NOTICE OF VIOLATION

Hurley Medical Center
Flint, Michigan

License No. 21-00338-02
Docket No. 030-01993

During an NRC inspection conducted from March 1-14, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

1. 10 CFR 35.32(a)(1) requires, in part that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objectives that: (1) prior to administration, a written directive is prepared for any brachytherapy, or administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, or any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131; (2) prior to each administration, the patient's identity is verified by more than one method; (3) final plans of treatment and related calculations for brachytherapy are in accordance with the written directive; (4) each administration is in accordance with the written directive; and (5) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

   Contrary to the above, between January 8, 1992, and March 1, 1994, the licensee did not establish and maintain a written quality management program to provide high confidence that byproduct material would be administered as directed by the authorized user.

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

2. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

   Contrary to the above, as of January 8, 1992, the licensee had not developed procedures for conducting a review to verify compliance with the licensee's quality management program.

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

3. 10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of Radiation Safety Officer, the radiation safety program.

   Contrary to the above, from February 27, 1992 until March 1, 1994, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

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

4. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

   Contrary to the above, from at least February 27, 1992 to March 2, 1994, the licensee did not survey with a radiation detection survey instrument the radioactive waste storage room, an area where radiopharmaceutical waste is stored.

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

5. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

   Contrary to the above, from at least February 27, 1992 to March 2, 1994, the licensee did not survey for removable contamination in the radioactive waste storage room, an area where radiopharmaceuticals were routinely stored.

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

6. 10 CFR 35.70(h) requires in part that a record of each survey be made that includes the trigger level established for each area.

   Contrary to the above, no trigger level was indicated on the records of contamination surveys that were made since at least February 27, 1992.

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

Pursuant to the provisions of 10 CFR 2.201, Hurley Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated 5/25/94

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosure 2

During this inspection, the inspector identified that the quality management program you submitted in January 8, 1992, did not provide the essential elements of policies/procedures that indicate how you will meet the objectives listed in 10 CFR 35.32. Please provide policies and procedures that will meet the requirements for each modality of use.

1. You must have policies and procedures that require the preparation of written directives prior to the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 (10 CFR 35.32(a)(1)). The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared prior to each patient administration.

2. Your written directive for radiopharmaceutical therapy for a radiopharmaceutical other than sodium iodide I-125, or I-131 does not include the radiopharmaceutical, the dosage, and the route of administration as defined in 10 CFR 35.2.

3. 10 CFR 35.32(a)(1) requires that QMPs for brachytherapy include a procedure for the preparation of written directives prior to administration of any brachytherapy dose. The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared for each patient.

4. Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10 CFR 35.2, must include:

   a. Prior to implantation: the radioisotope, number of sources, and source strengths; and

   b. After implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

   Your QMP must include a written policy/procedure that requires that any written directives for brachytherapy doses will include all treatment parameters prior to administration.

5. Written directives for high-dose-rate remote afterloading brachytherapy must include the total dose, dose per fraction, treatment site and overall treatment period as defined in 10 CFR 35.2. Your QMP must include a written policy/procedure that requires that all written directives for brachytherapy doses at your facility will include all treatment parameters prior to administration.

6. Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. Your QMP should include a policy/procedure that requires that revisions to written directives will be made prior to administration.

7. Revisions to written directives for brachytherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Your QMP should include a policy/procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose, or the next brachytherapy fractional dose.

8. Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each brachytherapy or radiopharmaceutical administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

9. Your submittal does not include adequate policies/procedures that ensure that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should include:

   a. a plan of treatment will be prepared in accordance with the respective written directive;

   b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations);

   c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources;

   d. performance of acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations.

10. Your submittal for radiopharmaceutical administration does not include adequate policies/procedures to ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive.

11. Your submittal for brachytherapy does not include adequate policies/procedures to ensure that each administration is in accordance with the written directive. Your procedures should include:

    a. verification, before administering each brachytherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

    b. procedures for checking the dose calculations before administration of the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations.

    c. prompt recording, by the authorized user, of the number of sources, the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record, and the method for verification that the sources have been loaded in the correct position.

12. Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive.

13. A commitment to maintain a written record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d)(2). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.

14. Your QMP must include a commitment to maintain a written record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d)(2). Your QMP should describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

15. Your QMP for brachytherapy and radiopharmaceutical therapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5).

16. Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

17. Your submittal for brachytherapy and radiopharmaceutical therapy does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). Your procedure should include the time intervals for your reviews (in months) and describe your representative sample. These reviews should be conducted at intervals no greater than 12 months. Program reviews must include an evaluation of a representative sample of all patient administrations, and should include all recordable events and misadministrations. Your QMP review should include provisions to expand the review in the event that unidentified reportable events or misadministrations are found. Your QMP should describe your procedure for evaluating each of these reviews, and for making modifications to meet the objective of the QMP. Regulatory Guide 8.33, Section 6 (enclosed) may be of help in developing procedures for review of your QMP.

18. Your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP.

19. Your QMP must include procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

20. Please include a provision to submit modifications to your QMP to the NRC within 30 days after the modification has been made.

21. Your QMP must include assurance that records of each review and evaluation must be maintained for three years.

22. Multiple misadministrations and other errors have occurred due to sources that are inaccurately placed or have moved. In addition, wrong organs have been irradiated as a result of unintentional and undetected movement of the source, once implanted. Each licensee should review their procedures to ensure that source positions are verified and frequently checked.

Your response to Violations 1. and 2. of the attached Notice of Violation must include the information requested above.