NOTICE OF VIOLATION

Luther Hospital

License No. 48-02122-04
License No. 48-02122-05

As a result of the inspection conducted on September 1, 1988, and in accordance with 10 CFR Part 2, Appendix C - General Statement of Policy and Procedure for NRC Enforcement Actions (1988), the following violations were identified:

License No. 48-02122-05

1. 10 CFR Part 35.59(g) states that each licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession.

   Contrary to the above, cesium-137 brachytherapy sources were not inventoried as required from August 1987 to January 12, 1988 and from January 12 to July 1, 1988, periods exceeding one quarter.

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

2. 10 CFR Part 35.415(a)(4) states that for each patient receiving implant therapy a licensee shall promptly, after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20 of this chapter. A record of each survey is to be retained for two years.

   Contrary to the above, you failed to make surveys as were necessary to show compliance with 10 CFR Part 20.105(b)(1), which states no licensee shall possess or use licensed material in such a manner as to create in any unrestricted area radiation levels which, if a person were continuously present in the area, could result in an individual receiving a dose in excess of two millirems in any one hour. Specifically, during a cesium-137 implant performed on August 9, 1988 a survey was not conducted in contiguous unrestricted areas. On July 12, 1988 and August 8, 1988, records of implant surveys performed in contiguous areas were not retained.

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

3. 10 CFR 35.70(f) requires the licensee to conduct the contamination surveys required by Paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

Contrary to the above, since the inception of the requirement on April 4, 1988, the licensee has analyzed contamination survey wipe samples with a Victoreen Thyac III G-M survey meter which is not capable of detecting 2000 disintegrations per minute.

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

4. 10 CFR Part 35.59(h) requires a licensee in posse sion of a sealed source or brachytherapy source to measure the ambient dose rates quarterly in all areas where such sources are stored.

Contrary to the above, the licensee has not performed ambient dose rate measurements in the cesium-137 brachytherapy source storage area since the date the requirement became effective on April 4, 1988.

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

5. 10 CFR Part 35.60 requires a licensee to conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical.

Contrary to the above, the licensee has not conspicuously labelled each syringe, or syringe shield that contains a syringe with a radiopharmaceutical since the requirement began on April 4, 1988.

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

License No. 48-02122-04

6. License Condition No. 15 states the license is based on the licensee's statements and representations listed in letter dated July 20, 1987. Exhibit No. II of letter dated July 20, 1987, states that emergency dry run procedures are conducted once every six months so all staff members are thoroughly familiar with emergency procedures.

Contrary to the above, emergency dry run exercises have not been performed since June 10, 1987.

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 violation: (1) the

corrective actions that have been taken and the results achieved; (2) the corrective actions that will 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.

October 7, 1988
Dated

Bruce S. Mallett, 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.