ENCLOSURE 2

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

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Licensee:	Department of Veterans Affairs Medical Center
Facility:	Department of Veterans Affairs Medical Center
Location:	3710 S.W. U.S. Veterans Hospital Road Portland, Oregon
Dates:	January 7 through 31, 1997
Inspector:	David D. Skov, Sr. Health Physicist (Materials)
Approved By:	Frank A. Wenslawski, Chief, Materials Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Department of Veterans Affairs Medical Center
NRC Inspection Report 030-02935/97-01

This was a special announced inspection conducted in response to a telephonic notification of a misadministration following the diagnostic use of iodine-131 (I-131). The inspection evaluated the misadministration, its causes and contributing factors, notification, reports and records of the misadministration, licensee routine implementation of its quality management program (QMP), and its corrective actions in response to the misadministration.

Direct, Contributing and Root Causes of the Misadministration

- The misadministration was directly caused by the failure of a supervised individual to follow existing departmental procedures requiring specific physician approval for a radiopharmaceutical dosage that was not within the approved dose range. The misadministration also resulted from the individual's failure to obtain a written directive prior to administration of the dosage (Section 4).

- Contributing causes of the misadministration were the miscommunication among certain personnel concerning the correct radioactivity to use, and the lack of a standard format and content for recording physician orders for most nuclear medicine procedures. The root cause of the misadministration was the individual's lack of knowledge that a written directive was required for the dose administered (Section 4).

Quality Management Program

A violation was identified involving the failure to maintain a written QMP that met the objective that prior to administration, a written directive was prepared for each administration of I-131 in quantities greater than 30 microcuries as required by 10 CFR 35.32(a) (Section 5).

- The failure to prepare a written directive in accordance with the licensee's established QMP and the resulting misadministration was an isolated case and did not demonstrate a general programmatic weakness or breakdown in implementation of the program (Section 5).

Misadministration Notification and Reports

- The licensee properly identified and reported the I-131 dosage error as a misadministration to the referring physician and to NRC. However, a violation was identified involving a failure to notify the patient of the misadministration within 24 hours after its discovery as required by 10 CFR 35.33(a) (Section 6).

Consequences

- The additional dose and any clinical effect resulting from the misadministration was judged to be insignificant as compared to the patient's subsequent therapy dose (Section 7).

Licensee Corrective Actions

- The licensee's corrective actions consisted of additional refresher training with a re-emphasis on minimum dose levels requiring written directives, and a revised policy for more specific and detailed prescriptions for any I-131 dosages. (Section 8).

Report Details

1 Program Overview (87100 and 87103)

1.1 Inspection Scope

The inspector reviewed the license docket file, QMP program records, and previous NRC inspection findings. The inspector conducted interviews with all licensee staff in the nuclear medicine department to characterize the past and present program involving the diagnostic and therapeutic use of iodine-131.

1.2 Observations and Findings

The Department of Veterans Affairs Medical Center, Portland (VAPO), is authorized under its NRC license to use byproduct material for diagnostic and therapeutic procedures as defined in 10 CFR 35.100-500, and for clinical research activities conducted under the specific approval of the radiation safety committee. Routine procedures involving use of radiopharmaceuticals have been conducted under the overall supervision of the Chief of Imaging Service. The nuclear medicine department was staffed by three authorized user physicians, two nuclear medicine fellows, a radiology resident, four staff technologists, and an imaging service medical physicist. The licensee has performed an average of 10-12 nuclear medicine procedures daily. Most of the these procedures involved administration of radiopharmaceuticals labeled with technetium-99m received in the form of bulk and single unit-dose shipments from a local radiopharmacy.

In 1996, the licensee conducted nine nuclear medicine procedures using Sr-89 for palliative treatments of metastatic bone disease, and another 21 procedures using I-131 for the diagnosis and treatment of thyroid disorders. Sodium iodide (NaI) I-131 in amounts exceeding 5 millicuries (5 mCi or 5000 μCi) had been used for whole-body scans and for treatment of hyperthyroidism and thyroid ablation on 18 separate occasions. Dosages of approximately 5 μCi had been administered to patients in oral form for the measurement of thyroid uptake on three other occasions. In addition, 100-300 μCi of NaI I-123 had been repeatedly administered for use in thyroid uptake measurements and imaging scans (I-123 is a cyclotron-produced radionuclide, and is therefore not regulated by NRC).

1.3 Conclusions

The licensee has a moderately large nuclear medicine program that includes extensive use of radioiodine labeled material for patient diagnosis and therapy. Conduct of the program was consistent with that authorized under the license.

2 Background (87103)

At 2:41 p.m. (Pacific Time) on December 19, 1996, the licensee's radiation safety officer (RSO) notified the NRC Operations Center of a misadministration involving a diagnostic dosage of I-131 that occurred on December 18, 1996. At 3 p.m., the RSO also reported the incident to the Walnut Creek Field Office (WCFO). The licensee's initial report was supplemented with additional information provided to NRC Region IV staff during a telephone conference call on December 20, 1996. The licensee reported that an authorized user physician had prescribed a thyroid uptake dose for a 63 year old male patient, which was intended to contain 10-15 μCi of I-131. The uptake measurement was needed to determine the subsequent dosage needed for treatment of the patient's hyperthyroid condition (therapy dose). A nuclear medicine technologist had misinterpreted the authorized user's instructions and instead administered a 300 μCi dose of I-131 to the patient. No written directive was prepared for the uptake study because the authorized user intended to administer a dosage of less than 30 μCi. The event was reported because the dosage administered (300 μCi) differed by more than 20 percent of the prescribed dosage (30 μCi) and the difference between each exceeded 30 μCi, which is defined by 10 CFR 35.2 as a misadministration for reporting purposes under 10 CFR 35.33.

3 Sequence of Events (87103)

3.1 Inspection Scope

The inspector interviewed licensee personnel and examined nuclear medicine records to reconstruct the events associated with the misadministration.

3.2 Observations and Findings

The following is a chronological sequence of events that occurred prior to, during, and following the misadministration:

- On December 4, 1996, a VAPO referring physician (Physician A) requested that the hospital's nuclear medicine department evaluate a male patient (Patient A) for treatment of Graves disease which results in a hyperactive thyroid condition. Information about the request was entered by a clerk on a standard radiology request form (consult sheet) using a hospital-wide computer system. The consult form was then transmitted electronically to the imaging service office where a hard copy was printed the same day.

- On December 4 or 5, a radiology resident (Physician B) examined the consult to evaluate the requested procedure. The resident said he probably discussed the case with a nuclear medicine staff physician but he could not remember whom. The resident then approved the request for treatment and wrote an order for the pre-therapy thyroid uptake measurement on the

consult form. The resident wrote "uptake 131," signed the order with his initials, and drew a line around the entire written order to highlight it on the consult. This clinical procedure was prescribed to determine the percentage of oral sodium iodide (NaI) I-131 activity accumulated by the patient's thyroid as measured during a post administration 6 hour and 24 hour thyroid count. The data collected would subsequently be used to calculate the amount of NaI I-131 therapy dose needed for treatment. As was normal practice, the resident did not specify the dosage to be administered in his written order since the actual dose ordered and used for the uptake would be determined later by a department technologist based on a dose range previously approved by nuclear medicine. After writing the I-131 uptake order, the resident placed the consult in a designated tray or stack in an office "alcove" for retrieval and use by nuclear medicine technologists.

- On December 5, 6, or 9, Technologist A retrieved Patient A's consult along with consults for other patients who needed to be scheduled for nuclear medicine studies. Technologist A stated that she examined the patient's consult containing the approved thyroid uptake order and probably asked her immediate supervisor, Technologist B, "How much (dose) are we giving the patient for uptake studies now .... 5 μCi?" Technologist B responded back, "No...300 μCi." Technologist A, indicating surprise at this answer, asked "300?" Technologist B replied: "Yes." Technologist B answered "300 μCi" because he assumed Technologist A was asking about the standard dosage for an uptake study using I-123. Technologist A said she probably specified the radionuclide, I-131 during this brief discussion but she was not sure. Technologist A, although still unsure about the I-131 amount to order, wrote an activity of 300 μCi on the consult form next to, but outside, the resident's written "uptake 131" order. However, Technologist B said he could not recall whether Technologist A identified the radionuclide (I-131) during their discussion, but remembered that he did not look at the consult sheet.

- On December 9 and 11, Technologist A said she tried to telephone the patient to schedule him for the I-131 uptake, but was unsuccessful, and as a result, she did not order the dose. Technologist A stated that she made no further effort to verify the correct dose for the I-131 uptake study, but would have done so before ordering the dose.

- Sometime between December 9 and 17, Technologist B telephoned the patient to schedule his appointment for the thyroid uptake and therapy at VAPO on December 18-19, 1996. Technologist B wrote the following entries on the December 18, 1996, page of the nuclear medicine appointment book: patient A's name, social security number, appointment times (8 a.m. and 2 p.m.), and "I-131 admin" and "I-131 upt." Based on similarity of handwriting, Technologist B apparently wrote "300 μCi" next to

the 8 a.m. appointment as noted above. (Technologist B did not remember writing this activity but acknowledged that he may have written it.)

- Late in the afternoon of December 17, Technologist C examined the appointment book and noted the activity of 300 μCi was a high dose for an I-131 uptake study. Technologist C retrieved the patient's clinical chart and checked the original consult form to confirm that the radionuclide and dose was as prescribed by the nuclear medicine physician. He assumed that someone had already talked to Physician B about the dose and as a result, the dosage "300 μCi" was added to the consult. Technologist C recalled that because he was still uncertain about what dose to order, he attempted to check with Physician B. However, Physician B was not in the nuclear medicine "reading room," an area where residents and staff routinely view imaging films and review patient casework. Technologist C said he then showed the patient's consult to Technologist B and questioned him about the correct dose to order/administer. (Technologist B disputed this version, stating that he did not remember looking at the consult and was only asked whether the dose had been ordered and not its amount.) Technologist C said he concluded the 300 μCi I-131 order was accurate since the radionuclide and amount appeared in two places (appointment book and consult form).

- Late afternoon on December 17, Technologist C ordered a single-unit capsule dose of 300 μCi I-131 from a local commercial radiopharmacy (Mallinckrodt, Inc.).

- Early on the morning of December 18, the nuclear medicine radiopharmacy laboratory received a single unit dosage containing one NaI I-131 capsule. At approximately 8 a.m. (Pacific Time) on December 18, Technologist C assayed the I-131 capsule in a dose calibrator, measuring 320 μCi. After the patient arrived, Technologist C said he verified his identity, obtained patient consent, and administered the oral capsule. (Nuclear medicine dose logs indicate the patient's dose was administered at 8:10 a.m.) Technologist C did not ask for a written directive and none was prepared before the dose was administered.

- On December 19, Technologist C calculated the amount of I-131 accumulated by the patient's thyroid corresponding to the 6 hour and 24 hour uptake measurements. At approximately 10:30 a.m. (Pacific Time), a nuclear medicine fellow (Physician C) reviewing the patient's chart noted that the I-131 dose administered was much larger than that normally used by nuclear medicine for this procedure (accepted range: 5-25 μCi). Shortly after discussing the dose with the radiology resident and Technologist B, Physician C recognized the error as a possible misadministration and notified the Chief of Imaging Service (CIS). The nuclear medicine staff physician on duty that day (Physician D) discussed the problem with the imaging service

medical physicist. The medical physicist telephoned the RSO at his home to discuss whether the error should be considered as a misadministration.

- During late morning on December 19, the RSO discussed the incident with the CIS who agreed that the error constituted a misadministration. The RSO later notified VAPO management of the misadministration. Physician C called the referring physician to discuss the clinical consequences of the patient receiving a larger than customary uptake dose. Physician C, in consultation with the referring physician, agreed to continue with the planned treatment with 10 mCi NaI I-131.

- Physician D wrote a written directive for an oral dose containing 10 mCi of NaI I-131 using the licensee's QMP designated checklist form. Technologist B assayed a single capsule dose in a dose calibrator which measured 10.3 mCi, and the dose was administered to Patient A without incident at 1:25 p.m. on December 19.

- The RSO reported the misadministration to the NRC Operations Center at 2:41 p.m. (Pacific Time) on December 19, and to the Region IV WCFO at 3 p.m. the same day.

4 Causes of the Misadministration (87103)

4.1 Inspection Scope

Through interviews of licensee personnel, reviews of misadministration related reports and records, and analysis of nuclear medicine procedures, the inspector evaluated the event to determine its direct, root, and contributing causes.

4.2 Observations and Findings

As part of this evaluation, the inspector examined the licensee's customary practice for prescribing, scheduling, and ordering nuclear medicine procedures. A request for a nuclear medicine clinical procedure ("Radiology Request" or medical consult form) initiated by a referring physician has typically been sent electronically to Imaging Service where a copy is printed for use by nuclear medicine staff. According to the licensee, staff technologists would give the consult to a nuclear medicine resident, fellow, or staff physician who reviews the requested study, confers with the referring physician as necessary, specifies the type of procedure to be conducted on the same consult, and returns the consult form to the technologist to schedule the patient's procedure and to order the radiopharmaceutical dose.

Nuclear medicine residents, fellows, and staff physicians have all been authorized to approve referral requests and prescribe routine diagnostic procedures, including I-131 dosages for uptake studies containing less than 30 μCi. Physicians have typically recorded only the clinical study to be performed on consult forms, although

specific dosages were also written on occasion for diagnostic studies with I-131. If a physician did not specify a dosage on the consult, technologists were approved to order and administer dosages with activity levels previously authorized by the CIS for each type of clinical procedure. No specific approval from a physician was required by policy unless the activity did not agree with or fell outside the standard dose or dose range authorized.

Nuclear medicine written procedures for uptake studies specified standard dosages of 100 μCi for I-123 and a range of 5-25 μCi for I-131 administered orally in capsule form. These and other clinical procedures were documented in nuclear medicine's "In-Vivo Procedures Manual." The procedures were maintained for reference use by the nuclear medicine staff at the technologist's alcove. In addition, a table listing radionuclides, chemical forms, and "authorized prescribed activity" for each routine nuclear medicine clinical procedure, including those for I-123 and I-131 uptake studies, was available for reference in the "Radiopharmacy Manual" in the department's Radiopharmacy Laboratory. More recently, an authorized activity range of 100-300 μCi I-123 had been approved for the uptake procedure and the radiopharmacy manual table was revised accordingly.

For other diagnostic and therapeutic procedures using NaI I-131 exceeding 30 μCi (i.e., thyroid imaging, whole body scans, hyperthyroid therapy, and thyroid ablation), the same dose table noted above also specified acceptable doses or dose ranges. However, in such cases, specific doses have been prescribed by only a staff physician in the form of a signed and dated written directive. The written directive is prepared on a "Checklist Report" form in accordance with the licensee's QMP.

4.2.1 Direct Cause

The inspection determined that the direct cause of the misadministration was the failure of a supervised individual to follow existing departmental procedures for dose ordering and patient administration. Technologists B and C indicated that they were familiar with the nuclear medicine clinical procedures manual specifying standard dosages of 100-300 μCi of I-123 and 5-25 μCi of I-131 for thyroid uptakes. Indeed, Technologist C had reviewed the consult form and questioned his supervisor (Technologist B) about the correct dose to use after he noted the abnormally high activity for the I-131 uptake study recorded in the appointment book. Although Technologist C had concluded that Physician B had ordered the 300 μCi dose, he did not know why. He incorrectly assumed that the higher activity was required to suppress the effect of medication previously taken by the patient. (This was a drug administered to reduce the overactive thyroid (hyperthyroid) function. However, other licensee staff indicated the patient had halted drug use, as was customary before I-131 was administered, to avoid inaccurate 6 hour and 24 hour uptake measurements.)

Despite the questionable 300 μCi I-131 entries in the appointment page and consult sheet, neither individual (Technologists B and C) checked with the nuclear medicine resident who ordered the study to verify the dose, which was contrary to the departmental policy requiring specific physician approval for each dosage that was outside its accepted range. Technologist C indicated that he was unable to review the dose with the resident because he was not in the nuclear medicine reading room, and because he did not want to delay ordering the dose from Mallinckrodt since it was late afternoon and the dose had to be ordered before he left the hospital at the end of the work shift. Consequently, Technologist C made no further attempt to communicate with the resident or other nuclear medicine physicians to verify the dose before it was ordered and administered. However, as was acknowledged by Technologist C, the resident and other nuclear medicine physicians carried beepers and could have been paged to review the accuracy of the I-131 dose before it was ordered or administered.

4.2.2 Root Cause

The inspection established that the licensee did not prepare a written directive at any time for the I-131 uptake study although a written directive was not initially required for the dose of 5-25 μCi intended. However, Technologist C did not ask for a written directive either before the 300 μCi dose was ordered or before the assayed 320 μCi dose was administered. As noted earlier, use of a written directive was required by departmental QMP prior to administration of any quantity greater than 30 μCi of NaI I-131. Technologist C stated that he did not ask for a written directive because he did not know or did not remember that one was required for a dose exceeding 30 μCi. The failure of the technologist to recognize the need for the written directive was identified as a root cause of the misadministration. Had the technologist either checked with a nuclear medicine physician or requested a written directive prior to administration, the dosage error probably would have been discovered and the I-131 misadministration could have been prevented.

4.2.3 Contributing Causes

One contributing cause of the misadministration was the faulty communication between the three technologists who had discussed the case. Technologist A apparently did not identify the radioisotope when she questioned her supervisor about the correct dose to use, but assumed that he understood she was referring to I-131. The supervising technologist assumed that Technologist A was referring to the use of I-123 for the uptake study, and accordingly answered "300 μCi" to her question about the correct I-131 dose to order. This erroneous response was likely made based on the licensee's frequent use of I-123 for thyroid uptake studies in 1995 and 1996. (Only two I-131 uptake procedures were performed in 1996.) The supervisor also indicated that he did not look at the patient's consult when questioned by Technologists B and C, nor did he spend any effort to evaluate and

discuss the case before answering each technologist because he was busy at the time and was distracted by other tasks.

A second contributing cause was the absence of a standard format and content for recording physician orders for non-QMP nuclear medicine diagnostic procedures that clearly and unambiguously specified the doses to be ordered and administered. Physician orders were typically handwritten on the consult form which identified the study to be performed but did not always specify the dosage. Nuclear medicine personnel had been allowed to handwrite clinical data and other patient-related information anywhere on the consult sheet. In the case involving the misadministration, Technologist B wrote an activity of 300 μCi near the physician's order on the consult which was interpreted as being written or authorized by the physician and which caused subsequent confusion about the correct dose to use for the I-131 uptake study.

4.3 Conclusions

The misadministration was directly caused by the failure of a supervised individual to follow existing departmental procedures which, in part, required specific nuclear medicine physician approval for an I-131 dosage outside of the acceptable dose range established. The misadministration could still have been prevented if the individual had checked for a written directive which was also required under the licensee's QMP prior to administration of the dose. However, the individual did not know or did not remember that a written directive was required, which was identified as a root cause of the misadministration. Contributing causes of the misadministration included the miscommunication among certain personnel concerning the correct dose activity to use for the uptake study, and the lack of standard format and content for recording physician orders for most nuclear medicine procedures.

5 QMP (87103, 87100, 87101)

5.1 Inspection Scope

The licensee's QMP was reviewed to evaluate its effectiveness and compliance with the requirements of 10 CFR 35.32 for the diagnostic and therapeutic administration of radiopharmaceuticals. The inspector interviewed licensee personnel and reviewed records related to the administration of I-131 and Sr-89 radiopharmaceuticals since January 1, 1996.

5.2 Observations and Findings

10 CFR 35.32(a) requires the licensee to establish and maintain a written QMP to provide high confidence that a radiopharmaceutical dose will be administered to patients as directed by the authorized user. To comply with this rule, the program must include written policies and procedures to meet the specific objectives that,

prior to each administration, (1) a written directive is prepared for any radiopharmaceutical dose, (2) the patient's identity is verified by more than one method as the individual named in the written directive, (3) each administration agrees with the written directive, and (4) any unintended deviation from the written directive is identified and evaluated, and that appropriate correction action is taken.

On January 6, 1992, the licensee submitted to NRC and implemented a written QMP for the administration of I-131 radiopharmaceutical material exceeding 30 μCi. Subsequent written modifications to the original QMP, which was later expanded to include Sr-89 and P-32, were sent to NRC within 30 days following changes to the program, as required by 10 CFR 35.32(e). The licensee's QMP, submitted to the NRC on June 21, 1995, and revised on June 11, 1996, specified, in part, that a "Checklist Report" form would be used for the administration of a dosage of sodium iodide I-131 exceeding 30 μCi. This form contained data entry fields in a checklist format for preparing a written directive (e.g., radionuclide, radioactivity, route of administration), as well as information related to patient identification and radiopharmaceutical verification.

The inspector's review indicated the licensee had established and routinely implemented a QMP which included general written administrative polices and procedures that met the above required objectives as applied to the diagnostic and therapeutic use of I-131 and Sr-89. Checklist report forms, including written directives, had been routinely completed as required. Routine quarterly audits of the program were conducted by the RSO and reviewed by the licensee's radiation safety committee and management to identify and correct program deficiencies. Licensee audit records indicated that deviations from the QMP had occurred on a few occasions. These included such missing items as signatures and dates, radiopharmaceutical activity and form, and route of administration on written directives. However, with the exception of the current I-131 misadministration, written directives were consistently prepared and followed when required. No other misadministrations or recordable events were identified during the inspection.

Nuclear medicine technologists, physicians, and other departmental staff interviewed during the inspection were generally knowledgeable about QMP program requirements. Three of the four technologists said they were previously aware (i.e., before the misadministration incident) that written directives were required prior to administration of any I-131 dosage greater than 30 μCi. All four technologists indicated they had received initial and annual QMP training provided by the RSO and during nuclear medicine staff meetings, and that they had either read or knew where to find the department's written QMP procedures. Technologist B stated that he knew written directives were required for diagnostic and therapeutic doses containing millicurie quantities of I-131, but as noted earlier, he did not remember that written directives were also required for any I-131 dosage larger than 30 μCi. Technologist B acknowledged that he had probably read the written QMP although he did not remember receiving any instruction during licensee QMP training regarding the threshold dose for I-131 written directives. However,

information provided by the RSO and interviews of other nuclear medicine staff indicated that this requirement had been discussed during previous QMP training.

5.3 Conclusions

Based on the inspector's evaluation, the licensee's failure to prepare a written directive for the administration of the unintended I-131 dosage that resulted in the misadministration appeared to be an isolated occurrence and did not demonstrate a general programmatic weakness or breakdown in implementation of the program. Nevertheless, the licensee's failure to implement its QMP, which required a written directive prior to administration of the 320 μCi I-131 dosage, was identified as a violation of 10 CFR 35.32(a) (Violation 03014522/9701-01).

6 Misadministration Notification and Reports (87103)

6.1 Inspection Scope

The licensee's notification and reporting of the misadministration was evaluated for compliance with the requirements of 10 CFR 35.33. The inspector interviewed VAPO personnel and reviewed licensee records and reports of the misadministration and notifications of the referring physician, patient, and NRC.

6.2 Observations and Findings

After discovery of the dosage error and subsequent discussions between nuclear medicine staff and the RSO late in the morning on December 19, 1996, the error was immediately reported to the CIS. The licensee evaluated the event against NRC reporting requirements and it was properly classified as a misadministration. The RSO reported the misadministration by telephone to the NRC Operations Center and to the Region IV WCFO the same day. The licensee submitted a written report of the misadministration to Region IV on January 2, 1997. The licensee's verbal notification and written report were therefore received within the required 24 hour and 15 day time limits after discovery, respectively.

The licensee also notified the referring physician by telephone of the misadministration within 24 hours after discovery, as required by 10 CFR 35.33(a)(3). Physician C telephoned the referring physician and they agreed that the medical significance and consequences of the higher I-131 dose were inconsequential and would not alter the planned treatment. The referring physician agreed that no further action in response to the misadministration was necessary. However, the need to notify the patient of the misadministration was not discussed at that time. Physician D, who was present but did not participate in the telephone discussion, later decided not to notify the patient. According to Physician D, he did not plan to notify the patient because the medical consequences were negligible, and because the possible discomfort experienced by the patient would not be justified by the small risk from the excess dose. Physician D also

indicated that he and the medical physicist had reviewed the NRC reporting requirement of 10 CFR 35.33 and concluded that patient notification was not required.

However, during a telephone conference call with VAPO at 1 p.m. on December 20, 1996, NRC advised the licensee that 10 CFR Part 35 required the patient or responsible relative (or guardian) be informed, and that the only valid reason for not notifying the patient was if the referring physician believed that notification would cause medical harm to the patient (or responsible relative or guardian). The CIS agreed to ask the referring physician about the medical harm aspect and if none existed, she would contact the patient.

The inspector reviewed the licensee's followup actions involving patient notification. The CIS first attempted to telephone the patient on either December 23 or 24, but she only reached the patient's answering machine and left no message. The CIS said she made no attempt to call the patient after the Christmas holiday on both December 26 and 27 because the CIS was unable to retrieve the patient's chart (a winter storm caused a hospital wide power outage and a resulting shortage of hospital staff hindered retrieval of patient charts). Notification did not occur until the CIS reported the misadministration to the patient by telephone during the morning of December 30, and by letter that was mailed later the same day. Consequently, initial patient notification did not occur until 12 days after its discovery. The written report to the patient was sent within 15 days after discovery and adequately described the event and the medical consequences, as required by 10 CFR 35.33(a)(4). The CIS said that after she notified the patient, she discussed the issue with the referring physician and he agreed that patient notification had been appropriate in this case. Although the licensee eventually reported the misadministration to the patient, its failure to provide notification within 24 hours of its discovery was identified as a violation of 10 CFR 35.33(a)(3) (03002935/9601-02).

6.3 Conclusions

The licensee properly identified and reported the I-131 dosage error as a misadministration to the referring physician and to NRC. However, the licensee did not notify the patient of the misadministration until 12 days after its discovery. The failure to notify the patient within the required 24 hour period after discovery of the misadministration was identified as a violation. The initial delay in patient notification was caused by the licensee's misinterpretation of the NRC reporting requirement.

7 Consequences (87103)

7.1 Inspection Scope

The inspector interviewed licensee personnel and reviewed nuclear medicine records and reports to determine the consequences of the misadministration.

7.2 Observations and Findings

As noted earlier, the I-131 dosage received by the patient (320 μCi) as a result of the misadministration was approximately 10-12 times larger than the dosage that normally would have been administered (5-10 μCi) or permitted (5-25 μCi) for the thyroid uptake procedure. One day after the misadministration, a much larger therapy dose (10.3 mCi) was administered in accordance with the planned treatment of the patient's hyperthyroid condition. According to the licensee, an appropriate therapeutic dose in normal cases of this type would have been selected from an activity range of 10 mCi to 12 mCi. Consequently, the uptake dose was relatively insignificant as compared to the therapy dose and the total dose was within the range of that normally prescribed. The authorized physician user stated that she and the referring physician took the higher uptake dose into account when planning the subsequent therapy dose.

The referring physician said no ill effects were reported by the patient or observed by the licensee following the misadministration and none are expected. The referring physician said the patient will return to the hospital in February 1997 for clinical tests to evaluate the need for any additional hyperthyroid treatment with NaI I-131.

The NRC independently determined that a medical consultant was not required to review the misadministration because of the minor health consequences expected in this particular case.

7.3 Conclusions

The additional dose received by the patient and any clinical effect associated with the misadministration was evaluated to be insignificant as compared to the subsequent therapy dose administered.

8 Corrective Actions (87103)

8.1 Inspection Scope

The inspector interviewed licensee personnel and reviewed records regarding the corrective actions taken or planned in response to the misadministration.

8.2 Observations and Findings

QMP refresher training of all nuclear medicine staff was provided by the medical physicist two days after the misadministration, and by the RSO during a staff meeting on December 31, 1996. The training reemphasized the requirement for written directives for dosages exceeding 30 μCi of I-125 or I-131. All nuclear medicine technologists and other staff interviewed by the inspector acknowledged receiving this training and understood the written directive requirement. The licensee is planning to conduct more frequent training sessions in the future.

On December 20, 1996, the licensee established a new policy regarding physician approved orders for all patient doses containing I-125 and I-131. All such orders, regardless of radioactivity, will now require a written prescription on consult forms which specifies the procedure ordered, radionuclide, radiopharmaceutical form, and activity. The new procedure is in addition to the requirement for separate written directives for doses exceeding 30 μCi of I-131. At the time of the inspection, a memorandum describing this procedure was posted for viewing on a bulletin board in the nuclear medicine reading room used by the staff physicians and radiology residents. All nuclear medicine staff interviewed by the inspector were familiar with the new procedure.

As of January 13, 1997, the licensee was planning, but had not yet implemented, other program changes. These included ending its current practice of sending telephone orders to its supplier and replacing it with a form listing each radionuclide and standard dose, and posting the activity ranges permitted for each radiopharmaceutical study at the technologist alcove and behind the dose calibrator in the nuclear medicine radiopharmacy.

The RSO stated that proposed changes and corrective actions will be reviewed during the next quarterly meeting of the licensee's radiation safety committee.

8.3 Conclusions

Corrective actions implemented by the licensee to date consisted of more frequent refresher training with additional emphasis on dose activity levels requiring written directives, and a new policy requiring more specific and detailed prescriptions for I-131 dosages, including those less than 30 μCi. These corrective actions appear to address the major causes of the misadministration.

Exit Meeting Summary

The inspector presented the inspection results to licensee management during a preliminary site exit meeting on January 10, 1997, and during a final exit via telephone on January 31, 1997. The inspector discussed the probable causes of the misadministration and reviewed two violations of NRC requirements that were identified during the inspection. The licensee acknowledged the inspector's

findings. The inspector noted that no proprietary information was reviewed or appears in the inspection report.

ATTACHMENT 1

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Michael Bays, M.D., Chief Operating Officer
Paul Brown, Medical Physicist, Imaging Service
Maggie Chester, Nuclear Medicine Technologist
Carl Christensen, M.D., Radiology Resident
William Ted Galey, M.D., CEO
Suzan Gilbert, Quality Management Specialist
Marsha Holly, Nuclear Medicine Technologist
Deborah Hiedeman, Director, Imaging Service Administration
Anthony McCall, M.D., Endocrinologist
Kathryn Morton, M.D., Chief, Imaging Service
Jess Moses, Chief, Facilities Service
Joseph Murley, M.D., Chief Medical Executive
Robert Nance, M.D., Staff Nuclear Medicine Physician
Hilton Smith, Nuclear Medicine Technologist
Bill Stewart, Safety Manager
Richard Tinkham, Nuclear Medicine Technologist
William Tuttle, Ph.D., Medical Center RSO
Annette White, M.D., Nuclear Medicine Fellow

INSPECTION PROCEDURES USED

IP 87100: Licensed Materials Programs, Nuclear Medicine
IP 87101: Performance Evaluation Factors
IP 87103: Inspection of Incidents at Nuclear Materials Facilities

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-02935/97-01	VIO	Failure to prepare a written directive as required by the licensee's quality management program for the administration of 320 microcuries of sodium iodide I-131.
030-02935/97-02	VIO	Failure to inform a patient of a misadministration involving a radiopharmaceutical dosage within 24 hours after its discovery by the licensee.

LIST OF ACRONYMS USED

CIS	Chief of Imaging Service
IP	Inspection Procedure
μCi	Radionuclide activity in microcuries
mCi	Radionuclide activity in millicuries (1 mCi = 1000 μCi)
NRC	Nuclear Regulatory Commission
QMP	Quality Management Program
RSO	Radiation Safety Officer
VAPO	Veterans Affairs Medical Center, Portland
VIO	Violation
WCFO	Walnut Creek Field Office

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600)[1] 60 FR 34381, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VII.B.1 of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations are documented on Form 591 (for materials licensees)

[1]Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions. The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

   - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

- Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

- Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an auditable record and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

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Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices