IE-07

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Washington University
Medical School
ATTN: Robert J. Hickok
Assistant Vice Chancellor
for Medical Affairs,
Chief Facilities Officer
Box 8034
660 South Euclid Avenue
St. Louis, MO 63110

Licenses No. 24-00167-11
24-00063-13
24-00063-10
24-00167-13
Docket Nos. 030-02271
030-31205
030-15101
030-33008

Dear Mr. Hickok:

This refers to letter dated February 10, 1994 from Dr. John Eichling in response to our letter dated January 12, 1994, transmitting a Notice of Violation. Our letter and Notice describes violations and areas of concern identified during the inspection November 15 through November 18, 1993.

In your response, you challenge the validity of certain cited violations and concerns that were described in the letter and the Notice. After careful review, we have concluded, for the reasons stated below, that the violations are valid as stated in the Notice, a copy of which is attached. A written response to the Notice is required within 30 days of the date of this letter.

Violation No. 1.

You contest the first violation, failure to conduct a survey with a radiation survey instrument at the end of each day, of the cesium room at Barnes Hospital where iodine-131, phosphorus-32, and strontium-89 are routinely prepared for use, on the basis that you believe that the activities performed with the radiopharmaceuticals in the cesium room at Barnes Hospital do not constitute routinely preparing for use. In your letter you state that removing the radiopharmaceuticals from the shipping containers and placing them in the dose calibrator and then removing them and placing back into the shipping containers, does not constitute preparing the radiopharmaceuticals for use. We find your interpretation of the regulations unacceptable because to prepare means to make ready. In order to be ready to use the material the dose must be calibrated. Unpacking, and removing the doses from shielded containers and the actual dose calibration is part of the dose preparation process.

Good laboratory health physics practices dictate that radiopharmaceuticals, although in sealed containers, should not be considered in the same class as sealed sources such as brachytherapy sources since the probability of inadvertent leakage of the contents from vials and syringes is much higher.

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As stated in your letter dated February 10, 1994, you apparently agree that part of the purpose of performing the daily ambient dose rate surveys is to determine the "presence of unintended significant sources of radiation." Since significant sources of radiation (100 millicuries of iodine-131) are prepared for use, temporarily removed from their shielded containers, and temporarily stored in the cesium room of Barnes Hospital, we believe there exists significant radiation safety cause to perform daily surveys.

Violation No. 2

Your response to violation No. 2, failure to conduct weekly radiation surveys in a Nuclear Medicine radiopharmaceutical waste room is considered inadequate in that you have not described what actions have been taken to prevent reoccurrence of the violation.

Violation No. 3

Your response to Violation No. 3. regarding opening a sealed source containing ytterbium-169 prompted two areas of concern: (1) a technician responsible for the routine leak tests of sealed sources apparently did not fully understand the hazards associated with handling sealed sources; and (2) once the source was broken inappropriate emergency action was taken to ensure that spread of radioactivity had not occurred. Your response to the associated areas of concern are unacceptable for the following reasons.

You indicate in your response that there was prior knowledge of the nature of the source (e.g. that it was in the form of a ytterbium rod that had been activated with neutron bombardment). You further indicate that because the ytterbium-169 activity was contained in a thin encapsulation to seal the ytterbium wire, you believe that the ease with which the source was damaged is an indication of the low hazard associated with damaging the sealed source. Nevertheless, we see no basis in your conclusions for not taking appropriate emergency action to prevent the potential spread of contamination.

Regardless of whatever prior knowledge the individuals may have had concerning the ytterbium source, good health physics practice should have dictated implementing emergency procedures including a quick check with a survey instrument to ensure that major contamination of the laboratory had not occurred before leaving the area.

It is our judgement that both the technician and the authorized user demonstrated that they did not fully understand the hazards associated with handling sealed sources, and that the actions taken as described to the inspector by the technician and the authorized user at the time of inspection were inappropriate to mitigate contamination had it occurred. Our conclusion is based on the following:

1. The technician did take wipe samples as stated in the response to the Notice of Violation. However, the technician stated to the inspector that no determination of contamination was done until after he returned to the Radiation Safety Office. He left the area before the extent of contamination was known.

   In an emergency situation it is imperative that (1) one assures that all personnel are safe from exposure to radiation and free of radioactive contamination and (2) one determines the extent of contamination immediately to avoid spread of contamination to other areas. Neither of these details were taken care of by the technician or the authorized user.

2. The interview with the authorized user on the day of the inspection demonstrated that the program for posting emergency procedures and providing general training is not effective in assuring that users understand proper emergency response. His response to a hypothetical question that if he were to accidently drop a therapy dose of iodine-131 on the floor and it broke, he would immediately remove his shoes and leave the laboratory to obtain assistance. If such an accident were to occur this response could result in a very serious incident because of contamination to himself and the surrounding area.

Posting emergency instructions in use areas and stressing the importance of emergency response in annual refresher training was apparently ineffectual in preventing the wrong response to this incident. In your response to this letter please state the corrective actions you have or will take to assure that users of radioactive material and your own staff will respond properly to emergency situations.

Violation No. 4.A.

You have challenged the validity of the cited violation which involved the failure to discontinue patient treatment when patient viewing via video camera was not available. After careful review, we have concluded, for the reasons stated below, that the violation is valid as stated in the Notice.

Your statement that this ruling is an intrusion into standards of medical practice is unsubstantiated in that the use of the video monitor system was a commitment made in your license application in a letter dated September 9, 1987.

In the referenced document to which the violation refers, you requested permission to obtain and use several Nucletron Low Dose afterloading devices including the device involved in the reported incident.

You have claimed that the commitment to have patient viewing available via video camera is only a commitment to have a viewing apparatus or "facility" available for elective use of the nursing staff. Further, it is claimed that no commitment to staff this viewing system is implied. You argue that the original intent of the viewing system was for "visualizing" the patient not to confirm the patients condition, or state of the remote afterloading system at required intervals. Nevertheless, this information is not contained in the letter of application nor in any other documents referenced in the license.

NRC staff determined that the licensing guide in use at the time of the application (enclosure 2 to NRC Policy and Guidance Directive 86-4) (enclosed) on Page 3. of the referenced guide under V. Facilities, item B. recommends that the reviewer ask the licensee to describe primary continuous viewing system for each treatment room and asks for a description of the backup system if the primary system fails or requests that the licensee commit to halting treatments. Since this guide would have been used by the license reviewer and since the format of the application follows this Policy and Guidance Directive, it appears likely your intent and the understanding of the license reviewer, at the time of the application, was that a continuous viewing of the patient via video monitor would be provided, and that if the system failed, treatment would be discontinued. Furthermore, it is reasonable to assume that the reason for having any safety device such as a video monitor implies that it is present for the purpose of being used.

In the incident referred to in the Notice Of Violation, it was determined that no one was posted at the nursing station where the monitors were located for at least 4 hours and therefore during that time, patient viewing was not available and treatment was not halted, a failure to comply with a key statement in the your application.

The inspection also disclosed through interviews with nursing staff, that it had not been impressed on the nursing staff that the use of the monitors was required at any particular interval. If your intent was rarely, if ever, to use the video monitor system it should have been so stated in your application, rather than leaving the impression that it would be used as a functional part of the radiation safety program.

The arguments put forth in items (e) and (f) on p. 3 of your response are not relevant in that the issue is not whether or not other methods of detection of patient actions would be adequate, or whether the CCTV monitoring system is infallible in providing information on possible afterloader malfunctions or patient distress, but rather the issue is failure to adhere to commitments made in your license application. Our concern remains your failure to impress on the nursing staff that the regular use of the video monitors is a necessary part of your license commitments.

We acknowledge that you have correctly identified an error on page 9 of our inspection summary in which it is stated that a letter dated April 18, 1988 states "Patient viewing is available via video camera and monitoring systems. If patient viewing is not available then treatment will be halted." The correct reference for the letter which contains this statement is as stated in the Notice of Violation, letter dated September 9, 1987.

Area of Concern

With regard to the area of concern stated in our Inspection Summary p. 12., which stated the following: "The inspectors identified one area of concern while inspecting the medical program. Area surveys performed with a radiation detection survey meter in the nuclear medicine department, 9th Floor West Pavilion, Barnes Hospital, were only being performed at the center of each room. Routine weekly contamination wipe test records indicate that contamination was periodically found when wipe tests were conducted. Daily surveys should be performed adequately enough to detect radioactive material contamination and when found, should be decontaminated at once, rather than having a 7-day interval to pass before radioactive material contamination is identified. Procedures followed in the performance of area surveys and weekly contamination tests are an area of concern to the NRC."

You have correctly concluded that one of the purposes of the daily instrument survey is intended to identify the presence of any unintended significant source of radiation exposure. However, our concern is about the fact that a single dose measurement at the center of the room may not identify an unintended significant source of radiation exposure whether the origin be a significantly contaminated spot or an unknown sealed source. In other words the inspector questions the significance of the survey as performed. Our letter pointed out the fact that in some of the scanning rooms in question, routine weekly contamination wipe tests indicate that contamination is periodically found when wipe tests were conducted. Since these contamination surveys are only performed on a weekly basis it may be possible that larger (significant) quantities of radioactivity was present on the date of actual contamination which would have been detected by an adequate ambient dose rate survey.

The fact that one recording is made in Exhibit 16. Regulatory Guide 10.8 does not imply that one should take one reading in the center of the room. A better technique would be to walk around scanning the room and record the highest reading. The method of performing the required ambient dose rate surveys still remains an area of concern.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you may have concerning this matter.

Sincerely,

ORIGINAL SIGNED BY W. L. AXELSON

APR 0 8 1994

Dated

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

Enclosures:
1. Notice of Violation
2. Enclosure 2 to NRC Policy
and Guidance Directory 86-4.

cc w/enclosures:
John Eichling, Ph.D.,
Radiation Safety Officer

(YES)

RIII	RIII	RIII	RIII	RIII
Matson/jaw	Jones	Cantano	DeFayette	Axelson
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