JUN 2 7 1983

Docket Nos. 030-09049 ✓
030-19445
070-01795

License Nos. 08-00216-22 ✓
08-00216-23
SNM-1499

MEMORANDUM FOR: James M. Allan, Acting Regional Administrator

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

FROM: James H. Joyner, Chief, Nuclear Materials and Safeguards Branch, DETP

SUBJECT: PRE-BRIEFING FOR ENFORCEMENT CONFERENCE ON GEORGE WASHINGTON UNIVERSITY'S VIOLATIONS

Attached is background information for the enforcement conference to be held at Region I at 1:00 p.m. on July 19, 1983, with George Washington University. The meeting will be limited to discussion of the violations identified and management's control of the radiation safety program.

A pre-briefing is scheduled at 10:00 a.m., July 19, 1983, in the Main Conference Room.

Original Signed by:

ANTHONY GODY

for James H. Joyner, Chief
Nuclear Materials and Safeguards
Branch

Attachments:
1. Notice of Significant Licensee Meeting
2. Briefing Package
3. Inspection History

cc w/attachments:
J. Glenn
J. Kinneman
J. Johansen
T. Darden
D. Holody
J. Gutierrez
T. Martin
J. Joyner



7

| OFFICE | RI:DETP | RI:DETP | RI:DETP | RI:DETP | RI:DETP | | |
|---|---|---|---|---|---|---|---|
| SURNAME | Johansen/lp | T Darden | Glenn for J.H. | Kinneman | Joyner | | |
| DATE | 6/16/83 | 6/17/83 | 6/17/83 | 6/23/83 | 6/24/83 | | |

## ENFORCEMENT CONFERENCE WITH GEORGE WASHINGTON UNIVERSITY

The enclosed Materials Inspection Program briefing package in three parts is for use in the pre-enforcement conference for the Region I staff at 10:00 a.m., July 19, 1983, and in the enforcement conference with the licensee at 1:00 p.m., July 19, 1983.

## OVERVIEW

Part I - Inspection Findings

Part II - Staff Evaluation/Consequences/Observations of Performance

Part III - Escalated Enforcement Action Recommendation

## Part I - Inspection Findings

(NRC Combined Inspection Report 30-09049/83-01, 30-19445/83-01 and 070-01795/83-01)

A. Results

A routine unannounced inspection of licensee's radiation safety program was conducted at Washington, D.C., on June 1 and 2, 1983, by two NRC Region I inspectors.

The licensee was found to be in compliance with all regulations except for the following violations: (1) Failure to maintain effluent concentrations at levels specified in Appendix B, Table II, 10 CFR 20, when averaged over a 1 year period; (2) failure to dispose of radioactive waste through an authorized method; (3) failure to report diagnostic misadministrations; (4) failure to perform leak tests of sealed sources at 6 month intervals; (5) failure to perform dose calibrator linearity tests quarterly; (6) failure to calibrate survey meters biannually (every 6 months); (7) failure to wear gloves when handling radioactive material; (8) failure to refrain from smoking, eating, and drinking in a restricted area; (9) failure to wear TLD finger badge; (10) failure to dispose of radioactive waste in specifically designated receptacles; (11) failure to refrain from mouth pipetting of radioactive materials; (12) failure to perform daily surveys.

Additionally, an allegation that a worker had been exposed to an unshielded source of radium for four and one-half months of her pregnancy was investigated and found to be an isolated event involving a check source of < 6 microcuries, 5 meters from the individual's desk which was in the area two days rather than 4½ months (See full report, Item 19).

## Part II - Staff Evaluation/Consequences of Violation

1. Failure to Maintain Effluent Concentrations at Levels Specified in Appendix B, Table II, 10 CFR 20, When Averaged Over a One (1) Year Period

10 CFR 20.106(a) requires that no licensee release radioactive material to an unrestricted area in concentrations which exceed the limits specified in 10 CFR 20, Appendix B, Table II, when averaged over one year.

Contrary to the above, during the period ending March 31, 1982, xenon 133 was released in the stack effluent in concentrations of $7.5 \times 10^{-7}$ microcurie per milliliter when averaged over one year, 2.5 times the limit in 10 CFR 20, Appendix B, Table II.

Review of Radiation Safety Committee minutes, the Radiation Safety Office's 1982 annual report and incident reports indicated that the licensee identified an effluent release problem in nuclear medicine which continued for about a 6-month period during 1981-1982. The total activity released to the environment over a 1-year period ending March 31, 1982, was 3.856 curies. The effluent releases were evaluated and found to be 2.5 times the limit in 10 CFR 20, Appendix B, Table II. The licensee took action to increase the exhaust ventilation rate of the hood from 300 cfm to 555 cfm in the room where the xenon-133 was stored. An additional recommendation of the radiation safety officer to purchase airtight syringes was negated by the Technical Administrator of Nuclear Medicine as too costly. Weekly releases after March 31, 1982, have averaged 25-30% MPC and an annual averaging period ending January 1, 1983, indicated effluent releases at 72% MPC. Further, the licensee is now using two crushers. A second crusher allows them to hold the licensed xenon for an additional two weeks (2.7 half lives) before releasing it. This is a corrective action taken to assure decreased effluent rates.

Although the licensee identified the release as exceeding 20.106(a) MPC limits averaged over a one year period ending March 31, 1982, and determined that the effluent releases did not require notification of the NRC by either a 24-hour or 30-day report, he did allow, after his first identification, the effluent releases to exceed MPC values for over a 6-month period. It is the opinion of the inspectors that this delay demonstrates a reactive rather than preventive radiation safety program and is contrary to good ALARA practice.

2. Failure to Dispose of Radioactive Waste Through an Unauthorized Method

10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures.

Contrary to the above, as of January 25, 1983, a bag of waste consisting of disposable protective clothing and plastic back absorbent pads containing ≈ 70 microcuries of iodine-125 were removed from a restricted laboratory and placed in the normal trash without a survey as required by License Condition 21. Subsequently this waste was removed and transported to a public landfill near Lorton, Virginia.

Review of the March 24, 1983, Radiation Safety Committee minutes indicated the licensee had lost a small amount of radioactive material. Radiation Safety Office incident file (February 3, 1983) indicated that on January 25, 1983, a bag of radioactive waste consisting of protective clothing and plastic back absorbent pads containing activity less than 70 microcuries (licensee evaluation) of iodine-125 was removed from a restricted area and placed in the Ross Hall trash compactor. The trash was removed later that day and transported to a landfill near Lorton, Virginia.

The licensee took corrective actions and evaluated that the radiation levels from the waste would not constitute a substantial hazard to the public or the environment and therefore did not report the loss to the NRC Regional Office. The inspectors agreed that based on the licensee's evaluation, the handling of the waste did not represent a significant hazard to the public or the environment, therefore, it was not reportable. However, the licensee's incident report failed to recognize that this was an unauthorized disposal with regard to 10 CFR 20.301 and demonstrated poor physical control and poor management control of licensed materials.

3. Failure to Report Diagnostic Misadministrations

10 CFR 35.43 requires diagnostic misadministrations be reported to the NRC Regional Office within 10 days after the end of the calendar quarter in which the misadministration occurred.

Contrary to the above, as of June 2, 1983, misadministrations which occurred on October 13, 1982, and November 16, 1982, were not reported to the NRC Regional Office within 10 days after the end of the 4th quarter 1982 (December 31, 1982).

Discussions with Nuclear Medicine personnel and review of incident reports in Nuclear Medicine and the Radiation Safety Office indicate that investigations of the misadministrations as to causes and corrective actions were taken. There were no indications, however, that the reports were forwarded to the NRC. This violation was identified during the inspection. The Radiation Safety Officer admitted he was unaware of the regulation to report diagnostic misadministrations to the NRC. This violation demonstrates lack of management control.

4. Failure to Perform Leak Tests of Sealed Sources at 6 Month Intervals

Condition 13 of License No. 08-00216-22 requires that sealed sources containing byproduct material be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, as of June 2, 1983, sealed sources containing millicurie quantities of cesium-137 for brachytherapy were not leak tested the 2nd half of 1982 and a cesium-137 check source containing 184 microcuries had not been leak tested the 1st half of 1981 and the entire year of 1982.

Records reviewed in the Radiation Safety Office indicated that cesium-137 brachytherapy sources were leak tested June 24, 1982, and again on May 31, 1983. No leak test was performed during the 11 month interval. A cesium-137 check source containing 184 microcuries (9/20/74) was leak tested on November 4, 1981, and again on May 31, 1983. No records could be found for a leak test for the 11 month period prior to November 4, 1981, and for the 18 month period between November 4, 1981, and May 31, 1983.

Radiation Safety Officer stated that because of the turnover in the staff the leak tests were not performed as required. Although the leak tests were not performed at the required intervals, the May 31, 1983, leak tests indicated that there was no leakage of any sealed source equal to or greater than the 0.005 μCi limit. This violation could present a possible hazard should the sealed sources have been leaking. It does represent a loss of management control.

THE FOLLOWING 8 VIOLATIONS CONCERN LICENSE CONDITION 21.

Condition 21. of License No. 08-00216-22 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in applications dated March 21, 1978, and January 31, 1979; letters with attachments dated March 27, 1979, and April 18, 1979; Items A (ALARA Program), D. and E. of letter dated May 15, 1981; and letters dated January 28, 1982, July 1, 1982, and July 13, 1982.

5. Failure to Perform Dose Calibrator Linearity Tests Quarterly

Item No. 10 of attachment to the letter dated March 27, 1979, requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8 (January 1979).

Procedure E of Appendix D, Section 2, requires dose calibrators to be tested for linearity quarterly.

Contrary to the above, as of June 1, 1983, linearity tests on your dose calibrator were not performed for the 3rd and 4th quarters of 1980, the 1st, 2nd, and 4th quarters of 1982, and the 1st quarter of 1983.

Review of the Radiation Safety Office records demonstrated that linearity tests were performed during June 1980, July 1981, August 1982, and March 1983. These frequencies reflect 13, 13, and 7 month intervals rather than the 3 month intervals required. No records on the Nuclear Cardiology dose calibrator were available for review.

Since each test that was performed indicated linearity was maintained within $\pm$ 5% and the test performed for the 2nd quarter of 1983 also

demonstrated this linearity, there was no appreciable hazard impact; however, failure to perform tests at required intervals does reflect on management control of the program.

6. Failure to Calibrate Survey Meters Biannually

Item No. 10 of the attachment to the letter dated March 27, 1979, requires that survey meters be calibrated biannually (every 6 months).

Contrary to the above, as of June 2, 1983, several survey meters found in the research laboratories had not been calibrated since March 1982, an interval in excess of 6 months.

Licensee's statements to the Commission do not differentiate calibration of survey meters based on the qualitative or quantitative function of the survey meter. The survey meters in the research area which were out of calibration were count rate meters with pancake probes used to identify contamination levels rather than radiation levels. The survey meters did function for use intended for the survey meter in the laboratory. The R.S.O. performs daily or monthly surveys for contamination levels and the survey instruments used by the R.S.O. were calibrated.

In the inspectors' opinion, the failure to perform survey meter calibrations at the required interval demonstrates a lack of management control rather than a hazard to personnel or the environment.

7. Failure to Wear Gloves While Handling Radioactive Material

Rule 2 of Appendix G requires that disposable gloves be worn at all times while handling radioactive materials.

Contrary to the above, on June 1, 1983, personnel in the Nuclear Medicine Department failed to wear disposable gloves while handling radioactive materials, specifically, while injecting radiopharmaceuticals.

Failure to wear gloves is a hazard to the individual user as radioactive materials may be absorbed through the skin, and contamination from the hands could be ingested or spread to other individuals.

8. Failure to Refrain From Smoking, Eating, and Drinking in Restricted Areas

Rule 5 of Appendix G requires that there be no eating, drinking, smoking, or application of cosmetics in any area where radioactive materials are stored or used.

Contrary to the above, as of June 2, 1982, an individual was smoking in Room 407AB Ross Hall and evidence of eating and drinking were found in several other of the research laboratories inspected in the building.

These are activities which could lead to ingestion of radioactive material. Ingestion of radioactive material can lead to significant internal doses to individuals.

9. Failure to Wear TLD Finger Badge

Rule 8 of Appendix G requires that TLD finger badges be worn during elution of generators, and during preparation, assay and injection of radiopharmaceuticals.

Contrary to the above, on June 1, 1983, a student technologist did not wear a TLD ring badge while preparing radiopharmaceuticals.

Failure to wear TLD finger badges when handling millicurie quantities of radioactive materials to prepare radiopharmaceuticals is a hazard to the individual in that high extremity doses are possible and monitoring is required to evaluate exposures.

This is a repeat of an Inspection No. 80-01 finding.

10. Failure to Dispose of Radioactive Materials in Specifically Designated Receptacles

Rule 9 of Appendix G requires that radioactive waste be disposed of only in specifically designated receptacles.

Contrary to the above, as of June 2, 1983, a receptacle designated as non-radioactive "cold trash" contained radioactive materials having a radiation level of 7 milliroentgen per hour at the surface of the receptacle.

Placement of radioactive wastes into receptacles specifically designated for non-radioactive waste presents a hazard from radiation exposure and/or contamination to individuals who may handle the waste, and may lead to improper disposal of radioactive material.

This is a repeat of an Inspection No. 80-01 finding.

11. Failure to Refrain From Mouth Pipetting

Rule 10 of Appendix G requires that there be no pipetting by mouth.

Contrary to the above, as of June 2, 1983, evidence of mouth pipetting was found in Room 234, Ross Hall, involving millicurie amounts of P-32.

Pipetting by mouth in any form presents a hazard of ingestion of radioactive materials and the internal exposure of individuals. The fact that the Radiation Safety Office was aware of this practice and allowed it to continue while studies of other Universities' laboratory practices was performed indicates poor management control.

12. Failure to Perform Daily Surveys

Rule 11 of Appendix G requires surveys of generator, kit preparation, and injection areas after each procedure or at the end of the day.

Contrary to the above, as of June 1, 1983, surveys were not performed on May 9 and 10, 1983, in the Nuclear Medicine areas and for the days between June 18 to August 2, 1982, October 10 to November 8, 1982, and December 18, 1982, to January 31, 1983, in the Nuclear Cardiology areas.

Surveys are required to evaluate possible radiation levels or contamination which may present a hazard to individuals working in the area and expose the individuals to unnecessary external or internal radiation.

## Part III - Enforcement Action Recommendation

A. Discussion

The findings that the licensee released effluent xenon-133 to the unrestricted area (environment) ($7.5 \times 10^{-7}$ µCi/ml) 2.5 times the allowable annual limit as stated in 10 CFR 20.106(a) and a bag of waste containing > 70 µCi iodine-125 was disposed of in a method not authorized by 10 CFR 20.301 or License Condition are classified as Severity Level III violations (Supplement IV).

The two Severity Level III violations in themselves are not very significant because of the low levels of activity involved. The licensee did not take advantage of any dilution factors from the stack exit point to the breathing zone on individuals in the unrestricted area, approximately a 120-foot decrease in elevation for the public and a 4-foot decrease in elevation for a worker on the facility roof which, although controlled, is not a restricted area. The licensee performed reactive correction to the unauthorized disposal by giving refresher training to custodians and declaring restricted area laboratories as off-limits to these persons. There was no exposure either to a member of the public or an employee in excess of normal background (0.02 mR/hr) for either incident; however, these violations are symptomatic of poor program control.

The other 10 findings, classifed as Severity Level IV violations with two being repeat items from Inspection No. 80-01, are symptomatic of poor program control.

B. 10 CFR Part 2 Applications

1. Violations Potentially Assessed Civil Penalty

Failure to maintain annual effluent limits to 10 CFR 20, Appendix B, Table II values.

Disposal not authorized by 10 CFR 20.301.

These are Severity Level III violations (Supplement IV).

2. Violations Not Assessed Civil Penalty

Failure to report diagnostic misadministrations.

Failure to leak test sealed sources.

Failure to perform quarterly linearity tests.

Failure to calibrate survey meters.

Failure to wear protective gloves.

Failure to refrain from smoking, eating, and drinking in a restricted area.

*Failure to wear assigned TLD finger badge.

*Failure to dispose of radioactive material in specifically designated receptacle.

Failure to refrain from mouth pipettin

Failure to perform daily surveys.

These are Severity Level IV violations (Supplement VI).

*Repeat items from Inspection No. 80-01.

Because two Severity Level III violations and ten Severity Level IV violations were identified, of which two were repeats from Inspection 80-01, it is recommended that a two-thousand dollar civil penalty be imposed. This recommendation is based on the results of the 83-01 inspection and the licensee's enforcement history, which indicates two previous management meetings that involved the licensee's control of the radiation safety program. Two violations have been identified on prior inspections and the licensee has a history of uncontrolled airborne concentrations in restricted and unrestricted areas.

It is apparent that the licensee's program is in a reactive rather than a preventive mode. The licensee does identify problems and take corrective action, but these evaluations and corrective actions occur after the fact. There is no indication that possible problems such as airborne xenon-133 in effluent in excess of MPC were evaluated in advance of the use of bulk quantities nor were ALARA considerations implemented once a problem was identified.

Assessment of a civil penalty appears to be appropriate even if the licensee presents strong assurance of corrective action, including management control, at the enforcement meeting.

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

George Washington University
Inspection History

| Inspection | Results |
|---|---|
| 74-01 | Category II - 10 CFR 20.201(b)<br>Failure to survey to determine airborne concentration in restricted area did not exceed limits of 10 CFR 20.103.<br><br>Category II - 10 CFR 20.201(b)<br>Failure to survey to determine airborne concentrations in unrestricted area did not exceed limits of 10 CFR 20.106.<br><br>Category II - 10 CFR 20.105<br>Failure to survey for radiation levels in unrestricted area.<br><br>Category II - License Condition 18<br>Failure to survey in radioactive material use areas for contamination.<br><br>Category III - 10 CFR 20.401(b)<br>Failure to maintain survey records.<br><br>Deficiency - Standard Safety Practice<br>Storage I-125 waste in unsealed container in unventilated area of lab. |
| 75-01<br>(Subsequent telephone call) | Infraction - 10 CFR 20.201(b)<br>Failure to survey for airborne concentrations on all occasions when high specific-activity iodine-125 was used with regard to 10 CFR 20.103 (Repeat 74-01).<br><br>Infraction - 10 CFR 20.201(b)<br>Failure to survey for air concentrations in unrestricted area to determine compliance with 10 CFR 20.106 (Repeat 74-01). |
| 76-01<br>(Subsequent telephone call on recurrent items, management control) | Infraction - 10 CFR 20.201(b)<br>Failure to survey for air concentrations on all occasions when high specific-activity iodine-125 was used in regard to 10 CFR 20.103 (Repeat 74-01, 75-01).<br><br>Infraction - 10 CFR 20.201(b)<br>Failure to survey for air concentrations in unrestricted area to determine compliance with 10 CFR 20.106 (Repeat 74-01, 75-01). |

| Inspection | Results |
|---|---|
| 76-01 (continued) | Infraction - License Condition 18<br>Failure to perform contamination surveys at frequency required (Repeat 74-01). |
| | Infraction - License Condition 18<br>Failure to place radioactive waste in designated receptacle. |
| | Deficiency - 10 CFR 19.11(a)(b)<br>Failure to post required documents. |
| 77-01 (Subsequent telephone call management meeting) | Infraction - 10 CFR 20.103(a)(1)<br>Exposure to individual in unrestricted area to air concentration in excess of limits for quarter. |
| | Infraction - 10 CFR 20.201(b)<br>Failure to adequately evaluate samples taken to determine compliance with 10 CFR 20.106 (Repeat 74-01, 75-01, 76-01). |
| | Infraction - 10 CFR 20.201(b)<br>Failure to adequately evaluate samples taken to determine compliance with 10 CFR 20.106 (Repeat 74-01, 75-01, 76-01) |
| | Infraction - License Condition 15(A)<br>Failure to bioassay at required H-3 levels. |
| 77-02 (Subsequent telephone call Management control emphasized on second date reinspection) (Inspection July 13 and repeat July 22, 1977) | Infraction - 10 CFR 20.103(b)(2)<br>Failure to fully evaluate, take action or document actions to prevent recurrence of airborne concentration intake in excess of limits. |
| | Infraction - 10 CFR 19.12<br>Failure to train - re 10 CFR 20.103(b) license conditions. |
| | Infraction - 10 CFR 20.207(a)<br>Failure to secure radioactive material. |
| 77-03 | Clear |
| 78-01 | Infraction - 10 CFR 20.201<br>Failure to survey to assure airborne concentration in unrestricted area did not exceed values stated in 10 CFR 20.106 (Identified previously 74-01, 75-01, 76-01, 77-01) |

| Inspection | Results |
|---|---|
| 78-02 | Infraction - License Condition 18<br>Smoking and drinking in laboratories. |
| 80-01 | Infraction - License Condition 21<br>Failure to wear TLD finger badges. |
| | Infraction - License Condition 21<br>Failure to dispose of radioactive material in designated receptacle (Identified previously 76-01). |
| | Infraction - License Condition 21<br>Failure to do contamination surveys (Identified previously 74-01, 76-01). |
| 83-01 | Severity Level III violation - 10 CFR 20.106(a)<br>Failure to maintain unrestricted airborne concentrations to Appendix B, Table II limits as averaged over a one year period.<br>(Similar to 74-01, 75-01, 76-01, 77-01, 78-01) |
| | Severity Level III violation - 10 CFR 20.301<br>Unauthorized waste disposal. |
| | Severity Level IV - 10 CFR 35.43<br>Failure to report diagnostic misadministration. |
| | Severity Level IV - License Condition 13<br>Failure to leak test sealed sources. |
| | Severity Level IV - License Condition 21<br>Failure to perform linearity tests quarterly on dose calibrator. |
| | Severity Level IV - License Condition 21<br>Failure to calibrate survey meters biannually. |
| | Severity Level IV - License Condition 21<br>Failure to wear gloves. |
| | Severity Level IV - License Condition 21<br>Smoking, eating, drinking, in restricted laboratories (Previously identified 78-02). |
| | Severity Level IV - License Condition 21<br>Failure to wear TLD finger badges (Repeat 80-01). |

| Inspection | Results |
| --- | --- |
| 83-01 (continued) | Severity Level IV - License Condition 21 Failure to dispose of radioactive waste in designated receptacle (Repeat 80-01, 76-01). |
| | Severity Level IV - License Condition 21 Mouth pipetting of radioactive materials. |
| | Severity Level IV - License Condition 21 Failure to do daily surveys (Similar to 80-01, 76-01, 74-01). |

JUN 3 0 1983

Docket Nos. 030-09049
030-19445
070-01795

License Nos. 08-00216-22
08-00216-23
SNM-1499

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

Gentlemen:

Subject: Inspection No. 83-01

This refers to the routine safety inspection conducted by Jenny M. Johansen and Teresa H. Darden of this office on June 1-2, 1983, of activities authorized by NRC License Nos. 08-00216-22, 08-00216-23, and SNM-1499 and to the discussions of our findings held by Ms. Johansen with yourself and Drs. M. Werner and M. Selikson at the conclusion of the inspection, and to a subsequent telephone discussion between Mr. James Joyner and yourself on June 14, 1983.

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 certain of your activities were not conducted in full compliance with NRC requirements, as discussed in the enclosed inspection report. We are considering appropriate enforcement action for these violations and will advise you later of our decision.

This letter also confirms that an Enforcement Conference will be conducted in our Region I office on July 19, 1983, at 1:00 p.m. to discuss these violations. At that Enforcement Conference you should be prepared to discuss the causes of the violations and your proposed corrective action.

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.

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NRC FORM 318 (10-80) NRCM 0240

No reply to this letter is required. Your cooperation with us in this matter is appreciated.

Sincerely,

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

Enclosures:
Combined NRC Region I Inspection Report No. 030-09049/83-01; 030-19445/83-01
070-01795/83-01
NRC Enforcement Policy (10 CFR Part 2, Appendix C)
Directions from Philadelphia International Airport to USNRC Office

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

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

bcc:
Region I Docket Room (w/concurrences)
Senior Operations Officer (w/o encl)
D. Holody
J. Gutierrez

| OFFICE | RI:DETP | RI:DETP | RI:DETP | RI:DETP | RI:DETP | RI:IE | |
|---|---|---|---|---|---|---|---|
| NAME | Johansen/tp | Darden | Glenn | Kinneman | Jordan for | Holody | Martin |
| DATE | 6/16/83 | 6/16/83 | 6/16/83 | 6/14/83 | 6/24/83 | 6/29/83 | 6/28/83 |

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-09049/83-01
030-19445/83-01
070-01795/83-01

Docket Nos. 030-09049
030-19445
070-01795

License Nos. 08-00216-22
08-00216-23
SNM-1499

Priority II III III

Category G1 E G

Licensee: The George Washington University Medical Center

2300 K Street N.W.

Washington, D.C. 20037

Facility Name: The George Washington University Medical Center

Inspection At: Washington, D.C.

Inspection Conducted: June 1-2, 1983

Inspectors: Jenny M. Johanson — June 16 1983 date
Jenny M. Johanson
Radiation Specialist

Teresa Hall Darden — June 16, 1983 date
Teresa H. Darden
Radiation Specialist

Approved by: for Lawrence F. Friedman — 6/16/83 date
John E. Glenn, Ph.D., Chief
Nuclear Materials Section B

Inspection Summary:

Inspection conducted June 1-2, 1983 (Combined Report No. 030-09049/83-01, 030-19445/83-01, 070-01795/83-01

Areas Inspected: Routine unannounced inspection of a pacemaker implant program, small animal irradiator program, and 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 measurements by the inspectors, and review of allegation concerning radiation safety program. The inspection involved 40 hours on site time by two NRC inspectors.

Results: Twelve violations were identified: Failure to maintain effluent concentrations below regulatory limits, unauthorized waste disposal, failure to report diagnostic misadministrations, failure to leak test sealed sources at required frequency, failure to perform linearity tests on dose calibrator each calendar quarter, failure to calibrate survey instruments biannually (every 6 months), failure to wear extremity dosimeters, failure to wear protective gloves, failure to refrain from smoking, eating, and drinking in restricted areas, failure to dispose of waste in designated receptacles, failure to refrain from mouth pipetting, failure to perform daily surveys.

## DETAILS

1. Persons Contacted

*Mark Selikson, Ph.D., Radiation Safety Officer
*Mario Werner, M.D., Chairman, Radiation Safety Committee
*Fred Leonard, Ph.D., Associate Dean for Research
Michael Cianci, Technical Manager, Nuclear Medicine
S. Barth, Nuclear Medicine Technologist
A. Prats, Student Technologist
J. Rae, Nuclear Medicine Technologist
D. Hixson, Chief, Imaging
A. Castanogo, Technical Manager, Radiation Therapy
G. Goode, Assistant Radiation Safety Officer
Barbara Francis, Researcher
Dr. W. Eckelman, Researcher
D. Kean, Researcher
Dr. R. Williams, Researcher
M. C. Augustyn, Researcher
Judith Bageant, Researcher
Karen Anderson, Researcher
Pao Mai, Researcher
Dr. DeAngelo, Researcher
M. S. Driver, Researcher Radiopharmacy
E. Jogoda, Researcher Radiopharmacy
P. Maloney, Researcher
A. Kumar, Researcher
Ms. Gaffney, Radiation Safety Technician
Various other personnel in research laboratories and Nuclear Medicine.

*Denotes those present at exit interview.

2. Licensee Action on Previous Inspection Findings

(Open) Inspection 80-01: License No. 08-00216-22 - Failure to wear TLD finger badge during preparation of radiopharmaceuticals. This item has recurred.

(Open) Inspection 80-01: License No. 08-00216-22 - Failure to dispose of radioactive waste in specially designated receptacles. This item has recurred.

(Closed) Inspection 80-01: License No. 08-00216-22 - Failure to survey the laboratory for contamination following use of 50 millicuries of phosphorus-32. The inspectors reviewed survey records of laboratories authorized to use 5 millicuries or more of P-32 and found that the Radiation Safety Office surveys these laboratories on a weekly frequency. If contamination problems were noted during these surveys, a more frequent schedule of surveys was instituted until problems of contamination were resolved.

3. License No. 08-00216-22

This license authorizes broad scope use of radionuclides for medical research, diagnosis and therapy, research and development as defined by 10 CFR 30.4(q) and animal studies.

4. Organization

The Radiation Safety Committee 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 totals 16 individuals representing the various departments involved with the use of radioactive materials or radiation sources.

Since the previous inspection April 10, 1980, the minutes of the Committee and the Radiation Safety Office's Annual Report indicate the Committee has met at least once per calendar quarter.

The Radiation Safety Officer is responsible to the President of the University through the Vice President of the 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, two Radiation Safety Technicians, a secretary (vacant), and a summer student.

Since the previous inspection 80-01 (April 10, 1980), the Radiation Safety Officer stated that he has had difficulty in maintaining full staffing due to turnover in personnel.

Records in the Radiation Safety Office indicate authorizations have been granted to 45 major users in various research areas. In addition, there are numerous individuals using radioactive materials under these 45 major authorized users.

Clincal 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, including about 12 xenon-133 scans. An average of 6 brachytherapy implants are performed per month using Cs-137, Ir-192, or I-125.

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

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 by 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.

5. Licensee Internal Audits

The licensee has an informal audit program which identifies deficiencies and suggests corrective actions. This program is part of the weekly and monthly routine surveys performed by the Radiation Safety Office staff. Reports of deficiencies are reviewed at the Radiation Safety Committee meetings and have resulted in a full investigation of particular users' laboratories and various problems such as waste disposal techniques and xenon releases to the environment.

The Radiation Safety Officer meets with each authorized user annually to review his or her use of radioactive materials.

A formal audit report form has been developed by the Radiation Safety Officer; however, this form has not yet been used.

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

6. Training

Interviews with nuclear medicine personnel indicated that they have received "in house" training as to the procedures for handling radioactive materials and the requirements for recordkeeping pertaining to the license.

All researchers interviewed indicated that they had to pass a required examination to use radioactive materials.

From the Radiation Safety Officer's annual report it was determined that personnel who did not pass the examination were required to attend a lecture series given by the Radiation Safety Officer.

Interviews with female employees of childbearing age working with radioactive materials indicated they had received information from the Radiation Safety Office contained in Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure."

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

7. Radiation Protection Procedures

A review of patient records, survey records, and discussions with the Radiation Safety Officer 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 prior to the discharge of patients were performed. Patients containing iodine-131 were released when 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.

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

8. Use of Materials

License Condition 13 requires that sealed sources containing 100 microcuries or more beta-gamma emitting byproduct material be tested for leakage and or contamination at intervals not to exceed six months. From a review of records and discussions with the Radiation Safety Officer, it was determined that the cesium-137 brachytherapy sources were not leak tested during an eleven month period from June 24, 1982, to May 31, 1983. A cesium-137 reference source containing 184 microcuries (9/20/74) had not been leak tested during an eleven month period prior to November 4, 1981, nor for the eighteen month period between that date and May 31, 1983.

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 records for the linearity tests were kept in the Radiation Safety Office. Review of the linearity test records determined that quarterly linearity tests were not performed on the Nuclear Medicine dose calibrator in the thirteen month period from June 1980 to July 1981, the thirteen month period from July 1981 to August 1982, and the seven month period from August 1982, to March 1983. Linearity tests for the dose calibrator in Nuclear Cardiology were not available.

The finding that sealed sources containing 100 microcuries or more of beta/gamma emitting byproduct material were not leak tested at 6 month intervals is a violation of License Condition 13.

The finding that a dose calibrator linearity test was not performed for each calendar quarter during 1980, 1981, 1982, and 1983 is a violation of License Condition 21.

9. 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.

Visits to the research laboratories determined that laboratories containing radioactive materials are locked when unattended.

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

10. Facilities

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

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

11. Instruments

License Condition 21 requires that survey meters be calibrated biannually (every 6 months).

The inspectors found several survey meters in the research laboratories which had not been calibrated since March of 1982.

The finding that several survey meters were not calibrated biannually is a violation of License Condition 21.

12. Receipt and Transfer of Material

The licensee maintains a procedure for safely opening packages of radioactive materials which includes 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 records kept of the survey.

Records reviewed in the Radiation Safety Office indicated several transfers to other broad licensed institutions have occurred. Shipping papers and vouchers examined indicated these were shipped in accordance with regulations in 10 CFR 71.5.

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

13. Personnel Protection - External

A student nuclear medicine technologist was observed during the elution of the generator and preparation of radiopharmaceuticals. The student was not wearing a TLD finger badge. She stated that she had forgotten to put it on. The student placed the TLD ring on her right hand, put on new gloves and continued working.

The nuclear medicine technologist was observed injecting a patient without wearing gloves. The technologist stated that she did not routinely wear gloves when injecting older patients as veins were hard to find. The inspector surveyed the technologist's hands and found no contamination. The technologist stated that she did check her hands frequently throughout the day to assure she was not contaminated.

The daily surveys of the generator, kit preparation, and injection areas of the nuclear medicine hot lab and nuclear cardiology hot lab were reviewed with the technologist. The records indicated surveys were not performed on May 9-10, 1983, in the Nuclear Medicine Hot Lab and for the days between June 18 to August 2, 1982, October 10 to November 8, 1982, and December 18, 1982, to January 31, 1982, in Nuclear Cardiology.

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

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.

The finding that an individual did not wear the assigned TLD finger badge when preparing radiopharmaceuticals is a violation of License Condition 21.

The finding that an individual did not wear gloves when injecting radiopharmaceuticals is a violation of License Condition 21.

The finding that daily surveys were not performed in the generator, kit preparation or injection areas of the Nuclear Medicine and Nuclear Cardiology Hot Labs is a violation of License Condition 21.

14. 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 radionucide.

The licensee performs thyroid monitoring for personnel handling millicurie quantities of iodine-131 or 125. Records indicated no person exceeded an uptake level of 0.12 microcuries of iodine-125 nor 0.04 microcuries of iodine-131.

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

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

15. Effluent Control, Waste Disposal

Radioactive waste is stored for decay and surveyed before disposal in ordinary waste, 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.

Review of Radiation Safety Committee minutes, 1982 annual report of the Radiation Safety Officer and Incident files indicated that the licensee identified an effluent release problem in nuclear medicine which continued for about a 6 month period during 1981-1982. For the period ending March 31, 1982, xenon-133 was released in the stack effluent in concentration of $7.5 \times 10^{-7}$ microcuries per milliliter when averaged over one year. This quantity is 2.5 times the limit allowable for xenon-133 as stated in 10 CFR 20, Appendix B, Table II.

Licensee took corrective actions which increased the effluent air flow rate and switched to two crushers. The second crusher holds the unused xenon for an additional two weeks before it is released. Concentration for a period ending January 1, 1983, indicate levels at 72% of the MPC ($3.0 \times 10^{-7}$ µCi/ml xenon-133). Levels after March 31, 1982, varied from 25 to 50% of the MPC value.

Radiation Safety Office incident records indicated that on January 25, 1983, a bag of waste consisting of disposable protective clothing and laboratory chucks containing less than 70 microcuries of iodine-125 was removed from a restricted area by the custodial staff and placed in the Ross Hall trash compactor. The trash was later removed and transported to a public landfill near Lorton, Virginia. The licensee made an evaluation for the loss of the material which indicated no significant hazard to the public or the enivronment and therefore did not notify the NRC in accordance with 10 CFR 20.402. Corrective action was taken to assure further loss of material did not occur.

License Conditon 21 requires that radioactive waste be disposed of only in specifically designated and properly shielded receptacles.

The inspectors surveyed a waste container labeled "cold trash" from the nuclear medicine "hot lab." Radiation levels of 7 mR/hr were detected using a Ludlum Model 3 G-M survey meter calibrated May 11, 1983. Licensee's Texas Nuclear survey meter calibrated March 31, 1983, indicated a radiation level of 4.0 mR/hr with the use of an X2 correction factor.

Review of shipping papers and waste disposal records in the Radiation Safety Office indicates the licensee disposes of 3-5 barrels (55-gallon) of radioactive waste per month through a commercial waste disposal company. Procedures and records appeared in order.

The finding that xenon-133 was released in the stack effluent in concentrations of $7.5 \times 10^{-7}$ microcuries per milliliter as averaged over a one year period ending March 31, 1982, a quantity 2.5 times the limit in 10 CFR 20, Appendix B, Table II, is a violation of 10 CFR 20.106(a).

The finding that a bag of radioactive waste containing < 70 microcuries of iodine-125 was placed in the normal trash which was later removed and transported to a public landfill is a violation of 10 CFR 20.301.

The finding that radioactive waste was not placed in specially designated receptacle is a violation of License Condition 21.

16. Notifications and Reports

Discussions with nuclear medicine technologists, the Technical Manager of Nuclear Medicine, and review of records in the Nuclear Medicine and Radiation Safety Offices indicated that on October 13, 1982, and November 16, 1982, diagnostic misadministrations occurred involving a radiopharmaceutical given to the wrong patient and the administration of a radiopharmaceutical other than the one intended. Diagnostic misadministrations are reportable to the appropriate NRC Regional Office within 10 days after the end of the calendar quarter in which they occur.

The finding that diagnostic misadministrations which occurred during the 4th quarter of 1982 were not reported to the appropriate NRC Regional Office is a violation of 10 CFR 35.43.

17. Posting

All required notices were posted.

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

18. Other License Conditions

License Condition 21 requires that "General Rule for the Safe Use of Radioactive Material" found in NUREG-0338 be followed. These rules forbid eating, drinking, and smoking in areas where radioactive materials

are used or stored and strictly forbid pipetting of radioactive materials by mouth. Further, procedures for handling radioactive materials found on page 40 of the licensee's "Radioactive Users Guide" strictly forbids eating, smoking, and mouth pipetting while working with radioactive materials.

The inspectors observed an individual smoking in Ross Hall, Room 407AB and found evidence of eating and drinking in other laboratories in Ross Hall. Each laboratory visited was clearly posted with a "Caution Radioactive Materials" sign.

In laboratory areas connected to Ross Hall 232 posted with a "Caution Radioactive Materials" sign the inspectors observed several mouth pipetting hoses. The inspectors questioned the researcher in charge of the laboratory concerning the pipetting hoses. He stated that the laboratory personnel pipetted microliter quantities of radioactive materials by mouth using the hoses and this had been his practice at his previous place of employment. Authorization for this laboratory indicates that up to 1.3 curies of P-32 and 10 millicuries each of H-3, C-14, and S-35 may be used for the year in this laboratory.

The finding that smoking, eating, and drinking occurred in laboratories where radioactive materials were used or stored is a violation of License Condition 21.

The finding that radioactive materials were pipetted by mouth is a violation of License Condition 21.

19. Allegation Regarding Adequacy of Radiation Safety Program

On April 1, 1983, NRC Materials Licensing Branch anonymously received a copy of an employee's resignation letter which alleged that the employee had been exposed to an unsealed source of radium at George Washington University during 4½ months of her pregnancy.

The inspectors discussed the allegation with the Radiation Safety Officer. He stated that on February 16 and 17, 1983, one of the technicians had stored a check source of ≈ 6 microcuries of radium-226 next to the window approximately 5 meters from where the office secretary sat. It is a normal occurrence for the technicians to sign out from storage and to carry a small check source with them when doing weekly/monthly laboratory surveys in order to check laboratory survey meters for response. They are to return the source to the storage room after use rather than leave it in the office for convenience. On February 17, 1983, he told the technician to remove the source immediately to the storage room. The employee immediately complied. The pregnant employee overheard the conversation and was upset that a radiation source had been in the office. After calming the employee, the Radiation Safety Officer told

her he would do a "worst case" evaluation of her possible radiation exposure so she could take the document to her private physican and be reassured by an outside source (see Attachment A).

On February 22, 1983 (see Attachment B), the Radiation Safety Officer gave the employee a "worst case" report, he informed her verbally that the calculations were based on the assumption that the source had been in the office the entire length of her pregnancy rather than the actual two days.

The inspector took photographs of the office (see Attachment C) and measured a distance of 5 meters from the employee's desk to the window where the source was stored. Additionally, the inspectors observed that a large metal file cabinet situated halfway between the employee's desk and the window provided some shielding for any individual sitting at the employee's desk.

Without the source present the inspectors surveyed the office area and measured background levels of 0.02-0.03 milliroentgens per hour as determined by a Ludlum Model 3 thin end window (1.4 mg/cm$^2$ mica) G-M survey meter calibrated May 11, 1983.

The inspectors reviewed the exposure calculation given the employee. This calculation indicated that, in the "worst case," where the source was present from October 25, 1982, to February 17, 1983, the total exposure would have been 0.36 milliroentgens (0.02 mR/week) whole body. however, the source was only present from February 16 to February 17, 1983. The inspectors confirmed that the evaluation of the calculations were reasonable. Normal background radiation corresponds to approximately 2 milliroentgen per week.

The worker sitting at the desk approximately 1 meter from the source (see Attachment C) would have received an exposure of 0.16 mR for the two days (8 hour/day) the source was actually present and 7.2 mR if the source had been present for 18 weeks based on the exposure data in Attachment B.

The inspectors were given the telephone number of the former employee and tried to contact the employee on twenty different occasions during June 1, 2, 3, 4, and 6, 1983. No response was obtained.

Throughout the inspection, discussion with the individual women working in restricted and unrestricted areas who were of childbearing age concerning pregnancy policy and working with radioactive materials while pregnant indicated that the allegation was an isolated event involving non-NRC regulated materials and is not indicative of the Radiation Safety Officer's control of NRC regulated materials in an area where pregnant employees are working.

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

20. License No. 08-00216-23

This license authorizes 2,500 curies of cesium-137 in a custom made (Gamma radiator 100) irradiator for radio-biological studies with non-human specimens.

The inspectors confirmed that the irradiator located in Ross B-38 is secured at all times when an individual user is not present. Key control to the irradiator is supervised by the Radiation Safety Officer. A copy of the operating manual for the irradiator is located in Ross B-38.

Leak tests on the irradiator were performed once every 6 months.

Surveys by the inspector confirmed the licensee's initial survey for radiation levels. Radiation levels in the unrestricted area did not exceed 0.05 milliroentgen per hour.

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

21. License No. SNM-1499

This license authorizes storage and the implantation of Coratomic nuclear powered pacemakers (Pu-238) in patients. The inspectors reviewed records maintained in the Radiation Safety Office and discussed the conditions of the license with the Radiation Safety Officer.

The licensee has maintained contact with the individuals implanted on a regular 6 month frequency. A record from Coratomic Inc. indicated that one pacemaker was returned to Coratomic after removal of the unit from the patient.

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

22. Exit Interview

The inspectors discussed the results of the inspection with the individuals identified in Section 1. The inspectors expressed their concern over the number of violations and the lack of management control which appear to be the cause. The inspectors discussed the possibility of escalated enforcement action and reviewed the Commission's possible enforcement action. The licensee's representatives stated their corrective action for licensee identified items and their intent to take corrective actions to correct the other violations identified and to strengthen management control of the program.

Attachment A

NRC Combine Report No. 30-09049/83-01, 030-19949/83-01, 070-01795/83-01

Radiation Safety Office
(202) 676-2630

THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

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

DATE: 11 March 1983
TO: The file
FROM:
SUBJECT:

[redacted] has worked on and off in this office for several years. She is intelligent and industrious. Recently, there has been a fall off in the quantity and quality of her work as well as deteriorating attitude towards her co-workers.

A written dose estimate was made for [redacted] so that she might take the document to her private physician and be reassured by an outside source. The calculation was based on gross over estimates in that it (1) Assumed no shielding; there were file cabinets, books, and furniture along the path. (2) Assumed the check source had been in the office longer than two days; it was also clear the check source had been in Ross Hall many times over the past few months. (3)Assumed no background with exposure meter reading; the reading at one meter was at least 50% background. In spite of these assumptions the gross over estimate of exposure was still indistinguishable from natural background radiation levels. Therefore, there was no incident.

I have also learned that [redacted] has indicated to other workers that due to health problems she did not intend to work here anymore and was not looking forward to going anymore than the minimum two week notice. I can only add that [redacted] has difficulty accepting criticism. Furthermore, she has never been asked to work late (she catches a shuttle at a specific time each day) despite the fact that she has been granted numerous leaves to attend to her medical problems.

[redacted] could be an asset to this office, if she were to continue, and if she were to regain the same attitude she had when she first started working here.

Attachment B

NRC Combine Report No. 30-09049/83-01, 030-19949/83-01, 070-01795/83-01

THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

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

Radiation Safety Office
(202) 676-2630

TO:

FROM: Radiation Safety Officer

DATE: February 22, 1983

RE: Exposure calculation from check source

was exposed to an unshielded sealed source of Radium-226 (half life 1600 years) from October 25, 1982 to February 17, 1983.

The following is an estimate of exposure rate for this check source:

| | |
|---|---|
| Exposure 3 feet | .01 mR/hr @ 3 feet |
| Background | .005 mR/hr |
| Distance from source | 4 meters |
| Shielding assumed | 0 |
| Time/week | 40 hrs/week for 18 weeks |

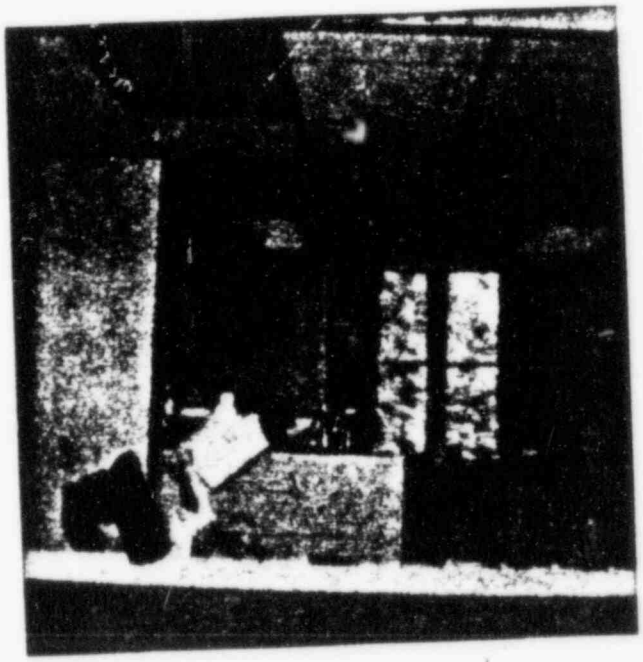
$$\text{Exposure rate @ 4 meters} = \frac{.01}{\left(\frac{4}{.91}\right)^2} \times 40 = .020 \text{ mR/week}$$

.020 x 18 weeks = .36 mR total for period from 10-25-82 to 2-17-83

A background of 120 mR/year corresponds to a weekly exposure of 2.3 mR/week.

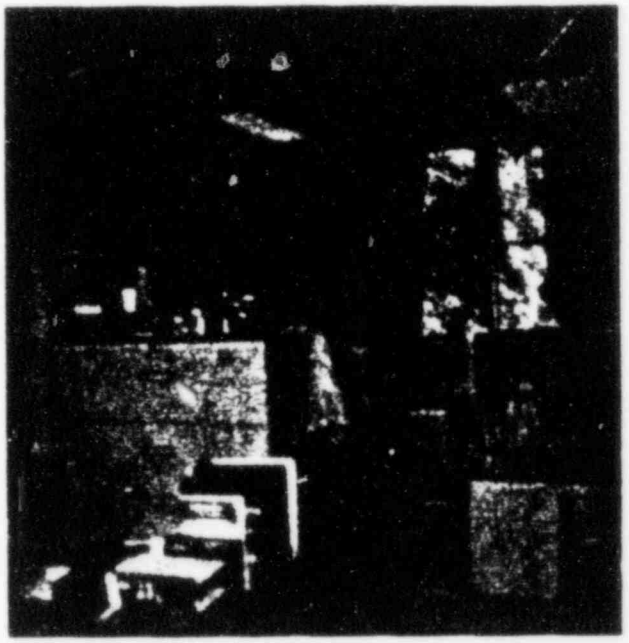
Attachment C

NRC Combine Report No. 030-09049/83-01, 030-19949/83-01, 070-01795/83-01

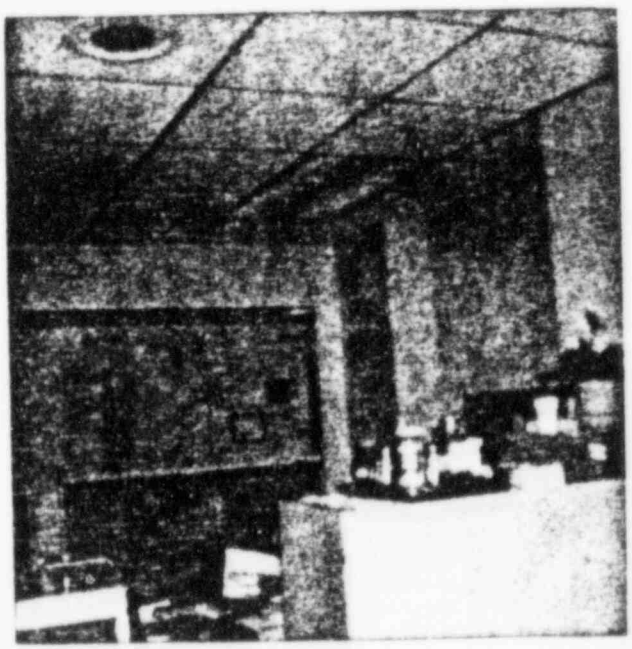


X = secretary's seating space

$X_1$ = temporary check source storage space behind file cabinet



X - indicates storage area of 6 Ci radium check source

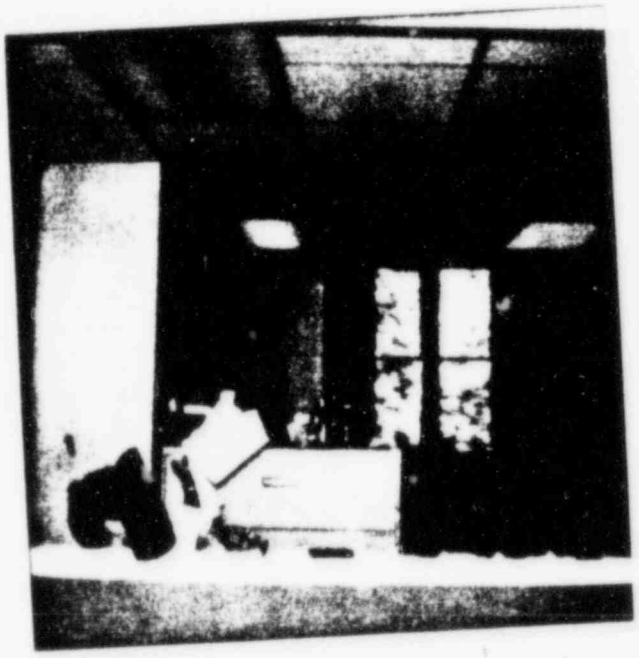


X = Secretary's seating space shielded by filing cabinet

Distance from this area to Secretary's desk measured 5 meters

Attachment C

NRC Combine Report No. 030-09049/83-01, 030-19949/83-01, 070-01795/83-01



X1 = Sec
Y = seating space
X2 = temp storage space behind file cabinet
check source

X = indicate storage area of 6 4Ci radium check source

X = Secu... seating space
shield by filed cabinet

Distance from point where source was to secretary's desk measured 5 meters

37 FR 15127

tion for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license, provided that the permit or license so issued contains the condition specified in § 50.55b of this chapter.

46 FR 53083

(f) Hearings on antitrust aspects will be conducted by a presiding officer, either an Administrative Law Judge or an atomic safety and licensing board comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom will have such technical or other qualifications as the Commission deems appropriate to the issues to be decided.

35 FR 19555

(g) When the Attorney General has advised that there may be adverse antitrust aspects and recommends that a hearing be held, the Attorney General or his designee may participate as a party in the proceedings.

46 FR 53083

(h) At the hearing, the presiding officer will give due consideration to the advice received from the Attorney General and to evidence pertaining to antitrust aspects received at the hearing.

(i) The presiding officer will, in the initial decision, make a finding as to whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in section 105a of the Act. If the presiding officer finds that such a situation would be created or maintained, it will consider, in determining whether the permit or license should be issued or continued, such other factors as it deems necessary to protect the public interest, including the need for power in the affected area. The certainty of contravening the antitrust laws or the policies clearly underlying these laws is not intended to be implicit in this standard, nor is mere possibility of inconsistency. The finding will be based on reasonable probability of contravention of the antitrust laws or the policies clearly underlying these laws. The presiding officer will conclude whether, in its judgment, it is reasonably probable that the activities under the license would, when the license is issued or thereafter, be inconsistent with any of the antitrust laws or the policies clearly underlying these laws.

(j) On the basis of the findings in the proceeding on the antitrust aspect of the application, the presiding officer may (i) authorize the issuance of the permit or license after favorable consideration of matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, at the hearing described in sections I–VIII of this appendix; (ii) authorize the continuation of a permit or license already issued; (iii) direct the denial of the application for the permit or license, or the rescission of a permit or license already issued; or (iv) authorize the issuance of a permit or license subject to appropriate conditions, and subject to favorable consideration of matters of radiological health and safety and common defense matters raised under the National Environmental Policy Act of 1969 at the hearing described in sections I–VIII of this appendix.

## Appendix C—General Policy and Procedure for NRC Enforcement Actions

The following statement of general policy and procedure explains the enforcement policy and procedures of the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions and of presiding officers, the Atomic Safety and Licensing Appeal Boards, and the Commission in reviewing these actions. This statement is applicable to enforcement in matters involving the public health and safety, the common defense and security, and the environment.[1]

### I. Introduction and Purpose

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, the common defense and security, and the environment by:

47 FR 9987

- Ensuring compliance with NRC regulations and license conditions;
- Obtaining prompt correction of noncompliance;
- Deterring future noncompliance; and
- Encouraging improvement of licensee performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the NRC expects of its licensees.

47 FR 16005

It is the Commission's intent that noncompliance should be more expensive than compliance.

Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

### II. Statutory Authority and Procedural Framework

#### *A. Statutory Authority*

47 FR 9987

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Section 186 authorizes NRC to revoke licenses under certain circumstances (e.g., for material false statements, in response to conditions that would have warranted refusal of a license on an original application, for a licensee's failure to build or operate a facility in accordance with the terms of the permit or license, and for violation of a NRC regulation). Section 234 authorizes NRC to impose civil penalties not to exceed $100,000 per violation per day for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and for violations for which licenses can be revoked. Section 232 authorizes NRC to seek injunctive or other equitable relief for violation of regulatory requirements.

47 FR 9987

Section 206 of the Energy Reorganization Act authorizes NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

Chapter 18 of the Atomic Energy Act provides for varying levels of criminal penalties (i.e., monetary fines and imprisonment) for willful violations of the act and regulations or orders issued under Sections 65, 161(b), 161(i), or 161(o) of the Act. Section 223 provides that criminal penalties may be imposed on certain individuals employed by firms constructing or supplying basic components of any utilization facility if the individual knowingly and willfully violates NRC requirements such that a basic component could be significantly impaired. Section 235 provides that criminal penalties may be imposed on persons who interfere with inspectors. Section 236 provides that criminal penalties may be imposed on persons who attempt to or cause sabotage at a nuclear facility or to nuclear fuel. Alleged or suspected criminal violations of the Atomic Energy Act are referred to the Department of Justice for appropriate action.

#### *B. Procedural Framework*

10 CFR Part 2, Subpart B, of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. 10 CFR 2.201 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 10 CFR 2.205. This regulation provides that the appropriate NRC Office Director initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the licensee's response, the Director may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed.

The procedure for issuing an order to show cause why a license should not be modified, suspended, or revoked or why such other action should not be taken is set forth in 10 CFR 2.202. The mechanism for modifying a license by order is set forth in 10 CFR 2.204. These sections of Part 2 provide an opportunity for a hearing to the affected licensee. However, the NRC is authorized to make orders immediately effective if the public health, safety or interest so requires or, in the case of an order to show cause, if the alleged violation is willful.

[1] Antitrust enforcement matters will be dealt with on a case-by-case basis.

III. Severity of Violations

Regulatory requirements [1] have varying degrees of safety, safeguards, or environmental significance. Therefore, it is essential that the relative importance of each violation be identified as the first step in the enforcement process.

Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following seven activity areas:

Reactor Operations;
Facility Construction;
Safeguards;
Health Physics;
Transportation;
Fuel Cycle and Materials Operations; and
Miscellaneous Matters.

Within each activity area Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern: *i.e.*, if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

The relative seriousness of violations at the several severity levels applies within each activity area, but comparisons between activity areas are inappropriate. For example, while the immediacy of any hazard to the public associated with Severity Level I violations in Reactor Operations is greater than that associated with Severity Level I violations in Reactor Construction, both areas have violations which cover the full range of severity levels. This disparity in relative seriousness of violations in different activity areas is due to the diversity of licensed activities regulated by NRC and the need for continuing improvement in licensee performance of certain activities.

While examples are provided in Supplements I through VII for determining the appropriate severity level for violations in each of the seven activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. They reflect the seriousness of violations of requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. Licensed activities not directly covered by one of the above listed areas, e.g., export license activities, will be placed in the activity area most suitable in light of the particular violation involved.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not comprehend acts which do not rise to the level of careless disregard. In determining the specific severity level of a violation involving willfulness consideration will be given to such factors as the position of the person involved in the violation (e.g., first line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained by the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

The NRC expects licensees to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

IV. Enforcement Actions

This section describes the enforcement sanctions available to NRC and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, NRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters.

With very limited exceptions, whenever noncompliance with NRC requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, action by an NRC regional office is appropriate in the form of a Notice of Violation requiring a formal response from the licensee describing its corrective actions. The relatively small number of cases involving elevated enforcement action receives substantial attention by the public, and may have significant impact on the licensee's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

*A. Notice of Violation*

A notice of violation is a written notice setting forth one or more violations of a legally binding requirement. The notice normally requires the licensee to provide a written statement describing (1) corrective steps which have been taken by the licensee and the results achieved; (2) corrective steps which will be taken to prevent recurrence; and (3) the date when full compliance will be achieved. NRC may require responses to notices of violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

NRC uses the notice of violation as the standard method for formalizing the existence of a violation. A notice of violation is normally the only enforcement action taken, except in cases where the criteria for civil penalties and orders, as set forth in Sections IV.B and IV.C respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

Because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, NRC will not generally issue a notice of violation for a violation that meets all of the following tests:

(1) It was identified by the licensee;
(2) It fits in Severity Level IV or V;
(3) It was reported, if required;
(4) It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and
(5) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

Licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors. Enforcement actions involving individuals, including licensed operators, will be determined on a case-by-case basis.[2]

*B. Civil Penalty*

A civil penalty is a monetary penalty that may be imposed for violation of (a) certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders, (b) any requirement for which a license may be revoked, or (c) reporting requirements under Section 206 of the Energy Reorganization Act. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Generally, civil penalties are imposed for Severity Level I and II violations, are considered and usually imposed for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar

[1] The term "requirement" as used in this policy means a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

[2] Section 234 of the Atomic Energy Act gives the Commission authority to impose civil penalties for violations on "any person." "Person" is broadly defined in Section 11s of the AEA to include individuals, a variety of organizations, and any representatives or agents. This gives the Commission authority to impose civil penalties on employees of licensees or on separate entities when a violation of a requirement directly imposed on them is committed.

[3] The word "similar," as used in this policy, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action for the previous violation.

violations discussed in a previous enforcement conference, and for which the enforcement conference was ineffective in achieving the required corrective action.

In applying this guidance for Severity Level IV violations, NRC normally considers civil penalties only for similar violations that occur after the date of the last inspection or within two years, whichever period is greater. Enforcement conferences are normally conducted for all Severity Level I, II, and III violations and for Severity Level IV violations that are considered symptomatic of program deficiencies, rather than isolated concerns. Licensees will be put on notice when a meeting is an enforcement conference.

Civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act, and for any willful violation, including those at any severity level.

NRC imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various reactor, fuel cycle, and materials programs. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the NRC's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, NRC will consider as necessary an increase or decrease on a case-by-case basis.

NRC attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee, provided that such violations were not disclosed as a result of overexposures or unplanned releases of radioactivity or other specific, self-disclosing incidents.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations or serious breakdown in management controls, NRC intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of $100,000 per violation, per day.

NRC reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. After considering all relevant circumstances, adjustments to these values may be made for the factors described below:

1. *Prompt Identification and Reporting.* Reduction of up to 50% of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the NRC. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, and the promptness and completeness of any required report. This factor will not be applied to violations which constitute or are identified as a result of overexposures, unplanned releases of radioactivity or other specific, self-disclosing incidents. In addition, no consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

2. *Corrective Action to Prevent Recurrence.* Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty as much as 50% of the base value shown in Table 1. On the other hand, the civil penalty may be increased as much as 25% of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action—such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

3. *Enforcement History.* The base civil penalty may be increased as much as 25% depending on the enforcement history in the general area of concern. Specifically, failure to implement previous corrective action for prior similar problems may increase the civil penalty value.

4. *Prior Notice of Similar Events.* The base civil penalty may be increased as much as 25% for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific NRC or industry notification, and had failed to take effective preventive steps.

5. *Multiple Occurrences.* The base civil penalty may be increased as much as 25% where multiple examples of a particular violation are identified during the inspection period. This factor is applicable only where NRC identifies the violation, or for violations associated with self-disclosing incidents.

The above factors are additive so that the civil penalty for any severity level may range from plus or minus 100% of the base value. However, in no instance will a civil penalty for any one violation exceed $100,000 per day.

The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. Generally, if a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and, as such, subject to a separate additional civil penalty.

Generally, for situations where a licensee is unaware of a condition resulting in a continuing violation, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so. Civil penalties in excess of 3.75 times the maximum civil penalty for a single Severity Level I violation for each type of licensee require specific Commission approval in accordance with guidance set forth in Section VI below.

NRC statutory authority permits the assessment of the maximum civil penalty for each violation. The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, to emphasize the focus on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem will generally be based on the amount shown in the table, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In this regard, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty.

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TABLE 1A.—BASE CIVIL PENALTIES

(For Severity I Violations)

| | Plant operations, construction and health physics | Safeguards | | Transportation | |
|---|---|---|---|---|---|
| | | Category 1[1] | Noncategory 1 | High level waste, spent fuel [2] | Low specific activity [3] |
| a. Power Reactors | $80,000 | $80,000 | $40,000 | $80,000 | $5,000 |
| b. Test Reactors | 10,000 | 10,000 | 5,000 | 10,000 | 2,000 |
| c. Research Reactors and Critical Facilities | 5,000 | 5,000 | 2,500 | 5,000 | 1,000 |
| d. Fuel Facilities | 40,000 | 80,000 | 40,000 | 40,000 | 5,000 |
| e. Industrial Users of Material [4] | 8,000 | | | 5,000 | 2,000 |
| f. Waste Disposal Licensees | 8,000 | | | 8,000 | 3,000 |
| g. Academic or Medical Institutions [5] | 4,000 | | | 2,500 | 1,000 |
| h. Other Material Licensees | 1,000 | | | 2,500 | 1,000 |

[1] Category 1 licensees are those authorized to possess formula quantities of strategic special nuclear material (10 CFR 73.2(bb)).

[2] Also Type B packages.

[3] Also Type A limited quantity packages.

[4] Includes industrial radiographers, nuclear pharmacies, industrial processors and firms engaged in manufacturing or distribution of byproduct or source materials.

[5] This applies to nonprofit institutions not otherwise categorized under a through f in this table.

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TABLE 1B.—BASE CIVIL PENALTIES

| Severity level | Base civil penalty amount [1] |
|---|---|
| I | 100 |
| II | 80 |
| III | 50 |
| IV | 15 |
| V | 5 |

[1] Percent of amount listed in table 1A.

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### C. Orders

An order is a written NRC directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take such other action as may be proper (*see* 10 CFR 2.202 and 2.204). Orders may be issued as set forth below. Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate.

(1) License Modification Orders are issued when some change in licensee equipment, procedures, or management controls is necessary.

(2) Suspension Orders may be used:

(a) To remove a threat to the public health and safety, common defense and security, or the environment;

(b) To stop facility construction when (i) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, or (ii) the licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

(d) When the licensee interferes with the conduct of an inspection or investigation; or

(e) For any reason not mentioned above for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

(3) Revocation Orders may be used:

(a) When a licensee is unable or unwilling to comply with NRC requirements,

(b) When a licensee refuses to correct a violation,

(c) When a licensee does not respond to a notice of violation where a response was required,

(d) When a licensee refuses to pay a fee required by 10 CFR Part 170, or

(e) For any other reason for which revocation is authorized under Section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by NRC that such activity is unauthorized.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the NRC believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

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### D. Escalation of Enforcement Sanctions

NRC considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, NRC will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. NRC carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in Sections IV.B and IV.C, above.

Examples of enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

Normally the progression of enforcement actions for similar violations will be based on violations under a single license. When more than one facility is covered by a single license, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a physical security violation at Unit 2 of a dual unit plant that repeats an earlier violation at Unit 1 might be considered similar.

TABLE 2.—EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA UNDER THE SAME LICENSE

| Severity of violation | Number of similar violations from the date of the last inspection or within the previous 2 years (whichever period is greater) | | |
|---|---|---|---|
| | 1st | 2d | 3d |
| I | a+b | a+b+c | d, |
| II | a, | a+b, | a+b+c, |
| III | a [1] | a, | a+b, |

a Civil penalty.

b Suspension of affected operations until the Office Director is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements; or modification of the license, as appropriate.

c Show cause for modification or revocation of the license, as appropriate.

d Further action, as appropriate.

[1] Consideration of.

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### E. Related Administrative Actions

In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, NRC also uses administrative mechanisms, such as enforcement conferences, bulletins, circulars, information notices, generic letters, notices of deviation, and confirmatory action letters to supplement its enforcement program. NRC expects licensees to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to make sure that such commitments are met.

(1) Enforcement Conferences are meetings held by NRC with licensee management to discuss safety, safeguards or environmental problems, licensee's compliance with regulatory requirements, a licensee's proposed corrective measures (including schedules for implementation) and enforcement options available to the NRC.

(2) Bulletins, Circulars, Information Notices and Generic Letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

(3) Notices of Deviation are written notices describing a licensee's or a vendor's failure to satisfy a commitment. The commitment involved has not been made a legally binding requirement. The notice of deviation requests the licensee or vendor to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.

(4) Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

*F. Referrals To Department of Justice*

Alleged or suspected criminal violations of the Atomic Energy Act (and of other relevant Federal laws) are referred to the Department of Justic for investigation. Referral to the Department of Jusuce does not preclude the NRC from taking other enforcement action under this General Statement of Policy. However, such actions will be coordinated with the Department of Justice to the extent practicable.

V. Public Disclosure of Enforcement Actions

In accordance with 10 CFR 2.790, all enforcement actions, inspection reports, and licensees' responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Levels I, II, or III press releases are issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for Notices of Violation.

VI. Responsibilities

The Director, Office of Inspection and Enforcement, as the principal enforcement officer of the NRC, has been delegated the authority to issue notices of violations, civil penalties, and orders.* In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, the Director must exercise judgement and discretion in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to impose a civil penalty and the amount of such penalty, after considering the general principles of this statement of policy and the technical significance of the violations and the surrounding circumstances.

The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will be consulted prior to taking enforcement action in the following situations (unless the urgency of the situation dictates immediate action):

(1) An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation;

(2) Proposals to impose civil penalties in amounts greater than 3.75 times the Severity Level I values shown in Table 1A;

(3) Any proposed enforcement action on which the Commission asks to be consulted; or

(4) Any action the Office Director believes warrants Commission involvement.

Supplement I—Severity Categories

*Reactor Operations*

A. Severity I—Very significant violations involving:

1. A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications, being exceeded;

2. A system * designed to prevent or mitigate a serious safety event not being able to perform its intended safety function † when actually called upon to work;

3. An accidental criticality; or

4. Release of radioactivity offsite greater than ten (10) times the Technical Specifications limit.*

B. Severity II—Very significant violations involving:

1. A system designed to prevent or mitigate serious safety events not being able to perform its intended safety function; or

2. Release of radioactivity offsite greater than five (5) times the Technical Specifications limit.

C. Severity III—Significant violations involving:

1. A Technical Specification Limiting Condition for Operation being exceeded where the appropriate Action Statement was not satisfied that resulted in:

(a) Loss of a safety function; or

(b) A degraded condition, and sufficient, information existed which should have alerted the licensee that he was in an Action Statement condition;

2. A system designed to prevent or mitigate a serious safety event not being able to perform its intended function under certain conditions (e.g., safety system not operable unless offsite power is available; materials or components not environmentally qualified);

3. Serious dereliction of duty on the part of personnel involved in licensed activities;

4. Changes in reactor parameters which cause unanticipated reductions in margins of safety;

5. Release of radioactivity offsite greater than the Technical Specifications limit; or

6. 10 CFR 50.59 such that a required license amendment was not sought.

D. Severity IV—Violations involving:

1. 10 CFR 50.59 that do not result in a Severity Level I, II, or III violation;

2. Failure to meet regulatory requirements that have more than minor safety or environmental significance; or

3. Failure to make a required Licensee Event Report when the reported matter does not constitute a violation.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement II—Severity Categories

*Part 50 Facility Construction*

A. Severity I—Very significant violations involving a structure or system that is completed * in such a manner that it would not have satisfied its intended safety related purpose.

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B. Severity II —Very significant violations involving:

1. A breakdown in the quality assurance program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). Such deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation; or

2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.

C. Severity III—Significant violations involving:

1. A deficiency in a licensee quality assurance program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). Such significant deficiency normally involves the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;

2. Failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

3. Failure to make a required 10 CFR 50.55(e) report.

D. Severity IV—Violations involving failure to meet regulatory requirements including one or more Quality Assurance Criteria not amounting to Severity Level I, II, or III violations that have more than minor safety or environmental significance.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement III—Severity Categories

*Safeguards*

A. Severity I—Very significant violations involving:

1. An act of radiological sabotage or actual theft, loss, or diversion of a formula quantity of strategic special nuclear material ** (SSNM);

2. Actual entry of an unauthorized individual into a vital area or material access area from outside the protected area (i.e., penetration of both barriers) that was not detected at the time of entry; or

3. Failure to promptly report knowledge of an actual or attempted theft or diversion of SSNM or an act of radiological sabotage.

B. Severity II—Very significant violations involving:

1. Actual theft, loss or diversion of special nuclear material (SNM) of moderate strategic significance.**

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* The Directors of the Offices of Nuclear Reactor Regulation and Nuclear Material Safety and Safeguards have also been delegated similar authority, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions necessary in the interest of public health and safety. The Director, Office of Administration, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license fees. It is planned to consider redelegation of some or all of these authorities to the Administrators of the NRC Regional Offices over the next several years.

* "System" as used in these supplements, includes administrative and managerial control systems, as well as physical systems.

† "Intended safety function" means the total safety function, and is not directed toward a loss of redundancy. For example, considering a BWR's high pressure ECCS capability, the violation must result in complete invalidation of both HPCI and ADS subsystems. A loss of one subsystem does not defeat the intended safety function as long as the other subsystem is operable.

* The Technical Specification limit as used in this Supplement (Items A.4, B.2 and C.5) does not apply to the instantaneous release limit.

* "Completed" means completion of construction including review and acceptance by the construction QA organization.

** See 10 CFR 73.2(bb).

** See 10 CFR 73.2(x).

2. Failure to use established security systems (including compensatory measures) designed or used to prevent any unauthorized individual from entering a vital area or material access area from outside the protected area (i.e., entry through two barriers) so that access could have been gained without detection;

3. Failure to implement approved compensatory measures when the central (or secondary) alarm station is inoperable;

4. Failure to establish or maintain safeguards systems designed or used to prevent or detect the unauthorized removal of a formula quantity of SSNM from areas of authorized use or storage; or

5. Failure to use established transportation security systems designed or used to prevent the theft, loss, or diversion of a formula quantity of SSNM or acts of radiological sabotage.

C. Severity III—Significant violations involving:

1. Failure to control access to a vital area or material access area from inside the protected area or failure to control access to a protected area from outside the protected area; (i.e., such that only a single security element remained);

2. Failure to control access to a transport vehicle or the SNM being transported that does not constitute a Severity I or II violation;

3. Failure to establish or maintain safeguards systems designed or used to detect the unauthorized removal of SNM of moderate strategic significance from areas of authorized use or storage; or

4. Failure to properly secure or protect classified or other sensitive safeguards information.

D. Severity IV—Violations involving:

1. Failure to establish or maintain safeguards systems designed or used to detect the unauthorized removal of SNM of low strategic significance [17] from areas of authorized use or storage;

2. Failure to implement 10 CFR Parts 25 and 95 and information addressed under Section 142 of the Act, and the NRC approved security plan relevant to those parts; or

3. Other violations, such as failure to follow an approved security plan, that have more than minor safeguards significance.

E. Severity V—Violations that have minor safeguards significance.

Supplement IV—Severity Categories

*Health Physics 10 CFR Part 20* [18]

A. Severity I—Very significant violations involving:

1. Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of 10 CFR 20.106;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.303; or

5. Exposure of a worker in restricted areas of ten times the limits of 10 CFR 20.103.

B. Severity II—Very significant violations involving:

1. Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;

2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of 10 CFR 20.106;

4. Failure to make an immediate notification as required by 10 CFR 20.403(a)(1) and 10 CFR 20.403(a)(2);

5. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.303, or

6. Exposure of a worker in restricted areas in excess of five times the limits of 10 CFR 20.103.

C. Severity III—Significant violations involving:

1. Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;

2. A radiation level in an unrestricted area that exceeds 100 millirem/hour for a one hour period;

3. Failure to make a 24-hour notification as required by 10 CFR 20.403(b) or an immediate notification required by 10 CFR 20.402(a);

4. Substantial potential for an exposure or release in excess of 10 CFR 20 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

5. Release of radioactive material to an unrestricted area in excess of the limits of 10 CFR 20.106;

6. Improper disposal of licensed material not covered in Severity Levels I or II;

7. Exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103;

8. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically unqualified person; or

11. Significant failure to control licensed material.

D. Severity IV—Violations involving:

1. Exposures in excess of the limits of 10 CFR 20.101 not constituting Severity Level I, II, or III violations;

2. A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one hour period or 100 millirem in any seven consecutive days;

3. Failure to make a 30-day notification required by 10 CFR 20.405;

4. Failure to make a followup written report as required by 10 CFR 20.402(b), 20.408, and 20.409; or

5. Any other matter that has more than minor safety or environmental significance.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement V—Severity Categories

*Transportation* [19]

A. Severity I—Very significant violations of NRC transportation requirements involving:

1. Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

2. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the NRC limits.

B. Severity II—Very significant violations of NRC transportation requirements involving:

1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of NRC requirements;

2. Surface contamination or external radiation levels in excess of three times NRC limits that did not result from a breach of package integrity; or

3. Failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity III—Significant violations of NRC transportation requirements involving:

1. Breach of package integrity;

2. Surface contamination or external radiation levels in excess of, but less than a factor of three above NRC requirements, that did not result from a breach of package integrity;

3. Any noncompliance with labelling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

a. Improper identification of the type, quantity, or form of material; or

b. Failure of the carrier or recipient to exercise adequate controls; and

c. Substantial potential for personnel exposure or contamination, or improper transfer of material; or

4. Failure to make required initial notification associated with Severity Level III violations.

D. Severity IV—Violations of NRC transportation requirements involving:

1. Package selection or preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of NRC requirements; or

2. Other violations that have more than minor safety or environmental significance.

E. Severity V—Violations that have minor safety or environmental significance.

[17] See 10 CFR 73.2(y).

[18] Personnel overexposures and associated violations, incurred during a life saving effort, will be treated on a case-by-case basis.

[19] Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper (10 CFR 73.20) and a carrier (10 CFR 70.20a). When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensees which under the circumstances of the case may be one or more of the licensees involved.

47 FR 9987

Directions to NRC Region I from Philadelphia Airport

Exit from the airport onto PA 291 East. Immediately move to the left lane. After about 1/4 mile (first light) turn left at sign "To I-76." After about 1/4 mile turn right, again at sign "To I-76." After about 3.5 miles, be in the left lane for a left turn at sign "Schuylkill Expressway" (the I-76 North sign is somewhat hidden on the right side of the road). For the next 20 miles stay on I-76 and follow signs for "Valley Forge." Exit from I-76 at Exit 25 (about 100 yards before the toll gates for the Pennsylvania Turnpike - so be sure to exit). Bear to the right at the first light and bear right again onto PA 363 North at the next light. Go 1.2 miles (second light) and turn right onto First Avenue. Go past one light (at Moore Road) and take the next right onto Park Avenue. The NRC office will be the two story white building about 100 yards on the left.

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

Radiation Safety Office
(202) 676-2630

TO: Incident File

FROM: Gary Good, Assistant Radiation Safety Officer

DATE: February 3, 1983

RE: Loss of a Small Amount of Radioactive Material

On January 25, 1983 it was discovered that someone had entered Ross 657 between 5:00 pm January 24, 1983 and 8:00 am January 25, 1983 and had removed a bag (about 10 gallon) of dry solid radioactive waste. This waste, stored in a sealed, but unlabeled bag, consisted of disposable protective clothing and laboratory chucks slightly contaminated with In-111. Then on February 1, 1983 it was discovered that a bag (about 10 gallon) of I-125 contaminated dry laboratory waste (chucks and protective clothing) had also been removed from a waste receptacle between December 20, 1982 and February 1, 1983. An investigation determined that both losses probably occurred at the same time and most likely resulted from night shift housekeeping personnel entering the restricted laboratory and removing the radioactive waste material by mistake.

Activity Estimates

A. In-111

The In-111 waste resulted from a labeling procedure that took place on January 19, 1983. In this reaction, the starting material was 836 uCi of In-111. From the laboratory records it was determined that 111 uCi was recovered as labeled red blood cells and was removed to a hot waste storage area. 563 uCi was recovered as unbound indium and was also taken to the hot waste storage area. 151 uCi was recovered as labeled platelets which were later injected in a patient. This leaves 11 uCi of In-111 unaccounted for. Some of this would remain in the reaction vessel and the transfer pipets which were moved to the hot waste storage area. Therefore, it is estimated that the chucks and gloves were contaminated with no more than 5 uCi of In-111 when they were packed in the bag on January 19, 1983. This activity would have decayed down to 1 uCi when the bag was removed on January 25, 1983.

B. I-125

The I-125 waste resulted from an iodination performed on December 20, 1983. In this procedure, the starting material was 6.7 mCi of $Na^{125}I$. Laboratory records showed 1.4 mCi of this material could not be recovered from the shipping vessel and was moved to hot waste storage. It is also noted that 2.1 mCi of labeled product was recovered and moved to another

laboratory for subsequent animal injections. Waste records also show that 3.0 mCi of solid waste were properly disposed of from this procedure on January 11 and January 25, 1983. This leaves a deficit of 0.2 mci most of which would have remained on the column that went to hot waste storage. It is then estimated that no more than 100 uCi of I-125 contaminated waste was placed in the low-level receptacle on December 20, 1982. This activity would have decayed down to less than 70 uCi when it was lost on January 25, 1983.

Exposure Estimates

The In-111 waste was sealed in a plastic bag and the I-125 waste was double bagged. We found no evidence of contamination in the laboratory or the hall. We concluded that the involved housekeeping person was not contaminated with In-111 or I-125 and all exposure came from a "sealed" source. The exposure expected from 1 uCi of In-111 and 70 uCi of I-125 at 0.5 m is approximately 0.02 $mR_{\gamma}hr$. Therefore, exposure to the housekeeping worker from this incident would be insignificant.

Release to the Environment

Both bags of waste were placed in the Ross Hall garbage compactor on January 25, 1983. Later that day the garbage was removed and transported to a landfill near Lorton, Virginia. Eventual release would be insignificant and would present no hazard to the public or the environment.

Corrective Action

1. Housekeeping Director notified by memo of all off-limit laboratories in Ross Hall.

2. "No Admittance" signs placed on these laboratory doors.

3. In Service for the night shift housekeeping personnel will be performed as soon as possible.

4. Radiopharmaceutical Chemistry Department notified that all radioactive waste containers, permanent or temporary, shall be clearly marked "Radioactive".

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

Radiation Safety Office
(202) 676-2630

TO: Incident File

FROM: Gary Good

DATE: December 7, 1982

SUBJ: Contamination of Radiation Worker with I-125.

During a routine 24 hour post-iodination thyroid uptake measurement performed on Barbara Francis of the Radiopharmaceutical Chemistry Department on Wednesday, November 24, 1982, an area of unusually high contamination was found on her hair and scalp. Surveys performed with a Ludlum Model 2 survey meter with a low energy NaI scintillation probe showed contamination levels of greater than 50,000 cpm over an area of less than 25 $cm^2$. Decontamination and treatment began immediately as outlined below:

1. Hair and scalp were washed several times with shampoo.

2. Some of the contaminated hair was removed. The combination of washing and removal lowered the level of contamination to 10,000 cpm.

3. Drug therapy was started after a consultation with Dr. Richard Reba of the Nuclear Medicine Department. Dr. Reba suggested the medication, Cytomel (L-triiodothyronine), which would act to block the thyroid of any additional I-125 uptake. This therapy was discontinued on Monday, November 29, 1982 when hair and scalp contamination levels were at 3,000 cpm.

Thyroid uptake measurements for Barbara Francis were performed on November 24, 1982 and November 29, 1982. They showed burdens of 62.7 and 70.0 nCi respectively. Her last previous thyroid measurement for I-125 showed 18.5 nCi on October 28, 1982. therefore, it can be estimated that the uptake from this incident did not exceed 64 nCi.

*NRC regulations state that a licensee shall not allow personnel to work in an area where he/she could inhale a quarterly limit of radioactive material, i.e. 520 MPC-hours. Our personnel monitoring using breathing zone charcoal tubes showed that 5 MPC-hours were used up in this incident.

THE GEORGE WASHINGTON UNIVERSITY

INTERDEPARTMENTAL MEMORANDUM

January 20, 1983

TO: Mark Selikson, Ph.D.
Radiation Safety

FROM: W. C. Eckelman, Ph.D.
Professor of Radiology
Chief, Radiopharmaceutical Chemistry

In reference to your incident file report of December 7, 1982 and our conversation, we would like to suggest that the most likely time of contamination is when the reaction vial is opened. As a result we will puncture the seals of the reaction vial with a needle fitted to a syringe filled with charcoal. The end of the syringe will be connected to the house vacuum. These charcoal filters will be saved for counting by radiation safety.

We will use a 1 cc tuberculin syringe fitted with a 27 guage stainless steel needle and connected by tygc tubing to the house vacuum system.

cc: B. Francis

NRC regulations also state that a licensee is in violation if a worker using radioactive material of such form that intake by absorption through the skin is likely, obtains a body burden equivalent to someone breathing in 520 MPC-hours. This would amount to a body burden of 3.15 uCi or a thyroid burden of 945 nCi/qtr or 72.7 nCi/week. Our thyroid uptake measurements show a maximum thyroid burden of 64 nCi. Therefore, it can be assumed that this incident did not violate NRC regulations.

*10CFR,20.103 (a) (1)