

September 10, 1999

Mr. Russell N. Stein
Vice President
GrayStar, Inc.
Mt. Arlington Corporate Center
Suite 103
200 Valley Road
Mt. Arlington, NJ 07856

Dear Mr. Stein:

This is in response to the requests in your letter dated August 12, 1999, regarding NRC's questions for additional information. We have reviewed the issues addressed in your letter and reached the following conclusions.

1. Your request to extend the response time to NRC's deficiency questions from August 26, 1999, to September 26, 1999, is granted.

2. You requested that the classification of the GrayStar Model 1 irradiator be modified from Category II to Category I as defined in ANSI 43.10. We continue to maintain that the design of the GrayStar Model 1 fits the definition of Category II in ANSI 43.10, as well as the definition of "Panoramic dry-source-storage irradiator" in 10 CFR 36.2. Therefore, we ask you to proceed in developing your response to our questions in terms of such a classification. You may request exemptions, under 10 CFR 36.17, from those parts of the regulations which do not apply to your specific design.

3. We have reviewed the information which you provided regarding the provisions of 10 CFR 52.21 and 22. Based on this information, we made a determination that an environmental report is not necessary for the safety evaluation of your design as a sealed source and device.

If you have any questions, please contact me at (301) 415-7904 or Mr. Frederick C. Sturz at (301) 415-7273.

Sincerely,

[original signed by]
John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards -

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