NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Beth Israel Hospital
Boston, Massachusetts 02215

Docket No. 30-09062
License No. 20-00742-18
EA 84-113

An NRC inspection of activities authorized under NRC License No. 20-00742-18 was conducted on August 27, 1984. During the inspection, eleven violations of NRC requirements were identified. Collectively, these violations represent inadequate management control and oversight of the radiation safety program.

In accordance with the General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C, as revised, 49 FR 8583 (March 8, 1984), and pursuant to Section 234 of the Atomic Engergy Act of 1954, as amended ("Act"), 42 U.S.C. 2282, PL 96-295, and 10 CFR 2.205, the particular violations and the associated civil penalties are set forth below:

A. 10 CFR 19.12 requires that all individuals working in or frequenting any portion of a restricted area be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the restricted area; be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; and be instructed in, and instructed to observe, to the extert within the worker's control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation or radioactive materials occurring in such areas.

Contrary to the above, as of August 27, 1984, a nuclear medicine technologist was not instructed in the licensee's molybdenum-99 assay procedures in accordance with 10 CFR 35.14(b)(4)(ii); a nuclear medicine technologist had not been instructed in the applicable DOT shipping regulations as stated in 10 CFR 71.5; and the Radiation Protection Officer had not been instructed in the applicable DOT shipping regulations as stated in 10 CFR 71.5.

B. 10 CFR 20.105(b) requires that radiation levels in unrestricted areas be limited so that an individual who was continuously present in the area could not receive a dose in excess of 2 millirems in any hour or 100 millirems in any seven consecutive days, except as authorized by the NRC pursuant to the conditions of 10 CFR 20.105(a). 10 CFR 20.3(a)(17) defines an unrestricted area as any area to which access is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, between October 30, 1982 and August 27, 1984, radiation levels in excess of 2 millirems in any one hour existed on a number of occasions in unrestricted areas surrounding the rooms of brachytherapy patients implanted with iridium-192. For example, from January 1, 1984 to June 30, 1984, radiation levels in excess of 2 millirems per

hour and as high as 5 millirems in any one hour were recorded for 29 implant cases, and the licensee had not requested nor been granted a variance from these radiation level limits in accordance with 10 CFR 20.105(a).

C. 10 CFR 20.205(d) requires that each licensee establish and implement procedures for safely opening packages in which licensed material is received.

Section 5.4 of the Radioisotopes Manual and the licensee's form entitled "Radioisotope Order/Receipt/Package Survey Log" require that liquid shipments containing more than 100 millicuries of technetium-99m be surveyed at the package surface and at 3 feet from the package surface.

Contrary to the above, on August 27, 1984, a received package containing a liquid shipment of more than 500 millicuries of technetium-99m was surveyed at a point 12 inches from the package surface rather than at the surface and at three feet from the package surface.

D. 10 CFR 20.401(b) requires that each licensee maintain records showing the results of monitoring of packages required by 10 CFR 20.205 in the same units as stated in Part 20.

Contrary to the above, on August 27, 1984, the record of the package wipe test required by 10 CFR 20.205 was recorded as 0.1 mR/hr and not in units of dpm or microcuries as used in 10 CFR 20.205.

E. 10 CFR 30.34(g) requires that molybdenum-99 assays be performed in accordance with 10 CFR 35.14(b)(4)(i) through (iv).

10 CFR 35.14(b)(4)(ii) requires that technetium-99m separated from molybdenum-99, either by elution of a molybdenum-99/technetium-99m generator or by an extraction process, be tested to detect and quantify molybdenum-99 activity or the concentration of molybdenum-99 prior to administration to patients according to written procedures.

Contrary to the above, on August 26, 1984, technetium-99m eluted from a generator was not adequately assayed for molybdenum-99 activity, in that the reading obtained from the dose calibrator was not multiplied by a factor stated in the licensee's written procedures.

F. Condition 22 of License No. 20-00742-18 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated December 20, 1978, and letters dated December 20, 1978, October 30, 1980, April 3, 1981, April 21, 1981, February 8, 1982 and August 9, 1983.

1. Item 3.4.5 of the Radioisotopes Manual submitted as part of the licensee's application requires that individuals take appropriate protective measures (i.e., use remote handling tools) when in contact with radioactive materials.

Contrary to the above, on August 27, 1984, a nuclear medicine technologist handling unshielded vials of technetium-99m, containing up to 500 millicuries of activity, did not take appropriate protective measures in that she did not use tongs.

2. Items 3.4.5 and 6.5.6 of the Radioisotopes Manual submitted as part of the licensee's application require that gloves be worn as protective measures when handling licensed materials.

   Contrary to the above, on August 27, 1984, a nuclear medicine technologist handled a vial containing 18 millicuries of technetium-99m without wearing gloves.

3. Item 6.4.1 of the Radioisotopes Manual submitted as part of the licensee's application requires that where the hand dose may exceed 25% of the relevant limit, finger or wrist dosimeters must be worn.

   Contrary to the above, on August 27, 1984, a nuclear medicine technologist transferred unshielded vials containing up to 500 millicuries of technetium-99m with her without wearing a finger or wrist dosimeter on her right hand.

4. Item 23, Appendix K, Part I, of the application requires that whenever iodinations using 100 microcuries or more of iodine-125 are performed, thyroid monitoring must be performed within the two weeks of the iodination.

   Contrary to the above, as of August 27, 1984, thyroid monitoring was not performed within two weeks of 5 separate iodinations using more than 100 millicuries of iodine 125 which occurred between June 1, 1984 and July 30, 1984.

5. Item 6 of the letter dated October 30, 1980 requires that survey be performed in accordance with Appendix I, Regulatory Guide 10.8 (Rev 1), October, 1980.

   Item 1 of Appendix I requires daily surveys of all elution, preparation and injection areas.

   Contrary to the above, on August 26, 1984, a daily survey was not performed in the injection, preparation, or elution areas of the nuclear medicine department.

G. 10 CFR 71.5(a) requires that no licensee deliver any licensed material to a carrier for transport without complying with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170-189.

1. 49 CFR 173.427 permits an empty radioactive materials package to be unmarked and unlabeled provided that the package complies with 49 CFR 173.421(b), (c) and (e); the package is unimpaired and securely closed; the internal contamination does not exceed 100 times the limits specified in 173.443(a); and any labels previously applied in conformance with Subpart E of Part 172 are removed, obliterated or covered, and the EMPTY label prescribed in 172.450 is applied to the package.

   49 CFR 173.421(b) requires the external radiation level not exceed 0.5 millirem per hour.

   49 CFR 173.421(c) requires the removable surface contamination not exceed limits in 173.443(a).

   49 CFR 173.421(e) requires the package not contain more than 15 grams of uranium-235.

   49 CFR 173.443(a) specifies a removable contamination limit of 10^{-5} uCi/cm² or 22 dpm.

   49 CFR 172.203(e) requires that the shipping paper for empty packages containing residue of radioactive material describe the contents of the package as EMPTY, or EMPTY: Last contained Radioactive Material.

   49 CFR 172.450 describes the EMPTY label.

   Contrary to the above, on August 27, 1984, the licensee delivered to a common carrier an empty package which was not prepared, evaluated, or labeled in accordance with DOT regulations in 49 CFR 173.427, 173.421(b) and (c), 173.443(a) and 172.450; nor were shipping papers prepared in accordance with 49 CFR 172.203(e). Specifically, a nuclear medicine technologist did not perform a survey of the inside or outside of a shipping container to assure compliance with 49 CFR 173.421 and 173.433(a); the technologist did not remove or obliterate the Radioactive Yellow II DOT shipping label or apply an Empty label on a shipping container in compliance with 49 CFR 173.427(d) and 172.450; the technologist did not complete shipping papers which described the contents of the package as empty.

Collectively, these violations have been categorized in the aggregate as a Severity Level III problem (Supplements IV and VI). Cumulative Civil Penalties - $1,250 assessed equally among the violations.

Within the same time as provided for the response required above under 10 CFR 2.201, Beth Israel Hospital may pay the civil penalties in the amount of One Thousand Two Hundred Fifty Dollars ($1,250) or may protest imposition of the civil penalties in whole or in part by a written answer. Should Beth Israel Hospital fail to answer within the time specified, the Director, Office of Inspection and Enforcement, will issue an Order imposing the civil penalties in the amount proposed above. Should Beth Israel Hospital elect to file an

answer in accordance with 10 CFR 2.205 protesting the civil penalties, such answer may: (1) deny the violation 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 penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties. In requesting mitigation of the proposed penalties, the five factors contained in Section V.B of 10 CFR Part 2, Appendix C, as revised, 49 FR 8583 (March 8, 1984) 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 by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of Beth Israel Hospital 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 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.

FOR THE NUCLEAR REGULATORY COMMISSION

Original Signed by
Thomas E. Murley
Thomas E. Murley
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 21st day of February 1985