

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Bluefield Community Hospital
Bluefield, West Virginia

Docket Nos.: 030-17038 and 030-19174
License Nos.: 47-19142-01 and 47-19142-02
EA 89-142

During the Nuclear Regulatory Commission (NRC) inspection conducted on June 14 and 16, 1989, 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 (1989), 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:

I. Violations of License No. 47-19142-01

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on June 14, 1989, licensed material consisting of cesium-137 brachytherapy sources and a strontium-90 calibration source stored in the teletherapy treatment room, an unrestricted area, was not secured against unauthorized removal, in that, neither the vault containing the sources nor the door to the teletherapy treatment room was locked and access to the area was not controlled outside normal Oncology Department working hours.

- B. 10 CFR 20.203(e) requires that each area or room in which licensed material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in an amount exceeding ten times the quantity of such material specified in Appendix C of Part 20, be conspicuously posted with a sign or signs bearing the radiation symbol and the words "Caution - Radioactive Material(s)."

Contrary to the above, on June 14, 1989, two doors which accessed the Nuclear Medicine Department, where licensed material consisting of iodine-131 and technetium-99m radiopharmaceuticals exceeding ten times the quantities specified in Appendix C are used for diagnostic imaging and quantitative studies, were not conspicuously posted with "Caution - Radioactive Material" signs.

- C. 10 CFR 35.51(d)(1) and (2) require each survey instrument calibration record to include among other things the certified exposure rates from

the source, the rates indicated by the instrument being calibrated, and a description of the calibration procedure.

Contrary to the above, between April 1, 1987 and June 14, 1989, the survey instrument calibration records did not contain the certified exposure rates from the source, the rates indicated by the instrument being calibrated, nor a description of the calibration procedure.

- D. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of licensed byproduct material.

Contrary to the above, between April 16, 1986 and June 14, 1989, the required records, showing the receipt and transfer of byproduct material consisting of a strontium-90 therapeutic eye applicator, were not kept.

- E. 10 CFR 35.205(c) and (d) require that before receiving, using, or storing a radioactive gas, the amount of time needed after a spill to reduce the concentration in the room to the limit listed in 10 CFR Part 20, Appendix B be calculated, that a record of these calculations be made, and that the calculated time, and safety measures to be instituted in case of a spill be posted at the area of use.

Contrary to the above, between April 1, 1987 and June 14, 1989, the licensee failed to post the calculated time and safety measures to be instituted in case of a xenon-133 radioactive gas spill in the Nuclear Medicine Department.

- F. 10 CFR 35.51(c) requires that each survey instrument be checked for proper operation with a dedicated check source each day of use. 10 CFR 35.5(a)(3) requires that the apparent exposure rate from dedicated check source as determined at the time of calibration be conspicuously noted on the survey instrument.

Contrary to the above, checks with a dedicated check source performed for proper operations of each survey meter, each day of use between April 1, 1987 and June 14, 1989 were inadequate, in that the nuclear medicine technologist failed to compare the exposure rate obtained with the dedicated check source with the apparent exposures rate from the source as determined at the time of instrument calibration which was conspicuously noted on the survey instrument.

- G. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170 through 189.

49 CFR 173.415(a) requires each shipper of a Specification 7A package to maintain on file for at least one year after the latest shipment a complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above, on June 14, 1989, documentation of the appropriate tests for a Specification 7A package was not maintained on file for the molybdenum-99/technetium-99m generator packages shipped between June 14, 1988 and June 14, 1989.

- H. License Condition 8.B limits the amount of each byproduct material authorized in Subitem 6.B. that may be possessed at any one time to no more than three curies. Subitem 6.B. permits the licensee to possess molybdenum-99/technetium-99m generators listed in 10 CFR 35 Schedule A, Group III, the revision of 10 CFR 35 in effect when the license was issued.

Contrary to the above, on May 27, 1989, the possession limit authorized by the license was exceeded, in that, at approximately 6:00 a.m., the licensee received a molybdenum-99/technetium-99m generator containing an amount greater than three curies. Specifically, the generator was assayed by the supplier to be three curies on May 29, 1989, at 8:00 p.m.

- I. License Condition 20 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated September 6, 1979, letter dated October 29, 1979; Model ALARA program contained in Appendix O of Regulatory Guide 10.8 (Rev. 1), October 1980; letter dated May 26, 1981; application dated February 16, 1983; and letters dated February 23, 1983, November 3, 1983, and October 1, 1984.

- 1. Item 9 of the letter dated October 29, 1979, requires that the xenon trap system be surveyed on a weekly frequency in order to ensure that the filter has not become saturated.

Contrary to the above, between April 16, 1986 and May 2, 1989, surveys of the xenon trap were performed on a monthly rather than on a weekly frequency.

- 2. Item 14, Procedures B. 3 and 4 of the application dated September 6, 1979, require that unopened packages containing radioactive material be monitored with a survey meter; that the package not be opened if the radiation level exceeds 200 mR per hour at the surface, or 10 mR per hour at three feet; and that if the radiation levels are exceeded, the radiation safety officer or health physics consultant and chief of the department be notified for further instruction. The radiation safety officer or consultant shall notify the appropriate officials of the Nuclear Regulatory Commission or State Health Department, the final delivery carrier, and the vendor.

Contrary to the above, packages containing radioactive material received on May 8 and September 8, 1988, February 22, March 1 and

May 27, 1989, which had radiation levels between 12 and 35 mR/hr at 3 feet from the surface of the unopened package as monitored by a survey meter, were opened and the required notifications were not made.

3. Item 14, Procedure B. 8, of the application dated September 6, 1979, requires, in part, that the packing material and empty packages, used for shipping radioactive material, be monitored for contamination before discarding in either the radioactive or regular trash.

Contrary to the above, between April 16, 1986 and June 14, 1989, packing material and empty packages, used for shipping radioactive iodine-131 and xenon-133, were not monitored for contamination before discarding into the hospital's trash.

4. Item 10, Procedure 3, of the application dated September 6, 1979, requires that survey meters be calibrated on a quarterly basis.

Contrary to the above, between August 22, 1986 and June 14, 1989, two survey meters (Eberline E 120, Serial No. 7522 and Eberline E-130G, Serial No. 6919) were not calibrated on a quarterly basis. Additionally, between August 21, 1987 and June 14, 1989, another survey meter (Micron Surveyor 2000, Serial No. A 230 K) was not calibrated on a quarterly basis.

5. Item 20 of the application dated February 16, 1983, requires that procedures described in Appendix L of Regulatory Guide 10.8, Revision 1, October 1980 be followed.

Item 6. of Appendix L requires that nurses caring for brachytherapy patients be assigned film or TLD badges and that TLD finger badges also be assigned to nurses who must provide extended personal care to the patient.

Contrary to the above, between April 16, 1986 and June 14, 1989, neither film or TLD badges nor TLD finger badges were assigned to nursing personnel who either cared for brachytherapy patients or provided extended personal care for brachytherapy patients undergoing therapeutic applications using cesium-137.

6. Item 12. of the application dated September 6, 1979, requires that in addition to on-the-job training, all individuals who work with radioactive sources receive periodic training at least annually in radiation safety. The training subjects shall include, but not be limited to, radiological safety procedures described in the license.

Contrary to the above, between April 16, 1986 and June 14, 1989, Nuclear Medicine Technologists, individuals who work with radioactive sources, did not receive the periodic training at least

annually in radiation safety which included the radiological safety procedures described in the license.

7. Item 12. of the application dated February 16, 1983, requires that an inventory of all brachytherapy sources be performed at least monthly.

Contrary to the above, between April 16, 1986 and June 14, 1989, an inventory of all brachytherapy sources was not performed at least monthly.

8. 10 CFR 35.14(f)(2) (effective up to April 1, 1987) requires that a quarterly physical inventory be conducted to account for all sources received and possessed.

Contrary to the above, a quarterly physical inventory of a cesium-137 reference source (NEN, Cat. NES-356, #3560584A-30) and cobalt-60 reference source (NEN, Cat. NES-354, #3540584A-04) was not performed between February 4, 1986 and July 1, 1986; and between July 1, 1986 and January 13, 1987.

II. Violations of License No. 47-19142-02

License Condition 22 requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in the application dated March 13, 1986, and letter with attachments received September 3, 1986.

1. Attachment 2, Item 15, of the letter with attachments received September 3, 1986, requires that practice drills of the teletherapy emergency procedures be performed at least once a year with all appropriate personnel. New personnel shall perform practice drills as soon as these individuals report for duty.

Contrary to the above, between November 2, 1986 and September 29, 1988, teletherapy emergency practice drills were not performed at least annually with all appropriate personnel.

2. Attachment 4 of the letter with attachments received September 3, 1986, requires that the items listed below be checked and logged in the appropriate records weekly.

- (a) teletherapy timer
- (b) beam "on" and "off" lights on the console, machine head, and above the door
- (c) emergency switches
- (d) door interlocks
- (e) beam collimators using radiographic film and a densitometer
- (f) two independent TV monitor systems

Contrary to the above, between May 13 and June 16, 1988, and between July 15 and 29, 1988, the teletherapy timer, beam "on" and "off" lights, emergency switches, door interlocks and two independent TV monitor systems were not checked weekly. Additionally, between April 7 and May 5, 1987, between May 5 and June 2, 1987, and between June 2 and July 3, 1987, such checks were not logged in the appropriate records. Further, between June 14, 1987 and June 14, 1989, the beam collimators were not checked using radiographic film and a densitometer on a weekly frequency.

3. Attachment 2, Item 3, of the letter with attachments received September 3, 1986, requires that daily checks of the teletherapy beam-on monitor and survey instrument be performed.

Contrary to the above, between May 13 and June 16, 1988 and between July 15 and 29, 1988, daily checks of the beam-on monitor and survey instrument were not performed.

The above violations have been categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

Cumulative Civil Penalty - \$5,000 (assessed equally among the 19 violations).

Pursuant to the provisions of 10 CFR 2.201, Bluefield Community Hospital (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 violation: (1) admission or denial of the violation, (2) the reasons for the violation if admitted, (3) the corrective steps which have been taken and the results achieved, (4) the corrective steps 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 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the licensee may pay the civil penalty by letter addressed 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 the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, 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, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or part, (2) demonstrate extenuating circumstances, (3) show error in

Notice of Violation

- 7 -

this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C 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., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay the penalty due, which has been subsequently 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. 2282.

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, Region II.

FOR THE NUCLEAR REGULATORY COMMISSION

ORIGINAL SIGNED BY

SDEbnetter

Stewart D. Ebnetter
Regional Administrator

Dated at Atlanta, Georgia
this 4th day of September 1989