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OFFICE OF SECRETARY
ADJUDICATIONS

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges:

Ann Marshall Young, Presiding Officer
Thomas D. Murphy, Special Assistant

In the Matter of	
GRAY*STAR, INC.	Dkt. No. SSD 99-27 ASLBP No. 00-778-06-ML
(Suite 103, 200 Valley Road, Mount Arlington, NJ 07856)	October 30, 2000

GRAY*STAR, INC.'S RESPONSE TO NRC STAFF'S BRIEF REGARDING THE APPLICATION FOR REGISTRATION OF MODEL GS-42 SEALED SOURCE

I. INTRODUCTION

Pursuant to the Presiding Officer's unpublished order dated September 14, 2000 ("Adressing Matters Considered at September 7, 2000, Telephone Conference"), Gray*Star, Inc. ("Gray*Star") hereby submits this brief in response to the NRC staff's "Initial Written Presentation," dated September 25, 2000 ("Staff's Brief"), in the above-captioned matter. This case concerns the NRC staff's May 24, 2000 denial of Gray*Star's application for registration pursuant to 10 C.F.R. § 32.210, of its Gray*Star Model GS-42 sealed source, which is only employed in the Gray*Star Model 1 irradiator.

Template = SECY-021

SECY-02

II. ARGUMENT

A. The Staff Fails to Adequately Articulate and Substantiate Its Reasons For Denial

In its denial letter and brief, the staff fails to adequately articulate and substantiate the basis for the denial of Gray*Star's registration application for its GS-42 sealed source. The NRC Staff may not deny any application without giving the reasons for the denial, and indicating how the application failed to comply with statutory and regulatory requirements. Kerr-McGee Chemical Corp., (West Chicago Rare Earths Facility), LBP-85-3, 21 NRC 244, 250 (1985), citing, SEC v. Chenery Corp., 318 U.S. 80, 94 (1943), Commonwealth Edison Co. (Byron Nuclear Power Station, Units 1 and 2), ALAB-770, 19 NRCX 1163, 1168-69 (1984), 5 U.S.C. 555(e), 10 CFR § 2.103(b). In general, the Staff does not occupy a favored position at hearing. It is, in fact, just another party to the proceeding. Vermont Yankee Nuclear Power Corp., (Vermont Yankee Nuclear Power Station), ALAB-138, 6 AEC 520, 532 (1973). The Staff's views are in no way binding upon the Board and they cannot be accepted without being subjected to the same scrutiny as those of other parties. Consolidated Edison Co. of N.Y., Inc. (Indian Point Nuclear Generating Station, Units 2 & 3), ALAB-304, 3. As discussed in detail below, the staff's denial and brief, which are primarily based on a generalized complaint that the cesium chloride (CsCl) used in the GS-42 sealed source is not "as nondispersible as practical," fail to adequately specify how Gray*Star's application for registration does not meet the relevant statutory and regulatory requirements governing sealed sources.

B. The Staff Fails To Recognize That Gray*Star Is Merely Seeking A Registration, Not A License For The GS-42 Dry Sealed Source

As discussed in Gray*Star's initial brief dated September 25, 2000, this proceeding is governed by Subpart L ("Informal Hearing Procedures for Adjudications in Materials and

Operator Licensing Proceedings"), pursuant to the Commission's order wherein it stated that since Subpart L "ordinarily governs materials licensing cases, including the NRC staff denials of requested agency approvals," and because "Part 36 involves materials licenses," it is "sensible" to apply Subpart L to this case. In the Matter of Gray*Star, Inc., 2000 NRC LEXIS 68 (June 13, 2000). In its order, the Commission further noted that Subpart L "expressly covers agency licensing actions 'subject to' Part 30." Id., citing 10 C.F.R. § 2.1201(a). As Gray*Star indicated in its initial brief, it does not contest the Commission's determination that Subpart L should govern Part 36 licensing cases, Gray*Star submits however, that this is not a licensing case under Part 36. Rather, the matter at issue in this case is the registration, as opposed to the licensing, of the GS-42 sealed source pursuant to 10 C.F.R. § 32.210. Contrary to the Commission's and the staff's apparent understanding, Gray*Star has not requested a license under Part 36 at this time. The staff's misunderstanding of this fact is reflected in the denial letter where it states that the GS-42 source design is "not acceptable for registration and licensing under 10 C.F.R. § 32.210 and 10 C.F.R. 36.21." Denial Letter at 1 (emphasis added). While a specific byproduct material license ultimately will be necessary in the future (e.g. for Gray*Star and/or its customers) for sealed sources in a Model 1, a license request is not at issue here. Furthering the confusion, the staff does not address this issue in its brief but merely states "[t]his proceeding concerns the staff's denial of an application filed by Gray*Star, Inc. for registration of its Model GS-42 sealed source." See Staff Brief at 1 (emphasis added). The Staff also fails to address the appropriate standard of review for denial of an application for registration.

With respect to the application of Part 36 specifically, on page 2 of its brief, the staff states that "GrayStar had earlier recognized 10 C.F.R. Part 36's applicability here, stating in its April 1999 application that the Model GS-42 sealed source would meet the requirements of 10

C.F.R. [section] 36.21 'when installed in a GrayStar Model 1' irradiator." This is incorrect. Gray*Star's application says

> The GS-42 irradiation source meets the requirements of 10 C.F.R. 36.21 when installed in a GRAY*STAR Model 1 . . .

The application goes on explain how the Model 1 meets the requirements of 10 C.F.R. § 36.21(a)(2)-(5) or why it is not required to meet them. There is no "recognition" of Part 36's applicability, but merely a statement that if Part 36 does indeed apply, Gray*Star's sealed sources satisfy the requirements of the regulations.

Perhaps most importantly, the staff continues to ignore the fact that it has agreed that the use of cesium-137 chloride in sealed sources generally, and in the Model GS-42 sealed source particularly, is not foreclosed by regulation. See Transcripts of Aug. 15, 2000 Telephone conference. The staff repeatedly states in support of its denial that section 36.21(a)(3) requires that "material to be used in irradiators must be 'as nondispersible as practical.'" See e.g. Staff's Brief at 3, 4, and 15. Here, and continually throughout the NRC's response, they leave off the remainder of the language in section 36.21(a)(3) - - " . . . if the source is used in a wet-source-storage or wet-source-change irradiator." Not only is the failure to cite the entire section misleading, it conveniently leads to the result desired by the staff - - denial of the registration based on the fact that it employs cesium-137 chloride. If section 36.21(a)(3) is read in its entirety, it is clear that the regulation applies to wet-storage use only, not dry-storage use like the GS-42.

In light of the staff's continued misunderstanding and misquoting of what it perceives as the governing regulation, which is subsequently relied on in its denial of Gray*Star's application, and its failure to set forth the regulatory language governing registration in its brief, Gray*Star

once again briefly reviews below the relevant regulatory sections governing its GS-42 sealed source.

With regard to the registration of a sealed source, 10 C.F.R. § 32.210 provides that any manufacturer of a sealed source whose product is intended for use under a specific NRC license may request that the NRC evaluate the radiation safety information about the product for registration. 10 C.F.R. § 32.210(a). Section 32.210(c) requires that a request for review of a sealed source include "sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing . . . to provide reasonable assurance that the radiation safety properties of the source [ ] are adequate to protect human health and minimize danger to life and property."[1] 10 C.F.R. § 32.210(c) (emphasis added). Section 32.210(d) states that "[t]he NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor." 10 C.F.R. § 32.210(d) (emphasis added). Finally, if the registration application is deemed adequate, the Commission issues a certificate of registration which acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the sealed source. 10 C.F.R. § 32.210(e).

As discussed above, 10 C.F.R. § 32.210, which permits the registration of products, provides that the NRC evaluates a sealed source for registration purposes using radiation safety

[1] Manufacturers seeking the registration of devices employing a sealed source must also include in their request for registration information regarding installation, service and maintenance, operating and safety instructions, and potential hazards. 10 C.F.R. § 32.210(c). Since only the registration of the GS-42 sealed source is at issue in this proceeding, the requirements pertaining to devices containing a sealed source are inapplicable.

criteria in accepted industry standards or reasonable standards developed with the help of the manufacturer. In contrast, section 36.21 of the NRC's regulations specifies design and performance criteria for certain sealed sources that are subject to a specific NRC license[2]:

(a) *Requirements*. Sealed sources installed after July 1, 1993:

(1) Must have a certificate of registration issued under 10 CFR § 32.210;

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is nondispersible as practical and that is insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator[3];

(4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316 L stainless steel or other material with equivalent resistance if the sources are for use in irradiation pools; and

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[2] Notably, the requirements set forth in 10 C.F.R. § 36.21 only apply to sealed sources *installed* in an irradiator after July 1, 1993. See 10 C.F.R. § 36.21(a). Arguably then, the requirements of 10 C.F.R. § 36.21 do not apply to the GS-42 sealed source because it has not been installed in an irradiator that is seeking a specific license under 10 C.F.R. Part 36. Moreover, while section 36.21(a)(1) requires that sealed sources installed after July 1, 1993 have a certificate of registration issued under 10 C.F.R. § 32.210, section 32.210 does not require that sealed sources seeking registration comply with the performance requirements in section 36.21. If the GS-42 sealed source need not meet the requirements set forth in section 36.21 for registration purposes, the NRC Staff's denial of the registration of the sealed source must be invalidated, as it is based wholly on alleged deficiencies under section 36.21 (See e.g. Denial Letter at 1 ("radioactive material in irradiator [must] be as nondispersible as practical").

[3] Notably, the regulation only requires wet-source storage or wet-source-change irradiators to use radioactive material that is "nondispersible as practical and that is as insoluble as practical." Moreover, the fact that the regulation requires the radioactive material to be nondispersible as practical and non-soluble as practical, rather than as nondispersible as practicable and as non-soluble as practicable, is a distinction with a difference. See e.g., Websters II New College Dictionary (1995) ("Practicable refers to something that can be put into effect [i.e. accomplished]. Practical refers to something that is also sensible and worthwhile. Thus, it might be practicable to transport children to school by balloon, but it would not be practical.")

(5) In prototype testing of the sealed source, must have been leaked tested and found leak-free after each of the tests described in paragraphs (b) through (g) of this section.

10 C.F.R. § 36.21.

Thus, the requirements that Gray*Star must meet to obtain a registration pursuant to section 32.210 differ from those that a party seeking a specific license for a sealed source pursuant to 10 C.F.R. § 36.21 must satisfy. Again, Gray*Star has only requested the registration of, not a specific license for, its GS-42 sealed source. Thus, Gray*Star's GS-42 sealed source need only meet "acceptable industry standards" or in their absence, a "reasonable standard" developed by the Staff with assistance from Gray*Star. The GS-42 meets "acceptable industry standards."

C. The Staff Misinterprets and Misapplies 10 C.F.R. § 36.21(a)(3)

Essentially, the staff's denial is premised upon its conclusion that the GS-42's use of cesium-137 chloride powder fails the "nondispersible as practical" standard set forth in 10 C.F.R. § 36.21(a)(3). See Staff Brief at 4. The staff reaches this conclusion by misquoting, misinterpreting, and misapplying section 36.21(a)(3). As discussed above and in Gray*Star's initial brief, section 36.21(a)(3) does not apply here as Gray*Star is not requesting a license for its GS-42 sealed sources at this time and the sealed sources have not yet been installed in an irradiator. See 10 C.F.R. 36.21. Based on the plain language of the text of 10 C.F.R. § 36.21(a)(3), it applies only where "the source is used in a wet-source storage or wet-source change irradiator." Thus, section 36.21(a)(3) only applies to wet-source storage, not dry-source

storage irradiators like the GS-42, and Model 1. The staff fails to recognize this point or even attempt to explain how or why the regulation applies to dry source use.[4]

The plain meaning of the text, as provided above, is also supported by the regulatory history of 10 C.F.R. § 36.21(a)(3). The proposed rulemaking for 10 C.F.R. Part 36 clearly demonstrates that the rulemaking was driven in response to a leaking source accident at a wet-source-storage irradiator in Decatur, Georgia, in 1988. See 55 Fed. Reg. 50,008, 50,010 (1990). The particular water pool irradiator that experienced the leak accident used cesium chloride sources in the WESF encapsulations. There was no requirement like the final section 10 C.F.R. § 36.21(a)(3) in the proposed rule. During the rulemaking period, the issue of the continued use of cesium chloride and the WESF canisters was discussed and considered. On this subject, one key commenter, Greta Dicus, now a Commissioner of the NRC, while agreeing the WESF source encapsulations should no longer be used, recommended that cesium-137 not be excluded as a source material "so long as it is appropriately encapsulated in appropriate form for the kind of irradiator that it is going to be used in."[5] Another commenter, Mr. Dietz, stated in the same meeting that "[c]esium is a pretty good source, and it's a good national asset. What is at fault is the encapsulation. I don't think it would be fair to bar cesium forever because we had an inappropriately encapsulated source which was designed for a totally different operation used in an irradiator and had this kind of problem."[6]

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[4] The staff's reference to the Federal Register notice establishing Part 36 is misplaced as the language in the notice referenced by the staff was focused on the use of cesium chloride in wet-source storage irradiators, not dry-source storage irradiators like the Model 1. See Staff Brief at 5, citing 58 Fed. Reg. 7715, 7716 col. 2 (Feb. 9, 1993).

[5] Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation Meeting Transcript, "Licenses and Radiation Safety Requirements for Large Irradiators" at 52 (Feb. 12, 1991) (emphasis added).

[6] Id. at 50.

In response to public comments concerning the wet-source-storage irradiator leak, the NRC staff proposed in its SECY to the Commission on the final rulemaking a new section of Part 36, to be numbered 10 C.F.R. § 36.21(a)(3) that stated simply that sealed sources:

> (3) Must use radioactive material that is as insoluble and nondispersible as practical.

SECY-93-323, "Final Rule on 'Licenses and Radiation Safety Requirements for Irradiators," enclosure 1 at 70 (Sept. 18, 1992). The proposed final rule did not differentiate between the various types of irradiators in existence at the time. The regulatory basis in the NRC staff's SECY supporting the proposed final rule (i.e., the proposed Statement of Considerations for the final rule) stated that "[t]he requirement that the radioactive material in the sources be as insoluble and nondispersible as practical not included in the proposed rule, although comment was sought on whether the use of cesium-137 should be permitted in irradiators in view of its solubility." Id. at 15. The staff's basis for this new requirement, however, only identified leakage events at water pool irradiators (particularly the WESF encapsulation failure at the water pool irradiator facility in Decatur, Georgia), and failed to identify even a single leakage event at a dry-source-storage irradiator.[7] Id. at 7. The Commission approved the NRC staff's proposed final rule, but in his approval NRC Chairman Selin made a comment specifically regarding the scope of 10 C.F.R. § 36.21(a)(3), as proposed by the staff. SRM-921027, "Staff Requirements – Affirmation Session/Discussion and Vote, 10:30 a.m., Tuesday, October 27, 1992," Encl. 3 at 1 ("Chairman Selin's Comments on SECY-92-323"). In his comments, NRC Chairman Selin

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[7] After discussing the WESF source failure in the water pool irradiator in Decatur, Georgia, the staff's proposed regulatory basis promptly concluded that "[a]s a consequence, this final rule was written to require that irradiators use radioactive materials that are as insoluble and nondispersible as practical, which would typically be cobalt-60." Id. at 7.

recognized the disconnect between the general wording of the proposed 10 C.F.R. § 36.21(a)(3), and its regulatory basis, which applied only to water pool irradiators. Chairman Selin stated:

> The effective prohibition of the use of radioactive cesium as a source material (except on a case-by-case basis) applies for both wet and dry irradiator applications. The justification for this is primarily the recent incident involving a leaking cesium source in a pool facility in Georgia. The justification for this requirement for dry irradiator facilities should be discussed in the rulemaking package.

Id. However, in the rulemaking package for the final rule, the Statement of Considerations again discusses only the leaking source at the water pool irradiator in Decatur, Georgia. 58 Fed. Reg. 7,715, 7,716 (1993). In fact, the staff simply restated essentially word-for-word the identical justification for 10 C.F.R. § 36.21(a)(3) in the final rulemaking package that it had provided to the Commission in SECY-92-323 (which had drawn Chairman Selin's comment). Compare SECY-92-323, Encl. 1 at 7 with 58 Fed. Reg. at 7,716. The Staff never did add any "justification for this requirement for dry irradiator facilities . . . in the rulemaking package," as Chairman Selin had directed. Instead, the NRC staff changed the wording of the final rule from the open-ended "[m]ust use radioactive material that is as insoluble and nondispersible as practical" proposed in SECY-92-323, to the irradiator-type specific wording "[m]ust use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator" used in the final version of 10 C.F.R. § 36.21(a)(3). Compare SECY-92-323, Enclosure 1 at 70 with 58 Fed. Reg. at 7,716 (emphasis added). In the end, in light of the comments of NRC Chairman Selin, the NRC staff revised the final language of 10 C.F.R. § 36.21(a)(3) to apply only to wet-source-storage and wet-source-change irradiators. The regulatory history of the development of 10 C.F.R. § 36.21(a)(3) again demonstrates that "nondispersible as practical" requirement does not apply to dry-source-storage irradiators.

The NRC staff provides this same, consistent interpretation in its guidance to license applicants concerning compliance with its requirements. Two years after its guidance to its own reviewers in NUREG-1550, in 1998 the NRC staff published guidance for license applicants addressing compliance with the requirements of 10 C.F.R. Part 36. In NUREG-1556, "Consolidated Guidance About Materials Licenses, Volume 3 – Applications for Sealed Source and Device Evaluation and Registration," the NRC staff provides guidance to applicants regarding requests for sealed source registrations. NUREG-1556, Volume 3 at iii (July 1998). NUREG-1556 addresses 10 C.F.R. § 36.21(a)(3). In Volume 3 of NUREG-1556 the NRC staff again states:

> Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21. One such requirement is that the licensed material be as insoluble and nondispersible as practicable if used in a wet-source-storage or wet-source-change irradiator.

NUREG-1556, Vol. 3 at 4-9 (emphasis added). Again there is no mistaking NRC staff's written meaning and intent - the "nondispersible" requirement applies only to sources "used in a wet-source-storage or wet-source-change irradiator." Once again, the staff's published guidance is fully consistent with the plain text reading provided above.

Another NRC staff guidance document providing the same interpretation is the Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses fro Non-Self-Contained Irradiators." In Draft Reg. Guide DG-0003, the NRC staff states:

> In general, the use of cesium-137 chloride is not acceptable in pool (*Category III and Category IV*) irradiators or (*Category II*) dry-source-storage irradiators that load or unload sources under water at the irradiator because it does not meet the requirements of 10 CFR 36.21(a)(3).

Draft Reg. Guide DG-0003 at section 3.5 (emphasis added). This shows the same consistent NRC staff interpretation in its published guidance documents – the requirements in 10 C.F.R. §

36.21(a)(3) apply only to wet-source-storage and wet-source-change irradiators, and do not apply to dry-source-storage irradiators that do not use water pools for source storage or to load or unload sources at the irradiator. This published NRC staff interpretation of 10 C.F.R. § 36.21(a)(3) is once again consistent with the plain meaning of the text of the regulation.

The plain language of 10 C.F.R. § 36.21(a)(3) agrees with the NRC staff's published interpretation of the regulation and the regulatory history of the development of the regulation. The requirement in 10 C.F.R. § 36.21(a)(3) applies only to wet-source-storage or wet-source-change irradiators, and does not apply to dry-source-storage irradiators. Since the GS-42 sealed source is to be use solely and exclusively in a dry-source-storage irradiator (the Gray*Star Model 1 irradiator), the requirement in 10 C.F.R. § 36.21(a)(3) does not apply to the GS-42 sealed source. As a result, registration of the GS-42 sealed source, for use solely in the Gray*Star Model 1 irradiator, cannot be denied on the grounds of 10 C.F.R. § 36.21(a)(3), and a demonstration that the GS-42 sealed source is "as nondispersible as practical" is uneccessary.[8]

D. Even Assuming Arguendo That 10 C.F.R. § 36.21(a)(3) Applies, The GS-42 Sealed Sources Meet The Requirements Contained Therein

1. The Staff Applies The Wrong Standard

Even assuming arguendo that 10 C.F.R. § 36.21(a)(3) were to somehow apply to Gray*Star's registration of its GS-42 sealed source, the GS-42 satisfies the requirements of that regulation.

In support of its denial, the staff asserts that Gray*Star has not provided "adequate justification" for using cesium-137 chloride powder in its Model GS-42 sealed source but fails to

[8] The fact that Gray*Star has demonstrated that the GS-42 source, as used in the Gray*Star Model 1 irradiator is "as nondispersible as practical" even though not required to do so adds even more defense-in-depth to the overall safety of the GS-42 sealed source and Gray*Star Model 1 irradiator design.

point to any authority that requires Gray*Star to provide "adequate justification." Indeed, the staff manufactures an even greater burden than "adequate justification" in that it later demands that Gray*Star "justify" its use of cesium chloride. This recurring theme throughout the staff's brief morphs into "GrayStar should provide much more substantial mitigation provisions to justify use of dispersible cesium-137." See e.g. Staff's Brief at page 6. In fact, a thorough review of NRC's regulations shows that "adequate justification" is not a standard employed by any regulation concerning irradiators or sealed sources, nor is Gray*Star required by regulation to "justify" its use of cesium chloride in its dry-sources, much less provide "substantial justification" for doing so.[9]

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[9] For example, the Staff states at page 9, of its brief that - "In light of the Commission's qualified ban on any new use – in panoramic irradiators – of sealed sources containing dispersible cesium, substantial justification must be provided before the Staff would approve any wide-scale use of such material in irradiators. The justification would have to be based either on factors which did not exist when the 10 C.F.R. Part 36 rules were established in 1993, or on unique design features which would mitigate the consequences of a leak of dispersible material from the Model GS-42 sealed source, when used in the Model 1 irradiator." Here again, the staff cites no rule nor provides any support for its position that a "qualified ban" exists with regard to its claim that Gray*Star would have to point to factors which did not exist in 1993. The "as practical" requirement does not equate to a "qualified ban." Rather, it is a requirement that one do the best one can reasonably do to make the source nondispersible under the given circumstances. See supra. fn. 3 for comparison of "as practical" and "as practicable." Moreover, Gray*Star submits that in 1993, all major commercial irradiators were wet-storage or wet-change irradiators, which raised concern after the Decatur, Georgia incident due to the use of cesium in water. See also Staff's Brief at 11 ("However, as discussed above, GrayStar has failed to provide adequate justification for the proposed use of cesium-137 in any form, rather than using nondispersible cobalt-60."); Staff's Brief at 12, "GrayStar did not describe any features in its Model GS-42 sealed source that go substantially beyond the safety requirements applicable to sealed sources in general." (emphasis added). Similarly, on page 12, the staff states "GrayStar's general statement that its Model 1 irradiator is dry does not constitute an adequate justification for its proposed use of cesium chloride powder in its Model GS-42 sealed source." Staff Brief at 15 (". . . the Staff's position in this proceeding is that, in order to justify the use of cesium chloride powder, GrayStar should be required to demonstrate that a leak is substantially less likely for its sources, than would be the case for sources containing nondispensible material.")(emphasis added).

Further, the staff asserts without justification that the form of cesium-137 chloride powder used in the GS-42 somehow "is highly dispersible." See Staff Brief at 4 ("In this form [powder], cesium-137 is highly dispersible."). The staff ignores the fact that in and of itself, cesium-137 chloride is not dispersible. For cesium chloride, or any substance to be dispersible, there must be a medium for dispersion, such as water. In the GS-42 there is no water, and its double encapsulation keeps the cesium chloride, which is in cake form in the GS-42 not powder form, from being subject to any other dispersal medium; therefore, contrary to the staff's assertion, cesium-137 chloride is not "highly dispersible" in the GS-42.[10]

Gray*Star adds that as discussed in its initial brief, the GS-42 was designed in accordance with the IAEA Safety Standards, Safety Series No. 6, 1985 Edition (As Amended 1990), which states "[s]pecial form radioactive material shall mean either an indispersible solid radioactive material or a sealed capsule containing radioactive material." See IAEA Para. 502-504. The IAEA Safety Series sets forth requirements regarding dispersibility which the GS-42 satisfies.

E. The Staff's Concerns Regarding Leaking Sources Are Unsubstantiated And Unfounded

The staff states in its brief that "GrayStar's September 1999 response (Hearing File Tab VI) did not address the safety issues related to dispersibility," that "GrayStar has [ ] failed to adequately explain how the consequences of a leak of dispersible cesium-137 would be mitigated," and that "[n]either the April 1999 application nor the Hearing Request presented preventive measures which would mitigate dispersion of radioactive material in the case of an accident, such as a leak." Staff Brief at 4, 6. The staff ignores the fact that the only known leak

[10] The staff never mentions the "solubility" of cesium chloride apparently acknowledging its irrelevance because of the dry source design of the Gray*Star.

in CsCl irradiator sources was small and localized (i.e. pinhole leaks), and only occurred in a water environment with thermal cycling. To ensure that there are no flaws in the GS-42 sealed sources, Gray*Star has developed a quality assurance program (NQA-1) that has been approved by the NRC (Approval No. 0898, Sept. 22, 1998). See Attachment 1. This NQA-1 program is a rigid quality control program that once committed to subjects the registrant to criminal penalties for knowing violations of performance criteria. Therefore, the NQA-1 ensures that the GS-42 will meet the relevant performance criteria or it will not be marketed. Moreover, each of the GS-42 sealed sources will be cold tested and inspected prior to filling with source material to ensure the integrity of the welds on both the inner and outer capsules. The GS-42 is specifically designed to avoid thermal cycling and to avoid placing cyclical thermal expansion stresses on the source containers by maintaining the sources in a dry environment and at a consistent temperature.

Perhaps most importantly with the respect to source leaks, since there is no medium (such as water) in the GS-42 that will quickly transfer or disperse the caked CsCl, any material leaked from the source will be localized in the second encapsulation, and if that should somehow leak, within the Gray*Star dry Model 1 irradiator. Should some of the CsCl migrate somehow, such migration will be detected as leak detection tests will be performed every six (6) months to ensure that any leaks are detected and adequately remediated. If a leak is detected, the leaking source can be isolated within the GraySafe™.

If a leak were to somehow occur in both the inner and outer encapsulation of a particular GS-42, the Gray*Star Model 1 irradiator is better suited for remediation than any Category II, III or IV irradiator. The staff acknowledges this fact on pages 13 and 14 of the its brief wherein it recognizes that the Model 1 irradiator could be moved off-site in the case of a leak. The staff

states however, that it does not view this feature as "adequate justification" for the use of "dispersible" cesium chloride. Again, the staff creates a standard not contained in the regulations, claims the GS-42 does not meet it, and fails to explain why or how. Moreover, the staff again ignores the language in section 36.21 stating that the "nondispersible as practical" requirement relates only to wet-source storage.

The staff claims that "there is considerable uncertainty as to whether a leak would be confined to the irradiator as maintained by GrayStar." Staff Brief at 14. Here again, the staff fails to explain what is meant by "considerable uncertainty" or to substantiate its claim. In any event, the lower portion of the Model 1 irradiator is specifically designed to contain a leaking source.

If a leak is detected or is suspected to have occurred, the NRC or the appropriate Agreement State would be immediately notified. Remedial action would be conducted with the cooperation of the NRC or Agreement State pursuant to the NRC license of the user or Gray*Star.

Finally, the staff claims that "whether a Model 1 irradiator containing a leaking source could be safely transported is uncertain." Staff Brief at 14. Notably, the staff makes no mention of the method of transportation or provides support for its claim in any way. The shipping package portion of the Model 1, called the Graysafe™, is designed as a cask. The staff has provided no support or explanation for its claim that the cask could not be shipped safely, in accordance with relevant laws. Similarly, the staff argues that "it is questionable whether overall the movement of the Model 1 irradiator offsite would be safer than addressing the leaking source onsite." Id. Leaking sources must be addressed on a case-by-case basis. The Model 1 allows

for a leak to be addressed on-site, off-site, or both depending on the circumstances and nature of the leak, and in a more timely manner than with other irradiators.

F. The History of Other Sources Is Relevant To The Registration of the GS-42

On page 7 of its brief, the staff questions the relevance of historical data concerning other sources to the GS-42 sealed source. Staff Brief at 7. Gray*Star finds it ironic that the staff takes the position that historical information is irrelevant to the registration of the GS-42 sealed source while at the same time arguing that cesium chloride is dispersible based on historical uses. The staff cannot have it both ways - - citing historical information, e.g. information concerning the leaking WESF sources when it supports the staff's claim regarding dispersibility, and discounting historical information, e.g. source history, when it is unfavorable to its position. Contrary to staff's assertion, the historical information provided by Gray*Star is relevant.

The NRC and DOE maintain information on incidents, accidents and design problems with sealed sources. For example, in the past, both WESF and BNL sources have deformed or failed.[11] Gray*Star employed this failure information when designing the GS-42 sealed source to decrease the probability of having similar source failures. Gray*Star is unaware of any deformations or leaks associated with CsCl irradiator sources other than WESF and BNL sources.

Importantly, the staff also fails to point out that other CsCl sealed sources have been given a Certificate of Registration by NRC in the recent past. See e.g. Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source No. CA598D115S (Dec. 14, 1984), amended in its entirety June 6, 1990, amended pages 1 - 3, 10 and 16, June 14, 1994).

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[11] There has been one confirmed leak in the over 1,300 WESF capsules and no confirmed leaks but merely deformations in the 297 BNL capsules. See Hearing File VI.C.7 and VI.C.4.

CsCl sealed sources have been approved for use in Category II irradiators with curie levels up to 14,000 curies per source. Gray*Star is unaware of any safety concerns resulting from the use of these sources.

With regard to dispersion, not only does the staff ignore the history of the use of CsCl, but also fails to acknowledge the fact that there is no evidence to indicate that a leak in a large source will disperse more material than a leak in a small source. It is an elementary principle that the size of the leak and the rate of leak are independent of source size. Any material that was to leak would have similar specific activity. The worst leak in a CsCl irradiator source was the leaking WESF source in a wet, thermal cycling environment.[12] This leak ultimately released 8 curies out of source containing over 50,000 curies into the pool water, far less severe than several of the cobalt-60 irradiator source leaks, which have occurred in the past and have lead to significant dispersion beyond the confines of the irradiator. See e.g., Draft Regulatory Guide DG-003, (January 1994) at C-5. Also, had the WESF cesium sources not been stored in water and not subjected to thermal cycling, but rather in a dry source storage environment, the leak would not have occurred.

A thorough review of the "problematic" history of the use of CsCl in sealed sources shows that there has been only one documented leak in an irradiator. There are hundreds of CsCl sources that have operated without problem for more than 30 years. With respect to the WESF sources discussed above, there is only one confirmed leak out of 766 sources, which were employed in four different irradiators, stored in water, and used for many years. These same

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[12] There were 252 WESF capsules in the Decatur, Georgia facility that were subjected to 7,300 thermal cycles with a change of over 300 degrees fahrenheit per cycle. See Hearing File VI.C.7 at 41, 55 and 59.

aged sources and others are still stored underwater in a pool, which would be equivalent to use in a Category III irradiator, without incident.

Finally, and most significantly, the NRC itself has recognized that there is little risk of encapsulation failure and CsCl dispersion. Specifically, NUREG/CR-6642 states "[t]he accident risk for the Co-60 device is larger than that for the Cs-137 device because of the larger assumed source strength. While the form of the Cs-137 is more prone to spreading contamination if the encapsulation fails, this is not a major risk contributor." (emphasis added). This conclusion, coupled with the GS-42 and the Gray*Star Model 1, additional design safety features, supports Gray*Star's claim that the GS-42 poses little, if any, threat to public health safety.

G. The GS-42 Sealed Source Employs Beneficial Safety Features

The Staff takes issue with the safety of the GS-42: " . . . GrayStar failed to demonstrate that its proposed safety features represented an overall substantial safety improvement, sufficient to offset the safety risks associated with using dispersible cesium in an irradiator." Staff Brief at 8 (emphasis added). "The most important safety factors weighing against approval of GrayStar's application are discussed above in Sections 1a, 1.d(ii), 1.d(iv), 1.d(v) and 1.d(vi). These are the most important safety factors because they involve GrayStar's failure to show that its proposed sealed sources would use radioactive material which is an nondispersible as practical, as required by 10 C.F.R. § 36.21(a)(3)." The staff states that other safety concerns are "of lesser significance." Staff Brief at 17. Thus, with respect to safety, the Staff's concerns relate to the use of CsCl in the source because in its view, by definition such use violates the "nondispersible as practical" requirement in section 36.21(a)(3). For the reasons discussed in GrayStar's initial brief and above, the staff's safety concerns are unfounded because the "nondispersible as practical" requirement does not apply to the GS-42 dry storage source but even if it were to

apply, "nondispersible as practical" does not constitute a ban but merely encourages practical efforts to minimize dispersibility because as noted above, the standard is "as practical."

With respect to the Staff's other "lesser significant" concerns, it points to leak mitigation and applicability of historical data. These concerns are addressed above. Finally, the staff asserts in its brief that the "general value of irradiation to help prevent food-borne disease" and the comparison of CsCl to other sources are "irrelevant" to the staff's denial. See Staff Brief at 14.

H. Assuming Arguendo That The Prototype Tests In 10 CFR § 36.21(a)(5) Are Applicable, The GS-42 Satisfies Those Tests

On page 16 of its brief, the Staff states that "it would now conclude that even if Gray*Star had chosen to use a nondispersible material, GrayStar's sealed source design . . . would fail to meet [10 C.F.R. § 36.21 (a)(5) and § 36.21 9a)(2)]."[13] Staff Brief at 16. The basis of the Staff's conclusion is "[the] reports show that on day three of the testing, two outer capsule leaks occurred. . . . Additionally, on day five of the testing, an inner capsule failure occurred." Staff Brief at 15-16. These assertions fail to tell the whole story. A thorough discussion of the testing of the GS-42 is contained in Gray*Star's initial brief at 49-53. In short, after the completion of additional welding, the final prototypes were subjected to the tests required by regulation. "Both specimens passed the leak test (TRS-020) for both inner and outer encapsulations." See Hearing File Tab IV.E, at 20.

Moreover, the staff ignores the conclusion provided by an independent third party:

> Only the Thermal Test (TRS-005) produced a helium leak in the outer encapsulation at the seal plug. After applying a seal weld to

[13] 10 C.F.R. § 36.21(a)(5) provides that during prototype testing of the sealed source, the source "must have been leak tested and found leak free after each of the tests." 10 C.F.R. § 36.21(a)(2) provides that sealed sources, be "doubly encapsulated."

> the outside of the outer seal plug, the source assemblies passed this test. Although not required, it would be prudent to either seal weld the seal plug (as tested) or take some other remedial approach. With the incorporation of a welded outer seal plug, there is reason to believe that production GS-42 source assemblies will satisfy all of the performance specifications.

Hearing File Tab. IV.E, at 13*)*. Thus, contrary to the Staff's assertion, there were no leaks from either the inner or outer capsule in the final design assemblies of the GS-42 and the final design assemblies passed all of the tests for both sealed sources and "special form radioactive material."

Further, with respect to the staff's statement that Gray*Star did not demonstrate that the GS-42 "maintained double encapsulation during testing," there is nothing in 10 CFR 36.21(a)(2) which requires that sealed sources "maintain" double encapsulation. Rather the regulation merely requires that sources be "doubly encapsulated." The tested sources passed the applicable standard and where the encapsulation leaked, the sources were modified and retested with the final sources found not to leak from either the inner or the outer encapsulation.[14] There is nothing in 58 Fed. Reg. 7715 that supports the NRC's interpretation that "leak-free after each of the tests" means that there cannot be a leak during a preliminary test on a preliminary model, or even that the failure of one encapsulation in a doubly encapsulated source is a failure of the test.

Finally, if the Staff's interpretation were correct, how could the NRC justify the issuance of a Certificate of Registration for the C-188 where several of the outer or inner encapsulations fractured or ruptured? See Registry of Radioactive Sealed Sources and Devices, Safety Evaluation of Source (Amended Copy), No. NR-169-S-142-S, (Dec. 23, 1985) at 4.

Finally, at page 16-17 of its brief, the Staff states that "because, as discussed in Section 1, supra, the Staff concluded that GrayStar's Model GS-42 sealed source did not meet NRC safety

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[14] The final GS-42 sealed sources satisfied all of the requirements set forth in Attachment 2.

requirements due to the dispersibility problem, the Staff has not yet taken a position on whether the use of non-radioactive cesium for testing purposes would be acceptable in this case." With regard to the latter portion of its statement, 10 C.F.R § 71.75 provides: "[e]ach solid radioactive material or capsule specimen to be tested must be manufactured or fabricated so that it is representative of the actual solid material or capsule that will be transported, with the proposed radioactive content duplicated as closely as practicable. Any difference between the material to be transported and the test material, such as the use of non-radioactive contents, must be taken into account in determining whether the test requirements have been met." (emphasis added). Gray*Star used cesium-133 chloride for its tests which "duplicates as closely as practical" the qualities of radioactive cesium-137 chloride in all respects except for radioactivity. The helium leak test performed by Gray*Star addresses the question of whether any radioactive activity would escape the encapsulation. To suggest that the test should have been performed with radioactive cesium-137 chloride is well beyond the bounds of normal testing. Certainly the standards do not require testing with radioactive material which would require the NRC to license the applicant to allow it to use cesium-137 for such tests, which is not reasonable. Further, radioactive specimen testing will lead to major safety, ALARA and disposal issues. To the best of Gray*Star's knowledge, NRC has never required that entities seeking registration conduct sealed source testing using actual radioactive material for a commercial irradiator source. In addition, Gray*Star's testing complies with the ISO Standard 2919, "Sealed Radioactive Sources-Classification," and ANSI/HPS N43.6, "Sealed Radioactive Sources-Classification," which define a "Dummy sealed source" and a "Dummy source" as:

> Facsimile of a radioactive sealed source, the capsule of which has the same construction and is made with exactly the same materials as those of the sealed source that it represents but containing, in

> place of the radioactive material, a substance resembling it as closely as practical in physical and chemical properties.

ISO Standard 2919.

I. The Vibration Testing Conducted By Gray*Star Satisfies § 36.21(e)

The Staff states on page 17 of its brief that - "The pertinent ANSI standard specifies that, for sources comparable to the Model GS-42 sealed sources, three axis should be tested. . . GrayStar tested the sources along the strongest two axes only." The Staff misreads the standard. Section 7.5 of ANSI/HPS N43.6-1997 provides that each axis of the source be tested. At footnote 3, the standard describes the test for spherical or oval sources:

> A spherical source has one axis taken at random. A source with an oval or disc-type cross-section has two axes: one of revolution and one taken at random in a plan perpendicular to the axis of revolution. Other sources have three axes taken parallel to the significant overall dimensions.

The shape of the GS-42 is obround, which is an oval shape. Since the GS-42 is oval shaped, in accordance with the standard set forth above, Gray*Star tested it along both of its axis. The staff's assertion that the GS-42 was not tested along three axes ignores the standard.

With regard to the Staff's claim that "GrayStar tested the sources along the <u>strongest</u> two axes only," (emphasis added), again, footnote 3 says a test shall be performed on each axis. For a source with two axes, the axes are "one of revolution" and "one taken at random in a plan perpendicular to the axis of revolution." The test performed by the independent third party describes the axes tested as "long axis and perpendicular to the long axis/parallel to the long obround axis." Hearing File Tab IV.E, page 9 of 19. These axes were chosen in consultation with the NRC staff as being the axes most susceptible to stress and possible fatigue. In fact, the NRC was provided with a test schedule that clearly and completely identified the tests to be

performed. See Facsimile from Russell Stein, Gray*Star, Inc. to John Jankovich, NRC (Jan. 12, 1999) (Attachment 3).

Finally with regard to the hertz range tested, the Staff admits that it overlooked the fact that Gray*Star correctly tested the GS-42 sources; therefore, it withdrew this allegation as a basis for the denial.

J. The Staff's Concerns Regarding Source Construction and Durability Are Unfounded

1. Pitting Is Not A Concern With The GS-42

The main issue presented by the Staff with regard to the construction and durability of the GS-42 relates to "the degree to which cesium chloride may cause pitting to occur in the . . . encapsulations." Staff Brief at 17. On page 17 and again on page 19, the staff states that "[t]he historical evidence relied on by GrayStar to show that such pitting will not occur was found not to be applicable by the Staff, due to differences between the sealed source fabrication procedures previously used, and the fabrication procedures used by GrayStar." Staff Brief at 17 and 19. Beyond its broad assertion that fabrication procedures differ, the staff fails to explain the differences, why and how the differences support the denial, or explain how Gray*Star's use of the historical data is somehow misguided. Without more, the staff fails to substantiate its basis for denial.

2. Corrosion During Filling is Not A Concern With the GS-42

Next, the staff asserts on page 17 that ". . . GrayStar provided no data showing that the conditions present during the filling process would be unlikely to cause corrosion of the Model GS-42 sealed source encapsulations." Gray*Star addresses this concern in detail at pages 61 - 62 of its initial brief. In short, even assuming that the staff's corrosion data are applicable, if the amount of corrosion were calculated using the that data for the period during filling when CsCl is

in solution, because the longest the CsCl will be in solution is four (4) hours, the amount of corrosion would be insignificant, or 0.000009 inches. See Gray*Star Brief at 62, fn. 40.

3. Corrosion During Operation is Not A Concern With the GS-42

The staff also expresses concern that corrosion of the GS-42 will occur during operation of the Model 1. Staff Brief at 19 (" . . . the Staff calculated that, after fabrication, moisture remaining in the Model GS-42 sealed source would compromise the source wall integrity in 25 years."). The staff cites a "Corrosion Data Survey," Metals Section, 6th Edition, where a 5% - 15% solution of cesium chloride in water at a temperature between 150 - 250 degrees could have a penetration rate of 0.002 to 0.020 inches per year in Type 316 stainless steel. The staff's calculations are based on its unfounded conclusion that a significant level of moisture will be present within the source encapsulation throughout the lifetime of the source. The moisture level the staff assumes is well above the upper bound moisture content level of 0.01% by weight that the drawings prepared under Gray*Star's Quality Assurance Plan (ASME-NQA-1) require. See Gray*Star Brief at 62. Moreover, as discussed in Gray*Star's initial brief, "the CsCl source will be dry during the operational lifetime" because any moisture in the source encapsulation will be evaporated and then vacuumed out of the encapsulation leaving only a dry CsCl cake on the inner surface of the source tube. Id. at 61-64.

4. Crevice Corrosion Is Not A Concern With the GS-42

On page 19 of its brief, the staff states that "[it] found that GrayStar had not provided evidence showing that the evaporative procedure to be used would adequately remove moisture from crevices." Staff Brief at 19. The staff continues that on page 20 that "GrayStar failed to show that the impurities would not, during the operational life of the proposed Model GS-42 sealed source, compromise the source wall integrity. . . . Consequently, with respect to any adverse impacts the impurities may have on the Model GS-42 sealed sources, the Staff was not

able to determine the relevance of the 17 historical documents referenced in Exhibit 2." Here again, the staff ignores the performance-based standard that the GS-42 must satisfy as part of the NQA-1 plan. The drawings prepared under the plan require that each source contain less than 0.01% water by weight. A further discussion of this point is made at pages 64-65 of Gray*Star's initial brief.

K. GS-42 Is Not a Category II Irradiator

While not strictly at issue in this hearing because this proceeding is concerned solely with the GS-42 sealed source, for the reasons discussed in Gray*Star's initial brief at pages 68-72, the GS-42 sealed source need not meet the requirements governing Category II irradiators. In sum, Gray*Star's Model 1 irradiator satisfies all of requirements of a Category I irradiator, except that human access is possible when the sources are unexposed. Once the source is exposed however, human access is impossible.

L. Section 36.35 Is Inapplicable to the GS-42

During the September 7, 2000, telephone conference, counsel for the staff stated that the staff would like to raise Gray*Star's compliance with 10 C.F.R. § 36.35 in further support of its denial. The Presiding Officer granted the staff leave to do so. In its brief however, the Staff merely refers the reader to its earlier argument and nowhere cites the language of the regulation. This is fatal to the staff's position because a simple reading of the regulation shows that it is inapplicable to the GS-42. Specifically, the regulation only governs those irradiators where "the product to be irradiated moves on a product conveyor system." 10 C.F.R. § 36.35. The Model 1 irradiator does not employ a product conveyor system. Nevertheless, the Model 1 irradiator has a barrier between the sources and the product.

M. Gray*Star Provided Sufficient Information About The Design Of The GS-42 To Provide Reasonable Assurance of Safety

Finally, the staff asserts that Gray*Star failed to provide sufficient information regarding the final source weld procedures, source filling procedures, including adequacy of the moisture removal process and prevention of corrosion, the effect of source filling on the seals, and seal torquing. See Staff Brief at 23-26. Gray*Star addressed each of these issues in its initial brief at pages 81 through 85, and as discussed, Gray*Star provided specific data and analyses regarding the design, manufacture, and prototype testing of the GS-42 sealed source that is sufficient to provide assurance that its radiation safety properties are adequate.

III. CONCLUSION

For the aforementioned reasons, the staff's denial of the registration of the GS-42 sealed source was without merit.

Respectfully submitted this 30th day of October, 2000.

By: _____

Anthony J. Thompson
David C. Lashway
SHAW PITTMAN
2300 N Street, N.W.
Washington, D.C. 20037
(202) 663-8000

ON BEHALF OF GRAY*STAR, INC.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges:

Ann Marshall Young, Presiding Officer
Thomas D. Murphy, Special Assistant

In the Matter of	)	
GRAY*STAR, INC.	)	Dkt. No. SSD 99-27 ASLBP No. 00-778-06-ML
(Suite 103, 200 Valley Road, Mount Arlington, NJ 07856)	)	October 30, 2000

CERTIFICATE OF SERVICE

I hereby certify that I caused true and complete copies of the foregoing GRAY*STAR, INC.'S RESPONSE TO THE NRC STAFF'S BRIEF REGARDING APPLICATION FOR REGISTRATION OF MODEL GS-42 SEALED SOURCE in the above-captioned matter to be served, via first class mail delivery and electronic mail on this 30th day of October, 2000 to:

Administrative Judge
Ann M. Young, Presiding Officer
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Mail Stop T-3 F23
Washington, D.C. 20555-0001
(E-mail: amy@nrc.gov
Fax: 301/415-5599)

Adjudicatory File
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Mail Stop T-3F23
Washington, D.C. 20555-0001

Office of the Secretary
Attn: Rulemakings and Adjudications Staff
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Mail Stop O-16G15
Washington, D.C. 20555-0001
(E-mail: hearingdocket@nrc.gov
Fax: 301/415-1101)

Office of Commission Appellate Adjudication
U.S. Nuclear Regulatory Commission
Mail Stop O-16G15
Washington, D.C. 20555-0001

Administrative Judge
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David C. Lashway

David C. Lashway
SHAW PITTMAN

ATTACHMENT 1

(1)

NRC FORM 311
(9-1997)

U.S. NUCLEAR REGULATORY COMMISSION

QUALITY ASSURANCE PROGRAM APPROVAL
FOR RADIOACTIVE MATERIAL PACKAGES

1. APPROVAL NUMBER: 0898
REVISION NUMBER: 0

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 5 by the person named in Item 2, the Quality Assurance Program identified in Item 5 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval is subject to all applicable rules, regulations, and orders of the U.S. Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

2. NAME: Gray Star, Inc.

3. EXPIRATION DATE: September 30, 2003

STREET ADDRESS: 200 Valley Road, Suite 103

4. DOCKET NUMBER: 71-0898

CITY	STATE	ZIP CODE
Mt. Arlington	NJ	07856

5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S): July 20, 1998

6. CONDITIONS

Activities conducted under applicable criteria of Subpart H of 10 CFR Part 71 to be executed with regard to transportation packagings. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, repair, and use of transportation packagings.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

SIGNATURE: for Charles J. Haughney

DATE: September 22, 1998

PATRICIA L. ENG, CHIEF
TRANSPORTATION AND STORAGE INSPECTION SECTION
SPENT FUEL PROJECT OFFICE
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ATTACHMENT 2

CLASS E-4342' 'EQUIREMENTS
FOR
GS-42 SOURCE TUBE ASSEMBLY TESTING

TRS #	SELECT x T COR FACT = USE (2 Tubes each test)	10CFR36 Test 1 tube	10CFR71 Subpart F Test 1 tube	ISO-2919 Test 1 tube	ANSI N43.6 Test 2 tubes except 6xx series	ANSI N433.1 Test 1 tube	IAEA Safety Series #6 Test 1 tube
002 Bending, Impact	1.4 kg from 1 m x 1.7 = 2.38 kg from 1 m (5.25 lbs fr 39.38")		75.b.3 1.4 kg from 1 m		609 1.4 kg from 1 m		609 1.4 kg from 1 m
003 Bending Static	204 kg x 1.7 = 346.8 kg (764.55 lbs)	21.g 204 kg				4.2.2 class 4 102 kg	
004 Temperature	-40 for 20 min 800 for 1 hr x NA = -40 for 20 min 800 for 1 hr	21.b -40 for 20 min 600 for 1 hr	75.b.4 800 for 10 min (may do ISO-2919 class 6 temperature)	8.2 class 4 -40 for 20 min 400 for 1 hr	7.2 class 4 -40 for 20 min 400 for 1 hr 610 800 for 10 min (may do ISO-2919 class 6 temperature)		610 800 for 10 min (may do ISO-2919 class 6 temperature)
005 Thermal Shock	600/20 in 15 sec x NA = 600/20 in 15 sec	21.b 600/20 in 15 sec		8.2 class 4 400/20 in 15 sec	7.2 class 4 400/20 in 15 sec		
006 External Pressure	25 kN/m² (2x5 min) 2 MN/m² (2x5 min) x 1.7 (low P only) = 14.71 kN/m² (absolute) (2.13 psi) (absolute) 2 Mn/m² (absolute) (290 psi) (absolute)	21.c 2 MN/m² 2 x 5 min		8.3 class 3 25 kPa 2 x 5 min 2 Mpa 2 x 5 min	7.3 class 3 25 kN/m² 2 x 5 min 2 MN/m² 2 x 5 min		
007 Impact	2 kg from 1 m x 1.7 = 3.4 kg from 1 m (7.5 lbs)	21.d 2 kg from 1 m	75.b.1 9 m free fall (may do ISO-2919 class 4 impact)	8.4 class 4 2 kg from 1 m	7.4 class 4 2 kg from 1 m 607 9 m free fall (may do ISO-2919 class 4 impact)		607 9 m free fall (may do ISO-2919 class 4 impact)
008 Vibration	25-500 hz at 5 g 30 min at res x 1.21 = 25-500 hz at 6.1 g 30 min at res	21.e 25-500 hz at 5 g 30 min at res		8.5 class 2 25-500 hz at 5 g 30 min at res	7.5 class 2 25-500 hz at 5 g 30 min at res		
009 Puncture	50 g from 1 m x 1.7 = 85 g from 1 m (3 oz)	21.f 50 g from 1 m		8.6 class 4 50 g from 1 m	7.6 class 4 50 g from 1 m		
NA Percussion	NA		75.b.2 1.4 kg from 1 m (may do ISO-2919 class 4 impact)		608 1.4 kg from 1 m (may do ISO-2919 class 4 impact)		608 1.4 kg from 1 m (may do ISO-2919 class 4 impact)

ATTACHMENT 3

FAX Transmission

From: Russell Stein
Questions? Call 973-398-3331
Fax 973-398-8310

GRAY*STAR, Inc.
200 Valley Rd., Ste. 103
Mt. Arlington, NJ 07856

To: John Jankovich
Company: NRC
Address:

301-415-5369, 301-415-7904

Date: January 12, 1999
Time: 12:59 PM

Pages: 3 (including this one)

John:

Attached is the preliminary schedule for our source testing. We would be pleased if you and/or your associates could be present during any or all of the testing.

The test sources are undergoing their final manufacturing steps. I trust they will be ready on time; however, it is possible they might be delayed and the tests postponed.

The "Vibration Tests" (TRS-008) might be moved to a different date due to a conflict of schedule at that test lab.

If there are any changes in the schedule or if there is a delay in the schedule, you will be the first to know.

Please let me know if you need any assistance with travel, directions, rides etc.

Unfortunately, I won't be able to attend the Sealed Source Workshop if I'm going to meet this schedule. Look forward to seeing you next week.

Thanks, Russell

GRAY*STAR GS-42 Testing Schedule

PRELIMINARY

Jan 17, 1999

	Company	Monday Jan 18, 1999			Tues Jan 19, 1999			Wed Jan 20, 1999			Thurs Jan 21, 1999			Fri Jan 22, 1999		
		8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M
Phase 1																
1. **Preparation**	Smithers															
Set Up Fill Assembly Area																
Smithers Training on Leak Detector																
QA Review																
2. **Fill Source Tube Asmb L1**	Smithers															
- Purge w/ helium for 2 min (min)																
- Weigh Out Cesium for 1 Assembly																
- Add Cesium to Assembly																
- Heat Assembly @ 120 deg C For 2 Hrs																
- Purge Void in Inner Tube W/ He																
- Install Inner Plug. Record torque																
- Leaktightness Test per TRS-020																
- Install Outer Plug. Record torque																
Fill Source Tube Asmb L2																
Fill Source Tube Asmb L3																
Fill Source Tube Asmb L4																
Fill Source Tube Asmb L5																
Fill Source Tube Asmb L6																
3. **TRS-004 Cold Test, Tube L1 & L2**	Experimental															
- Cool to -40/-75 deg C w/in 45 min.																
- Hold For 20 min.																
- Return to Ambient																
- Drill / Fit Schrader Valve																
- Leaktightness Test per TRS-020																
4. **TRS-004 Heat Test, Tubes L1 & L2**	Peterson															
- Fit / Weld Plug																
- Heat to 600 deg C w/in 70 min.																
- Hold for 1 Hour																
- Return to Ambient																
- Drill / Fit Schrader Valve																
- Leaktightness Test per TRS-020																
- Fit / Weld Plug																
5. **TRS-005 Quench Test, Tubes L1 & L2**	Peterson															
- Heat to 600 deg C w/in 70 min.																
- Hold for 15 min																
- Quench w/in 15 Sec																
- Drill / Fit Schrader Valve																
- Leaktightness Test per TRS-020																

Address	Smithers Scientific Services, Inc. 425 Market St Akron, OH 44303-2069	Experimental Services Inc. 595 Waterloo Rd Akron, OH 44314	Peterson Heat Treating 4142 Mogadore Rd Kent, OH
Phone:	(330) 762-7441	(330) 628-2771	(330) 253-7779
FAX:	(330) 762-7447	(330) 628-1556	(330) 253-3920
Contact:	Lenny Hanson	Carl Winkler	Chris Powell

GRAY*STAR GS-42 Testing Schedule

PRELIMINARY

Jan 12, 1999

		Company	Monday Jan 18, 1999			Tues Jan 19, 1999			Wed Jan 20, 1999			Thurs Jan 21, 1999			Fri Jan 22, 1999		
			8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M	8 - 11 AM	11 - 2 PM	2 - 5M
	Phase 2																
1	**TRS-010 End Cap/Plug Test**	Experimental															
	- Clean Caps & Tubes																
	- Thermal Cycle 100 C-400 C, 75 Times																
	- Leaktightness Test per TRS-031																
2	**TRS-009 Vibration Test Tubes L3 & L4**	Experimental															
	- Mount Source Perpendicular to Long Axis																
	- Cycle 1, 10 min, 25/500 Hz at 6.1g																
	- Cycle 2, 10 min, 25/500 Hz at 6.1g																
	- Cycle 3, 10 min, 25/500 Hz at 6.1g																
	- Resonnace Test, 30 min each frequency																
	- Mount Source Parallel to Long Axis																
	- Cycle 1, 10 min, 25/500 Hz at 6.1g																
	- Cycle 2, 10 min, 25/500 Hz at 6.1g																
	- Cycle 3, 10 min, 25/500 Hz at 6.1g																
	- Resonnace Test, 30 min each frequency																
	- Fit Schrader Valve																
	- Leaktightness Test per TRS-020																
3.	**TRS-002 Puncture Test Tubes L3 & L4**	Smithers															
	- Mount Source on Anvil																
	- Drop 65 g Hammer from 1 m (39.37")																
	- Leaktightness Test per TRS-020																
4.	**TRS-007 Impact Test Tubes L3 & L4**	Smithers															
	- Mount Source on Anvil																
	- Drop 3.4 kg Hammer from 1 m (39.37")																
	- Leaktightness Test per TRS-020																
5.	**TRS-002 Impact Bending Test Tubes L3 & L4**	Smithers															
	- Clamp Tube																
	- Drop 2.38 kg Hammer from 1 m (39.37")																
	- Leaktightness Test per TRS-020																
6.	**TRS-003 Static Bending Test Tubes L3 & L4**	Smithers															
	- Clamp Tube																
	- Apply 348.8 kg Force Slowly																
	- Leaktightness Test per TRS-020																
7	**TRS-006 ExtPressure Test Tubes L3 & L4**	Experimental															
	- Place Sources in Chamber																
	- Pressurize to 2.13 PSI Absolute For 5 Min																
	- Return to Atmosphere																
	- Pressurize to 2.13 PSI Absolute For 5 Min																
	- Return to Atmosphere																
	- Remove Source From chamber																
	- Fit Schrader Valve																
	- Leaktightness Test per TRS 020																
	- Fit / Weld Plug																
	- Place Sources in Chamber																
	- Fill With Water																
	- Pressurize to 290 PSI Absolute For 5 Min																
	- Return to Atmosphere																
	- Pressurize to 290 PSI Absolute For 5 Min																
	- Return to Atmosphere																
	- Drain Chamber & Remove Source																
	- Leaktightness Test per TRS-020																