U. S. NUCLEAR REGULATORY COMMISSION

REGION II

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Report No.:	47-23035-01/98-01
Licensee:	West Virginia University
Location:	Morgantown, West Virginia
Dates:	January 26-28, 1998, and telephone conversations held on February 20 and April 1, 1998
Inspectors:	David J. Collins, Health Physicist Wade T. Loo, Health Physicist
Approved by:	Mark S. Lesser, Chief Materials Licensing/Inspection Branch 2 Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

West Virginia University
NRC Inspection Report No. 47-23035-01/98-01

This routine, unannounced inspection included discussions with cognizant licensee representatives, reviews of documents, and direct observations of licensed activities. The inspection included a review of management oversight, organization and scope of the program, facilities, equipment and instrumentation, training, retraining and instruction to workers, area radiation surveys and contamination surveys, personnel radiation protection, radioactive waste management program, transportation, computer requirements for Year 2000, and Quality Management Program. The report covers operations conducted by the licensee between August 1997 and January 1998.

Management Oversight

The Radiation Safety Officer reported to the Associate Vice President of the West Virginia University's Robert C. Byrd Health Sciences Campus. Oversight of the Radiation Safety Office was provided by the Radiation Safety Officer and the Radiation Safety Committee. The Radiation Safety Committee provided oversight as documented in meeting minutes.

Organization and Scope of the Licensee Program

Licensed materials were used in nuclear medicine, radiation oncology, and research. The organization of those areas were found to be adequate and in accordance with the licensee's application.

Facilities

The licensee conducted licensed activities in the Departments of Nuclear Medicine and Radiation Oncology and in various research laboratories. The inspector identified one violation involving failure to secure from unauthorized removal or limit access to millicurie quantities of licensed materials in research laboratories and the licensee did not control and maintain constant surveillance of this licensed material.

Equipment and Instrumentation

Equipment and instrumentation used and maintained by the licensee was found to be properly tested and calibrated, and users were found knowledgeable in the use of the instrumentation. However, the Radiation Safety Manual (Revised December 1996) does not contain clear instructions to authorized users that require calibration of survey instruments on an annual (12 month) frequency; and, also does not require Radiation Safety staff to perform independent contamination and/or radiation surveys in areas of use, either within the Hospital or the Robert C. Byrd Health Sciences Center.

Training, Retraining and Instructions to Workers

The inspector identified one violation regarding inadequate training for an individual who verified that fire extinguishers were properly charged in the research laboratories.

Personnel Radiation Protection

The Radiation Protection Program appear to be in compliance with NRC Regulatory requirements and the licensee's application.

Radioactive Waste Management

The inspector found that the licensee adequately maintained radioactive material waste for decay in storage and/or properly disposed of waste in accordance with NRC regulatory requirements and the licensee's application.

Year 2000 Computer Preparations

The licensee's preparations for monitoring and ensuring the appropriate modifications for computers performing radiation safety calculations were found to be adequate.

Transportation

The inspector determined that transportation activities involving licensed materials were conducted in accordance with NRC and U. S. Department of Transportation regulatory requirements.

Quality Management Program

The licensee's Quality Management Program was found to be implemented as written. The licensee's annual review of the Quality Management Program was found to be timely and comprehensive.

REPORT DETAILS

01. Management Oversight (87100)

a. Scope

The inspector reviewed the licensee's organization and management oversight to determine whether the organization and staffing were as required by the license.

b. Observations and Findings

Oversight of the Radiation Safety program was vested in the Radiation Safety Committee (RSC) and the Radiation Safety Office as required by 10 CFR 33.13. The Radiation Safety Officer (RSO) had direct access to the President of the Hospital, the Provost of the University and the Chair of the RSC in the event of identification of activities requiring immediate suspension of licensed activities because of excessive radiation hazard (i.e., stop work authorization). The inspector reviewed RSC minutes for calendar year 1997, and determined that evaluations of staff qualifications and experimental protocols had been made as required. Licensee staff named as authorized users were required to meet the requirements in 10 CFR 33.15, and met the requirements.

c. Conclusions

The licensee's management oversight of licensed materials use were found to be adequate to provide sufficient support to the University and the Hospital management.

02. Organization and Scope of the Licensee Program (87100)

a. Scope

The inspector reviewed the licensee's activities to determine whether the materials possessed and activities were as authorized by the license.

b. Observations and Findings

Through discussions with licensee representatives, review of records, and direct observations, the inspector found that the licensee used radioactive material in the various research laboratories, and the Departments of Nuclear Medicine and Radiation Oncology. The Nuclear Medicine staff used radiopharmaceuticals for diagnostic and therapeutic purposes. This included the use of technetium-99m, iodine-131 (I-131), strontium-89, and phosphorus-32 labeled radiopharmaceuticals for various imaging studies. In addition, the licensee used xenon-133 for lung imaging, and I-131 in liquid form on a weekly basis for therapy. The Radiation Oncology staff utilized iridium-192 in a

high-dose-rate afterloader and iodine-125 seeds for treating prostate cancer. The Research staff used various isotopes in non-human research. The licensee named authorized users and radioactive material use areas through the RSC. The licensee conducts three radiation safety user courses each academic year, attendance at one of which is a requirement for radiation workers. The principal investigator was assigned the responsibility of ensuring staff attends and qualifies.

c. Conclusions

The licensee's organization and use and possession of radioactive material was found to be in accordance with the licensee's application.

03. Facilities (87100)

a. Scope

The inspector reviewed the licensee's facilities to determine if they were as described in the license application and if they were adequate for conducting activities authorized by the license.

b. Observations and Findings

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas.

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an 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. The inspector toured the Departments of Nuclear Medicine and Radiation Oncology and several research laboratories and interviewed various nuclear medicine, radiation oncology and research staff over three separate days. During those tours, involving approximately 62 laboratories, the inspector identified two laboratories and/or rooms (3088 and 3101 Health Sciences Center) in which there were no staff present and millicurie (mCi) quantities of materials 2.5 mCi of hydrogen-3; 1 mCi of carbon-14; 2.2 mCi of phosphorous-32, and less than 200 microcuries (uCi) of sulfur-35 were present. The licensee's Radiation Safety staff stated that there had been intermittent instances where they had found laboratories unlocked, unattended with mCi quantities of licensed materials. Failure of the licensee to secure from unauthorized removal or access licensed materials that were stored in unrestricted areas was identified as a violation of 10 CFR 20.1801 and 20.1802 (47-23035-01/98-01-001) as documented in NRC IR 47-23025-01/98-01.

c. Conclusions

One violation was identified for failure of the licensee to secure licensed materials from unauthorized removal or access in various research laboratories.

04. Equipment and Instrumentation (87100)

a. Scope

The inspector reviewed records and interviewed cognizant licensee personnel to determine if the licensee's maintenance and calibration of equipment and instrumentation conformed to regulatory and license requirements for both the Hospital and the Medical Sciences Center.

b. Observations and Findings

Through discussions with cognizant licensee representatives, a review of records, and direct observations, the inspector determined that linearity, constancy, and accuracy checks were performed as required for the two dose calibrators used in the Department of Nuclear Medicine and found to be within manufacturer specifications. Through further discussions, reviews and observations, the inspector determined that monthly and quarterly checks for the high-dose-rate afterloader used in the Department of Radiation Oncology were performed as required and in accordance with the license application. In addition, the licensee possessed numerous radiation detection instruments located in the Departments of Nuclear Medicine and Radiation Oncology, various Research Laboratories, and the Radiation Safety Office. The licensee performed its own calibration, and survey meters were calibrated on an annual basis to ensure accurate (+/- 10 percent) counts per minute response, and checked against a cesium-137 source for proper probe/meter operability. The licensee had Liquid Scintillation counters available for counting swipes for low level energy contamination in various research areas while Nuclear Medicine utilized a well counter to count swipes. Also, the inspector determined that the licensee properly tested and maintained the fume hoods located in the Department of Nuclear Medicine in accordance with the license application.

The licensee's RSM (January 1994, Revised December 1996), Section 8.9, discusses radiation survey instruments with the caveat that an appropriate survey would be provided (purchased) by the Authorized User (AU) as part of the research grant. The inspector's review of the laboratory and Nuclear Medicine areas showed that while the approximately 62 laboratories possessed instruments, and most of them had been calibrated within the previous 12 months, three laboratories had contamination survey instruments which were not calibrated within the past 14-15 months and/or had not been calibrated since purchase some years ago (up

to 5 years). Section 3.6 of the RSM assigns the responsibility for performing calibration of instruments to the RSO. However, the Radiation Safety Staff indicated that they were not sure of the location or status of survey instrumentation in all facilities. Section 3.8 of the RSM describes the responsibilities of the AU to include Item 19 requiring instruments to be calibrated periodically. However, the inspector was unable to determine a definition of "periodically" or an acceptable calibration interval. The RSO stated that the University would amend the RSM to create a definite interval for calibration of survey instrumentation and strengthen its knowledge of instrumentation in each laboratory.

c. Conclusions

Through discussions with licensee representatives, a review of records, and direct observation of licensee activities, the inspector determined that the licensee maintained equipment and instrument in accordance with the license application. However, the licensee's RSM does not address any requirement that instruments be registered with the RSO nor state a specific requirement for calibration interval for laboratory instruments.

05. Training, Retraining, and Instructions to Workers (83822)

a. Scope

The inspector reviewed training records and lesson plans, observed training of new employees, and interviewed cognizant personnel to determine if the licensee provided training as required by 10 CFR 19 and by license conditions.

b. Observations and Findings

Through discussions with cognizant personnel, a review of training records, and direct observations, the inspector determined that individuals working with licensed materials, to include nuclear medicine, radiation oncology, nurses and researchers, received training prior to working with licensed materials and annually thereafter. Ancillary personnel such as housekeeping, security, maintenance, and warehouse personnel received training appropriate to their responsibilities. The training was provided by the Radiation Safety staff. In addition, during the onsite inspection, the inspector observed training given to new employees and refresher training to current employees and found the training given to those individuals to be in accordance with NRC regulatory requirements and the licensee's application.

10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable

provisions of the Commission's regulations and licenses. During the onsite inspection, the inspector identified a contractor who had entered various research laboratories to validate fire extinguishers, including Laboratory BS 4029, an area controlled for radiation protection purposes. During discussions with the contractor and licensee representatives, the inspector determined that fire extinguisher contractors who inspected fire extinguishers were not instructed in the precautions and procedures to minimize exposure to radioactive materials in the various research laboratories. Failure of the licensee to instruct the fire extinguisher contractors who conducted activities in the various research laboratories was identified as a violation of 10 CFR 19.12 (47-23035-01/98-01-002) as documented in NRC IR 47-23025-01/98-01.

c. Conclusions

One violation was identified for failure of the licensee to instruct a fire extinguisher contractor in the precautions and procedures to minimize exposure to radioactive materials in the various research laboratories.

06. Area Surveys and Contamination Control (83822)

a. Scope

The inspector reviewed the records of radiation area surveys and removable contamination surveys, and discussed survey requirements with cognizant licensee personnel to determine if the licensee met NRC regulatory requirements and license conditions. The inspector observed survey activities and contamination and radiation records of facilities in the Health Sciences Center and the Hospital.

b. Observations and Findings

10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored. Through discussions with licensee representatives, a review of survey records, and direct observations, the inspector determined that the licensee conducted daily removable contamination surveys (more frequently than the required weekly surveys) of the two nuclear medicine hot laboratories. However, the inspector determined that, from August 21, 1997 to the date of the onsite inspection, neither the licensee's Nuclear Medicine nor Radiation Safety Office staff conducted weekly removable contamination surveys of the nuclear medicine imaging room, an area in which radiopharmaceutical are routinely administered to patients. Failure to conduct weekly removable contamination surveys of the nuclear medicine imaging room was dispositioned as a violation in NRC IR 47-23066-02/98-01.

c. Conclusions

One violation was identified for failure to conduct weekly removable contamination surveys of the nuclear medicine imaging room.

07. Personnel Radiation Protection (83822)

a. Scope

The inspector reviewed radiation exposure records from January to September 1997, and discussed those records with cognizant licensee personnel to determine if the licensee was in compliance with limits specified in 10 CFR Part 20. The inspector toured areas of the facilities where licensed materials were used and stored.

b. Observations and Findings

Through discussions with cognizant licensee representatives and review of records, the inspector determined that, for the exposure period reviewed, the highest deep and shallow dose equivalent whole body was 580 and 1,530 millirem, respectively. Through further discussions with cognizant licensee representatives and a review of exposure records, the inspector determined that personnel were issued whole body and extremity dosimetry as required, and the dosimetry was exchanged on a monthly basis. The licensee required workers to wear dosimetry while working with more than 500 uCi of phosphorous-32 and 1.0 mCi of I-131. During the inspection, the inspector observed licensee personnel wearing radiation dosimetry appropriately to detect radiation exposure during the handling and use of radioactive material at the facility.

c. Conclusions

The inspectors determined that dosimetry was properly administered.

08. Radioactive Waste Management (87100)

a. Scope

The inspector reviewed licensee procedures, toured radiation waste storage areas, radioactive waste records, and interviewed cognizant licensee personnel to determine if radioactive waste was managed in accordance with NRC regulatory and license requirements.

b. Observations and Findings

The licensee was authorized to dispose of radioactive waste in several ways. Radioactive material with a half-life of less than 65 days was held for decay-in-storage before disposal as ordinary waste, after surveys demonstrated that the waste was at or below background. Waste from nuclear medicine was disposed as biohazardous waste after decay, or was transferred to the waste storage area. Unused radiopharmaceuticals were returned to the supplier. Liquid scintillation counting vials were disposed of by transfer to a commercial incinerator. Other waste and animal carcasses were transferred to a commercial radioactive waste burial site.

c. Conclusions

The licensee maintained its waste management program in accordance with the RSM and regulatory requirements.

09. Awareness of Potential Computer Problems in the Year 2000

a. Scope

The inspector interviewed the licensee's Radiation Safety Office staff, and the Radiation Oncology staff to determine their awareness of the potential for the Year 2000 to cause interference or safety errors in the radiation protection program or the computer-driven devices in Nuclear Medicine and Oncology.

b. Observations and Findings

The inspector discussed with the Radiation Safety and Oncology staff the potential harm because of mathematical errors which could be induced by failure to handle calendar year properly. NRC Information Notices 96-70, "Year 2000 Effect on Computer System Software," and 97-61, "U.S. department of Health and Human Services Letter, to Device Manufacturers, on the Year 2000 Problem," had been received by the licensee. The licensee staff stated that arrangements with the program vendors for all computer systems and devices concerning patient dose and treatment use had been made for upgrading if needed. The staff also stated that there were no outstanding systems identified which were affected by the problem.

c. Conclusions

The licensee was found to be cognizant of the potential for computer problems based upon the approach of the year 2000.

10. Transportation (86740)

a. Scope

The inspector reviewed the licensee's transportation practices to ensure that they were conducted in accordance with NRC and DOT regulatory requirements.

b. Observations and Findings

Through discussions with licensee representatives, a review of transportation records, and direct observations, the inspector found those shipping papers reviewed to be accurate and complete. During the onsite inspection, the inspector observed licensee representatives retrieving radiopharmaceuticals that had been delivered by a commercial nuclear pharmacy in a secured storage room located in the Department of Radiology. From those direct observations, reviews of records and discussions with cognizant licensee representatives, the inspector determined that the licensee conducted adequate radiation surveys and prepared the shipments for return in accordance with NRC and Department of Transportation (DOT) regulatory requirements and the licensee's application.

c. Conclusions

The licensee was found to have conducted its transportation program in accordance with regulatory requirements.

11. Quality Management Program

a. Scope

The inspector reviewed the licensee's Quality Management Program (QMP) and annual audit to determine if the licensee was conducting its QMP in accordance with regulatory requirements. The inspector conducted discussions with cognizant licensee representative and reviewed QMP records.

b. Observations and Findings

The inspector discussed the QMP, the annual review and its results with the RSO and the Nuclear Medicine staff. The inspector reviewed the most recent annual review of the QMP contained in the meeting notes for the RSC. There were no misadministrations or recordable events identified in the review.

c. Conclusions

The inspector concluded that the licensee conducted its QMP in accordance with NRC regulatory requirements.

EXIT MEETING SUMMARY

Exit meetings were held with licensee representatives on January 28, February 20 and April 1, 1998. The overall findings from the inspection, including the violations were discussed. The licensee advised that they would address the issues of imprecise corrective and preventive measures for safety related items in the RSM. The licensee did not specify any information reviewed during the inspection as proprietary in nature and no dissenting comments were received from the licensee.

ATTACHMENT

1. LIST OF PERSONS CONTACTED

*R. Biddington, D.D.S., Associate Vice President, Robert C. Byrd Health Sciences Center (HSC), West Virginia University (WVU)
T. Delaney, Radiation Safety Specialist, WVU
&#*K. Douglass, Ph.D., Radiation Safety Officer (RSO), WVU
*M. Frick, M.D., Chairman, Department of Radiology (RAD), West Virginia University Hospitals, Inc. (WVUH)
#J. Hackett, Associate Vice President, HSC, WVU
*L. Halliburton, Ph.D., Chairman, Radiation Safety Committee, WVU
*D. Healdley, Manager, Advanced Imaging & Treatment Services, RAD, WVUH
*N. Gupta, M.D., Chief, Section of Nuclear Medicine (SNM), RAD, WVUH
S. Keener, Imaging Specialist, SNM, RAD, WVUH
*K. Krishna, Ph.D., Assistant Professor, Medical Physics, Section of Radiation Oncology, RAD, WVUH
#E. Raudenbush, Alternate RSO, WVU
N. Ravminafar, Senior Radiation Safety Specialist, WVU
#D. Shock, Administrative Director, Department of Radiology and Radiation Therapy, WVUH
*S. Tancin, Vice President, WVUH
*J. Weiser, Ph.D., Chief, Medical Physics, Section of Radiation Oncology, RAD, WVUH

Other licensee staff contacted during the onsite inspection included administrative, nuclear medicine, radiation oncology, radiation safety, student and professional research laboratory personnel

#Attended January 26, 1998 Entrance Meeting
*Attended January 28, 1998 Exit Meeting
&Attended February 20 and April 1, 1998 Exit Telephone Calls

2. INSPECTION PROCEDURES USED

IP 87100	Licensed Materials Programs
IP 83822	Radiation Protection
IP 86740	Inspection of Transportation Activities
IP 84900	Low Level Radioactive Storage

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Description
47-23035-01/98-01-001	Open	VIO - Failure of the licensee to secure licensed materials from unauthorized removal or access.

47-23035-01/98-01-002	Open	VIO - Failure of the licensee to instruct individuals in the precautions and procedures to minimize exposure to radioactive materials.

4. LIST OF ACRONYMS

AU	Authorized User
CFR	Code of Federal Regulations
DOT	Department of Transportation
I-131	iodine-131
IR	Inspection Report
mCi	millicurie
No.	Number
NRC	Nuclear Regulatory Commission
QMP	Quality Management Program
RSC	Radiation Safety Committee
RSM	Radiation Safety Manual
RSO	Radiation Safety Officer
uCi	microcurie
VIO	Violation