RAS 2225 September 25, 2000

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED 09/26/00

BEFORE THE PRESIDING OFFICER

In the Matter of	)	
	)	
GRAYSTAR, INC.	)	Docket No. SSD 99-27
200 Valley Road	)	
Mt. Arlington, New Jersey 07856	)	

NRC STAFF'S INITIAL WRITTEN PRESENTATION

INTRODUCTION

Pursuant to the Presiding Officer's unpublished orders dated August 17, 2000 ("Setting Schedule for Proceedings and Addressing Other Matters Considered at August 15, 2000, Telephone Conference") (August 17 Order), and September 14, 2000 ("Addressing Matters Considered at September 7, 2000, Telephone Conference") (September 14 Order), and in accordance with 10 C.F.R. § 2.1233, the Staff files this written presentation in the above-captioned proceeding. This proceeding concerns the Staff's denial of an application filed by GRAY*STAR, Inc. (GrayStar) for registration of its Model GS-42 sealed source. The Staff documented its reasons for denying GrayStar's application in a letter to GrayStar dated May 24, 2000 (Denial Letter), and in Enclosure 1 to the Denial Letter.

BACKGROUND

In April 1999, GrayStar submitted a 38-page registration application, which included Appendices A-D and eleven exhibits. The application included a request that GrayStar's

proposed Model 1 irradiator be registered.[1] GrayStar officials met with the Staff on May 11, 1999, as a follow-up to submitting its registration application, and provided a set of slides. In June 1999, the Staff completed its initial acceptance review of GrayStar's registration application, and began its technical review. To facilitate its technical review, the Staff met with GrayStar's Russell Stein on July 13, 1999. The Staff continued its technical review of the registration application, and by cover letter to GrayStar dated July 26, 1999, enclosed a Request For Additional Information (RAI) containing 60 numbered items. After reviewing the RAI, GrayStar requested a meeting, which was held at the NRC on August 11, 1999. Among other issues, GrayStar raised the question of whether the requirements of 10 C.F.R. Part 36 were applicable to the review of its April 1999 registration application.[2] GrayStar provided written comments on the Part 36 question in its letter to the Staff dated August 12, 1999. By letter to GrayStar dated September 10, 1999, the Staff stated why the requirements of 10 C.F.R. Part 36 are applicable here, and withdrew its earlier request that GrayStar submit an environmental report as part of its registration application.

GrayStar responded to the July 1999 RAI by cover letter dated September 27, 1999, enclosing a 110-page response (plus five volumes of attachments) to the RAI's 60 numbered items. The Staff's review of GrayStar's RAI response is reflected in the Denial Letter. The Staff found that GrayStar's proposed use of cesium-137 chloride powder

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[1] Enclosure 2 to the Denial Letter discusses why review of this part of the April 1999 GrayStar registration application was suspended. By agreement of the parties, this licensing action by the Staff is not part of this proceeding. *See* August 15 conference Tr., at 12-13.

[2] 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. § 36.21 "when installed in a GrayStar Model 1" irradiator. Hearing File Tab IV.B, at 5.

violated the requirements of 10 C.F.R. § 36.21(a)(3), which specifies that radioactive material to be used in irradiators must be "as nondispersible as practical." *See* Denial Letter, at 1. The bases supporting the decision not to register the Model GS-42 sealed source were set forth in Sections 1-4 of Enclosure 1 to the Denial Letter, and these sections were titled, respectively: (1) Dispersibility; (2) Testing of Sealed Sources; (3) Sealed Source Construction and Durability; and (4)The Design Has Not Been Finalized. *See* Denial Letter, Enclosure 1, at 1-3. Therein, the Staff concluded that the proposed design for the Model GS-42 sealed source would not adequately protect health and minimize danger to life and property. *Id.* (Section 4), *citing* 10 C.F.R. § 32.210(c).

GrayStar challenged the registration denial, and requested a hearing, in a letter dated June 1, 2000 (Hearing Request). This Hearing Request was subsequently granted, and the Staff established and distributed a Hearing File. *See* Staff's letter dated August 1, 2000 (as supplemented by the Staff's letter dated September 6, 2000).

DISCUSSION

This initial written presentation is organized below into the sub-sections requested by the Presiding Officer in her outline. *See* August 17 Order, at 3-5. This outline is largely based on the issues as set forth in the Denial Letter's Enclosure 1. As previously noted by the Staff during the August 15, 2000 conference call (*see* Tr., at 28-30), GrayStar in its Hearing Request chose not to address the issues discussed in Sections 2, 3, and 4 of Enclosure 1. *See* Hearing Request, at 2. Since the positions GrayStar will take on these issues of sealed source testing, construction, and design, are thus not yet known, this initial written presentation -- insofar as it pertains to these issues -- will be somewhat limited.

In this regard, Sections 2, 3, and 4 below provide the relevant findings made by the Staff in Sections 2, 3, and 4 of the Denial Letter's Enclosure 1, but the discussion in these sections does not further expand on the Enclosure 1 analyses. Additionally, as requested by the Presiding Officer (*see* August 17 Order, at 5, ¶ 6, first sentence), Sections 2, 3, and 4 below provide specific cites to the GrayStar application materials which the Staff quoted and referenced in Sections 2, 3, and 4 of the Denial Letter's Enclosure 1.

1. Dispersibility of cesium 137 chloride powder in the Model GS-42 Sealed Source, under 10 CFR § 36.21(a)(3) and as discussed in Enclosure 1 to NRC Staff's May 24, 2000, letter.

   a. Appropriateness/inappropriateness/practicality of other sources as compared to cesium-137 chloride powder.

GrayStar has not provided adequate justification for using cesium-137 chloride powder in its Model GS-42 sealed source. In this form, cesium-137 is highly dispersible. Accordingly, the Staff in its July 1999 RAI had requested GrayStar to provide justification for the selection of such a cesium compound. *See* Hearing File Tab V.B., at 1, ¶ 2, noting that pursuant to the requirements of 10 C.F.R. § 36.21(a)(3), radioactive material to be used in irradiators must be "as nondispersible as practical." GrayStar's September 1999 response (Hearing File Tab VI) did not address the safety issues related to dispersibility. Instead, GrayStar's response was limited to issues of heat generation, ease of hot cell operations, costs, and operational history, and contained only a cursory analysis of a source leak accident. *See* Hearing File Tab VI, at 2-3.

Moreover, in its Hearing Request (Hearing File Tab VIII), GrayStar simply repeated in verbatim fashion its September 1999 arguments regarding heat generation, ease of hot cell operations and handling, cost effectiveness, and history of use. *Cf.* Hearing File Tab VIII (Hearing Request), at 8, to Hearing File Tab VI (GrayStar's September 1999 response

to the RAI), at 2-3. Thus, the Hearing Request did not provide any new information addressing the Staff's safety concerns regarding dispersibility.

GrayStar stated that, in the Denial Letter, the Staff implied "that other isotopes can be used in lieu of cesium-137," and that this unfairly raised a new issue on which GrayStar had not been given an opportunity to respond. Hearing Request, at 2.[3] This charge has no basis. Any reference in the Denial Letter to the potential use of isotopes other than cesium-137 does not unfairly raise a new issue, and provides no basis to challenge the Staff's denial of the registration application. The issue of whether chemical forms other than cesium chloride should be used was brought to GrayStar's attention in the July 1999 RAI. *See* Hearing File Tab V.B., at 1, ¶ 2. Furthermore, in the 1993 rulemaking establishing 10 C.F.R. Part 36, the irradiator industry received notice that 10 C.F.R. § 36.21 "was written to require that irradiators use radioactive materials that are as insoluble and nondispersible as practical (typically cobalt-60)." 58 Fed. Reg. 7715, 7716 col. 2 (February 9, 1993). This rulemaking action reflected the NRC's decision "not to approve further use of cesium sources" in irradiators. *Id.*, at 7718, col. 2. However, the rule's use of the term 'as practical' would allow the NRC to make an exception to this cesium ban if adequate justification is provided by the applicant. *Id.*

b. <u>Leak potential/danger with regard to cesium-137 chloride; unique design features to mitigate consequences of any leak.</u>

In its Hearing Request, GrayStar provided a short summary of the Model GS-42 sealed source features designed to contain radioactive material during fabrication and

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[3] This charge is apparently based on the Staff's statement that there are "many operating irradiators, used for purposes similar to the applicant's proposed irradiator, which use nondispersible radioactive material." Denial Letter, Enclosure 1, at 1.

subsequent use in GrayStar's Model 1 irradiator, and stated that any potential leaks would be small and would be correctable offsite. *See* Hearing Request, at 10. But this is the same information which the Staff had already reviewed during its evaluation of GrayStar's April 1999 application (*see* Hearing File Tab IV.B, at 10-13), and did not address the issue of dispersibility. GrayStar has thus failed to adequately explain how the consequences of a leak of dispersible cesium-137 would be mitigated. Neither the April 1999 application nor the Hearing Request presented preventive measures which would mitigate dispersion of radioactive material in case of an accident, such as a leak. In light of the specific safety concern identified by the Commission regarding potential cesium-137 leaks (*see* discussion in 1.a, *supra*), GrayStar should provide much more substantial mitigation provisions to justify use of dispersible cesium-137. Moreover, in its Hearing Request, GrayStar did not provide any additional safety information regarding the integrity of the proposed Model GS-42 sealed source design, and provided no information regarding interaction among the materials involved.

c. <u>Comparison to smaller irradiators and sealed sources using cesium-137 chloride.</u>

GrayStar stated that the Denial Letter "implies that small source history is not applicable" to its proposed Model GS-42 sealed source. Hearing Request, at 9. The Staff did more than imply this, stating as follows:

> 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 bequerel and 1.9 E15 bequerel 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.

Denial Letter, Enclosure 1 at 1. In its Hearing Request, GrayStar stated that "all the history, especially that relating to safety performance, is important," and that "a leak in a small source would have the same effect as that of a large source," but no further analysis on this point is provided. Hearing Request, at 9. The Staff does not discount the importance of operational history as a general matter, but the Staff does not accept the transferability of such history here, given the large difference between 30 curies and 51,500 curies, as discussed above. GrayStar has not provided an engineering analysis supporting the transferability of operational history from irradiators using small sealed sources to irradiators using large sealed sources of radiation.

d. Other unique circumstances relating to GS-42, including applicant's response numbers I-VII in June 1, 2000, letter from Russell N. Stein to Donald A. Cool.

i. General value of irradiation to help prevent food borne disease.

GrayStar argued in its Hearing Request, at 2-3, that there is a potential for increased demand for food irradiation services, and that such services are valuable in helping to prevent food borne disease. While this may be true, such issues are not related to NRC safety requirements, and are therefore irrelevant here. The Staff's denial of the registration application was based solely on NRC safety requirements and concerns.

ii. Comparison of GS-42, which is a self-shielded gamma irradiator with no on-site source transfer, vs. other irradiators.

A. Water storage and/or water irradiation irradiators
B. Dry storage on-site loading irradiators
C. Dry storage irradiators with interlocks (panoramic irradiators where the source is independent of the radiation chamber)
D. Machine source irradiators

GrayStar contended that its proposed irradiator design incorporated substantial safety improvements over older designs (*e.g.*, better access control, avoidance of onsite source

transfers, fewer source exchanges, improved product dosimetry), and that use of cobalt-60 in its Model 1 irradiator would be impractical. *See* Hearing Request, at 3-8. As discussed below, 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.

The access control and dosimetry features are safety improvements which are not related to the use of dispersible cesium. These are features which could just as easily be incorporated into irradiators using nondispersible material. The presence of these safety features does not constitute a justification for the use of dispersible cesium.

The avoidance of onsite source transfers, and the reduction in source exchanges, are design features on which GrayStar based its conclusion that use of cobalt-60 in its irradiator would be impractical, since cobalt-60 requires heavier transportation shielding and has a shorter half-life than cesium-137. *See* Hearing Request, at 7-8. GrayStar further argued that it is safer to transport an irradiator as a complete unit, and that there will be an increase in safety since its proposed sealed source could be exchanged offsite, and less frequently than would be the case if cobalt-60 is used. *Id.* GrayStar also made economic arguments related to the preference and advantage of locating relatively more numerous, smaller, lower-capacity irradiators near food processing locations. *Id.*, at 4. But again, these arguments do not address the paramount safety problem of using cesium chloride powder in irradiators, *i.e*, dispersibility.

Moreover, while cobalt-60's need for heavier shielding, and the fact that it has a shorter half-life -- thus requiring more frequent source changes -- may be viewed as drawbacks when compared with using cesium-137 in irradiators, the Commission was

aware of these factors when it established 10 C.F.R. § 36.21's performance criteria for sealed sources in 1993. *See* discussion in 1.a, *supra.* 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. The Staff determined that GrayStar failed to provide such justification, since it did not identify any factors not present in 1993, nor did it describe in a safety analysis any unique design features addressing the issues of dispersibility, solubility, and other safety factors.[4]

Insofar as GrayStar's Hearing Request arguments may be viewed as challenging the requirements of 10 C.F.R. § 36.21 (*see*, *e.g.*, Hearing Request, at 7-8), the Presiding Officer has the discretion to refer the matter to the Commission pursuant to 10 C.F.R. § 2.1209(d). Parties in Subpart L adjudicatory proceedings are not authorized to challenge NRC regulations without first obtaining a waiver or exception from the Commission. *See* 10 C.F.R. § 2.1239(b). *See also Public Service Co. of New Hampshire* (Seabrook Station, Units 1 and 2), CLI-90-10, 32 NRC 218, 223 (1990) (rulemaking is proper forum in which

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[4] For example, GrayStar did not address the fact that cesium-137's dispersibility, combined with its longer half-life -- and longer decay time-- would present an increased safety risk in comparison with cobalt-60, if a leak from its Model GS-42 sealed source, or other safety problem, occurred. Similarly, GrayStar did not address whether there may be an increased safety risk associated with a proliferation of smaller-scale irradiators in the vicinity of food processors, whose personnel have no previous training or experience with radiation safety.

to challenge Commission regulations, rather than in a licensing hearing). As discussed in Section 1.a, *supra*, the 10 C.F.R. § 36.21 sealed source performance criteria are based on the NRC's finding that cobalt-60 is safer for use in panoramic irradiators than is dispersible cesium-137. *See* 58 Fed. Reg. 7715, at 7716 col. 2, and 7718, col. 2.

iii. Comparison of Cesium-137 with other source types: (A) Cobalt-60; (B) Electron beams (e-beam); (C) Bemsstrahlung Radiation (X-rays)

In its Hearing Request, at 6-7, GrayStar compared cesium-137 with other sources of radiation used to treat food, but does not discuss the dispersibility issue. The discussion is thus not relevant to the Staff's denial of GrayStar's application for registration of the Model GS-42 sealed source.

iv. Basis for selection of cesium-137 for GS-42 as compared to cobalt-60.

GrayStar argued that use of cobalt-60 in its Model GS-42 sealed source, as an alternative to using cesium-137, is impractical. *See* Hearing Request, at 7-8. These arguments are addressed in Sections 1.a and 1.d.ii, *supra*.

v. Practicality and safety of using cesium-137 chloride as compared to other forms of cesium-137.

GrayStar has maintained that cesium-137 chloride powder, which is highly dispersible, is the only practical form of cesium that can be used in its Model 1 irradiator, but this argument is properly considered only if the broader dispersibility issue (*i.e.*, using cesium-137 rather than cobalt-60) is decided in GrayStar's favor. As noted in Section 1.a, *supra*, GrayStar's Hearing Request in this regard repeated its September 1999 arguments regarding heat generation, ease of hot cell operations and handling, cost effectiveness, and history of use. *Cf.* Hearing File Tab VIII (Hearing Request), at 8, to Hearing File Tab VI (GrayStar's September 1999 response to the RAI), at 2-3. These arguments are brief

generalizations, and are inadequate to demonstrate that less dispersible forms of cesium are impractical. The arguments might, if supplemented with more technical detail, demonstrate that cesium chloride powder is the only practical form of cesium-137 for use in large-scale irradiator operations. 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.

vi. Unique design features of GS-42 (numbered (1)-(12) in Russell Stein's June 1, 2000, letter

GrayStar described design features which it claimed would minimize dispersal of cesium chloride powder. *See* Hearing Request, at 9-11. GrayStar maintained that its quality assurance plan, as well as its design and fabrication techniques, assure a safe product which is unlikely to leak. *Id.*, at 10, items 1-8. NRC regulations require that all sealed sources, regardless of whether they contain dispersible or nondispersible material, be designed and fabricated such that they are unlikely to leak, as demonstrated by successful leak testing. *See* 10 C.F.R. § 36.21(a)(5). 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.

GrayStar argued that if its proposed sealed source were to leak, the dispersal hazard would be minimal, because its Model 1 irradiator is dry and there is no thermal cycling. *See* Hearing Request, at 10, items 9 and 11. However, the potential for dispersal following a leak would be the same for any dry irradiator, and is not unique to GrayStar's Model 1 design. 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.

GrayStar referenced the fact that the State of California, in 1998, granted a certificate of registration involving the use of cesium chloride in irradiators. *See* Hearing Request, at 9. California's action was not an initial approval for using a cesium chloride source, but simply updated an approval granted in 1990. *See* California document No. CA598S119S, "Registry of Radioactive Sealed Sources and Devices, Safety Evaluation of Sealed Source," dated April 2, 1990, attached hereto as Staff Exhibit 1. The NRC's Part 36 regulations did not become effective until 1993. *See* 10 C.F.R. § 36.21(a) (regulations applicable only to sealed sources installed after July 1, 1993). Accordingly, California's action is not relevant here.

Moreover, California's approval applied to sealed sources used in small, self-contained irradiators,[5] in which the length of the source capsule is no more than 15.5 inches (*see* Table 1 of Staff Exhibit 1), as compared with GrayStar's Model GS-42 sealed source capsules, which would be 46 and 38 inches long. *See* GrayStar's September 1999 revised application for sealed source registration, Hearing File Tab VI.F.1, at page 10 of 38. Additionally, these GrayStar sealed source capsules would be used in sets of 64 capsules per Model 1 irradiator (*see id.*), as compared with one source capsule per irradiator in the 1990 model licensed by California.

GrayStar stated that its sealed sources containing the cesium chloride powder would be isolated from the product chamber, in order to reduce the risk of damage. *See* Hearing Request, at 10, item 10. However, similar features to prevent sealed source damage would

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[5] The Part 36 regulations do not apply to small irradiators of this type, in which the sealed source and irradiation chamber are not accessible by personnel. *See* 10 C.F.R. § 36.1(c). Pursuant to the Presiding Officer's September 14 Order, ¶ 5, at 2, the applicability of Part 36 to GrayStar's April 1999 registration application is discussed in Section 3.5.a, *infra*.

be required for other irradiators, in accordance with 10 C.F.R. § 36.35, “Source Rack Protection”, even if they contain nondispersible material. Therefore, this design feature does not constitute an adequate justification for use of dispersible material in the Model GS-42 sealed sources.

GrayStar further maintained that if a leak were to occur, the entire irradiator could be moved to an off-site facility for corrective action. *See* Hearing Request, at 10, item 12. Although this is a mitigating factor, the Staff does not view this feature as an adequate justification for use of dispersible cesium chloride powder in the Model GS-42 sealed sources because: (1) the safety benefit appears to be minimal; (2) there is considerable uncertainty as to whether a leak would be confined to the irradiator as maintained by GrayStar; (3) whether a Model 1 irradiator containing a leaking source could be safely transported is uncertain; and (4) it is questionable whether overall the movement of the Model 1 irradiator offsite would be safer than addressing the leaking source onsite.

In the Hearing Request, at 9, GrayStar argued that the history of successful use of small cesium sources is relevant to its case. The Staff disagrees, as discussed in Section 1.c, *supra*. GrayStar also claimed that the Staff in its Denial Letter implied that there is a bias against using large sealed sources in irradiators. *See* Hearing Request, at 9. The Staff does not have a bias against the use of large sources for irradiation purposes. Rather, as discussed in Section 1.c, *supra*, the Staff position is that GrayStar has not adequately demonstrated that the history of use of small cesium sources is applicable to GrayStar’s larger Model GS-42 sealed sources.

vii. Other.

The Staff is aware of no other issues requiring discussion under Section 1.d of the Presiding Officer's outline.

e. Relation of a - d to each other, in terms of safety, relative importance, etc.

The most important safety factors weighing against approval of GrayStar's application for registration of the Model GS-42 sealed source are discussed above, in Sections 1.a, 1.d(ii), 1.d(iv), 1.d(v) and I.d(vi). These are the most important safety factors because they involve GrayStar's failure to show that its proposed sealed source would use radioactive material which is as nondispersible as practical, as required by 10 C.F.R. § 36.21(a)(3). The discussion in Section 1.b involves a related safety issue, in that GrayStar failed to demonstrate unique safety features in its Model GS-42 sealed source design which would mitigate leaks. Section 1.c is of lesser significance, as it relates to the applicability of historical data. The discussion in Sections 1.d(i) and I.d(iii) pertains to issues which are irrelevant to the Staff's May 24 denial decision.

f. Other matters relating to dispersibility issue.

The Staff is aware of no other issues requiring discussion under Section 1 of the Presiding Officer's outline.

2. Prototype testing of GS-42 sealed sources under 10 C.F.R. § 36.21(a)(5)

a. Design of inner capsule relative to leak potential

Exhibit 3 of GrayStar's April 1999 application (Hearing File Tab IV.E) contained test reports showing that the prototype sealed sources leaked. Specifically, these reports show that on day three of the testing, two outer capsule leaks occurred. *See* tenth page of Hearing File Tab. IV.E (test report pages not numbered). Additionally, on day five of the

testing, an inner capsule failure occurred. *See* twelfth and thirteenth pages of Hearing File Tab. IV.E. GrayStar further described the failures of the outer capsules in its RAI response number 1, noting there a design change it made which added a weld to the outer capsule. *See* Hearing File Tab VI.B, at 1. As stated in Section 2, page 1, of the Denial Letter's Enclosure 1, the Staff determined that GrayStar did not meet the safety requirement 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)(5). Additionally, 10 C.F.R. § 36.21 (a)(2) requires that sealed sources be "doubly encapsulated." The information provided by GrayStar did not demonstrate that the prototype Model GS-42 sealed sources maintained double encapsulation during testing.

The leaks during prototype testing indicate that the design of the Model GS-42 sealed source is deficient, in spite of the fact that GrayStar drew "upon the histories of large and small cesium sources." Hearing Request, at 9. The Staff would now conclude that even if GrayStar had chosen to use a nondispersible material, GrayStar's sealed source design, as presented in GrayStar's application materials, would fail to meet the above-referenced NRC requirements. Moreover, 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 nondispersible material. In this regard, the Staff notes that GrayStar conducted its tests with non-radioactive cesium rather than radioactive cesium. Because, as discussed in Section 1, *supra*, the Staff concluded that GrayStar's Model GS-42 sealed source did not meet NRC safety 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.

b. Vibration testing

i. Along weakest axis

The "industry standards" referenced in Section 2, page 2, of the Denial Letter's Enclosure 1, are found in Section 7.5.2 of the American National Standards Institute, Inc. (ANSI) document N43-1997. The pertinent ANSI standard specifies that, for sources comparable to the Model GS-42 sealed sources, three axes should be tested. A copy of the relevant ANSI page is attached hereto as Staff Exhibit 2. GrayStar's April 1999 application described the vibration test in Exhibit 3 (Hearing File Tab IV.E), and in its RAI response numbers 3 and 10. *See* Hearing File Tab VI.B. GrayStar tested the sources along the strongest two axes only.

ii. Range to 500 hertz

In reviewing the GrayStar submittals, the Staff realized that it overlooked the fact that GrayStar had correctly tested its Model GS-42 sealed sources over the required test range of 25-500 hertz. Therefore, the Staff hereby withdraws this vibration testing issue (2.b.ii) as a basis for the registration application denial.

3. GS-42 sealed source construction and durability under 10 C.F.R. §36.21(4)

3.1. Integrity of source housing

a. Relevance of historical evidence using different fabrication procedures

The issue here is the degree to which cesium chloride may cause pitting to occur in the Model GS-42 sealed source encapsulations. The 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. *See* Section 3.1 of the Denial Letter's Enclosure 1. The historical evidence in question was provided in GrayStar's RAI response numbers 13 and 16. *See* Hearing File Tab VI.B, at pages 17 and 20, respectively. GrayStar's description of the processes it used to fill the Model GS-42 sealed sources with cesium chloride powder is found in GrayStar's RAI response numbers 4, 21, and 22. *See* Hearing File Tab VI.B, at pages 5-6, 25-26, and 27, respectively. GrayStar's claim that this filling process does not last long enough to promote corrosion -- quoted by the Staff in Section 3.1 of the Denial Letter's Enclosure 1 -- is stated in GrayStar's RAI response number 13(A). *See* Hearing File Tab VI.B, at page 17.

b. Possibility of corrosion during filling process based on conditions present during the filling process:

i. pH,
ii. Time,
iii. Temperature,
iv. Concentration of impurities,
v. Other.

As stated by the Staff in Section 3.1 of the Denial Letter's Enclosure 1, 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. Corrosion issues are discussed further in Section 4.2, *infra*.

c. Possibility of corrosion during operation, based on adequacy of evaporation procedure to remove all moisture in source tube

GrayStar's statement that moisture is not an issue (quoted by the Staff in Section 3.1 of the Denial Letter's Enclosure 1) is found in GrayStar's RAI response number 13(B). *See* Hearing File Tab VI.B, at page 17. As explained in Section 3.1 of the Denial Letter's

Enclosure 1, the Staff calculated that, after fabrication, moisture remaining in the Model GS-42 sealed source would compromise the source wall integrity in 25 years. This is a much shorter period of time than the Model 1 irradiator's anticipated service life of 60 years. *See* GrayStar's April 1999 application, Hearing File Tab IV.B, at 9. Moisture and corrosion issues are discussed further in Section 4.2, *infra*.

3.2 Crevice corrosion:

a. Relevance of historical evidence using different filling procedure

The issue here is the degree to which cesium chloride may cause corrosion to occur in crevices on the Model GS-42 sealed source encapsulation walls. The historical evidence relied on by GrayStar to show that such corrosion will not occur was found not to be applicable by the Staff, due to differences between the filling procedures previously used, and the filling procedures used by GrayStar. *See* Section 3.2 of the Denial Letter's Enclosure 1. The historical evidence in question was provided in GrayStar's RAI response number 14. *See* Hearing File Tab VI.B, at page 18. More general corrosion issues are discussed further in Section 4.2, *infra*.

b. Special difficulty removing moisture from crevices

GrayStar relied on the absence of an electrolyte to show that cesium chloride would not cause corrosion to occur in crevices. *See* Section 3.2, page 3, of the Denial Letter's Enclosure 1. The GrayStar response cited there by the Staff is found in GrayStar's RAI response number 14. *See* Hearing File Tab VI.B, at page 18. The Staff found that GrayStar had not provided evidence showing that the evaporative procedure to be used

would adequately remove moisture from crevices. *See* Section 3.2, page 3, of the Denial Letter's Enclosure 1. More general corrosion issues are discussed further in Section 4.2, *infra*.

3.3 Role of impurities in sealed source materials - relevance of historical evidence using different filling procedures

The historical evidence relied on by GrayStar to show that any impurities in the cesium chloride to be used would have no impact on corrosion mechanisms (referenced by the Staff in Section 3.3 of the Denial Letter's Enclosure 1) is found in GrayStar's RAI response number 16. *See* Hearing File Tab VI.B, at page 20. The following discussion provides further background information on this issue.

In Exhibit 2 of GrayStar's April 1999 application, GrayStar listed materials impurities likely to be found in the cesium chloride, which it plans to obtain from the Waste Encapsulation and Storage Facility (WESF), located on the Hanford Reservation in Richland, Washington. *See* Hearing File Tab IV.D, first page (pages not numbered). GrayStar's RAI response numbers 16, 17, and 28 (*see* Hearing File Tab VI.B) discussed possible consequences of using cesium chloride containing these impurities. 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. For example, GrayStar's RAI response number 28 stated that there "is no direct cross reference" between the impurities listed on the first page of Exhibit 2, and the 17 historical documents listed on the last two pages of Exhibit 2. Hearing File Tab VI.B, at 35. 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.

3.4 Long-term reliability and failure modes:

a. Relevance of historical experience with WESF sources
b. Potential failure modes specific to GS-42

In Section 3.4 of the Denial Letter's Enclosure 1, the Staff quoted a statement in GrayStar's probabilistic risk assessment (PRA) regarding the long-term reliability of sealed sources. This GrayStar statement is found in GrayStar's RAI response number 58. *See* Hearing File Tab VI.B, at page 104, n.8. This RAI response (*see* Hearing File Tab VI.B, at 98-104) supplemented Exhibit 7 of GrayStar's April 1999 application (*see* Hearing File Tab IV.I), which provided a PRA of sealed source failure modes. However, the PRA and supplemental PRA information presented by GrayStar was primarily based on historical data regarding WESF capsules, and thus did not adequately identify and analyze the potential failure modes of the Model GS-42 sealed source.

3.5 Other

a. The applicability of 10 C.F.R. Part 36 to GrayStar's registration application

As discussed below, the 10 C.F.R. Part 36 regulations were properly applied by the Staff in denying GrayStar's April 1999 request to register its Model GS-42 sealed source, because these sealed sources are intended for use in an irradiator -- GrayStar's Model 1 irradiator -- which is large enough for a person to enter. In its letter to GrayStar dated September 10, 1999,[6] the Staff explained that GrayStar's Model 1 irradiator is a "panoramic dry-source-storage irradiator," as this term is defined in 10 C.F.R. § 36.2. This definition states that a "panoramic dry-source-storage irradiator" is one "in which the irradiations

[6] This letter was added to the Hearing File as a supplemental document. *See* Staff letter to Presiding Officer, dated September 6, 2000.

occur in air in areas potentially accessible to personnel." As GrayStar admitted in its "Exhibit 1" attachment to the August 12, 1999 letter GrayStar sent the Staff,[7] GrayStar's Model 1 irradiator would be accessible to personnel. Specifically, GrayStar stated that "human access to the volume undergoing irradiation is physically possible" in the Model 1 irradiator, since the irradiation chamber's space is "roughly the size of a commercial pallet" on which food to be irradiated is placed, and the height of the irradiation chamber "is approximately 55 inches." GrayStar's August 12, 1999 "Exhibit 1," at ¶ II.4. Moreover, GrayStar made clear that while no one would enter the irradiation chamber during routine operations, entry would be necessary to conduct maintenance activities. *See id.*, at ¶ II.4.A. Therefore, the fact that the irradiation chamber of GrayStar's Model 1 irradiator is large enough for a person to enter is not open to question.

Accordingly, because GrayStar's registration application sought approval to use Model GS-42 sealed sources -- containing radioactive material -- in panoramic irradiators whose irradiation chambers are accessible to personnel, these sealed sources are properly subject to the general provisions of 10 C.F.R. Part 36 (*see* 10 C.F.R. § 36.1(b)), as well as the specific sealed source performance criteria set forth in 10 C.F.R. § 36.21.

b. <u>Compliance with 10 C.F.R. § 36.35</u>

See discussion in Section 1.d.vi, *supra*.

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[7] GrayStar's August 12, 1999 letter and its two attachments (Exhibits 1 and 2) were added to the Hearing File as supplemental documents. *See* Staff letter to Presiding Officer, dated September 6, 2000. Exhibit 1 is titled "Evaluation of the application for Device Review as a Category I versus a Category II irradiator."

4. Sufficiency of information about the design of GS-42 "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" under 10 CFR 32.210(c) - *i.e.* finality and verifiability of design, generally.

4.1 Sufficiency of information about final design of source welding procedures

GrayStar's statement revealing the as-yet-to-be determined status of its welding procedures (quoted by the Staff in Section 4.1 of the Denial Letter's Enclosure 1) is found in GrayStar's RAI response number 8. *See* Hearing File Tab VI.B, at pages 10-11. The following discussion provides further background information on this issue.

GrayStar's April 1999 application generally referenced welding procedures for the Model GS-42 sealed source in various places. *See, e.g*, Section 1 of the application (Hearing File Tab IV.B.), at 10; and on the third page of the first section of the application's Exhibit 3 (Hearing File Tab IV.E.), titled "Sealed Source Qualification Testing - Overview" (pages not numbered). While GrayStar's RAI response number 8 contained a more detailed discussion of welding procedures, this response indicated that the procedures had not been finalized. GrayStar's RAI response number 24 also discussed welding issues, but this response pertained to weld inspections rather than how the welds will be initially performed. *See* Hearing File Tab VI.B. at 30.

4.2 Sufficiency of information about final design for source filling of GS-42

a. Adequacy of moisture removal procedure
b. Prevention of corrosion

On page 10 of GrayStar's April 1999 application (Hearing File Tab IV.B), the procedure for filling the Model GS-42 sealed sources with cesium chloride is only vaguely referenced. While GrayStar's RAI response number 21 provided some clarifying

information in this regard, the exact process for filling the Model GS-42 sealed sources with cesium chloride is still not specified. *See* Hearing File Tab VI.B, at pages 25-26.

Citations to the Hearing File supporting the Staff's related discussions on moisture and corrosion issues (*see* Section 4.2 of the Denial Letter's Enclosure 1) are as follows: (1) GrayStar's generalized description of steps in which heat, generated by cesium chloride within the Model GS-42 sealed sources, will "drive off all moisture," is found in GrayStar's RAI response number 20 (Hearing File Tab VI.B), at 24, ¶ 2; (2) GrayStar's reference to the exact filling procedures being "dependent on the hot cells used," is found in GrayStar's RAI response number 22 (Hearing File Tab VI.B), at 27, as is GrayStar's reference to an evaporation process which, if employed, would use "both a vacuum and heat process to drive off the water;" (3) GrayStar's reference to "future alternative filling methods" is found in GrayStar's RAI response number 17 (Hearing File Tab VI.B), at 21; (4) GrayStar's unsupported statement that within the Model GS-42 sealed sources, the distribution of the cesium chloride powder "will be uniform," is found in Exhibit 7 of GrayStar's April 1999 application (Hearing File Tab IV.I); third page, ¶ 5 (pages not numbered); and (5) GrayStar's unsupported assumptions that no moisture would be present within the Model GS-42 sealed sources during 60 years of operation, are found in GrayStar's RAI response numbers 2, 13, 15, 17, 23, and 59. These responses are contained in Hearing File Tab VI.B, at pages 2, 17, 19, 21, 28-9, and 105, respectively.

In summary, GrayStar did not demonstrate that the untested evaporative procedure it described would adequately remove moisture from the sealed source tubes. The extent of moisture removal and corrosion prevention within the Model GS-42 sealed sources was thus not adequately determined by GrayStar. Processes which will only be finalized later,

by organization(s) who are still to be selected, do not form a basis on which the Staff could make adequate safety findings.

4.3 Sufficiency of information about source filling to determine the effect of cesium chloride and impurities on silver sealant for inner and outer seal plugs, and basis for conclusion that contact with silver seal "will not result in any degradation of sealing properties."

Section 4.3 of the Denial Letter's Enclosure 1 (at page 4) discussed whether the silver sealant would be degraded if it came into contact with the cesium chloride powder during the filling of the Model GS-42 sealed sources. GrayStar's RAI response number 17 (*see* Hearing File Tab VI.B., at 21) is the source of the statements quoted and referenced by the Staff regarding this issue, which is discussed further below.

GrayStar's April 1999 application briefly noted the use of silver sealant in the process for silver-plating the seal plugs. *See* Hearing File Tab IV.B, at 10; *see also* Exhibit 3 of the application, Hearing File Tab IV.E, third page (pages not numbered). GrayStar's RAI response number 25 revealed problems involving the silver sealant, which arose during testing,[8] but new tests using modified procedures regarding the silver sealant were apparently not performed. *See* Hearing File Tab VI.B, at 31-32. Moreover, since the specific process regarding how the Model GS-42 sealed sources will be filled with cesium-137 chloride has not been finalized (*see* Section 4.2, *supra*), it remains unclear what the effects would be if the cesium chloride powder (and any impurities therein) comes into contact or otherwise interacts with the silver sealant. This is another example where a lack of finality exists on an important design issue.

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[8] In this regard, the Staff notes that RAI response number 25 appears to conflict with GrayStar's discussion in RAI response number 7, regarding the use of silver plating. *See* Hearing File Tab VI.B, at 9.

4.4 Sufficiency of information about seal torquing, maximum allowable torque, and uniformity of construction.

The torque issues raised by the Staff are reflected in GrayStar's RAI response number 8. *See* Hearing File Tab VI.B., at 10-11. This GrayStar response was not adequate, as indicated in Section 4.4 of the Denial Letter's Enclosure 1.

4.5 Other

The Staff is aware of no other issues requiring discussion under Section 4 of the Presiding Officer's outline.

CONCLUSION

GrayStar's application for registration of its Model GS-42 sealed source, and its Hearing Request, both fail to demonstrate that the safety requirements of 10 C.F.R. §§ 32.210(c) and 36.21 have been met. GrayStar has failed to provide reasonable assurance that the radiation safety properties of its proposed sealed source, when used in the proposed GrayStar Model 1 irradiator, would be adequate to protect health and minimize danger to life and property. Accordingly, the Presiding Officer should affirm the Staff's denial of GrayStar's application for registration of its Model GS-42 sealed source.

Respectfully submitted,

John T. Hull ***/RA/***
Counsel for NRC Staff

Dated at Rockville, Maryland
this 25th day of September 2000

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE PRESIDING OFFICER

In the Matter of	)	
	)	
GRAY*STAR, INC.	)	Docket No. SSD 99-27
	)	
(Suite 103, 200 Valley Road	)	
Mt. Arlington, New Jersey 07856	)	

CERTIFICATE OF SERVICE

I hereby certify that signed copies of "NRC STAFF'S INITIAL WRITTEN PRESENTATION" have been served on those listed below either by U.S. Mail, first class, or by internal distribution, this 25th day of September 2000. Additionally, electronic copies have been transmitted this date to those listed below and marked by single asterisks.

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