

January 27, 1987

MEMORANDUM FOR: File

FROM: William H. Schultz, Enforcement Coordinator, Enforcement and  
Investigation Coordination Staff

SUBJECT: RADIATION STERILIZERS, INC.  
LICENSE NO. 04-19644-01  
ENFORCEMENT BOARD BRIEFING

An enforcement board was held on January 23, 1987 to review the findings of an inspection that was conducted on January 14, 1987. During the inspection it was determined that a significant breakdown had occurred in the management control system at this facility. Although the significance of the violations would lead to a classification of the problem at Severity Level III it was concluded by the Board that it was more properly classified at Severity Level II. This decision was based on the following considerations:

1. Repeat violations.
2. Duration of violations.
3. Operating the irradiation facility with the knowledge that important safety alarm systems were inoperable.
4. Awareness of these problems by licensee management.

As a result, it was agreed that the Severity Level of the problem would be increased from Severity Level III to Severity Level II because of careless disregard for regulatory requirements by licensee management. It was concluded that an \$8,000 civil penalty would be recommended and no increase would be made because of multiple examples since it was the multiple examples that led to the conclusion that there was a major breakdown in the program.

It was also agreed that additional actions would be taken to make changes in the license. No clear decision was reached regarding how this would be accomplished. The two major proposals were that the licensee would be asked to voluntarily commit, in the license renewal application, to more restrictive operating procedures or to issue an Order Amending the License. Both of these options are still being considered. On January 27, 1987 further discussion was held between DRSS and RA and it was agreed an attempt would be made to accomplish necessary license revisions with commitments from the licensee, and if that proved unsuccessful, then an Order would be used to modify the license and effect necessary changes.

Original signed by  
[Signature]

William H. Schultz  
Enforcement Coordinator

See Attached Distribution

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