

Mitchell



SOUTHEAST
MISSOURI
HOSPITAL

April 30, 1992

Mr. Gary L. Shear, Chief
Nuclear Materials Safety Section 2
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: Reply to a Notice of Violation
License No. 24-00128-03
License No. SNM-1595

Dear Mr. Shear:

This correspondence is a follow-up to my initial response dated March 31, 1992 regarding the safety inspection conducted by Mr. Mike Mitchell at Southeast Missouri Hospital on February 11-12, 1992.

Through communication with Mr. Mitchell, I was advised that additional information was required to adequately respond to the violations under License No. 24-00128-03. As a result, this letter is to be considered as the revised response to violations noted during the February survey conducted by Mr. Mitchell.

The responses and described action are as follows:

Violation No. 1

10 CFR 35.415(a)(4) requires, in part, that a licensee promptly after implanting brachytherapy sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

Contrary to the above, since September 18, 1990, the licensee implanted brachytherapy sources and did not survey the dose rates in restricted and unrestricted areas contiguous to the room of the implanted patient to demonstrate compliance with the requirements of 10 CFR Part 20.

Reason for Violation

Oversight

9205210116 920514
REG3 LIC30
24-00128-03 PDR

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Corrective Action

All brachytherapy implant room surveys will be recorded on a new summary sheet. This summary sheet will include the dose rates in restricted/unrestricted areas contiguous to the room of the implant patient.

Steps taken to avoid further violation

Revised summary sheet to include all corrective information.

Date of Full Compliance

February 25, 1992

Violation No. 2

10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on numerous occasions from September 18, 1990 until February 11, 1992, the licensee did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely prepared for use and administered. For example, no such survey was performed during the weekends when radiopharmaceuticals were used.

Reason for Violation

Surveys were not done when procedures were performed after normal department hours, i.e. weekends and nights, because procedures were usually of an emergency nature.

Corrective Action

A survey with an appropriate radiation detection meter will be conducted at the end of each day of nuclear medicine activities in all designated areas and where radiopharmaceuticals are routinely prepared, stored and administered.

Steps taken to avoid further violation

Radiation Safety Committee, at their quarterly meetings, will review daily patient log sheets and survey report forms to determine that requirements are met.

Date of Full Compliance

February 12, 1992

Violation No. 3

10 CFR 35.70(d) and (g) require, in part, that a licensee establish radiation dose trigger levels for the daily and weekly survey of areas where radiopharmaceuticals are routinely prepared for use or administered, and areas where radiopharmaceuticals or radiopharmaceutical waste is stored and removable contamination trigger levels for weekly surveys of all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, as of February 12, 1992, the licensee did not establish radiation dose trigger levels or removable contamination trigger levels for its surveys of the "hot" laboratory and imaging laboratory areas where radiopharmaceuticals were prepared, administered, stored, or held as waste.

Reason for Violation

Staff was not aware that trigger levels were required.

Corrective Action

Trigger levels have been established for surveys for the following physical areas:

1. Radiopharmaceutical preparation, administration, and imaging areas.
2. Radiopharmaceutical waste storage and holding areas.

The trigger levels have also been established for removable contamination in these areas.

Steps taken to avoid further violation

Survey forms will be reviewed by Radiation Safety Officer on a monthly basis to confirm that department is in compliance with requirements.

Date of Compliance

February 12, 1992

Violation No. 4

10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on September 19, 1991, the licensee's Radiation Safety Committee met and conducted business and the Radiation Safety Officer was not present.

Reason for Violation

Management was not aware that it was mandatory to have the Radiation Safety Officer present to conduct the meeting. Regarding the meeting in question, a number of committee members were present with expertise in the area of radiation safety. This included a Radiologist, a Radiation Oncologist and a Ph.D Physicist.

Corrective Action

A Radiation Safety Committee meeting will not be held unless all of the following conditions are met:

1. A quorum of committee members present
2. The presence of the Radiation Safety Officer
3. The presence of an administrative representative

Steps taken to avoid further violation

Meeting attendance requirements have been reviewed with Radiation Safety Committee members in order to avoid a future problem.

Date of Compliance

March 19, 1992

Violation No. 5

Condition 15 of License No. 24-00128-03 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated August 15, 1990.

Item 8 of this application requires that personnel training for housekeeping and security personnel be conducted on an annual basis and documented.

Contrary to the above, since September 18, 1990, the licensee failed to document training for housekeeping and security personnel.

Reason for Violation

Miscommunication between staff that should have provided training.

Corrective Action

Both Security and Housekeeping personnel will be inserviced on an annual

basis. Training sessions will be provided for these personnel and appropriate documentation will be maintained.

Steps taken to avoid further violation

Radiation Safety Committee will review training activity for all staff on a regular basis to determine that program is in compliance with license requirements.

Date of Compliance

Security personnel, March 24, 1992
Housekeeping personnel, April 29, 1992

Violation No. 6

10 CFR 35.70(h) requires, in part, that the licensee retain a record of each required removable contamination survey and that the survey include removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Contrary to the above, from September 18, 1990 to February 12, 1992 the licensee did not record the surveys with the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Reason for Violation

Staff thought they were complying with requirements of license.

Corrective Action

Based on direction of the inspector (Mr. Mitchell), removable contamination in each area that is surveyed will be expressed in terms of disintegration per minute per 100 sq. cm.

Steps taken to avoid further violation

Purchased Victoreen Deluxe Wipe Test Counter which mathematically converts counts per minute to disintegration per minute. In addition, the Radiation Safety Officer will review wipe test reports for the Nuclear Medicine Department on a monthly basis.

Date of Compliance

Department began manual calculation February 12, 1992.

Mr. Gary L. Shear, Chief
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If additional information is required pertaining to the action taken to correct the violations noted during the February 11-12, 1992 safety inspection, please contact me.

Sincerely,



Richard W. Meyer
Assistant Administrator

RWM:jss

pc:J. W. Wente, Administrator
Southeast Missouri Hospital
Craig Williams, M.D., Chairman
Radiation Safety Committee
Dix Morgan, M.D., Radiation Safety Officer
Walter J. Kopecky, Ph.D. Physicist
Rob Scheper, RTT, Chief
Radiation Therapy Technologist
Vincent Glueck, CNMT, Senior
Nuclear Medicine Technologist
Mike Mitchell, Radiation Specialist
Nuclear Regulatory Commission