U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-01988/90001(DRSS);	Category F(1) A	Priority I
Report No. 030-00251/90001(DRSS);	Category E	Priority III
Report No. 030-06958/90001(DRSS);	Category E(3)	Priority I
Report No. 040-08787/90001(DRSS);	Category E	Priority III
Report No. 070-00192/90001(DRSS)	Category E(2)	Priority V
Report No. 070-01418/90001(DRSS);	Category K	Priority VII
Report No. 070-01856/90001(DRSS);	Category E(2)	Priority V
Report No. 070-02864/90001(DRSS);	Category E(2)	Priority V

License No. 21-00215-04 - Broad Scope Academic/Medical (01100)
License No. 21-00215-05 - Irradiator (03511)
License No. 21-00215-06 - Irradiator (Pool) (03521)
License No. SUD-1398 - Subcritical Assembly (11300)
License No. SNM-179 - Special Nuclear Material Sources (22120)
License No. SNM-1377 - Medical Pacemaker Program (22160)
License No. SNM-1529 - Plutonium/Beryllium Source (22120)
License No. SNM-1835 - Neutron Howitzer (22120)

Licensee: University of Michigan
Radiation Safety Service
1101 North University Building
Ann Arbor, MI 48109

Inspection Conducted: March 12-22, 1990

Inspection Locations:
- Ford Nuclear Reactor (FNR) North Campus
  Ann Arbor, Michigan
- H. H. Dow Building, North Campus
  Ann Arbor, Michigan
- Phoenix Memorial Laboratory, North Campus
  Ann Arbor, Michigan
- Willow Run Labs
  Belleville, Michigan
- University Hospital, Central Campus
  Ann Arbor, Michigan
- C. S. Mott Childrens Hospital, Central Campus
  Ann Arbor, Michigan
- Auxiliary Services Complex
  1919 Green Road
  Ann Arbor, Michigan
- Incinerator Building, North Campus
  Ann Arbor, Michigan
- Ann Arbor Waste Water Treatment Plant
  Ann Arbor, Michigan

- Building 1331, Central Campus
  Ann Arbor, Michigan
- School of Public Health, Central Campus
  Ann Arbor, Michigan

NRC Team Members: D. G. Wiedeman, Team Manager
J. L. Lynch, Team Leader
S. J. Mulay, Medical Program Reviewer
D. B. Howe, Ph.D., Medical Product Distribution Reviewer
W. J. Adam, Ph.D., License Reviewer
K. G. Null, License Reviewer

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(Onsite March 13, 1990)
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(Onsite March 13, 1990)
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(Onsite March 13, 14, and 15, 1990)
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Approved By:

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Inspection Summary

Inspection on March 12-22, 1990 [Reports No. 030-01988/90001(DRSS); No. 030-00251/90001(DRSS); No. 030-06958/90001(DRSS); No. 040-08787/90001(DRSS); No. 070-00192/90001(DRSS); No. 070-01418/90001(DRSS); No. 070-01856/90001(DRSS); No. 070-02864/90001(DRSS)]

Areas Inspected: This was a special, announced inspection conducted at the licensee's facilities by a team composed of personnel from NRC Region III, NRC Headquarters, U.S. Environmental Protection Agency, Michigan Department of Public Health and U.S. Department of Health and Human Services, Food and Drug Administration. The inspection reviewed eight of the University's nine materials licenses. The bulk of the inspection involved review of activities conducted under the broadscope academic/medical license (21-00215-04). Included in the inspection was a review of the radiation protection program, manufacturing and distribution, environmental impact, and industrial safety and chemical hazards. The purpose of the inspection was to review conditions at the licensee's facilities to determine whether there are potential safety hazards, which when combined with facility operations, could adversely impact public health and safety.

Results: Five apparent violations of NRC requirements were identified: (1) Release of licensed material to the normal trash, 10 CFR 20.301 [Section VI(A)(11)]; (2) Transport of licensed material without compliance with DOT regulations, 10 CFR 71.5(a) [Section VI(A)(7)]; (3) Failure to maintain security over licensed material, 10 CFR 20.207 [Section VI(A)(9)]; (4) Failure to perform conductivity tests in irradiator pool, License Condition No. 16 [Section VI(C)]; and (5) Failure to perform sealed source leak tests. License Condition No. 12.A. [Section VI(H)]. Two of the apparent violations were corrected during the inspection (Nos. 2 and 3). In addition to the apparent violations, the team also identified numerous concerns which necessitate the attention of licensee management to assure public health and safety. These concerns are identified in the report and in Enclosure 2 to this report. Overall, the University of Michigan radiation safety program was found to be excellent. Considering the number of licenses reviewed and the extensive effort by the participating agencies, few problems were identified. Of the violations and concerns identified, none were of significance to health and safety.

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EXECUTIVE SUMMARY

The University of Michigan is licensed by the NRC for a research reactor, an extensive radioisotope research program and a medical program which utilizes radioactive materials. The scope of this inspection was to review, with the assistance of other federal and state agencies, the research and medical programs. (See Section II of this report for the basis of the team inspection.)

Of the nine material (non-reactor) licenses that the University has with the NRC, eight were reviewed during this inspection. The main effort by the inspectors concentrated around License No. 21-00215-04 which is the broadscope academic/medical license. This license governs most of the research and medical use of radioactive materials, for which the NRC has jurisdiction.

There are currently 389 authorized users of radioactive material in approximately 900 laboratories throughout the campus. Some 3012 technicians, researchers, and laboratory assistants use radioactive material under the supervision of an authorized user. The University Hospital performs over 800 nuclear medicine and radiation therapy procedures per month (see Section III of this report for a more detailed description of the licensed programs which were reviewed during this inspection).

In general, the University was found to have a well-run, effective radiation safety program. Considering the number of licenses reviewed and the extensive inspection effort by NRC staff and the participating agencies, few problems were identified. Of those violations and concerns, none were of significant health and safety concern.

The most significant items identified by the NRC team members were:

- The continued inadvertent disposal of radioactive material contaminated diapers to the trash and commercial landfills (see Section VI(A)(11)).

- The apparent shortage of technically trained personnel in the Radiation Safety Service group. Significant delays in processing waste are resultant from this shortage (see Section III).

- The delay in the construction of the waste handling facility proposed for North Campus. The facility should be expedited in the event that the Midwest Low-Level Waste Compact burial site is not completed by January 1, 1993. Continued sharing of the incinerator/waste disposal facility with University maintenance personnel is also of concern (see Section VI(A)(11)).

The Environmental Protection Agency's major concern addresses operation of the North Campus incinerator. They suggest that a detailed analysis of effluent releases be performed to determine if current incineration practices will be allowed by proposed EPA radionuclide emission standards.

The Michigan Department of Public Health found excellent occupational safety practices in laboratories reviewed. Their findings identify the need for a comprehensive emergency response plan for the University.

The Food and Drug Administration had only two comments for program improvement, neither of which were major concerns.

DETAILS

I. Persons Contacted

*William Krumm, Ph.D., Associate Vice President for Business Operations
*Kenneth C. Schatzle, Director, Department of Occupational Safety and Environmental Health
@*Mark Driscoll, Health Physicist, Interim Radiation Safety Officer, Radiation Safety Service (RSS)
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Robert Blackburn, Research Associate II, Phoenix Memorial Laboratory (PML)
Clark Hagen, Research Associate I, PML
Donald Wieland, Ph.D., Associate Professor, Internal Medicine
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Phil Simpson, Assistant Laboratory Manager, Research, PML
Arthur Glatfelter, Irradiator Operator, Health Science Research Assistant II

Timothy Almburg, Research Technician, Willow Run Labs
Glenn F. Knoll, Ph.D., Professor and Chairman, Department of Nuclear Engineering
*Henry Griffin, Ph.D., Professor of Chemistry, Chairman, Radiation Policy Committee
Ruth R. Lewis, R.N., Clinical Nurse Specialist, Division of Cardiology
Michael deDuitleir, M.D., Assistant Professor, Division of Cardiology, Department of Internal Medicine
Bob Smith, Manager, Pediatric Cardiology Service
Macdonald Dick II, M.D., Professor of Pediatric Cardiology
Beth Yanke, Chief Dosimetrist, Department of Radiation Oncology
*Cathy Basso, Secretary, Occupational Safety and Environmental Health, RSS
*William C. Kelly, Interim Vice President for Research
*Ron Olsen, Associate Vice President for Research
Jeanette Roesner, Research Associate, Kresge I Building Laboratory
Renato Del Rosario, Senior Research Associate, Kresge I Building Laboratory

*Denotes those present at the exit meeting on March 16, 1990.
@Denotes those present at the Licensing exit meeting on March 22, 1990.

II. Background

As a result of the accident involving the release of uranium hexafluoride from Kerr-McGee's Sequoyah Fuels Facility in Gore, Oklahoma in 1986, the NRC initiated team inspections at selected materials licensees' facilities.

The team assessment is designed to evaluate existing conditions at each facility and to determine whether there are potential safety hazards that, when combined with facility operations, could impact adversely upon public health and safety. Further, the assessment will assist the NRC in determining if additional license conditions are needed to minimize such impact. During each assessment, the team determines whether the licensee has systems and procedures in place to identify and correct industrial safety problems that could result in radiological safety consequences, and determines whether the licensee is adequately implementing those procedures to prevent or mitigate such problems. During this team assessment areas reviewed included the licensee's overall radiation protection program, waste management, manufacturing and distribution, environmental monitoring, and industrial safety. Upon completion of the inspection, the team findings were reviewed with the licensee. These findings will also be forwarded to appropriate NRC Program Offices and to regulatory agencies having jurisdiction over the licensee.

III. Licensed Programs

The University of Michigan owns and controls some 20,000 acres of property and 1,200 buildings. Present student enrollment at the Ann Arbor campus is 36,338 students, while the total combined enrollment at all three campuses (Ann Arbor, Flint and Dearborn) is approximately 50,642 students. This special team inspection consisted of a review of

eight NRC licenses consisting of three Byproduct Material Licenses, four Special Nuclear Material Licenses and one Source Material License.

License No. 21-00215-04 is the main broadscope license that authorizes certain medical, academic, and research uses of licensed materials at Ann Arbor, Dearborn, Flint, Pellston, Ypsilanti, Belleville and temporary field sites within the State of Michigan.

A concern was noted during the inspection regarding the locations of use listed in License Condition No. 10.A. It was noted that Willow Run Labs is located in Belleville rather than Ypsilanti as stated. Also, the 1919 Green Road facility should be added to and the Environmental Research Institute should be deleted from the license. These changes would better describe the licensed program.

There are currently 389 authorized users of radioactive material in approximately 900 laboratories throughout the campus. Approximately 3,012 technicians, researchers and laboratory assistants use radioactive material under the supervision of an authorized user.

The nuclear medicine department at this large 880 bed University Hospital performs approximately 800 routine diagnostic procedures per month, 70-75% of which are technetium-99m related. The department employs twelve full-time technologists and rotates one through the pediatric nuclear medicine satellite at the C.S. Mott Childrens Hospital. The licensee also employs four radiopharmacists responsible for generator elution and dose preparation. Nuclear medicine staff members complete a rotational assignment through the pharmacy to become familiar with radiopharmaceutical preparation technique and procedures. The licensee routinely performs technetium-99m DTPA aerosol ventilation studies and has not performed ventilation studies with xenon-133 for approximately two years. On an average, two therapy treatments with iodine-131 for hyperthyroidism are performed each week. Approximately 20 procedures for thyroid cancer are performed annually. All iodine-131 doses are in liquid form. The licensee has two bone mineral densitometers which are infrequently used.

The brachytherapy program performs approximately 60 procedures annually, 50 utilizing cesium-137 and the remainder with iodine-125 and iridium-192. No misadministrations have occurred since the last routine inspection in July 1987.

Two Investigational New Drug (IND) products are manufactured and distributed under this license. In 1989, approximately 1000 of these iodine-131 labelled doses were distributed.

The 21-00215-05 license authorizes the use of a Theratron 80 teletherapy unit for purposes of non-human irradiation research. Until July 1986, the unit was used in the medical radiation therapy program. It contains a sealed cobalt-60 source of approximately 2250 curies and is used to irradiate animals, biological samples and inanimate objects.

License No. 21-00215-06 authorizes the use of cobalt-60 sealed sources in a pool irradiator. The irradiator is used for gamma irradiation of research materials and bone cartilage (human and animal). The facility currently contains 9200 curies of cobalt-60.

Source Material License No. SUD-1398 authorizes 2500 kilograms of natural uranium in a subcritical assembly, for storage only. The unit has been in storage for years and there are no immediate plans to take it out of storage.

Special Nuclear Material License No. SNM-179 allows possession and use of plutonium-238 and 239 sealed sources, plutonium and uranium target foils, neptunium-237 and americium-243. The licensed materials are used for research, student instruction, instrument calibration and activity standards.

Special Nuclear Material License No. SNM-1377 authorizes the recovery of plutonium nuclear pacemakers. Nuclear pacemakers have not been implanted in over ten years and the University is currently following up on three devices which remain in use.

Special Nuclear License No. SNM-1529 authorizes one plutonium/beryllium neutron source to be used for dosimeter irradiation. The source has been in storage for several years.

Special Nuclear License No. SNM-1835 allows possession and use of a neutron howitzer employing an 80 gram plutonium source. The unit is used for neutron activation research and student instruction.

IV. Organizational Structure

The Board of Regents is made up of eight elected individuals. These individuals are elected by the voters in the State and/or selected by the Governor if a vacancy occurs. Each Regent serves an eight year appointment. James Duderstadt, Ph.D., is the President of the University and answers directly to the Board of Regents. F. W. Womack is Vice President and Chief Financial Officer and W. B. Krumm is Associate Vice President for Business Operations. Radiation Safety Service is presently under K. C. Schatzle, Director, Occupational Safety and Environmental Health, who answers to W. B. Krumm. Presently the licensee is recruiting for the position of Director of Radiation Safety Service. Mark Driscoll is temporarily assigned as Interim Director until the vacancy is filled. Presently the Radiation Safety Service staff consists of four full-time health physicists and three full-time health physics technicians. The licensee is currently recruiting for two additional full-time health physics technicians and a Director of Radiation Safety Service.

The Radiation Safety Service (RSS) is the section of the Department of Occupational Safety and Environmental Health (OSEH) that was established to provide training and control in the use, possession, transportation and disposal of all radioactive materials and sources of radiation used by the University of Michigan.

Henry Griffin, Ph.D., is Chairman of the Radiation Policy Committee (RPC) and Radiation Policy Sub-Committee (RPSC). The RPC meets quarterly and the RPSC meets monthly. The RPC advises the Director of Radiation Safety Service on policy matters and the RPSC is responsible for review and approval of all applications for the use of radioactive materials. The Directors of RSS and OSEH are ex offico members of the committees. During 1989, forty-four new applications for use of radioactive material were approved and eight-six amendments to previous applications were approved along with one hundred fifty renewals for continued use of materials.

During 1988-1989, the RPC took action on several items regarding radiation policy. A revised policy on occupational exposure limits to females in the child bearing age and pregnant workers was developed and issued. A policy regarding the use and disposal of radium-226 was also passed. ALARA reports, incidents and events are reviewed and follow-up actions were approved. During 1988, a new policy regarding the use of non-hazardous liquid scintillation media was formulated which eliminated all hazardous liquid scintillation counting media on campus.

Brahm Shapiro, M.D., is Chairman of the Radioactive Drug Research Committee and Sub-Committee on Human Use of Radioisotopes which meet monthly. These committees are subcommittees of the RPC and review all applications involving the proposed use of radioactive materials in humans. The Director of RSS is an ex offico member of these committees. During 1989, twenty-four applications for human use were reviewed and approved. During this same period, nine amendments to previous approvals were reviewed.

A concern was identified with respect to radiation safety staffing. The RSS group is currently experiencing a shortage of technician level staff. The shortage results in radioactive waste accumulation and requires that the health physicists, including the RSO, spend considerable amounts of time performing routine duties such as waste analysis. Their time would be better spent overseeing the program.

No violations of NRC requirements were identified.

V. Previous Inspections

License No. 21-00215-04

- September 1988, special inspection of allegations, no violations were identified.
- July 1987, routine inspection, two violations were identified (beverage in laboratory refrigerator and failure to report diagnostic misadministrations).

Licenses No. 21-00215-05, No. 21-00215-06, No. SUD-1398, No. SNM-179, No. SNM-1835

- July 1987, routine inspection, no violations were identified.

License No. SNM-1377

- July 1987, routine inspection, one violation was identified (failure to ensure recovery of a nuclear pacemaker).

License No. SNM-1529

- January 1983, routine inspection, no violations were identified.

The violations identified in the above-referenced inspections were found to be corrected as described in the licensee's letter dated September 10, 1987, in response to a Notice of Violation.

VI. Radiation Protection Findings

A. License No. 21-00215-04

1. Audits and Surveys

Audits of the nuclear medicine program are conducted formally every two or three months by the medical health physics staff. Daily surveys are conducted by the nuclear medicine staff at the end of the day. In addition, the medical health physics department has instituted a weekly, monthly, quarterly and annual checklist system to insure that proper frequencies are followed. During routine audits by medical health physics personnel, survey reports, exposure results, etc., are reviewed. When violations are identified, they are documented on the nuclear medicine inspection form along with the appropriate corrective action.

Areas in the nuclear medicine department and waste storage areas are surveyed for contamination at the end of the day of use and surveyed weekly for removable contamination. A review of records showed that the surveys have been conducted as required.

The licensee performs surveys inside iodine-131 therapy patient rooms. The licensee believes that in-room surveys along with attenuation factors are sufficient to remove the need for surveys in areas adjacent to iodine-131 therapy patient rooms, assuring compliance with 10 CFR 20.105. The NRC inspectors did not dispute this claim, but requested the licensee to demonstrate that additional surveys are not necessary.

A random review of recent brachytherapy patient files revealed that the proper room and patient surveys have been performed as required. Further, all sources are inventoried and accounted for before and after an implant.

All four brachytherapy rooms are dedicated for radiation oncology use and are all lead lined for adjacent area shielding.

A concern regarding potential sealed source degradation was raised at the Willow Run laboratory facility. Two californium-252 sealed sources (1.76 and 0.46 millicuries) are stored in a four foot deep water tank built into the floor. A hoist system allows the raising of the larger source for panoramic irradiations. The smaller source remains stored in the pool at all times. The tank water is not recirculated nor tested for quality. A visual examination showed debris on the water surface; however, due to the pool configuration and available lighting, the pool water could not be judged for clarity/ turbidity. The licensee has not tested the water for conductivity to determine whether a corrosion threat exists. Leak tests of the sources have been negative to date. The inspector recommended that a full evaluation of this water storage system be performed.

Research laboratories using unsealed material are audited by RSS staff on monthly or quarterly frequencies depending on the radiotoxicity of the materials used. The audits include a walkthrough inspection, record review and contamination surveys. Laboratories which have only sealed or plated sources, such as gas chromatograph electron capture detectors, are audited semiannually when leak tests are performed.

No violations of NRC requirements were identified.

2. Manufacturing and Distribution

Radiopharmaceutical manufacturing and distribution of two Investigational New Drug (IND) products is authorized under License No. 21-00215-04. The NRC inspectors were accompanied by a representative of the U.S. Food and Drug Administration (FDA) during the review of this program. All manufacturing, preparation and distribution of these radiopharmaceuticals are performed at the Phoenix Memorial Lab (PML). Both products have been approved for human use by the FDA. The primary product distributed is known as NP59 which has an IND No. 11,463. This material is also called I-131-6B-iodometylnorcholesterol and is used for imaging the adrenal cortex. The other product is known as NP292 which has an IND No. 17,239. This material is also called I-131-metaiodobenzylguanidine Sulphate and is used for imaging the adrenal medulla and is also used as a radiopharmaceutical therapy agent for neuroblastoma and pheochromocytoma. The NRC inspectors reviewed the licensee's distribution records for 1989. These records show that during this period, 806 non-therapy shipments were made which consisted of 2.85 curies of materials distributed. During this same period, 213 therapy doses were transferred to University Hospital.

The NRC inspectors reviewed radiation survey records and procedures, bioassay results, disposal records, effluent monitoring and radiation exposure results.

The FDA inspector reviewed his findings with the licensee on March 15, 1990 and presented the licensee representatives with Form FDA-483 which outlined two recommendations to improve the manufacturing program (Attachment 3).

The NRC inspectors also reviewed the procedures and practices for manufacture and distribution of in-vitro and in-vivo kits at the licensee's facility located at 1919 Green Road, Ann Arbor. It appears that the licensee is following the procedures described in their letters dated April 6, 1988 and July 17, 1989 and the NRC inspectors did not identify any deviation from these procedures.

No violations of NRC requirements were identified.

3. Training

To date, over 4,000 persons using radioactive material have attended the licensee's in-house training program which is used to satisfy the training requirements outlined in 10 CFR Part 19. The training program is presented in a monthly two-hour session which is offered by RSS and in special cases customized training courses are given. The major use of radioactive materials is at the Ann Arbor campus; however, limited use and research is conducted at the Dearborn and Flint, Michigan campuses.

Training in the medical complex is provided by the medical health physicist for persons who may come in contact with radioactive materials or who may care for patients undergoing diagnostic and therapy procedures. New students in the nuclear medicine department receive initial training that includes a 40-hour radiation safety course established by the medical health physicist. Annual training is provided by the health physics staff and includes lectures to technical members of the department and instruction in the form of memoranda to persons who may enter restricted areas during the course of their work such as housekeeping, clerical, security, transporters, and nursing. Further, a nuclear medicine department meeting is held weekly to discuss procedures and radiation safety.

Interviews with the medical, nursing, and research laboratory staff revealed adequate knowledge of radiation safety and emergency procedures.

No violations of NRC requirements were identified.

4. Personnel Radiation Protection - External

The licensee uses film badges supplied by an NRC-approved vendor. Film badges are exchanged monthly and are promptly reviewed by the Radiation Safety Service and the medical health physicist at University Hospital.

The broadscope license calls for investigation levels of 1500 millirem per year for exposure to the whole body and 37,500 millirem per year for extremities. However, RSS staff members responsible for review of exposure data initiate an investigation if the levels of 100 millirem per month (whole-body) and 1000 millirem per month (extremity) are exceeded. The results of any investigation of elevated exposure under this program is forwarded to the Radiation Policy Committee (RPC) with appropriate corrective action.

A review of personnel exposure records showed that exposures to radiation workers were below the limits set in 10 CFR Part 20; however, extremity exposures to various nuclear pharmacists totalled between 13,500 and 22,300 millirem annual exposure in 1989. Similar exposures were observed in 1988. This was noted in the nuclear medicine audit report and has been investigated by the health physics staff and reported to the RPC as required.

No violations of NRC requirements were identified.

5. Personnel Radiation Protection - Internal

The licensee has not performed a lung ventilation study using xenon-133 for approximately two years. Ventilations are presently performed using technetium-99m DTPA aerosol.

The potential for iodine-131 and iodine-125 uptake to radiation workers exists. The licensee uses volatile liquid iodine-131 for hyperthyroid and thyroid cancer treatments. Doses are prepared in a fume hood within the nuclear pharmacy and personnel involved in the administration and/or preparation of liquid iodine-131 have a bioassay completed by the medical health physics staff monthly. However, during the inspection of license requirements for bioassay frequency, it was determined that several different bioassay intervals exist within the referenced license documents. For example, the license application dated October 28, 1982, states in Item 12 that workers handling 5 millicuries or more of iodine-125 or iodine-131 must have their thyroids counted within five days for iodine-131 or 30 days for iodine-125 and workers routinely handling 5 millicuries or more of these isotopes must have their thyroids counted monthly. Further, internal documentation received by Radiation Safety Service dated October 20, 1982, references Regulatory Guide 8.20 which

recommends bioassays for this program to be at a quarterly frequency. Documentation dated March 23, 1982 and referenced in License Condition 27.B. states, in part, that bioassay frequency as referenced in the Radiation Safety Manual, revised June 1984, will be 10 working days for iodine-131 or 25 working days for iodine-125. Presently bioassays are performed monthly for workers involved in diagnostic and/or therapeutic use of volatile iodine-125 and iodine-131.

As part of the team inspection effort, licensing representatives will clarify the frequency of bioassays under specific regulatory requirements during the license renewal process.

A review of bioassay results indicated that 10 CFR Part 20 concentration limits were not exceeded.

No violations of NRC requirements were identified.

6. Inventory

License Condition No. 8 specifies activity limits for all authorized radioisotopes. RSS is aware of those possession limits and as they receive most incoming shipments of radioactive materials, the limits are continuously monitored by a computer database system. A sampling of inventory records was reviewed during the inspection with no discrepancies noted.

No violations of NRC requirements were identified.

7. Receipt and Transfer

Radioactive material arrives at the University by common carrier from various suppliers and distributors of radioactive material. All radioactive material coming into the University is received at RSS where it is entered into the master inventory then checked for contamination prior to distribution to the authorized users. During 1989, 8,578 packages of radioactive material containing 167,369 millicuries of various radionuclides were received by RSS for distribution. In 1988, a computer database system for tracking packages was instituted which identifies possible errors in ordering and/or shipping and alerts the RSS staff if such an event occurs. To verify the information contained in the computer system, every six months a letter is sent out to each authorized user of radioactive material and requests that they verify the information against the user's records for accuracy and return the form to RSS.

Other radioactive material is produced at the University with a 30 MEV cyclotron and at the Ford Nuclear Reactor (FNR). The materials produced in the cyclotron are used primarily in the Positron Emission Tomography (PET) facility. Transfer of material from the PET facility to the Nuclear Medicine Department

is by way of a pneumatic transfer system. Transfers of material from FNR to other areas of the campus is performed by RSS staff. During 1989, the licensee made approximately 911 internal transfers of radioactive material (laboratory to laboratory) containing approximately 8,902 millicuries of various radionuclides.

License Condition No. 24 of License No. 21-00215-04 requires the licensee to transport licensed material or deliver licensed material to a carrier in accordance with the provisions of 10 CFR Part 71. 10 CFR 71.5(a) requires that the licensee comply with the regulations in 49 CFR Parts 170 through 189. During the NRC inspector's review of procedures to ensure proper transfer and transport of radioactive materials, it was noted that for materials being transported from the PML (North Campus) to the University Hospital (Central Campus), the licensee did not label packages and prepare shipping papers as required in 49 CFR for internal transfers of radiopharmaceuticals. The failure by the licensee to label packages and prepare shipping papers for radiopharmaceutical transfers from PML to other areas of the campus constitutes an apparent violation of License Condition No. 24. This item was discussed with University staff at PML and RSS and all individuals were unaware that this license condition applied to internal transfers within the University system while traveling over public roadways. The licensee immediately implemented a new procedure (Procedure No. 111) entitled, "Radioactive Material Release and Shipment," trained all cognizant staff involved in internal transfers and assured the NRC inspectors that the new procedures would be implemented immediately. Full implementation of Procedure No. 111 was verified during the team inspection. A response to this apparent violation is not required as corrective action was taken during the inspection.

Nuclear medicine and radiation therapy pharmaceutical doses are prepared in the Nuclear Pharmacy and are made available for pickup at the designated pharmacy window. All syringes containing radioactive material are shielded by pharmacy technicians prior to pickup by the nuclear medicine staff. Doses sent to C. S. Mott Childrens Hospital are prepared specifically for pediatric administration and are transported in lead shields. Syringe shields are available and are used at this nuclear medicine satellite facility.

The Nuclear Pharmacy receives two 2.7 curie molybdenum-99/technetium-99m generators each week. A review of the quality control records revealed that the licensee performs molybdenum-99 and alumina breakthrough tests on each elution. Chromatography checks are performed on at least one daily elution. The licensee representative stated that "super kits" were not used. The Quality Control/Quality Assurance (QC/QA) tests indicated the distributed products to be greater than 95% pure.

One apparent violation of NRC requirements was identified.

8. Instrumentation

The University uses a variety of radiation detection instruments. Instruments used to detect and measure ambient radiation fields and to quantify contamination levels are calibrated in-house using appropriate calibration standards. Instruments used to specifically quantify radiation hazards are calibrated on an annual frequency.

Stationary room monitors are used to detect unexpected increases in radiation levels in various clinical and research areas. All monitors reviewed during the inspection appeared fully functional. One concern regarding radiation monitor systems was noted at the Willow Run self-shielded irradiator facility. A "Caution-Radiation" illuminated sign outside the irradiation room displays if the monitor detects radiation. When the monitor was exposed to a radiation field, the sign was delayed several seconds before illuminating. The sign is apparently fitted with a fluorescent light bulb which is slower to illuminate than an incandescent bulb would be. It was recommended that the sign be replaced or modified to immediately identify radiation level increases outside the irradiator room.

The licensee uses Capintec dose calibrators. Two are used in the Nuclear Pharmacy (Model No. CRC-12 and CRC-10R) and one Model No. CRC-10N in C. S. Mott Childrens Hospital. Dose calibrator constancy, linearity, and accuracy checks appear adequate and are performed at the required frequencies.

The NRC inspectors observed the pharmacy technician conduct a constancy check on a dose calibrator and observed a mock generator elution, to include a check of the eluant for molybdenum-99 and alumina contamination, as well as chromatography purity verification.

Another dose calibrator is used in the PML for verification of the IND product doses prior to distribution. This instrument is not calibrated because doses are calibrated upon receipt by the hospital. It would be prudent for the licensee to calibrate the dose calibrator, in accordance with 10 CFR Part 35 requirements, to provide an additional check of the doses.

No violations of NRC requirements were identified.

9. Security

The Phoenix Memorial Laboratory and Ford Nuclear Reactor have controlled, escort-required access.

Inadequate security was identified in the School of Public Health, Engineering Bay. Approximately 400 millicuries of carbon-14 are in use in lysimeters which simulate waste landfill environments. The Engineering Bay door was closed but not secured or under the direct surveillance of the licensee. The unsecured door leads to an unrestricted hallway. The failure to maintain proper security constitutes a violation of 10 CFR 20.207 which requires: (1) licensed material be secured from unauthorized removal from the place of storage; and (2) licensed material not in storage to be tended under the constant surveillance and immediate control of the licensee. The licensee corrected this violation during the inspection by installing a lock on the access door. The RSO stated that licensed material use areas around the University would be reviewed in the next few weeks to assure compliance with 10 CFR 20.207. A response to this apparent violation will not be required as corrective measures have been taken.

Other University facilities appeared to be in compliance with 10 CFR 20.207 requirements; however, a recommendation was made with regard to the Nuclear Pharmacy. During this and a past NRC inspection, it was noted that control of nuclear medicine doses could be improved in the Nuclear Pharmacy. It was recommended that doses be kept at an appropriate distance from the pickup window and/or that Nuclear Medicine technologists specifically ask for the dose at the window to prevent unauthorized removal of radioactive material from the pickup area.

Medical brachytherapy sealed sources are secured within a locked preparation room in either a locked safe or cabinet. Twenty physicists have keys to the preparation area. Security in the area appears adequate. Transportation of sources to patient rooms for implant is performed in authorized shielded pull-carts. Sources are implanted in dedicated patient rooms to minimize transportation of sealed sources in unrestricted areas of the hospital.

One apparent violation of NRC requirements was identified.

10. Posting and Labeling

Walkthrough inspections of the PML, nuclear pharmacy, nuclear medicine, radiation oncology, waste disposal facilities and research laboratories identified compliance with NRC requirements. Restricted areas were appropriately posted with "Caution-Radioactive Material," "Caution-Radiation Area" and/or "Caution-High Radiation Area" signs. Packages, drums and other containers were also labeled as required.

NRC Form-3 documents and notices describing the location of 10 CFR Parts 19 and 20 are posted at various locations throughout the University.

No violations of NRC requirements were identified.

11. Waste Disposal

The largest percentage of University radioactive waste is due to research-related activities, primarily medical. RSS is responsible for the collection, storage, analysis, processing, manifesting and disposal of all radioactive waste generated by the University. Waste is comprised of six basic forms:

a) Dry solids
b) Animals
c) Air releases
d) Aqueous liquids
e) Organic liquids
f) Scintillation fluid

RSS supplies fiber drums and plastic jugs to researchers for collection of wastes. When a container is filled, RSS is called to retrieve the waste for processing. Waste generators are responsible for the proper segregation and quantification of waste sent to RSS; however, a waste analysis is performed by RSS prior to disposal. Researchers are informed of discrepancies identified by those analyses.

Solid, dry waste is placed in reusable fiber drums with plastic linings. The contents are compacted into 55-gallon steel drums (DOT-7A, 17H) for commercial disposal or for decay-in-storage at the Willow Run facility. Approximately 70% of waste is long-lived (half-life greater than 60 days) and shipped to a commercial waste site via a waste broker. Shipments are performed about every three weeks. Short-lived materials are stored at Willow Run for decay, surveyed and disposed of as normal trash. Waste containers stored at Willow Run show some deterioration (e.g., rusting drums) due to exposure to the elements in unheated buildings. The RSO stated that a shortage of technicians has caused a back-up of waste in storage. Some of the drums at the facility bear dates of 1984, indicating material that is long since decayed to background levels. It was recommended to the licensee that old, decayed waste in storage be processed and delabeled in a more expedient manner.

Animal carcasses are normally transferred directly by RSS from research laboratories to the North Campus pathological incinerator. That incinerator is licensed and approved for the cremation of sacrificed research animals, animal bedding, feces and blood containing tracer quantities of radioactive material. It is the only incinerator at the University licensed for radioactive material disposal. The incinerator is located on the North Campus in a fenced area. University maintenance personnel work in and store equipment and supplies in adjacent buildings in the fenced area. This site is planned to be a new waste handling facility which is proposed for Spring 1991.

The facility would handle the processing and storage of waste currently performed in the RSS offices and at Willow Run. It was recommended to the licensee that an evaluation be performed as to whether or not to have a combined waste facility/ maintenance personnel operation as is currently in place. The incinerator is secured when not under direct supervision of RSS personnel.

During 1989, approximately 125 incinerator burn days were recorded. The records indicate that over 500 animal carcasses were incinerated during this period. In addition to carcasses, the incinerator burns included animal bedding and plastic animal cages. The NRC inspectors reviewed the licensee's evaluation of gas effluent monitoring to restricted and unrestricted areas around the incinerator to determine compliance with 10 CFR 20.106 and 20.103. The inspectors concluded that air releases meet NRC requirements. It was concluded; however, that the licensee needs to reevaluate the incinerator air effluent waste streams to ensure future compliance (see concerns identified below).

The licensee continuously monitors the incinerator stack effluent with an activated charcoal and particulate sampler (non-isokinetic). The samples are analyzed for gross beta and radioiodine concentrations. Particulate sampler filter papers are exchanged weekly. The maximum concentration identified in 1989 for particulate samples was 3.285 E-11 microcuries/milliliter (uCi/ml), well within 10 CFR 20.106 unrestricted limits for the isotopes incinerated (i.e., carbon-14, hydrogen-3, phosphorus-32, sulfur-35, scandium-46, etc.).

Iodine charcoal samples are analyzed bi-weekly by NaI spectroscopy. Most of the iodine released from the burns is iodine-125. The maximum concentration collected on the incinerator stack outlet was 1.018 E-09 uCi/ml, which is higher than 10 CFR 20.106 limits for release to an unrestricted area (8.0 E-11 uCi/ml). The unrestricted area limit was exceeded at least twice in 1989, for weeks ending July 24, 1989 and November 10, 1989. The licensee has, however, maintained the roof of the two-story incinerator building, approximately 18 feet below the stack opening, as a restricted area. Access to the roof area is not allowed during incinerator operations. Therefore, the excessive concentrations do not constitute a violation of 10 CFR 20.106 when considering dilution factors.

The licensee maintains an air sampling station on top of the nearest building (campus laundry, 130 feet distant) with a sampling system similar to that on the incinerator stack. Particulate and radioiodine sample concentrations were well within 10 CFR 20.106 limits in 1989.

Specific weekly incineration limits for particular isotopes are referenced in License Condition No. 27 (March 23, 1983 letter). Releases have been maintained under those limits for burns in 1989.

Three concerns were raised during the inspection regarding the incinerator program.

- Air monitoring is not performed on the incinerator building roof or on the ground near the incinerator building to verify that air concentrations meet 10 CFR Part 20 requirements. NOTE: Air monitoring on the stack and laundry building, while keeping within burn limits was approved by the NRC in License Condition No. 27.

- Air monitoring is not performed at stations in the prevailing wind downwind direction. The prevailing winds in the area travel from the southwest to the northeast. The laundry building, where the air sampler is located, is due east of the incinerator.

- The licensee conservatively records the entire radioactive content of incinerated pathological waste to have been volatilized into the air, when it has not, such as isotopes which remain fully or partly in the resultant ash. An obvious example of this is radioactive microspheres, which are not volatilized during incineration. Conversely, the licensee also records the entire radioactive content of incinerated material as having been retained in the ash, which is obviously not the case. Licensee waste disposal records for incinerated material therefore account for twice as much radioactive material waste as has actually been produced. The shipping manifest which accompanies ash to radioactive material burial sites is therefore also overestimated.

A breathing zone air monitoring system is operated continuously inside the incinerator building. Particulate and radioiodine concentrations measured in 1989 were well within 10 CFR 20.103 and 20.106 standards.

Other radioactive air effluent sites exist under the broadscope license program. These facilities primarily release small amounts of radioiodine. The PML and approximately 15 iodination facilities have appropriate air monitoring equipment in place. A review of 1989 air effluent records for these facilities showed that 10 CFR 20.106 release limits are being met. No releases in excess of NRC regulatory limits were identified for these facilities.

Liquid waste is collected in reusable single-seam plastic jugs provided by RSS. Generators are instructed to segregate liquids into aqueous, organic and scintillation fluid categories. Laboratory personnel are not allowed to dispose of radioactive material into the sewer system. All jugs are sampled by RSS personnel by counting a one milliliter aliquot in a liquid scintillation counter. Aqueous waste, which accounts for approximately 90% of liquids, if short-lived, is stored for decay at the Willow Run facility. If the radioactive material has a long half-life (> 60 days), it is absorbed and shipped for commercial disposal. Sewer disposal of aqueous waste is performed, normally, only after decay to background levels.

An incident did occur, however, on December 1, 1989, in which concentrated aqueous radioactive material awaiting absorption was disposed of to the sewer system. The licensee filed a report to the NRC per 10 CFR 20.405(a) on December 19, 1989. The disposal occurred when a technician mistakenly dumped eighty-eight gallon jugs of waste. The waste contained 115 millicuries of hydrogen-3, 12 millicuries of sulfur-35, 0.2 millicuries of carbon-14 and 0.03 millicuries of iodine-125, all aqueous solutions. Considering the volume of water released, over 5000 gallons/day from local buildings (North University, Dental, Power Plant), the inspection determined that sufficient dilution occurred to diminish concentrations below 10 CFR 20.303 limits. The release did not constitute a violation of NRC regulations and was not required to be reported per 10 CFR 20.405(a).

Non-aqueous liquid waste (organics, liquid scintillation fluid) is disposed of as chemical waste. The licensee has used biodegradable (non-toluene, non-xylene) liquid scintillation cocktails since 1988.

A sludge sample was taken by the NRC inspectors at the Ann Arbor waste water treatment plant which handles sewage from the campus. The sludge is currently being analyzed for isotopic content. The purpose of the sampling is to determine whether isotopic reconcentration is occurring in the sewer system. A significant result would not necessarily be due to University operations as the sewage system is shared with other radioactive material users. The analysis report will be reviewed with the licensee when it is received. Should significant concentrations be found, the licensee intends to initiate further investigation into the origin of the material.

Radioactive material waste produced in the clinical medical program is held in the radiopharmacy area and is segregated according to short and long-lived material. This waste, including molybdenum-99/technetium-99m generators, is stored for at least ten half-lives, surveyed to assure radiation levels cannot be distinguished from background and released for

disposal as ordinary trash. Iodine-131 in liquid form is sent to the RSS for disposal. Disposal records and results of surveys are maintained as required.

The licensee had three incidents involving the release of disposable diapers containing diagnostic, microcurie amounts of iodine-131. On February 14, 1990, March 6, 1990 and March 20, 1990, the licensee inadvertently released contaminated diapers to the normal trash. The contaminated diapers triggered a commercial landfill's sodium iodide detectors indicating the presence of radioactive material.

With reference to the March 20, 1990 release, the licensee realized that diapers containing iodine-131 had been placed in a dumpster. The dumpster was fully loaded and retrieval before dispatch to the landfill would have been very difficult. The licensee assigned a technician with a GM detector to monitor the shipment as it was being transported to the landfill to detect the contaminated diapers as the entire dumpster was unloaded. During unloading, the contaminated diapers were retrieved as planned. The licensee subsequently recovered all diapers contaminated with iodine-131 for the other two incidents as well. The quantity of iodine-131 that was reportedly in the disposed diapers ranged from 150 to 290 microcuries. 10 CFR 20.301 requires that no licensee dipose of licensed material except by certain referenced procedures. The licensee's release of licensed material for disposal in normal trash is a violation of 10 CFR 20.301.

One apparent violation of NRC requirements was identified.

12. Notifications and Reports

No exposures in excess of 10 CFR Part 20 limits were identified. No thefts or losses of licensed material were reported during the inspection period (see the previous section of this report for review of incidents involving shipments of diapers containing radioactive material).

During a previous inspection, one violation was cited for failure to report diagnostic misadministrations. The licensee has since modified reporting procedures to notify NRC of misadministrations as required by 10 CFR Part 35. RSS is responsible for reporting the misadministrations. A review of records and reports revealed that the licensee had five diagnostic misadministrations since May 1988, all of which were reported to NRC.

No violations of NRC requirements were identified.

13. Independent Measurements

Radiation measurements were performed with an Eberline E-520 end window GM, Serial No. 2181; Xetex 305B GM, Serial No. 13168; and

Xetex 305B, Serial No. 8365. All NRC instruments were calibrated in January 1990.

Radiation levels in unrestricted areas were found to be below 10 CFR 20.105 limits. Radiation levels in restricted areas appeared acceptable and were in good agreement with surveys performed with University instrumentation.

Independent measurements outside the room of an in-house radiation therapy patient revealed no readings above 10 CFR Part 20 limits in the hallways and adjacent patient room.

No violations of NRC requirements were identified.

B. License No. 21-00215-05

This license authorizes the use of a Theratron 80 teletherapy machine for purposes of non-human irradiation research in the 1331 building at 1331 E. Ann Street. Currently, a sealed cobalt-60 source of approximately 2250 curies is installed in the unit. A new source is expected in 1990. The machine is used to irradiate animals, biological samples and inanimate objects. The unit is used under the supervision of six authorized users who are named on the license. One of the authorized users must be within five minutes of the unit before it may be operated by one of 27 operators currently trained to use the teletherapy machine. All operators and users wear film badges which are exchanged on a monthly frequency. No significant radiation exposures have been identified.

The console-door-unit interlocks appear to be functioning as required by the license and in accordance with 10 CFR 20.203(c)(6). The audible and visual alarms and the interlock system were tested during the inspection and appeared adequate. Authorized users audit the teletherapy safety systems on a monthly frequency as required.

In addition, a quality control (QC) checklist is completed for each day that the irradiator is used. The checks appear to be performed as required with one minor exception. A review of QC checks identified several failures to test one of the two emergency stop buttons on the treatment couch; however, the other button was tested adequately. Medical physicist and authorized user, Karen Hutchins, stated that frequent audits of the checklists will be performed by the authorized users to assure that all QC checks are performed according to University policy. These checks will be in addition to the monthly audits of the entire teletherapy safety system.

An in-room radiation monitor with battery back-up provides operators a secondary beam condition indicator. It was suggested during the inspection that the battery unit be tested during the monthly safety system tests. Portable calibrated survey instruments are readily available, if needed.

Leak tests of the sealed cobalt-60 source are performed every six months as required by License Condition No. 12.

The licensee is aware of reporting requirements for source installation, room modification or changes in the use of the teletherapy unit. A change in shielding was appropriately reported to the NRC in January 1989. No other modifications have been made, according to Ms. Hutchins.

Confirmatory surveys by the NRC inspector in the teletherapy room and in areas adjacent to the room showed compliance with 10 CFR 20.105 and 20.201.

No violations of NRC requirements were identified for this license.

C. License No. 21-00215-06

This license authorizes the use of cobalt-60 sealed sources in a pool irradiator located at PML. Current loading of the irradiator is approximately 9200 curies. The facility is operated by a single individual, Mr. Robert Blackburn, with health physics support from RSS and the research reactor staff.

The irradiator is used for gamma sterilization of research materials and for irradiation of bone cartilage (human and animal). The cartilage irradiations are performed for University research scientists as well as commercially for various tissue banks.

Irradiator construction and equipment appears to be as described in the license application dated September 21, 1972. The only modification since the last inspection occurred in April 1989. At that time, the water supply and drain pipes to the pool were shortened to approximately 16 inches below the water surface to prevent a possible siphoning effort from draining a significant quantity of water from the pool. This modification is not forbidden by License Condition No. 15 of the license which limits alterations of the irradiator.

Leak tests of the sealed sources are performed at six month intervals by analyzing pool water samples with a gas proportional detector. No unusual results have been detected. A suggestion was made during the inspection to procure test samples from the bottom portion of the pool rather than near the surface as is presently done. Leaking cobalt-60 products may be relatively insoluble and have a high density decreasing the probability of finding the material near the pool surface.

The following safety systems were checked for proper operation during the inspection:

- Source hoist system
- Door interlocks

- Pool limit switch
- Pool lid displacement microswitch
- Emergency stop button
- Audible and visible alarms
- Radiation monitor

No problems were identified for these systems. The systems are checked for proper operation on a quarterly frequency by the licensee. Records of the above referenced tests are maintained as required.

Area surveys are performed monthly and wipe tests are conducted daily in the PML facility. No significant radiation levels or contamination have been detected around the irradiator facility. Personnel radiation exposures are well within 10 CFR Part 20 limits. NRC surveys with a Xetex 305B GM survey instrument confirmed the licensee's findings.

Pool water quality was discussed in detail during the inspection. The pool water is continuously recirculated through an ion exchange resin bed. License Condition No. 16 (November 19, 1973 and March 27, 1979 letters) requires that the water be checked every six weeks for conductivity. The licensee, however, stated that pool water conductivity is not routinely measured at the facility and has not been measured since at least 1988. The failure to test the irradiator pool water for conductivity on a six-week frequency constitutes an apparent violation of License Condition No. 16.

The inspector performed a conductivity measurement of the pool water with a Fisher Scientific Model 09-327 conductivity meter, Serial No. 15220. The pool water conductivity was measured to be 3.1 micromhos, well below the industry standard of 10 micromhos. The pool water conductivity and purity appear adequate.

One apparent violation of NRC requirements was identified for this license.

D. License No. SUD-1398

This Source Material License authorizes 2,500 kilograms of natural uranium in the form of annular slugs canned in aluminum tubes for a subcritical assembly, in storage. The NRC inspectors observed the unit in storage in the northwest corner of the Beam Port Floor of the Ford Nuclear Reactor Building. The licensee performs an inventory and leak test of the slugs every six months. There are approximately 1,432 slugs and each fuel rod is made up of four slugs. The NRC inspector observed that one slug appeared distorted and recommended that the licensee immediately remove the slug and properly dispose of it.

No violations of NRC requirements were identified for this license.

E. License No. SNM-179

This Special Nuclear Material license authorizes various plutonium-238 and 239 sealed sources along with specified uranium and plutonium target foils. This license also authorizes neptunium-237 and americium-243 (byproduct materials). These materials are authorized for laboratory research, student instruction, instrument calibration, and activity standards. Most of the licensed materials possessed under this license were in storage in the Beam Port Floor and Floor 1 of the Ford Nuclear Reactor Building. The NRC inspector's review of records of inventory, wipe tests and direct area radiation surveys showed all records to be complete and accurate. During the NRC inspector's review of authorized user protocols under this license, it was noted that a protocol was submitted and approved for use of 50 milligrams of neptunium-237 (powdered oxide) in 1983; however, in April 1985, a researcher working under the supervision of the authorized user, ordered and may have received 50 milligrams of neptunium-237 in liquid form. This chemical and physical form was not authorized in the license at that time; however, it was unclear if the researcher received the material in liquid form or if it was received in powdered form and then changed to liquid form. This apparent deviation from an approved protocol was discussed with the licensee. This event appears to be an isolated event and the NRC inspectors could not find any indication that this was an ongoing problem.

Licensed material used and stored under this license are secured in locked storage vaults and secured areas within the Reactor Building. Four keys are distributed to selected staff for the materials stored on Floor 1 and only two keys are available to selected staff to the locked vaults in the Beam Port Room.

No violations of NRC requirements were identified for this license.

F. License No. SNM-1377

The nuclear pacemaker program was last inspected in August 1987. One violation was identified for failure to return a nuclear pacemaker to the manufacturer following removal in 1978. A review of this area during this inspection indicated that licensee has taken corrective action and this issue is considered closed.

Presently, the pacemaker program follows three patients, one pediatric (Coratomic Model C-101) and two adults (both Medtronic 9000). No implants have been performed since approximately 1977 and no new implants are planned. A review of records indicated that the pediatric patient has been followed-up annually by the licensee and semiannually by a cardiologist in Bay City, Michigan. The licensee has experienced some difficulty following this patient due to changes in her physician and home address. The licensee has made both telephone (March 1990) and letter (June 1989) attempts to follow-up on this patient. The patient and her family have been

made aware of the need to maintain contact with the Pacemaker Surveillance Program. This was documented in a letter to the patient dated June 28, 1989.

The licensee was reminded of Information Notice No. 86-59: "Increased Monitoring of Certain Patients with Implanted Coratomic Inc. Model C-100 and C-101 Nuclear-Powered Pacemakers," and will adjust its follow-up procedures to reflect the recommended three-month frequency. It was suggested that the licensee use the patient's new physician as liaison between the University and patient for future follow-ups.

The licensee maintains close rapport with both adult pacemaker patients and is making contact at six-month intervals. The last disposal (by return to the manufacturer) occurred in January 1989. The last adult implant was in February 1977.

There have been no reported malfunctions or adverse reactions associated with the nuclear pacemakers implanted by the licensee.

One incident involving a Medtronic 9000 pacemaker occurred in March 1988 when an implanted patient died and the pacemaker was not recovered. The licensee conducted a detailed investigation and determined that the pacemaker could not be found. The NRC was notified of the incident in a letter dated March 10, 1988.

No violations of NRC requirements were identified for this license.

G. License No. SNM-1529

This license authorizes the possession and use of a plutonium/beryllium neutron source in Room B157, School of Public Health, Central Campus. The device consists of 15 grams of plutonium-239 and 1 gram of plutonium-241 in a sealed source (Monsanto Research Corporation). The source is authorized to be used for the irradiation of personal dosimeters and is stored in a 15 gallon, paraffin-filled steel drum. According to RSS personnel, the source has not been used since at least 1988.

Leak tests are performed on the source at six-month intervals as required with the last test being performed in October 1989. A concern was identified during the inspection that the closure ring on the drum was broken and would not close. This defective ring was also noted by RSS personnel performing leak tests over the last year. It is recommended that the licensee repair or replace the broken ring to ensure that the drum is adequately sealed.

Radiation levels around the drum were measured with a GM survey instrument. No significant or unusual radiation levels were detected. Neutron measurements were not performed during this inspection.

No violations of NRC requirements were identified for this license.

H. License No. SNM-1835

This neutron howitzer is authorized to be used by, or under the supervision of individuals designated by Henry C. Griffin, Ph.D., Chairman, Radiation Policy Committee. The source size of 80 grams of plutonium does not exceed the authorized possession limit.

The howitzer is used by research staff to bombard stable elements, (i.e., silver, iodine, or iridium), and study the radioactive byproducts of the bombardment for half-life, beta detection and emissions. Dr. Griffin intends to begin using the unit again for research and teaching purposes in the fall of 1990.

The unit is secured by means of a locked lid and is locked in Laboratory Room 3514 in accordance with the license conditions.

Independent measurements of the howitzer were taken with a Xetex 305B GM, calibrated January 9, 1990, revealing 2.5 mR/hr at the unit surface and 0.6 mR/hr at one foot. Comparison measurements with the licensee's pancake probe provided similar results.

The license generally performs leak tests of the unit at intervals not to exceed six months. However, between May 25, 1989, and March 8, 1990, no leak test of the neutron howitzer was performed. License Condition No. 12.A.(1) requires that the sealed howitzer source be tested for leakage and/or contamination at intervals not to exceed six months. The failure by the licensee to perform leak tests at six-month intervals is a violation of License Condition 12.A.(1).

Dr. Griffin verified that only students enrolled in the research or Senior Honors research program are permitted to operate the unit.

One apparent violation of NRC requirements was identified for this license.

VII. Exit Meetings

Two separate exit meetings were conducted at the University of Michigan facilities on March 16 and March 22, 1990. Licensee attendance at these meetings is detailed in the Persons Contacted section of this report. University representatives were informed of NRC inspection findings, apparent violations, concerns and license renewal expectations. No written material was left with the licensee. In addition, no proprietary information is included in this report.

Attachments:
1. U.S. EPA Inspection Report dated April 10, 1990
2. Michigan Department of Public Health Inspection Report dated April 9, 1990.
3. U.S. FDA Inspection Report dated March 15, 1990.

ATTACHMENT 1

U.S. Environmental Protection Agency
Inspection Report
April 10, 1990

ATTACHMENT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
230 SOUTH DEARBORN ST.
CHICAGO, ILLINOIS 60604

REPLY TO THE ATTENTION OF:

APR 10 1990

Darrel Wiedeman, Chief
Nuclear Materials Safety Section No. 1
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Wiedeman:

Thank you for the opportunity to participate in the Nuclear Regulatory Commission (NRC) Team Inspection of the University of Michigan in Ann Arbor Michigan on March 13, 1990. As requested, I am enclosing observations made by the Radiation Program Staff on the radiation facilities observed on that date. These observations are related to the radionuclide emission standard at 40 CFR Part 61, Subpart I, 54 Federal Register 51697 (December 15, 1989), the "National Emission Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H".

Briefly, the radionuclide emission standard for facilities subject to Subpart I is twofold. As stated in 40 CFR 61.102, emissions of radionuclides from a facility, including iodine, shall not exceed those amounts that would cause any member of the public to receive an effective dose equivalent of 10 millirem per year (mrem/yr). Also, emissions of iodine shall not exceed those amounts that would cause any member of the public to receive an effective dose equivalent of 3 mrem/yr. Compliance with this emission standard is determined through the use of either the United States Environmental Protection Agency (EPA) computer code COMPLY or the alternative requirements of Appendix E (§61.103). Facilities are subject to permitting, reporting and monitoring requirements, as well.

Our general concern at the University of Michigan is related to the operation of the "North Campus Incinerator". Current calculations of maximum allowable burn quantities, the current stack sampling scheme and flow rate measurements, and current radionuclide isotopic analyses performed on stack emissions suggest that operation of the incinerator would probably not meet the dose standard and emission monitoring requirements of Subpart I. Please see the attached recommendations.

The University of Michigan Radiation Safety Services (RSS) staff needs to carefully survey all release points on the campus, using the required computer model COMPLY, to address the emission monitoring requirements of §61.107(b)(4)(i). This will require more effort than, it appears, was originally anticipated. The problem is complicated by the fact that different maximally exposed individuals reside/work in proximity to each

emission point. However, it appears to be soluble by direct application of the COMPLY users manual. We would encourage RSS to begin to seriously think about this task.

Finally, the Radiation Safety Staff should become generally familiar with the Subpart I regulations, to ensure they are in compliance with other requirements.

Please note that Subpart I is stayed until July 13, 1990, which essentially means that the radionuclide standard for NRC licensees will be in effect on that day, and the licensees will have 90 days after the effective date to be in compliance with the standard.

If you have any questions about these observations, please contact Deborah Arenberg or James Benetti, of my staff, at (312)/FTS 353-2654 or (312)/FTS 886-6175, respectively.

Sincerely yours,

Gary V. Gulezian
Radiation Program Manager

Enclosure

cc: Mark Driscoll, Acting Radiation Safety Officer
University of Michigan

George Bruchmann, Chief
Division of Radiological Health
Michigan Department of Public Health

Nuclear Regulatory Commission Team Inspection

University of Michigan

March 13, 1990

United States Environmental Protection Agency Points of Concern
Related to the Radionuclides NESHAPs Standard at 40 CFR 61, Subpart I

NORTH CAMPUS INCINERATOR

A. The COMPLY code needs to be run on the current incinerator configuration in order to derive maximum allowable burn quantities. The point of application (receptor) should be the laundry at 130 feet from the stack base. Note that the total effective dose equivalent for this receptor point from the combined isotopes (including iodines) from the incinerator and any other release points must not exceed 10 mrem/yr and for iodines must not exceed 3 mrem/yr.

B. The use of emission control equipment on the incinerator or increasing the stack height should be seriously considered. It may be that the application of a 10 mrem/yr (3 mrem/yr iodine) standard at the same point of compliance (laundry) at which derivation based upon 500 mrem/yr analysis have been applied may so severely limit burn quantities that these measures would offer the only means of practical operation of the incinerator.

C. Isokinetic sampling should be installed on the stack (post controls, if installed) per requirements of 40 CFR 61.107 in 54 Federal Register 51697 dated December 15, 1989.

D. Analysis needs to be performed using the COMPLY code to determine which isotopes contribute 10% or greater to the total effective dose equivalent for the incinerator (iodines included). Analysis of stack samples needs to be conducted for each such isotope which contributes to 10% or greater, and for each iodine isotope. Note that the analysis methods must meet the requirements of Appendix B, Method 114.

E. The current stack sampling scheme departs from requirements of the standards at §61.107 (not isokinetic) and from guidance of ANSI N.13.1. There is a bend in line of the iodine sampler prior to the cartridge and there is no flow rate calibration. This would be a moot point if an isokinetic sampler were installed.

GENERAL

A survey using the COMPLY code should be made for all release points on the campus. All release points having potential to result in any member of the public receiving in excess of 0.1 mrem/yr (all isotopes) or 0.3 mrem/yr (iodine) need to be addressed per the requirements of §61.07 (b)(4)(i).

ATTACHMENT 2

Michigan Department of Public Health
Inspection Report

April 9, 1990

ATTACHMENT 2
C#108061094
SIC #8221

STATE OF MICHIGAN

JAMES J. BLANCHARD, Governor

DEPARTMENT OF PUBLIC HEALTH

3423 N. LOGAN
P.O. BOX 30195, LANSING, MICHIGAN 48909
Raj M Wiener, Director

April 9, 1990

Darrel Wiedeman, Chief
Nuclear Materials Safety Section No. 1
United States Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mr. Wiedeman:

Our Division wishes to thank you for the opportunity to participate in your team inspection at the University of Michigan during the week of March 12 - 16, 1990. We believe that such cooperation between state and federal programs not only allows for a more comprehensive inspection but also allows our staff an opportunity to audit and review our own inspection practices. We believe that future cooperation between our staff should be encouraged.

Our facility walkaround included tours of Laboratories 3105 and 3230, Dow Building, and of Waste Storage Rooms 1118 and 1112, North Union Building. We also reviewed equipment aboard UM's Haz - Mat Response Truck. Occupational health programs and documentation pertaining to facility emergency planning, response and investigation were reviewed.

We wish to thank UM's Occupational Safety and Environmental Health staff, especially Kathryn Barnes and Michael Dressler for their assistance throughout our inspection. A closing conference was held with Ms. Barnes, Mr. Dressler, Edward Valentine and Kenneth Schatzle to review our inspection findings and recommendations.

Part I of the attached report contains a summary of our major inspection findings and recommendations while Part II provides a more detailed inspection record.

Please feel free to contact this office if you have any questions regarding any aspect our participation in your inspection or these findings and recommendations.

Sincerely,

BUREAU OF ENVIRONMENTAL
AND OCCUPATIONAL HEALTH

William W Bosch

William W. Bosch, Ind. Hygienist
Division of Occupational Health

APR 11 1990

WWB:kh
Enclosure

I. Summary of principle inspection findings and recommendations.

The University of Michigan (UM) must develop a comprehensive Emergency Response Plan which meets the requirements of 29 CFR 1910.120, paragraph (Q).

UM must improve their Respiratory Protection Program as it pertains to expected respirator use during emergency response activities.

We recommend UM increase its Occupational Safety & Environmental Health (OSEH) staff involvement in laboratory activities, especially in employee training and laboratory safety surveys.

We recommend UM improve its Material Safety Data Sheet (MSDS) storage/retrieval system to more quickly provide MSDS to laboratory staff.

In general, we observed excellent occupational safety and hygiene practices and programs in toured laboratories. Please see Section II for specific comments.

1) Our inspection indicated UM laboratories use a wide variety of highly toxic, flammable or otherwise hazardous chemicals in small quantities. Typically, each laboratory may have several gallons of solvents, caustics and acids in one gallon glass containers, powdered materials in plastic containers and cylinders of various flammable and/or toxic gases. Due to the large number of laboratories and employees handling hazardous chemicals we believe UM has a high potential for laboratory spills or gas/vapor releases. While the small container size is a limiting factor in quantity that could be released, a spill of even one gallon of a flammable and/or toxic chemical could lead to employee injuries and/or laboratory fire.

2) The OSHA "Hazardous Waste Operations and Emergency Response" standard, 29 CFR 1910.120 requires facilities using hazardous chemicals to develop evacuation and/or emergency response procedures. Each facility must differentiate between "incidental releases" which can be handled by employees in the immediate release area and "emergency response" which is conducted by responders from outside the immediate release area. UM must develop criteria to evaluate chemical releases as an "incidental" or "emergency" release.

3) UM has an emergency response team staffed by OSEH personnel. 29 CFR 1910.120 would require emergency response team personnel to be trained as required by paragraph (q)(6)(ii), "First Responder Operations Level", or paragraph (q)(6) (iii), "Hazardous Materials Technician", depending on desired staff response capabilities. Our discussions with OSEH staff indicate UM's desire to train emergency responders as "Haz-Mat Technicians" to allow the greatest on-site response capabilities. Therefore, emergency responders must receive 24 hours of initial training in emergency response procedures.

4) A written Emergency Response Program must be developed to meet requirements of 29 CFR 1910.120, paragraph (Q)(2). A written Emergency Action Plan, addressing evacuation on non-essential personnel in emergency conditions, must be developed to meet 1910.38 (A) requirements. Evacuation routes should be posted in all buildings.

5) Several types of staff, with different levels of education or experience, may be present in UM laboratories when a chemical release occurs. These may include Professors, Research Assistants, Teaching Assistants, Maintenance, Janitorial or Custodial staff. Each laboratory's head administrator (usually Professor) is responsible for ensuring his staff receive training required by the Hazard Communication Standard (HCS), paragraph (h), which is provided by OSEH staff. To ensure proper training of all employees who may, at some time, work in UM laboratories during normal and potential emergency conditions, we recommend:

   A. OSEH staff should check the UM employee register against their Hazard Communication trainee list to ensure all employees have received basic information and training required by the HCS. Employees who haven't received HCS required training should be scheduled for training as soon as possible.

   B. Laboratory staff must be trained to recognize and respond to "incidental" and "emergency" releases in an appropriate fashion. Since any employee who works in a laboratory may discover an emergency response condition, we recommend staff be trained in accordance with 29 CFR 1910.120, paragraph (q)(6)(i), at the "First Responder Awareness Level".

C. Laboratory staff should be trained to respond to "incidental" releases so as to minimize their potential exposure to hazardous chemicals.

D. Periodic drills should be held to test laboratory staff evacuation procedures.

6) OSEH staff are not routinely informed of a laboratory's purchase and subsequent use of highly toxic, flammable or otherwise hazardous chemicals. During our walkaround of two laboratories we observed laboratory storage of several such materials (hydrogen, hydrogen sulfide, phosgene, etc.). Many chemical specific OSHA standards (ex: benzene, formaldehyde, ethylene oxide) have requirements addressing employee exposure monitoring, information and training, and medical surveillance. The new OSHA standard "Occupational Exposure to Hazardous Chemicals in Laboratories", 29 CFR 1910.1450 will require laboratories to meet certain provisions of these chemical specific standards.

We recommend OSEH staff "flag" certain hazardous chemicals to ensure proper enforcement of 29 CFR 1910.1450 and to plan for laboratories which use highly toxic, flammable or otherwise hazardous chemicals which present the greatest potential for creating an "emergency response" situation.

7) OSEH staff are currently developing a Chemical Hygiene Plan as required by 29 CFR 1910.1450. Development and implementation of this plan should help to centralized information pertinent to laboratory usage of hazardous chemicals.

8) OSEH staff currently conduct safety inspections of laboratories at the request of the laboratory or building administration. We recommend OSEH staff expand this program to conduct non-announced inspections of laboratories using highly toxic, flammable or otherwise hazardous chemicals.

9) UM has not conducted air modeling to determine whether a chemical release may affect the surrounding community. CAMEO and ARCHIE air modeling programs are available free of charge from the federal government to assist emergency planners in estimating off-site impact.

10) UM maintains a Haz - Mat Response Truck which carries appropriate emergency equipment to respond to small chemical spills. Our review of truck contents indicated three deficiencies in UM's Respiratory Protection Program:

A. Two gas masks were equipped with non-approved canisters which had expiration dates of 09/02/85.

B. 15 minute "Scramble" self contained breathing apparatus (SCBA), used by UM's Public Safety officers to perform rescue, are not approved for entry into hazardous atmospheres and have limited application in emergency response to hazardous chemical release situations. These units should be replaced with 30 minute SCBA.

C. All emergency use respirators, specifically including SCBA, must be inspected monthly as required by Rule 3502, paragraph (6)(b). These monthly SCBA inspections are either not currently being done or not being documented.

11) A "Lab Safety Manual" (LSM) was provided at each inspected laboratory. In general, the LSM appears to be an excellent document for employee reference. However, we have the following comments:

pg. 4) Emergency Procedures listed here are too general! Terms such as "Alert everyone" and "Provide adequate ventilation" provide very limited information to lab staff responding to a chemical spill.

We recommend the LSM be revised to include a summary of UM's Emergency Response Program and Emergency Action Plan so that laboratory staff can receive pertinent information regarding proper response activities.

pg. 4) Lab staff must call the OSEH office to obtain MSDS information for spilled chemicals. Since the OSEH office has four different sources for MSDS, it could take from five to thirty minutes for lab staff to receive chemical information. This delay could aggravate the release situation.

We recommend MSDS access be improved so that laboratory staff may obtain pertinent data regarding hazardous chemicals much more quickly. Placing MSDS onto UM's computer would allow direct laboratory access.

pg. 8) We did not observe the "protective bottle carriers" or the "Pathfinder" labeling system in use in toured labs.

pg. 14) Appropriate compressed gas signs were not always posted in laboratories.

pg. 18) All Spill kits referenced (acid, caustic, cyanide, mercury, flammable solvent) were not observed in toured labs even when the hazardous materials were present.

pg. 22) Data provided in Appendix B - "Compatibility of Chemicals" and "Reactive Chemicals" can be expanded to include additional chemicals.

12) In general, good occupational safety and health programs were observed to be in place in toured laboratory facilities. Specifically, we noted:

A) Sprinkler systems and fire alarms were in place in each toured laboratory.

B) Fire extinguishers were in place in each toured laboratory.

C) Emergency use eyewash/showers were in place in hallways immediately outside of each toured laboratory.

ATTACHMENT 2

D) Laboratory fume hoods were in place in each toured laboratory.

E) Chemicals were stored by hazard class (acids, caustics, flammables and powdered) in separate cabinets in each toured laboratory.

F) Compressed gas cylinders were chained in place in each toured laboratory.

G) The "Lab Safety Manual" was in each toured laboratory.

H) Good housekeeping was observed in each toured laboratory.

I) Proper labeling observed on most containers of hazardous chemicals.

J) MSDS posters were in place in each toured building.

K) Fume hoods, eyewash/showers, fire extinguishers were being inspected at periodic intervals.

L) Chemical inventories posted at laboratory doors.

M) Laboratories were maintained under negative pressure with respect to hallways.

However, we have the following specific comments regarding toured laboratories:

Room 3105

A) Fume hood #5 had not been inspected and tested since March, 1985.

B) Laboratory apparatus set up outside of fume hood #5.

C) A container of formaldehyde solution was stored in the same cabinet as inorganic acids (potentially reactive materials).

D) Improper labeling of chemical storage cabinets was noted. For example, acids were stored in a cabinet labeled "flammables".

E) The first aid kit needed to be restocked.

F) The 1989 fire extinguisher inspection was missed.

G) "Pathfinder" labeling system not observed in use.

H) Bottle of "Berol 353" was observed with no hazard warning.

I) Dust/mist masks were in laboratory unknown to OSEH staff.

J) Eye protection not used by most laboratory visitors during our inspection.

K) No evacuation procedures posted.

Room 3230

A) The 1989 fire extinguisher inspection was missed.

B) Several gallons of flammables were not stored in an appropriate cabinet.

C) Chemical storage cabinets were not labeled.

D) No chemical inventory posted at door.

E) Eye protection not used by most laboratory visitors during our inspection.

F) No evacuation procedures posted.

Waste Storage - Room 1118/1112/Garage North Union Building

A) Improved storage is necessary for one gallon bottles. Currently, bottles are stacked three high with cardboard dividers and are also stacked on the floor blocking exit accessibility.

B) Drums need labeling either as a "Hazardous Waste" or hazardous chemical.

C) The hazard label can be provided by a placard with chemical identification and appropriate hazard warning where one gallon bottles containing flammables are stored.

D) One full face respirator was noted to be stored improperly in Room 1118.

E) Empty drums stored in this area should have their old labels removed or painted over to prevent potential mislabeling.

13) Other general recommendations.

A) We encourage better coordination and communication with local emergency response agencies. Coordinated response drills between on-site and off-site responders is recommended.

B) UM OSEH staff investigate spills or occupational injuries/illnesses. We recommend annual reports summarizing these investigations be developed to assist staff in emergency planning.

ATTACHMENT 3

U.S. Department of Health and Human Services,
Food and Drug Administration
Inspection Report

March 15, 1990

ATTACHMENT 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER 1560 E. Jefferson Ave Detroit, MI 48207 313-226-6260
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Neil A Peters	PERIOD OF INSPECTION 3/14-15/90 / C. F. NUMBER
TITLE OF INDIVIDUAL Director	TYPE ESTABLISHMENT INSPECTED Radiopharmaceutical Plant
FIRM NAME University of Michigan	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 1500 E. Medical Center Dr.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE (Zip Code) Ann Arbor MI 48109	CITY AND STATE (Zip Code) Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

1. The product dispensing record of I-131 NP-242 (MIBG) does not indicate which vials are decayed to waste. Example: Batch 072589 NP242263.

2. The 0.2 micron sterilizing filter for the dispensing operation of NP-242 is not integrity tested after the dispensing operation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dennis F. Savaiano	EMPLOYEE(S) NAME AND TITLE (Print or Type) Dennis F. Savaiano Investigator	DATE ISSUED 3/15/90