U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Reports No. 030-03444/94002(DRSS);
030-11119/94002(DRSS); 030-17197/94002(DRSS)

Docket Nos. 030-03444; 030-11119; 030-17197

Licenses No. 48-04193-01; 48-04193-03; 48-04193-04

Licensee: Milwaukee County Medical Complex
8700 W. Wisconsin Avenue
Milwaukee, Wisconsin 53226

Enforcement Conference Conducted: May 23, 1994

Enforcement Conference At: NRC Region III Office, Lisle, Illinois

Inspection Conducted: March 21-24, 1994 with continuing NRC review through April 14, 1994

Inspectors: _____ 6/9/94
W. Reichhold Date
Radiation Specialist

_____ 6/9/94
S. Mulay Date
Radiation Specialist

_____ 6/9/94
R. Gattone Date
Radiation Specialist

Reviewed By: _____ 6/9/94
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: _____ 6/9/94
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Meeting Summary

Enforcement Conference on May 23,1994, Reports No. 030-03444/94002(DRSS); 030-11119/94002(DRSS); 030-17197/94002(DRSS))
Areas Discussed: A review of the apparent violations and areas of concern identified during the inspection, and corrective actions taken or planned by the licensee. The enforcement options pertaining to the apparent violations were also discussed with the licensee.

DETAILS

1. Persons Present at Conference

Licensee Attendees

S. Tomkalski, Associate Administrator/Hospital Services
B. David Collier, M.D., Chairman Radiation Safety Committee
R. Grunewald, Ph.D., Radiation Safety Officer
J. McClutchy, Corporate Counsel, Milwaukee County

NRC Attendees

R. W. DeFayette, Director, Enforcement and Investigation Coordination Staff
R. J. Caniano, Chief, Nuclear Materials Safety Branch
B. J. Holt, Chief, Nuclear Materials Inspection Section 1
W. P. Reichhold, Radiation Specialist
S. Mulay, Radiation Specialist
R. Gattone, Radiation Specialist

2. Enforcement Conference

An enforcement conference was held in the NRC Region III office on May 23, 1994. This conference was conducted as a result of the preliminary findings of the inspection conducted on March 21-24, 1994 through April 14, 1994, in which apparent violations of NRC regulations and license conditions were identified. Inspection findings are documented in Inspection Reports No. 030-03444/94001(DRSS); 030-11119/94001(DRSS); 030-17197/94001(DRSS) which was transmitted to the licensee on May 16, 1994.

The purpose of this conference was to: (1) discuss the apparent violations, causes, and the licensee's corrective actions; (2) discuss several areas of concern; (3) determine if there were any escalating or mitigating circumstances; and (4) obtain any additional information which would help determine the appropriate enforcement action.

During the conference, the licensee's representatives indicated that Section 8 of the aforementioned inspection report should have clearly emphasized that the authorized user in question was authorized to use iridium-192. According to the licensee, this fact was not obvious when reading the report. The licensee's representatives also expressed concern with Section 13 of the inspection report pertaining to the completeness of information on the written directive. According to the licensee, abbreviations such as H and N for head and neck are common in the medical profession and should be allowed on the written directive. Also, the written directive form used for brachytherapy eye treatments implies the use of iodine-125 if no other isotope is specified (see Attachment 1). Therefore, according to the licensee, iodine-125 does not need to be circled or otherwise highlighted. Finally, the licensee

representatives stated that for brachytherapy implants, the iridium-192 ribbon is considered the source and not the individual seeds. The number of ribbons is specified on the written directive instead of the number of seeds because the ribbons are purchased to specified lengths with a standard number of seeds per active length of ribbon. The licensee also indicated that because of ALARA considerations, the individual seeds contained in the ribbon are not counted.

The licensee's representatives did not contest any other violations or the concerns noted in the inspection report.

The licensee's representatives described the events which lead to the violations, including root causes and corrective actions taken. In summary, the corrective actions include the following:

(1) The teletherapy room was equipped with an extra warning light to indicate when the source is in an unshielded position.

(2) The Radiation Safety Department will improve the audit program in the Radiation Oncology Department.

(3) All work on teletherapy units will be performed by a person authorized by the NRC or an Agreement State to perform such activity. The licensee's administration will also approve all work on teletherapy units.

(4) The licensee is developing a policy and procedure for the override or bypass of the door interlock for the teletherapy unit.

(5) Radioactive material in the research laboratories and halls will be secured from unauthorized removal. The Radiation Safety Department staff will conduct "walk around" audits to ensure radioactive material has been secured.

(6) The licensee submitted a request for an exemption to Part 36 for its teletherapy units.

(7) The Radiation Safety Department will use its newsletter to communicate regulatory requirements and the results of the NRC inspection to users and other key individuals.

The NRC staff acknowledged the licensee's statements and indicated that they would be considered in the NRC's decision for enforcement action.

3. Concluding Statement

NRC representatives summarized the NRC Enforcement Policy and process and indicated that the licensee will be notified in writing of NRC's proposed enforcement actions.

Attachment: As stated

ATTACHMENT 1

Brachytherapy Working Directive
Eye Application

Patient Name: MRN:
Staff Resident:
Treatment Site: _____

Initial Request
Applicator: _____
Isotope: I 125 or _____ Number of Sources: _____
Source Pattern and Activities: (If needed, use a separate sheet)
COMS: 12 mm, 14 mm, 16 mm, 18 mm, 20 mm

Custom Plaque Total Measured Activity: ____mCi

_____ _____, M.D. Date: _____

During Implant

Changes in above: No Yes

Insertion Date and Time: _ _____,_____AM, PM

Projected total time (hrs): _____

_____, M.D. Date: _____

At Completion of Implant

Changes in Above: No Yes

Removal Date and Time: _____,_____AM, PM

Actual Total Time (hrs): _____

Actual Total Time (hrs): _____

_____, M.D. Date: _____