel. Consequently, the licensee was generally unaware of the problems associated with package receipt and distribution.

10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, comply with the applicable requirements of the regulations appropriate to the mode of transport found in the Department of Transportation (DOT) regulations, 49 CFR Parts 170 through 189.

49 CFR 177.842 requires, in part, that packages of radioactive materials be so blocked or braced that they cannot change position during conditions normally incident to transportation.

However, the inspection revealed that from 1995 to June 25, 1996, the RSOF routinely transported DOT labeled packages containing varying quantities and types of radioactive material outside the confines of its plant from the university receiving dock to various campus research buildings, and the packages were not normally blocked or braced within the transport vehicle to prevent shifting during normal conditions incident to transportation. **Failure to block or brace packages of radioactive material within the transport vehicle is an apparent violation of 10 CFR 71.5.**

49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, the driver shall clearly distinguish the shipping paper, if it is carried with other shipping papers or other papers of any kind, by either distinctively tabbing it or by having it appear first.

However, the inspection revealed that from 1995 to June 25, 1996, the RSOF routinely transported radioactive material packages outside the confines of its plant from the university receiving dock to various campus research buildings, and the driver of the vehicle did not ensure that the shipping papers were clearly distinguished from other documents carried in a binder within the transport vehicle. **Failure to clearly distinguish hazardous material shipping papers from other documents carried within a transport vehicle is an apparent violation of 10 CFR 71.5.**

In addition to the above apparent violations, the inspectors identified concerns with the security of radioactive materials packages during the distribution process. Specifically, both DOT labeled and unlabeled packages delivered to the requestor's laboratory can be accepted by any laboratory representative, including individuals not authorized to handle radioactive materials or familiar with the security provisions of 10 CFR 20.1801/20.1802. Moreover, unlabeled packages, which constitute about 50% of all radioactive materials received by the university, are handled and distributed by receiving department staff similar to non-hazardous materials packages. These distribution practices increase the likelihood of security problems, particularly since receiving department workers are generally not familiar with radioactive material security and control requirements.

Additionally, a potential contamination control concern was identified with the methods used by the RSOF to transport labeled packages. Specifically, packages are handled in the receiving department by the RSOF technician, loaded onto the transport vehicle and transported to the RSOF, before the results of package contamination smear surveys are known. This practice could spread contamination to personnel who come in contact with packages and to the delivery vehicle before a problem is identified.

In response to these apparent violations of DOT requirements, the licensee committed to provide training to all staff involved in the transportation of radioactive material by October 30, 1996. The licensee's commitments were confirmed in a Confirmatory Action Letter (CAL) dated August 22, 1996. Notwithstanding these commitments, as of December 5, 1996, training in the transport of radioactive materials was not provided to those researchers transporting moisture/density gauges from the university's Piketon, Ohio facility. The followup inspection in December 1996 also disclosed that the RSOF possessed little knowledge of licensed activities conducted at the Piketon, Ohio research facility. The licensee's actions in response to the CAL are discussed further in Section 16.

7.3 Conclusions

As evidenced by the apparent violations and other concerns discussed above, certain of the licensee's radioactive material receipt and distribution practices are in need of improvement. Enhanced RSOF oversight of package handling and distribution activities and transportation activities at the Piketon, Ohio facility are warranted. While no radioactive material security or contamination control problems were specifically attributed to radioactive material package distribution, similar practices at other institutions have resulted in radiological control problems.

8. External and Internal Exposure Controls and Monitoring

8.1 Inspection Scope

The inspectors reviewed aspects of the licensee's program for controlling and monitoring radiation dose from both external and internal sources. The review included discussions with RSOF staff, tours of research labs to interview workers and observe practices, and selective review of procedures and dosimetry processing and bioassay results for 1995 through May 1996.

8.2 Observations and Findings

The licensee has implemented a program for monitoring external and internal occupational dose pursuant to 10 CFR 20.1502. Both whole body film and thermoluminescent dosimeter (TLD) extremity devices are provided and exchanged for vendor analysis on a monthly basis. TLD extremity devices are issued to those individuals who routinely handle in excess of specified quantities of beta/gamma emitting material in the departments of Radiation Oncology, Nuclear medicine and Radiation Safety. Researchers that use millicurie quantities of byproduct material above specified thresholds or whose work creates the potential for extremity dose in excess of 10% of regulatory limits, are also issued TLD extremity devices. About 3000 individuals were previously assigned whole body and/or extremity monitoring devices. However, in late 1995, the licensee reevaluated its dosimetry program and reduced its external dose monitoring service by about 50%, discontinuing service for many lab workers and ancillary staff who historically incurred little to no dose.

The license has implemented programs for informing its staff of declared pregnant worker (DPW) policies and procedures and for monitoring and recording fetal dose, as required by 10 CFR 20.1208 and 20.2106. DPWs are provided separate fetal dose monitors and doses are individually tracked and monitored. Monthly bioassays are also performed on DPWs through urinalysis or thyroid monitoring, as appropriate.

The inspectors cursorily reviewed vendor processing reports for 1995 through May 1996 for selected researcher staff, no problems were noted. According to the

licensee, the maximum occupational whole body and extremity dose in 1995 from NRC-licensed activities was less than 13% and 10%, respectively, of applicable 10 CFR 20.1201 limits.

The licensee has implemented a bioassay program to monitor potential intake of radioactive material. Routine urinalysis and thyroid monitoring are conducted on workers that handle unsealed forms of certain radioisotopes such as tritium and radioiodines above specified thresholds. For researchers, the RSOF logs all radioactive material purchases and tracks the use of those materials which may warrant a worker bioassay.

In 1995, the licensee reevaluated its bioassay program and as a result, significantly increased its radioactive material use bioassay thresholds. The revised program was approved by the RSC in late 1995 and its implementation began in April 1996. Program modifications were evaluated by the inspectors and determined to be based on sound health physics principles and the guidance provided in Regulatory Guide 8.25, "Air Sampling in the Workplace" and Regulatory Guide 8.9, "Acceptable Concepts, Models Equations and Assumptions for a Bioassay Program." Implementation of the revised program has reduced the number of bioassay measurements performed on a routine basis by over 50%.

8.3 Conclusions

The licensee's routine program for controlling and monitoring of external and internal occupational dose is adequate and satisfies regulatory requirements. Modifications made over the last couple years to both external dose monitoring and internal dose bioassay programs were based on appropriate health physics principles.

9. Radiological Survey Program

9.1 Inspection Scope

The inspectors reviewed the routine radiological survey program implemented in labs using radioactive materials for research purposes. The surveys consist of those performed by researchers and the RSOF staff. Inspector review included interviews of RSOF and researcher staffs, tours of selected labs, inspector independent surveys and review of lab survey records.

9.2 Observations and Findings

a. Researcher Laboratory Surveys

Researchers are required to conduct surveys of their laboratory use and storage areas on weekly or monthly frequencies, depending on the quantity of radioactive material used. Surveys are required to include both radiation level measurements, if applicable, and a series of wipe tests for removable contamination.

During the inspection, the inspectors toured about 30 laboratories and found that surveys were performed at required frequencies using appropriate instrumentation. However, inspector confirmatory surveys disclosed isolated contamination on floor surfaces of one lab in excess of acceptable thresholds. This was identified to the licensee and the area was decontaminated immediately. Moreover, the inspectors learned that researcher surveys have not always included floor surfaces in all areas of radioactive material use. This concern was brought to the licensee's attention and corrective action taken.

b. RSOF Laboratory Surveys

The RSOF conducts radiation surveys as part of its routine laboratory audit program, as described in section 6. The surveys include direct measurements and smear surveys in areas where contamination may occur. Appropriate instrumentation, techniques and smear analyses are conducted. Records of RSOF laboratory surveys were selectively reviewed for 1996 to the date of the inspection. No problems were identified with program implementation.

9.3 Conclusions

The licensee's routine radiological survey program conducted in research labs was implemented properly with some exceptions. Although no violation of regulatory requirements was identified, a concern associated with the thoroughness of researcher laboratory area smear surveys was noted.

10. Radwaste and Effluents

10.1 Inspection Scope

The inspectors reviewed the licensee's waste management program for all forms of radwaste generated in research labs. Waste disposal methods consist of transfer of solid waste to contractors for subsequent disposal by burial, decay of short-lived material in storage, discharge of liquids into the sanitary sewer system and release of airborne effluents to the environment.

10.2 Observations and Findings

a. Solid Radwaste

Solid radwaste generated in research labs is segregated by radiological half-life and either held for decay if the half-life is less than 90 days, or transferred to the Office of Environmental and Occupational Health & Safety for processing and packaging in the BCW. Long-lived waste is subsequently transferred offsite to a licensed contractor for supercompaction, followed by

burial at the Barnwell Low Level Waste Disposal Facility. Short-lived wastes are stored in research labs or the BCW for at least ten half-lives prior to disposal in the normal trash. Waste held for decay in storage is surveyed by both lab personnel and Office of Environmental and Occupational Health & Safety waste handlers prior to disposal in the non-radioactive trash.

The licensee made one shipment of solid radwaste in 1995 to the date of the inspection in July 1996. Thirty-eight 55-gallon drums of laboratory trash was transferred to the Barnwell site in August 1995.

No problems were noted with the solid radwaste management program other than as previously described in section 5 regarding storage of waste in excess of License Conditions 20 and 21 limits.

b. Liquid Radwaste

Based on historical daily water usage at the university, the licensee had established a 40 microcurie (1480 K Bq) per radioisotope daily disposal limit for each of the approximately 200 lab sinks approved by the RSOF (i.e. hot sink) for disposal of licensed material to the sanitary sewer system.

Each laboratory is required to evaluate the quantity of radioactive material discharged into the "hot" sink and maintain disposal records for each discharge. Disposal records are reviewed during RSOF lab audits and forwarded by the researchers to the RSOF every six months. The RSOF tabulates the disposal data to determine the gross cumulative quantities discharged for comparison with 10 CFR 20.2003 limits. Licensee records showed that about 6.8%, less than 1% and 26.5% of 10 CFR 20.2003 gross annual limits for H-3, C-14 and all other radioactive materials combined, respectively, was discharged into the sewer system in 1995. In 1996 through mid-July 1996, records showed that similar cumulative quantities were discharged to the sewer system.

In October 1995, the licensee began evaluating the solubility of radioactive material sewer effluents as part of its authorized supervisor approval process. The evaluations were made following the guidance in NRC Information Notice No. 94-07, "Solubility Criteria For Liquid Effluent Releases to the Sanitary sewer Under the Revised 10 CFR 20." Authorized supervisor application forms were revised in October 1995 to require that applicants specify the chemical forms and water solubility of radioactive materials they intend to use, to ensure NRC solubility criteria are met should sewer discharge be used as a disposal method. Prior to this time, the RSOF had not evaluated discharges of licensed material into the sewer system for solubility as part of the authorized user approval process. In addition, although those applications for radioactive material use approved by the RSC since October 1995 address the solubility of discharges to the sanitary

sewer system as required by 10 CFR 20.2003, the licensee had not evaluated the solubility of licensed material discharged into the sewerage system by researchers approved before October 1995. According to the licensee, 54 applications or 11.7% of all applications approved by the RSC between August 1991 and July 1996 included an evaluation for water solubility. Approximately 200 authorized supervisors were approved to use radioactive material prior to October 1995, many of which may have disposed of liquids tagged with radioactive materials into the sewer system.

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

However, as described above, the licensee did not make surveys to assure compliance with 10 CFR 20.2003(a), which limits the disposal of licensed material by release into the sanitary sewerage system. Specifically, from January 1994 to August 1996, the licensee discharged licensed material into the sewerage system and failed to evaluate the solubility of all materials discharged. **The failure to evaluate the water solubility of all licensed material discharged into the sanitary sewerage system is an apparent violation of 10 CFR 20.1501.**

At NRC request, beginning in July 1996, the licensee evaluated the licensed material discharged into the sanitary sewerage system for the two and one-half year period since January 1994, to determine solubility and biological dispersibility characteristics of the discharged materials. To perform the review, the licensee contacted each authorized supervisor approved by the RSC prior to October 1995, and obtained chemical form and water solubility information for each radioisotope used by the researcher. Hot sink disposal logs were then reviewed to identify all sewer discharges of insoluble or non-biologically dispersible licensed materials. The license's evaluation was completed in September 1996, and found that from January 1994 through August 1996, a total of 1.21 millicuries of insoluble H-3, 0.35 millicuries of insoluble C-14 and about 0.5 millicuries of insoluble I-125 was discharged into the sanitary sewerage system.

10 CFR 20.2003(a)(1) requires that licensed material discharged into the sanitary sewerage system be readily soluble or readily dispersible biological material in water.

However, as discussed above, during the period between January 1994 and August 1996, the licensee discharged small quantities of insoluble, non-biologically dispersible licensed material into the sanitary sewer. **The discharge of insoluble licensed materials into the sanitary sewer system is an apparent violation of 10 CFR 20.2003.**

Although the licensee's evaluation identified occasions when insoluble radioactive material was discharged into the sanitary sewer system, the gross quantities and concentrations released were only a fraction of the allowable limits. Therefore, these discharges did not pose a significant radiological hazard. Subsequent to its evaluation, the licensee provided researchers with information and guidance regarding solubility criteria so that future compliance would be achieved.

c. Airborne Effluents

License Condition No. 36 requires that stack effluent sampling be performed when the estimated aggregate release of all radionuclides through a fume hood exceeds 50% of a maximum permissible concentration (former 10 CFR 20 criteria), averaged over one month. As discussed in Inspection Report No. 030-02640/93001(DRSS), licensee calculations estimated that the 50% threshold was achieved if greater than 40 millicuries of I-125 was processed per month in an unfiltered fume hood. However, as described in the 1993 inspection report, the assumptions appeared to be very conservative, yielding an unrealistic stack effluent sampling threshold.

In 1994 and 1995, the licensee collected additional samples of air exhausted from its Nuclear Pharmacy Department's fume hoods during iodination procedures, to supplement those collected in 1993. The results of samples collected in 1994 and 1995 confirmed that the previously assumed radioiodine release fraction was overly conservative by approximately an order of magnitude. Based on the more recent sampling results, the stack effluent sampling threshold determined to satisfy License Condition No. 36 was recalculated and significantly increased. The revised threshold exceeds the quantity of radioactive material typically iodinated in a given month in the pharmacy's fume hoods. Consequently, since 1995, further sampling has not been required to satisfy License Condition No. 36. The air sampling results and calculational methods used by the licensee to establish the revised threshold were reviewed by the inspectors. No problems were noted.

The inspectors reviewed the licensee's evaluation to demonstrate compliance with air effluent limits of 10 CFR 20.1301 and 20.1302 for calendar year 1995, for all nuclides used at the university. The licensee evaluated the dose due to air effluents by determining the actual quantities used in both its research and medical programs, applying appropriate release

fractions and conservatively assuming that all releases occurred from a single release point. The results of the licensee's evaluation showed the dose from air effluents to be less than applicable NRC limits.

10.3 Conclusions

The licensee's waste management program for solid radwaste and the control of airborne effluents appears to be generally effective and in compliance with requirements. However, an isolated incident involving the disposal of a small quantity of solid radwaste in the normal trash was identified and is described in section 11.

As evidenced by the two apparent violations described in the subsection above, important aspects of the licensee's liquid radwaste management program have not been properly controlled and require additional RSOF and RSC oversight.

11. Independent Measurements, Facility Tours and Observations

11.1 Inspection Scope

The inspectors toured approximately 30 selected research labs, the Nuclear Medicine and Radiation Oncology Departments, the Reactor Building and the facilities of the RSOF. The tours included observation of activities in progress, interviews of radiation workers and ancillary staff, record reviews and independent radiological surveys using NRC instrumentation.

11.2 Observations and Findings

Caution signs, NRC-3 forms and license documents were found to be posted in accordance with 10 CFR 19 and 20 requirements. Radiation levels in unrestricted areas were found to be within regulatory limits. No evidence of eating, drinking, smoking or cosmetic application was observed. However, several radioactive material laboratory security problems were identified during inspector tours. Also, inspector surveys found contaminated solid waste located in the normal trash of a research lab.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed material that is stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Notwithstanding the above, on the evenings of June 25 and 27, 1996, the licensee did not secure from unauthorized removal or access licensed materials that were stored in unlocked containers (refrigerators and freezers) within open,

unattended research laboratories. These laboratories and licensed materials were readily accessible to the inspectors; therefore, the areas were unrestricted. The laboratories and the licensed materials stored therein at the time of the inspectors visit were as follows:

Location	Isotope	Quantity (mCi)
Biological Science Room # 953	S-35	.01
	P-32	0.15
	H-3	1.28
Biological Science Room # 715	P-32	.01
	S-35	0.1
	C-14	.017
Graves Hall Room # 2063G	S-35	15.0
	P-32	.093
	H-3	1.96
Graves Hall Room # 5126	C-14	15.39

The failure to secure from unauthorized removal or access licensed materials stored in unlocked refrigerators and freezers within open, unattended labs is an apparent violation of 10 CFR 20.1801. This is a repeat problem from both the 1993 and 1995 inspections.

In response to these problems, the licensee took several actions in an effort to improve the security of radioactive material in research labs. The licensee notified researchers of lab security policies and expectations, conducted off-hour security audits of research labs, and implemented an accelerated enforcement program against researchers that violate security policies. Despite these positive steps, additional examples of unsecured radioactive material in open, unattended research labs were identified by the inspector during the followup inspection on the evening of December 3, 1996. These examples are as follows:

Location	Isotope	Quantity (mCi)
Biological Science Room # 957	H-3	4.97
	S-35	.097
Medical Research Facility Room # 215	H-3	2.24
	C-14	.077

10 CFR 20.2001(a) requires that the licensee dispose of licensed material only by certain specified procedures.

However, during tours of research labs the evening of June 25, 1996, the inspectors discovered that the licensee disposed of paper contaminated with an unknown beta emitting radioactive material, by release to the non-radioactive trash stream of laboratory No. 719 in the Biological Sciences Building. This laboratory was unsecured and unoccupied at the time the waste problem was identified. Surveys of the waste paper with an NRC G.M. survey instrument and thin window pancake probe showed contact radiation levels of about 2 mrem/hour. The licensee later learned that the contaminated waste was blotter paper used in an experiment and was likely contaminated with P-32. **The failure to dispose of solid radioactive waste into an appropriate waste stream is an apparent violation of 10 CFR 20.2001.**

11.3 Conclusions

While facility tours identified laboratory posting and housekeeping to be satisfactory, and found that lab workers adhered to appropriate safety precautions associated with food consumption and related health physics practices, the repetitive problems identified with laboratory security indicates that a significant improvement remains to be made in this area.

The disposal of a small quantity of laboratory generated radioactive waste in the normal trash stream appears to be an isolated incident attributed to the sensitivity of the survey instrument used by the lab researchers.

12. Wet Storage (Pool) Irradiator (License No. 34-00293-14)

12.1 Inspection Scope

The inspectors reviewed selected activities conducted under License No. 34-00293-14, authorizing the possession and use of cobalt-60 sealed sources in a wet storage irradiator for in-water irradiation studies. The irradiator facility was evaluated for compliance with the requirements in the license and with 10 CFR Part 36. Areas reviewed included training and instruction to workers, operating and emergency procedures, facilities and equipment, maintenance, radiation surveys and personnel dosimetry.

12.2 Observations and Findings

The pool irradiator is located in the Nuclear Reactor Building, Bulk Shielding Facility. The irradiator pool was originally constructed to store spent fuel from the university's research reactor, which is adjacent to the irradiator pool. The fifteen

foot deep irradiator pool houses 14 cobalt-60 sealed source pencils totalling about 6500 curies. All irradiations are performed within the pool, with irradiation times varying with each experiment. Three authorized users and one trainee conduct irradiation studies about once per week.

The facility and its equipment was found to be as depicted in license documents. Safety systems appeared to be installed as required and functioned properly. License requirements and those in 10 CFR 36 were satisfied. However, the inspectors raised concerns with: (1) the representativeness of conductivity measurements and radiological analyses of pool water samples; and (2) the presence of cobalt-60 and cesium-137 contaminants in the pool water.

The irradiator is equipped with a pool water processing system designed to purify pool water through a filter demineralizer and to continually test water conductivity. The process system is operated about six hours per day. In order to prevent significant drainage of the pool in the event of a leak, the water processing system pumps water from and returns it to the top of the pool. Similarly, a float switch activated water supply system provides replacement water at the top of the pool to compensate for loss due to evaporation. Other than water circulation incident to the removal and return of water at the pool's surface and heat convection currents from the cobalt sources, no significant pool water circulation was observed. Consequently, the inspectors expressed concern that pool water conductivity measurements may not best represent the environment where the sources reside. Likewise, quarterly pool water samples collected from near the top of the pool may not be representative of the pool water conditions in the vicinity of the sources.

In response to this concern, subsequent to the site inspection in July 1996, the licensee analyzed pool water samples collected from near the bottom of the pool. The licensee reported no significant difference in the conductivity or radiological content of the sub-surface water. The licensee plans no further testing of sub-surface pool water at this time.

In 1988, the licensee placed highly enriched uranium fuel assemblies previously used in its research reactor for about 25 years, in the Bulk Shielding Facility pool. The highly enriched uranium was replaced with a lower enriched fuel at NRC direction. In 1992, the cobalt-60 sources were added to the same pool and irradiator operations commenced. The cask housing the cobalt-60 sources, which was off-loaded while submersed in the pool, was known to be contaminated internally with low levels of cobalt-60. In June 1995, the fuel assemblies were removed using baskets known to be contaminated with low levels of cesium-137. At inspector request, in July 1996, the licensee performed gamma spectral analysis of the three demineralizer tanks used to filter irradiator pool water since 1992. The analysis revealed the presence of cesium-137 and cobalt-60. Although OSU's research reactor license authorized storage of spent fuel in the pool which was later used as the cobalt-60 irradiator pool, License No. 34-00293-14, issued in 1991, did not address this matter. While the concentration of cobalt-60 and cesium-137 in

the pool water was very low (1 E-8 microcuries/ml) and has declined since 1995, the inspectors expressed concern that the contaminants possibly introduced by the fuel assemblies, the contaminated baskets and the shipping cask, could have degraded the cobalt-60 sources. In response to this concern, the licensee agreed to contact the NRC prior to introducing other potential contaminants into the pool, to determine the need for an evaluation or a license amendment.

12.3 Conclusion

No compliance problems or significant safety issues were identified with cobalt-60 irradiator activities. The facility appears to be operated in accordance with requirements. Nevertheless, the inspectors found that RSOF involvement in the irradiator facility to be limited. Research Reactor Laboratory personnel operated the facility somewhat autonomously, unlike other research activities approved by the RSC. For example, the RSOF was unaware of how conductivity measurements were made or knowledgeable of the radiochemistry sampling program and results. The RSO seldom visited the irradiator facility and admitted that his understanding of that facility's operations was very limited. Consequently, it appears that additional RSOF involvement in irradiator facility activities is desirable to ensure consistency of program oversight.

13. Followup on Reported Incidents

13.1 Inspection Scope

The inspectors reviewed four incidents reported to the NRC by the licensee since the last inspection. The incidents consisted of: (1) a researcher skin contamination that occurred on March 6, 1996; (2) a leaking sealed source discovered on February 29, 1996; (3) a patient lavatory contamination problem on September 12, 1995; and (4) the loss of four cesium-137 sealed sources reported on April 5, 1996.

The inspectors reviewed the circumstances surrounding the incidents, evaluated root and contributing causes and the licensee's corrective actions.

13.2 Observations and Findings

a. Lost/Missing Sealed Sources

On April 5, 1996, the license notified the NRC Operations center that it could not account for four nominal 15 millicurie cesium-137 sealed sources. The licensee submitted a written report to the NRC dated April 26, 1996, in accordance with 10 CFR 20.2201. The written report satisfied all informational requirements of 20.2201(b).

Inspector findings and conclusions regarding the missing source incident and related problems is provided in section 5.2.

b. Patient Room Contamination

The inspectors reviewed an incident involving iodine-131 contamination of two patient rooms at University Hospital on September 12, 1995. The contamination resulted from a damaged seal in the waste pipe of a toilet used by a patient undergoing iodine-131 treatment. Contaminated water leaked from the pipe through a common lavatory wall, and into an adjacent, vacant patient room. The contamination was limited to areas within the therapy patient's lavatory near the source of the leak, and the lavatory floor of the vacant room. About one gallon of water puddled in these areas. Contaminated water did not leak to other areas of the hospital.

The licensee appeared to respond promptly and effectively to the incident. Hospital staff immediately recognized the problem, and notified the appropriate staff to successfully prevent contamination spread. In accordance with 10 CFR 30.50, the licensee notified the NRC Operations Center of the incident by telephone on September 12, 1995, and submitted the required written report dated October 6, 1995. The RSOF staff performed appropriate radiation surveys to characterize the contamination and develop a decontamination plan. Contamination was isolated and ranged up to about 8000 dpm in the immediate area of the leaking pipe. The licensee investigated potential exposures to persons involved with the incident and performed bioassays of those personnel that may have come in contact with the contaminated areas. All bioassay results were negative. The rooms were effectively secured from unauthorized access pending decontamination to levels acceptable for release. The licensee determined the root cause of the event to be a broken pipe seal caused by excessive force on the toilet. Other similarly designed toilets used for housing radiopharmaceutical therapy patients were inspected for seal problems and none were found. No similar events had occurred since the incident.

c. Leaking Sealed Sources

On January 29, 1996, the licensee leak tested a nominal 600 millicurie americium-241 sealed source which had been out of service and in storage for several years. The source was previously used as a gamma emission source in an x-ray fluorescence analyzer. A small amount of leakage was identified; however, it was less than the regulatory limit. Additional leak testing on February 29, 1996, revealed 0.006 microcuries of removable contamination, slightly above the 0.005 microcurie limit of License Condition No. 13. The licensee filed a written report with the NRC dated March 4, 1996, in accordance with License Condition No. 13F. If source reclamation is not feasible, the licensee plans to apply an acrylic or similar sealant to the source and dispose of it as low level radwaste at the Barnwell site. A waiver from the State of South Carolina for disposal of this transuranic material may be necessary.

No problems were noted with the licensee's identification and reporting of the leaking source in February 1996. However, inspector evaluation of the licensee's radioactive material inventory and accountability program, as described in section 5, revealed a leaking sealed source incident which was not reported to the NRC as required.

Condition 15 of License No. 34-00293-02, Amendment No. 53 dated April 2, 1982 and Condition 13, Amendment No. 71 dated June 29, 1992, require, in part, that if a leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall file a report to the NRC within five days of the test describing the equipment involved, the test results, and the corrective action taken.

A leak test performed on March 25, 1991, showed 0.0292 microcuries of removable contamination from Source E (refer to section 5). After reporting the result to the Radiation Safety Officer (RSO), an HP was instructed to search for contamination in the file cabinet where it was stored and arrange for source disposal. No evidence of contamination was identified in the file cabinet, and the source was placed within a plastic bag and stored within Room 502 of the RSOF incident to final disposal. However, the licensee failed to report the leaking source to the NRC. **Failure to file a written report to the NRC within five days of a sealed source leak test that reveals the presence of greater than 0.005 microcuries of removable contamination is an apparent violation of License Condition No. 15, Amendment No. 53.**

The inspectors observed an HP perform a removable contamination survey of the exterior of the plastic bag which contained the leaking source, the shelf it was stored on, and a nearby counter top. Survey results were indistinguishable from background. The leaking sealed source appeared to be appropriately isolated and contained. The licensee plans to dispose of the source as radwaste through its broker.

d. Skin Contamination Incident

On March 6, 1996, an authorized user contaminated portions of his right hand while replacing the expelled cap of a vial that contained phosphorus-32. The incident occurred in the course of performing an experiment entitled "In Vivo Phosphorylation of Cells and Explants."

The researcher performed a tissue bath experiment in which a small quantity of animal tissue was incubated at a slow rate. Animal tissue samples were housed in two snap-cap type vials, each containing a 2.5 millicurie solution of P-32. The vials were to be heated in a water bath for about five hours.

About one hour into the heating process, the researcher returned to the lab and observed the cap on one of the vials loosen and fall into the water bath. The researcher retrieved the expelled cap and recapped the vial. Since the researcher was not actively involved in the experiment when he noticed the problem and had just returned to the lab, a laboratory coat and gloves were not worn while he responded to the problem.

License Condition No. 40 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in applications dated July 29, 1986 and February 21, 1991, and several referenced letters.

Item 15 of application dated July 29, 1986, entitled "General Rules for the Safe Use of Radioactive Material" requires that all laboratory procedures in the Approved Supervisors's approved application for the use of radioactive materials be followed. Item 15 also requires, in part, that laboratory coats and disposal gloves be worn. Moreover, the experimental protocol (lab procedure) for "In Vivo Phosphorylation of Cells and Explants" submitted by an approved supervisor applicant and subsequently approved by the radiation safety committee required, in part, that workers use double gloves and a lab coat. The approved procedure also specified that tissue samples be placed into screw cap flasks with 3 milliliter of media and 3 millicuries of P-32.

However, the inspectors found that required protective clothing was not worn in all instances of radioactive material use. Specifically, on March 6, 1996, a researcher failed to wear gloves and a lab coat while handling a vial containing 2.5 millicuries of P-32 during the in vivo cell phosphorylation experiment. As a result, the skin of the researcher's right hand was contaminated when the vial's cap was retrieved from a water bath after it was expelled.

Personnel radiation surveys conducted by the researcher immediately after handling the expelled cap found contamination on his thumb and forefinger. The researcher then washed the affected areas with detergent and a decontamination solution. According to the researcher, about two-thirds of the initial contamination was removed within a few minutes. Further decontamination was conducted under the supervision of the RSOF staff who were contacted by the researcher minutes after the incident, and responded about two hours later. The RSOF's response was not prompt because the researcher failed to convey the reason for the call in his voice mail message to the RSOF. Although contamination was found in the water bath and on the researcher's shoes and hands, no contamination was found outside the immediate area of the experimental setup.

On March 7, 1996, the licensee reported the incident to the NRC Operations center pursuant to 10 CFR 20.2202, as an exposure in excess of the occupational extremity dose limits of 20.1201. The licensee initially estimated the P-32 beta dose to the researcher's thumb at about 53 rem. The initial dose estimate, however, was overly conservative based on linearly extrapolating the results of contamination measurements taken at two and three and one-half hours post event, back to the time of the event, and discounting the full effectiveness of the decontamination efforts. After reexamining the survey results obtained by the RSOF when it responded, and applying conservative yet realistic assumptions, the dose to the researcher's extremity (thumb) was determined to be about 9 rem. Calculations performed by the inspectors using the VARSKIN program (NUREG/CR 5873) confirmed the accuracy of the licensee's dose estimate.

Inspector review of the researcher's experimental protocol for the tissue bath experiment disclosed that some of the laboratory equipment used in the experiment differed from that specified and approved by the RSC in the protocol. Specifically, on March 6, 1996, the P-32 labeled tissue samples were heated in a vial with a snap-type cap, rather than a screw cap flask specified in the protocol. During the experiment, pressure buildup caused the snap cap to loosen and be expelled, contaminating the experimental apparatus. The inspectors learned that the vial's cap expelled because: (1) the venting needle for the cap was clogged, creating excessive pressure in the vial; and (2) the snap-type cap was unable to withstand the pressure buildup. The researcher agreed that had a screw-type cap been used as specified in the lab protocol, the cap may not have loosed and been expelled.

Failure to wear appropriate protective clothing and use experimental apparatus as specified in the protocol approved by the RSC are apparent violations of License Condition No. 40.

The researcher committed to use appropriate screw-type caps and employ a larger venting needle system to prevent problem recurrence. Other corrective actions consisted of: (1) notification to all researchers of the problem and the need for prompt and appropriate RSOF notification in the event of personnel contamination; and (2) development of revised radiation safety standards that address the importance of proper adherence to RSC approved protocols, monitoring for personnel contamination and use of protective equipment at all times while handling radioactive material. In addition, the RSOF's short course has been supplemented to include skin contamination related topics.

13.3 Conclusions

Inspector review of four licensee reported incidents identified both appropriate and inappropriate licensee actions in response to these events. The licensee's response

to problems identified more recently in 1995 and 1996 was generally good. Timely reports were made to the NRC as required and corrective actions appeared adequate. Although two apparent violations related to the extremity contamination incident were identified, the violations were isolated and not indicative of generic problems. However, the licensee failed to adequately pursue potential problems with missing sealed sources in 1993 and again in 1994, and ensure NRC notification requirements were met for these missing source problems and for a leaking source incident in 1991.

14. HDR Remote Afterloader Brachytherapy Program

14.1 Inspection Scope

The inspectors reviewed selected aspects of the radiation safety program involving the use of a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit containing a nominal 10 curie sealed source of iridium-192. Areas reviewed included authorized user qualifications, training, facilities, equipment, sealed source calibration, device maintenance, operating and emergency procedures, personnel dosimetry, radiation surveys, and waste disposal.

14.2 Observations and Findings

Four physician authorized users, four physicists, two brachytherapy technologists, and two dosimetrists were involved with the administration of the treatment program. About seven HDR treatments were conducted per month under the supervision of the authorized users and consisted primarily of gynecological and endobronchial applications.

No problems or safety concerns were identified.

14.3 Conclusion

The HDR afterloader unit is used by appropriately qualified and trained individuals. The treatment program was found to be implemented as directed by the physician authorized users. The radiation safety program was likewise properly developed and implemented.

15. Brachytherapy Quality Management Program (QMP)

15.1 Inspection Scope

The inspectors reviewed the licensee's implementation of its brachytherapy QMP since the last inspection. The inspectors observed an HDR treatment, interviewed staff, and reviewed selected patient files to evaluate the effectiveness of the QMP.

15.2 Observations and Findings

The brachytherapy QMP has been properly developed and implemented in accordance with regulatory requirements. No compliance problems or safety issues were identified.

15.3 Conclusion

The licensee's brachytherapy QMP appeared effective in terms of satisfying the required objectives outlined in 10 CFR 35.32.

16. Confirmatory Action Letter

As a result of the number and scope of the apparent violations identified during the June and July 1996 inspection, particularly the continuing problems with radioactive material inventory, security and waste characterization, a Confirmatory Action Letter (CAL) was issued to the licensee on August 22, 1996. The CAL confirmed the licensee's plans to implement corrective actions for the problems identified during the inspection.

In response to the CAL, the licensee submitted a progress report dated October 4, 1996, outlining the corrective actions taken and providing timeliness goals for those actions not yet completed.

On December 3-5, 1996, a followup inspection was conducted to review the licensee's corrective actions for the apparent violations and other concerns identified in June and July 1996. The licensee's corrective action commitments were outlined in the subject CAL and progress report.

The inspection confirmed that adequate corrective actions were taken for most of the problems previously identified, as committed in the CAL. However, exceptions were identified in two areas, as follows:

(1) Not all radwastes held in long term storage at the BCW and CB were characterized by the contractor. About 23 gallons of bulk liquid in carboys and jugs, 3200 scintillation vials, approximately 50 small pieces of contaminated metal and eight sealed sources remained uncharacterized as of December 5, 1996. Also, as of December 5, 1996, not all characterized wastes have been disposed. Specifically, characterized wastes remaining in the licensee's BCW and CB storage areas include several decayed americium-241 sources and a krypton-85 source, about 56 gallons of bulk liquid, several accelerator targets, about 300 stock vials containing residual liquid, copper tubing contaminated with tritium and eighteen small bottles of uranium and thorium compounds.

The licensee will not meet its CAL commitment to characterize, package and dispose of all radwaste stored within the BCW and CB by December 1996. The licensee's failure to closely monitor contractor characterization activities and devote

sufficient staff resources to the project, precipitated by the termination of a health physicist in September 1996, appear to be the principal reasons why all commitments will not be met.

The licensee submitted a status report on its waste characterization and disposal project in a letter to the NRC dated December 30, 1996. The report outlines the licensee's plans to self-characterize all remaining unknown gamma-emitting materials and liquid waste in scintillation vials in January 1997. The licensee continues to work with a contractor in an effort to dispose of all characterized radwastes by February 1997, with the exception of mixed wastes, old sealed sources housed in lead containers, transuranic materials and liquid wastes of unknown chemical composition.

(2) The licensee has not provided training to researchers using moisture/density gauges at the Piketon, Ohio Research Facility. The licensee committed to provide this training to all applicable staff by October 30, 1996. Additionally, the licensee failed to evaluate the transportation practices at the Piketon, Ohio facility until prompted by the inspector on December 4, 1996. The licensee's subsequent review showed that researchers at the Piketon facility were unfamiliar with certain relevant DOT requirements and that researchers may have previously transported a moisture/density gauge without shipping papers or proper blocking and bracing of the device within the transport vehicle.

The RSOF suspended moisture/density gauge activities at its Piketon, Ohio facility on or about December 10, 1996. Activities will not be allowed to recommence until transport procedures are developed and approved by the RSC, and researchers are instructed in the procedures.

Exit Meeting Summary

The inspectors discussed the preliminary findings described in this report with licensee management and other licensee representatives during an exit meeting conducted at the university on July 12, 1996. The inspectors expressed particular concern that the licensee failed to address suspected problems with potentially missing sources and correct long term problems known to exist with waste characterization and disposal. The licensee acknowledged the findings presented.

One of the inspectors and the Chief, Nuclear Materials Inspection Branch No. 1, held an exit meeting with the licensee on December 5, 1996, to discuss the status of corrective actions and the licensee's corrective action program. The two exceptions in meeting the licensee's corrective action commitments were discussed at the meeting. The licensee did not identify any information reviewed during the site inspections as proprietary.

Partial List of Persons Contacted

+ * Will Benedetti, Radiation Safety Technician
+ * Charles Brooks, Radiation Safety Committee Member
+ * Vincent Burkes, Health Physicist
  * Amy Collins, Radiation Safety Technician
+ * Michael Darby, Chairman, Radiation Safety Committee
+ * Eric Denison, Radiation Safety Technician
+ * Reinhard Gahbanes, Director, Radiation Oncology
+ * Tim Govenor, Industrial Hygiene
+ George Hinkle, Vice Chairman, Radiation Safety Committee
  * Carol Jacobsen, Medical Center Safety
+ * Christos Kanellitsas, Radiation Safety Committee
+ Andy Karan, Health Physicist
+ * Joe Maus, Health Physicist
+ * Jeanne McGuire, Health Physicist
+ * Rick Myser, Associate Director, Nuclear Reactor Lab
+ * Kevin O'Hare, Radiation Safety Committee Member
  * Joseph Ottobre, Radiation Safety Committee
+ * Robert Peterson, Radiation Safety Officer
  Janet Pichette, Vice President for Business and Administration
+ * Cecil Smith, Associate Vice President, Environmental Health and Safety
+ James Stevens, Associate Vice President, Physical Facilities
  * Michael St. Clair, Environmental Manager
  * Ralph Stevens, Radiation Safety Committee
+ Ronald St. Pierre, Office of Health Sciences
  * Albert Vest, Health Physicist
  * Marshall Williams, Radiation Safety Committee

The inspectors also contacted other Ohio State University representatives including researchers and members of the Nuclear Medicine, Radiation Oncology and ancillary staffs.

* Denotes those persons present during the exit meeting held on July 12, 1996.
+ Denotes those present during the exit meeting held on December 5, 1996.

List of Acronyms Used in This Report

(OSU) Ohio State University
(AS) Authorized Supervisors
(RSOF) Radiation Safety Office
(BCW) Bulk Chemical Warehouse
(CB) Corrosives Bunker
(TLD) Thermoluminescent Dosimeter
(HP) Health Physicist