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APPENDIX A
NOTICE OF VIOLATION

Georgetown University Medical Center
Washington, D.C. 20007

Docket No. 30-01315
License No. 08-C1709-04

As a result of the inspection conducted on August 24, 25, 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, on August 25, 1982, the Nuclear Medicine Laboratory, which contained millicurie quantities of licensed material was unlocked when it was not under constant surveillance and immediate control.

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

- 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.

Contrary to the above, on July 7, 1982, August 9, 1982, August 17, 1982, and August 18, 1982, radiation levels of 1.9 millirem per hour, 2.2 millirem per hour, 2.5 millirem per hour, and 2.8 millirem per hour existed in the hallways outside of the doors of rooms C5-214, M7312, M5614, and M6108, in which patients were undergoing therapy treatment with 77 millicuries of iridium-192, 100 millicuries of iodine-131, 60 millicuries of iridium-192 and 60 millicuries of iridium-192, respectively.

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

- C. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary for you to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of August 25, 1982, daily surveys with a low-range survey meter were not performed in the injection/preparation areas of the Nuclear Medicine Department, weekly surveys were not performed in Room 312 of the Medical-Dental Building where licensed materials are used under Authorization No. 46, and monthly surveys were not performed in the Rooms in the Basic Science Building where licensed material was used under Authorization Nos. 32 and 63. The inspector identified radiation levels of 7 millirem per hour in the Nuclear Medicine hot laboratory, and radiation levels of 3 millirem per hour due to phosphorus-32 contamination in Room 312.

- D. Condition 22 of License No. 08-01709-04 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated May 8, 1980, and letters dated May 20, 1980, October 28, 1980, and ALARA Program dated October 28, 1980.

1. Block 10 of this application requires that the dose calibrator be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8.

Item A.1 of Appendix D, Section 2, requires that the linearity of the dose calibrator be determined at installation and quarterly thereafter.

Contrary to the above, as of August 25, 1982, dose calibrator linearity had not been determined since November 19, 1980, a period of more than a calendar quarter.

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

2. Item 15 of this application requires that the "General Rules for Safe Use of Radioactive Materials," contained in Appendix G of Regulatory Guide 10.8 be followed, with two exceptions.

Item 5 of Appendix G prohibits eating, drinking, smoking, or the application of cosmetics in any area where radioactive material is stored or used.

Contrary to the above, on August 25, 1982, food was being eaten in Room 309 of the Basic Science Building, a room posted with a Caution Radioactive Material sign.

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

3. Item No. 23 of this application contains additional radiation safety procedures for the use of radioactive materials.

Item 5 of these procedures requires that authorized users submit written results of contamination surveys to the Radiation Safety Office and that the Radiation Control Office inspect laboratories at

least quarterly to determine contamination levels, external radiation levels, records, signs, fumes hood function, security and general radiation safety requirements.

Contrary to the above, as of August 25, 1982, over 30 authorized users had not submitted written reports of contamination surveys for the first two quarters of 1982 and the Radiation Control Office inspections were performed annually rather than at a quarterly frequency.

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

Pursuant to the provisions of 10 CFR 2.201, Georgetown University 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.