U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-02984/94-002
030-00465/94-002

License Nos. 37-01421-01
37-01421-04

EA No. 94-066

Docket Nos.	Priority		Category	
030-02984		1		G1
030-00465		1		G3

Licensee: Geisinger Medical Center
100 North Academy Avenue
Danville, Pennsylvania 17822-0150

Facility Name: Geisinger Medical Center

Enforcement Conference Conducted At: King of Prussia, Pennsylvania

Enforcement Conference Conducted On: May 18, 1994

Inspectors: _____ May 23, 1994
Ihor M. Czerwinskyj, Health Physicist — date

Approved by: _____ May 23, 1994
Jenny M. Johansen, Chief — date
Medical Inspection Section

Conference Summary: An Enforcement Conference was held at the NRC Region I Office in King of Prussia, Pennsylvania on May 18, 1994 to discuss the apparent violations identified during a routine inspection conducted on March 29-31, 1994, and a special safety inspection conducted on April 25, 1994. Corrective actions taken and planned by the licensee since the inspection were also discussed. Enforcement options available to the Commission were explained.

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DETAILS

1. Attendees

Geisinger Medical Center:

Deborah Watson, Vice President & Administrative Associate Departments of Radiology
Joan Ross, General Counsel
Catherine Anderko, Senior Health Physicist and Radiation Safety Officer

NRC:

Charles W. Hehl, Director, Division of Radiation Safety and Safeguards
Karla D. Smith, Regional Counsel
Daniel J. Holody, Enforcement Officer
Jenny M. Johansen, Chief, Medical Inspection Section
Ihor M. Czerwinskyj, Health Physicist
Nader L. Mamish, Enforcement Specialist (by telephone)
Jim Smith, Health Physicist, NMSS (by telephone)
Kerri Cavanaugh, Health Physicist, NMSS (by telephone)

2. Summary

Representatives of Geisinger Medical Center met with NRC representatives on May 18, 1994 in the Region I Office at King of Prussia, Pennsylvania. The meeting was closed to the members of the public. In his opening remarks, Mr. Hehl explained the purpose of the conference. The Regional Enforcement Officer asked the licensee to go over the chronology of the incident. Licensee's counsel, and Radiation Safety Officer, provided the requested information. The licensee agreed that the malfunction of the primary timer on the cobalt-60 teletherapy machine was a serious incident and that the unit should have not been operated until the timer was replaced. The Director of DRSS asked the licensee to respond to the three apparent violations identified in NRC Inspection Report Nos. 030-02984/94-001 and 030-00465/94-001. He also indicated that the apparent violations maybe changed based on the information given by the licensee and the NRC's evaluation of that information. The licensee's counsel went over the three apparent violations and in addition presented a written response to the NRC on the three apparent violations (Attached).

On the apparent violation of 10 CFR 35.610(a)(2)(ii), the licensee admitted that the Radiation Safety Officer was not notified, as required. The licensee explained the circumstances contributing to the failure to notify the RSO in a timely manner, and the licensee's corrective actions undertaken since the event.

On the apparent violation of 10 CFR 30.50(b)(2)(i), the licensee denied the violation.

Licensee's interpretation of the reporting requirements of 10 CFR Parts 20, 30 and 35 are that this incident does not meet the reporting criteria in the above Parts.

On the apparent violation of 10 CFR 35.632(a)(2)(iii), the licensee denied the violation. The licensee contended that the term "source exposure assembly" is not defined in Part 35 and that, in any case, they performed the full calibration of the teletherapy unit, with the exception of uniformity of radiation field, and the output for all the fields used. The licensee contends that the two items which were not performed would not be affected by the replacement of the timer.

The NRC requested that the licensee provide information on the other two events which occurred since the last inspection, and about which the licensee notified the NRC. The licensee provided information on the April 27, 1994 teletherapy source drawer malfunction, and the April 18, 1994 iodine-131 MIBG incident.

3. Conclusion

The Enforcement Officer explained to the licensee the NRC's Enforcement Policy and the options available to the Commission.

Mr. Hehl thanked the representatives for their presentations. The meeting was adjourned.

Nuclear Regulatory Commission Enforcement Conference
May 18, 1994

Docket No. 030-02984
030-00464

License No. 37-01421-01
37-01421-04

EA 94-066

Subject: Geisinger Medical Center Response to NRC Inspection Nos. 030-02984/94-001, and 030-00465/94-001

Attendees for Geisinger: Catherine Anderko, Radiation Safety Officer
Deborah Watson, Vice President, Administrative Associate
Joan Ross, Esquire, General Counsel

I. 10 CFR 35.610 (a)(2)(ii) requires that the licensee post instructions at the teletherapy console which must inform the operator of the procedures to be followed if the teletherapy unit or console operates abnormally and the names and telephone numbers of the authorized user and the Radiation Safety Officer to be contacted immediately if the teletherapy unit or console operates abnormally.

CAUSES AND SAFETY SIGNIFICANCE:

- The instructions were posted at the teletherapy console and in place at the time of the main timer failure. The instructions did contain the procedures to be followed and the names and telephone numbers of the authorized teletherapy physicist named on the cobalt license and the Radiation Safety Officer to be contacted immediately if the teletherapy unit or console operated abnormally. We believe we met the intent of 10 CFR 35.610 (a)(2)(ii).

- The Radiation Safety Officer found no separate regulation defining abnormal operation of the teletherapy unit or console.

- The technologist operating the equipment did notify the authorized teletherapy physicist named on the cobalt license immediately regarding the timer issue. The teletherapy physicist determined the "significance" in this issue and in his analysis, this was not a serious problem. Therefore he did not report this to the Radiation Safety Officer. The technologist did follow the instructions as posted.

- The teletherapy physicist determined this was not an abnormal situation requiring reporting to the Radiation Safety Officer. It was the judgement of the teletherapy physicist that caused there to be no immediate reporting to the Radiation Safety Officer.

CORRECTIVE ACTIONS:

- A new timer was ordered on the same day the problem was identified. The main timer was replaced on April 5, 1993 with a new digital timer equipped with an internal back-up verification timer.

- An inservice was given in May 1993 to Radiation Oncology therapists, physicians, physicists and dosimetrists by the Radiation Safety Officer to review regulatory information, license requirements and conditions relative to the cobalt 60 teletherapy unit and Quality Management Program. Also reviewed were

items that constitute a recordable event and misadministration as well as the types of problems that the therapist should immediately report and to whom to report them.

- An annual follow-up inservice on the posted instructions and reporting requirements was given to the entire Radiation Oncology staff in April 1994 by the Radiation Safety Officer. This will continue to be given on a yearly basis.

- Enhanced instructions are now at the machine which correspond with the inservices that have been given. Added to the original instructions are titles of the individuals.

- Disciplinary action was taken against the teletherapy physicist involved in the situation: his directorship of the department of Medical and Health Physics was removed, there was a three day suspension without pay, and he is subject to further disciplinary action including termination if further incidents occur.

- In October 1993, the reporting relationship of the Radiation Safety Officer was changed from the Director of Medical and Health Physics (teletherapy physicist involved in this incident) to the administrator named on the NRC license. The reporting relationship was changed to ensure the independence of the Radiation Safety Officer.

- A second medical physicist is to be consulted whenever a problem of any magnitude arises with the cobalt machine.

OTHER INFORMATION:

- Because the cobalt machine had a secondary timer voluntarily installed prior to this incident, the technologist was able to immediately identify the problem with the main timer.

- The teletherapy physicist implemented a mechanism of a secondary backup with a second tech watching the back-up timer while the first tech monitored the patient treatment so that patients could be safely treated as prescribed by their physician.

- The patients were in fact safely treated and there were no misadministrations.

- The medical need to treat the patients was taken into consideration in the judgement of the teletherapy physicist.

II. 10 CFR 30.50(b)(2)(i) requires the licensee to notify the NRC within 24 hours after discovery of an event in which equipment is disabled or fails to function as designed and the equipment is required by regulation or license condition to prevent exposures to radiation exceeding regulatory limits, or to mitigate the consequences of an accident.

CAUSES AND SAFETY SIGNIFICANCE:

- The Radiation Safety Officer first reviewed Part 35 (Medical Use of Byproduct Material) after she was made aware of the incident. She deemed this not to be reportable as indicated in Part 35. She looked secondly at Part 20 (Standards for Protection Against Radiation). She deemed this not to be reportable as

indicated in Part 20. She thirdly looked at Part 30 (Rules for General Applicability to Domestic Licensing of Byproduct Material) and her interpretation was these regulations did not apply. This judgement was based on the fact that safeguards were in place: the machine was immediately shut down upon the notification of the Radiation Safety Officer and the back-up timer was used. There are no regulatory limits set for patients receiving radiation therapy. The Radiation Safety Officer did not think that this incident triggered the twenty-four hour notification.

- At the time of the incident, the Radiation Safety Officer was reporting to the teletherapy physicist involved in this situation.

- There were no misadministrations. No overexposure to patients or staff occurred as a result of this event. Although two patient treatments were affected by the main timer dragging, subsequent treatments were adjusted to compensate for this error and the total prescribed dose was correctly delivered.

- The machine was immediately shut down upon notification to the Radiation Safety Officer and there was no future risk to patients.

- The Radiation Safety Officer consulted with another medical physicist not involved with the incident. He suggested that the machine be taken out of service but there was no suggestion of a 24 hour reporting to the NRC.

- The teletherapy physicist did not consider this significant enough to turn off the machine and did not think it was necessary to notify the NRC.

- The patients were carefully monitored.

- The back up timer was a redundant system. Part 30.50 (b)(2)(iii) indicates this condition must be met or there is a twenty-four hour reporting requirement. Since the back up timer was in place, it was viewed as redundant equipment and therefore there was no twenty-four reporting required. The second tech was also a redundant system in monitoring the timer.

- As soon as the Radiation Safety Officer was made aware, safety precautions were taken by shutting down the machine. This was treated in a very serious manner.

CORRECTIVE ACTIONS:

- The reporting relationship of the Radiation Safety Officer was changed in October 1993. The organization recognized the need for independence of the Radiation Safety Officer.

- As a result of the inspection review in March 1993, there is now a heightened awareness of the need to consult with the NRC regarding these type incidents.

- An incident with the cobalt machine on 4/27/94 that occurred during a routine maintenance inspection was handled and reported to the NRC per regulations.

OTHER INFORMATION:

- The severity of the main timer failure was not apparent relative to other incidents requiring twenty-four hour notification to the NRC.

- "The equipment is required by regulation or license condition to prevent

releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits" does not seem to apply to a cobalt machine which has the function of delivering radiation doses to patients. There are no regulatory limits on the doses of radiation a radiation therapy patient may receive in the course of a treatment.

III. 10 CFR 35.632 (a)(2)(iii) requires the licensee to perform full calibration measurements on each teletherapy unit following any repairs of the components associated with the source exposure assembly.

CAUSES AND SAFETY SIGNIFICANCE:

- The "source exposure assembly" is not specified and defined. In a literal definition, the timer is not part of the source exposure assembly.

- The full calibration requires calibration of components that are not affected by the main timer. This appeared to the teletherapy physicists as a grey area and was unclear.

- Replacing the main timer was not considered a major repair by the teletherapy physicists.

- All components related to the main timer were checked after the installation of the new main timer. Testing was done on the timer to ensure it accuracy. No further problems were observed after the installation.

CORRECTIVE ACTIONS:

- A full calibration of the cobalt unit was conducted in December 1993.

- Full calibrations will be done in the future and the Radiation Safety Officer will insure that a full calibration occurs.

- A full calibration was performed after the discovery of a source drawer failure during a routine monthly output check on 4/27/94.

OTHER INFORMATION:

- Contacted other physicists outside of Geisinger who came to the same conclusion that a full calibration was not needed after the replacement of the main timer.

OTHER CONSIDERATIONS

IDENTIFICATION:

- This issue with the main timer failure was fully disclosed in the minutes of the May 17, 1993 Radiation Safety Committee meeting.

- There has never been an attempt to cover up this incident.

- Based on the review of the regulations, the Radiation Safety Officer did not believe this was a reportable event. She did treat it as a recordable event.

- The Radiation Safety Officer did report the event to the NRC when she was made aware of the need to report the event by the Inspector.

CORRECTIVE ACTION:

- Corrective actions were promptly taken at the time of the main timer failure and additional corrective actions were taken as soon as the Radiation Safety Officer became aware of the apparent violations.

LICENSEE PERFORMANCE:

- This license has had no significant violations to date.

- All violations from the last review and prior reviews have been satisfactorily corrected in a timely manner.

PRIOR OPPORTUNITY TO IDENTIFY:

- Geisinger has never experienced a similar incident before. In the future, the staff is aware of how to proceed with these issues.

- Since the inspection in March 1994, Geisinger has handled a problem with the source drawer assembly according to the regulations.

MULTIPLE OCCURRENCES:

- There were no previous occurrences.

DURATION:

- There were no misadministrations.

- The cobalt machine was shut down as soon as the Radiation Safety Officer was notified.

May 17, 1994 dcw

New Posting

ATTENTION

^{60}Co Teletherapy Users and Operators

Before the start of treatment or after a door interlock interruption, visually inspect the treatment room to ensure that the only person in the room is the patient.

If the source drawer fails to close, proceed as follows:

1. Remove the patient from the treatment room.

2. The drawer return emergency T-bar, which is supplied with the unit and located at the control console, should be placed over the beam condition indicating rod. Forward pressure on the source drawer with the T-bar will push the drawer backwards and into the safe position.

   Note: The amber colored portion of the emergency T-bar must be entirely inside the front head cover before the source is in the fully safe position. This will reduce external radiation fields to normal levels. The front portion of the T-bar is painted red and the source can be considered relatively safe if no red markings appear outside the front cover.

The primary concern in any emergency or abnormal occurrence is to remove the patient from the treatment room and to notify the appropriate personnel on the emergency call list.

Emergency Call List

In the event of an emergency, abnormal occurrence, or any machine malfunction notify a teletherapy physicist. If there are any radiation safety concerns, equipment/component failure or other significant problem notify the Radiation Safety Officer immediately.

John Glover, Ph.D.	Teletherapy Physicist	x4119, x6301, 473-3968
Vince Maier, M.S.	Teletherapy Physicist	x6934, x6301, 784-5038
R. Yankelevich, Ph.D.	Teletherapy Physicist	x3916, x6301, 275-6891
Marcus Brown, M.D.	Authorized User	X6304, 275-2071
Cathy Anderko, M.S.	Radiation Safety Officer	x5917, x6301, 275-0784