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

SUBJECT: TECHNICAL EVALUATION OF APPLICATION FOR CERTIFICATE OF REGISTRATION

Dear Mr. Stein:

This letter is in response to your application dated April 19, 1999, and your letter dated September 27, 1999, requesting registration of the Model GS-42 sealed source and the Model 1 irradiator. In accordance with 10 CFR 2.103, we are denying your request for registration of the Model GS-42 sealed source, and suspending review of the remainder of your application, as discussed below.

We have determined that your Model GS-42 source design is not acceptable for registration and licensing under 10 CFR 32.210 and 10 CFR 36.21. The provisions of 10 CFR 36.21 require that radioactive material in irradiators be as nondispersible as practical. Your application does not adequately justify your choice of cesium-137 chloride powder, a dispersible material. See Enclosure 1 for a detailed statement of the basis for the denial of the application which includes the issue of dispersibility.

With respect to your proposed design for the Model 1 irradiator, which would contain the Model GS-42 sources, your applications contain deficiencies which would have to be satisfactorily addressed before we would approve the design. These deficiencies are stated in Enclosure 2. In light of our denial of registration of your proposed sealed source design, we are suspending further review of your proposed Model 1 irradiator design. Therefore, you need not address the deficiencies in Enclosure 2 at this time.

In accordance with 10 CFR 2.103 you may request a hearing with respect to this denial of your source design application within 20 days of the date of this letter. If you wish to request a hearing, submit a written request to the Director, Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A request should reference this letter, and Sealed Source and Device Evaluation Case Number SSD 99-27.

Sincerely,

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Basis for Denial of Application for Registration of the Model GS-42 Sealed Source
2. Deficiencies in the Application for Registration of the GrayStar Model 1 Irradiator

cc. w/encl: SKimberly, LFDCB

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**no legal objection

Enclosure 1 to letter, Mr. Russell N. Stein, GrayStar, Inc.

Basis for Denial of Application
for Registration of the Model GS-42 Sealed Source

1. Dispersibility

> The application does not comply with the provisions of 10 CFR 36.21(a)(3), which require that the radioactive material in the irradiator sealed sources be as nondispersible as practical.

Contrary to these provisions, the application proposed to use cesium-137 chloride powder, a dispersible material. The application stated that it is not practical to use nondispersible material, but did not provide adequate justification.

Specifically, the application stated that the applicant chose the cesium-137 material based on considerations of cost savings, solubility in water for ease of fabrication, production requirements, heat output, ease in hot cell operations, and a long history of use in many types of irradiators. These are generic considerations which could apply to any irradiator, and are not adequate to demonstrate that less dispersible materials are not practical. There are many operating irradiators, used for purposes similar to the applicant's proposed irradiator, which use nondispersible radioactive material.

The application has not demonstrated that unique circumstances apply to this case which are not applicable to these other cases, nor has the application demonstrated that if a radioactive material leak did occur, there are unique design features which would mitigate the consequences of such a leak of dispersible material.

Furthermore, the history of the use of cesium chloride in irradiators, referred to in the application, is not applicable for this design, because those irradiators are generally smaller than GrayStar's Model 1. The individual sources are also smaller. Most of the individual sealed sources used in the referenced irradiators are only 30 curies, compared to 51,500 curies (1.11 E12 becquerel and 1.9 E15 becquerel respectively) in the proposed GrayStar sources. The application did not provide evidence that the historical experience with the smaller sources and irradiators is applicable to the GrayStar design.

2. Testing of Sealed Sources

> The provisions of 10 CFR 36.21(a)(5) require that the sources be found leak-free after certain prototype tests.

The proposed sealed source design did not comply with the prototype testing requirements in 10 CFR 36.21(a)(5). Specifically, the proposed sealed sources are designed to be doubly encapsulated. The application reported that in some of the prototype tests, both the inner and outer capsules leaked. To resolve the problem, the applicant only modified the design of the outer capsule. However, because the inner capsule design was not modified, the staff considers the inner capsule to be subject to leaks and, therefore, the design is unacceptable.

> The provisions of 10 CFR 36.21(e) require vibration testing sweeping from 25 hertz to 500 hertz.

Vibration testing of the source is incomplete. Vibration testing of the prototype sources should be performed along the weakest axis (i.e. transverse axis) instead of the stronger two axes according to accepted vibration testing practices as described in industry standards. The prototype sources were tested in the two other directions, but not in the direction of the weakest axis. Regarding the vibration spectrum, the regulatory requirement specifies a range of 25-500 Hz; the prototype has only been tested in the range of 25-100 Hz.

3. **Sealed Source Construction and Durability**

> The provisions of 10 CFR 36.21(a)(4) specify that the encapsulation must be resistant to general corrosion and to localized corrosion.

The application did not demonstrate that chloride corrosion, which could lead to leaks, would not form in the encapsulations during either the filling process or during operation as discussed below.

3.1 Integrity of Source Housing: The NRC letter dated July 26, 1999, asked the applicant to show that chlorides were not likely to form pits in the encapsulations during either the filling process or during the operation of the irradiator. The applicant's response cited historical evidence as proof that pitting would not occur. However, the sources containing cesium-137 chloride (hereafter "CsCl") in Type 316L stainless steel cited by the applicant were fabricated using different procedures than that proposed by GrayStar. GrayStar proposed to dissolve CsCl in water, pour the solution into the source tube, and then evaporate the water leaving a dry CsCl caked on the inner surface of the source tube. During this filling process pits may initiate and grow through the source tube. The response stated that "the time (in hours) involving the filling operation is not sufficient to significantly promote corrosion of the encapsulation material." However, no data were provided showing that the conditions present during the filling process (i.e. pH, time, temperature, concentration of impurities etc.) will be unlikely to cause corrosion of the stainless steel encapsulation.

The application stated that "[t]he CsCl source will be dry during the operational lifetime. Therefore, excessive moisture is not an issue." No evidence was provided to demonstrate that the evaporative procedure to be used will adequately remove moisture in the source tube. Moisture remaining in the source tube after fabrication could compromise the integrity of the stainless steel encapsulation. According to "Corrosion Data Survey", Metals Section 6th Edition, a 5-15% solution of CsCl in water between 150-250°F (66-121°C) can have an average penetration rate of 0.002 to 0.020 inches (0.05 to 0.51 mm) per year in Type 316 stainless steel (a steel similar to that proposed for used to encapsulate the source). The thickness of the inner source tube is 0.049 inch (1.24 mm). Assuming a corrosion rate of 0.002 in/yr (0.05 mm/yr), the 0.049 inch (1.24 mm) thick inner source tube would be compromised in 25 years. The anticipated service life of the GrayStar irradiator is 60 years.

3.2 Corrosion: The NRC staff asked the applicant to show that crevice corrosion could not be a problem in the sources. The response cited historical evidence against this corrosion mechanism. However, due to the differences in the filling procedure between the cited encapsulations and the GrayStar encapsulation design, this historical evidence is not applicable.

The response also cited the absence of an electrolyte as proof that crevice corrosion could not occur. No evidence was provided to demonstrate that the evaporative procedure to be used will adequately remove moisture in the source tube. Crevice corrosion is a concern, since it may be more difficult to remove moisture contained in these crevices.

3.3 Role of Materials Impurities: The effects that impurities in the CsCl source may have on the pitting, crevice, and stress corrosion cracking mechanisms was not resolved. The effect on integrity of the sources due to the presence of impurities, identified by the applicant, was not adequately addressed. The application cited historical evidence that these impurities would have no effect on these corrosion mechanisms. However, due to the differences in the filling procedure between the referenced encapsulations and the GrayStar proposed encapsulations, this historical evidence is not applicable.

3.4 Long Term Failure Modes: Regarding long term reliability of the sources, the response stated in the probabilistic risk assessment that "[t]he sources are designed to prevent all known previous source failure mechanisms" referring to the historical experience with the Waste Encapsulation and Storage Facility (WESF) sources. However, due the differences between the GS-42 and the WESF encapsulations, different failure mechanisms may occur, and the applicant did not adequately address such potential failures.

4. The Design Has Not Been Finalized

> The provisions of 10 CFR 32.210(c) specify that, for the review of a source, the application must contain sufficient information about the design, manufacture, and prototype testing to provide reasonable assurance that the radiation protection properties of the design are adequate to protect health and minimize danger to life and property.

Contrary to these requirements the application did not provide finalized and verifiable design configuration for a number of safety issues. Both the application and the additional information referred extensively to further research and development which is still needed to finalize the design. Some examples of information which have not yet been finalized, but would be needed for approval, are listed below in Sections 4.1 through 4.5.

4.1 Welding: Regarding the issue of welding the sources, the application indicated that "[t]he welding procedure and non-destructive examination methods for the redundant seal produced by the welding of the outer seal plug will be determined in cooperation with the organization operating the hot cell loading facility. Discussions with prospective suppliers have determined that TIG welding would be preferred welding method. During the weld development/qualification phase, minor modifications may be required in the weld prep area to facilitate the welding procedure qualification." Since the welding method and appropriate quality standards have not been determined, we cannot reach a conclusion about the adequacy of the source welds.

4.2 Source Filling: Several of NRC questions asked for a detailed description of the procedure by which CsCl is introduced into the stainless steel encapsulations. None of the responses to the questions provided adequate details. For example, one of the responses gave generalized steps which call for "[h]eat (or allow self heating) of the filled GS-42 encapsulations to drive off all moisture." The response to one of NRC's questions

(Question22) stated that "[t]he exact procedures used to place the CsCl in the encapsulations will be dependent on the hot cells used. However, any procedures used will require the removal of all water from the inside of the inner and outer encapsulation." The conditions (time, temperature, pressure etc.) to evaporate the water or the equipment to monitor/measure the process were not specified.

For NRC's technical evaluation, evidence must be provided to show (1) that moisture is adequately removed from the inner and outer source tubes prior to sealing and (2) corrosion did not occur in the source tube during the filling procedure such that the integrity of the source tube could be compromised. According to some technical references, pitting initiation times in stainless steel could occur within minutes if conditions (i.e. pH, temperature, chloride concentration) are severe enough.

The response to a related issue in the NRC question (Question 22) indicated a different filling method when stated that "[t]he evaporative process (if used) will use both a vacuum and heat process to drive off the water." However, another response (Question 17) referred to "[f]uture alternative filling methods," but the other filling processes were not specified.

Exhibit 7, Technical Issues to be Addressed in Application for Registration of the Model GrayStar Irradiator, of the original application stated that in the encapsulation "the distribution of the CsCl will be uniform." Since the filling procedure has still not been determined, this conclusion cannot be drawn.

Responses to other questions (Questions 2,13,15,17, 23, and 59) assumed that no moisture would be present during the 60 year operation life. But similarly to the uniformity issue, this conclusion cannot be drawn because the filling procedure has still not been determined.

4.3 Silver Seals: The effect of CsCl and its impurities on the silver sealant of the seal plugs was not clarified. The application stated that during the filling process neither the CsCl nor its impurities come into contact with the silver sealant for either the outer or inner seal plug. Since the precise filling process has not yet been determined, such a conclusion cannot be drawn.

The application also stated that "[f]uture alternative filling methods utilizing other sources of CsCl could result in CsCl residue on the sealing surfaces coming in contact with the silver. This condition will not result in any degradation of the sealing properties." Such a statement seems to call for future research and development to support this conclusion.

4.4 Seal Torquing: Regarding proper torquing of the seal plugs, the applicant has not specified a maximum allowable torque. Without technical specifications with tolerance values, the uniformity of construction cannot be assured.

Enclosure 2 to letter, Mr. Russell N. Stein, GrayStar, Inc.

Deficiencies in the Application for Registration of the GrayStar Model 1 Irradiator

The issues discussed below have not been adequately addressed in the application dated April 19, 1999, and in the additional information provided by the applicant in its letter dated September 26, 1999.

1. The Design Has Not Been Finalized

> The provisions of 10 CFR 32.210(c) specify that, for the review of a device, the application must contain sufficient information about the design, manufacture, and prototype testing to provide reasonable assurance that the radiation protection properties of the device are adequate to protect health and minimize danger to life and property.

Contrary to these requirements, the application did not provide finalized and verifiable design configuration for a number of safety issues. Both the application and the additional information referred extensively to further research and development which is still needed to finalize the design. Some examples of information which have not yet been finalized, but would be needed for approval, are listed below in Sections 1.1 through 1.10.

1.1. Dose Rate Calculations: For dose rate calculations to demonstrate that the GrayStar irradiator complies with the provisions of 10 CFR 36.25, the application stated that these calculations are difficult because of the complexities of the shield and proposed instead to perform surveys on the first unit, after its construction, at the loading facility to demonstrate compliance. Since the radiation profile of a device is a part of device registration, the results of such calculations or results from prototype testing are needed for evaluation of the safety features of the design.

The application referred to a Shield5 proprietary software package for dose rate calculations, without providing further information about code verification and validation of the software. The application indicated that the software models the contribution from all four source plaques, and that shield thickness and position are also modeled via the coordinate system. However, the sample calculations provided were based on a simplified model. It was unclear whether these simplifications were used when producing the dose rate calculations provided in Exhibit 4 of the Application. Actual calculations produced by the software were not provided.

Also, Assumption 9 stated that “2,800,000 curies of cesium-137 are used for the calculation. This is the actual nominal loading of the encapsulations. Other parts of the application document referred to a loading of a maximum of 3,000,000 curies. This is to account for loading tolerances. There was no correction for self absorption of the sources which would significantly lower the actual ‘effective’ curie loading to below 2,800,000 even if the GrayStar were actually loaded to a maximum of 3,000,000.” There were no calculations provided to support these self absorption claims, and the calculations provided in Exhibit 4 of the application stated that “this model accounts for some self absorption of the sources.” These statements were not clarified.

Other than for the inside of the product chamber, no new dose rate calculations were provided in response to the NRC staff's request for additional information. GrayStar stated that "due to the complexity of the shield, it is nearly impossible to interpret the flux due to scatter and columnation with any significant accuracy. Experience dictates that the shielding in adequate." The response further stated that the device will be surveyed, once it is built and constructed, and it will then be modified if necessary to comply with 10 CFR Part 36.

1.2 Shielding: The drawings, submitted regarding shielding arrangement and measures designed to reduce streaming, did not detail all shielding features of the design. For example, in an oral presentation to the NRC, stepping used for shielding in the retainer plugs immediately above the source racks was discussed. None of the drawings detailed this stepping. There may be additional shielding features that were not included in the drawings submitted. Penetrations in the shielding were not included in the drawings. Since there are provisions for draining water or other liquids from the bottom of the device, these pipes and valves need to be considered in the shielding design and calculations.

1.3 Ventilation: In discussing the ventilation system, the application contained many unsupported statements such as "a positive pressure design would have maximized dust to that portion of the unit".

The expected physical form/particle size of any potential leaking radioactive material was not addressed.

The efficiency of the system for collecting leaking radioactive material, including filter efficiency was not addressed. Deposit on surfaces was not considered by GrayStar when determining whether leaking material will actually reach the filters at the top of the unit. Also, since neither the expected particle size nor the filter efficiency have been determined, it was impossible to evaluate if the filter would collect leaking particles, and if the filter leak test would be adequate.

No calculations were provided to support the adequacy of the proposed flow rate. In fact, the adequacy of the design is still a question because the application stated that "should the venturi system not be sufficient to provide an appropriate negative pressure, a forced air system will be incorporated". No details were given as to when this might be decided, or what the forced air system would consist of.

1.4 Leak Testing: The filter leak test is GrayStar's proposed main leak test method for the device. The submitted procedures used a 1 mrem/hr (10 μSv/hr) decision level to determine whether any leaking radioactive material is present. This same decision level was used to determine whether the irradiator can continue to operate. This level is too high. By the time enough leaking cesium collected on the filter to read 1 mrem/hr (10 μSv/hr), a large quantity of material could have leaked from the sources and gone undetected. An evaluation of the sensitivity of the leak test methods was not provided.

1.5 Ozone Production: No calculations for potential ozone production were provided. The application also failed to provide flow rate calculations for the "hood" effect that was assumed to occur when the chamber doors are open. It was assumed only that any ozone contaminated air would be vented out of the top of the unit, and that no worker would be exposed. The assumption was not supported and, in fact, the operators will have to physically open the chamber doors to vent the ozone. The design contains ventilation ducts in the top of the

product chamber, but details of the chamber ventilation system were not given. Therefore, it was not possible to verify whether workers would be adequately protected from ozone. The application stated that further details will be worked out during prototype testing.

1.6 Seismic Analysis: Regarding seismic protection, no seismic capacity or its calculation was provided. The application did not demonstrate that the source would have time to return to the full down position after the onset of an earthquake. The application did not show that horizontal acceleration will not cause the device to topple or sustain damage that would prevent the source from returning to its permanent position. The issue concerning integrity between the hydraulic lug and the bottom yoke assembly was not addressed. The application only stated that the unit was monolithic in nature and was less likely than reinforced concrete to fail in a seismic event.

No calculations were provided to satisfy the requirements for the foundation and the anchorage for seismic areas.

The application stated that "[t]he foundation design for sites in seismic zones 2 and above will be site specific and will be included in that unit's By Product Material License application." However, without sufficient information in the device registration, the device cannot be registered for use in seismic areas.

1.7 Design of Source Rack: In accordance with 10 CFR 36.39(f), "... review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low..." The information provided to demonstrate that the sources will not get stuck in the up position due to a seismic event or other natural phenomena was inadequate. For example, no justification was provided for the assumption of simply supported edges in contrast to fixed supports for structural integrity analysis. Contrary to this assumption, the drawings in the application show a design with a fixed support. No calculation was provided to substantiate the statement that "[t]his force is not significant compared to the total 200 ton weight of the unit." No calculation was provided for the axial force due to a wind force of 27.6 tons to the steel plate. No calculation was provided for the local deformation due to tornado missiles and external explosions.

1.8 Instrumentation Settings: Regarding force specifications for the source movements, as specified in the provisions of 10 CFR 36.39(f), the response deferred future actions stating that "[b]oth of these values (operating pressure and threshold pressure to lower the door/source to the down position) will be determined as the prototype is tested prior to loading the sources."

1.9 Emergency Egress: The response did not address the issue of independent controls. The provisions of 10 CFR 36.23(a) state that "[t]he doors and barriers must not prevent any individual in the radiation room from leaving." Furthermore, 10 CFR 36.23(b) requires an "independent backup access control to detect personnel entry while the sources are exposed." For the GrayStar design, compliance with these requirements would include measures which could return the door/source to its storage position and which would activate audible and visible alarms. However, in the application an alarm button, located in the chamber, was proposed to meet the requirement in 36.23(a) described above. Consequently, the same alarm button cannot also serve as the independent backup access control to meet the provisions of the second requirement.

1.10 Engineering Drawings: All engineering drawings had been designated as "Preliminary Draft." No final drawings were provided as requested.

2. Installation and Operating Procedures

> The provisions of 10 CFR 32.210(c) specify that the application must include "sufficient information about installation, service and maintenance, operating and safety instructions and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property."

The application and the response to the request for additional information supplied only outlines of procedures or that of an operator's manual. The response suggested that once a prototype irradiator is built then that device could be used to work out the details requested.

3. Request for Exemptions

> The provisions of 10 CFR 36, Subpart C, specify the design and performance requirements for irradiators. For the operation of irradiators, the applicable safety requirements are listed in 10 CFR 36, Subpart D.

The application requested exemptions from certain provisions of both Subpart C and Subpart D in 10 CFR 36. However, the application did not provide adequate information to justify the exemptions. The specific deficiencies are delineated in Sections 3.1 through 3.4 below.

3.1 Exemption from Training Requirements: The provisions of 10 CFR 36.51 specify that "[b]efore an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed" in subjects listed in the regulations. The application requested that the operators of the GrayStar irradiator be allowed to substitute the training requirements for the panoramic irradiator for those of a self-shielded irradiator.

Training for users of a self-shielded irradiator is not adequate because it is necessary for personnel to enter the irradiation chamber to perform maintenance. The application has not demonstrated that a reduced level of training, as applicable to a self-shielded irradiator, can provide an equivalent level of health and safety protection. Due to the large amount of radioactive material contained within the GrayStar irradiator, it is reasonable to expect that the operators will be trained in accordance with 10 CFR 36.51.

3.2 Exemption from Personnel Dosimetry: The provisions of 10 CFR 36.55(a) specify that "irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator." The application requested that the GrayStar design be granted an exemption from 10 CFR 36.55, Personnel Monitoring.

The basis for the exemption request was a future determination of the dose rate as stated in the application that "[a]fter initial loading the prototype with radioactive material, a prospective evaluation will be performed demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits," and that "[d]ue to the specific design of the unit (compensatory safety measures), the applicant believes that

the radiation safety of the unit is more similar to a Self-Shielded Irradiator than a 'Panoramic dry-source-storage irradiator.'" Given the high level of activity of the sources, it is a reasonable precaution to monitor these individuals. Also, since accurate dose rates cannot be determined at this time, it is not possible to realistically predict exposures to personnel for granting an exemption.

3.3 Exemption from Area Radiation Monitor: The provisions of 10 CFR 36.23(c) specify that a "radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry." The application stated that "[p]ersonnel will not enter the irradiation chamber during normal operations. There are only a few maintenance/inspection operations where personnel are required to enter the chamber itself: during these times the sources are safely contained/shielded in the door/source in the down position."

Thus, the application indicated that personnel do enter the irradiation chamber. Furthermore, the application also indicated that the unit contains the "Autogray" system, which is an automated dosimetry system consisting of multiple ion chambers located in the ceiling and floor of the product chamber. The application gave no details of the system's operation. However, regarding the function of this system, the application stated that, in the future, the automated dosimetry system would be used in place of a hand held survey meter. Despite the presence of a proposed dosimetry system, the application requested an exemption from the provisions of 10 CFR 36.23(c) which require the use of a radiation monitor.

In view of the facts that personnel may enter the irradiation chamber, and that the design is to be equipped with an automated, but not yet designed, measuring system, the request to exempt users of the device from 10 CFR 36.23(c) is not adequately justified.

3.4 Exemption from Fire Protection: The application requested two exemptions regarding fire protection measures listed in 10 CFR 36.27.

(a) Smoke Detector: The first exemption from 10 CFR 36.27(a) requested to exclude the use of a smoke detector based on the assumption that the heat rise detector, whose design has not been finalized, will detect a fire in the chamber. But the application did not contain sufficient detail to allow evaluation of the proposed heat rise detector to detect a fire and to determine whether it could operate in the environment of the irradiator. The application did not select an appropriate detector and submit the specifications for review of the selection. In addition, the application did not demonstrate that the detector is adequately protected from mechanical and radiation damage.

(b) Extinguishing System: The second exemption request was to be exempted from the requirement for an "automatic" extinguishing system. The application lists, as arguments for an exemption for an automatic fire extinguishing system, that the chamber is small, the protection systems are located outside the chamber, water may come in contact with the sources, and that a false alarm may lead to unnecessary product damage.

The application did not address the intention of the requirement. Specifically, an automatic extinguishing system is not required by the regulations, but an extinguishing system is required (i.e. the extinguishing system could be automatic or could be activated by an operator). The regulatory requirements apply to both large and small units. Furthermore, the application did

not consider that the extinguishing system does not have to use water as the response to NRC's request for additional information indicated; there are many other fire extinguishing systems which use chemical compounds other than water and, thus, would not present an interaction problem with the cesium chloride material. The application did not analyze the use of such extinguishing systems.