Appendix A

NOTICE OF VIOLATION

Crittenton Hospital License No. 21-13562-01

As a result of the inspection conducted on November 17, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. License Condition No. 16 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 September 21, 1979, states in Item 7 that the procedures for the Medical Isotope Committee described in Regulatory Guide 10.8, Appendix B will be followed. Appendix B requires the committee to meet at least quarterly.

   Contrary to the above, the Medical Isotope Committee has met only semi-annually since January 1980.

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

2. License Condition No. 16 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 September 21, 1979, states in Item 10 that survey instruments will be calibrated in accordance with Regulatory Guide 10.8, Appendix D, Section 1. Appendix D, Section 1, requires survey meters to be calibrated annually.

   Contrary to the above, a Victoreen Model 491, G-M survey meter used daily has not been calibrated since September 23, 1981.

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

3. License Condition No. 16 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 September 21, 1979, states in Item 10 that the procedures for calibration of the dose calibrator described in Regulatory Guide 10.8, Appendix D, Section 2 will be followed. Appendix D, Section 2 requires that the dose calibrator be tested for geometrical variation at the time of installation and records maintained of the results.

Contrary to the above, records were not maintained of a geometrical variation test stated to have been performed in August 1981.

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

4. License Condition No. 16 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 September 21, 1979, states in Item 14 that procedures described in Regulatory Guide 10.8, Appendix F will be followed for safely opening packages. Appendix F requires that all incoming packages be surveyed at three feet, the surface, and that the final source container be wipe tested.

Contrary to the above, surveys at three feet from incoming packages and wipe tests of final source containers have not been performed since the requirement began in February 1980.

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

5. License Condition No. 16 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 September 21, 1979, states in Item 17 that surveys will be performed in accordance with Regulatory Guide 10.8, Appendix I. Appendix I requires elution, preparation and injections areas be surveyed daily with a G-M survey meter.

Contrary to the above, daily wipe tests were performed in these areas but G-M surveys were not performed daily since the requirement began in February 1980.

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

6. 10 CFR 20.401(c)(3) states records of disposal of licensed material made pursuant to 20.302 are to be maintained until the Commission authorizes their disposition. Under 20.302 the licensee has applied for approval to dispose of radioactive waste by the decay in storage method and was given approval by License Condition No. 16 which references the disposal procedures in the letter dated August 12, 1980.

   Contrary to the above, the licensee failed to maintain records of the disposal by decay of technetium-99m products such as unused kits, used vials, syringes and needles.

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

7. License Condition No. 16 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 letter dated August 12, 1980, states that records containing the date, activity and initials of personnel disposing of columns are kept for all disposal vials.

   Contrary to the above, records were not maintained of the results of surveys stated to have been performed on technetium-99m products such as vials, syringes, and needles.

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

8. 10 CFR 20.203(f)(4) states each licensee shall prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

   Contrary to the above, on November 17, 1982, a box marked with a Radioactive Yellow II label was discarded into ordinary trash and disposed of to an unrestricted area and the label was not defaced nor was there any clear indication that the container no longer contained radioactive material.

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

9. License Condition No. 9.D authorizes the possession of any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35 for storage only.

Contrary to the above, Group VI sources were used for patient treatment. Specifically, on November 20, 1980, a patient was treated with 13 millicuries of iodine-125 as permanent implant seeds.

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

10. 10 CFR 35.14(b)(6) requires that for Groups I, II and III any licensee using byproduct material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the labeling regarding:

(1) Chemical and physical form;
(ii) Route of administration; and,
(iii) Dosage range.

Contrary to this requirement, it was determined through statements by licensee representatives that during the last year, two intracatheterizations of the urinary bladder (Cystograms) were performed. This procedure is not described in the manufacturer's package insert as an authorized route of administration.

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

11. License Condition No. 14.a states for a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician has the prior written permission of the hospital's administrator and its Medical Isotopes Committee.

Contrary to the above, a visiting physician who used iodine-125 for a patient treatment on November 20, 1980, did not have prior written permission of the hospital's administrator or the Medical Isotopes Committee.

This is a Severity Level V 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.

DEC 28 1982

Dated

ORIGINAL SIGNED BY
JAMES R. MILLER

J. R. Miller, Chief
Technical Programs 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.