Appendix A

NOTICE OF VIOLATION

Toledo Hospital

License No. 34-01710-05
License No. 34-01710-07

Based on the inspection conducted on April 14, 1981, it appears that certain of your activities were in noncompliance with NRC Requirements, as noted below. Items 1 through 6 and Item 8 are infractions. Item 7 is a deficiency.

License No. 34-01710-05

1. 10 CFR 20.101(a) limits the whole body exposure of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b). Paragraph (b) allows a whole body exposure of three rems per calendar quarter provided certain specified conditions are met.

   Contrary to this requirement, an individual working in your restricted area received a whole body radiation dose of 2.350 rems during the second calendar quarter of 1979, and the conditions of paragraph (b) were not met.

2. 10 CFR 20.405(a) requires that you submit within 30 days a report to the Commission concerning each exposure to radiation in excess of any applicable limit in Part 20 or in your license. 10 CFR 19.12(a) requires that this report be submitted to the individual exposed.

   Contrary to these requirements, as of April 14, 1981, you failed to report to the Commission, and to the individual exposed, the exposure described in Item 1 above.

. Condition No. 17 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 March 13, 1978, states in Item No. 10, Appendix D, page 3, that a linearity test of the dose calibrator will be conducted quarterly.

   Contrary to the above, based on a licensee representative's statements and a review of records the dose calibrator was not calibrated for linearity from June 15, 1980, to the date of this inspection.

4. Condition No. 17 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 March 13, 1978, states in Item No. 7, Appendix A, page 3, that the Medical Isotope Committee shall meet as often as necessary, but not less than once in each calendar quarter.

   Contrary to the above, the Medical Isotope Committee did not meet from July 7, 1980, to the date of the inspection.

5. Condition No. 17 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 letter dated March 13, 1978, states in Item No. 14, Appendix H, that on receipt, packages containing radioactive material will be surveyed at three feet and at the surface, and surveyed for contamination on the external surface of the final source container.

   Contrary to the above, iridium-192 seeds and cesium-137 sources received during 1980, were not surveyed for radiation levels or contamination as required above.

6. 10 CFR 35.14(b)(5)(v) requires that your sealed sources possessed and used as per Schedule A of 10 CFR 35.100 under Group VI be physically inventoried once each calendar quarter to account for all the sources received and possessed.

   Contrary to this requirement, from the date of license issuance to April 14, 1981, physical inventories on cesium-137, strontium-90, and iridium-192 sources have not been performed once each quarter. Specifically, no inventories have been performed from the date the sources were received until the date the sources were returned, a period in excess of one quarter.

7. 10 CFR 35.14(b)(5)(ii) requires that records of leak test results be kept in units of microcuries.

   Contrary to this requirement, records of leak tests done every six months on a cesium-137 and a barium-133 source from February 1977, to the date of this inspection were not maintained in units of microcuries.

License No. 34-01710-07

8. Coudition No. 24 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, 1979, states in Item 11 a Victoreen Model 470-A survey meter will be calibrated yearly.

Contrary to the above, the licensee stated the Victoreen 470-A used for surveying was not calibrated from January 1979, to the date of this inspection.

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. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation. Consideration may be given to extending your response time for good cause shown.

Dated 6/26/81

D. J. Sreniawski

D. J. Sreniawski, Chief
Materials Radiation Protection
Section 2

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.