UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 27, 1997

Martin Stein, President
Gray Star, Inc.
Mt. Arlington Corporate Center
200 Valley Road, Suite 103
Mt. Arlington, NJ 07856

Dear Mr. Stein:

I am responding to Gray Star's request, dated September 1996, and delivered to my staff in person on September 18, 1996, for registration of a unique irradiator design. We understand that the first unit is likely to be located at a U.S. Department of Agriculture (USDA) facility located near Philadelphia, Pennsylvania. We further understand that USDA personnel have discussed this plan with representatives from NRC's Region I office. We would like to stress the need for a collaborative effort between all parties since this is a unique device design, as such, obstacles may surface during licensing and product registration that may be policy setting and require additional time to resolve.

We have performed a cursory review of the application to identify areas that we feel require more information or clarification. Specifically, our review reveals the following:

1. We are concerned with the choice of cesium-137 chloride from the Department of Energy (DOE) for use in the Gray Star source designs. Note: while 10 CFR Part 36 may not be directly applicable, use of soluble cesium is prohibited by that rule. While Gray Star does not plan to use the DOE supplied WESF capsules in the irradiator, the radioactive material purity is in question. Specifically, the affect of the cesium-137 chloride compound and its impurities on capsule wall integrity may be an issue. DOE reports involving destructive analysis of their source capsules show corrosion from the inside of the source capsule out. We request clarification on how the cesium-137 chloride will be purified, dried, and specifications on the chemical composition. Additionally, we request justification as to why an insoluble and nondispersable form of cesium cannot be used.

2. To substantiate the claim that the Gray Star irradiator is "inherently safe", we request you use the methodology of a Probability Risk Assessment (PRA) to develop a failure mode and affects analysis for each component of the system. If the failure rates of components are not available, its associated Health and Safety effects including radiation risks to workers, members of the general public, and on the environment may be used. Particular attention should be devoted to the hydraulic system used to move source racks. This effort should include, but not be limited to: the maintenance frequency, and justification for this frequency of the hydraulic system, the effects radiation will have on the components (seal, hydraulic fluid,

etc.); and the expected external radiation doses that workers may receive during maintenance and loading. Also, include the possible affects from natural phenomenan such as a facility fire, flood, earthquake and/or tornado on the irradiator design.

3. We note that the design of the irradiator involves metal to metal interfaces consisting of different materials. Please explain the criteria used in selecting these materials in view of electrochemical corrosion resulting from dissimilar metals. Specifically, address the effort of an aluminum shroud on the rack and/or sources.

4. We note that heat generation resulting from the decay of the cesium sources is quite high. Please provide justification that your design would not allow the stainless steel sources to become "sensitized". Sensitization of certain stainless steel occurs when the steel remains in the critical sensitization temperatures of 450°C to 800°C for a sufficient amount of time. If the material becomes sensitized, it becomes more vulnerable to corrosion. Also, provide justification and/or procedures that demonstrate that these temperatures will not be reached during transportation of the sources.

5. Please provide justification that thermal cycling and use temperatures would not have detrimental effects on the integrity of the sources. In particular, provide justification that the cesium chloride would not experience phase transformations with associated density change resulting in detrimental effects on the capsule material and welds.

6. Please identify the range of environments in which the device will be used. Include temperatures, humidity, vibration and the expected number of cycles the sources would be subject to over their life-span. Clarify the length of time the sources will be used before replacement. Include any corrosive environments the device could be subjected to during use. This description should include any affect of cleaning solutions or product residue that may contact the device.

7. Please explain your procedures/process for evaluating source leakage and the frequency for such evaluations.

8. The sealed source design is unique. As a result, the source will need to be tested to demonstrate that it will maintain integrity during the uses specified in the application in addition to any special form tests. Please note that ANSI/ISO standards for source performance classification may not be appropriate for the testing of the source due to its unique intended purpose. Please provide a proposed set of testing criteria and possible failure criteria for the various conditions the source will be subjected to during use and source loading. Include consideration for thermal load, other high activity source experience, and the internal pressure build-up that occurs.

9. The source is designed to allow all work to be certified as leak free before radioactive material is added. However, the source would also be sealed by the use of two plugs. Please provide a demonstration that this design will maintain its integrity for the recommended working life of the device.

10. Provide a proposed testing plan and expected results for the irradiator verifying that safety features are operational and would maintain the integrity of the unit.

The following items are supplied to you as clarification or for information purpose only.

11. Please note that the Department of Transportation is the approval authority for special certificates. Therefore, the special form testing plan should be sent to them for review.

12. Obtaining a transfer of compliance for the Type B shipping package is a critical issue associated with the use of this device, and therefore, we suggest you contact Mr. Bernard White at (301) 415-8515 to arrange meeting to discuss submisson of the package design for approval.

13. 10 CFR 71.12(b) requires the submission of a quality assurance (QA) program that satisfies the requirements of Subpart H of 10 CFR 71. Once approved, this QA program is to be applied to design, fabrication, construction, testing, operation, modification of the structures systems and components of the Type B transportation packaging that are important to safety. It is important to note that the applicant must establish and implement a quality assurance program to control all design activities in the development of the Safety Analysis Report of the Type B package before those activities are conducted. We would suggest that you contact Mr. Stephen C. O'Connor at (301) 415-8561 regarding how and what to submit for approval of a QA program.

14. The irradiation design appears to have characteristics for both a Category I and II irradiator. We plan to use the ANSI Standard for Category I and a draft developed by an ANSI subcommittee for Category II irradiators for our initial review of this design and effectiveness of its various safety features.

15. The U.S. Congress requires that NRC recover essentially 100% of its budget through fees. There are both one time and annual fees associated with approvals of Type B packages, Quality Assurance program and product registration and licensing. We understand you have been in contact Sandra Kimberley at (301) 415-6096 concerning fees associated with your request.

We have enclosed copies of Regulatory Guides 10.10 and 10.11 regarding how to file for a device or source evaluation and a copy of a Standard Review Plan, NUREG-1550, to aid you in responding to the above questions regarding registration of the product design.

Upon receipt of the above requested information, we will continue a more detailed review of the application and develop a detailed set of technical questions as necessary. Should you have any questions, please feel free to contact me at (301) 415-7231.

Sincerely,

Original Signed by
Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Regulatory Guides 10.10 & 10.11
2. NUREG-1550

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