

Appendix A

NOTICE OF VIOLATION

Botsford General Hospital

License No. 21-08892-01

As a result of the inspection conducted on February 8, 1983, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. License Condition No. 19 of your license 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 October 4, 1978, states in Item 7 the Medical Isotope Committee will meet quarterly.

Contrary to this requirement, review of records on the day of the inspection, revealed the Committee failed to meet in the first, third and fourth quarter of 1982.

This is a repeat item of noncompliance.

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

2. License Condition No. 19 of your license 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 October 4, 1978, states in Item 12 all clerical, housekeeping and security personnel shall receive instructions pertaining to radioactive material on an annual basis.

Contrary to this requirement, the above named personnel had not received training since October 1981.

This is a repeat item of noncompliance.

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

3. License Condition No. 18 requires that each sealed source containing licensed material, with a half-life greater than thirty days shall be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to this requirement, your americium-241 anatomical marker has not been tested for leakage since at least the date of the last inspection on April 18, 1980. In addition, your 219 microcurie cesium-137

and 270 microcurie barium-133 sources were not tested for leakage between May 1981 and December 1982. These intervals do not meet the semiannual requirement.

This is a repeat item of noncompliance.

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

4. License Condition No. 19 of your license 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 October 4, 1978, states in Item 10.E survey instruments will be calibrated at least annually.

Contrary to this requirement, on the day of the inspection, two Victoreen Frisker survey meters had not been calibrated since August 1980.

This is a repeat item of noncompliance.

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

5. License Condition No. 19 of your license 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 October 4, 1978, states in Item 10 the dose calibrators will be tested quarterly for linearity of response.


Contrary to this requirement, linearity tests of the dose calibrators were not performed between August 1980 and November 1982. This interval exceeds the quarterly requirement.

This is a repeat item of noncompliance.

This is a Severity Level IV violation (Supplement 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.

April 7, 1983
Dated


J. R. Miller, Chief

Materials 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.