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Washington
Hospital Center

MedStar Health

VIA FACSIMILE AND FIRST CLASS MAIL

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REGION 1

November 23, 2004

Pamela J. Henderson, Chief
Nuclear Material Safety, Branch 1
U.S. Nuclear Regulatory Commission Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Re: Response to Apparent Violation Described in Enforcement Action No. 04-157
Washington Hospital Center, NRC License No. 08-03604-03

03001325

Dear Ms. Henderson:

The purpose of this letter is to provide Washington Hospital Center's (WHC) Response to the Apparent Violation Described in EA No. 04-157, dated October 29, 2004.

By letter dated August 25, 2003,[1] WHC voluntarily notified the Nuclear Regulatory Commission (NRC) of the incident forming the basis of the violation, although such disclosure was not required. The letter also described the disciplinary and corrective actions that occurred immediately after the incident as a result of the preliminary and formal investigations.

By letter dated October 29, 2004,[2] NRC requested a written "Response to Apparent Violation Described in Enforcement Action #04-157" in the event that WHC opted to respond in writing rather than attend a predecisional enforcement conference. The letter requested that the response include (1) the reason for the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. The following sections provide the requested information.

In addition, while WHC admits that a violation of License Condition 11 and 10 C.F.R. § 35.27 has occurred, it believes that the violation was of low significance and should be assessed as a Level IV violation. Further, WHC believes the circumstances surrounding the violation meet the

[1] Letter from Shashadhar M. Mohapatra, Ph.D., Radiation Safety Officer, WHC, to Pamela J. Henderson, Chief, Nuclear Material Safety, Branch 1, NRC (Aug. 25, 2003).

[2] Letter from George Pangburn, Director, Division of Nuclear Materials Safety, NRC, to Kevin J. Harlen, Vice President for Professional Services, WHC (Oct. 29, 2004).

NMSS/RGNI MATERIALS-004

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However, as discussed in Section VI, should the NRC assess the violation's significance as Level III and issue a Notice of Violation (NOV), WHC believes that no civil penalty should be assessed.

I. THE REASON FOR THE APPARENT VIOLATION

On July 21, 2003, WHC discovered that, on the day before, a renal scan had apparently been performed without the required physician order. The WHC Nuclear Medicine Technologist working on July 20, 2003 was Fady Kassem. The patient identified on the renal scan was Lawrence Dioh, a former WHC Nuclear Medicine Technologist who was then employed by a private medical practice located at WHC. As of July 20, 2003, Mr. Dioh had also retained his PRN status at WHC, which permitted him to work as a Nuclear Medicine Technologist for WHC on an as-needed basis.

Upon learning of this apparent unauthorized renal scan, WHC immediately commenced a preliminary investigation into the facts and circumstances surrounding the incident. The preliminary investigation determined that a WHC employee discovered, on the morning of July 21, 2003, a renal scan in an image processor, which listed Mr. Dioh as the patient. Records were obtained from Eastern Isotopes, WHC's supplier of radioactive isotopes, which indicated that Mr. Kassem ordered two diagnostic doses of Technetium-99m (MAG-3, each 10 mCi) (TC-99m) on July 20, 2003. However, hospital records and the on-call physician for July 20, 2003 indicated that no renal scans had been ordered.

Because of the preliminary investigation's results, WHC conducted a formal fact-finding investigation that included the Assistant Vice President of Human Resources and outside nuclear counsel. The formal investigation consisted of interviews with relevant personnel and a review of WHC and Eastern Isotope records and procedures.

The formal investigation concluded that Mr. Kassem injected Mr. Dioh with a diagnostic dosage of TC-99m and then performed a renal scan on him, at his request, but without a required physician order. This conclusion was based on Mr. Dioh's admission, confirmation by another WHC employee of an earlier admission by Mr. Dioh, and information provided by Eastern Isotopes.

II. THE CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND THE RESULTS ACHIEVED

A. Resulting Disciplinary Action

After WHC's preliminary investigation identified Mr. Kassem's and Mr. Dioh's apparent involvement in the unauthorized renal scan, WHC suspended Mr. Kassem's employment and suspended Mr. Dioh's PRN status pending the completion of the formal fact-finding investigation.

As a result of WHC's formal fact-finding investigation, WHC terminated Mr. Kassem's employment and made him ineligible for rehire at WHC. WHC also revoked Mr. Dioh's PRN status, thus preventing him from performing work for WHC. Mr. Dioh is also prohibited from being present in or around the WHC Nuclear Medicine Department.

B. Corrective Actions

As discussed in the August 25, 2003 letter to NRC, WHC has taken comprehensive corrective actions beyond terminating Mr. Kassem's employment and prohibiting Mr. Dioh from working as a PRN at WHC. These additional corrective actions intended to deter and prevent any future unauthorized use of radiopharmaceuticals. The corrective actions fall within three categories: (1) event training; (2) inspection and audit of the Nuclear Medicine Department led by the Radiation Safety Officer; and (3) a review of Nuclear Medicine Department and Eastern Isotopes processes and procedures.

1. Event Training

To reinforce expectations within the Nuclear Medicine Department that strict adherence with NRC and WHC requirements is essential and a condition of employment at WHC, WHC's Manager of Nuclear Medicine, Wayne E. Dunkle, conducted event training with department staff, including all Nuclear Medicine Technologists. This training (1) discussed facts relating to the July 20, 2003 incident, (2) reviewed NRC and WHC requirements relating to the use of radiopharmaceuticals, (3) discussed WHC's expectations of employees if they inadvertently make or become aware of a mistake or noncompliance issue, and (4) made clear the consequences of failing to adhere to NRC and WHC requirements.

WHC's Director of Nuclear Medicine, Dr. Douglas Van Nostrand, also conducted training with the Nuclear Medicine Department physicians and professional staff to review the July 20, 2003 incident. During this session, Dr. Van Nostrand emphasized the importance of complying with NRC and WHC requirements and the need to reinforce this expectation within the entire Nuclear Medicine Department.

The Radiation Safety Department accelerated the Nuclear Medicine Department's 2003 annual training. The training was completed as of the August 25, 2003 notification letter to the NRC and included the following topics:

- NRC and DC Regulatory Affairs Regulations
- WHC's NRC License Requirements
- 10 C.F.R. Part 20 Requirements
- 10 C.F.R. Part 35 Requirements
- Dose Limits
- Survey and Monitoring Requirements
- Storage and Control of Licensed Material
- Precaution Procedures

- Worker Expectations including Deliberate Misconduct
- Notifications and Reports
- QMP
- Medical Events and Reporting of such events
- Release of Patients
- Emergent Situations
- WHC Security

2. Radiation Safety Department Inspection and Radiation Safety Audit

As described in the August 25, 2003 WHC letter to NRC, WHC's Radiation Safety Officer (RSO), Dr. Shashadhar M. Mohapatra, conducted an inspection of the Nuclear Medicine Department. This inspection confirmed that WHC requirements for securing the hot lab (where radiopharmaceuticals are stored) and employee badging were being met, and dose administration records (hard copies) were being printed from the UDM computer system and inserted into the dose administration binder in a timely manner. The daily reports are checked and signed by the hot lab technologist. On Mondays, the hot-lab technologist reviews the weekend studies and provides an oral report to the department manager regarding any unusual findings. The inspection also confirmed that scans performed during the previous two weekends were appropriate.

Since this inspection, the RSO has performed routine surprise inspections of the Nuclear Medicine Department. No unusual practices have been observed during the course of the surprise inspections. Further, one of the Radiation Safety staff was assigned to check the weekend doses ordered and the scans performed at the beginning of this incident for a period of time and found no suspicious scans.

As described in the August 25, 2003 WHC letter to NRC, after reviewing the Radiation Safety inspection finding, Mr. Dunkle requested that WHC's Radiation Safety Department conduct a comprehensive audit of the Nuclear Medicine Department to identify any weakness or improvement opportunities in the following areas:

- Radioactive Material Receipt
- QMP
- Radiopharmaceutical Administration Record
- Radioactive Material Shipment Record
- Radioactive Material Waste Disposal Record
- Dose Calibrator Constancy, Accuracy, Linearity and Geometry Checks
- Leak Test of Sealed Sources and Source Inventory
- Daily and Weekly Area Survey Records
- Dosimetry Record
- Room Ventilation and Clearance Time Calculation
- Uptake Probe Calibration Record

- Gamma Counter Quality Control Test
- Thyroid Bioassay Record
- Special Procedures
- Incident Report

3. Review of Nuclear Medicine Department Processes and Procedures

As a result of the July 20, 2003 incident and as discussed in the August 25, 2003 letter from WHC to NRC, WHC reviewed its procedures and processes for receiving, storing, administering and disposing of radiopharmaceuticals. As part of this review, WHC has met and worked with Eastern Isotopes to identify additional safeguards to better control the use of radiopharmaceuticals. This review sought to achieve the appropriate balance between the risk associated with certain radiopharmaceuticals and the costs associated with additional measures.

III. THE CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID FURTHER VIOLATIONS

A. Implementation of New Safeguard Measures

As a result of the review of the Nuclear Medicine Department's Processes and Procedures, WHC has put in place the following safeguard measures since WHC first notified the NRC of this violation on August 25, 2003. These measures aim to prevent any future unauthorized use of radiopharmaceuticals in Nuclear Medicine Department:

- WHC has purchased new dose management software, which provides additional functions for better tracking of radiopharmaceuticals.

- WHC has established an On-call log book to check for discrepancies between reading the physician log sheet and studies performed by the technologist.

- Daily dose report review has replaced monthly review and is intended to better identify radiopharmaceuticals ordered that do not correspond to a physician order.

- WHC now receives weekly e-mailed invoices from Eastern Isotopes instead of monthly, mailed invoices. This allows the Manager to check weekend activities/studies against Eastern Isotopes invoices and cross check doses against studies performed on weekends or On-call.

- WHC reviews, on a daily basis, the Nuclear Medicine Department's Income Distribution Report, which list all studies and radiopharmaceuticals used the day before.

B. Training

WHC believes that its annual training program is a key component to prevent future misuse of radiopharmaceuticals. The Radiation Safety Department has continued and will continue to

provide annual training to Nuclear Medicine Technologists, emphasizing the importance of complying with the policy of the Hospital Center and NRC's regulations, particularly 10 CFR 30.10, which covers "Deliberate Misconduct." The training program covers the following areas:

- NRC and DC Regulatory Affairs Regulations
- WHC's NRC License Requirements
- 10 C.F.R. Part 19
- 10 C.F.R. Part 20
- 10 C.F.R Part 30
- 10 C.F.R. Part 35
- Dose Limits and Exposure History
- Survey and Monitoring Requirements
- Storage and Control of Licensed Material
- Precaution Procedures
- Worker Expectations including Deliberate Misconduct
- Notifications and Reports
- QMP
- Medical Events and Reporting of such events

In addition, since WHC first notified the NRC of the violation, Radiation Safety Technicians working in the evening and night shifts have been instructed by the RSO to be vigilant especially towards suspicious activities while they are working in Nuclear Medicine Department and to report any suspicious activities immediately to the RSO.

C. Quarterly Audit

The quarterly audits are conducted by the Radiation Safety staff and are reviewed by the RSO. Thus far, no indication of unauthorized use of licensed materials have been found. The following items are reviewed during the audits:

- Radioactive materials received
- Radiopharmaceutical administration record
- Radioactive materials shipment
- Radioactive waste disposal
- Radiopharmaceutical quality control
- Dose calibrator tests
- Leak test and sealed source inventory
- Daily area survey records
- Weekly area contamination records
- Daily personnel monitoring and exposure report
- Xe-133 trap monitor, ventilation rates and clearance time record
- Uptake probe and gamma counter quality control
- Bioassay

- I-131 therapy and other therapies
- Incident report

D. Procedure Revision

The RSO has revised the Radiation Safety Manual and added a new procedure for "Lost, stolen or unauthorized use of radioactive materials by employees at the WHC." This procedure provides specific guidance on how to handle any incidents of lost, stolen, or misused radiopharmaceuticals. (See Attachment 1).

IV. THE DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED.

WHC is presently in full compliance with all of its License Conditions and NRC Regulations.

V. THE VIOLATION WAS OF LOW SIGNIFICANCE AND SHOULD BE ASSESSED AS A LEVEL IV NON-CITED VIOLATION

Through its Enforcement Policy,[3] the NRC seeks to deter noncompliance with its regulations and to encourage prompt identification and prompt, comprehensive correction of violations of NRC requirements.[4] Violators will be subject to enforcement action, and each enforcement action will depend on the circumstances of the case.[5]

The first step in the enforcement process is assessing the violation's level of significance because each violation can have varying degrees of safety, environmental, or safeguards significance.[6] The severity levels range from I (highest) to IV (lowest).[7] The NRC evaluates four criteria in determining a violation's significance: (1) were there actual safety consequences; (2) were there potential safety consequences; (3) did the violation impact the regulatory process; and (4) was the violation willful.[8] For example, a violation will be assessed as Level IV if it involves noncompliance with NRC requirements that are not considered significant based on risk.[9]

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[3] General Statement of Policy and Procedure for NRC Enforcement Actions, *available at* http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf (last visited Nov. 19, 2004) (Enforcement Policy).

[4] Id. at 4.

[5] Id.

[6] Id. at 8.

[7] Id. at 12.

[8] Id. at 8.

[9] Id. at 12.

After assessing a violation's significance, NRC will determine how to disposition the violation. The disposition will reflect the seriousness of the violation and the circumstances involved.[10] Violations can be dispositioned as NCVs, cited in NOVs, or issued with civil penalties and orders.[11] For example, a Level IV willful violation at a non-power reactor licensee can be dispositioned as an NCV if it meets four criteria: (1) the licensee identified the violation and reported it to the NRC even though it was not required to be reported; (2) the violation involved the acts of a low-level individual (not a licensee official); (3) the violation was an isolated act, without management involvement, not caused by lack of oversight, as evidenced by a history of isolated willful violations or lack of adequate audits; and (4) the licensee took significant remedial action commensurate with the circumstances, which demonstrated the seriousness of the event to other employees and created a deterrent effect.[12]

Moreover, the Enforcement Policy recognizes that nuclear facility regulation cannot employ a one-size-fits-all approach and, therefore, provides that "judgment and discretion must be exercised in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to issue a Notice of Violation, or to propose or impose a civil penalty...."[13]

Based on these criteria for evaluating the significance and disposition of violations, WHC believes this incident of willful misuse of radiopharmaceutical should be assessed as a Level IV violation and disposed of as an NCV. WHC is aware that Section 7.15 of the NRC Enforcement Manual[14] provides guidance on handling a violation involving the deliberate misuse of licensed material. That guidance states the underlying issue of misuse is normally assessed as Level IV or higher, and because the assessment for willful violations may be increased, a willful misuse may be categorized as Level III or higher.[15] A Level III significance normally results in a disposition by an NOV, and also carries the potential for a civil penalty.[16]

However, as the following sections detail, WHC believes NRC's assessment and disposition should reflect the violation's overall low significance, WHC's open, cooperative response to an incident that did not need to be reported, and the hospital's substantial corrective action measures taken in response. Therefore, NRC should assess the violation as a Level IV violation and should disposition it with an NCV.

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[10] Id. at 16.

[11] Id.

[12] Id. at 18-19.

[13] Id. at 7.

[14] NRC Enforcement Manual, available at http://www.nrc.gov/reading-rm/basic-ref/enf-man/manual.pdf (last visited Nov. 19, 2004) (Enforcement Manual).

[15] Id. at § 7.15.

[16] Enforcement Policy at 19.

A. NRC should assess the violation's significance as Level IV.

WHC believes this incident should be assessed as a Level IV violation on the NRC's significance scale. Although WHC takes the unauthorized acts of its employees very seriously, the violation itself was of low significance, and any enforcement action taken by the NRC should reflect that low significance. After evaluating the violation in light of the four criteria for assessing a violation's significance, WHC believes the NRC can and should reasonably conclude that this incident deserves a Level IV assessment.

1. Actual Safety Consequences

There were no actual safety consequences as a result of the incident.

2. Potential Safety Consequences

There were no potential safety consequences as a result of the incident. The Enforcement Policy evaluates potential safety consequences by whether or not there was a realistic likelihood of affecting safety, or if there were any credible scenarios with potentially significant consequences that could result from the incident.[17] Although the incident consisted of an unauthorized injection of radiopharmaceutical into a human being, only a diagnostic dosage of Tc-99m was employed, which has a half-life of six hours. Therefore, there was no realistic likelihood that any adverse safety consequences would result from the injection.

3. Impact on NRC's Regulatory Process

This incident did not adversely impact NRC's regulatory process. According to the Enforcement Policy, an adverse impact on NRC's regulatory process occurs when a violation consists of any failure to provide the NRC with required information or notice of any changes to licensed activities.[18] This violation does not meet those criteria. Rather, WHC's handling of the violation demonstrated the value it places on an open and cooperative relationship with the NRC. The violation was not required to be reported to the NRC, yet WHC voluntarily notified the NRC of it. Therefore, WHC's handling of the incident in fact aided NRC's regulatory process.

4. Willfulness

The NRC's Enforcement Policy provides that in evaluating a violation with willfulness, the NRC will consider several factors, such as (1) the position and responsibilities of the person involved; (2) the significance of the underlying violation; (3) the intent of the violator; and (4) economic advantage gained as a result of the violation.[19] After evaluating these four factors, WHC believes that NRC should conclude that this willful violation was of low significance.

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[17] Id. at 9.

[18] Id. at 9.

[19] Id. at 10.

a. Position and responsibilities of the person involved

Mr. Kassem was a technologist in the Nuclear Medicine Department. He held a low-level, non-supervisory position. He was not a "licensee official," as defined in the Enforcement Policy, because he was not (1) a first line supervisor (or above); (2) a licensed individual; (3) a radiation safety officer; or (4) an authorized user of licensed material.[20]

b. Significance of the underlying violation

This violation had low significance. There were no actual safety consequences as a result of this event, nor were there any potential safety consequences because only a diagnostic dosage of Tc-99m was injected by Mr. Kassem into Mr. Dioh. Nor did the violation adversely impact NRC's regulatory process.

c. Intent of the violator

The Enforcement Policy provides that the violator's intent or level of willfulness may range from careless disregard for requirements to deliberate intent to violate requirements. In this instance, Mr. Kassem acted deliberately when he injected Mr. Dioh with radiopharmaceutical at Mr. Dioh's request.

d. Economic advantage

WHC gained no economic advantage as a result of Mr. Kassem's actions. Indeed, his actions had an adverse impact because WHC paid for a dosage of Tc-99m that did not benefit a WHC patient.

5. Conclusion

Of the four criteria used to evaluate the willfulness of the violation, only the deliberate nature of Mr. Kassem's act counters the violation's otherwise very low significance. The violation had no actual or potential safety consequences and did not impact NRC's regulatory process. Although deliberate, the violation was an isolated incident by a low-level employee that caused WHC economic disadvantage.

Comparison to another NRC enforcement action against another licensee provides further support for assessing the significance of this violation as Level IV. The Department of the Navy (Navy) was assessed a Level III violation with no civil penalty as a result of an incident at the Naval Hospital in Portsmouth, VA.[21] The head of the hospital's Nuclear Medicine Branch approved the unauthorized use of a radiopharmaceutical on another medical technician, who volunteered for the injection.[22] The unauthorized radiopharmaceutical use involved an employee

[20] Id. at 10 n.5.

[21] Department of the Navy, EA-91-094, Notice of Violation (July 26, 1991).

[22] Id.

in a supervisory position and a willing nuclear technician, whereas in WHC's case, the violation involved a non-supervisory technician and a PRN who worked on an as-needed basis. WHC believes that a fair evaluation of its violation requires a lower assessment than that given to the Navy.

WHC takes full responsibility for the acts of its employees. The processes and procedures in place as of July 20, 2003, and reinforced and augmented since then, provided substantial deterrence against employee misconduct. However, WHC does not believe it or any licensee can fully prevent knowing, deliberate employee misconduct. Given this fact, the violation's overall low significance, WHC's prompt, voluntary, and not-required notification, and the strong corrective actions taken to punish the misconduct and to reinforce deterrence against future misconduct, WHC requests that NRC assess the violation's significance as Level IV.

B. NRC should dispose of the violation as an NCV.

In addition to being assessed as a Level IV violation, WHC believes the violation should be disposed of as an NCV. The Enforcement Policy provides that a Level IV violation will be considered for an NOV disposition if: (1) the licensee failed to identify the violation; (2) the licensee did not correct or commit to correct the violation; (3) the violation is repetitive as a result of inadequate corrective action; and (4) the violation was willful.[23]

As already detailed in this letter, the WHC violation meets only one of the above four criteria: willfulness. However, NRC's Enforcement Policy provides that a Level IV, willful violation may be disposed of as an NCV if four criteria are met: (1) the licensee identified the violation and reported it to the NRC even though it was not required to be reported; (2) the violation involved the acts of a low-level individual (not a licensee official); (3) the violation was an isolated act, without management involvement, not caused by lack of oversight, as evidenced by a history of isolated willful violations or lack of adequate audits; and (4) the licensee took significant remedial action commensurate with the circumstances, which demonstrated the seriousness of the event to other employees and created a deterrent effect.[24]

WHC believes the circumstances of this willful violation meet these four criteria. First, WHC voluntarily notified the NRC of this violation even though it was not required to be reported. Second, as previously discussed, Mr. Kassem was a low-level employee and was not a licensee official. Third, this violation was an isolated incident. WHC does not have a history of isolated, willful violations and performs regular audits to ensure safety; indeed, the event at issue here illustrates WHC's commitment to identifying and responding aggressively to any willful violation. Finally, as the contents of this letter describe, WHC has undertaken significant remedial action. WHC terminated the employment of one employee, prohibited any future interaction between the Nuclear Medicine Department and an affiliated individual, conducted

[23] Enforcement Policy at 18-19.

[24] Id. at 17-19.

event training, has increased the frequency of its audits, and has implemented additional safeguards measures.

All of these actions serve both to demonstrate the seriousness with which WHC viewed this event and to create a stronger deterrent effect among WHC employees. Therefore, WHC believes the Level IV violation should be disposed of as an NCV.

VI. IF THE NRC ASSESSES THE VIOLATION AS LEVEL III, NO CIVIL PENALTY SHOULD BE ASSESSED.

Should the NRC assess the significance of the violation as Level III, no civil penalty should be assessed. According to the Enforcement Policy, a Level III violation that receives credit for both identification and corrective action will be assessed no civil penalty.[25] WHC should receive credit in both regards. First, WHC identified the violation and reported it even though it was not required to be reported. Second, WHC has taken substantial corrective actions, both to respond to the violation and to increase deterrence against future violations. Therefore, WHC should not be assessed a civil penalty for this violation.

Sincerely,

Shashadhar Mohapatra

Shashadhar M. Mohapatra, Ph.D.
Radiation Safety Officer
Washington Hospital Center.

Attachment

[25] Id. at 22.

APPENDIX Y

LOST OR STOLEN OR UNAUTHORIZED USE OF RADIOACTIVE MATERIALS BY EMPLOYEES

1. A lost or stolen radioactive material (radiopharmaceutical in unsealed or capsule form ordered for a patient or a research subject, or a sealed calibration source) in any department must be notified to the Radiation Safety Officer as soon as its occurrence becomes known to the Authorized User.
2. Before administration of any radioactive material (unsealed or sealed radiopharmaceutical dose ordered for a patient or a research subject) for diagnostic studies or therapies, a written order or prescription that is signed and dated must be obtained from an Authorized User. Refer: QMP procedure for respective department.
3. An Authorized Physician User shall be responsible for any unauthorized use of radiopharmaceuticals performed by a supervised individual in his/her department. The Authorized Physician User must notify the Radiation Safety Officer as soon as unauthorized use is discovered. If it is a deliberate misconduct, then the supervised individual is subject to disciplinary action by the employer. A verbal report within 24 hours and a formal written report within 30 days to the NRC are required.
4. The supervised individual may be suspended with or without pay until the investigation by the employer is complete. If s/he is found guilty, then s/he may be subject to discipline, up to and including termination.

I. Reports of theft or loss of licensed material (NRC Part 20: 2201).

(a) Telephone reports. (1) Each licensee shall report by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas: or

(ii) Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C to part 20 that is still missing at this time.

(2) Licensee shall make reports by telephone to the NRC Operations Center (301-951-9550).

(b) Written reports. (1) The licensee is required to make a written report within 30 days after making the telephone report setting forth the following information.

(i) A description of the licensed material involved, including kind, quantity, and chemical and physical form; and

(ii) A description of the circumstances under which the loss or theft occurred: and

(iii) A statement of disposition, or probable disposition, of the licensed material involved; and

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(v) Actions that have been taken, or will be taken, to recover the material; and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(2) The licensee shall make reports to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§30.55(c), 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vi), 73.67(g)(3)(iii), 73.71, or §150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

II. Notification of incidents (20.2202).

(a) Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause any of the following conditions

(1) An individual to receive

(i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more;

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(b) Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours—

(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

(ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(c) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with 10 CFR 50.72; and

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center (301) 816-5100.