THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

Radiation Safety Office
(202) 676-2630

February 6, 1984

United States Nuclear Regulatory Commission
Region #1
631 Park Avenue
King of Prussia, PA 19406

Dear Sir:

This is notification of a diagnostic radiopharmaceutical misadministration that occurred at the George Washington University Medical Center on January 12, 1984. Below is the information required for this report:

Referring physicians: Chariklia Spiegel, M.D.
Keith Michl, M.D.

Description: A student nuclear medicine technologist entered a semi-private room to inject patient A with 20 mCi of ^{99m}Tc-MDP. Patient B responded affirmatively when questioned if he were patient A. Patient B was then misadministered the radiopharmaceutical.

Effect on Patient: None

Corrective Action: The student technologist was re-instructed that identification bracelets should be checked on every patient before injecting.

A complete file on this incident will be maintained at the George Washington University Radiation Safety Office for your inspection.

Sincerely,

Mark Selikson, Ph.D.
Radiation Safety Officer

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-09049/84-01

Docket No. 030-09049

License No. 08-00216-22 Priority II Category GI

Licensee: The George Washington University
Medical Center
2300 K Street, N.W.
Washington, D.C. 20037

Facility Name: The George Washington University

Inspection At: Washington, D.C.

Inspection Conducted: January 9, 10, 11, 12, 1984

Inspectors: Jenny M. Johansen, Radiation Specialist — date 3-3-84

Teresa H. Darden, Radiation Specialist — date

Approved by: John E. Glenn, Ph.D. Chief
Nuclear Materials Section B — date 3/6/84

Inspection Summary:
Inspection conducted January 9-12, 1984 (Report No. 030-09049/84-01)

Areas Inspected: Special, unannounced inspection of a broad scope program for medical research, diagnosis, and therapy, including licensee actions on previous inspection findings, organization, licensee audits, training, radiation protection procedures, use of materials, storage of materials, facilities, instruments, receipt and transfer of material, external and internal dosimetry, waste disposal, notification and reports, posting and independent measurements by the inspectors.

The inspection involved 82 hours on site time by two NRC inspectors.

Results: One violation was identified: Failure to perform tests for molybdenum-99 on each eluate from a technetium-99m/molybdenum-99 generator prior to administration to patients.

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DETAILS

1. Persons Contacted

*Ronald P. Kaufman, M.D., Vice President for Medical Affairs
*Michael Barch, Administrator, Medical Center
*L. Thompson Bowles, M.D., Dean for Academic Affairs
*Fred Leonard, Ph.D., Associate Dean for Research
*Mario Werner, M.D., Chairman, Radiation Safety Committee
*Charles Rogers, M.D., Acting Chairman, Department of Radiology
*Richard Reba, M.D, Director, Nuclear Medicine
*Vijay Varma, M.D., Nuclear Medicine
*Allan Goldstein, Ph.D., Chairman, Biochemistry, School of Medicine
*Allan Wasserman, M.D., Cardiology
*Michael Jackson, Ph.D., Physiology, School of Medicine
*Mark Selikson, Ph.D., Radiation Safety Officer
*Joan Fleeter, Assistant Administrator, Medical Center
*Neal Mohlmann, Safety Specialist, Medical Center Safety
*Michael Cianci, Technical Manager, Nuclear Medicine
*Gary Goode, Assistant Radiation Safety Officer
*E. Strouse, Radiation Safety Office
*M. Gaffney, Radiation Safety Office
*M. Heyert, Radiation Safety Office
*L. Meire, Radiation Safety Office
David J. Goodenough, Ph.D., Associate Professor of Radiology
Kenneth E. Weaver, M.S., Assistant Professor of Radiology
D. Hixson, Chief, Imaging
M. Daniels, Nuclear Medicine Technologist
J. Rae, Nuclear Medicine Technologist
S. Stricker, Nuclear Medicine Technologist
N. Cougan, Nuclear Medicine Technologist
W. Edwards, Nuclear Medicine Technologist
S. Barth, Nuclear Medicine Technologist
B. DeVries, Radiation Therapy
Dr. Clifton Ling, Medical Physicist, Radiation Therapy
E. Harvey, Security Officer, Medical Center
John Shea, Director of Security, Medical Center
R. Butler, Receiving Clerk
S. Milliken, Supervisor, Dr. Kramer's Laboratory
T. Lee, Researcher, Dr. Cassidy's Laboratory
Dr. M. Cassidy, Physiology, Researcher
E. Baily, Researcher, Dr. Jackson's Laboratory
E. Quinet, Researcher, Dr. Vahouney's Laboratory
Dr. G. Vahouney, Biochemistry, Researcher
K. Anderson, Researcher, Dr. Steinberg's Laboratory
J. McGillis, Graduate Student, Dr. Goldstein's Laboratory
Dr. A. Kumar, Biochemistry, Researcher
B. Tempel, Researcher, Dr. Kumar's Laboratory
C. Siegall, Researcher, Dr. Kumar's Laboratory
J. Connaughton, Researcher, Dr. Kumar's Laboratory

S. Frantz, Researcher, Dr. Reba's Laboratory
Dr. J. Straw, Pharmacology, Researcher
Dr. M. Reich, Nuclear Medicine, Researcher
Dr. P. Kind, Microbiology, Researcher

Various other personnel in research laboratories and at the medical center.

*Denotes those present at exit interview.

2. Licensee Action On Previous Inspection Findings

(Closed) Inspection 83-01: License No. 08-00216-22, 10 CFR 20.201(b) re:20.106 - Failure to perform surveys (evaluations) to assure compliance with regulatory limits for airborne concentrations in an unrestricted area. The inspectors verified that calculations (evaluations) now have been made at the boundary of the restricted area and that as of April 1, 1982 releases to the environment have been less than maximum permissible concentrations (MPCs) at the point of release from the stack.

(Closed) Inspection 83-01: License No. 08-00216-22, 10 CFR 20.301 re: condition 22 of license - Failure to survey for radioactivity prior to release of waste in normal trash. Inspectors verified training had been given the individuals involved and noted that radiation safety office surveys have prevented similar incidents.

(Closed) Inspection 83-01: License No. 08-00216-22, 10 CFR 35.43 - Failure to report diagnostic misadministrations. The inspectors verified that a report on the misadministrations had been received in the Region I NRC office by August 31, 1983. Additionally a procedure to report future misadministrations has been established.

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 13 - Failure to perform leak tests on sealed sources at required six month frequency. The inspectors verified that leak tests had been performed in the last 6 months for each sealed source.

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 21 - Failure to test linearity on dose calibrators quarterly. The inspectors verified that quarterly linearity tests had been performed for 1983 and there were no deviations greater than ±5% between calculated and actual measurements.

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 21 - Failure to calibrate survey meters every six months. The inspectors verified that all survey meters were now in calibration. Calibrations were performed in June and December, 1983

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 21 - Failure to wear gloves while handling radioactive material (RAM). The inspectors observed that individuals now wore gloves when handling RAM. Additionally, re-training had emphasized the requirement.

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 21 - Failure to refrain from eating, drinking, smoking or application of cosmetics in an RAM storage or use area. The inspectors observed no eating, drinking, smoking or application of cosmetics in any RAM storage or use areas. Additionally, re-training had emphasized the requirement.

(Closed) Inspections 83-01; 80-01: License No. 08-00216-22, Condition 21 - Failure to wear TLD ring badge dosimeters while preparing radiopharmaceuticals. The inspectors observed that all Nuclear Medicine Technologists wore TLD rings while preparing, and injecting, radiopharmaceuticals. Additionally, re-training had emphasized the requirement.

(Closed) Inspection 83-01; 80-01: License No. 08-00216-22, Condition 21 - Failure to dispose of radioactive waste in specially designated receptacles. The inspectors observed that all wastes in the Nuclear Medicine Hot labs are labelled RAM and considered such until surveyed to assure that no radiation levels exceeding background exist before the waste is disposed in the normal trash.

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 21 - Failure to refrain from pipetting RAM by mouth. The inspectors found no evidence of mouth pipetting nor was any individual observed pipetting by mouth in the laboratories visited in the medical center area. Additionally, re-training had emphasized the prohibition of mouth pipetting.

(Closed) Inspection 83-01: License No. 08-00216-22, Condition 21 - Failure to survey generator, kit preparation and injection areas daily. The inspectors observed that the daily surveys were performed and recorded in a log book. Additionally, re-training had emphasized the need for surveys and recordkeeping.

3. Organization

The Radiation Safety Committee (RSC) is responsible to the President of the University through the Vice President for Medical Affairs for matters involving policy, procedures, licensing and control of radioactive materials and/or radiation sources at George Washington University.

The current membership of the committee satisfies the requirements of 10 CFR 35.11 and specifically 35.11(b) in that an authorized user for each type of use permitted by the license, a representative of the institution's management, a representative from nursing, and the Radiation Safety Officer (RSO) compose the committee.

Since the previous inspection June 1-2, 1983 the minutes of the Committee indicate the Committee has met at least once per calendar quarter.

In addition, the RSC has set up an Executive Committee consisting of the Chairman of the RSC, the Chairman of the Department of Radiology, the Associate Dean for Research, and the RSO to assure timely enforcement and corrective actions are taken on violations identified in surveys and/or quarterly audits by the Radiation Safety Office. Actions involving enforcement can be appealed to the full RSC.

The Radiation Safety Officer is responsible to the President of the University through the Vice President for Medical Affairs through the Chairman of the Radiation Safety Committee.

The current staff of the Radiation Safety Office consists of the Radiation Safety Officer, an Assistant Radiation Officer, three full-time Radiation Safety Technicians, one part-time Radiation Safety Technician, one full-time secretary and one part-time secretary.

Records in the Radiation Safety Office indicate authorizations have been granted to fifty-one major users in various research areas. In addition, there are numerous individuals using radioactive materials under these fifty-one major authorized users.

Clinical use of radioactive materials involves Nuclear Medicine, Nuclear Cardiology, and Radiation Therapy.

Nuclear Medicine, including Nuclear Cardiology, performs an average of 130 scans per week. Statistics in the Nuclear Medicine Department showed that from July 1 to November 30, 1983, 237 xenon-133 studies were performed for an average of 11 scans per week. From June 2, 1983 to January 9, 1984, six therapeutic doses of iodine-131 had been administered which required patient hospitalization (i.e. greater than 30 mCi doses).

From June 30, 1983 to January 3, 1984 eleven cesium-137 and one iridium-192 brachytherapy implants were performed by the Radiation Therapy Department.

The Nuclear Medicine Department is staffed by approximately 12 Nuclear Medicine Technologists, including the Technical Manager and two Chief Technologists.

Radioimmunoassay studies are performed in a laboratory distinctly separate from Nuclear Medicine. These studies are carried out under a general license (NRC Form 483).

Brachytherapy implants are performed by physicians with assistance of the Medical Physics staff. The Radiation Safety Office performs inventory, audit and survey functions.

No violations of Commission rules, regulations, or license conditions were identified.

4. Licensee Internal Audits

The licensee has established a formal quarterly audit program which identifies violations, assigns a point value for each item identified, and requires corrective action to be taken. For a quarterly audit which identifies violations having a point value of 35 or more, the Authorized User is sent a formal written letter from the Chairman of the RSC to which a written reply is required within three weeks (See Appendix A).

Actions must be taken by the authorized user to correct violations identified in the audit. If violations identified in one quarterly audit report are identified in the next quarterly audit the point value of the violation is doubled.

Failure to reply to a letter from the Chairman of the RSC will result in actions to limit use privileges through actions of the Executive Committee and the RSC.

The first audit inspection was performed on December 6, 1983. Forty-three active authorized users were inspected with the following results:

Point Violation Range	No. of Authorized Users in Range
0 - 5	14
6 - 10	5
11 - 15	7
16 - 20	2
21 - 25	9
26 - 30	2
31 - 34	3
35 +	1

In discussions with the inspectors the RSO stated he had spoken with the authorized users having 20 violation points or more to emphasize that corrective actions were to be taken. The authorized user whose laboratory had more than 35 violation points was sent a written notice by the Chairman of the RSC. The committee was awaiting the authorized user's written reply.

Review of the July 13, 1983 RSC minutes indicates that one authorized user was placed on probation due to inadequate inventory and bioassay logs, failure to perform laboratory surveys, mouth pipetting, and eating, drinking or smoking in a radioactive materials area. The RSO correspondence file with this user revealed that the use of all RAM in the laboratory was suspended for two weeks, August 23, 1983 to September 8, 1983. On September 9, 1983, the authorized user formally responded to the RSO that he had corrected the violations cited by the RSC.

The inspectors' review of RSC Minutes, Quarterly Audit Reports, Executive Committee Minutes, RSO Survey reports, observations of individuals working with RAM, and discussions with many individuals identified in Section 1 of this report revealed several areas of the radiation safety program that needed further evalution to assure long-term adherence to the Commission's rules, regulations or license conditions (See Sections 6, 7, 9, 10, 12, 13, 14, 17 and 19).

The inspectors' observations were discussed with the RSO and with the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

5. Training

Interviews with nuclear medicine personnel indicated that the Radiation Safety Office had held a formal training session with them to review the violations identified in the previous inspection (June 1, 1983). They had received instruction on corrective actions needed to comply with the NRC license conditions. The need to prevent violations in the future was stressed.

Documents on training reviewed in the Radiation Safety Office showed that housekeeping personnel have received annual training. Security personnel had not had a formal training session since 1981, however the RSO stated individuals were instructed verbally at various times during the past two years and a formal session with Security was scheduled to be given sometime before January 26, 1984. The inspectors' interview with the Director of Security and two Security Officers indicated they were knowledgeable with the procedures for off-hour receipt of packages of RAM and the NRC regulations and license conditions applicable to their area of employment. The Nursing staff had received training and this training was emphasized each time an implant or iodine therapy patient was assigned to a floor in the hospital.

The RSO quarterly audit had identified several individuals who had not taken the required user's examination. The RSO stated these individuals were notified to attend the scheduled January 17, 19, or 24, 26, 1984 training/examination sessions. This was confirmed by the inspectors during interviews with research laboratory personnel.

No violations of Commission rules, regulations, or license conditions were identified.

6. Radiation Protection Procedures

A review of patient records, survey records, and discussions with the RSO confirmed that surveys were performed to assure radiation levels in the unrestricted areas adjacent to the rooms of brachytherapy and therapy iodine-131 patients did not exceed the limits specified in 10 CFR 20.105(b). Closeout surveys on brachytherapy patients and source counts were performed prior to the discharge of patients. Patient's containing iodine-131 were not released until activity levels were equal to or less than 30 millicuries.

Personnel interviewed in the clinical and research areas were aware of emergency procedures for spills and how to contact the Radiation Safety Office for assistance, however, the inspectors determined in these discussions that minor spills were not always reported to the RSO so that the clean up of the spill could be verified by a survey by the Radiation Safety Office technical staff.

The RSO indicated that the Medical Center had recently developed medical emergency procedures for the receipt and handling of personnel contaminated with radioactive materials. A dry run of the procedure involving hospital personnel had occurred, however, some departments having expertise in this area did not participate. The inspectors' agreed with some of the staff that for this procedure to be effective all types of hospital personnel having expertise in this type of medical emergency procedure should participate in future dry runs.

The inspectors' observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

7. Use of Materials

Review of utilization logs and inventories indicated that licensed materials on hand were within the limits allowable under the NRC license. The materials are used for medical diagnosis, therapy, and research and development, including research with human beings.

License Condition 20 requires that technetium-99m (Tc-99m) separated from molybdenum-99 (Mo-99) eluted from a Tc-99m/Mo-99 generator be tested to detect and quantify Mo-99 activity prior to administration to patients.

The inspectors observed that at 7:30 a.m. a nuclear medicine technologist performed a Mo-99 test on an elution that was recorded as having been eluted by the on-call technologist at 3:30 a.m. on January 9, 1984. The inspectors interviewed the on-call technologist who stated that a Mo-99 test had been performed at 3:30 a.m. when the generator was eluted and

showed the inspectors the results of the test which had been recorded at the time of the elution. The inspectors reviewed the on-call technologist's records, the elution records for November and December 1983, and the Mo-99 test record. The inspectors identified several dates that elutions of the generator had occurred, patients were injected with Tc-99m and records indicated no Mo-99 test was performed. The inspectors interviewed several technologists who had performed weekend or evening on-call patient scans during November and December of 1983. Several technologists admitted that they had not performed the required Mo-99 test on the Tc-99m eluted from the generator.

The inspectors reviewed the daily constancy checks of the dose calibrator with the nuclear medicine technologists. The dose calibrator in Nuclear Medicine is checked daily with a cesium-137 and cobalt-57 source on all appropriate settings. The dose calibrator in Nuclear Cardiology is checked daily with a cobalt-57 source. The technologists indicated that linearity tests were performed by the Radiation Safety Office and that records were kept in the Radiation Safety Office. Review of the linearity test records determined that quarterly linearity tests were performed for the 3rd (September 14-15, 1983) and 4th (December 13-15, 1983) quarters of 1983.

Records confirmed that leak testing of brachytherapy sources and all sealed sources containing more than 100 microcuries of beta-gamma emitting byproduct material was performed in June and December 1983 as required by License Condition 13.

The inspectors observed that all areas using radioactive materials were posted and labelled as required.

The RSO stated that the licensee was in the process of evaluating the Calicheck device as an alternative to the current procedures for the performance of dose calibrator linearity tests.

The NRC inspectors advised the RSO that any changes in linearity procedures would require an amendment of the license. The inspectors commented that linearity testing of the dose calibrators was a quality control procedure performed in most institutions by nuclear medicine personnel. The RSO would normally perform audits to assure the testing had been performed and occassionally perform a verification test.

The inspectors' observation were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

The finding that Tc-99m eluted from a Tc 99m/Mo-99 generator was not tested to detect and quantify Mo-99 activity prior to administration to patients is a violation of License Condition 20.

8. Storage of Materials

Licensed materials are stored in the Nuclear Medicine Hot Lab and Nuclear Cardiology Hot Lab, which are locked when unattended. Packages of radioactive materials are locked in the Nuclear Medicine Hot Lab when received during off hours. During normal working hours radioactive materials are received in the Ross Hall receiving room, which is under constant surveillance.

The inspectors determined by visits to the research laboratories in Ross Hall that laboratories containing radiaoctive materials are locked when unattended. The inspectors observed during the visit to one research lab area that the RSO identified and took corrective action to secure a door that was slightly ajar. The inspectors noted that access to Ross Hall is controlled by security guards. Licensee's employees and students must show identification cards and visitors must register and are usually accompanied.

No violations of Commission rules, regulations, or license conditions were identified.

9. Facilities

The facilities agreed with those described as part of the license application, letters, and support documents.

The inspectors observed that in one laboratory in Ross Hall only prepackaged kits of iodine-125 for clinical in vitro testing were used. The lab was in a separate and remote area of the building. The inspectors advised that since only kits authorized by 10 CFR 31.11(a) were used in this lab it should be evaluated for possible registration under a general license.

The inspectors' observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

10. Instruments

Review of calibration records and the inspectors' observations of instruments in the clinical and research laboratory areas verified that survey instruments had been calibrated in June and December of 1983.

During their visit to the Nuclear Medicine Hot Lab the inspectors observed that packages of radioactive materials were surveyed with a calibrated Texas Nuclear Lin-log side window survey meter and the results were

recorded. It was noted that several boxes were surveyed in quick succession in a low background area. The highest reading recorded was 1.5 mR/hr at the surface of the package having a yellow Radioactive II DOT label. Both inspectors surveyed the same package using NRC survey meters (calibrated November 22, 1983 and December 6, 1983) equipped with thin-end-window GM probes. Both instruments held with the side of the probe at the surface of the box read approximately 7 mR/hr.

The inspectors performed further surveys in the hot lab and found evidence of contamination in the sink and a hot spot reading approximately 7 mR/hr on a table by the injection chair. The inspectors asked the Chief of Imaging to verify the survey readings using the Texas-Nuclear instrument. The individual quickly surveyed the sink and the table. The instrument responded to the sink contamination, however, the instrument did not identify the hot spot on the table until the inspector showed the individual where to survey and the instrument was held over the hot spot for more than a minute. The licensee's instrument finally measured approximately 5 mR/hr on the hot spot found by the inspectors on the table.

The inspectors observed that the indicator on a Picker rate-meter set on the 3K scale was in the pegged position. The instrument was switched to the 10K scale (highest scale) and the indicator continued to be in the pegged position. Two lead "pigs" containing radioactive material were moved and the rate-meter indicator returned to a mid-scale position with the meter on the 3K scale. The inspectors questioned the placement of the instrument in a high background area and the value of the instrument since the individual in the hot lab had the audio signal turned off and never looked at the indicator to see that radiation levels changed.

The inspectors observed that the dose calibrator was registering a background of 149 microcuries. The Chief of Imaging removed the plastic insert from the well of the dose calibrator and the background read zero (0), indicating contamination of the insert. The insert was then decontaminated. The inspectors additionally observed that the licensee had placed a note on the dose calibrator indicating that the second decimal point light was burned out. The Chief of Imaging stated that this would be fixed.

The inspectors later learned in discussions with the RSO that the Texas-Nuclear instrument had a 60 second response time according to the manufacturer's operating manual.

The inspectors' observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

11 Receipt and Transfer of Material

The licensee maintains a procedure for safely opening packages of radioactive materials which include a survey for radiation levels and wipe tests of external and internal package surfaces. All packages are surveyed and inspected by the Radiation Safety Office or Nuclear Medicine when received, with survey results recorded.

Records reviewed in the Radiation Safety Office indicated 25 shipments of exempt and/or limited quantity packages of radioactive materials as defined by Department of Transportation (DOT) regulations were shipped in 1983. Shipping papers and vouchers examined indicated these were shipped in accordance with DOT regulations and the NRC regulations in 10 CFR 71.

No violations of Commission rules, regulations, or license conditions were identified.

12. Personnel Protection - External

The inspectors observed that all individuals in Nuclear Medicine wore TLD rings and whole body dosimeters, lab coats, and protective gloves when working with radioactive materials. It was noted that, because the vendor sent small TLD rings, technologists with thicker fingers had to wear the TLD ring on the little finger of the hand used to prepare and inject patient doses, rather than on the index or second finger of the hand.

Weekly Nuclear Medicine survey records were reviewed in the Radiation Safety Office. A survey performed on August 23, 1983 indicates that a technologist lost his ring badge on August 12, 1983 and did not inform the RSO in order to receive a replacement ring. The technologist was assigned in the hot lab during the period from August 12 to August 23, 1983. The RSO stated an evaluation of hand exposure for the time period would be done to determine the dose to be assigned for the period in question.

The daily surveys of the generator, kit preparation, and injection areas of the Nuclear Medicine Hot Lab and Nuclear Cardiology Hot Lab were reviewed in the Nuclear Medicine Department. The surveys had been performed daily since the June 1-2, 1983 inspection.

The licensee has an active ALARA Program and all exposures exceeding Investigation Levels I and II are investigated by the Radiation Safety Officer and reviewed with the Radiation Safety Committee quarterly with corrective actions and evaluations discussed and implemented.

Since the June 1-2, 1983 inspection the licensee has reported to the NRC two exposures in excess of 10 CFR 20.101 quarterly limits (See Section 15).

The inspectors observed that the licensee provided whole body and TLD ring badges to personnel working with radioactive materials in nuclear medicine, radiation therapy (brachytherapy source handlers) and the research areas (phosphorous-32 users).

The inspectors observed that for phosphorus-32 (P-32) users dosimetry records show that extremity doses have not exceeded 25% of the maximum limits allowed in 10 CFR 20.101. The RSO stated that ring badges were recommended to P-32 users as part of good health physics practice rather than as a requirement.

The inspectors observed that a worker in a P-32 laboratory was wearing a lab coat, gloves, and a whole body dosimeter, but no TLD ring badge. Survey and audit reports in the Radiation Safety Office indicated that this had been brought to the attention of the RSO and the Authorized User supervising the lab.

The RSO stated that the radiation protection practices in this laboratory and the user's authorization were to be discussed at the RSC meeting scheduled for January.

The inspectors' observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

13. Personnel Protection - Internal

The licensee performs air monitoring in the restricted areas to assure airborne concentration of radioactive materials are not exceeded.

Review of records in the Radiation Safety Office confirmed all levels to be well below 10 CFR 20.103 limits for each radionuclide.

The licensee performs thyroid monitoring for personnel handling millicurie quantities of iodine-131 or 125. Records indicated no person exceeded an uptake level of either 0.03 microcuries of iodine-125 or 0.06 microcuries of iodine-131.

Records in the Radiation Safety Office indicate the effluent from the xenon trap is checked monthly.

Review of monthly records and discussions with the Radiation Safety Technicians indicated they perform weekly surveys for contamination in the Nuclear Medicine, Nuclear Cardiology, and Iodination Laboratories and P-32 user's laboratories. Monthly surveys are performed in all other active researcher's laboratories.

Since each of the monthly survey records for all other laboratories indicated that only one smear was taken in each laboratory, the inspectors discussed the methodology for performing monthly surveys with the technicians. One technician confirmed that the documentation on the monthly survey record was correct. The inspectors pointed out the possibility of cross-contamination and suggested taking numerous smears in several different areas, not just one smear of a whole laboratory.

The inspectors reviewed the Radiation Safety Office's weekly surveys of a P-32 user's lab from the time the user was placed on probation by the RSC until November 15, 1983 (See Appendix B). The inspectors observed a trend of repeated contamination levels in the weekly survey records. Discussions with individuals in the P-32 laboratory and review of their survey records indicated that a repeated contamination - decontamination - contamination trend occurred on a daily basis in the laboratory.

The inspectors' review of the weekly surveys in Nuclear Medicine indicated that contamination levels as well as other items are identified and sent to the department for action. Discussions with individuals in Nuclear Medicine indicated that contamination is cleaned up, but no record was available of any resurvey showing the effect of the decontamination. The inspectors also observed that the scope of the Radiation Safety Office surveys did not include radiation level determinations and wipe tests for removeable contamination in imaging rooms, hallways, and in the bathrooms which patients, as well as the technical staff frequented.

The inspectors' observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

14. Effluent Control, Waste Disposal

Radioactive waste is stored for decay and surveyed before disposal in the ordinary trash, released as effluent to the environment, released to the sanitary sewer, released as having less than 0.05 mCi/gram of tissue or media, or packaged for disposal through commercial waste disposal service.

Records indicate that since April 1, 1982 the licensee has maintained releases to the environment of xenon-133, iodine-125, and iodine-131 within the regulatory limits defined in 10 CFR 20.106. Records review of xenon-133 releases from January 7, 1983 to January 7, 1984 indicated the licensee released 1.368 curies in the one year period. The licensee has a total yearly effluent air flow of 4.17×10^{13}. The release to the air in microcuries per milliliter averaged over the year reviewed was 3.2×10^{-8} microcuries per milliliter, approximately 11% of the regulatory limits allowed in 10 CFR 20, Appendix B, Table II.

The inspectors observed that waste in the Nuclear Medicine Hot Lab was placed in the designated receptacles for disposal. Liquid wastes were poured into the sink for release to the sanitary sewer in accordance with 10 CFR 20.303. The inspectors pointed out to individuals in the lab that the sink should be flushed with copious amounts of water after liquid wastes have been poured into the sink. The activity which is released to the sanitary sewer is documented and reviewed during weekly/monthly surveys by the Radiation Safety Technologist to assure releases are within Appendix B, 10 CFR 20 limits.

The licensee's records on decay-in-storage indicate that animal carcasses containing iodine-125 (half-life = 60 days) were held from 1 to 77 days, surveyed to assure radiation levels were indistinguishable from background and then placed in the normal waste cycle. The licensee's procedure were carried out under Condition 22 of the NRC license. The inspectors pointed out the RSO that it is standard health physics practice to decay-in-storage at least 10 half-lives and that current NRC policy recommends iodine-125 to be held several half-lives before disposal if the radiation levels surveyed are indistinguishable from background. The RSO indicated he would take this information under advisement and that the license renewal application to be submitted this spring would be reflective of NRC policy regarding iodine-125 wastes.

The inspector's observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

15. Notifications and Reports

Discussions with nuclear medicine technologists and the Technical Manager of Nuclear Medicine, and review of records in the Nuclear Medicine and Radiation Safety Office, indicated that no diagnostic misadministrations occurred during 1983.

Discussions with Radiation Safety Office staff, the RSO and review of the survey records and the quarterly audit reports indicated there had been no theft or loss of material; in fact, the Radiation Safety Office had prevented a bag of radioactive waste from being sent to the normal trash through their routine surveys.

Two exposures in excess of NRC limits were reported in accordance with the regulations in 10 CFR 20.405.

The licensee received notification from the dosimeter vendor that individual A had received a dose of 7.7 Rem on the July 1983 whole body personnel dosimeter. The licensee investigated possible explanations for this exposure and determined that the exposure was due to the badge being left

in the accelerator room while individual A was not wearing the badge. The vendor later informed the licensee that they had re-evaluated the exposure to the dosimeter to be 170 mRem. Individual A does not work with by-product materials.

The licensee concluded that individual A did not receive a whole body exposure of 7.7 Rem.

The licensee received notification from the dosimeter vendor that individual B had received a dose of 23 Rem on the July 1983 extremity TLD ring badge.

The licensee investigated this exposure and based on calculations of exposure time, distance of TLD ring from the radiation source, the axial orientation of the ring, previous exposure history in the same working conditions, and discussions with the employee, concluded that the exposure most likely occurred due to contamination of the TLD ring badge and was not a real exposure to the individual's extremity.

The inspectors interviewed individual B concerning the July, 1983, 23 Rem exposure. Individual B indicated he was assigned in the Nuclear Medicine Hot Lab and Nuclear Cardiology Hot Lab for the month of July. He could recall nothing unusual happening regarding spills etc. or any extra materials handling which could have led to the dose. He stated he did use syringe shields when preparing and injecting RAM. He wore gloves to inject all the time except in those difficult cases where the vein couldn't be found. In those rare cases, he stated he did survey his hands after washing them with TLD ring off. Individual B stated it may have been possible that he handled a patient who had voided on the stretcher and thus contaminated his ring badge, because he handled patients without gloves.

No violations of Commission rules, regulations, or license conditions were identified.

16. Posting

All required notices were posted.

No violations of Commission rules, regulations, or license conditions were identified.

17. Other License Conditions

The inspectors did not observe any mouth pipetting or personnel smoking, eating or drinking in the restricted areas. However, several cups were seen in areas where signs were either posted stating "No radioactive materials in this area" or the individuals were in the process of establishing an area of "No radioactive materials".

The inspector's observations were discussed with the RSO and the RSC members present at the exit interview and referred to them for further evaluation.

No violations of Commission rules, regulations, or license conditions were identified.

18. Independent Measurements

The inspectors took approximately 100 independent wipes for removable contamination in the clinical and research area where RAM is used. These wipes were analyzed in the Region I laboratory. The results of the Region I analysis were compared to the analysis of the wipes which the licensee took in the same areas and were found to be in agreement.

19. Exit Interview

The inspectors stated the purpose and scope of the special unannounced inspection. Corrective actions taken as a result of the violations identified in the June 1-2, 1983 inspection were discussed.
Dr. John E. Glenn, Chief, Nuclear Materials Section B, USNRC Region I, discussed the NRC's stance on management control and the reasons behind the civil penalty imposed after the June 1-2, 1983 inspection. He stated that the NRC would continue to monitor the licensee's program to assure that the corrective actions taken, were long-term, program-wide commitments and not stop-gap measures taken only to correct a specific violation. He further stated that it appeared that the licensee now had in place a mechanism to identify, correct, and enforce corrective actions for violations of NRC rules, regulations or license conditions.

The inspectors commented to the Vice President of Medical Affairs that, from their discussions with various authorized users and other technical personnel, and their review of Radiation Safety Committee and Executive Committee Minutes, there seemed to be differing professional opinions as to how to run an effective radiation safety program at the licensee's facilities. The inspectors suggested that the Vice President for Medical Affairs consider having an outside consultant, who has expertise in medical/academic broad scope licensed programs and credentials that are exceptable to the majority of the persons having differing professional opinions, perform a complete audit (evaluation) of the radiation safety program, including the RSC's actions, the RSO and individual user compliance with the Commission's rules, regulations, and license conditions.

The Vice President for Medical Affairs agreed to take the suggestion under advisement and stated he would institute such an audit if he could get the persons having differing professional opinions to abide by the consultant's findings.

The inspectors reviewed their findings of the January 9-12, 1984 inspection. (See Sections 1 through 17). The inspectors' noted that a strengthening was needed in communications between the RSO, RSC, and the authorized users and suggested that a training session be held for the committee members and for each authorized user to review the NRC rules, regulations, and commitments made by the licensee to obtain the broad scope license. Further, the inspectors suggested that a copy of the licensee's commitments be given to the committee members and authorized users.

The inspectors observations and the finding of one violation were discussed with the RSO and the RSC members present at the exit interview.

Appendix A

Quarterly Inspection Report

Explanation of Inspection Form

Example letter for 35+ points of violations identified by quarterly audits

QUARTERLY INSPECTION REPORT

Authorized User_____ Department_____

Date_____ Quarter_____ Inspector_____

Room (s)_____ Contact_____

Infraction Points_____

A. Approved User Practices

____ 1. Use of unauthorized RAM. (5)
____ 2. Use or storage of RAM in an unauthorized area. (5)
____ 3. Removal of RAM from GWU. (10)
____ 4. RAM ordered/received directly from supplier. (10)
____ 5. RAM provided to unauthorized staff. (10)
____ 6. Failure to provide training/ALARA sessions. (10)

B. Posting

____ 7. NRC-3 form not posted. (2)
____ 8. Radioactive material sign not posted. (2)
____ 9. Radiation area sign not posted. (2)
____ 10. High radiation area sign not posted. (2)
____ 11. Radioactive User's Guide inaccessible. (2)
____ 12. Personnel exposure records inaccessible. (2)

C. Records

____ 13. Log book records inadequate. (10)
____ 14. Laboratory survey records inadequate (where applicable). (10)
____ 15. Waste disposal records inadequate. (10)

D. Personnel Practices

____ 16. Personnel working with RAM prior to passing safety exam. (10)
____ 17. Personnel not wearing monitors as assigned. (5)
____ 18. Evidence of personnel eating, drinking, smoking in areas where RAM is used. (5)
____ 19. Personnel mouth pipetting RAM. (10)
____ 20. Personnel not wearing gloves and/or protective clothing while working with RAM. (5)
____ 21. Failure to use hood/gloves box as required. (5)
____ 22. Food/drink and RAM stored together. (10)
____ 23. Absorbent pads not properly used. (2)
____ 24. Unmarked and unattended labware containing RAM. (2)
____ 25. RAM inadequately shielded. (10)
____ 26. RAM not secured against theft. (5)
____ 27. Improper disposal of RAM wastes. (10)
____ 28. Appropriate survey meter not accessible. (5)

E. Comments

**SEE OVER

QUARTERLY INSPECTION REPORT

A. Approved User Practices

1. Use of unauthorized RAM. (5)
2. Use or storage of RAM in an unauthorized area. (5)
3. Removal of RAM from GWU. (10)
4. RAM ordered/received directly from supplier. (10)
5. RAM provided to unauthorized staff. (10)
6. Failure to provide training/ALARA sessions. (10)

B. Posting

7. NRC - 3 form not posted. (2)
8. Radioactive Material sign not posted. (2)
9. Radiation Area sign not posted. (2)
10. High Radiation Area sign not posted. (2)
11. Radioactive User's Guide inaccessible. (5)
12. Personnel exposure records inaccessible. (2)

C. Records

13. Log book records inadequate. (10)
14. Laboratory survey records inadequate. (where applicable.) (10)
15. Waste disposal records inadequate. (10)

D. Personnel Practices

16. Personnel working with RAM prior to passing safety exam. (10)
17. Personnel not wearing monitors as assigned. (5)
18. Evidence of personnel eating, drinking, and smoking in area where RAM is used. (10)
19 Personnel mouth pipetting (RAM). 10)
20. Personnel not wearing gloves and/or protective clothing while working with RAM. (5)
21. Failure to use hood/glove box as required. (5)
22. Food/drink and RAM stored together. (10)
23. Absorbant pads not properly used. (2)
24. Unmarked and unattended labware containing RAM. (2)
25. RAM inadequately shielded. (10)
26. RAM not secure against theft. (5)
27. Improper disposal of RAM waste. (10)
28. Appropriate survey meter not accessible. (5)

Explanation of Inspection Form

1. Use of unauthorized RAM (5)

   Deficiencies include the use or presence of a radionuclide not included in the list of authorized materials of the designated authorized user of the lab.

2. Use or storage of RAM in an unauthorized area (5)

   Deficiences include the use or storage of RAM in an area not designated by the authorized user in the most recent application involving the radionuclide(s), or in a memo to Radiation Safety requesting authorization of the new site.

3. Removal of RAM from GWUMC (10)

   Use of RAM as authorized by the institutional broad license is limited to locations specified in the license, i.e., GWU and GWUMC. Thus, RAM obtained under the authorization of the license must be used only at locations specified in the license. Proper transfer of RAM can be achieved by adherence to the requirements specified in 10 CFR Part 30.41. All transfers of RAM to other institutions, or from campus to campus, must be accomplished with the assistance of the Radiation Safety Staff.

4. RAM ordered/received directly from supplier (10)

   License condition requires that all research RAM including free samples, etc., be processed through Radiation Safety Office (X2630) and shipped to George Washington University Medical Center, Receiving Department, Corner 24th and I Streets, N.W., Washington, D.C. 20037,

5. RAM provided to unauthorized staff (10)

   License condition requires users to be approved by specified Committees for each radionuclide needed. Transfer between users is permitted if each is approved for use of the radionuclide and if they indicate the transfer in their logbooks.

6. Failure to provide training/ALARA sessions (10)

   Definition: Training/ALARA session is a lecture given by the principal investigator for the purpose of instructing personnel in all phases of radiation safety pertaining to the RAM used in their lab. Deficiencies include: 1) failure to provide a training/ALARA session each year, 2) failure to keep records of: date; personnel attending; personnel absent; dates of follow-up sessions and names of attendees.

7. NRC-3 form not posted (?)

   Federal regulation requires that the form be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe it on their way to or from work.

8. Radioactive material sign not posted (2)

Sign is to be conspicuously posted for <u>each</u> room in which RAM is used or stored.

9. Radiation area sign not posted (2)

Federal regulation requires posting to indicate radiation areas, i.e., areas where a major portion of the body could receive a dose in excess of 5 millirems in any one hour or in excess of 100 millirems in any 5 consecutive days.

10. High radiation area sign not posted (2)

Federal regulation requires posting of areas where a major portion of the body could receive a dose in excess of 100 millirems in one hours.

11. Radioactive User Guide Inaccessable (5)

One manual per authorized user is sufficient if all labs are on one floor. All personnel should know where the manual is and have access to it at all times.

12. Personnel exposure records not accessible (2)

All personnel should know where to find the dosimetry report.

13. Log book records inadequate (10)

Lab portion or receipt record which includes use, transfer, and date of final disposal, must be completely filled out.

14. Laboratory survey records inadequate (10)

Deficiencies include:

1. No survey or record of non-use during period for surveys, i.e., weekly or monthly.
2. No record of: radionuclides being used; date; and signature.
3. No indication of remedial action where contamination is found (must indicate result of re-wipe numerically).

15. Waste disposal records inadequate (10)

Deficiences include NOT having: 1) sink disposal form posted, 2) a record posted for amounts of activity in liquid waste and investigator (in a common area), 3) a record of disposal amounts and investigators for scintillation vials stored in a common area.

16. Personnel working with RAM prior to passing safety exam (10)

Deficiencies include individuals: 1) seen using RAM prior to passing exam, 2) who do not show up for the test and do not sign up again.

17. Personnel not wearing monitors as assigned (5)

Deficiencies include personnel: 1) not wearing his badge in a RAM area, 2) wearing someone else's badge/or the control badge, 3) not wearing a ring or other type badge while working with RAM (as appropriate).

18. Evidence of personnel eating, drinking, smoking in area where RAM is used (10)

Deficiencies include: 1) coffee cups, 2) ashtrays, 3) cigarette butts, 4) plates with food, and 5) soda cans in RAM areas. (If people are collecting aluminum, the container should be in a non-RAM area with its own sign on it.)

19. Personnel mouth pipetting in a RAM area (10)

Deficiencies include: 1) those people who were observed mouth pipetting by the inspector, 2) those people who reported an accident while mouth pipetting, and 3) finding a "hot" mouth pipette in a lab.

20. Personnel not wearing gloves and/or protective clothing while working with RAM (5)

As stated.

21. Failure to use hood/glove box as required (5)

Deficiency includes failure to use hood/glove box when using unbound iodine in non basic or oxidizing conditions.

22. Food/drink and RAM stored together (10)

Deficiencies include food or drink stored together with RAM anywhere (refrigertor, cabinet, or shelf, etc.)

23. Absorbent pads not properly used (2)

24. Unmarked and unattended labware containing RAM (?)

Deficiencies include unattended labware containing RAM without the following identification:

Radionuclide
date
amount uCi or mCi
caution radioactive materials and warning symbol label

25. RAM not adequately shielded (10)

This category applies to RAM in use or storage. Radiation levels should not exceed 0.2 mR/hr at one foot beyond shield, and Beta contribution should be completely shielded when RAM is in storage. Deficiencies include: 1) shielding of mCi amounts of high energy Beta emitter with lead only, 2) insufficient shielding of Gamma emitters so that exposure rates in occupied areas are significantly higher than those that could be achieved with a reasonable amount of additional shielding, 3) lack of or insufficient shielding when handling high energy Beta emitters in mCi amounts.

26. RAM not secured against theft (5)

Deficiencies include failure to lock RAM or RAM waste left unattended in areas of public access or RAM waste left outside official waste barrels overnight.

27. Improper disposal of RAM waste (10)

A. Improper disposal:
1. improper labeling/packaging of animal carcasses.
2. vials containing liquid in dry waste.
3. radiation symbols in decayed trash unobliterated.
4. dry waste in bags with animal carcasses.
5. corrosive liquid put in metal cans.
6. non-RAM waste in RAM waste can.
7. Disposal of RAM waste as nonradioactive.
8. Sink disposal of greater than 500 uCi liquid RAM waste in a 24 hour period.
9. Sink disposal of toxic or non-water miscible liquid Ram waste.
10. Exceeded air effluent concentration limits when disposing of gaseous RAM waste through venting to the atmosphere.

b. Improper labeling:
Deficiencies include: 1). inadequate or incomplete information on the waste transfer card. 2). failure to label RAM waste container with "Caution Radioactive Materials" sign or tape.

28. Appropriate survey meter not accessible (where applicable) (5)

Deficiencies include failure to have a calibrated (every 6 months) survey meter available when needed by lab personnel and capable of detecting the type of activity being used.

STATEMENT OF AUTHORITY

The Radiation Safety Committee derives its authority from the Vice President for Medical Affairs and is responsible for Radiation Safety at The George Washington University.

Dear Dr.

A quarterly inspection of your lab required by NRC was performed on
This has indicated the critical infractions detailed on the attached report. Please respond in writing within three weeks: (1) any extenuating circumstances, (2) the corrective action that has been taken, and (3) when compliance has been achieved (give effective date).

The Radiation Safety Office will reinspect your laboratory to verify corrective action. Failure to comply on your part may limit your authorized user privileges.

Sincerely,

Mario Werner, M.D.

Chairman
Radiation Safety Committee

Appendix B

Results of RSO weekly surveys of a P-32 users laboratory

Results of RSO Surveys

P-32 Lab

Date	Survey Result	Other Comments
7/22/83		Placed on probation by RSC
7/22/83	No detectable contamination (NDC)	
7/29/83	NDC	
8/5/83	Contamination of 40,000, 16,000, 4,000 cpm in lab	
8/12/83	5 areas of contamination found	
8/17/83	2 areas of contamination found	mouth pipetting observed
8/23/83	1 area of contamination found	survey meter not working due to dead batteries; receipt of licensed material not logged; mouth pipetting observed
8/23/83		All receipt of radioactive materials suspended for two weeks - until September 8, 1983
8/31/83		Authorized User states he has reviewed violations with staff and corrected problems.
9/8/83	2 areas of contamination found	"in-house" surveys inaccurate
9/9/83		Written memo from user indicating corrective actions. Use of RAM re-instated by RSO.
9/15/83	1 area of contamination found	
9/22/83	5 areas of contamination found	Bioassays not performed; No decontamination performed
9/30/83		Probation ended by RSO.

Date	Survey Result	Other Comments
10/12/83	1 area contaminated - centrifuge - 20,000 cpm	
10/20/83	2 areas of contamination found	
10/24/83	5 areas of contamination found	no "in-house" surveys performed
11/11/83	3 areas of contamination found	no "in-house" surveys performed
11/15/83	500 cpm on refrigerator	

26 MAR 1984

Docket No. 030-09049

The George Washington University
Medical Center
ATTN: Ronald P. Kaufman, M.D.
Vice President for Medical Affairs
901 23rd Street, N. W.
Washington, D.C. 20037

Gentlemen:

Subject: Inspection 030-09049/84-01

This refers to the special safety inspection conducted by Ms. Jenny M. Johansen and Ms. Teresa H. Darden of this office on January 9, 10, 11, and 12, 1984 of activities authorized by NRC License No. 08-00216-22 and to the discussions of our findings held by Ms. Johansen with yourself and members of the Medical Center's staff at the conclusion of the inspection.

Areas examined during this inspection are described in the NRC Region I Inspection Report which is enclosed with this letter. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Based on the results of this inspection, it appears that one of your activities was not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. This violation has been categorized by severity level in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C) published in the Federal Register Notice (47 FR 9987) dated March 9, 1982. You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

In accordance with 10 CFR 2.790(a), a copy of this letter and the enclosures will be placed in the NRC Public Document Room unless you notify this office, by telephone, within ten days of the date of this letter and submit written application to withhold information contained therein within thirty days of the date of this letter. Such application must be consistent with the requirements of 2.790(b)(1). The telephone notification of your intent to request withholding, or any request for an extension of the 10-day period which you believe necessary, should be made to the Supervisor, Files, Mail and Records, USNRC Region I, at (215) 337-5223.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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03/20/84

IE:07

Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:
James H. Joyner

Thomas T. Martin, Director
Division of Engineering and
Technical Programs

Enclosures:
1. Appendix A, Notice of Violation
2. NRC Region I Inspection Report Number 030-09049/84-01

cc w/encls:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

The George Washington University
Medical Center
ATTN: Fred Leonard, Ph.D
Associate Dean for Research
2300 I Street, N.W.
Washington, D.C. 20037

The George Washington University
Medical Center
ATTN: Mario Werner, M.D.
Chairman, Radiation Safety Committee
2300 K Street, N.W.
Washington, D.C. 20037

The George Washington University
Medical Center
ATTN: Mark Selikson
Radiation Safety Officer
2300 K Street, N.W.
Washington, D.C. 20037

bcc w/encls:
Region I Docket Room (w/concurrences)
Senior Operations Officer (w/o encl)

RI:DETP	RI:DETP	RI:DETP	RI:DETP	RI:DETP
Johansen/gcb	Darden	Glenn	Joyner	T.Martin
2/15/84		3/24/84	3/21/84	
3/21/84				

APPENDIX A

NOTICE OF VIOLATION

The George Washington University
Washington, D.C. 20037

Docket No. 030-09049
License No. 08-00216-22

As a result of the inspection conducted January 9-12, 1984 and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violation was identified:

License Condition 20 of License No. 08-00216-22 requires that technetium-99m separated from molybdenum-99 either by elution of molybdenum-99/technetium-99 generator or by an extraction process be tested to detect and quantify molybdenum-99 activity prior to administration to patients.

Contrary to the above, as of January 10, 1984, technetium-99m eluted from a generator was not always assayed for molybdenum-99 activity. Specifically records indicated and several technologists admitted that since June 3, 1983 they had not performed the required test when they had eluted the generator on weekends or for on-call emergencies.

This is a Severity Level IV violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, The George Washington University is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

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UNITED STATES NUCLEAR REGULATORY COMMISSION — REGION 1 — 631 PARK AVENUE — KING OF PRUSSIA, PENNSYLVANIA 19406

LICENSEE EVENT REPORT

Docket No. 30-09674

MLER - RI-84-33

I. Action Control Data

Licensee THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER

Event Description DIAGNOSTIC MISADMINISTRATION

Event Date 1-12-84

Report Date 2-6-84

II. Reporting Requirement

- ☐ 10 CFR 20.402 - theft or loss
- ☐ 10 CFR 20.403 (a)(b) overexposure/ release
- ☐ 10 CFR 20.405 - 30 day report
- ☐ Other
- ☐ 10 CFR 35.42 Therapeutic Misad
- ☑ 10 CFR 35.43 Diagnostic Misadm
- ☐ License Condition

III. Region I Response

- ☐ Immediate Site Inspection — Inspector ____ Date ____
- ☐ Special Inspection — Inspector ____ Date ____
- ☐ Telephone Inquiry — Inspector ____ Date ____

Licensee Representative and Title ____

- ☐ PN
- ☐ Daily Report
- ☐ Information entered - Region I log and Outstanding Items List.
- ☑ Review at next routine inspection

V. Report Evaluation

- ☑ Description of Event
- ☑ Levels of R/M involved
- ☑ Cause of Event
- ☑ Corrective Actions
- ☑ Calculation adequate
- ☐ Letter to Licensee requesting add information

Completed by R. H. Salmon — Date 3-21-84

Reviewed by ____ — Date 3/28/84

Special Instructions or Comments:

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THE
GEORGE
WASHINGTON
UNIVERSITY

Vice President for Medical Affairs / 2300 Eye Street, N.W. / Washington, D.C. 20037 / (202) 676-3727

April 20, 1984

United States
Nuclear Regulatory Commission
Region I
ATTN: Mr. Thomas T. Martin, Director
Division of Engineering and
Technical Programs
631 Park Avenue
King of Prussia, PA 19406

Gentlemen:

In response to your inspection report #030-09049/84-01 several actions have been initiated. A written record of these actions has been kept. The actions include:

1.) Formal training for the Security staff is a part of our regular In-Service Program. Four in-service lectures were given to the Security Staff on February 1 and 2.
2.) Our Emergency Protocol in dealing with accident victims contaminated with radioacitve material includes details of participation by the Division of Nuclear Medicine's staff.
3.) A new survey meter for Clinical Nuclear Medicine (Ludlum Model 177 - 2.2 second response time) has been purchased.
4.) Serial swipes have been instituted in the all research areas throughout the University (this includes Ross Hall and Bell Hall)
5.) The Radiation Safety Committee through its Executive Group is expeditiously dealing with problems as soon as they are identified, and sets new policy to prevent future incidents.
6.) Surveyed areas in Nuclear Medicine have been expanded to include areas outside the hot lab, and detailed records are kept.

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7.) An outside consultant has been engaged to perform an independent audit of our licensed activities. He is instructed to report to the Vice President of Medical Affairs. A list of charges has been worked out by the Executive Group of the Radiation Safety Committee, but the consultant is at liberty to expand his activities as he sees fit.

8.) A training session on the NRC's rules and regulations is scheduled for members of the Radiation Safety Committee. Sections of our procedure manual are distributed to authorized users as soon as completed.

Sincerely,

Ronald P. Kaufman, M.D.
Vice President for Medical Affairs

THE
GEORGE
WASHINGTON
UNIVERSITY

Vice President for Medical Affairs / 2300 Eye Street, N.W. / Washington, D.C. 20037 / (202) 676-3727

April 20, 1984

United States
Nuclear Regulatory Commission
Region I
ATTN: Mr. Thomas T. Martin, Director
Division of Engineering and
Technical Programs
631 Park Avenue
King of Prussia, PA 19406

Gentlemen:

As specified in your letter of March 26, 1984, I am reporting on our investigation of molybdenum-99 breakthrough in technetium-99m elutions. As indicated in the notice of violation in Appendix A this report includes: 1) our findings, 2) the corrective steps taken, 3) corrective steps taken to avoid problems in the future, 4) the date when full compliance will be achieved.

Findings

The assay for molybdenum-99 breakthrough has been carried out daily. Our test satisfies the criteria specified in license condition 20 as well as the more stringent standards of the U.S. Pharmacopoeia. Records of elutions performed after normal working hours or during holidays did not always contain data from breakthough tests. Therefore tne test may not have been performed.

Corrective Steps Taken

To correct the situation Nuclear Medicine personnel have again been instructed, immediately after your visit, that breakthrough tests must be performed and documented according to our written instructions after each elution. These points will also be emphasized in our annual inservice training. Further, the Technical Administrator of Nuclear Medicine has been instructed to monitor compliance on an ongoing basis.

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Preventative Steps Taken

To prevent future problems the Radiation Safety Office staff will monitor each week the Division of Nuclear Medicine's records of activities performed after 5:00 P.M. and on weekends. These findings will be confirmed by the Radiation Safety Office Staff in a written log.

Date of Compliance

We have been in full compliance from the time of inspection. (January 12, 1984)

Sincerely,

Ronald P. Kaufman, M.D.
Vice President for Medical Affairs

MAY 07 1984

Docket No. 030-09049

License No. 08-00216-22

The George Washington University
Medical Center
ATTN: Ronald P. Kaufman, M.D.
Vice President for Medical Affairs
2300 Eye Street, N.W.
Washington, D.C. 20037

Gentlemen:

Subject: Inspection No. 030-09049/84-01

This refers to your (2) letters dated April 20, 1984, in response to our letter dated March 26, 1984.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
John E. Glenn

Thomas T. Martin, Director,
Division of Engineering and
Technical Programs

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

The George Washington University
Medical Center
ATTN: Mario Werner, M.D.
Chairman, Radiation Safety Committee
2300 K Street, N.W.
Washington, D.C. 20037

The George Washington University
Medical Center
ATTN: Fred Leonard, Ph.D
Associate Dean for Research
2300 I Street, N.W.
Washington, D.C. 20037

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RL30-09049/84-01 - 0001.0.0
05/02/84

The George Washington University
Medical Center
ATTN: Mark Selikson
Radiation Safety Officer
2300 K Street, N.W.
Washington, D.C. 20037

bcc:
Region I Docket Room (w/concurrences)

RI:DETP	RI:DETP	RI:DETP	RI:DETP
Johansen/cjm	Darden	Glenn	Joyner
5/ /84	5/4/84	5/4/84	5/ /84