January 12, 1999

EA 98-523

Ann Regling
Senior Vice President Administration
Sinai Hospital
6767 West Outer Drive
Detroit, MI 48236

SUBJECT: PREDECISIONAL ENFORCEMENT CONFERENCE SUMMARY

Dear Ms. Regling:

On December 16, 1998, representatives of Sinai Hospital met with NRC personnel in the Region III office located in Lisle, Illinois, to discuss the apparent violations identified in NRC Inspection Report 030-00252/98001(DNMS). The conference was held at the request of Region III.

Sinai Hospital representatives presented a summary of the causes for the apparent violations and their corrective actions. Your staff also provided us with a written statement of perceived inaccuracies in the inspection report.

The attendance list, Sinai's written statement, and Sinai's written response *with* NRC's comments are enclosed.

In accordance with 10 CFR 2.790 of the NRC's Rules of Practice," a copy of this summary and its enclosures will be placed in the NRC Public Document Room.

Sincerely,

/s/ P. L. Hiland for

Roy J. Caniano, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-00252
License No. 21-00299-06

Enclosures: As stated (3)

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ENCLOSURE 1

ATTENDEES

Licensee Attendees
Beverly Simmons, Vice President Clinical Services Administrator, Cancer
Bridget Brambs, Manager of Patient Oncology
Praveen Dalmia, Radiation Safety Officer
Nathan Kaufman, M.D., Authorized User
Gary Ezzell, Ph.D., Medical Physicist Harper Hospital

NRC Attendees
Cynthia Pederson, Acting Deputy Regional Administrator
Bruce Berson, Regional Counselor
Brent Clayton, Enforcement/Investigations Officer
Toye Simmons, Enforcement Coordinator
Patrick Hiland, Acting Deputy Director, Division of Nuclear Materials Safety
Geoffrey Wright, Chief, Materials Inspection Branch 2
John Jones, Senior Radiation Specialist

Response to NRC Inspection Report Dated 11/27/98
DMC/Sinai Hospital, Detroit, MI
December 16, 1998

Why event occurred:

- In cases of emergency, the physician simulates the patient and prescribes a dose. The calculations are performed immediately and the patient treated without any blocks. The rest of the treatment is delivered with blocks, the calculations for which are performed after one/two days. *The dose for this second part of the treatment in such cases is normally the same as in the first part.*

- The normal dose for this type of treatment is 300 cGy/Fractions. The physician had, in fact, prescribed just that for the first two fractions. The dosimetrist expected to see 300 cGy for the second part of the prescription and, therefore, did not question what she saw.

- In reviewing the prescription, the therapists treating the patient did not effectively see or verify the dose. They saw what they expected to see, since 300 cGy is the normal dose for such cases.

- Had the dose for the second part of the treatment been anything other than 150 cGy (while remaining reasonable), the dosimetrist would have been unable to arrive at an integer number of treatment fractions. This would have flagged the error.

- The dosimetrist failed to log the calculation in the dosimetry log. This was an aberration, not a systematic problem, resulting from a human error. However, this resulted in the calculation not being checked, as required by the QMP. *A review of cases for the past six months has failed to product a single occurrence where the calculations had not been checked.*

- The therapists entering the data into the record and verify unit made an incorrect entry based on the dosimetrist's parameters.

- All patients are seen by the physician immediately following their treatment every Monday. Had the error not been noticed before the patient's treatment that Monday, it would have certainly been caught by the physician during the follow-up examination.

Factual inaccuracies in the report:

- Only *one dosimetrist* was interviewed. Melanie Teahan has been on medical leave of absence since August, 1998. (p. 4,1.7).

- *All errors and omissions were identified by the licensee and not by the NRC inspector during the review of the event* (p.4,1.13). Even the weekly chart check infraction had been identified by the management, and corrective actions were already being taken.

- Although the inspector did identify some missing chart checks, an infraction of the QMP, this infraction had already been identified by the licensee and corrective action taken, Besides, this did not contribute to the misadministration under discussion. The patient received the incorrect dose Monday through Friday of the week. In order to prevent the error from resulting in a misadministration, as defined in 10CFR35.2, the chart check would have had to be completed by Wednesday of that week. However, chart checks are normally performed on Fridays, by which time the error would have already resulted in a misadministration.

  The Site Specialist was aware of the missing chart checks. When the Director of the Department was informed by the Site Specialist about the deficiencies in chart checks, the Director had, in no uncertain terms, asked the Site Specialist to correct the situation immediately since it was a violation of NRC regulations and the QMP. Also, the Director had later checked with the Site Specialist to make sure that the deficiencies had not affected patients on the Cobalt-60 teletherapy unit. The Site Specialist, however, had failed to take proper corrective action and to inform the RSO.

  The management had already decided to re-assign the Site Specialist. Due to this misadministration, and in light of the failure to follow direct orders to remedy the chart-check situation, management re-assigned the Site Specialist immediately.

  The department's QMP required an annual audit of actual patient charts to check for compliance with applicable regulations. All past reviews had not shown any such transgressions. As such, the RSO had no reason to believe that the chart checks were not being performed. This misadministration was the first event which had exposed the problem. The issue was discussed immediately, and a policy to ensure compliance formulated and implemented. The occurrence was immediately forwarded to the Radiation Safety Committee for proper documentation.

- The report implies (p.4, 1.33) that the dosimetrist made the error in the dose due to the heavy case load. The patient load on that particular day was indeed high, but it was an aberration. The average load for the month was no different than in any other period. The high *case load, however, does not prevent the dosimetrist from verifying all pertinent data.* It may have, however, contributed to her failure to log the calculations.

- The report states that the therapists had failed to verify the specific details of the written directive prior to treatment. The *therapists had, in fact, reviewed the prescription before each treatment*, but had failed to notice the discrepancy. One of the very therapists who had been involved in several of the previous treatments actually noticed the error prior to the sixth treatment. Had the therapists not been verifying the necessary data prior to treatment,

the error would not have been noticed by them before the sixth treatment.

- The report states that the therapists failed to perform a chart check for two weeks of the patient's treatment. Although this is true and is a violation of the QMP, a chart check would not have prevented a misadministration in this case. This violation of the QMP was identified by the licensee, albeit after the misadministration. In order to prevent the error from resulting in a misadministration, as defined in 10CFR35.2, the chart check would have had to be completed by the Wednesday of that week. However, chart checks are normally performed on Fridays, by which time the error would have already resulted in a misadministration.

- The policy for the therapists to verify the presence of the physicist's initials in the chart check column shows that the licensee has multiple mechanisms in place, outside of the QMP, to prevent mistakes. This shows the licensee dedicated to quality.

- It is stated that (p.6, 1.1) the NRC inspector identified three apparent violations of the QMP. In fact, all the three violations had already been identified by the licensee and a written report was submitted to the inspector at the time of the inspection.

- The report states (p.6, 1.13) that the licensee failed to perform daily verifications of treatment versus the written directive. According to the therapists, this was indeed performed on each occasion of treatment. However, the therapists failed to notice the discrepancy on the first five of the six occasions. Had they not been performing the check, the error would not have been noticed before the sixth treatment.

- Besides the two independent physicists, the investigation team also included a physician from another hospital (p.6, 1.19). Only one dosimetrist was interviewed by this committee (p.6,. 1.24; p.7, 1.31).

- The report fails to note that the licensee determined that the therapists had verified the prescription before each fraction of treatment, but had failed to notice the discrepancy in the dose in each instance (Licensee report dated 10/19/98, p.2, 1.17).

- The staff's dependence on the dosimetry schedule to perform chart checks did contribute to this error. In fact, the new dosimetry log that was implemented immediately is designed to eliminate this very situation.

- The report correctly points out that *"the licensee's investigation into the event was thorough and comprehensive."* However, it also states that the "licensee...failed to evaluate the significance of previously identified problems with chart check assessment." ***This is***

incorrect.

A large part of the committee's time was spent in assessing and revising the implementation of the chart check policy. *The committee had, within hours of misadministration, revised the chart-check policy.* The new policy now requires the chart checks to be started on Wednesday of each week. The therapist performing the checks is required to submit a report regarding the status of the checks on Thursday to his/her supervisor. The supervisor is required to ensure that the task is completed on Friday and to submit a status report to the Director of Radiation Oncology each week. The inspector was informed of this new policy during the interviews at the time of the inspection and a statement to that effect is made in the licensee's submission dated 10/19/98 (p.4, 1.11).

The written report (dated 10/19/98) submitted to the NRC did not explicitly list the revised policy because, even if the chart check had been performed in this case, the error would have still resulted in a misadministration. The chart check may have flagged the error on Friday afternoon instead of Monday morning, when it actually was. The resulting deviation in the dose delivered would still have been the same. However, *the committee did recognize this as a transgression of the QMP and stated it as such in the submitted report.*

- The report correctly acknowledges that the review of multiple patient charts failed to reveal any other mistakes, besides instances of missing weekly chart checks. Since this had already been identified by the licensee, <u>the inspection did not reveal any additional violations</u>.

The report notes that all the therapists interviewed stated that "they understood that the chart checks were required by the QMP." This is very important for it shows the department's emphasis on, the staff's understanding of, the QMP. *The entire staff had been inserviced <u>at least</u> annually on the QMP and other relevant policies and procedures.*

The therapists assigned to the duty of chart checks were indeed responsible for the task. If a therapist was unable to complete the task, (s)he was required to report that to the supervisor. During the interviews, two of the therapists stated that they did not feel responsible for this task although it has been assigned to them via the schedule. However, one of these very therapists recalled specific instances when she had personally informed her supervisor when she was unable to complete the checks. In each such instance the supervisor failed to take necessary and effective action to eliminate the problem.

The Site Specialist (supervisor) had informed the Director of Radiation Oncology about this infraction in September and had been instructed by the Director to remedy the situation immediately since it was a violation of the QMP and NRC regulations. The Site Specialist, however, failed to correct the problem.

The process for chart checks has remained unchanged for the past eight years and has proven effective during the same period, as evidenced by the compliance shown since the implementation of the QMP. The violations noted in this instance were not due to an ineffective policy but due to an individual supervisor's failure to maintain compliance with the policy. The committee, as well as the management, recognized this deficiency and had already taken proper and comprehensive action within 24 hours of the misadministration. Also, as noted in the report, there were only two deficiencies noted in the month of October, showing the effectiveness of the corrective steps. Also, both these instances had been documented by the licensee in their report to the NRC.

- The report acknowledges that all the staff had been appropriately trained in the QMP and showed a good understanding of the QMP. However, it then concludes that the "implementation of the QMP was not clearly regarded as the highest priority" and therefore the "training appear(ed) to have been deficient with regard to stressing accountability for implementing the QMP."

  The staff interviewed stated that they were aware of the QMP requirements for patient treatment as well as chart checks. In fact, each staff member had been given a personal copy of the QMP at each in-service. *A survey of local institutions found that not one of them provided the staff with a personal copy of the document.* The implementation of the QMP regarding chart checks has not been in question since its inception in January, 1991.

  The department follows many policy and procedures, related or unrelated, to ensure proper patient treatment. For example, the therapists are required to take weekly port films on each patient under treatment, and check the output of each radiation beam on the linear accelerator every morning before using the machine. These tasks are not required by any regulatory bodies, but are good quality assurance tools to ensure proper treatment. The staff understands that they are required to perform these tasks and do so. However, few, if any, of them know if any of these are required by regulation. *They are expected to perform the assigned tasks irrespective of impact on regulations. It would not be in the patient's benefit to differentiate between tasks required by regulation those that are not.*

- The department delivers approximately 4,000 patient treatments per year on the cobalt unit. Records since 1991 show not one case of a missing chart check. A distinguished record such as this cannot be achieved without making the implementation of the QMP the highest priority and stressing accountability for its implementation.

  When informed of the transgression, the Director of the department had, in no uncertain terms, instructed the Site Specialist to rectify the situation immediately. She had also followed up with the Site Specialist to make sure that patients on the cobalt unit were not

affected by this failure. When the Director learned that the situation had indeed not been corrected, she immediately took over the day-to-day operations of the department. The accountability for implementation of the QMP was clearly understood.

- The report concludes that the "NRC inspector identified four examples where the licensee staff did not follow the requirements in its QMP." All these four transgressions had already been identified by the licensee prior to the inspection, as is evidenced in the report dated 10/17/98 submitted by the licensee and the corrective steps outlined in the NRC report (p.9, item 6.0).

- The report concludes that the root cause of the misadministration was similar to that in the case of the misadministrations in 1994 since they were all due to a programmatic weakness in the implementation of the QMP, namely, failure of the staff to verify correct parameters before commencing treatment.

  10CFR35.32 requires that the licensee establish and implement a QMP containing policies and procedures to ensure that each administration is in accordance with the written directive and that any unintended deviations are identified, evaluated, and appropriate action taken.

  In this case, the licensee's QMP clearly outlined the functions to be performed in order to ensure proper patient treatment. It also contained appropriate procedures to identify errors, when and if they occur. The licensee had also instructed all individuals in the QMP, provided them a copy of the same, and made them aware of their responsibilities. In this case, however, the staff failed to notice the inconsistency in the treatment they were delivering and the physician's directive. However, had the QMP not been in place and effective, the therapist delivering the treatment would not have identified the error.

  Since the events in 1994, the department has delivered approprimately 15,000 treatments using the cobalt-60 teletherapy unit <u>without a single error</u>. This record cannot be achieved without proper management, qualified personnel and a good, effective QMP.

  As the report points out, the Human Failure Analyst from the NRC had concluded that the '94 misadministrations were due to (i) human error due to stressful working environment in the department, and (ii) a lack of support job performance aids (e.g., check lists, dual verifications, etc.). Since 1994, the management has made a diligent effort to improve the stressful environment in the department. Indeed, not one of the employees questioned has even alluded to the presence of stress. Also, the department management has ensured that proper job performance aids are made available to the employees. Indeed, this department has the only record and verify unit in the entire country. ***Clearly none of these factors are common with the current misadministration.***

- The QMP does not imply that there will never be an error in a patient treatment. The QMP requires policies and procedures to ensure that the patient will be treated according to the written directive and error, if any, will be identified. The QMP at Sinai met these criteria and was well implemented, as evidenced by the interviews with the staff.

- The misadministrations in this case were due to human error, compounded by multiple missed opportunities to identify it.

    - The therapists did review the prescription, as required by the QMP, but did not effectively see or verify it. They saw what they expected to see.

    - The dosimetrist also saw what she expected to see, and what she saw was reasonable.

    - What they expected to see was usual, reasonable, and hence no harm was done to the patient.

    - Failure to document the calculation in the log was unusual, not systematic. It was the result of an atypical workload - a simple human error.

    - Failure to perform weekly chart checks was programmatic. However, it had been self-identified and direction had been given by the department Director to the Site Specialist to rectify the problem. Failure to fix the problem is a failure of the middle manager who was already slated for reassignment at the time of this error. The plan was to place the Director and a senior therapist to review and improve procedures, as necessary. Senior management had already begun an audit of the DMC system, but had not yet visited Sinai. Hence, upper management was already moving to identify and correct any programmatic failures.

    - The calculation checks were always performed and therapists were used to seeing the physicist's initials in the column. Failure to notice the missing initials was a human error.

    - A chart check in this case would not have prevented the misadministration.

- *The misadministration did not result from a violation of the 10 CFR Part 35.32 (i.e., an inadequate QMP or questionable implementation of the same). It was a result of human error made by knowledgeable professionals who knew what they were required to do but failed to do so. The error was identified by the licensee and immediate, exhaustive, and effective corrective action taken, as required by 10 CFR Part 35.32.*

Application of Enforcement Policy:

- NRC information notice 96-28 states that in applying the enforcement policy, importance should be given to taking prompt, comprehensive corrective action when problems are identified. It states that the "NRC encourages and expects [licensee] identification and prompt, comprehensive corrective action of violations," and that it "does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations."

  Within 1-2 hours of the identification of the violation, the licensee had put together a team of experts consisting of the RSO, physicians, physicists, and administrators from within and outside the institution. The committee was charged with examining the event and determining the root cause of the violation. The committee conducted a complete and thorough review of the circumstances that led to the violation by interviewing all the staff involved (therapists, dosimetrist, physicists, and management) directly or indirectly with the event. They also looked at policies and procedures in place, including the QMP, that should have prevented such an occurrence, including documents related directly or indirectly with the incident, actual logs, and records used in the department. Care was taken to compare the occurrences with past incidents that had transpired.

  The committee looked for and identified the root cause of the violation, as indicated in the report submitted to the NRC inspector at his arrival. It also took prompt and comprehensive corrective action as outlined in the various communications to the NRC. In arriving at the recommendations, great consideration was placed on ensuring that the corrective actions were not limited to the single violation/event, but that they encompassed similar potential situations. All these recommendations were implemented IMMEDIATELY (before the end of the day).

- Information notice 96-28 specifies a list of 20 steps that the development of effective corrective actions must follow. After evaluating the actions of the licensee and the committee, it shows that each criterion listed was satisfied:
  1. Was the management informed of the violations?
     Yes, immediately.

  2. Were programmatic implications of violation and potential weaknesses in other areas considered in arriving at the corrective actions?
     Yes. The committee, in fact, charged an expert in adult education to evaluate ALL departmental policies and procedures to ensure that (i) they are reasonable and intelligible, and (ii) evaluate the staff's understanding of the same to ensure that a similar

event does not occur.

3. Were precursor events considered and factored into corrective actions?
   Yes. The committee looked at the entire chain of events that led to the occurrence of this misadministration. It also evaluated and compared the events with those that have occurred in the past in this and other radiation oncology departments.

4. In the event of loss of radioactive materials, should security be enhanced?
   Not applicable.

5. Has the staff been adequately trained on the applicable requirements?
   Records indicated that all the staff had received training in all the requirements. Interviews indicated that the staff had a good understanding of the QMP and other requirements.

6. Should personnel be re-tested to determine adequacy of training?
   All the staff was re-trained. An expert in adult education was also called in to assess the level of training and understanding amongst the staff.

7. Has the staff been notified of the violation and corrective action?
   Yes, they were all informed immediately. In fact, they were part of the team recommending and implementing the corrective actions.

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
   The committee considered this issue very seriously to ensure that similar problems do not recur. It found the fact that chart checks were not being performed, and that the problem had not been corrected over a three month period, very disturbing. In order to ensure that the situation never arises again, they revised the implementation of the chart check policy. They also changed the audit/reporting frequency from monthly to weekly. This will ensure that the problem is identified immediately if it occurs, and does not go uncorrected for any period of time.

9. Is there a need to retain an independent technical consultant to audit the area of concern or revise your procedures?
   The committee consisted of two physicists and one physician from an independent institution. The expert in adult education who has been brought in has extensive experience in this field and is also from an independent institution.

10. Are the procedures consistent with current NRC requirements?

Yes, they are.

11. Is a system in place for keeping abreast of new or modified NRC requirements?
The RSO and all the physicists are knowledgeable in the current NRC requirements and made aware of new requirements and recommendations immediately through professional literature, NRC bulletins and notices, and the internet.

12. Does your staff appreciate the need to consider safety in approaching licensed activities?
Yes; there has not been any safety-related accident or incidence at this institution.

13. Are resources adequate to perform licensed activities? Has the RSO been provided sufficient time and resources to perform his duties?
The staffing levels for all areas were evaluated. The RSO has sufficient time to perform his duties, as is evident from his participation in this investigation.

14. Have work hours affected the employees' ability to safely perform the job?
Not applicable since there has been no change in the employees' job hours.

15. Are organizational changes necessary?
The committee evaluated the effectiveness of all personnel involved. Some organizational changes were made immediately, as outlined in the written response to the NRC.

16. Are management and RSO adequately involved in the oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
The committee increased the supervisory oversight through periodic audits, as described in the report to the NRC. The RSO will be advised of any future infractions in writing by the supervisor, as indicated in the revised QMP submitted to the NRC.

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?
The employees in the department enjoy a good working relationship with the management and feel free to discuss their concerns and air their feelings in a mutually beneficial manner, as is evidenced by their candid discussions with the committee and the NRC staff.

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?
The staff in the department is told to always give priority to quality. Each operating team

(therapists on a machine, dosimetrist, physicist, etc.) maintains its own schedule and sets its own time limits. The management's commitment to safety and compliance is evident from the fact that, at a great monetary expense, they have installed and maintain a record system on the cobalt unit, the only one of its kind in the country. The manufacturer of the cobalt unit does not produce such a system. The licensee had to work with several manufacturers and suppliers over a long period of time in order to implement this system.

19. Has management communicated its expectations for safety and compliance?
    At every meeting held in the department, safety and compliance are stressed. The management monitors several items on a continual basis to ensure safety and compliance. The entire staff is involved in monitoring these parameters in one form or another.

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?
    There is such an administrative policy in place and is followed throughout the institution.

- As stated in the enforcement policy (NUREG-1600), the first step in the enforcement process is the evaluation of the relative importance of the violation. It must be pointed out that the dose received by the patient was actually what is normally prescribed for such cases. In fact, the patient actually showed a faster response to the treatment due to the dose delivered. It should also be considered that no physical or other harm was done to the patient.

- Since the errors made in '94, the management has made a diligent effort to eliminate the problems for which the institute was then cited by the NRC. The employees feel free to voice their opinions and concerns, as was evident by their candid discussions with the NRC staff during the investigation. The licensee has also added numerous job performance aids such as a record and verify system, electronic verification system for wedges, and a patient treatment flow chart showing the processes to be followed for each treatment, to name just a few.

- Repetitive violations caused due to a licensee's failure to implement corrective action call for escalated action. However, although the NRC letter dated 11/27/98 concludes that these misadministrations are similar to the violations and the root causes of the misadministrations that occurred in 1994, this clearly is not the case since the root causes for the events in '94 (listed above) do not currently exist.

- When determining the proper penalty for a violation, one must take into account the frequency of the violations, their root causes, the adequacy of previous corrective actions, the period of time between the violations and the significance of the violations. When these factors are applied to this case, and once the licensee is given the credit it deserves for identifying the problem, conducting an immediate and thorough investigation, identifying the root causes, and taking prompt, effective, and comprehensive corrective action, it is clear that

the situation does not warrant an escalated enforcement action or a civil penalty.

- For a licensee-identified violation, an escalated action is warranted when the licensee is aware that a problem or violation requiring corrective action exists. This is not the case in this situation. Although chart-checks had been inconsistent for a short duration immediately preceding the misadministration, the situation had been corrected. In fact, at the time of the inspection, it was found that all patients currently under treatment had had their charts checked during the month of October. Besides, the missing chart checks in this case did not contribute to the misadministration in any fashion.

- In terms of identification of the misadministration, it should be noted that it was identified by the licensee as a result of licensee self-monitoring through its own policies and procedures.

- As stated in NUREG-1600, "the judgement of adequacy of corrective actions will hinge on whether the NRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive corrective action." This is clearly not the case in this situation since the identification of the root cause as well as all the corrective actions necessary to be taken had been performed by the licensee on its own initiative without any input from the NRC.

- This was not a willful violation. Neither could one *reasonably* expect this violation to be prevented by the licensee's corrective actions for the violation that occurred four years ago since the root-cause of the two events was not the same. On the other hand, the licensee had already committed to specific, immediate and comprehensive corrective action even before the NRC site visit following this event.

- The remedial action taken by the licensee against those responsible for failure to immediately rectify the chart check situation clearly demonstrated the seriousness of the violation to the other employees.

- This misadministration was not the result of any programmatic failure nor any programmatic weakness in the implementation of the QMP. The therapists were aware of the task which needed to be performed and had adequate knowledge and skills to perform those tasks. The errors associated with these incidents are what are termed "skill-based" slips or lapses. "The probability of skill based error can be reduced but cannot be eliminated," according to Dr. Dennis Serig, Senior NRC Human Failure Analyst. "It is understood that humans make errors." The therapists had clearly developed routines to detect errors prior to treatment. Had this not been the case, the therapist would not have identified the error when she did.

  In view of this, the licensee must develop procedures to reduce the likelihood of human error.

As is evident from the five distinct layers of safety that were breached in order for this error to occur, the licensee has exercised the utmost effort toward this end. It should also be noted that there was yet another check that was pending (a sixth layer), namely a routine personal patient checkup by the authorized user conducted every Monday. It can be stated with a very high degree of certainty that the error would have been caught during this examination since one of the primary goals of the physician is to check and document how well the patient is tolerating the treatment. The patient had indeed been seen the previous week but the error was not flagged since it had not yet occurred.

- In light of the licensee's history of some 15,000 treatments in the past four years without any errors, it can be stated that this violation is an isolated case of failure to follow the procedures clearly outlined in the licensee's QMP and does not demonstrate a programmatic weakness in the implementation of the QM program and has limited consequences for the program.

ENCLOSURE 3

LICENSEE'S RESPONSE WITH NRC COMMENTS

Response to NRC Inspection Report Dated 11/27/98
DMC/Sinai Hospital, Detroit, MI
December 16, 1998

Why event occurred:

Licensee Comments:

- In cases of emergency, the physician simulates the patient and prescribes a dose. The calculations are performed immediately and the patient treated without any blocks. The rest of the treatment is delivered with blocks, the calculations for which are performed after one/two days. The dose for this second part of the treatment in such cases is normally the same as in the first part.

- The normal dose for this type of treatment is 300 cGy/Fractions. The physician had, in fact, prescribed just that for the first two fractions. The dosimetrist expected to see 300 cGy for the second part of the prescription and, therefore, did not question what she saw.

- In reviewing *the* prescription, the therapists treating the patient did not effectively see or verify the dose. They saw what they expected to see, since 300 cGy is the normal dose for such cases.

- Had the dose for the second part of the treatment been anything other than 150 cGy (while remaining reasonable), the dosimetrist would have been unable to arrive at an integer number of treatment fractions. This would have flagged the error.

- The dosimetrist failed to log the calculation in the dosimetry log. This was an aberration, not a systematic problem, resulting from a human error. However, this resulted in the calculation not being checked, as required by the QMP. A review of cases for the past six months has failed to product a single occurrence where the calculations had not been checked. The therapists entering the data into the record and verify unit made an incorrect entry based on the dosimetrist's parameters.

- All patients are seen by the physician immediately following their treatment every Monday. Had the error not been noticed before the patient's treatment that Monday, it would have certainly been caught by the physician during the follow-up examination.

NRC Response:

Comments acknowledged.

Factual inaccuracies in the report:

Licensee Comment:

- Only one dosimetrist was interviewed. The second dosimetrist has been on medical leave of absence since August, 1998. (P. 4,13).

NRC Response:

The licensee is correct in saying that the inspector only interviewed one dosimetrist. The inspector mistakenly recalled, when writing the report, that one of the individuals interviewed was the second dosimetrist.

Licensee Comment:

- All errors and omissions were identified by the licensee and not by the NRC inspector during the review of the event (p.4,1.13). Even the weekly chart check infraction had been identified by the management, and corrective actions were already being taken.

NRC Response:

The report states that the licensee and the inspector identified a number of performance errors during the review of the event. This statement was not meant to imply that the licensee did not identify most of the performance errors prior to the inspection. The inspector verified the licensee's findings and independently identified the failure of the licensee to perform the weekly chart checks during August and September. The failure of the licensee to inform the RSO of the chart check problem was identified by the inspector.

Licensee Comment:

- Although the inspector did identify some missing chart checks, an infraction of the QMP, this infraction had already been identified by the licensee and corrective action taken, Besides, this did not contribute to the misadministration under discussion. The patient received the incorrect dose Monday through Friday of the week. In order to prevent the error from resulting in a misadministration, as defined in I0 CFR 35.2, the chart check would have had to be completed by Wednesday of that week. However, chart checks are normally performed on Fridays, by which time the error would have already resulted in a misadministration.

NRC Response:

The NRC agrees with this assessment.

Licensee Comment:

The Site Specialist was aware of the missing chart checks. When the Director of the Department was informed by the Site Specialist about the deficiencies in chart checks, the Director had, in no uncertain terms, asked the Site Specialist to correct the situation immediately since it was a violation of NRC regulations and the QMP. Also, the Director had later checked with the Site Specialist to make sure that the deficiencies had not affected patients on the Cobalt-60 teletherapy unit. The Site Specialist, however, had failed to take proper corrective action and to inform the RSO.

The management had already decided to re-assign the Site Specialist. Due to this misadministration, and in light of the failure to follow direct orders to remedy the chart-check situation, management re-assigned the Site Specialist immediately.

The department's QMP required an annual audit of actual patient charts to check for compliance with applicable regulations. All past reviews had not shown any such transgressions. As such, the RSO had no reason to believe that the chart checks were not being performed. This misadministration was the first event which had exposed the problem. The issue was discussed immediately, and a policy to ensure compliance formulated and implemented. The occurrence was immediately forwarded to the Radiation Safety Committee for proper documentation.

NRC Response:

The licensee appears in general to be in agreement with the NRC's interpretation of the facts in this issue. However, the NRC views with some concern the fact that the Director of the Department of Oncology and the Site Specialist failed to immediately notify the RSO of the situation with regard to repeated failure to perform the weekly chart checks during August and September.

Licensee Comment:

- The report implies (p.4, 1.33) that the dosimetrist made the error in the dose due to the heavy case load. The patient load on that particular day was indeed high, but it was an aberration. The average load for the month was no different than in any other period. The high case load, however, does not prevent the dosimetrist from verifying all pertinent data. It may have, however, contributed to her failure to log the calculations.

NRC Response:

The report states a fact that the licensee apparently agrees with, that the dosimetrist's schedule was unusually heavy that day (16 cases). According to the RSO a heavy workload would have been 5-10 cases per day. Failure to log the calculations was the second error which initiated the chain of events leading up to the misadministration. The fact that the average load for the month was no different than any other period reinforces the probability that the unusually heavy work load on the day the calculations were done contributed to the failure to log the calculations.

Licensee Comment:

- The report states that the therapists had failed to verify the specific details of the written directive prior to treatment. The therapists had, in fact, reviewed the prescription before each treatment, but had failed to notice the discrepancy. One of the very therapists who had been involved in several of the previous treatments actually noticed the error prior to the sixth treatment. Had the therapists not been verifying the necessary data prior to treatment, the error would not have been noticed by them before the sixth treatment.

NRC Response:

Failure to verify the specific details of the written directive prior to treatment is another way of saying the therapist failed to notice the discrepancy. The fact that on one occasion, the therapist effectively verified the specific details of the written directive, does not provide assurance that the same level of rigor was applied on all of the other occasions. The NRC is not aware of any evidence that the therapists reviewed the prescription prior to each treatment. Further, the therapists indicated to the inspector

that they did not review the specific details of the prescription prior to administering the treatments.

Licensee Comment:

- The report states that the therapists failed to perform a chart check for two weeks of the patient's treatment. Although this is true and is a violation of the QMP, a chart check would not have prevented a misadministration in this case. This violation of the QMP was identified by the licensee, albeit after the misadministration. In order to prevent the error from resulting in a misadministration, as defined in 10 CFR 35.2, the chart check would have had to be completed by the Wednesday of that week. However, chart checks are normally performed on Fridays, by which time the error would have already resulted in a misadministration.

NRC Response:

The NRC agrees with the licensee that if the chart checks are normally performed on Fridays, it is unlikely that a chart check would have identified the error in time to prevent a misadministration.

Licensee Comment:

- The policy for the therapists to verify the presence of the physicist's initials in the chart check column shows that the licensee has multiple mechanisms in place, outside of the QMP, to prevent mistakes. This shows the licensee dedicated to quality.

NRC Response:

The NRC agrees that the facility had appropriate mechanisms in place to prevent errors; however, the fact remains that on five separate occasions, trained nuclear medicine therapists working in pairs were inattentive to the fact that the physicists initials were not in the chart check column (an indication that the calculations had not been checked).

Licensee Comment:

- It is stated that (p.6, 1. 1) the NRC inspector identified three apparent violations of the QMP. In fact, all the three violations had already been identified by the licensee and a written report was submitted to the inspector at the time of the inspection.

NRC Response:

The NRC agrees that the licensee identified the violations. The statement was not meant to imply that the licensee did not identify the violations prior to the NRC inspectors review and identification of the apparent violations.

Licensee Comment:

- The report states (p.6, 1.13) that the licensee failed to perform daily verifications of treatment versus the written directive. According to the therapists, this was indeed performed on each occasion of treatment. However, the therapists failed to notice the

discrepancy on the first five of the six occasions. Had they not been performing the check, the error would not have been noticed before the sixth treatment.

NRC Response:

Failure to notice the discrepancy is again another way of saying the therapists failed to verify the specific details of the written directive prior to treatment. The fact that on one occasion, the therapist did attempt to verify the specific details of the written directive, does not connote that attempts were made on all of the other occasions. The inspector was told by the therapists he interviewed that they did not refer to the written directive prior to administering treatment but instead referred to the treatment plan from the dosimetrist to enter data into the Record and Verify system.

Licensee Comment:

- Besides the two independent physicists, the investigation team also included a physician from another hospital (p.6, 1.19). Only one dosimetrist was interviewed by this committee (p.6,1.24; p.7, 1.3 1).

NRC Response:

Correction noted.

Licensee Comment:

- The report fails to note that the licensee determined that the therapists had verified the prescription before each fraction of treatment, but had failed to notice the discrepancy in the dose in each instance (Licensee report dated 10/19/98, p.2, 1.17)

NRC Response:

The therapists did not verify the prescription before each fraction of treatment. Had they done so, the wrong treatment dose would not have been administered on each day that the patient was treated.

Licensee Comment:

- The staffs dependence on the dosimetry schedule to perform chart checks did contribute to this error. In fact, the new dosimetry log that was implemented immediately is designed to eliminate this very situation.

NRC Response:

Assuming the licensee intended to say calculation checks rather than "chart checks", the licensee is apparently stating that the staffs dependence on the dosimetry schedule to perform calculation checks did contribute to the error instead of may have contributed to this error.

Licensee Comment:

- The report correctly points out that "the licensee's investigation into the event was thorough and comprehensive. " However, it also states that the "licensee failed to evaluate the significance of previously identified problems with chart check assessment." **This is *incorrect***.

  A large part of the committee's time was spent in assessing and revising the implementation of the chart check policy. The committee had, within hours of misadministration, revised the chart-check policy. The new policy now requires the chart checks to be started on Wednesday of each week. The therapist performing the checks is required to submit a report regarding the status of the checks on Thursday to his/her supervisor. The supervisor is required to ensure that the task is completed on Friday and to submit a status report to the Director of Radiation Oncology each week. The inspector was informed of this new policy during the interviews at the time of the inspection and a statement to that effect is made in the licensee's submission dated 10/19/98 (p.4, 1.11).

NRC Response:

The comment in the report refers to the licensee's failure to evaluate the significance of previously identified problems with the chart check assessment when the problem was brought to the attention of the Department Manager and not reported to the RSO. Problems with performing the chart checks continued up to the time of the misadministration.

Licensee Comment:

- The written report (dated 10/ 19/98) submitted to the NRC did not explicitly list the revised policy because, even if the chart check had been performed in this case, the error would have still resulted in a misadministration. The chart check may have flagged the error on Friday afternoon instead of Monday morning, when it actually was. The resulting deviation in the dose delivered would still have been the same. However, the committee did recognize this as a transgression of the QMP and stated it as such in the submitted report.

NRC Response:

The NRC agrees with this assessment.

Licensee Comment:

- The report correctly acknowledges that the review of multiple patient charts failed to reveal any other mistakes, besides instances of missing weekly chart checks. Since this had already been identified by the licensee, the inspection did not reveal my additional violations.

NRC Response:

The NRC agrees with this assessment.

Licensee Comment:

- The therapists assigned to the duty of chart checks were indeed responsible for the task. If a therapist was unable to complete the task, (s)he was required to report that to the supervisor. During the interviews, two of the therapists stated that they did not feel responsible for this task although it has been assigned to them via the schedule. However, one of these very therapists recalled specific instances when she had personally informed her supervisor when she was unable to complete the checks. In each such instance the supervisor failed to take necessary and effective action to eliminate the problem

NRC Response:

The NRC agrees with this assessment.

Licensee Comment:

- The Site Specialist (supervisor) had informed the Director of Radiation Oncology about this infraction in September and had been instructed by the Director to remedy the situation immediately since it was a violation of the QMP and NRC regulations. The Site Specialist, however, failed to correct the problem.

NRC Response:

The NRC agrees with this assessment.

Licensee Comment:

- The process for chart checks has remained unchanged for the past eight years and has proven effective during the same period, as evidenced by the compliance shown since the implementation of the QMP. The violations noted in this instance were not due to an ineffective policy but due to an individual supervisor's failure to maintain compliance with the policy. The committee, as well as the management, recognized this deficiency and had already taken proper and comprehensive action within 24 hours of the misadministration.

NRC Response:

The NRC agrees that for some period of time the chart checks were done according to existing policy, however, a large number of chart checks were not performed in accordance with the QMP during August and September 1998.

Licensee Comment:

- Also, as noted in the report, there were only two deficiencies noted in the month of October, showing the effectiveness of the corrective steps. Also, both these instances had been documented by the licensee in their report to the NRC.

NRC Response:

Comment acknowledged.

Licensee Comment:

- The report acknowledges that all the staff had been appropriately trained in the QMP and showed a good understanding of the QMP. However, it then concludes that the "implementation of the QMP was not clearly regarded as the highest priority" and therefore the "training appear(ed) to have been deficient with regard to stressing accountability for implementing the QMP."

NRC Response:

Failure to properly implement the QMP by not one but several individuals during the week suggests that implementation of the QMP was not regarded as the highest priority by the individuals. The report points out that two of the therapists interviewed indicated that they simply did not go by the weekly schedule given to them by the site manager and all persons interviewed indicated that they understood that the chart checks were required by the QMP, but claimed work load prevented them sometimes from completing the chart check.

- **Licensee Comment**:

The staff interviewed stated that they were aware of the QMP requirements for patient treatment as well as chart checks. In fact, each staff member had been given a personal copy of the QMP at each in-service. A survey of local institutions found that not one of them provided the staff with a personal copy of the document. The implementation of the QMP regarding chart checks has not been in question since its inception in January, 1991.

NRC Response:

Providing individuals with a copy of the QMP is a positive action; however, it is more important to ensure that individuals understands the importance of the document, and effectively implements it.

Licensee Comment::

- The department follows many policy and procedures, related or unrelated, to ensure proper patient treatment. For example, the therapists are required to take weekly port films on each patient under treatment, and check the output of each radiation beam on the linear accelerator every morning before using the machine. These tasks are not required by any regulatory bodies, but are good quality assurance tools to ensure proper treatment. The staff understands that they are required to perform these tasks and do so.

However, few, if any, of them know if any of these are required by regulation. They are expected to perform the assigned tasks irrespective of impact on regulations. It would not be in the patient's benefit to differentiate between tasks required by regulation those that are not.

NRC Response:

Comment acknowledged.

Licensee Comment:

- The department delivers approxirnately 4,000 patient treatments per year on the cobalt unit. Records since 1991 show not one case of a missing chart check. A distinguished record such as this cannot be achieved without making the implementation of the QMP the highest priority and stressing accountability for its implementation.

NRC Response:

Comment acknowledged; however, hospital staff performance in August and September 1998, did not appear to reflect this level of accountability.

Licensee Comment:

- When informed of the transgression, the Director of the department had, in no uncertain terms, instructed the Site Specialist to rectify the situation immediately. She had also followed up with the Site Specialist to make sure that patients on the cobalt unit were not affected by this failure. When the Director learned that the situation had indeed not been corrected, she immediately took over the day to day operations of the department. The accountability for implementation of the QMP was clearly understood.

NRC Response:

The NRC recognizes the actions taken by the line manager; however, the fact that the RSO was never informed of the problem by either the Site Specialist or the Director of the department suggests a breakdown in communications.

Licensee Comment:

- The report concludes that the NRC inspector identified four examples where the licensee staff did not follow the requirements in its QMP." All these four transgressions had already been identified by the licensee prior to the inspection, as is evidenced in the report dated 10/17/98 submitted by the licensee and the corrective steps outlined in the NRC report (p.9, item 6.0).

NRC Response:

The NRC agrees that the licensee identified the issues. The NRC inspector independently verified the four examples of failure to follow the requirements of the QMP.

Licensee Comment:

- The report concludes that the root cause of the misadministration was similar to that in the case of the misadministration in 1994 since they were all due to a programmatic weakness in the implementation of the QMP, namely, failure of the staff to verify correct parameters before commencing treatment.

10 CFR 35.32 requires that the licensee establish and implement a QMP containing policies and procedures to ensure that each administration is in accordance with the

written directive and that any unintended deviations are identified, evaluated, and appropriate action taken.

In this case, the licensee's QMP clearly outlined the functions to be performed in order to ensure proper patient treatment. It also contained appropriate procedures to identify errors, when and if they occur. The licensee had also instructed all individuals in the QMP, provided them a copy of the same, and made them aware of their responsibilities. In this case, however, the staff failed to notice the inconsistency in the treatment they were delivering and the physician's directive. However, had the QMP not been in place and effective, the therapist delivering the treatment would not have identified the error.

Since the events in 1994, the department has delivered approximately 15,000 treatments using the cobalt-60 teletherapy unit without a single error. This record cannot be achieved without proper management, qualified personnel and a good, effective QMP.

As the report points out, the Human Failure Analyst from the NRC had concluded that the '94 misadministration were due to (i) human error due to stressful working environment in the department, and (ii) a lack of support job performance aids (e.g., check lists, dual verifications, etc.). Since 1994, the management has made a diligent effort to improve the stressful environment in the department. Indeed, not one of the employees questioned has even alluded to the presence of stress. Also, the department management has ensured that proper job performance aids are made available to the employees. Indeed, this department has the only record and verify unit in the entire country. ***Clearly none of these factors are common with the current misadministration.***

NRC Response:

In the 1998 event as in the 1994 event, the cause of the misadministration was due to programmatic weakness in the implementation of the QMP, (failure of the staff to verify correct parameters before commencing treatment). It is not clear what human factors may have contributed to the multiple errors committed during the 1998 treatment, however, heavy work load appears to have contributed to the dosimetrists failing to correctly complete the dosimetry log which resulted in the calculation not being checked by the physicist.

Licensee Comment:

- The QMP does not imply that there will never be an error in a patient treatment. The QMP requires policies and procedures to ensure that the patient will be treated according to the written directive and error, if any, will be identified. The QMP at Sinai met these criteria and was well implemented, as evidenced by the interviews with the staff.

NRC Response:

The NRC disagrees that the QMP in this case was well implemented. The QMP is designed to ensure the treatment prescribed is the treatment administered. The process is one of multiple barriers; calculations are double checked, written directives are checked against dose to be administered, and weekly chart checks are performed to

ensure the requested treatment is being administered. In this case the QMP was not well implemented, i.e., all barriers failed, resulting in a misadministration.

Licensee Comment:

- The misadministration in this case were due to human error, compounded by multiple missed opportunities to identify it.
  - The therapists did review the prescription, as required by the QMP, but did not effectively see or verify it. They saw what they expected to see.
  - The dosimetrist also saw what she expected to see, and what she saw was reasonable.
  - What they expected to see was usual, reasonable, and hence no harm was done to the patient.
  - Failure to document the calculation in the log was unusual, not systematic. It was the result of an atypical workload - a simple human error.
  - Failure to perform weekly chart checks was programmatic. However, it had been self-identified and direction had been given by the department Director to the Site Specialist to rectify the problem. Failure to fix the problem is a failure of the middle manager who was already slated for reassignment at the time of this error. The plan was to place the Director and a senior therapist to review and improve procedures, as necessary. Senior management had already begun an audit of the DMC system, but had not yet visited Sinai. Hence, upper management was already moving to identify and correct any programmatic failures.
  - The calculation checks were always performed and therapists were used to seeing the physicist's initials in the column. Failure to notice the missing initials was a human error.
  - A chart check in this case would not have prevented the misadministration..

NRC Response:

These statements were addressed in NRC comments above.

Licensee Comment:

- The misadministration did not result from a violation of the 10 CFR Part 35.32 (ie., an inadequate QMP or questionable implementation of the same). It was a result of human error made by knowledgeable professionals who knew what they were required to do but failed to do so. The error was identified by the licensee and immediate, exhaustive, and effective corrective action taken, as required by 10 CFR Part 35.32.

NRC Response:

The NRC disagrees. The failure to effectively implement the QMP, i.e., human errors in carrying out the QMP requirements, caused the misadministration. The purpose and importance of implementation of the QMP is to avoid human errors negatively impacting patients by identifying and correcting errors before they have negative results. Had the QMP been properly implemented, the misadministration would not have occurred.

Application of Enforcement Policy:

Licensee Comment:

- NRC information notice 96-28 states that in applying the enforcement policy, importance should be given to taking prompt, comprehensive corrective action when problems are identified. It states that the NRC encourages and expects [licensee] identification and prompt, comprehensive corrective action of violations," and that it "does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations."

  Within 1-2 hours of the identification of the violation, the licensee had put together a team of experts consisting of the RSO, physicians, physicists, and administrators from within and outside the institution. The committee was charged with examining the event and determining the root cause of the violation. The committee conducted a complete and thorough review of the circumstances that led to the violation by interviewing all the staff involved (therapists, dosimetrist, physicists, and management) directly or indirectly with the event. They also looked at policies and procedures in place, including the QMP, that should have prevented such an occurrence, including documents related directly or indirectly with the incident, actual logs, and records used in the department. Care was taken to compare the occurrences with past incidents that had transpired.

  The committee looked for and identified the root cause of the violation, as indicated in the report submitted to the NRC inspector at his arrival. It also took prompt and comprehensive corrective action as outlined in the various communications to the NRC. In arriving at the recommendations, great consideration was placed on ensuring that the corrective actions were not limited to the single violation/event, but that they encompassed similar potential situations. All these recommendations were implemented IMMEDIATELY (before the end of the day).

- Information notice 96-28 specifies a list of 20 steps that the development of effective corrective actions must follow. After evaluating the actions of the licensee and the committee, it shows that each criterion listed was satisfied:

1. **Was the management informed of the violations?**

   Yes, immediately.

2. **Were programmatic implications of violation and potential weaknesses in other areas considered in arriving at the corrective actions?**

   Yes. The committee, in fact, charged an expert in adult education to evaluate ALL departmental policies and procedures to ensure that (i) they are reasonable and

intelligible, and (ii) evaluate the staff s understanding of the same to ensure that a similar event does not occur.

3. **Were precursor events considered and factored into corrective actions?**

Yes. The committee looked at the entire chain of events that led to the occurrence of this misadministration. It also evaluated and compared the events with those that have occurred in the past in this and other radiation oncology departments.

4. **In the event of loss of radioactive materials, should security be enhanced?**

Not applicable.

5. **Has the staff been adequately trained on the applicable requirements?**

Records indicated that all the staff had received training in all the requirements.

6. Interviews indicated that the staff had a good understanding of the QMP and other requirements.

Should personnel be re-tested to determine adequacy of training?

All the staff was re-trained. An expert in adult education was also called in to assess the level of training and understanding amongst the staff.

7. **Has the staff been notified of the violation and corrective action?**

Yes, they were all informed immediately. In fact, they were part of the team recommending and implementing the corrective actions.

8. **Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?**

The committee considered this issue very seriously to ensure that similar problems do not recur. It found the fact that chart checks were not being performed, and that the problem had not been corrected over a three month period, very disturbing. In order to ensure that the situation never arises again, they revised the implementation of the chart check policy. They also changed the audit/reporting frequency from monthly to weekly. This will ensure that the problem is identified immediately if it occurs, and does not go uncorrected for any period of time.

I. **Is there a need to retain an independent technical consultant to audit the area of concern or revise your procedures?**

The committee consisted of two physicists and one physician from an independent institution. The expert in adult education who has been brought in has extensive experience in this field and is also from an independent institution.

J. **Are the procedures consistent with current NRC requirements? Response to NRC Inspection Report Dated 11/12/1998 DMCI Sinai Hospital, Detroit, MI December 16,1998 Page: 10**

Yes, they are.

K. **Is a system in place for keeping abreast of new or modified NRC requirements?**

The RSO and all the physicists are knowledgeable in the current NRC requirements and made aware of new requirements and recommendations immediately through professional literature, NRC bulletins and notices, and the Internet.

L. **Does your staff appreciate the need to consider safety in approaching licensed activities**?

Yes; there has not been any safety-related accident or incidence at this institution.

M. **Are resources adequate to perform licensed activities? Has the RSO been provided sufficient time and resources to perform his duties?**

The staffing levels for all areas were evaluated. The RSO has sufficient time to perform his duties, as is evident from his participation in this investigation.

N. **Have work hours affected the employees' ability to safely perform the job?**

Not applicable since there has been no change in the employees' job hours.

O. **Are organizational changes necessary?**

The committee evaluated the effectiveness of all personnel involved. Some organizational changes were made immediately, as outlined in the written response to the NRC.

16. **Are management and RSO adequately involved in the oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?**

The committee increased the supervisory oversight through periodic audits, as described in the report to the NRC. The RSO will be advised of any future infractions in writing by the supervisor, as indicated in the revised QMP submitted to the NRC.

17. **Has management established a work environment that encourages employees to raise safety and compliance concerns?**

The employees in the department enjoy a good working relationship with the management and feel free to discuss their concerns and air their feelings in a mutually beneficial manner, as is evidenced by their candid discussions with the committee and the NRC staff.

18 **Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?**

The staff in the department is told to always give priority to quality. Each operating team (therapists on a machine, dosimetrist, physicist, etc.) maintains its own schedule and sets its own time limits. The management's commitment to safety and compliance is evident from the fact that, at a great monetary expense, they have installed and maintain a record system on the cobalt unit, the only one of its kind in the country. The manufacturer of the cobalt unit does not produce such a system. The licensee had to work with several manufacturers and suppliers over a long period of time in order to implement this system.

19. **Has management communicated its expectations for safety and compliance?**

At every meeting held in the department, safety and compliance are stressed. The management monitors several items on a continual basis to ensure safety and compliance. The entire staff is involved in monitoring these parameters in one form or another.

20. **Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed? There is such an administrative policy in place and is followed throughout the institution?.**

- As stated in the enforcement policy (NUREG-1600), the first step in the enforcement process is the evaluation of the relative importance of the violation. It must be pointed out that the dose received by the patient was actually what is normally prescribed for such cases. In fact, the patient actually showed a faster response to the treatment due to the dose delivered. It should also be considered that no physical or other harm was done to the patient.

- Since the errors made in '94, the management has made a diligent effort to eliminate the problems for which the institute was then cited by the NRC. The employees feel free to voice their opinions and concerns, as was evident by their candid discussions with the NRC staff during the investigation. The licensee has also added numerous job performance aids such as a record and verify system, electronic verification system for wedges, and a patient treatment flow chart showing the processes to be followed for each treatment, to name just a few.

- Repetitive violations caused due to a licensee's failure to implement corrective action call for escalated action. However, although the NRC letter dated 11/27/98 concludes that these misadministration are similar to the violations and the root causes of the misadministration that occurred in 1994, this clearly is not the case since the root causes for the events in '94 (listed above) do not currently exist.

- When determining the proper penalty for a violation, one must take into account the frequency of the violations, their root causes, the adequacy of previous corrective actions, the period of time between the violations and the significance of the violations. When these factors are applied to this case, and once the licensee is given the credit it deserves for identifying the problem, conducting an immediate and thorough investigation, identifying the root causes, and taking prompt, effective, and

comprehensive corrective action, it is clear that the situation does not warrant an escalated enforcement action or a civil penalty.

- For a licensee-identified violation, an escalated action is warranted when the licensee is aware that a problem or violation requiring corrective action exists. This is not the case in this situation. Although chart-checks had been inconsistent for a short duration immediately preceding the misadministration, the situation had been corrected. In fact, at the time of the inspection, it was found that all patients currently under treatment had their charts checked during the month of October. Besides, the missing chart checks in this case did not contribute to the misadministration in any fashion.

- In terms of identification of the misadministration, it should be noted that it was identified by the licensee as a result of licensee self-monitoring through its own policies and procedures.

- As stated in NUREG-1600, "the judgement of adequacy of corrective actions will hinge on whether the NRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive corrective action." This is clearly not the case in this situation since the identification of the root cause as well as all the corrective actions necessary to be taken had been performed by the licensee on its own initiative without any input from the NRC.

- This was not a willful violation. Neither could one reasonably expect this violation to be prevented by the licensee's corrective actions for the violation that occurred four years ago since the root-cause of the two events was not the same. On the other hand, the licensee had already committed to specific, immediate and comprehensive corrective action even before the NRC site visit following this event.

- The remedial action taken by the licensee against those responsible for failure to immediately rectify the chart check situation clearly demonstrated the seriousness of the violation to the other employees.

- This misadministration was not the result of any programmatic failure nor any programmatic weakness in the implementation of the QMP. The therapists were aware of the task which needed to be performed and had adequate knowledge and skills to perform those tasks. The errors associated with these incidents are what are termed "skill-based" slips or lapses. "The probability of skill based error can be reduced but cannot be eliminated," according to Dr. Dennis Serig, Senior NRC Human Failure Analyst. "It is understood that humans make errors." The therapists had clearly developed routines to detect errors prior to treatment. Had this not been the case, the therapist would not have identified the error when she did.

- In view of this, the licensee must develop procedures to reduce the likelihood of human error.

As is evident from the five distinct layers of safety that were breached in order for this error to occur, the licensee has exercised the utmost effort toward this end. It should also be noted that there was yet another check that was pending (a sixth layer), namely a routine personal patient checkup by the authorized user conducted every Monday. It can be stated with a very high degree of certainty that the error would have been caught during this examination since one of the primary goals of the physician is to check and

document how well the patient is tolerating the treatment. The patient had indeed been seen the previous week but the error was not flagged since it had not yet occurred.

- In light of the licensee's history of some 15,000 treatments in the past four years without any errors, it can be stated that this violation is an isolated case of failure to follow the procedures clearly outlined in the licensee's QMP and does not demonstrate a programmatic weakness in the implementation of the QM program and has limited consequences for the program.

NRC Response:

Comments acknowledged.