

JE-0711
PUBLIC

MAY 27 1994

Hurley Medical Center
ATTN: Apparad Mukkamala, M.D.
Chairman, Department of
Radiology
One Hurley Plaza
Flint, MI 48502

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

Dear Dr. Mukkamala:

SUBJECT: NOTICE OF VIOLATION DATED APRIL 13, 1994

This refers to our letter dated April 13, 1994, transmitting a Notice of Violation, and to a teleconference between Dr. Sudhakara Dandala, Hurley Medical Center Radiation Safety Officer and Mr. John D. Jones of my staff on May 16, 1994.

Due to an administrative error in the last paragraph of the Notice of Violation we failed to specify Hurley Medical Center as the licensee required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrentonville Road, Lisle, Illinois. We have enclosed a corrected copy of the letter with the NOTICE OF VIOLATION.

We have reviewed your corrective actions stated in your letter dated May 5, 1994 and have determined that they fail to provide all of the information required.

1. In your response, you failed to state the reason for each violation.
2. In your response, you failed to indicate the corrective steps which will be taken to avoid future violations. Your letter addresses the specific cases but fails to describe the method you will use to assure that license conditions and NRC regulations are understood and followed by your staff in the future.
3. As stated in Enclosure 2 of our letter dated April 13, 1994, the inspector identified that the quality management program you submitted on 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. Specifically, you failed to provide the required information described in Enclosure 2 in response to Violations 1. and 2. of the attached Notice of Violation.

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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, 60532-4351, within 15 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.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

Sincerely,

Original Signed by John R. Madera for
 Roy J. Caniano, Chief
 Nuclear Materials Safety Branch

Enclosure: Notice of
 Violation

bcc w/enclosure:
 Fred Combs, NMSS
 PUBLIC

RIII
[Signature]
 Jones/jaw
 05/23/94

RIII
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 DeFayette
 05/25/94

RIII
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 Caniano
 05/25/94

APR 13 1994

Hurley Medical Center
ATTN: Apparad Mukkamala, M.D.
Chairman, Department
of Radiology
One Hurley Plaza
Flint, MI 48502

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

Dear Dr. Mukkamala:

This refers to the routine safety inspection conducted by John D. Jones of this office from March 1-14, 1994, of activities authorized by NRC Byproduct Material License No. 21-00338-02 and to the discussion of our findings with you and other members of your staff on March 2, 1994.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspectors examined actions described in your letter dated March 25, 1992, regarding violations found during our February 27, 1992, inspection. We have no further questions regarding these matters.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

With regard to violations 1. and 2., pertaining to your Quality Management Program (QMP) you submitted January 8, 1992, we have determined a number of deficiencies. These are described in the enclosed attachment to this letter as Enclosure 2. Please refer to this and the enclosed Regulatory Guide 8.33 in responding to this letter and the Notice of Violation.

In addition to the above, the inspector expressed concern that the Radiation Safety Officer (RSO), may have insufficient time to devote to his responsibilities as RSO as required under Subpart B, General Administrative Requirements 10 CFR 35.21. In addition to his job as RSO, he is currently acting as the only Physicist for the oncology department. The dividing of his time between the two jobs may be having a deleterious effect on performance as RSO as evidenced by the increased number of apparent violations since the last inspection. In your response to this letter and Notice of Violation please describe what actions you will take or have been taken to ensure that radiation safety activities are being performed in accordance with license commitments and the regulations.

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APR 13 1994

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed by

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosures:

- 1. Notice of Violation
- 2. Regulatory Guide 8.33
- 3. Enclosure 2

bcc w/enclosures:
Fred Combs, NMSS
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RIII
[Signature]
Jones/jaw
05/24/94

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Caniano
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