



October 4, 1985

Director
Office of Inspection & Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

*SNM-1393
21-0038-00*

Gentlemen:

Pursuant to the provisions of 10 CFR 2.201, Hurley Medical Center hereby submits the attached written statement of explanation in response to a Notice of Violation and proposed imposition of civil penalties (NCR Inspection Reports Nos. 030-01993/85001(DRSS) and 070-01396/85001(DRSS)).

Please be advised that Hurley Medical Center has also elected to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty. This answer is set forth separately from the statement in reply pursuant to 10 CFR 2.201.

If you have any questions, or require any additional information in regard to the above, please contact my office at (313)257-9046.

Very truly yours,

J. Dagenais
Jack Dagenais
Assistant Director

JD:bsj

Attachment

pc: Regional Administrator
U.S. Nuclear Regulatory Commission Region III

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HURLEY MEDICAL CENTER

RESPONSE TO NOTICE OF VIOLATION

AND PROPOSED IMPOSITION OF CIVIL PENALTIES

(NRC INSPECTION REPORTS NOS. 030-01993/85001(DRSS)

AND 070-01396/85001(DRSS))

During an NRC inspection conducted on May 2, 3 and 24, 1985, violations of NRC requirements were identified. In accordance with provisions of 10 CFR 2.201, Hurley Medical Center hereby submits the following written statement of explanation:

- A. License Condition No. 24 of License 21-00338-02 requires that all licensed material be possessed and used in accordance with statements and procedures in the application dated September 23, 1983. The application dated September 23, 1983 states that the Medical Isotope Committee shall meet no less than once in each calendar quarter.

Contrary to the above, the Medical Isotope Committee did not meet quarterly. Specifically, the Medical Isotope Committee failed to meet during the first, third and fourth quarters of 1981 and 1982, the second and third quarters of 1983, the first and second quarters of 1984, and the first quarter of 1985.

RESPONSE

During the specified review, Hurley Medical Center's Medical Isotope Committee did not meet quarterly. Failure to meet quarterly was the result of a lack of understanding of NRC requirements. Since the Medical Isotope Committee was reestablished as the hospital Radiation Safety Committee in November of 1982, it was the understanding of the Committee representatives that the requirement was to meet semi-annually. Immediately following the recent NRC inspection of May 2, 3 and 24, 1985, administrative directive was distributed establishing standing quarterly meetings. Meetings have been conducted regularly since that time and, in addition, special monthly meetings have been held to monitor progress and compliance with other NRC requirements.

In addition, committee membership has been strengthened to include additional representatives from the departments of Pharmacy, both administrative and medical representatives from Cardiovascular Services, technical representation from the divisions of Nuclear Medicine and Radiation Therapy, and additional medical staff representation from the Department of Radiology.

Full compliance was achieved immediately following the most recent NRC inspection.

- B. License Condition No. 24 of License 21-00338-02 requires that licensed materials be used in accordance with the application received February 8, 1978, the application dated September 23, 1978 and the application dated September 23, 1983. These applications describe Room 22, equipped with a ventilation system, as the area where xenon-133 would be used.

Contrary to the above, on several occasions since November 1984, xenon-133 was used in a room other than Room 22. Specifically, xenon-133 was used in Room 20, an area not authorized by the license. Although Room 20 was equipped with an exhaust fan, the air flow rates and xenon-133 concentrations had not been evaluated or approved by NRC.

RESPONSE

Hurley Medical Center did not amend its license to reflect that the room used for xenon-133 procedures had been changed. Although failure to amend the license was an oversight, the Radiation Safety Officer was aware that the air flow was sufficient in the room in question. The health and safety of patients and staff occupying these areas was not compromised.

The xenon procedures imaging room license amendment and accompanying floor plan were forwarded to the NRC on June 6, 1985. This information is included as Attachment 1 to this document.

- C. License Condition No. 24 of License 21-00338-2 requires licensed material be possessed and used in accordance with the application received February 8, 1978. The application received February 8, 1978 contains precautions and procedures to be followed when caring for patients treated with therapeutic quantities of radionuclides. Item 8 states nursing personnel entering the patients' rooms are to wear film badges.

Contrary to the above, nursing personnel entering therapy patients' rooms did not always wear film badges. Nursing personnel did not wear film badges in cases where brachytherapy (cesium-137) implants were performed on October 8 and 29, 1984, November 13 and 19, 1984, December 3, 1984, January 22, 1985 and March 19 and 26, 1985.

RESPONSE

Hurley Medical Center did not issue film badges to nursing personnel entering therapy rooms. The Radiation Safety Officer offers the following explanation for this action: "The number of Cs-137 Sealed Source therapies performed has decreased to 30 in 1983 and 14 in 1984. Each treatment lasts about three days. Nursing involvement with these patients is minimal, about 14 minutes per day or 45 minutes to one hour total. The measured exposure rate at bedside of these patients is about 10mR/hr @ 1 Meter, so that the probable exposure to nurses is 10mR. If the same nurse attended three patients per month, she would receive 30mR per month or 90mR per quarter. This is less than one quarter of the maximum allowed dose of 1200mR per quarter. According to 10 CFR 20.202a(1), film badges are not necessary under these conditions. Our results of monitoring nurses' radiation exposure confirms these calculations. In accordance with license conditions, badges are

assigned to nursing personnel attending radioactive implants and radioiodine therapies."

Since the most recent NRC inspection, a new standard practice has been developed in order to assure assignment and monitoring of nursing personnel assigned to the care of radioactive implant patients. This policy states that badges will be ordered and assigned by the Radiation Safety Officer. The supervisor of the Radiation Therapy Department will provide the badges and be responsible for the evaluation of personnel for the duration of the patient's implant. A copy of the standard practice is included as Attachment 2 to this response.

Full compliance with this license condition was achieved June 7, 1985.

- D. License Condition No. 24 of License 21-00338 requires that licensed material be possessed and used in accordance with statements and procedures in the application received February 8, 1978. The application received February 8, 1978 contains precautions and procedures to be followed when caring for patients treated with therapeutic quantities of radionuclides. Item 4 states that surveys of exposure rates in the patient's room and adjacent areas will be performed.

Contrary to the above, surveys were not always performed of the patients' rooms and adjacent areas. Specifically, fourteen (14) cesium-137 sealed source implants were performed between February 6, 1984 and March 26, 1985 and only two surveys were conducted. No patient room surveys were conducted during fourteen (14) cesium-137 sealed source implants between April 5 and September 28, 1982.

RESPONSE

Hurley Medical Center did not perform surveys of patients' rooms and adjacent areas following treatment with radionuclides. The Radiation Safety Officer has offered the following explanation for this action: "State of Michigan Radiation Rule 465(2) states: 'Calculations based on previous surveys will comply with this subrule', i.e., a survey performed for each patient. A series of surveys of patients' rooms and adjacent areas was taken to determine the radiation levels present during treatment. No excessive radiation levels were recorded. Calculations were made of exposure rate per mCi of activity used in treatment: 0.30 mR/hr @ 1 Meter. The exposure rates in subsequent therapies were calculated from this value. This complies with State of Michigan Radiation Rules. No excessive radiation levels or exposures were measured or calculated."

Since the last NRC inspection, a new standard practice has been developed and implemented to assure compliance with this condition. It is the responsibility of the Radiation Physicist to perform these surveys, and the responsibility of the Radiation Therapy Supervisor to monitor compliance with this practice. These actions will be reported at the quarterly Radiation Safety Committee meeting. A copy of the standard practice is included as Attachment 3 to this response.

Compliance was achieved by June 7, 1985.

- E. License Condition No. 16 of License SNM-1393 requires that licensed material be possessed and used in accordance with statements, representations, and procedures in a letter dated April 24, 1973. The letter dated April 24, 1973 states the physician responsible for nuclear pacemaker studies was William J. Weber, M.D.

Contrary to the above, licensee personnel other than the physician listed in the April 24, 1973 letter as the responsible individual are currently responsible for the nuclear pacemaker program.

RESPONSE

Hurley Medical Center did not amend its license properly to reflect physicians in charge of the nuclear pacemaker program. While Hurley Medical Center did recognize the need to renew its nuclear pacemaker license, amending the physician's name responsible for the new pacemaker program was overlooked. Hurley Medical Center has not implanted a nuclear pacemaker in a number of years. As a result, it was understood that no physician needed to be authorized for the implant of these pacemakers. On June 7, 1985, Hurley Medical Center provided a new amendment to this license which was incorrect. Hurley Medical Center is providing a corrected amendment to this license naming a responsible physician in order that the three remaining nuclear pacemaker patients may be monitored appropriately. This license amendment request is provided as Addendum 4 to this response.

It is the responsibility of the Director of Cardiovascular Services to assure that any change in physician control or responsibility for this program be communicated to the Radiation Safety Officer and to Administration for appropriate amendment of this license.

Hurley Medical Center will be in compliance with this condition when the NRC acknowledges this license amendment request.

- F. Item 9A of License SNM-1393 authorizes the possession of nuclear pacemakers for purposes of explantation, recovery and disposal. License Condition No. 16 (license SNM-1393) requires that licensed material be possessed and used in accordance with statements and procedures contained in a letter dated April 24, 1973. The letter states that William J. Weber, M.D. is the individual responsible for nuclear pacemaker studies.

Contrary to the above, the licensee failed to explant, recover and return for disposal a nuclear pacemaker from a patient who died in February 1985. Specifically, licensee personnel other than the responsible individual listed in the April 24, 1973 letter requested that a funeral director remove a nuclear pacemaker from the body of a patient after realizing that the patient had been the recipient of a nuclear pacemaker. The funeral director, who was not authorized by this license, was also requested to return the nuclear pacemaker to the manufacturer for disposal. The licensee did not participate in or supervise the explant, recovery or return of the nuclear pacemaker.

RESPONSE

Hurley Medical Center can neither confirm nor deny violation of this license condition. Conversations held with the funeral director in question indicate that he cannot recall whether the pacemaker was removed prior to contacting Hurley Medical Center personnel or whether Hurley Medical Center personnel instructed him to remove the pacemaker. Hurley Medical Center personnel state that the pacemaker was removed prior to being contacted by the funeral home director and that at no time were instructions given to explant the pacemaker.

A standard practice has been developed which outlines the proper procedure to be followed upon the death of a pacemaker patient. This standard practice is provided as Addendum 5 to this response. All Cardiovascular Study Unit staff have been informed of proper procedure, and it is the responsibility of the supervisor of this unit to monitor compliance. This activity will be monitored on a quarterly basis by the Radiation Safety Committee.

Hurley Medical Center cannot determine whether or not a violation of this nature occurred.

- G. License Condition No. 13 of License SNM-1393 states that the licensee shall report to the NRC, within 24 hours of occurrence, the death of any nuclear pacemaker patient.

Contrary to the above, the licensee failed to report to the NRC that nuclear pacemaker patients died in November 1984 and January 1985.

RESPONSE

Hurley Medical Center did not notify the NRC within 24 hours of discovering the death of two pacemaker patients. At the time of the deaths of these patients, it was thought that it was the responsibility of the physician following the patient to notify the NRC. However, since this time, Hurley Medical Center has officially notified the NRC of these deaths in a memorandum dated May 30, 1985. A copy of this letter is included as Addendum 6 to this response.

Since this time, Hurley Medical Center has developed a standard practice to ensure regular follow up for their pacemaker patients at six-month intervals, and also includes provisions to contact the NRC within 24 hours of the death of a patient. It is the responsibility of the supervisor of the Cardiovascular Study Unit to notify the NRC of these deaths. This practice will be monitored by the Director of Cardiovascular Services and reported to and reviewed by the Radiation Safety Committee at its quarterly meetings. A copy of the standard practice outlining this procedure is also included as Addendum 6 to this response.

Hurley Medical Center was in full compliance with the condition on June 7, 1985.

- H. License Condition No. 14 of License SNM-1393 states that the licensee shall contact the NRC within 10 days after loss of contact with a nuclear pacemaker patient.

Contrary to the above, the licensee failed to report the loss of contact with nuclear pacemaker patients in March, April and November 1982, and in March 1984.

RESPONSE

Hurley Medical Center did not report the loss of contact with a nuclear pacemaker patient as required. This occurred as a result of failing to comply with the condition of contacting pacemaker patients at pre-determined intervals. Since that time, Hurley Medical Center has contacted all current nuclear pacemaker patients and determined their whereabouts.

A standard practice has been developed that includes the provision that loss of contact will be reported within ten days. It is the responsibility of the supervisor for the Cardiovascular Study Unit to initiate this contact. It will be the responsibility of the Director of Cardiovascular Services to monitor this activity with quarterly reports to be made to the Radiation Safety Committee.

Hurley Medical Center was in compliance with this condition on June 7, 1985.

- I. License Condition No. 16 of License SNM-1393 requires that all licensed material be possessed and used in accordance with statements, representations, and procedures contained in a letter dated April 24, 1973. The letter dated April 24, 1973 states that nuclear pacemaker patients shall be contacted each month.

Contrary to the above, nuclear pacemaker patients were not contacted each month. Specifically, the licensee failed to contact pacemaker patients approximately five times in 1982, eleven times in 1983 and eleven times in 1984.

RESPONSE

Hurley Medical Center did not contact all nuclear pacemaker patients monthly as required. This occurred as a result of Cardiovascular Study Unit staff not being properly inserviced as to the necessity of this contact.

Since that time, Hurley Medical Center has requested that its license be amended to allow contact to be made semi-annually. In addition, a standard practice has been developed which ensures that this activity will take place at regularly scheduled intervals. It is the responsibility of the supervisor of the Cardiovascular Study Unit to make this contact. The Director of Cardiovascular Services will monitor this activity and will report to the Radiation Safety Committee on a quarterly basis.

Full compliance with this license condition was achieved June 7, 1985.

- J. 10 CFR 35.14(b)(5)(v) states that the licensee shall conduct a quarterly physical inventory to account for all Group VI sources and devices received and possessed.

Contrary to the above, the licensee failed to conduct a quarterly physical inventory to account for all Group VI sources and devices received and possessed. Specifically, Group VI sources such as the 3M cesium-137 needles, the Nuclear Associates cesium-137 microrad after loading sources, and the cobalt-60 needles were not inventoried quarterly. The last inventory was September 1983.

RESPONSE

Hurley Medical Center did not conduct quarterly physical inventories to account for all Group VI sources and devices. The Radiation Safety Officer offers the following explanation for this occurrence: "The Co-60 and Cs-137 needles have not been used in four years and are in storage. Regulation 35.14e(1)i(b) states: 'no wipe tests are needed on sources which are being stored and not used.' This was confirmed by verbal communication with the NRC Region III Office in Chicago and the Inspector pointed out that the regulation cited concerns calibration sources only.

Also, the Co-60 needles had not been wipe tested during previous NRC inspection of June 23, 1981. We were not cited at that time nor were we informed of the required wipe testing even if source is in storage."

A standard practice outlining the quarterly inventory and wipe tests required has been developed and is included as Attachment 7 to this response.

Full compliance with this license condition was achieved June 7, 1985.

- K. 10 CFR 35.14(f)(2) states that quarterly physical inventories shall be performed to account for all calibration sources received and possessed.

Contrary to the above, quarterly inventories of calibration sources were not performed. Specifically, a barium-133 source and a cobalt-60 source had not been inventoried since the last inspection on June 23, 1981.

RESPONSE

Quarterly inventory of calibration sources was not performed. However, this was due to an oversight by the Radiation Safety Officer who believed that annual inventories (that were conducted in December, 1981, December 1982, December 1983 and December 1984) and wipe test that were also conducted semi-annually since June 23, 1981 (and are in effect an inventory), satisfied the intention of this requirement.

A standard practice has been developed in order to assure that quarterly inventories are now performed and is included as Attachment 8 to this response.

Hurley Medical Center has been in full compliance with this requirement since June 7, 1985.

- L. 10 CFR 35.14(5)(i) states that Group VI sealed sources shall be tested for contamination and/or leakage at intervals not to exceed 6 months.

Contrary to the above, Group VI sources had not been leak tested since the last inspection on June 23, 1981.

RESPONSE

Hurley Medical Center did not conduct quarterly leak tests at specified intervals.

Since the last NRC inspection, the Co-60 and Cs-137 sources have been scheduled to be wipe tested at six-month intervals. All other Group VI sources except the 3M Cs-137 tubes have been wipe tested at the required six-month intervals. The 3M Cs-137 tubes have a three year interval. A standard practice which outlines these procedures has been developed since that time and specifies that the Radiation Safety Officer will perform these tests. This policy also states that the supervisor of Radiation Therapy will monitor compliance and will report the results of these tests at the quarterly scheduled Radiation Safety Committee meetings. (Standard practice is attached as Addendum 9).

Hurley Medical Center has been in compliance with this requirement since June 7, 1985.

- M. 10 CFR 71.5 states that no licensee shall transport licensed material out of his facility unless the licensee complies with 49 CFR Parts 170-189.

49 CFR 173.475(i) states that before each shipment of any radioactive materials package, the shipper shall ensure by examination or appropriate tests that external radiation and contamination levels are within the allowable limits specified in this chapter.

Contrary to the above, the licensee failed to ensure that the external radiation and contamination levels were within allowable limits for packages containing molybdenum/technetium returned to the manufacturer for disposal. Since the date of license issuance, the licensee had not performed direct radiation surveys and wipe tests for removable contamination on packages returned to the manufacturer.

RESPONSE

Hurley Medical Center did not document that it performed required tests of external radiation and contamination levels of packages that were returned to manufacturers for disposal. These tests, however, were performed during the past review period. It should be noted that all generators undergo a six-week decontamination period equivalent to 15 half lives. For this reason, it is not felt that "hot" radioactive material is being transported.

A standard practice has been developed which outlines the required testing which must be performed and the fact that this activity must be documented. It is the responsibility of the Nuclear Medicine technologist to perform these tests, and the responsibility of the Nuclear Medicine supervisor to assure that these activities are performed. The results will be reviewed at the quarterly Radiation Safety Committee meetings. A copy of this standard practice is provided as Addendum 10 to this response.

Full compliance with this license condition was achieved June 7, 1985.

- N. 10 CFR 20.401(b) requires that the licensee maintain records showing the results of surveys made to assure compliance with 10 CFR 20.201(b).

Contrary to the above, the licensee failed to maintain records of surveys of technetium-99m contaminated waste to document that no measurable radiation above background was present before disposal. Records of surveys have not been maintained since the date of license issuance.

RESPONSE

Hurley Medical Center did perform the appropriate waste disposal activities, but did not maintain records of these surveys. It should be noted that waste is stored a minimum of 28 half lives (i.e. one week) prior to disposal. At this time, waste is surveyed to ensure that non-technetium radioisotopes have not been inadvertently mixed with technetium waste.

Our license renewal application of 1978 includes the procedures of radioactive waste disposal. These procedures explicitly describe the waste disposal methods we will follow and did not mention recording results. These procedures were approved by the NRC and we were not cited for these methods during the previous inspection of June 1981. Since the most recent inspection, a standard practice has been developed which outlines that survey results will be recorded and is attached to this response as Addendum 11. It is the responsibility of the Nuclear Medicine technologist to perform these activities. The supervisor of the division of Nuclear Medicine will monitor these activities and report quarterly to the Radiation Safety Committee meeting.

Hurley Medical Center has been in full compliance with this condition since June 7, 1985.

ATTACHMENTS

1. Xenon Procedures Imaging Room License Amendment (and accompanying information)
2. Badge Assignment Standard Practice
3. Implant Patients Room Survey Standard Practice
4. Nuclear Cardiology License Amendment Request
5. Nuclear Pacemaker Patient Expiration Notice and Follow Up Procedure
6. Amendment to Nuclear Pacemaker Patient Reporting Requirements
7. Group VI Quarterly Inventory Standard Practice
8. Quarterly Physical Inventory for Calibration Sources Standard Practice
9. Group VI Sealed Source Leak Test Standard Practice
10. Generator Return Standard Practice
11. Contaminated Waste Disposal Procedures