MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-5936

M. Julie Hanser
Hospital Administrator

February 7, 1991

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

License No.: 48-04193-01
Docket No. : 030-03444
EA No. : 90-181

Reply to a Notice of Violation

Gentlemen:

The following is our response to your letter dated January 11, 1991 requesting resubmission of responses to the Notice of Violation and Proposed Imposition of Civil Penalty dated November 23, 1990.

A. Reference: 10 CFR 20.105(b)

1. The violation did occur.

2. The technician who performed the survey on September 14, 1990 failed to notify anyone that the radiation level was in excess of 19 mrem/hr. No survey was performed in the stairwell on May 19, 1989 and consequently the excess radiation level was not noted. The failure to survey and to take action when an excess level was found was due to the remoteness of this stairwell and its infrequent use. This stairwell while accessible to the public during fire emergencies is not used by the general public and it was mistakenly treated as a restricted area.

3. An admendment pursuant to 10 CFR 20.105(a) has been submitted.

4. This stairwell is being treated as an unrestricted area and surveys are performed for all brachytherapy. If levels are in excess of permitted levels, a bedside shield will be used or the patient will be moved to another location.

5. Compliance was achieved on October 29, 1990.

IE14
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B. Reference: 10 CFR 10.201(b)

1. The two violations did occur.

2. The failure to survey the stairwell was due to its remote location and infrequent use and our treatment of it as a restricted area. This survey was not performed in a timely manner because the implant was performed after normal working hours.

3. To insure that complete surveys are performed in the future, a new survey form has been developed which shows the location for all measurements. For all implants which are performed after 4:30 pm, a member of the Radiation Safety staff will be on call and available to perform the survey. Since the inspection, surveys have been performed on the day of implant.

4. The Radiation Safety Officer will review surveys for completeness and timeliness.

5. Compliance was achieved on October 29, 1990.

C. Reference: License Condition No. 28

1. The four-part violation did occur.

2. Radiation Oncology staff, on the occasions specified, failed to complete the necessary inventory records.

3. The inventory form has been revised to obtain all required information.

4. To insure that these records are completed and in compliance, these inventory records will be reviewed quarterly by the Radiation Safety Office.

5. Compliance was achieved on October 29, 1990.

D. Reference: License Condition No. 28

1. On the occasions specified, the possession limits established by the Radiation Safety Committee for the authorized users were exceeded.

2. All orders of radioactive material were reviewed to insure compliance with possession limits established by the Radiation Safety Committee. The health physics technician incorrectly approved purchase orders by these two investigators.

3. To avoid a reoccurrence of this violation, inventories of non-sealed radioactive materials will be prepared weekly showing the amount of material possessed by each authorized user and the user's total possession limit. The health physics technician, prior to approving an order, will use this information to verify that the activity ordered is within the authorized user's possession limit.

4. The Radiation Safety Officer will monitor the technician's process randomly to insure the procedure is being followed.

5. Compliance was achieved on October 29, 1990.

E. Reference: License Condition No. 28

1. The violation did occur.

2. This violation arose from the Radiation Safety Committee not completely documenting the training and experience of individuals requesting authorization to use radioactive materials. On numerous occasions, a committee member would verify the training and experience of the individual requesting authorization. These comments were frequently not documented in the minutes of the meeting.

3. To insure complete documentation of the Radiation Safety Committee's deliberation, procedures for reviewing the training and experience of individuals requesting authorization have been revised. In the response to the letter of confirmatory action, all individuals training and experience were examined and authorizations were restricted to conform with the stated training and experience of the authorized user. A new form for documenting training and experience to provide the necessary detail was implemented.

4. The Radiation Safety Committee will be acting on applications where documentation is complete.

5. Compliance was achieved on October 29, 1990.

F. Reference: 10 CFR 33.13(c)

1. This violation did occur.

2. The cause of this violation is lack of sufficient manpower to carry out all of the material control and management reviews required. The graduate student identified as having received no training in proper survey and monitoring requirements was interviewed by Standard Nuclear Consultants. They state, "during our visit to the research labs, I interviewed (on 11-2-90) the graduate student who had been questioned by the NRC inspector. The graduate student seemed to be very timid and he told me that he had indeed been instructed by the user in the laboratory concerning radiation safety requirements."

3. The Radiation Safety Committee is committed to re-establishing administrative control and has met numerous times during the previous three months in an effort to tighten management policies and procedures. Additional resources have been committed to the Radiation Safety Office and a full-time RSO is being recruited. An additional health physics technician position has been created and this position has been filled.

4. In addition to adding staff, all authorized users have been directed to provide instructions and training to new employees working in their laboratories. A checklist of topics to be covered has been developed and a short quiz designed to test the knowledge of staff. Verification that training has been provided by the authorized user will be made by the Radiation Safety Office during the quarterly audit.

5. Compliance was achieved on December 18, 1990.

G. Reference: License Condition No. 28

1. The violations did occur.

2. The cause of these violations which involved individual users or groups not performing laboratory surveys as specified and failure of the Radiation Safety Office to perform monthly radiation surveys of waste storage and holding areas was the lack of adequate Radiation Safety Office staff. The lack of staff made it difficult to perform routine audits of laboratories to insure that surveys were being performed as required.

3. Audits of all laboratories have been performed and surveys are continuing as required. A schedule has been established for the Radiation Safety Office to follow for insuring compliance.

4. The organization has committed to increasing the Radiation Safety Office staff and two positions, a health physics technician position and a full-time RSO position have been created. Recruitment for the RSO position is underway. The technician position has been filled. The Radiation Safety Committee also will receive quarterly reports describing the results of the laboratory surveys.

5. Compliance was achieved in October 29, 1990.

H. Reference: 10 CFR 30.34(c)

1. This violation, as specified, is denied, i.e., "used iridium-192 as sealed sources in a Nucletron Corp. Model 4000 Remote Afterloader Brachytherapy device for intercavitary treatment of cancer."

2. The Nucletron Corp. Model 4000 Remote Afterloading device was used on a number of occasions during the period of time from 1987 through mid 1990. Iridium-192 as sealed sources were used; however, in no instances were these sources used for intercavitary treatment of cancer. (See Attachment 1)

3. An amendment requesting authorization to use the Nucletron Corp. Model 4000 has been submitted. In addition, a letter has been sent to the Office of Nuclear Materials Safety and Safeguard requesting clarification of the apparent restriction of Iridium-192 field sources to only interstitial applications. (Attachment 2)

4. None.

5. The remote afterloading device is not being used.

I. Reference: License Condition No. 28

1. The violation did occur.

2. In reviewing bioassay records, data of one of the two absent bioassays (dated 12-29-89) was located. We believe that both bioassays were, in fact, performed because the investigator involved has always been extremely diligent in this regard. However, it cannot be shown that the other missing bioassay was actually performed. The reason for the lost record was due to the practice of allowing researchers to leave the bioassay counting data at the counter on a piece of notepaper if the Radiation Safety Officer or other members of the staff were not available.

3. To insure that the required bioassays are performed, the I-125 to be used for radioiodination will be kept by the Radiation Safety Office until the labeling is to be performed. The I-125 will then be given to the authorized user and a pre-labeling bioassay will be performed. At that time, an appointment for the post-labeling bioassay will be scheduled. If the user fails to keep his or her appointment, he/she will be contacted.

4. None.

5. Compliance was achieved on October 29, 1990.

J. License Condition No. 28

1. The violation did occur.

2. The cause of this violation was the failure to perform routine and detailed audits. The failure to perform audits was due to lack of sufficient Radiation Safety Office staff.

3. The institution has committed to increasing the Radiation Safety Office staff and two positions; a health physics technician position and a full-time RSO position have been created. Recruitment for the RSO position is underway. The technician position has been filled.

4. The Radiation Safety Committee will review quarterly reports of the audits performed.

5. Compliance was achieved October 29, 1990.

K. License Condition No. 28

1. The violation did occur.

2. The cause of this violation was the lack of review by the Radiation Safety Office of laboratories in the institution. This was due to the lack of staff in the Radiation Safety Office.

3. The institution has committed to increasing the Radiation Safety Office staff and two positions; a health physics technician position and a full-time RSO position have been created. Recruitment for the RSO position is underway. The technician position has been filled.

4. The requirement that eating, drinking or storage of food or beverages is prohibited in laboratories using radioactive materials has been emphasized to all authorized users. Compliance with the requirement is being monitored during the quarterly audits conducted by the Radiation Safety Office.

5. Compliance was achieved on October 29, 1990.

L. Reference: 10 CFR 20.401(b)

1. The violations did occur.

2. a) Monthly personnel exposure records were previously routinely reviewed. If, however, the previous exposure history of the employee who had lost a dosimeter indicated minimal exposure was likely, no further investigation or modification of the employee's cumulative exposure history was made.

   b) Although authorized users were expected to record disposal of any activity into the sewer system, some users did not estimate or record the small activity released during the washing of glassware and laboratory utensils.

3. a) In the future, any individual who fails to submit a personnel dosimeter will be required to provide to the Radiation Safety Office, in writing, the reason for the unreturned dosimeter. The employee will also be asked for a statement of their estimated exposure during the time period for which the dosimeter was lost. An estimate of the dose based on this information and the past exposure history will be used to adjust the individual's cumulative exposure history.

   b) Sink disposal logs are available in all laboratories and authorized users have been directed to record all activities disposed of into the sanitary sewage system.

4. a) The Radiation Safety Committee will review quarterly reports on lost dosimeters.

   b) Compliance with this requirement is being monitored during the quarterly audits conducted by the Radiation Safety Office.

5. Compliance was achieved on December 18, 1990.

M. Reference: License Condition No. 28

1. The violation did occur.

2. The failure of the Radiation Safety Office to perform quarterly audits was due to lack of adequate Radiation Safety Office staff.

3. The institution has committed to increasing the Radiation Safety Office staff and two positions; a health physics technician position and a full-time RSO position have been created. Quarterly audits are being performed by the Radiation Safety Office staff.

4. The Radiation Safety Committee will receive quarterly reports describing the results of the audits.

5. Compliance was achieved on October 29, 1990.

The violations identified were all corrected by December 18, 1990, with the majority of them corrected by October 29, 1990. The organization and its affiliated institutions are committed to providing the management control and oversight of the program to meet the Nuclear Regulatory Commission's requirements. The Radiation Safety Committee has recognized its important responsibility in providing program oversight. With the change to a full-time Radiation Safety Officer and Administration's more active role in managing the program, the safe performance of licensed activities will be insured and NRC requirements met.

If you wish additional information or clarification of any statements in this report, please contact my office at 414-257-5936.

Prepared by Charles R. Wilson, Ph.D., Radiation Safety Officer.

Sincerely,

Julie Hanser

Julie Hanser, FACHE
Hospital Administrator

JH:mb
Attachments
cc: A. Bert Davis
Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

(Attachment 1)

MEDICAL COLLEGE OF WISCONSIN

12/5/90

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Department of Radiation Oncology

Radiation Safety Office
Milwaukee County Medical Complex
Attn: Charles Wilson, PhD

Dear Chuck,

In their correspondence of November 23, 1990, the U.S. Nuclear Regulatory Commission in section H of the Notice of Violation and Proposed Imposition of Civil Penalty states that "the licensee purchased and, on several occasions from 1987 through mid-1990, used Ir-192 as sealed sources in a Nucletron Corporation Model 4000 remote afterloader brachytherapy device for intravcavitaty treatment of cancer." The Department of Radiation Oncology denies that such actions ever took place. The Department has used this device for interstitial and intraluminal procedures, but never for intracavitary procedures.

Perhaps the most comprehensive definition of intracavitary brachytherapy can be found in Physical Aspects of Brachytherapy by T..J. Godden, which is published by Adam Hilger. Chapter 7 of this text states the following:

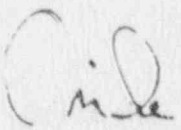
> Intracavitary brachytherapy, as the name implies, involves the insertion of radioactive sources into natural body cavities. Over the years various lesions in sites such as bladder, anus, rectum, antrum, oesophagus, nasopharynx and auditory tube have been treated in this way. The most widespread use of this form of therapy, however, has been in the treatment of gynaecological malignancies. In the treatment of carcinoma of the uterus and uterine cervix the sources, in suitable containers, are inserted directly into the vagina and the uterus....

ICRU Report 38, Dose and Volume Specification for Reporting Intracavitary Therapy in Gynecology, can also be cited to support the position that intracavitary refers primarily to gynecologic work.

In any case, the Department has not performed any intracavitary procedure, as defined above, with Ir-192 sources. The Department views any restriction that limits the use of Ir-192 sources to interstitial therapy only as unduely restrictive and not in the interest of good medical care or radiation safety. (Why use an isotope with limited physical lengths and more penetrating gamma rays, Cs-137, when other isotopes with adjustable lengths and less penetrating gamma rays, e.g. Ir-192, are available?) In a separate correspondence to you, the Department will request a license amendment to a more flexible position, which reflects comtemporary practice. Sealed source brachytherapy includes intracavitary, interstitial, intraluminal, and mold techniques. If it is necessary to explicitly state each isotope and each use, then the Department is anxious to work with Radiation Safety Personnel to create such a document.

Thank you for your consideration of this. Additional information will be supplied, if requested.

Sincerely,



Michael T. Gillin, PhD
Associate Professor
Radiation Oncology

cc: J. Frank Wilson, MD