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U.S. Nuclear Regulatory Commission  
Region III  
Attn: B.J. Holt, Chief  
Nuclear Materials Inspection  
Section I  
799 Roosevelt Road  
Glen Ellyn, IL 60137

Re: REPLY TO A NOTICE OF VIOLATION  
License No. 13-01264-05  
Docket No. 030-07609

Gentlemen:

This letter is in response to your November 5, 1993 letter, regarding an inspection conducted on September 29, 1993. For convenience the items in this response are keyed to the items in your letter.

- A. (1) The named individual has not been available as chairman of our radiation safety program since approximately May, 1992, because he left our employ.
- (2) An interim chairman of the Radiation Safety Committee has been appointed.
- (3) A license amendment will be requested by January 31, 1994, to permanently correct this deficiency.
- (4) Full compliance will be achieved when the amendment is received.
- B.1. (1) The Radiation Safety Committee failed to meet at least each calendar quarter because of the absence of a chairman and our inability to constitute a committee quorum.
- (2) Since October 19, 1992, the committee has met at least once each calendar quarter.
- (3) In the future, management shall ensure that the committee meets once each calendar quarter.
- (4) Full compliance was achieved on October 19, 1992.

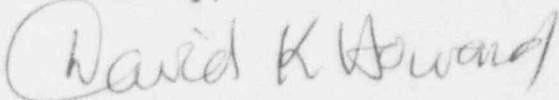
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2. (1) The Radiation Safety Committee did not perform the required annual audit because of the absence of a chairman and our inability to constitute a committee quorum.
  - (2) An audit was performed by the committee on October 29, 1993.
  - (3) Full compliance was achieved on October 29, 1993.
  - (4) In the future, management shall ensure that required audits are performed.
3. (1) Minutes for the May, 1993 Radiation Safety Committee meeting had not been typed and notes taken during the meeting were not available at the time of the inspection.
  - (2) Notes of the meeting were placed in the committee minutes file on October 28, 1993.
  - (3) Full compliance was achieved on October 28, 1993.
  - (4) In the future, management shall ensure that committee minutes are maintained.

If you have any questions or require additional information, please contact our Radiation Safety Officer, Ron Boyll, at (708) 949-3354.

Sincerely,



David Howard, Ph.D.  
Director, Pharmaceutical Development