Appendix

NOTICE OF VIOLATION

Bethesda Hospital License No. 34-16710-01

As a result of the inspection conducted between June 26 and July 11, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

1. License Condition No. 22 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated December 15, 1980 states in Attachment Section 3.3 that the Radiation Safety Officer will conduct a semiannual review of radiation safety surveys performed by the consulting physicist and will review the written report of radiation surveys with the consulting physicist and the technologists. Section 3.4 states, in part, that the Radiation Safety Officer will annually review all reports, including instrument control data and personnel control data.

   Contrary to the above, your Radiation Safety Officer has not been conducting an appropriate review of these survey results and reports since your previous inspection on March 17, 1982.

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

2. 10 CFR 35.14(e)(1)(i) requires that sealed calibration or reference sources possessed pursuant to 10 CFR 35.14(d) be tested for leakage and/or contamination at intervals not to exceed six months.

   Contrary to the above, you have not been performing leak tests on your sealed americium-241 and cesium-137 sources at appropriate intervals. Specifically, these sources have been leak tested only twice since your previous inspection on March 17, 1982.

   This is a repeat item of noncompliance.

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

3. License Condition No. 22 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated December 15, 1980 states in Item 10 that procedures on file in NRC license No. 34-16779-01 will be used to calibrate survey instruments. License Condition No. 16 of license No. 34-16779-01 states that Appendix D procedures of Regulatory Guide 10.8 will be followed for survey instrument calibration. Section 1 of

Appendix D requires that records be maintained of survey instrument calibrations. Section 1 also requires that the exposure rate measured by the instrument differ from the true exposure rate by less than 10 percent. Readings within ±20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within 10 percent for radiation protection purposes.

Contrary to the above, the 1983 calibration records for your Victoreen 493-817 and Victoreen 470A (S/N 1785) were not available during this inspection. In addition, the June 7, 1984 calibration record of your Victoreen 493-817 indicated that the instrument measured up to 40% error from the true exposure rate.

The June 9, 1985 calibration record for this meter indicated that it measured up to 17.5% error from the true exposure rate. The September 1984 calibration record for your Victoreen 470A (S/N 1785) indicated that it measured up to 30% error from the true exposure rate. No calibration chart, graph, or response factor was prepared and used in accordance with Appendix D for the calibrations from 10 to 20% nor were the instruments repaired for differences greater than 20%.

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

4. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated December 15, 1980 states in Item 10 that procedures on file in NRC license No. 34-16770-01 will be used to calibrate the dose calibrator. License Condition No. 16 of license 34-16779-01 states that Appendix D procedures of Regulatory Guide 10.8 will be followed for calibrating the dose calibrator. Appendix D, Section 2, requires that instrument linearity be checked at installation, quarterly thereafter, and following repair. Also, the measured activity should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

Contrary to the above, linearity checks were not performed during six calendar quarters in the last three years. In addition, your linearity check in December, 1984, indicated measured activity in error of up to 75% from the calculated activity; and your linearity check in April 1985, indicated measured activity in error up to 9.9% from the calculated activity. As of the date of inspection, the dose calibrator was in routine use and had not been repaired or adjusted.

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

5. License Condition No. 22 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated December 15, 1980 states in Item 17 that certain appropriate laboratory areas will be surveyed and wipe tested daily for unusual exposure levels and/or contamination.

   Contrary to the above, area surveys and wipe tests are not performed daily. Approximately 30% of the time, when licensed material is routinely used, appropriate laboratory areas are not surveyed and wipe tested.

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

6. License Condition No. 22 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated December 15, 1980 states in Item 21(f) that xenon-133 gas will be adsorbed onto a charcoal trap and monitored periodically to evaluate the trapping efficiency. The effluent will also be collected in a plastic bag and monitored for radioactivity. Whenever the effluent shows increased radioactivity, indicating reduced trapping efficiency, the filters will be replaced.

   Contrary to the above, you have not been monitoring your charcoal trap for evaluation of trapping efficiency, and saturation. Specifically, you have not been surveying the trap, the effluent, or effluent collected in a plastic bag.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

AUG 13 1985

Dated

W. L. Axelson, Chief for
Nuclear Materials Safety and
Safeguards Branch

Appendix B

MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office provides the following as the acceptance criteria for adequate management control for materials licensees. "Management Control" is a system instituted by management to assure that licensed activities are performed safely and in accordance with regulatory requirements (license conditions and applicable regulations).

This will include:

a. Delineation of duties and responsibilities of all persons involved in licensed activities.

b. Providing for indoctrination and training of all personnel performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.

c. Verification, as by checking, auditing and inspecting, that activities affecting safety related functions have been correctly performed. The verifying process should be performed by individuals or groups other than those performing the safety related procedures.

d. Insuring continued compliance of licensed activities throughout periods during which routine activities may be interrupted, such as changes in equipment, personnel or facilities.

Because of the many variables involved, such as the number of personnel, type of activity being performed and the location or locations where activities are performed, the organizational structure for executing the management control program may take various forms; however, irrespective of the organizational structure, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as required to maintain compliance with NRC regulations and license conditions.