NOTICE OF VIOLATION

Northeastern Ohio General Hospital License No. 34-16763-01

As a result of the inspection conducted on January 15, 1986, and in accordance with the "General Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1985), the following violations were identified:

1. License Condition No. 17 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 January 28, 1981 states that Appendix B of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix B requires that the medical isotopes committee meet at least quarterly and that records of these meetings be maintained.

   Contrary to the above, a licensee representative stated that the medical isotopes committee has not met formally since April 1984.

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

2. 10 CFR 19.12 requires that all individuals working in a restricted area be instructed in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

   Contrary to the above, the technician in your nuclear medicine department did not know which constancy readings would indicate a need for adjustment of your dose calibrator (a protective device). In addition, this technician did not know what ALARA or the regulations in 10 CFR 19 and 20 referred to.

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

3. License Condition No. 17 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 January 28, 1981 states that Appendix G of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix G requires that food cannot be stored with radioactive material.

   Contrary to the above, on the day of the inspection, two containers of french onion dip were stored in a refrigerator in your hot-lab and imaging room. The refrigerator and the room were posted with "Caution: Radioactive Material" signs and radioactive material was being stored in the room.

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

4. License Condition No. 17 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 November 10, 1982 states that Appendix D of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix D requires that survey meters be calibrated at least annually.

   Contrary to the above, your survey meter has not been calibrated since April 11, 1984, an interval of nearly two years.

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

5. License Condition No. 17 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 November 10, 1982 states that Appendix D of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix D requires that the predicted activity compared with the measured activity, be accurate to within 5% for each source used in the daily constancy test of the dose calibrator. In addition, Appendix D requires that the test for dose calibrator linearity should be performed quarterly and that the test for dose calibrator accuracy should be performed annually.

   Contrary to the above, none of these requirements were being met.

   This is a repeat violation.

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

6. License Condition No. 17 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 November 10, 1982 states that Appendix F of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix F requires that a wipe of the external surface of the final source container of incoming radioactive material packages be assayed for amount of removable radioactivity.

   Contrary to the above, a licensee representative stated that wipes of final source containers have not been taken for three years.

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

7. License Condition No. 17 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 January 28, 1981 states that Appendix G of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix G requires that personnel wear TLD finger badges during preparation, assay, and injection of radiopharmaceuticals.

Contrary to the above, the technician in the nuclear medicine department has not been provided with a TLD finger badge since beginning work in the department in October 1985.

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

8. License Condition No. 17 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 January 28, 1981 states that Appendix I of Regulatory Guide 10.8, Revision 1, dated October 1980 will be followed. Appendix I requires that a permanent record of all survey results will be maintained and that this record should include the name of the person conducting the survey, the serial number and counting efficiency of equipment used for the survey, and the results of wipe tests.

Contrary to the above, records of daily surveys for the past three years were not maintained, and records of weekly and monthly surveys for the past three years did not include the name of the person conducting the survey, the serial number and counting efficiency of survey equipment, and the results of wipe tests.

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 violation: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

2/11/86
Dated

W. L. Axelson, Chief
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.