Appendix A

NOTICE OF VIOLATION

Trumbull Memorial Hospital

License No. 34-02400-02
License No. 34-02400-03

As a result of the inspection conducted on February 10 and 23, 1983, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

License No. 34-02400-03:

1. 10 CFR 35.25(c) requires each teletherapy licensee to maintain records of their evaluation of the qualified expert's training and experience under 35.24.

   Contrary to the above, as of the day of the inspection, no records of evaluation of your current qualified expert's (radiological physicist) training and experience were available. You assumed that your current consulting physicist met the requirements of 10 CFR 35.24.

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

License No. 34-02400-02:

1. 10 CFR 20.105(b) requires that radiation levels in unrestricted areas be limited so that if an individual were continuously present in the area, he could not receive a dose in excess of 2 millirems in any hour or 100 millirems in any seven consecutive days.

   Contrary to this requirement, on September 21-22, 1982, inspector calculations and surveys indicated that radiation levels in unrestricted areas existed of such a magnitude that if an individual had been continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour. Specifically, NRC surveys performed on February 23, 1983, simulating the conditions of September 21-22, 1982, showed that radiation levels in an unoccupied patient room adjacent to an iodine-131 therapy patients room, were approximately 60 millirems per hour.

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

2. 10 CFR 20.201(b)(1) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to this requirement, you failed to make such surveys as were necessary to determine that individuals who handled millicurie quantities of iodine-131 were not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103, "Exposure of individuals to concentrations of radioactive materials in air in restricted areas." Specifically, on September 21, 1982, a dose of 103 millicuries of iodine-131, in liquid or uncontained form, was orally administered to a patient without the performance of surveys (evaluations, such as thyroid monitoring) on the technologist administering this dose. This particular dose was opened and administered in the patient's private room. Also, lesser doses of iodine-131, typically 10 millicuries, have been administered in your Nuclear Medicine scanning room on numerous occasions, without the performance of bioassays.

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

3. License Condition No. 17 requires that licensed material be possesed and used in accordance with statements, representations, and procedures contained in application dated March 9, 1979; and various dated letters.

The above referenced application, Item 10, requires that the procedures described in Appendix D of the NRC Medical Licensing Guide, Revision 1, dated November 1, 1977 will be followed for calibration of the dose calibrator. This guide requires that daily constancy and quarterly linearity checks of the dose calibrator be performed and recorded. The constancy check should be performed on all of the commonly used radionuclide settings.

Contrary to this requirement, constancy checks were not extended to include all of the commonly used radionuclide module settings and linearity tests have not been performed quarterly. Specifically, linearity checks have been performed only twice since January 1980.

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 statements, representations, and procedures contained in application dated March 9, 1979; and various dated letters.

The above referenced application, supplemental Item 21, "Procedures and Precautions for use of Xenon-133", requires all exhaust vents to be checked twice a year to confirm their efficiency. Records verifying these procedures will be maintained.

Contrary to the above requirement, it was learned from statements of licensee representatives, that exhaust vents (i.e., fume hood) have not been checked for efficiency since the inception of this requirement.

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

5. 10 CFR 35.14(e) 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 this requirement, as of the day of the inspection, leak tests have not been performed on your nominal 214 microcurie cesium-137 dose calibrator reference sources since initially leak tested by the manufacturer in March 1978.

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

6. License Condition No. 17 requires that licensed material be possesed and used in accordance with statements, representations, and procedures contained in application dated March 9, 1979; and various dated letters.

The above referenced application, Item 17, requires that the survey procedures described in Appendix I of the NRC Medical Licensing Guide, Revision 1, dated November 1, 1977 will be followed. Appendix I requires that weekly surveys include a series of wipe test to measure contamination levels.

Contrary to this requirement, area wipe tests have not been performed since inception of this requirement.

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

7. License Condition No. 17 requires that licensed material be possesed and used in accordance with statements, representations, and procedures contained in application dated March 9, 1979; and various dated letters.

The above referenced application, supplemental Item 12, requires all personnel (technologists) to participate in monthly in-service programs with the Radiation Safety Officer to insure knowledge of current uses of radioactive materials, changes in duties, regulations, and terms of the NRC license. This was confirmed in your letter dated May 24, 1979, Item 2B.

Contrary to this requirement, it was learned through statements of licensee representatives, that in-service radiation safety training programs, or their equivelent, have not been given for at least one year.

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

8. License Condition No. 17 requires that licensed material be possesed and used in accordance with statements, representations, and procedures contained in application dated March 9, 1979; and various dated letters.

   The above referenced application, Item 10, states that survey instrument calibrations will be performed at two points on each scale.

   Contrary to the above, survey instrument calibrations are currently performed at one point on each scale.

   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.

MAR 2 3 1983

ORIGINAL SIGNED BY
JAMES R. MILLER

Dated

J. R. Miller, Chief
Division of Radiological and Materials
Safety Program, Branch No. 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.