DCD/DCB

Bethesda

April 4, 1994

Mr. W. [illegible] Axelson, Director
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60432-4351

RE: License #34-10921-03
Docket No. 030-02809

Dear Mr. Axelson:

Your letter of March 21 stated that no response was required. However, we feel the report is inaccurate in several respects, so we feel an immediate response is appropriate.

Apparent Violation #4

Messrs. Reichhold and Slawinski had indicated only six apparent violations at the summary meeting on January 28, 1994. A seventh apparent violation identified as item #4 on page 2 of the report, was never mentioned. Page 8 of the report claims "A third nurse... had not received the annual refresher training." According to our records this statement is not accurate.

The third nurse had been initially trained and had received Bethesda's annual refresher training on September 30, 1993. We showed the inspector the record of nurse's retraining. The inspector also reviewed our training videos and administered a verbal test to this nurse. He expressed his satisfaction with both the adequacy of our training videos and the knowledge demonstrated by this nurse.

We wish to again make it clear that we have maintained a pool of well trained nurses to care for brachytherapy patients. Theses nurses have received not only initial training, but yearly refresher training. We have documented this training and presented it to the inspectors. It was an administrative assignment error, which caused the wrong nurses to be assigned to this patient during the overnight shifts. This resulted in apparent violation #3. We believe apparent violation #4 to be an error. We have not failed to retrain our nurses annually.

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Apparent Violation #5 and Implied Lack of Oversight

We take issue with statements in the report which suggest a less than vigorous and vigilant oversight of our program. For example, on page 10 the report states the "the physicist admitted that the review did not include a detailed audit of the dates and signatures of the authorized users". This is not an accurate statement.

As part of the annual QMP review conducted by Bethesda, each brachytherapy chart was meticulously examined to be sure that each and every required element of the written directive was present. Indeed, each and every chart was found by the inspectors to have both a signature and date. But since the NRC has not defined "signature" in its QMP regulations, we did not realize that physician initials would not be acceptable. Physician initials are accepted throughout the hospital and by the JCAHO. So absent of any contrary indication by the NRC, we interpreted initials as sufficient.

Similarly, we never failed to date a written directive. The definition of written directive states "An order in writing for a specific patient, dated and signed by an authorized user... "We understood this to mean a statement signed by the physician which included the patient name, date, isotope, etc. We did not realize that the date must be written by the physician. Had the definition been worded "signed and dated by an authorized user" the NRC's intent would have been evident.

It is interesting to note the NRC's response when we asked what constitutes a "signature". Must the full name be written out? Could the middle initial be used? What about first initial with full last name? The NRC's response was that the authorized user must use his "legal signature". This term is certainly not defined or easily inferred from the regulations. When we asked what this means we were told "how he signs his checks". We doubt that authorized users across the nation are signing their written directives exactly as they sign their checks. Are they also in violation of the signature requirement?

We believe this apparent violation did not result from poor oversight or inadequate review as suggested by the report. Quite the contrary. In spite of our most diligent efforts, we were victimized by new regulations which are in conflict with common medical practice, and absent adequate explanation. Had the NRC clarified these issues in a Regulatory Guide, we would have implemented our QPM program accordingly. We have not met the "letter of the law" only because the NRC has waited until now to explain it. But we certainly have met the "spirit of the law". The physician's initials, as used throughout the patient's chart, unambiguously identify him/her as the authorized user approving all elements of the written directive including the date.

Apparent Violation #6

On page 10, the report finds fault with a written directive which "indicated the time when sources were to be explanted, rather than the total dose or total treatment time". The report fails to mention the NURSING INSTRUCTION FORM which was completed at the time the patient was implanted. It recorded the implant time as 12:30pm, April 10, 1992. The written directive dated April 10, 1992 provided the following explant instructions "remove 12:00 noon 4/12/92." The NRC requires that "exposure time" be specified prior to explant. These two documents, both completed prior to explant, meet this requirement literally, i.e., the start and finish times for the implant are explicitly stated. The total exposure time is also clear, i.e., the 47½ hours from 12:30pm on April 10 to 12:00 noon on April 12. We believe this meets the requirement that the written directive contain "information" including "exposure time".

We did not contest this issue more vigorously at the time of the summary meeting with Messrs Reichhold and Slawinski, because they had combined this issue with the signature and date issue into a single apparent violation. However, now that it has evolved into an apparent violation of its own, we must object. We believe we have met both the intent of the regulation and even its most literal interpretation.

The Unresolved Issues

Throughout the investigation of this incident, we repeatedly encountered surprising and inconsistent interpretations of NRC regulations. We provide some examples below to demonstrate how difficult it is for a well intentioned facility to comply with such regulations. It's like trying to hit a moving target - we aim to do what we believe the NRC requires, only to discover the NRC's interpretations is different, and even contradictory.

Verbal Revision - Consider the issue of verbal revision to a written directive. As our letter to B. J. Holt (February 2, 1994) makes clear, an implant mistakenly removed 9% early is not even a reportable event. But if the physician knowingly instructs the removal of the implant 1% ahead of schedule, this revision constitutes a violation (unless the directive is rewritten to reflect the 1% change). Does it make sense that a 9% mistake is permitted, while a 1% planned deviation is a regulatory violation?

In response to my letter, Ms. Holt had Mr. Reichhold contact me by telephone. He explained that the QMP program is performance based so we could alter our program to permit verbal revisions. He even offered suggestions such as having the physician countersign the verbal order at a later time. He stated a letter

he was preparing would explain it more fully, I reminded Mr. Reichhold that the regulatioins specifically prohibit verbal revisions unless the patient's health is in jeopardy. So if we implemented his suggestions we would be in violation of QMP regulations. I was curious to see how this contradiction would be resolved in his letter. I have yet to receive it. The regulations do not permit revisions as he described.

How are we to comply with these QMP regulations when the "experts" offer contradictory advice. There is an obvious fault with the regulations - should a 1% intended deviation be a violation if a 9% error is not even a reportable event? Should we be cited with a violation because we intentionally removed an implant 45 minutes early as instructed by the physician, a 3% change known to have no medical significance?

"Discovery" - We also encountered a surprising interpretation of the word "discovery". The NRC requires the licensee to notify the NRC the next calendar day after discovery of the misadministration. The patient must be notified within 24 hours of discovery. We assumed the "24 hours clock" began when we first "discovered" that a misadministration might have occurred, i.e., when we found the source to be dislodged. This was insufficient time for us to fully analyze data and interview all participants, so we reported the incident the next day as a possible misadministration.

We were surprised when inspectors told us that "discovery" was interpreted by the NRC to mean "after gathering the data and reaching the conclusion that a misadministration had occurred". They told us we could have taken more time to assess the incident and come to a more definitive conclusion. Consider the contradictions that this interpretation creates:

> **Is Notification Urgent or Not**? - How long could we have taken to gather and analyze data? What if we had taken four days, four weeks, or four months (as the NRC has)? Clearly, there must be a limit. An unspecified delay, as permitted by this interpretation, is clearly inconsistent with the NRC's need to act quickly in such events. We were also told that patient notification is similarly not required until it is "concluded" that a misadministration has occurred. According to the inspectors, we did not have to notify the patient since we quickly concluded that no misadministration occurred. However, if the NRC decides this to be a misadministration, we were told, we must notify the patient within 24 hours of our notification by the NRC. It has been nearly four months and the NRC has yet to make a decision. Does it make sense to require us to notify the patient within 24 hours, subsequent to a delay by the NRC of four months or more?

Misadministration - Isn't there also something wrong with the definition of misadministration? Should it take four months for the NRC to decide if a misadministration has occurred? What if we had taken four months to "discover" if the dislodged source constituted a misadministration? Would it have been acceptable to the NRC if we reported it four months after it occurred?

It is unfortunate that this report, with potential inaccuracies, has become part of the public record. Yes, a source became dislodged - an incident we regret. Yes, the wrong nurse was mistakenly assigned to care for this patient. These two "incidents" precipitated three apparent violations: untrained nurses, uncontrolled source, and public area exposure rate. But after two full days of examining the brachytherapy and QMP program, the two inspectors could find only one other (very minor) apparent violation - a survey meter was checked quarterly instead of with each use.

The remaining apparent violations we dispute. One is obviously in error - the third nurse was retrained. The remaining two resulted from regulations which are ambiguously worded and inadequately explained. The NRC is interpreting these regulations in ways we never envisioned... "legal name" must be signed, dates must be written by physicians only, and start-stop times may not be substituted for hourly elapsed time. Should these be violations when they meet the spirit of the regulations and reflect an honest effort by the licensee to interpret and implement the regulations correctly?

We appreciate your consideration in this matter and await your response and findings. If we can be of any help regarding the contents of this letter, please feel free to contact us at 513-569-5195.

Sincerely,

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cc: B.J. Holt
W. Groneman