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APPENDIX A

Atlantic City Medical Center
Atlantic City, New Jersey

Docket Nos. 030-02515
030-00361
License Nos. 29-08622-04
29-08622-03

As a result of the inspection conducted on October 13, 1982, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

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, as of October 13, 1982, the Nuclear Medicine Laboratory, which contained millicurie quantities of licensed material, was unlocked when it was not under constant surveillance and immediate control. Additionally, the cobalt-60 unit in Radiation Therapy was not under constant surveillance or immediate control of the licensee as a result of the key being left in the control panel of the unit while the Department was unattended.

This is a Severity Level IV violation. (Supplement IV)

B. 10 CFR 35.14(b)(6) requires that any licensee using byproduct material authorized pursuant to Groups I, II and III of Schedule A of 10 CFR 35.100 for clinical procedures other than those specified in the product labeling (package insert), comply with the product labeling regarding route of administration, unless an IND has been accepted by the FDA for an alternate use.

Contrary to the above, on October 11, 1982, technetium-99m labelled sulfur colloid was used to study gastro-esophageal reflux, a procedure not specified in the product labeling, and the radiopnarmaceutical was administered orally, a route not described in the product labeling, and an IND had not been accepted by the FDA for this use.

This is a Severity Level IV violation. (Supplement VI)

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C. Condition 17 of License No. 29-08622-04 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated March 28, 1979, and letter dated February 21, 1980.

1. Item 17 of the application dated March 28, 1979, requires that surveys be performed in accordance with the "Area Survey Procedures" in Appendix I of Regulatory Guide 10.8.

   Item 1 of Appendix I requires that all elution, preparation and injection areas be surveyed daily. Item 4.b of this appendix requires that weekly surveys include wipe tests.

   Contrary to the above, as of October 13, 1982, injection areas had not been surveyed at weekly intervals, and no wipe tests had been performed since August 13, 1982.

   This is a Severity Level IV violation. (Supplement VI)

2. Item 10 of this application requires that the procedures described in Appendix D, Section 2, of Regulatory Guide 10.8 be used for calibration of dose calibrators.

   Appendix D, Section 2, requires that records be maintained of the results of quarterly linearity tests of dose calibrators.

   Contrary to the above, as of October 13, 1982, no records were maintained of the linearity tests performed in July and September, 1982.

   This is a Severity Level V violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Atlantic City Medical Center is hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.