NOTICE OF VIOLATION

Alpena General Hospital
Alpena, Michigan

Docket No. 030-13274
License No. 21-17754-01
EA 89-97

During an NRC inspection conducted on April 19, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions, "10 CFR Part 2, Appendix C, 53 Fed. Reg. 40019 (October 13, 1988)," the violations are listed below:

A. License Condition No. 17 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 13, 1983. The application requires that radioactive material be ordered in accordance with Appendix E of Regulatory Guide 10.8, October 1980.

Item 2.b. of Appendix E requires that, when ordering materials for therapeutic uses, a written request indicating the isotope, compound, and activity be obtained from the physician who will perform the procedure; and that persons ordering materials for therapeutic uses reference the physician's written request when placing the order.

Contrary to the above, on December 11, 1988, a technologist employed by the licensee ordered a dose of iodine-131 for therapeutic use without obtaining a written request from the physician who was going to perform the procedure.

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

B. License Condition No. 17 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 13, 1983. Item 7 of the application requires the licensee to follow the procedures in Appendix B of Regulatory Guide 10.8, October 1980.

Appendix B requires the Medical Isotopes Committee (Radiation Safety Committee) to meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

Contrary to the above, the Medical Isotopes Committee failed to meet during the third quarter of 1984, the first and second quarters of 1985, the third quarter of 1986, and the first and third quarters of 1987.

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

8907050399 890628
REG3 LIC30
21-17754-01 PNU

C. 10 CFR 35.22(a)(1) requires that the membership of the Radiation Safety Committee (RSC) include, among other individuals, a representative of the nursing service.

Contrary to the above, as of April 19, 1989, the licensee's RSC membership did not include a representative of its nursing service.

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

D. License Condition No. 17 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 13, 1983. Item 10 of the application requires the licensee to follow the procedures in Appendix D of Regulatory Guide 10.8, October 1980.

Appendix D, Section 2, requires the licensee to test dose calibrators for linearity at installation and quarterly thereafter.

Contrary to the above, the licensee's Capintec CRC-12 dose calibrator was not tested for linearity during the first, second, and third quarters of 1985 and during the first and fourth quarters of 1987.

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

E. 10 CFR 35.315(a)(8) requires the licensee to measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage to a patient hospitalized for compliance with 10 CFR 35.75.

Contrary to the above, the licensee failed to measure the thyroid burden of an individual who helped prepare and administer a dosage of iodine-131 on March 11, 1988, to a patient who was hospitalized for compliance with 10 CFR 35.75.

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

Pursuant to the provisions of 10 CFR 2.201, Alpena General Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, U.S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation if admitted; (2) the corrective

actions that have been taken and the results achieved; (3) the corrective actions that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time. If an adequate reply is not received within the time specified in this Notice, an Order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 28 day of June 1989.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-13274/89001(DRSS)

Docket No. 030-13274 Category G Priority 3

License No. 21-17754-01

Licensee: Alpena General Hospital
1501 W. Chisholm Street
Alpena, MI 49707

Inspection At: Alpena, Michigan

Inspection Conducted: April 19, 1989

Inspector: J. R. Madera — 5/5/89
J. R. Madera
Senior Licensing Reviewer
Date

Reviewed By: G. M. McCann, Chief — May 5, 1989
G. M. McCann, Chief
Nuclear Material Licensing
Section
Date

Approved By: B. S. Mallett, Ph.D., Chief — 5/5/89
B. S. Mallett, Ph.D., Chief
Nuclear Materials Safety
Branch
Date

Inspection Summary

Special Inspection on April 19, 1989, (Report No. 030-13274/89001(DRSS))
Areas Inspected: Announced, special safety inspection to review the facts surrounding a potential iodine-131 therapy misadministration reported to the NRC on December 14, 1988. Other areas inspected included a review of the following: Organization; materials; facilities; equipment; training; radiation protection; ordering, receipt and transfer; surveys; personnel monitoring; waste disposal; and confirmatory measurements.
Results: Of the areas inspected, five apparent violations and two areas of concern were identified against License No. 21-17754-01. The specific violations were:

1. Ordering an iodine-131 therapy dose without a written request from the physician who performed the procedure, License Condition No. 17 (Section 9);
2. Radiation Safety Committee did not meet quarterly, License Condition No. 17 (Section 4);

8905180200 PDR

3. Radiation Safety Committee membership did not include a representative of the nursing service, 10 CFR 35.22(a)(1) (Section 4);
4. Dose calibrator linearity check not performed quarterly, License Condition 17 (Section 7); and
5. Thyroid burden measurement not performed on individual that prepared and administered 51 millicuries of iodine-131, 10 CFR 35.315(a)(8) (Section 12).

DETAILS

1. Persons Contacted

John A. McVeety, Administrator
*Al Moe, Assistant Administrator
William Walker, M.D.
*Brad Berrier, Radiation Safety Officer
Paul Sylvester, Assistant Director Radiology
Dave Trimbath, Chief Nuclear Medicine Technologist

*Attended exit interview on April 19, 1989.

2. Purpose of Special Inspection

This was a special inspection to review the facts surrounding a potential iodine-131 therapeutic misadministration which was reported to the NRC. A dose of 6 millicuries was requested by the patient's referring physician. The actual dose administered to the patient was 15.2 millicuries.

On December 8, 1988, a request for the treatment of a patient for hyperthyroidism with iodine-131 was received by the Alpena General Hospital's nuclear medicine department. The request was made by the patient's attending physician, an endocrinologist, who filled out a standard nuclear medicine requisition form. On the form, the attending physician also indicated a request for a dose of 6 millicuries of radioactive iodine (RAI).

On Monday, December 11, 1988, the Chief Nuclear Medicine Technologist overlooked the request for 6 millicuries of RAI written on the requisition form and ordered 15 millicuries of iodine-131. The following day, December 12, 1989, the patient was examined by the authorized user, who determined that the calibrated dose of 15.2 millicuries of iodine-131 was within the appropriate range (4-15 millicuries) and verbally authorized the administration of the dose.

During review of the patient's requisition form the following day, December 13, 1989, the authorized user realized that the attending physician's request for the iodine-131 therapy dose was 6 millicuries not the 15.2 millicuries which was administrated. The attending physician was contacted by the authorized user and the situation was explained. On December 14, 1989, the Region III Office of the NRC was contacted by telephone and the incident was reported.

This special inspection included a review of the institutions routine nuclear medicine program. The previous item of noncompliance found during the last routine inspection has been corrected. However, five items of noncompliances and two areas of concern were identified during this special inspection.

3. Inspection History

* May 16 and 17, 1984 - routine inspection, one violation identified:

  * Dose calibrator linearity test performed using Calicheck's procedures which were not authorized.

  A Notice of Violation (NOV) was sent to the licensee on June 1, 1984.

  The licensee responded to the NOV with letter dated June 13, 1984. The response letter requested amendment of their license to authorize the use of the Calicheck system for performing dose calibrator linearity tests. In accordance with this letter, NRC License No. 21-17754-01 was amended on July 16, 1984, to allow the use of the Calicheck system.

  No violations were identified.

4. Organization

The administrator at Alpena General Hospital is John A. McVeety, the Assistant Administrator is Al Moe. The principle users of licensed material under license No. 21-17754-01 are Phillip S. Rudman, M.D. and William L. Walker, M.D. Brad Berrier is the Radiation Safety Officer for the hospital.

The Radiation Safety Committee is comprised of: Ellen Tupper, Continuing Education Coordinator and the management representative on the Committee; Brad Berrier, Radiation Safety Officer; Phillips S. Rudman, M.D. and William L. Walker, M.D., authorized users; and Dave Trimbath, Chief Nuclear Medicine Technologist.

The Radiation Safety Committee is required by 10 CFR 35.22(a)(1) to maintain a membership of at least three individuals which must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.

During the inspection, it was determined that the Radiation Safety Committee membership did not include a representative of nursing service.

The licensee's failure to include a representative of nursing service on the Radiation Safety Committee constitutes a violation of 10 CFR 35.22(a)(1).

License application dated April 13, 1983, referenced in License Condition No. 17, states that the procedures described in Appendix B of Regulatory Guide 10.8, October 1980, will be followed when conducting the duties of

the Radiation Safety Committee. Appendix B requires the Radiation Safety Committee to meet as often as necessary to conduct its business but not less than once in each calendar quarter.

Upon review of the Radiation Safety Committee meeting minutes, it was discovered that from 1984 through 1987, the Radiation Safety Committee did not meet on a quarterly basis. Specifically, the Radiation Safety Committee did not meet during the third quarter of 1984, the first and second quarters of 1985, the third quarter of 1986, and the first and third quarters of 1987.

The failure of the Radiation Safety Committee to meet quarterly from 1984 through 1987 constitutes a violation of License Condition No. 17.

The licensee has one full-time technologist working with the chief nuclear medicine technologist, and the Radiation Safety Officer is a registered nuclear medicine technologist capable of performing nuclear medicine studies.

Two apparent violations were identified.

5. Materials

The licensee receives a 900 millicurie molybdenum-99/technetium-99m generator weekly from DuPont NEN products. Technetium-99m doses are prepared from generator elutions. Xenon-133 gas vials and iodine-131 in capsules or liquid are also received as needed. The hospital is of moderate size with a 175 bed capacity. The nuclear medicine department performs approximately 123 diagnostic procedures and approximately one iodine-131 therapy procedure per month.

No violations were identified.

6. Facilities

A tour of the nuclear medicine department revealed that the facilities were as described in the license application. Posting and labeling was in accordance with applicable sections of 10 CFR 19.11(a) and 20.203. A series of lockable lead lined drawers and cabinets inside the hot lab as well as a lockable outer door to the hot lab demonstrated an adequate regard for security.

No violations were identified.

7. Equipment

The licensee possesses two dose calibrators, a Capintec CRC-12 and CRC-10, for dose preparation and assay. The Capintec CRC-10 is used only as a backup unit. License application dated April 13, 1983, referenced in License Condition No. 17, stated that procedures described

in Appendix D of Regulatory Guide 10.8, October 1980, will be followed when calibrating the dose calibrator. Appendix D requires, among other tests, that the licensee check the dose calibrator for linearity upon installation and quarterly thereafter.

According to a discussion with the chief nuclear medicine technologist and a review of the available records, the licensee's dose calibrator was not tested for linearity on a quarterly basis. Specifically, linearity tests were not performed during the first, second and third quarters of 1985 and during the first and fourth quarters of 1987.

The licensee's failure to perform the required linearity checks quarterly on the dose calibrator, constitutes a violation of License Condition No. 17.

Appendix D of Regulatory Guide 10.8, October 1980, also requires the licensee to check the dose calibrator for: constancy daily; instrument accuracy at installation and annually thereafter; and geometrical variation at installation. According to a review of the records and interviews with licensee representatives, these test were performed as required.

The licensee uses three survey instruments in its radiation safety program. The instruments are a Texas Nuclear Log scale capable of measuring fields up to 2 R/hr, an EON Geiger Muller with a maximum range of zero mR/hr to 50 mR/hr and a Bicron 2000 Geiger Muller with an internal chamber and a maximum range of zero mR/hr to 2 R/hr. These instruments meet the requirements of 10 CFR 35.120 and 35.220.

The instruments were compared during the inspection with an NRC Xetex 305B survey instrument.

The licensee's instruments and the NRC instrument recorded similar results when exposed to radiation fields inside the hot lab and patient scanning room.

One apparent violation was identified.

8. Training

The authorized users meet the qualifications set forth in 10 CFR Part 35 Subpart J for the material they are authorized to use under this license. The nuclear medicine technologists are all registered and certified nuclear medicine technologists with the American Registry of Radiologic Technologists (ARRT) and the Nuclear Medicine Technology Certification Board (NMTCB).

Training of all radiation workers and ancillary staff is provided upon employment and annually thereafter in accordance with 10 CFR 19.12.

No violations were identified.

9. Radiation Protection

Basic radiation protection guidelines appear to be followed in the licensee's facility except where noted elsewhere in this report. The use of gloves, syringe shields and vial shields was observed during the inspection. Eating, drinking, smoking and storage of food in restricted areas is not permitted by the licensee.

No violations were identified.

10. Ordering, Receipt and Transfer

License application dated April 13, 1983, referenced in License Condition No. 17, states that the procedures outlined in Appendix E of Regulatory Guide 10.8, 1980, shall be followed when ordering and accepting delivery of radioactive material. Appendix E requires that prior to the ordering of specially used materials (e.g., therapeutic uses) a written request will be obtained from the physician who will perform the procedure.

During the inspection, it was found that the nuclear medicine department typically orders therapeutic doses of iodine-131 without a written request from the physician who will perform the procedure. As an example, on December 11, 1989, the chief nuclear medicine technologist ordered a 15 millicurie iodine-131 therapy dose without obtaining a written request from the physician who performed the therapy procedure.

The licensee's failure to obtained the required written request from the physician performing the iodine-131 therapy procedure, prior to ordering the iodine-131 therapy dose, constitutes a violation of License Condition No. 17.

The licensee receives and transfers radioactive material in accordance with the procedures outlined in their application dated April 13, 1983, referenced in License Condition No. 17.

One violation was identified.

11. Surveys

In-house surveys to detect contamination and measure ambient radiation exposure rates have been performed by the licensee in accordance with procedures outlined in application dated April 13, 1983, referenced in License Condition No. 17 of the licensee.

The licensee performs the required surveys and tests necessary to check for Xenon-133 gas trap efficiency and proper room ventilation. The tests and frequency of these tests are performed in accordance with the procedures submitted with the above stated application.

Leak tests of sealed sources are performed every six months as required by 10 CFR 35.59. The licensee possesses two NRC-regulated sealed sources

manufactured by NEN which are required to be tested for leakage. One source contains approximately 152 microcuries of cesium-137 and the other approximately 258 microcuries of barium-133. These sources were analyzed by the licensee's consulting service in a timely manner and the results of the last leak test showed less than .005 microcuries of removable contamination.

No violations were identified.

12. Personnel Monitoring

To meet personnel monitoring requirements imposed by 10 CFR 20.202, the licensee issues film badges and TLD ring badges to employees. Badges are supplied by R. S. Landauer, Jr. and Company and exchanged on a monthly basis. Maximum annual exposures for Nuclear Medicine Department employees for the period of January 1984 to April 1989 were 2,450 millirem whole-body and 2,720 millirem extremity. Exposures are within 10 CFR Part 20 limits.

10 CFR 35.315(a)(8) requires the licensee to measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 to patients hospitalized for compliance with 10 CFR 35.75.

On March 11, 1988, a patient at Alpena General Hospital was administered 51 millicuries of iodine-131. Upon review of the records and interviews with licensee personnel, it was learned that the individual who prepared and administered the dose did not have his thyroid burden measured.

The licensee's failure to measure the thyroid burden of the individual who prepared and administered a dosage of iodine-131 to a patient hospitalized for compliance with 10 CFR 35.75, constitutes a violation of 10 CFR 35.315(a)(8).

One violation was identified.

13. Waste Disposal

Molybdenum-99/technetium-99m generators are decayed to background levels in accordance with 10 CFR 35.92 requirements, then they are dismantled for waste disposal and lead recovery. Other radiopharmaceutical waste is decayed for disposal in the same fashion. Waste storage for decay of the generators and other radiopharmaceutical waste is performed in the nuclear medicine department hot lab, inside lead lined cabinets. Proper disposal records are maintained.

No violations were identified.

14. Confirmatory Measurements

Confirmatory measurements were performed at the licensee's facility using a Xetex 305B survey instrument, Serial No. 11310, calibrated on March 7, 1989.

Surveys of the Nuclear Medicine Department by the NRC inspector did not identify excessive radiation levels. Maximum readings in accessible areas were approximately 0.3 mR.hr. Comparisons with licensee-owned instruments provided similar results.

No violations were identified.

15. Exit Interview

On April 19, 1989, an exit interview was held at Alpena General Hospital's Assistant Administrator's office. Mr. Al Moe and Mr. Brad Berrier represented the licensee at the meeting. The apparent violations and NRC enforcement options were discussed at the meeting. Two areas of regulatory concern were also discussed with the licensee. These concerns were:

a. All previously reported diagnostic misadministrations and the potential therapy misadministration which occurred on December 12, 1988, apparently were caused by one individual.

b. Certain apparent violations found during the inspection could have been avoided if the new 10 CFR Part 35 would have been followed. Also, potential violations may be identified in future inspections if the transition from the current program to the new 10 CFR Part 35 requirements is not made correctly upon licensee renewal.

The licensee acknowledged that all previous misadministrations reported to the NRC were caused by one individual. The Assistant Administrator and the Radiation Safety Officer assured the NRC inspector that the individual would be counseled and trained in the new quality assurance/ quality control procedures instituted by the Nuclear Medicine Department. The licensee also assured the inspector that the new Part 35 requirements will be incorporated into their renewal application. The licensee has been working with their consulting service in order to complete their license renewal package in accordance with Regulatory Guide 10.8, Revision 2, August 1987. This regulatory guide assists medical programs in preparing applications for byproduct material use under the new 10 CFR Part 35 regulation.

No written material was left with the licensee. Proprietary information was excluded from the report.

An enforcement conference is scheduled with the licensee on May 8, 1989, at 9:00 a.m. (CDT) by telephone.