

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-00252/94002(DRSS)

License No. 21-00299-06

EA No. 94-168

Licensee: Sinai Hospital
6767 West Outer Drive
Detroit, MI 48235

Meeting Conducted: September 8, 1994

Type of Meeting: Enforcement Conference

Inspector: Michael F. Weber
Michael F. Weber
Radiation Specialist

9/14/94
Date

Reviewed By: John A. Grobe
John A. Grobe, Chief
Nuclear Materials Inspection
Section 2

9/21/94
Date

Approved By: Roy J. Caniano
Roy J. Caniano, Chief
Nuclear Materials Safety Branch

9/21/94
Date

Meeting Summary

Enforcement Conference on September 8, 1994 (Report No. 030-00252/94002(DRSS))

Areas Discussed: This conference included a review of the apparent violation and area of concern identified during the special inspection of Sinai Hospital on July 29 through August 12, 1994, and the corrective actions taken or planned by the licensee. The enforcement options pertaining to the apparent violation were also discussed.

Details

1. Conference Attendees

Sinai Hospital

Robert Reed, M.D., Executive Vice President, Medical Affairs
James Schoeck, Vice President, Professional Services
Andrew Saxe, M.D., Chairman, Radiation Oncology
Praveen Dalmia, Radiation Safety Officer, Medical Physicist

U.S. Nuclear Regulatory Commission

Charles Weil, Senior Enforcement Specialist, Region III
John A. Grobe, Chief, Nuclear Materials Inspection Section 2, Region III
Michael F. Weber, Radiation Specialist, Region III
Thomas F. Young, Radiation Specialist, Region III
Dennis I. Serig, Senior Human Factors Analyst, Office of Nuclear
Material Safety and Safeguards

2. Enforcement Conference Summary

An enforcement conference was held in the NRC Region III office on September 8, 1994, as a result of the preliminary findings of the inspection performed on July 29 through August 12, 1994, in which one apparent violation of NRC requirements and one area of concern were identified. These preliminary findings were documented in Inspection Report No. 030-00252/94001(DRSS) which was sent to the licensee on September 2, 1994.

The purposes of this conference were to: (1) discuss the apparent violation and area of concern, the root causes, safety significance and the licensee's corrective actions; (2) determine if there were any escalating or mitigating circumstances; (3) provide the licensee an opportunity to point out any errors in our inspection report; and (4) obtain any other information which would help determine the appropriate enforcement action.

The licensee representatives indicated that they were in agreement with the NRC's understanding of the facts pertaining to the apparent violation, except for a few minor details concerning the teletherapy incidents.

The licensee stated that the major cause of the apparent violation was failure to follow the written Quality Management Program, which, in turn, was due to skill-based human errors. The long term corrective actions were presented (these are listed in Inspection Report No. 030-00252/94001(DRSS)). In addition, a review of these corrective actions, etc., by an outside expert was presented (enclosed).

The meeting was closed by NRC representatives with a discussion of the NRC Enforcement Policy. The licensee was told that further enforcement actions were possible, and they would be notified in the near future of the final enforcement action.

Enclosure: Consultant Physicist's Report

Catherine Alekhteyar, MS
7649 Cedar Elm
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September 7, 1994

Phillip S. Schaengold, J.D.
President and Chief Executive Officer
Sinai Hospital of Detroit
6767 West Outer Drive
Detroit, MI 48235

Dear Mr. Schaengold:

I have reviewed the findings, conclusions, and recommendations of the Sinai Hospital Radiation Safety Sub-Committee regarding the recent Co-60 teletherapy misadministrations in the Radiation Therapy Department. My comments and observations are as follows:

1. Given that the patient load was very low on the cobalt machine, that the therapists had complete control of their machine's schedule, and that the therapists assigned to the machine had no responsibilities elsewhere which may have distracted them from their duties, it is difficult to imagine what might have led to these misadministrations. Although it was mentioned that the setups were perhaps complex, involving the use of immobilization devices, cast blocks, wedges, collimator and gantry angles, these techniques are actually quite standard in the field, and any registered therapist would be well aware of this. A therapist from a different background who is trained in-house might not know what procedures are common elsewhere. It is a standard part of the therapist's job to be able to keep track of the many parameters involved in patient setups. Additionally, properly trained therapists might better appreciate the possible severity of the impact of a misadministration caused by parameter oversight. As Sinai has already recommended, properly trained, registered therapists are an essential part of a quality program.
2. There seems to be some concern over the number of changes which have taken place in the Radiation Therapy Department in the recent past. However, these changes reflect the clinical progress toward the development of a high quality, competitive department. It should be mentioned that of the 9 currently employed therapists, 5 have been hired within the past year and had never known the "old" department (i.e., these people never observed the departmental changes since they were already in place when they were hired.) Note also that all therapists involved in the misadministrations were the remaining 4 out of 9 who are not registered. Also, the fact that some treatment protocols were recently changed should have had little impact on the therapists' job demands. Treatment protocols for various disease sites generally vary in the dosage and/or fractionation pattern, not so much in the use of unfamiliar beam arrangements or associated setup parameters.
3. The decision to assign certain therapists to a single machine on a long-term basis is a good one because it provides continuity for both the patient and the therapy staff. The additional requirement that a therapist who is familiar with a particular patient case must be present at the time of setup and treatment also enhances the ease of flow of information regarding the particulars of that specific setup. Both of these steps should help minimize the potential for error.

4. The new requirement that 2 therapists be present for each *entire* setup and that an almost double-blind double check procedure will be performed in each case goes well beyond the standard of care and should be an additional step toward the reduction of human error. This process adds to the setup time, but is effectively used in many stereotactic radiosurgery procedures, whereby a high dose of radiation is delivered in a single fraction. In these instances it is critical that all setup parameters are exactly in place prior to treatment.

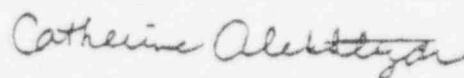
5. Two out of the 3 misadministrations were associated with a filming process. The current filming routine appears to be designed to save some time by first treating a port, opening the collimator jaws for the second exposure, setting up for the next port while maintaining the wide jaw setting, then treating the subsequent port with its proper collimator setting and associated blocking device. Filming sequences which alternate the order of the film/treatment process are confusing and can lead to additional oversights such as those discovered in these cases. I strongly recommend that a regular filming sequence be established, such that all filming take place *prior* to the treatment of its associated port.

6. The record and verify system (RVS) which is currently being retrofitted to the Co-60 unit illustrates a positive commitment by the hospital toward further minimizing treatment setup errors, especially given that the retrofit process has not been previously performed in the US, and that these devices are not commonly employed with Co-60 units. The RVS is capable of detecting errors in field size, collimator and gantry rotation, wedge identification, specific blocking devices, and timer setting. It also allows for port filming and a check on the proper treatment settings for the actual treatment which follows. However, one should be aware that, although the RVS is potentially a valuable tool on the Co-60 unit, it is by no means a substitute for meticulous attention to setup detail by the therapists in the treatment room. Setup errors such as setting the wrong SSD or pedestal angle, using the wrong tattoo marks, etc, will not be detected by the RVS. Additionally, due to the unique nature of this particular RVS, its use should not be required for cobalt machine treatments.

7. In conclusion, the hospital has demonstrated a strong commitment to quality, as demonstrated by the fact that it has (1) required that all therapists on staff be registered (this represents a high standard of practice) and has provided provisions and incentives for the 4 unregistered therapists to become registered within the next 2 years; (2) a very well-written and thorough QMP, with frequent in-services including QMP handouts to the technical staff (as recently as one week prior to one of the incidents), and (3) well-designed patient charts which are very comprehensive in their current form. The additional 2 columns which provide backup for the therapists are a feature which go far beyond any standards in the field and further illustrate a serious commitment to improve treatment quality. Given all of the above procedures and precautions, however, one of the most important factors in preventing errors is a positive and conscientious attitude by *all* of the departmental staff. This type of attitude is and should be expected of any professional. The fact that negative actions might be taken by individual(s) does not necessarily reflect on the institution or its commitments, provided that appropriate subsequent disciplinary action is taken. Communication within any department is also a key element to success.

If you have any questions or need further information, please do not hesitate to contact me at (214) 831-8620.

Sincerely,



Catherine Alekhteyar, MS
Consultant Physicist
ABR Certified - Therapeutic
Radiological Physics