

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

St. Louis University
St. Louis, MO

Docket No. 030-11623
License No. 24-04581-19
EA 87-234

During an NRC inspection conducted on December 3 through 11, 1987, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1987), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. 10 CFR 20.101(a) requires that no licensee possess, use, or transfer licensed material in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from radioactive material a total whole body occupational dose in excess of 1.25 rems.

Contrary to the above, during the fourth calendar quarter of 1987, an individual using licensed material in a restricted area received a whole body occupational dose of at least 7.5 rems.

- B. 10 CFR 20.201(b) requires that each licensee make such surveys as (1) may be necessary for the licensee to comply with the regulations in Part 20, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "Survey" means an evaluation of the radiation hazards incident to the use or presence of radioactive materials under a specific set of conditions.

Contrary to the above, the licensee did not make a survey (evaluation) of a radiation hazard to assure compliance with 10 CFR 20.101(a) in that an individual entered a teletherapy room on October 27, 1987, while an 8990 curie cobalt-60 source was in an exposed position and did not evaluate the radiation hazard by surveying the radiation field or by observing the warning light on the control panel, the warning light above the entrance door to the teletherapy room or the Primealert warning light in the maze entrance to the teletherapy room.

- C. 10 CFR 20.403(b) requires that a licensee within 24 hours of discovery of an event, report any event involving licensed material possessed by the licensee that may have caused or threatens to cause exposure of the whole body of any individual to 5 rems or more of radiation.

Contrary to the above, on October 27, 1987, the licensee was aware of an overexposure event that threatened to cause whole body exposure in excess of 5 rems and failed to report the event to the NRC within 24 hours. Subsequently, on November 18, 1987, the licensee was informed by its badge processor, Radiation Detection Company, that an individual involved in that event had received a whole body dose of 7.5 rems; however, the licensee did not report the event to the NRC until November 23, 1987.

Collectively, these violations have been classified as a Severity Level II problem (Supplement IV).

Cumulative Civil Penalty - \$6,000 (assessed equally among the violations).

Pursuant to the provisions of 10 CFR 2.201, St. Louis University (Licensee), is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2032, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, or money order payable to the Treasurer of the United States in the amount of civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, the answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty the answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the five factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1987), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g.,

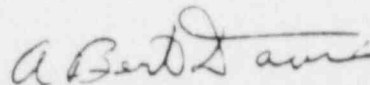
January 29, 1988

citing page and paragraph numbers) to avoid repetition. The attention of Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses to the Director, Office of Enforcement, noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk,, Washington, DC 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137.

FOR THE NUCLEAR REGULATORY COMMISSION



A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 29th day of January 1988

U.S. NUCLEAR REGULATORY COMMISSION

Region III

Report No. 030-11623/87001(DRSS)

Docket No. 030-11623

License No. 24-04581-19

Category G

Priority II

Licensee: St. Louis University
Medical School Building
1402 South Grand Boulevard
St. Louis, MO 63104

Special Safety Inspection Conducted: December 3 and 11, 1987

Inspector: T. L. Simmons
Radiation Specialist

D. J. Krenianski for

12/24/87
Date

Approved By: Bruce S. Mallett, Ph.D.
Chief, Nuclear Materials
Safety and Safeguards Branch

D. J. Krenianski for

12/24/87
Date

Inspection Summary

Inspection on December 3, and 11, 1987 (Report No. 030-11623/87001(DRSS))

Areas Inspected: This was an announced special inspection to review the circumstances surrounding a licensee reported overexposure of a radiation therapy physicist. The inspection included a review of therapy procedures and records, personnel monitoring results, a reenactment of the event, and interviews with personnel.

Results: Three violations of NRC requirements were identified:

- (1) 10 CFR 20.101(a) occupational dose in excess of 1.25 rems in one quarter;
- (2) 10 CFR 20.201(b) failure to adequately evaluate a radiation hazard;
- (3) 10 CFR 20.403(b) failure to report an exposure to the whole body in excess of 5 rems in a timely manner.

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DETAILS

1. Persons Contacted

*James Fletcher, M.D., Chairman Radiation Safety Committee
Sain Ahuja, Ph.D., Physicist
*Roger Munday, Radiation Safety Officer
Susan Toelle, Chief Technologist
Janet Dyer, Assistant Chief Technologist
Linda Arnold, Simulator Technologist

*Exit interview attendees

2. Purpose of Inspection

This inspection was conducted in response to a licensee reported overexposure received by the radiation therapy physicist during an area survey procedure.

3. Licensed Program and Inspection History

NRC Byproduct Material License No. 24-04581-19 was originally issued to St. Louis University on January 26, 1976, and was last renewed in its entirety on September 9, 1981. The license authorizes possession of 9000 curies of cobalt-60 in the form of a sealed source to be housed in a Siemens Gammatron S teletherapy unit.

This licensee has been inspected three other times since 1976. The last routine inspection was performed on January 7 through 28, 1986; three violations were identified - failure to calibrate dosimetry system every two years, failure to conduct practice runs of teletherapy emergency procedures every six months, and use of two unauthorized but qualified users.

4. Inspection Findings

a. Operation Resulting in Overexposure

On the afternoon of October 27, 1987, the University of St. Louis radiation therapy physicist and the Radiation Safety Officer (RSO) were performing surveys of various areas surrounding the cobalt-60 teletherapy room. These surveys, performed with the source exposed, are required following a source change.

Traditionally, this institution includes a survey of the room entrance with the door open. According to the physicist and the RSO, this survey provides an estimation of staff exposure in the event of an interlock or source retraction failure during a whole body palliative treatment. In order to conduct this survey, the

interlock is bypassed. During this incident, the beam was oriented off the beam stopper, the collimator jaws open to the largest field size and the beam was directed toward the operator's console (See Attachment A for diagram).

After the survey results were noted, the physicist stated that he hit the beam off button and walked into the room in front of the beam to the pendulum which is suspended from the ceiling and houses the unit's mobility controls. Within seconds the RSO entered the room with a survey meter and began to survey the unit's head noting that the source was exposed. Prior to that, neither individual observed the beam on condition at the control panel, the light indicator above the door, or the primalert in the room. All of these safety devices were operational and indicated that the source was in the exposed position. Failure to adequately evaluate the conditions of the beam prior to entry and observe the safety devices in place is a violation of 10 CFR 20.201(b), which requires the licensee to evaluate the extent of radiation hazards that may be present to assure compliance with Part 20. At about the same moment, both individuals realized that the unit was in the beam on mode and immediately left the room. The source was returned to the shielded position. It was determined that the physicist apparently did not securely press the "beam off" button. The unit did not malfunction.

One violation was identified.

b. Dose Calculation - Personnel Monitoring

Following the incident, the RSO and physicist estimated their exposures to be between 2 and 3.5 rems (See Attachment B). Since the estimated figures did not meet or exceed 5 rems, the licensee did not notify the NRC.

During the incident, both individuals wore whole body badges supplied by Radiation Detection Company (RDC). In addition, the RSO wore a ring badge on his right 5th finger. The physicist's ring badge was in his left trouser pocket. Ring badges are supplied by Landauer.

On November 11, 1987, all monitoring devices were sent to the processors. An emergency reading was not requested. On November 16th and 18th, the RSO called both companies for their results. Neither had processed the badges at that time; however, RDC called the RSO with whole body results on the evening of the 18th to report the following results:

- RSO - 60 millirem
- Physicist - 7500 millirem

The RSO indicated that he was confident that the calculated doses were over-estimated and was very surprised by RDC's results. He decided to wait for Landauer's report before contacting NRC. Landauer called on November 23rd to report the following:

- RSO - 120 millirems
- Physicist - 9080 millirems

The RSO contacted the Region III NRC office on November 23, 1987. The physicist was removed from all work involving radioactive materials on November 30, 1987, for the rest of the quarter.

The licensee was aware on October 27th of an event that threatened to cause whole body exposure in excess of 5 rems to an individual. The licensee was notified on November 18th of a whole body dose in excess of 5 rems. The licensee failed to report these events to the NRC on a timely basis. This is in violation of 10 CFR 20.403(b) which requires the licensee to report within 24 hours after discovery of an event in which an individual may have received or threatens to receive 5 rems or more radiation to the whole body. In addition, the licensee is in violation of 10 CFR 20.101(a) which prohibits a worker from receiving an occupational dose to the whole body in excess of 1.25 rems per calendar quarter.

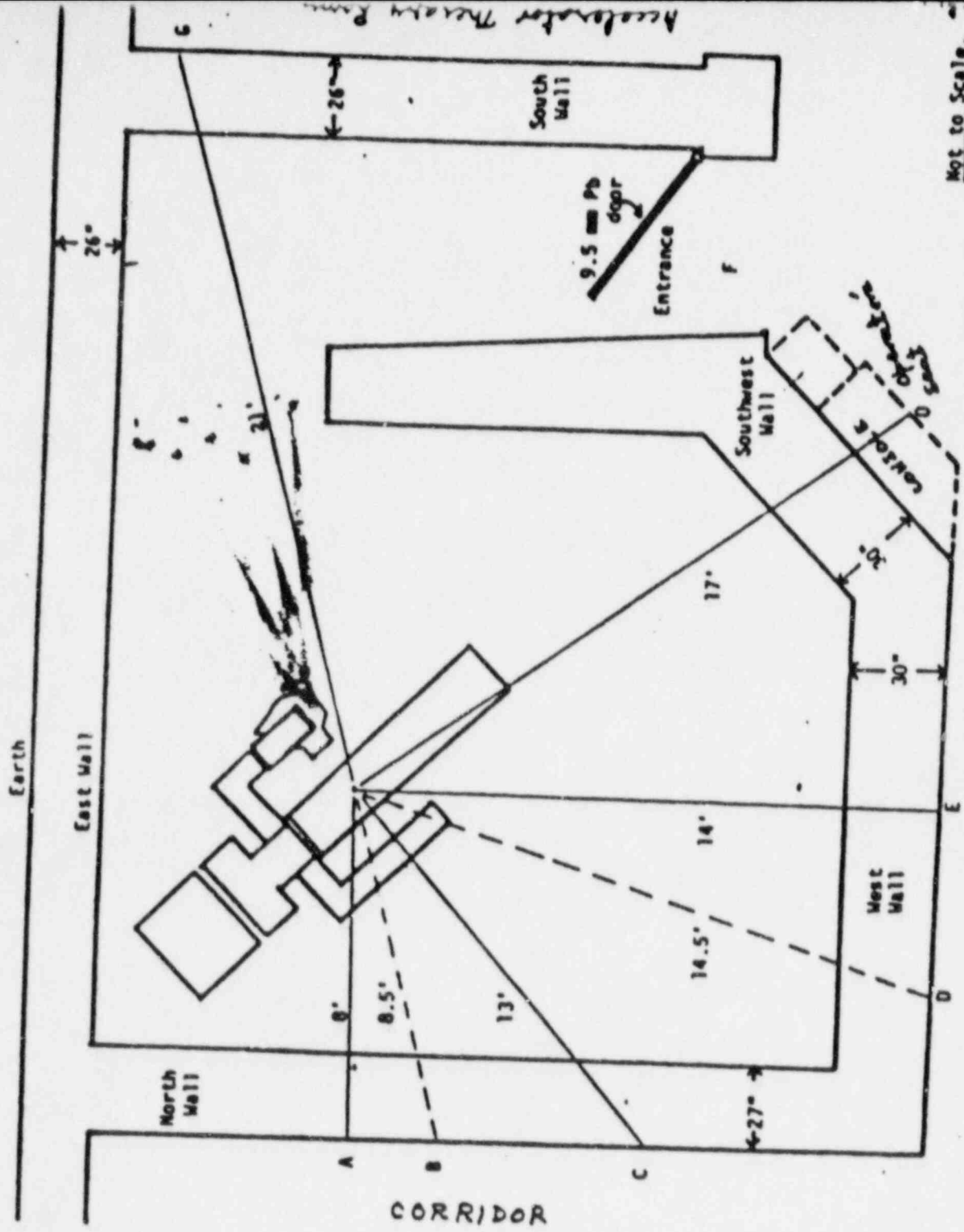
Two violations were identified.

5. Exit Interview

At the conclusion of the onsite inspection on December 3, 1987, the inspector met with those individuals designated in Section 1 of this report to discuss the apparent violations identified at that time and the possibility of escalated enforcement based on the overexposure.

Attachments:

- A - diagram of teletherapy room
- B - calculations following event



ATTACHMENT A

10-27-87 (Tuesday)

Accidental exposure to Co^{60} beam
during survey

Time \sim 4:30 PM CST

Exposure time: ~ 10 sec (SDA), but ~ 5 sec (RM)

Distance \sim 280 cm from head (SDA), (in front of collimator)
 \sim 55 cm from head (RM), (lateral to collimator)

F.S. $\sim 40.5 \times 40.5 \text{ cm}^2$

Estimated radiation exposure

$$\text{SDA} \approx 260 \left(\frac{40.5}{280} \right)^2 \times \frac{1}{6}$$

$$\text{RM} \approx 25 \times \frac{1}{12}$$

Output ~ 260 rads/min (wat.
at 80.5 cm [In Beam])
but ~ 25 (in perimetric)
on the surface
 ~ 3.5 rads
 ~ 2 rads

ATTACHMENT B