NOTICE OF VIOLATION

Springfield Community Hospital
3535 South National
Springfield, MO 65807

Docket No. 030-18266
License No. 24-20553-01
EA 86-141

During an NRC inspection conducted on June 12 and July 16, 1986 violations of NRC requirements were identified. In accordance with "General Statement of Policy and Procedure for NRC Enforcement Action," 10 CFR Part 2, Appendix C (1986), the violations are listed below:

A. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of 10 CFR Part 20 and are reasonable under the circumstances to evaluate the extent of radiation hazards that my be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on March 25, 1986, surveys were not made of the unrestricted area (outside the building) adjacent to a brachytherapy patient's room. Such surveys were necessary under the circumstances to evaluate the extent of radiation hazards that might have been present in the area and to evaluate the need for any protective measures.

B. 10 CFR 35.14(b)(5)(v) requires that any licensee who possess and uses Group VI sources or devices containing byproduct material shall conduct a quarterly physical inventory to account for all sources and devices received and possessed.

Contrary to the above, during the first quarter of 1986, the licensee did not conduct a physical inventory of cesium-137 Group VI sealed sources.

C. 10 CFR 35.14(e)(1)(i) requires that any licensee who possesses sealed sources as calibration or reference sources pursuant to 10 CFR 35.14(d) test the sources for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, during the period October 1985 through June 12, 1986, a 203 microcurie cesium-137 sealed source possessed pursuant to 10 CFR 35.14(d), had not been tested for leakage and/or contamination.

D. License Condition No. 12 requires that licensed material be used by or under the supervision of individuals designated in License Condition No. 12.

Contrary to the above, during the period June 1985 through July 1986, an individual used licensed material although he was not designated in Licence Condition No. 12 or under the supervision of an individual designated in License Condition No. 12.

E. License Condition No. 19 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated December 2, 1982 and the letter dated March 24, 1983.

1. The application dated December 2, 1982 designates Dr. Melguiadito M. Allego as the Radiation Safety Officer.

   Contrary to the above, during the period Spring of 1983 through July 16, 1986, an individual other than Dr. Allego functioned as the Radiation Safety Officer.

2. Item 6, "Radiation Safety Procedures for the Therapeutic Use of Brachytherapy Sources, General Instructions," of the letter dated March 24, 1983 requires that nurses caring for brachytherapy patients will be assigned film badges.

   Contrary to the above, between November 1985 and May 1986, nurses who cared for four brachytherapy patients were not assigned film badges.

3. The application dated December 2, 1982 states that the procedures described in Appendix I of Regulatory Guide 10.8 will be followed for performing area wipe tests. Appendix I requires that the method for analyzing wipe tests will be sufficiently sensitive to detect 200 dpm (disintegrations per minute).

   Contrary to the above, since the licensee's license was issued in 1983, the licensee used a survey meter to analyze wipe test samples which was not sensitive enough to detect 200 dpm.

4. Item 1, "Radiation Safety Procedures for the Therapeutic Use of Brachytherapy Sources, Handling Equipment," of the letter dated March 24, 1983 states that remote handling devices will be used to reduce general radiation exposure and brachytherapy sources will never be touched with the hands.

   Contrary to the above, on June 12, 1986 an individual failed to use a remote handling device and held a plastic vial containing brachytherapy sources with his hand.

5. Item 2, "Radiation Safety Procedures for the Therapeutic Use of Brachytherapy Sources, Storage Facilities," of the letter dated March 24, 1983 states that sources will be stored in a safe in lead lined trays which are provided with separate compartments for different source activities to permit immediate and easy identification of its contents from the outside.

Contrary to the above, on June 12, 1986, brachytherapy sources of different source activities were all stored in a single plastic vial in one compartment and did not permit identification of the contents from the outside of the vial.

6. The application dated December 2, 1982 requires that TLD devices will be used to monitor finger doses.

Contrary to the above, on December 11, 1985 and March 25, 1986, a physician implanted brachytherapy sources and did not use a TLD device to measure the dose to his finger.

Pursuant to the provision of 10 CFR 2.201, Springfield Community Hospital is hereby required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each violation: (1) admission or denial of the violation, (2) the reason for the violation if admitted, (3) the corrective steps which have been taken and the results achieved, (4) the corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending your response time.

FOR THE NUCLEAR REGULATORY COMMISSION

James G. Keppler
Regional Administrator

Dated at Glen Ellyn, Illinois,
this 19th day of September 1986.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-18266/86001(DRSS)

Docket No. 030-18266

License No. 24-20335-01 Priority 6 Category 3

Licensee: Springfield Community Hospital
3535 South National
Springfield, MO 65807

Facility: Springfield, MO

Inspection Conducted: June 12 and July 16, 1986

Enforcement Conference: August 6, 1986

Inspector: W. P. Reichhold for
Radiation Specialist — Date: 8-28-86

Reviewed By: D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2 — Date: 8-28-86

Approved By: W. L. Axelson, Chief
Nuclear Materials Safety
and Safeguards Branch — Date: 8/28/86

Inspection Summary

Inspection on June 12 and July 16, 1986 (Report No. 030-18266/86001(DRSS))
Areas Inspected: This was an unannounced routine safety inspection of activities conducted under License No. 24-20335-01. The inspection included a selective review of the organizational structure, training, radiological protection procedures, facilities and equipment, audits, leak tests of sealed sources, inventory of sealed sources, receipt and transfer of radioactive material, personnel monitoring, radiation survey records, waste disposal records, posting, and independent measurements.
Results: Fourteen areas were inspected. Ten apparent violations were identified: (1) License Condition No. 19 - unauthorized radiation protection officer. (2) License Condition No. 12 - unauthorized user. (3) 10 CFR 35.14(b)(5)(v) - inventory of Group VI sources not performed quarterly. (4) License Condition No. 19 - nurses were not issued film

badges. (5) License Condition No. 17 - method used to analyze wipe samples not sensitive enough to detect 200 dpm. (6) 10 CFR 20.201(b) - Unrestricted areas adjacent to brachytherapy patient rooms were not surveyed. (7) License Condition No. 19 - remote handling devices were not used when working with brachytherapy sources. (8) License Condition No. 19 - brachytherapy sources were not stored as described in the license application. (9) License Condition No. 19 - finger TLD badge not used to measure extremity exposure. (10) 10 CFR 35.14(e)(1)(i) - calibration source not tested for leakage every six months.

DETAILS

1. Persons Contacted

+**Lynda Donegan, Assistant Administrator
+Dan Sullivan, M.D., Authorized User and Radiation Protection Officer
John Morgan, M.D., User
+Tammy Blackington - Guy, Director of Radiology
*Peter Holloway, Nuclear Medicine Technologist
+Emory Larimore, M.S., Consultant, Radiation Consultants of Mid America

*Indicates individual present at exit interview on June 12, 1986.
**Indicates a telephone contact on July 16, 1986.
+Indicates presence at enforcement conference on August 6, 1986.

2. Purpose of Inspection

This was a routine safety inspection of the activities conducted under license 24-20335-01.

The last inspection was performed on September 21, 1983. That inspection was the licensee's initial inspection. No apparent violations were identified.

3. Organization

Lynda Donegan, R.N., B.S.N., Assistant Administrator
Dan Sullivan, M.D., Radiation Protection Officer
Tammy Blackington - Guy, Director of Radiology
Peter Holloway, Nuclear Medicine Technologist

The management and staff has changed since the initial September 1983 inspection. A new assistant administrator was appointed in March 1986, and a new nuclear medicine technologist was hired about April 1986. The Director of Radiology had been changed since the last inspection. The authorized Radiation Protection Officer ceased his duties in January 1983, and Dr. Sullivan assumed the Radiation Protection Officer's duties in January 1983. A Radiation Protection Officer not authorized by the license is a violation of License Condition No. 19. Dr. Sullivan is authorized by the license for Groups I, II and III and in vitro studies.

There are seven individuals listed on the license as authorized users. Three users have left since the last amendment dated January 16, 1984. John Morgan, M.D. started using licensed material in June 1985, but he was not added to the license as an authorized user. Licensed material used by an unauthorized individual is a violation of License Condition No. 12.

Two violations were identified.

4. Training

Nurses that care for brachytherapy patients have received training in radiation safety and radioactive implants. The nuclear medicine technologist stated that they received retraining when the consultant visited the program. He stated imaging procedures were also periodically discussed. The technologist had just started working with Group VI procedures about two months ago. The inspector observed that the technologist was not familiar with handling brachytherapy sources (this issue is discussed in Section 5.).

No violation was identified.

5 Radiological Protection Procedures

The nuclear medicine technologist performed an inventory of the brachytherapy sources during the inspection. He started using tongs (remote handling devices) to remove the sources from a lead container, but he was unable to remove the sources from the container. The inspector observed the technologist use his hands to remove a plastic vial (containing the sources) from the lead container. The technologist held the plastic vial in his hand while he counted the sources. Item 1, "Radiation Safety Procedures for the Therapeutic Use of Brachytherapy Sources, Handling Equipment," of the letter dated March 24, 1983, referenced in License Condition No. 19 states that remote handling devices will be used to reduce general radiation exposure and brachytherapy sources will never be touched with the hands. Failure to use remote handling devices when handling brachytherapy sources is a violation of License Condition No. 19.

The inspector observed that the brachytherapy sources were all stored in one lead vial in one drawer of the sealed source safe. The outside of the drawer was not marked to identify the contents. The licensee's letter dated March 24, 1983, states that brachytherapy sources will be stored in separate compartments within a lead lined tray. Each source compartment will be marked to permit immediate and easy identification of its contents from the outside. Failure to store and label the brachytherapy sources as described in letter dated March 24, 1983, is a violation of License Condition No. 19.

Two violations were identified.

6. Facilities and Equipment

The nuclear medicine department floor plan was as described in the sketch submitted with license application dated December 2, 1982.

The licensee has a Ludlum Model 3 (Serial No. 24977) G-M survey meter, with pancake probe, Model 44-9 (Serial No. PR-8249). The technologist used the G-M meter to analyze the area wipe test samples. The license application dated December 2, 1982, states that the method used to analyze wipe tests will be sensitive enough to detect 200 disintegrations

per minute (dpm). A G-M survey meter is not sensitive enough to detect 200 dpm. Using a method for analyzing wipe tests that is not capable of detecting 200 dpm is a violation of License Condition No. 17.

One violation was identified.

7. Audits

Radiation Services (consultant) audited the nuclear medicine program every six months. The consultant gave the licensee a written report of the audit which included the dose calibrator linearity checks. The reports were reviewed by the inspector and the linearity checks were within the required limits.

No violation was identified.

8. Tests for Leakage of Sealed Sources

10 CFR 35.14(5)(i) requires that Group VI sources shall be tested for leakage every six months. The Group VI sources (cesium-137 brachytherapy sources) used at the hospital have a NRC approved leak test frequency of three years (see attached authorization of leak test interval). The last leak test for the cesium-137 brachytherapy sources was performed on September 23, 1985. The leak test results showed no leakage.

10 CFR 35.14(e)(1)(i) states that sealed calibration or reference sources shall be tested for leakage and/or contamination every six months. The cesium-137 calibration source used in the nuclear medicine department had been tested for leakage in April 1984, February 1985 and October 1985. Failure to leak test the cesium-137 calibration source every six months is a violation of 10 CFR 35.14(e)(1)(i).

One violation was identified.

9. Inventory of Sealed Sources

The regulations require that calibration sources be inventoried quarterly. The cesium-137 calibration source used for the dose calibrator was inventoried almost daily (the calibration source is used almost every day).

The last inventory for the Group VI (cesium-137 brachytherapy sources) was in November 1985. There was no inventory for the first quarter of 1986. Failure to perform a quarterly inventory of Group VI (brachytherapy sources) is a violation of 10 CFR 35.14(b)(5)(v). The inspector observed the nuclear medicine technologist performing an inventory of the cesium-137 brachytherapy sources on June 12, 1986. The technologist stated all the sources were present.

One violation was identified.

10. Receipt and Transfer of Radioactive Material

A selective review of the package receipt records was made for 1985 and 1986. The package surveys appeared adequate. Decayed technetium-99m generators were transferred to the manufacturer for disposal.

No violations were identified.

11. Personnel Monitoring

Film badges and ring TLD's (thermoluminescent dosimeter) are used for personnel monitoring. The film badges and ring TLD's are exchanged monthly. On the day of inspection the nuclear medicine technologist wore a ring TLD badge on each hand and a whole body film badge.

The procedures described in license application December 2, 1986, states that finger TLD badges will be used as extremity monitoring devices. Finger TLD badges were not worn by all individuals to monitor extremity dose. A physician did not wear a finger TLD badge when he performed brachytherapy implants on December 11, 1985, and March 25, 1986. Failure to use a finger TLD badge to monitor extremity dose is a violation of License Condition No. 19.

The brachytherapy procedures described in letter dated March 24, 1983, states that nurses caring for brachytherapy patients will be assigned film badges. Four patients were treated with brachytherapy sources between November 1985 and May 1986. Nurses caring for the brachytherapy patients were not assigned film badges to monitor their dose. Nurses were given pocket dosimeters to monitor their radiation dose, rather than film badges. The licensee could not show any evidence that these pocket dosimeters were calibrated. Failure to assign film badges to nurses caring for brachytherapy patients is a violation of Licensee Condition No. 19.

Two violations were identified.

12. Radiation Survey Records

A selective review of survey records was performed. The records showed results of surveys performed in the nuclear medicine department. G-M surveys and wipe tests appeared to be performed as required.

10 CFR 20.201(b) requires that surveys be made to show compliance with 10 CFR Part 20. 10 CFR 10.105(b) requires that unrestricted areas may not exceed a dose of two millirem in any one hour. Surveys were not performed to show that the radiation levels were within the regulatory limits for all unrestricted areas. On March 25, 1986, the unrestricted areas (outside the building), adjacent to a brachytherapy patient's room were not surveyed. The unrestricted areas were accessible to the public. Failure to perform surveys to show compliance with 10 CFR 20.105(b) is a violation of Part 20.201(b).

One violation was identified.

13. Waste Disposal Records

The licensee's procedures require that radioactive waste be held until the radioactivity reaches background radiation levels. Records of survey results showed that waste was at background radiation levels when it was discarded. Used molybdenum/technetium generators were returned to the manufacturer for disposal.

No violations were identified.

14. Posting

On June 12, 1986, forms and documents were posted as required by Part 19.

No violations were identified.

15. Independent Measurements

Surveys were performed using an Eberline Model E-520 G-M meter, NRC Serial No. 009571. The cesium-137 check source measured 0.3 mR/hr at the start and finish of the survey. Background radiation levels were 0.02 mR/hr. Radiation surveys were performed in the hot laboratory and in the areas adjacent to the hot laboratory. Radiation surveys in the hot laboratory showed the following: 1.5 mR/hr was measured at the surface of an iridium-192 storage container; 0.9 mR/hr was measured at the surface of the cesium-137 safe; 2 mR/hr was measured at the surface of the generator. The washroom adjacent to the hot laboratory showed a maximum of 0.4 mR/hr at one foot from the wall. The ultrasound room adjacent to the hot laboratory showed a maximum of 0.4 mR/hr at one foot from the wall. The hallway adjacent to the hot laboratory showed a maximum of 0.02 to 0.03 mR/hr at one foot from the wall. These radiation levels were typical for nuclear medicine facilities with similar work loads.

16. Enforcement Conference

An enforcement conference was held in the Region III office on August 6, 1986. The conference was held because numerous violations were identified during a routine safety inspection. The purpose of the conference was to (1) discuss the apparent violations, their significance and causes, the licensee's corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, and (3) obtain other information which would help determine the appropriate action.

Mr. J. A. Hind, (Director, Division of Radiological Safety and Safeguards), started the meeting by describing the purpose and scope of the meeting, the NRC enforcement policy, and the NRC's concerns about the licensee's radiation safety program.

The licensee acknowledged the apparent violations as presented by the Region III staff. The licensee's corrective actions and actions to prevent repeat violations were discussed. The licensee has hired a new consultant as part of their corrective actions. The new consultant has

reviewed the licensee's program and made his recommendations. The hospital is following the consultants recommendations. The new consultant is scheduled to audit the program quarterly (the former consultant was scheduled to audit the program every six months).

NRC Region III management expressed concern that the apparent violations appeared to represent a breakdown in the radiation safety program and stated that escalated enforcement action was being considered.