

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED 10/30/00

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 RESPONSE TO GRAYSTAR'S WRITTEN PRESENTATION

INTRODUCTION AND SUMMARY

This proceeding concerns the Staff's denial of an application for a certificate of registration regarding a sealed source -- intended for use in devices to irradiate food -- in accordance with the standards stated in 10 C.F.R. §§ 36.21 and 32.210. GRAY*STAR, Inc. (GrayStar) and the Staff filed their initial written presentations on September 25, 2000. See "Gray*Star, Inc.'s Brief in Support of Application for Registration of Model GS-42 Sealed Source" (GrayStar's Presentation), and "NRC Staff's Initial Written Presentation" (Staff's Presentation), respectively.¹ The Staff now responds to GrayStar's Presentation.

The key issues here are (1) the applicability of the 10 C.F.R. Part 36 requirements to GrayStar's application for a certificate of registration regarding its Model GS-42 sealed source, which would be used in GrayStar's Model 1 irradiator; (2) whether GrayStar's Model 1 irradiator is a panoramic irradiator subject to the 10 C.F.R. Part 36 requirements; (3) whether the sealed source performance criterion regarding dispersibility, stated in 10 C.F.R. § 36.21(a)(3), applies to sealed

¹ On October 3, 2000, GrayStar filed a corrected version of its written presentation, correcting what were mostly typographical errors. In this Staff Response, all citations to GrayStar's Presentation are to the corrected version dated October 3, 2000. The page numbers in the corrected version differ from those found in the electronic and signed paper copies of GrayStar's Presentation dated September 25, 2000.

sources to be used in dry-storage irradiators such as GrayStar's Model 1 irradiator; and (4) whether GrayStar has submitted adequate technical justification to show that its proposed use of cesium chloride powder -- rather than the less dispersible cobalt-60 -- overcomes the Commission's qualified ban on using cesium in commercial irradiators.

The legal issues raised here are discussed in Section I, *infra*. Section I.A pertains to GrayStar's "Standard of Review" argument. In Section I.B, the Staff rebuts GrayStar's argument that its Model GS-42 sealed sources are not subject to the 10 C.F.R. Part 36 requirements. The Staff demonstrates that on the contrary, GrayStar's April 1999 registration application was generally subject to the 10 C.F.R. Part 36 requirements. In Section I.C, *infra*, the Staff addresses GrayStar's argument that the dispersibility requirements of 10 C.F.R. § 36.21(a)(3) apply only to sealed sources to be used in wet-storage irradiators. The Staff shows that these dispersibility requirements apply to sealed sources to be used in the type of dry-storage irradiator represented by GrayStar's Model 1 irradiator. Section I.D, *infra*, establishes that GrayStar misreads the applicable NRC regulations in arguing that because it was not seeking a license, only the requirements of 10 C.F.R. § 32.210 should have been applied by the Staff in reviewing GrayStar's April 1999 registration application. The Staff addresses in Section I.E the contention that the requirements of 10 C.F.R. § 36.21(a)(4) apply only to sealed sources to be used in wet-storage irradiators. The Staff agrees with GrayStar on this point.

The technical issues raised here are discussed in Section II, *infra*. After reviewing GrayStar's Presentation, the Staff is convinced that the technical reasons for denying GrayStar's April 1999 registration application remain valid. The new technical information contained in GrayStar's Presentation is summarized in Section II.A. GrayStar has still not adequately addressed the technical issues of dispersibility (discussed in Sections II.B., C., D., E., and F., *infra*) and testing (discussed in Sections II.G., and H). Regarding dispersibility, radioactive material leaking from a

source in a dry-storage irradiator can be dispersed by physical forces, such as air turbulence, physical contact, fire, or explosion. These forces do not require water to disperse radioactive cesium. Therefore, there is a sound underlying safety basis for requiring that radioactive material -- contained in sealed sources and used in dry-storage irradiators -- be nondispersible.

After reviewing the Staff's response to GrayStar's Presentation, the Presiding Officer should affirm the Staff's denial of GrayStar's application for registration of its Model GS-42 sealed source.

BACKGROUND

In 1993, 10 C.F.R. Part 36 was added to the NRC's regulations. See 58 Fed. Reg. 7715 *et seq.* (February 9, 1993). As explained in the Statement of Considerations (SOC) published with 10 C.F.R. Part 36, the newly added "Performance Criteria for Sealed Sources" (stated in 10 C.F.R. § 36.21) supplemented the existing requirements of 10 C.F.R. § 32.210,² regarding the registration of sealed sources and irradiators containing sealed sources. See 58 Fed. Reg. at 7718, cols. 2-3. The 1993 SOC also described the four general categories of irradiators -- designated as Categories I - IV -- as defined by the American National Standards Institute (ANSI). *Id.*, at 7715-16. ANSI Category I refers to the small, dry-source storage irradiators, in which human access is not physically possible. This type of irradiator is not covered by the 10 C.F.R. Part 36 requirements. *Id.*, at 7715, col. 3. ANSI Category II refers to the larger panoramic, dry-source storage irradiators, in which the irradiations occur in a room which is accessible to personnel. This type of irradiator is covered by the 10 C.F.R. Part 36 requirements. *Id.*, at 7715, col. 3, to 7716, col. 1.³ The ANSI definitions describing these irradiator categories are not part of 10 C.F.R.

² The 10 C.F.R. § 32.210 requirements were added to the NRC's regulations in 1987. See 52 Fed. Reg. 27786 (July 24, 1987).

³ ANSI Category III and IV irradiators employ storage pools, and, while these types of irradiators are also covered by the 10 C.F.R. Part 36 requirements (see 58 Fed. Reg., at 7716, col. 1), they are not at issue in this proceeding. One of the questions at issue here is whether GrayStar's sealed source is intended for use in an ANSI Category I irradiator (GrayStar's position), or an ANSI Category II irradiator (Staff's position). This question is addressed in Section I.B., *infra*.

Part 36. However, the 10 C.F.R. § 36.2 definition of a “panoramic dry-source-storage irradiator” as being one “in which the irradiations occur in air in areas potentially accessible to personnel,” is similar to the ANSI Category II irradiator definition. Likewise, wording similar to the ANSI Category I irradiator description is used to exclude Category I irradiators from 10 C.F.R. Part 36 coverage.⁴

Prior to publication in the *Federal Register*, as part of its normal rulemaking practice, the Staff had given the proposed final 10 C.F.R. Part 36 rule and its associated SOC to the Commission for its review and approval. See SECY-92-323, “Final Rule on Licenses and Radiation Safety Requirements for Irradiators,” dated September 18, 1992, and Enclosure 1 thereto (setting forth the proposed final rule and SOC). In a Staff Requirements Memorandum (SRM) dated November 2, 1992 (SRM-921027), the Commission unanimously approved the new 10 C.F.R. Part 36, making only editorial changes to the SOC. See SRM-921027, at 1-2.

One of the topics discussed in both Enclosure 1 of SECY-92-323, and the final SOC published in 1993, was the use of sealed sources containing cesium-137 produced at the Department of Energy’s Waste Encapsulation and Storage Facility (WESF) in Hanford, Washington. See Enclosure 1 to SECY-92-323, at 7; and 58 Fed. Reg., *supra*, at 7716, col. 2, respectively. Following the 1988 leak of a WESF source at an irradiator facility in Georgia, the NRC “decided that the long-term use of WESF sources is unacceptable” in NRC-licensed commercial facilities. SOC, 58 Fed. Reg., *supra*, at 7716, col. 2. Accordingly, the 10 C.F.R. Part 36 regulations covering ANSI Category II-IV irradiators were written to require that these irradiators “use radioactive materials that are as insoluble and nondispersible as practical (typically cobalt-60).” *Id.* The SOC discussion specifically regarding 10 C.F.R. § 36.21 stated that the

⁴ As stated in the general provisions of 10 C.F.R. § 36.1(c), the Part 36 regulations “do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel)”

adoption of these performance criteria for sealed sources reflected the NRC's decision "not to approve further use of cesium sources" in Category II-IV irradiators. *Id.*, at 7718, col. 2. However, the use of the term 'as practical' in 10 C.F.R. § 36.21(a)(3) would allow the NRC to make an exception to this cesium ban, if adequate justification is provided by the applicant. *Id.*

In April 1999, GrayStar applied for registration of its Model GS-42 sealed source, and Model 1 irradiator. By cover letter to GrayStar dated July 26, 1999, the Staff enclosed a Request For Additional Information (RAI) pertaining to the April 1999 application. GrayStar responded to the 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 reasons for denying GrayStar's registration application are stated in the Staff's letter to GrayStar dated May 24, 2000 (Denial Letter), and in Enclosures 1 and 2 to the Denial Letter.⁵

The Staff found that GrayStar's proposed use of cesium-137 chloride powder in its Model GS-42 sealed source did not meet the dispersibility and other performance criteria stated in 10 C.F.R. § 36.21. See Enclosure 1 of the Denial Letter. Therein, the Staff also 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). The requirements of 10 C.F.R. § 32.210 are incorporated by reference in the "Performance Criteria for Sealed Sources." See 10 C.F.R. § 36.21(a)(1).

⁵ The Denial Letter's Enclosure 1 discussed the Staff's bases for rejecting GrayStar's application to register its Model GS-42 sealed source. Sections 1-4 of Enclosure 1 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. The parties' initial written presentations were organized to address these issues in this order, at the Presiding Officer's request. See August 17 Order, at 3-5. Enclosure 2 to the Denial Letter discussed why review of GrayStar's application to register its Model 1 irradiator was suspended. By agreement of the parties, the licensing action reflected in Enclosure 2 is not part of this proceeding. See August 15 conference Tr., at 12-13.

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). 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), GrayStar's Presentation and Staff's Presentation were filed on September 25, 2000. GrayStar's Presentation included as an attachment a report written by Russell Stein, "Mitigation Design Techniques Incorporated in GS-42 Sealed Sources for Use in [GrayStar] Model 1 Self-Shielded Irradiators," dated July 24, 2000 (Attachment A); and a three-page set of technical drawings as a second attachment (Attachment B). Pursuant to the September 14 Order, the Staff's response to GrayStar's Presentation is due October 30, 2000.

DISCUSSION

I. Legal Issues

GrayStar's legal arguments largely pertain to questions of regulatory interpretation. See, e.g., GrayStar's Presentation, at 10-14, 33, 48-49, 68-80, and 81. After addressing, in Section I.A, *infra*, GrayStar's "Standard of Review" argument (see GrayStar's Presentation, at 8-9), the Staff in Section I.B rebuts GrayStar's argument that since its Model GS-42 sealed sources are intended for use in an irradiator -- *i.e.*, the GrayStar Model 1 irradiator -- which should be classified as an ANSI Category I dry-storage irradiator, the sealed sources are therefore not subject to the 10 C.F.R. Part 36 requirements. See, e.g., GrayStar's Presentation, at 10-14, and 68-80. The Staff demonstrates that on the contrary, because GrayStar's Model GS-42 sealed sources are intended

for use in an ANSI Category II dry-storage irradiator, GrayStar's April 1999 registration application was generally subject to the 10 C.F.R. Part 36 requirements.

In Section I.C, *infra*, the Staff addresses GrayStar's argument that the dispersibility requirements of 10 C.F.R. § 36.21(a)(3) apply only to sealed sources to be used in wet-storage irradiators. *See, e.g.*, GrayStar's Presentation, at 68-80. The Staff demonstrates that the dispersibility requirements of 10 C.F.R. § 36.21(a)(3) apply to sealed sources to be used in ANSI Category II dry-storage irradiators, as well as to sources for use in ANSI Category III-IV wet-storage irradiators. The Staff regards 10 C.F.R. § 36.21(a)(3) as the most important regulation at issue here, and holds the firm view that dispersion of radioactive cesium as the result of a leaking sealed source capsule is a safety concern for both wet and dry irradiators. *See generally* NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," vol. 2, at 3-439 to 440.⁶ As discussed further in Section II.E, *infra*, radioactive material leaking from a source in a dry-storage irradiator can be dispersed by physical forces, such as air turbulence, physical contact, fire, or explosion. These forces do not require water to disperse radioactive cesium. Therefore, there is a sound underlying safety basis for requiring that radioactive material -- contained in sealed sources and used in dry-storage irradiators -- be nondispersible.

As discussed in Section I.D, *infra*, GrayStar misreads the applicable regulations in arguing that because it was not seeking a license, only the requirements of 10 C.F.R. § 32.210 should have been applied by the Staff in reviewing GrayStar's April 1999 registration application. *See* GrayStar's Presentation, at 10-12, and nn. 6-7.

⁶ GrayStar cites, but does not discuss, this portion of NUREG/CR-6642. *See* GrayStar's Presentation, at 13.

In Section I.E, *infra*, the Staff addresses the contention that the requirements of 10 C.F.R. § 36.21(a)(4) apply only to sealed sources to be used in wet-storage irradiators. See GrayStar's Presentation, at 57. The Staff agrees with GrayStar on this point.

A. Preponderance of the Evidence Standard Applies Here

A license applicant's position on adjudicatory issues must be supported by a preponderance of the evidence. See *Philadelphia Electric Co.* (Limerick Generating Station, Units 1 and 2), ALAB-819, 22 NRC 681, 720 (1985). This evidentiary standard is applied by presiding officers in materials licensing cases. See *In the Matter of Hydro Resources, Inc.*, LBP-99-30, 50 NRC 77, 110 (1999), *petition for review denied*, CLI-00-12, 52 NRC 1 (2000).⁷ In applying this standard, the NRC adjudicator is not required to do independent research or conduct *de novo* review of a license application, but may rely upon uncontradicted Staff and applicant evidence. See *Consumer Power Co.* (Midland Plant, Units 1 and 2), ALAB-123, 6 AEC 331, 334-35 (1973). In NRC adjudications involving the Staff's evaluation of applications, the issue for decision is not the adequacy of the Staff's review, but whether the application raises health and safety concerns. See *In the Matter of the Curators of the University of Missouri*, CLI-95-8, 41 NRC 386, 395-96 (1995) (a case involving an intervenor's contentions that the Staff improperly granted the University of Missouri's request to amend its materials license). Presiding officers have no authority to direct the Staff in the performance of its safety reviews, and in NRC adjudicatory proceedings, the burden of proof rests on the party seeking the Staff's regulatory approval. See *In the Matter of the Curators of the University of Missouri*, CLI-95-1, 41 NRC 71, 121 (1995), *petition for reconsideration granted*, CLI-95-8, 41 NRC 386 (1995).

⁷ GrayStar may be correct in stating that the denial of an application for a certificate of registration -- as opposed to an application for a license -- is a case of first impression at the NRC. See GrayStar's Presentation, at 8 n.4. But due to the connection between registration and licensing (discussed in Section I.D, *infra*), the Staff maintains that the same preponderance-of-the-evidence standard applies here as would apply in any materials licensing proceeding.

GrayStar's argument concerning this issue (see GrayStar's Presentation, at 8-9)⁸ confuses the Commission's role of reviewing a presiding officer's adjudicatory decision (pursuant to the standards of 10 C.F.R. §§ 2.1253 and 2.786), with a presiding officer's role of reviewing a Staff licensing decision. These reviews are different, in part, because, unlike the inherent supervisory authority the Commission holds with respect to its licensing boards and presiding officers,⁹ the Presiding Officer here has no authority to direct the Staff in the performance of its safety reviews. See *University of Missouri, supra*, 41 NRC at 121. GrayStar's argument on this point also confuses industrial safety standards (referenced in the 10 C.F.R. § 32.210(d) provisions cited by GrayStar) with the evidentiary standard of proof to be used in an NRC adjudicatory hearing. See GrayStar's Presentation, at 8 n.4. Accordingly, GrayStar's standard of review arguments should be disregarded.

A point related to GrayStar's burden of proof in this proceeding requires clarification. GrayStar states that the Staff has acknowledged that both cobalt-60 and cesium-137 (in the form of cesium chloride) "can be used in sealed sources for irradiators within the requirements of 10 C.F.R. Part 36." GrayStar's Presentation, at 13, *citing* August 17 Order, at 1. See also GrayStar's Presentation, at 48-49. On this point, what the Presiding Officer actually stated provides the more accurate description:

⁸ In its standard of review argument, GrayStar cites *In the Matter of the Curators of the University of Missouri*, "1995 NRC LEXIS at *104-6." GrayStar's Presentation, at 8. The correct cite to this decision is CLI-95-1, 41 NRC 71 (1995), *petition for reconsideration granted*, CLI-95-8, 41 NRC 386 (1995). If further filings are made in this proceeding, the Staff requests that GrayStar's counsel -- who have prior experience in NRC proceedings -- use the accepted format of citing to the NRC volumes of case law, rather than to LEXIS. The LEXIS "104-6" cite corresponds with CLI-95-1, 41 NRC at 121; the LEXIS "*Id.* at *105" cite corresponds with CLI-95-1, 41 NRC at 121 n.67; and the LEXIS "21, *43" cite corresponds with CLI-95-1, 41 NRC at 95-96.

⁹ As part of its supervisory authority, the Commission has the power to assume part or all of a presiding officer's functions in a given adjudication. See *Public Service Co. of New Hampshire* (Seabrook Station, Units 1 and 2), CLI-90-3, 31 NRC 219, 229 (1990).

The parties also agreed that the use of cesium-137 chloride is not absolutely foreclosed for use in the Model GS-42 sealed source, provided adequate justification for such use is demonstrated with regard to all issues set forth in Enclosure 1 to the NRC Staff's May 24, 2000, letter to GrayStar Vice President Russell N. Stein, with the burden being on GrayStar to show that the registration should be granted.

August 17 Order, at 1.

B. GrayStar's Model 1 Irradiator is an ANSI Category II Irradiator

As the Staff has already shown in its September 25 filing (see Staff's Presentation, at 20-21), because GrayStar's Model 1 irradiator is large enough for a person to enter, it is a "panoramic dry-source-storage irradiator," a defined term in 10 C.F.R. § 36.2. Additionally, the 10 C.F.R. Part 36 requirements are made generally applicable to panoramic irradiators "that have either dry or wet-storage of the radioactive sealed sources." 10 C.F.R. § 36.1(b). Sealed sources to be used in GrayStar's irradiator are thus generally subject to the requirements of 10 C.F.R. Part 36.

The Staff affirmed its position on this issue with GrayStar in 1999, stating that GrayStar's Model 1 irradiator, in addition to being a "panoramic dry-source-storage irradiator," also "fits the definition of Category II in ANSI 43.10." Staff letter dated September 10, 1999, at 1 (letter added to the Hearing File as a supplemental document). GrayStar's Presentation ignores this letter, and thus fails to show why any of the Staff's findings there were incorrect.

A "panoramic dry-source-storage irradiator" is one "in which the irradiations occur in air in areas potentially accessible to personnel." 10 C.F.R. § 36.2. Regarding access to the irradiation chamber, this Part 36 definition makes no distinctions as to when such access may occur, and nothing in the 1993 SOC indicates that this question of timing should be considered in determining whether a dry-storage irradiator is an ANSI Category I or II irradiator. GrayStar previously acknowledged that its Model 1 irradiator would be accessible to personnel. See GrayStar's letter

dated August 12, 1999, and "Exhibit 1" attached thereto.¹⁰ 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. Thus, GrayStar's Model 1 irradiator is a large one -- when compared with the ANSI Category I small, self-contained, dry-source storage irradiators, in which human access is not physically possible -- and is properly regarded as an ANSI Category II irradiator.

In arguing to the contrary, GrayStar states that human access to the radiation chamber of the GrayStar Model 1 irradiator is not required (see GrayStar's Presentation, at 70)¹¹, but this ignores the fact that entry into the irradiation chamber will be required for maintenance purposes. While the radiation chamber of GrayStar's Model 1 irradiator may be "much smaller than the building-sized chambers used in standard Category II-IV "facility-type" irradiators" (GrayStar's Presentation, at 19), the key point here is whether personnel can gain access to the chamber. For purposes of categorizing the GrayStar Model 1 irradiator as a "panoramic dry-source-storage irradiator" -- *i.e.*, an ANSI Category II irradiator -- it makes no difference that access to its radiation

¹⁰ This letter and its attachments were added to the Hearing File as a supplemental item. *See Staff's letter dated September 6, 2000.* GrayStar does not reference the August 12, 1999 letter (or the attachments thereto) in its September 25 filing, but does emphasize there that its Model 1 irradiator is large enough to accommodate loaded pallets of food. *See GrayStar's Presentation, at 21, 22, 29, and 44 n.23.*

¹¹ In arguing here that its Model 1 irradiator is an ANSI Category I irradiator, GrayStar focuses on the ANSI Standard N433.1 definition. *See GrayStar's Presentation, at 69-70.* But it is the irradiator definitions in 10 C.F.R. § 36.2 which govern here.

chamber “would be difficult and extremely uncomfortable.” *Id.*, at 71. The determinative fact is that human access to the radiation chamber is physically possible -- a fact which GrayStar admits. *Id.*¹²

Accordingly, as shown above, because GrayStar’s registration application pertained to the use of Model GS-42 sealed sources in a “panoramic dry-source-storage irradiator,” GrayStar’s sealed sources are properly subject to the general provisions of 10 C.F.R. Part 36, and many of the specific sealed source performance criteria set forth in 10 C.F.R. § 36.21.

C. The Requirements of 10 C.F.R. § 36.21(a)(3)

GrayStar argues in the alternative that even if the 10 C.F.R. Part 36 requirements are generally applicable here, the nondispersibility requirement of 10 C.F.R. § 36.21(a)(3) -- one of the performance criteria for sealed sources -- applies only to sealed sources to be used in wet-storage irradiators (*see, e.g.*, GrayStar’s Presentation, at 10-14, 33, 48-49, and 68-80), and because the GrayStar Model 1 irradiator is a dry-storage irradiator, the Staff improperly applied 10 C.F.R. § 36.21(a)(3) in its review of GrayStar’s request to register the Model GS-42 sealed source. *Id.* As shown below, GrayStar misreads 10 C.F.R. § 36.21(a)(3).

The nondispersibility requirement states as follows:

Performance Criteria for Sealed Sources.

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

(3) Must 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.

10 C.F.R. § 36.21(a)(3). The starting point in construing this, or any other NRC regulation, is its “language and structure.” *In the Matter of Louisiana Energy Services, L.P.* (Claiborne Enrichment

¹² Without identifying which one, GrayStar states that at least one ANSI Category I irradiator has a radiation chamber 14 inches high, 10 inches wide, and 10 inches deep, and that while human access to this chamber “may not be practical, a small human could physically access such a radiation chamber.” GrayStar’s Presentation, at 71 n.48. This argument borders on the ludicrous.

Center), CLI-97-15, 46 NRC 294, 299 (1997), *citing In the Matter of Long Island Lighting Co.* (Shoreham Nuclear Power Station, Unit 1), ALAB-900, 28 NRC 275, 288 (1988), *review declined*, CLI-88-11, 28 NRC 603 (1988). Any regulatory interpretation must be consistent with the “plain meaning” of the regulatory wording at issue, and the entire provision must be given effect. *Shoreham, supra*, 28 NRC at 288 (citations omitted). NUREGS and other guidance documents do not establish regulatory requirements, and when the words in such documents “conflict or are inconsistent with a regulation,” the wording of the regulation prevails. *Id.*, at 290. *Accord, University of Missouri, supra*, 41 NRC at 397 (statements in NRC regulatory guides and NUREG documents do not impose legal requirements on the NRC). However, if the wording of a regulation’s SOC is consistent with the regulation, the SOC wording may be viewed as having been implicitly endorsed by the Commission, and such SOC wording is entitled to correspondingly special weight. *See Shoreham, supra*, 28 NRC at 290-91.

The Staff has examined the language and structure of 10 C.F.R. § 36.21(a)(3), in accordance with these principles, and has also consulted with Dr. Stephen McGuire, the author of this regulation. *See* Dr. McGuire’s affidavit, attached hereto as Staff Exhibit 1. As attested to by Dr. McGuire, 10 C.F.R. § 36.21(a)(3) means that all sealed sources to be installed in panoramic irradiators (*i.e.*, ANSI Category II, III, and IV irradiators), after July 1, 1993, must use radioactive material that is as nondispersible as practical; additionally, all sealed sources to be installed in wet-storage panoramic irradiators (*i.e.*, those irradiators with storage pools), must use radioactive material that is as insoluble as practical. *See* Staff Exhibit 1, at ¶ 4. The “nondispersible” and “insoluble” requirements are stated separately within 10 C.F.R. § 36.21(a)(3) due to the differences between wet-storage and dry-storage irradiators. Problems caused by radioactive material being soluble in water are generally not present in dry-storage irradiators, but problems caused by radioactive material being dispersible in air and water are present in both wet and dry-storage

irradiators. The wording of 10 C.F.R. § 36.21(a)(3) is structured to account for these differences. See Staff Exhibit 1, at ¶¶ 5-6.

If, as GrayStar argues, the plain language of 10 C.F.R. § 36.21(a)(3) means that the dispersibility requirement applies only to sealed sources to be used in wet-storage irradiators (see GrayStar's Presentation, at 13, and 73), the repetitious use of the phrase "as practical" in 10 C.F.R. § 36.21(a)(3) would be needless excess verbiage. Logically, if GrayStar's argument were correct, subsection 3 would instead state:

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

In fact, this type of condensed wording is used in 10 C.F.R. § 39.41(a)(2). This NRC regulation is functionally related to 10 C.F.R. § 36.21(a)(3), and states as follows:

Design and Performance Criteria for Sealed Sources.

(a) After July 14, 1989, a licensee may not use a sealed source in well logging unless the sealed source --

(2) Contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical...

10 C.F.R. § 39.41(a)(2) (emphasis added). See also Staff Exhibit 1, at ¶¶ 7-9.

Moreover, construing the dispersibility requirement of 10 C.F.R. § 36.21(a)(3) as applying only to sealed sources to be used in wet-storage irradiators is inconsistent with the wording of the general provisions of 10 C.F.R. Part 36. Unless a particular provision states otherwise,¹³ the 10 C.F.R. Part 36 requirements are made generally applicable "to panoramic irradiators that have either dry or wet-storage of the radioactive sealed sources." 10 C.F.R. § 36.1(b) (emphasis added). Such broad coverage was needed to address the many serious -- and sometimes fatal --

¹³ Many provisions in 10 C.F.R. Part 36 are worded to apply only to sealed sources to be used in wet-storage irradiators, or to the wet-storage irradiators themselves. See, e.g., 10 C.F.R. §§ 36.21(a)(4); 36.23(i); 36.25(b); 36.33; 36.39(c); and 36.39(d).

accidents which had occurred in large irradiators.¹⁴ Contrary to GrayStar's contention that the 10 C.F.R. Part 36 rulemaking was driven solely by incidents at wet-source-storage irradiators such as the 1988 accident in Decatur, Georgia (see GrayStar's Presentation, at 76-77, *citing* the 1990 SOC for the draft 10 C.F.R. Part 36 rule, at 55 Fed. Reg. 50008, 50010 (December 4, 1990)), accidents at dry-source-storage irradiators can also lead to operator fatalities. See 1990 SOC, 55 Fed. Reg. at 50011, col. 3 (discussing 1975 incident at dry-source-storage irradiator in Italy, used to irradiate corn).

Any doubt about the proper meaning of 10 C.F.R. § 36.21(a)(3) is resolved by the 1993 SOC discussion regarding 10 C.F.R. § 36.21. See 58 Fed. Reg., *supra*, at 7718, cols. 1-3. There, the Commission referenced the 10 C.F.R. Part 36 requirement "that sealed sources installed after July 1, 1993 ... [must] use radioactive material that is as insoluble and nondispersible as practical." *Id.*, at 7718, col. 2. No SOC statements here or elsewhere indicate that this reference to "sealed sources installed [in irradiators] after July 1, 1993" excludes ANSI Category II irradiators. GrayStar's argument that 10 C.F.R. § 36.21(a)(3) is limited in scope to only sealed sources to be used in ANSI Category III and IV irradiators thus finds no support in the 1993 SOC. Given the clarity of the above-quoted SOC statement, there is no need to look elsewhere for the meaning of 10 C.F.R. § 36.21(a)(3).

Remarkably, while GrayStar's 85-page September 25 filing contains scattered references to the 1993 SOC (see, e.g., GrayStar's Presentation, at 17, 68, and 79), the SOC's discussion specific to 10 C.F.R. § 36.21 is never cited by GrayStar. Instead, GrayStar focuses much of its 10 C.F.R. § 36.21(a)(3) argument on various NRC guidance documents, comments made by NRC

¹⁴ Many of these accidents are discussed in NRC Information Notice No. 91-14: "Recent Safety-Related Incidents at Large Irradiators," dated March 5, 1991.

officials,¹⁵ and other miscellaneous items. See GrayStar's Presentation, at 72-79.¹⁶ As discussed above, such materials do not constitute NRC requirements. Assuming *arguendo* that the Presiding Officer, in determining the intended meaning of 10 C.F.R. § 36.21(a)(3), finds it necessary to go outside the regulation's wording, the Presiding Officer should not regard the extraneous materials cited by GrayStar as adequate substitutes for the 1993 SOC.¹⁷ See *University of Missouri, supra*, 41 NRC at 397 (statements in NRC regulatory guides and NUREG documents do not impose legal requirements on the NRC); see also *Shoreham, supra*, 28 NRC at 290 (when the wording in NUREGS and other guidance documents conflict with a regulation's wording, the wording of the regulation prevails). As discussed above, because the wording of 10 C.F.R. § 36.21(a)(3) is consistent with the discussion in the 1993 SOC, the Presiding Officer should give special weight to the 1993 SOC in determining the intended meaning of 10 C.F.R. § 36.21(a)(3). See *Shoreham*,

¹⁵ Any statements made by past or present NRC officials which may pertain to 10 C.F.R. Part 36 regulatory requirements are not binding on the NRC. Other than a regulatory interpretation issued by the NRC's General Counsel, such statements have no legal effect. See 10 C.F.R. § 36.5.

¹⁶ The materials GrayStar relies upon in this portion of its written presentation are set forth in chronological order, as follows: SEA Report No. 87-288-09-A, "Draft Regulatory Analysis and Environmental Assessment of NRC Regulations on Licenses and Radiation Safety Requirements for Large Irradiators," dated February, 1989; transcript of NRC February 12, 1991, public meeting, on "Licenses and Radiation Safety Requirements for Large Irradiators" (including comments of Greta Dicus, now an NRC Commissioner); enclosure 1 of SECY-93-323, "Final Rule on Licenses and Radiation Safety Requirements for Irradiators," dated September 18, 1992; enclosure 3 of SRM-921027, "Staff Requirements – Affirmation Session/Discussion and Vote, 10:30 a.m., Tuesday, October 27, 1992" (comments of former NRC Chairman Ivan Selin, on SECY-92-323); Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses for Non-Self-Contained Irradiators," dated January, 1994; NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," dated November, 1996; and NUREG-1556, "Consolidated Guidance About Materials Licenses, Volume 3 – Applications for Sealed Source and Device Evaluation and Registration," dated July, 1998.

¹⁷ For example, page 1 of the January, 1994, Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses for Non-Self-Contained Irradiators," contains the warning that it "has not received complete staff review and does not represent an official NRC staff position."

supra, 28 NRC at 290-91. GrayStar's evident effort to focus attention elsewhere than on the 1993 SOC should thus be rejected.

Even if the Presiding Officer is inclined to give any weight to materials other than the 1993 SOC in examining the meaning of 10 C.F.R. § 36.21(a)(3), the materials cited by GrayStar for the most part do not support its argument that this provision is limited in scope to sealed sources to be used in wet-storage (*i.e.*, ANSI Category III and IV) irradiators. Three of the references GrayStar relies upon to support its argument in this regard are discussed below.

In its September 25 filing, GrayStar cites NUREG-1556, "Consolidated Guidance About Materials Licenses, Volume 3 – Applications for Sealed Source and Device Evaluation and Registration," (July 1998),¹⁸ and includes the following excerpt therefrom:

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 C.F.R. 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 supplied by GrayStar). This describes one requirement of 10 C.F.R. § 36.21(a)(3), as it applies to wet irradiators.¹⁹ But, as shown above, for ANSI Category II dry irradiators, the sealed source material must also be as "nondispersible as practical," pursuant to 10 C.F.R. § 36.21(a)(3).

In further support of its argument that 10 C.F.R. § 36.21(a)(3) is limited in scope to sealed sources to be used in wet-storage irradiators, GrayStar in its September 25 filing cites the 1994

¹⁸ See GrayStar's Presentation, at 75-76. GrayStar also includes an identical excerpt from NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," published in November, 1996. See GrayStar's Presentation, at 75.

¹⁹ The NUREG-1556 excerpt actually mis-quotes the terms of 10 C.F.R. § 36.21(a)(3), by using the word "practicable" instead of "practical." GrayStar claims that there is "a distinction with a difference" between these two words, but does not explain why any difference in meaning should be regarded as significant. See GrayStar's Presentation, at 12 n.8.

Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses from Non-Self-Contained Irradiators," and includes the following excerpt therefrom:

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 C.F.R. 36.21(a)(3). Cesium-137 chloride is generally acceptable for exclusively dry-use irradiators.²⁰

Draft Reg. Guide DG-0003, at section 3.5 (emphasis supplied by GrayStar) (footnote added by Staff). The last sentence of this guidance is not accurate, and only confirms the need for the warning noted above that this draft document "has not received complete staff review and does not represent an official NRC staff position." Draft Regulatory Guide DG-0003, at 1. This error is corrected in Volume 6 of NUREG-1556, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Materials Licenses, Final Report," dated January, 1999 (not cited by GrayStar), which states that for any sealed source not yet installed in an irradiator, the source "must meet the requirements" of 10 C.F.R. § 36.21. NUREG-1556, Volume 6, at 8-5. See also Staff Exhibit 1, at ¶¶ 10-11.

In GrayStar's Presentation, at 78-79, in further support of its 10 C.F.R. § 36.21(a)(3) limited-scope argument, GrayStar notes that the wording of this provision was changed after former NRC Chairman Ivan Selin in SRM-921027 stated as follows:

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.

²⁰ See GrayStar's Presentation, at 76. GrayStar's excerpt did not include the last sentence of this quotation.

SRM-921027, Enclosure 3, at 1 (commenting on SECY-92-323). As discussed below, far from supporting GrayStar's 10 C.F.R. § 36.21(a)(3) limited-scope argument, SECY-92-323 and SRM-921027 are contrary to GrayStar's position.

As GrayStar states, the Commission voted to approve the issuance of the new 10 C.F.R. Part 36 requirements. See GrayStar's Presentation, at 78. As presented to the Commission in SECY-92-323, these requirements would be generally applicable "to panoramic irradiators that have either dry or wet-storage of the radioactive sealed sources." SECY-92-323, Enclosure 1, at 62 (presenting what would become 10 C.F.R. § 36.1(b)). Additionally, the Commission knew that while the new 10 C.F.R. Part 36 requirements would not apply to ANSI Category I dry-storage irradiators, they would apply to ANSI Category II dry-storage irradiators, and ANSI Category III and IV wet-storage irradiators. See SECY-92-323, Enclosure 1, at 3-5 (presenting what would become the 1993 SOC discussion, 58 Fed. Reg., *supra*, at 7715-16). Moreover, in SECY-92-323, the proposed 10 C.F.R. § 36.21(a)(3) stated as follows:

Performance Criteria for Sealed Sources.

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

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

SECY-92-323, Enclosure 1, at 69-70. Thus, in approving 10 C.F.R. § 36.21(a)(3) as worded in SECY-92-323, the Commissioners knew that this nondispersibility requirement would apply to ANSI Category II dry-storage irradiators, as well as to ANSI Category III and IV wet-storage irradiators. Even if one assumes -- as GrayStar apparently does -- that Chairman Selin's comment was

expressing disapproval with 10 C.F.R. § 36.21(a)(3) as it was worded in SECY-92-323,²¹ and that the Staff therefore changed this provision to make the nondispersible requirement apply only to sealed sources to be used in wet-storage irradiators, such action on the Staff's part would have been contrary to the Commission's majority vote approving 10 C.F.R. § 36.21(a)(3) and the other 10 C.F.R. Part 36 requirements as worded in SECY-92-323. In other words, there would have been no proper reason for the Staff, in revising the wording of 10 C.F.R. § 36.21(a)(3) as it did, to change its scope and make the nondispersibility requirement apply only to sealed sources to be used in wet-storage irradiators. Yet, if GrayStar's argument is accepted, it must be assumed that the Staff acted in disobedience of the Commission's majority vote. Essentially, GrayStar is asking the Presiding Officer here to find that the Staff intentionally disobeyed SRM-921027, in re-wording 10 C.F.R. § 36.21(a)(3) as it did.

Accordingly, Chairman Selin's comment, and the other materials discussed above, do not support GrayStar's argument that 10 C.F.R. § 36.21(a)(3) is limited in scope to sealed sources to be used in wet-storage irradiators.

GrayStar's misreading of 10 C.F.R. § 36.21(a)(3) is illustrated by another argument GrayStar repeatedly makes, in which it claims that its Model GS-42 sealed source is designed so that the cesium-137 chloride powder will not be dispersed. See, e.g., GrayStar's Presentation, at 42.²² GrayStar states in similar regard as follows:

²¹ Rather than advocating that changes be made in 10 C.F.R. § 36.21(a)(3), as worded in SECY-92-323, former Chairman Selin's comment is more reasonably viewed as requesting that the SOC (*i.e.*, the "rulemaking package") be revised to explain why the nondispersibility requirement covered dry-storage irradiators. Graystar states that the Staff in the SOC "simply restated essentially word-for-word the identical justification" as had been made in SECY-92-323, thereby failing to comply with Chairman Selin's request. GrayStar's Presentation, at 79. In any event, the 1993 final SOC reflected Chairman Selin's input. *Cf.* 58 Fed. Reg., *supra*, at 7718 (bottom of col. 1), to SECY-93-323, Enclosure 1 (draft SOC), at 15.

²² This claim is repeated several times. See, e.g., GrayStar's Presentation, at 43, 45, and 47.

Once cesium-137 was selected as the only appropriate source material for the Gray*Star Model 1 irradiator, the design team set about making the GS-42 source encapsulations, as used in the Gray*Star Model 1 irradiator, as nondispersible as practical.

GrayStar's Presentation, at 27. It is not the sealed source encapsulations which must be as nondispersible as practical. Rather, the regulation requires that sealed sources installed after July 1, 1993 must use "radioactive material that is as nondispersible as practical." 10 C.F.R. §36.21(a)(3) (emphasis added). GrayStar's focus has thus evidently been on encapsulation design issues, rather than on the more fundamental safety issue, *i.e.*, which radioactive material is to be used as the source material in GrayStar's Model 1 irradiator. GrayStar's approach here is contrary to the requirements of 10 C.F.R. § 36.21(a)(3).

Accordingly, the Presiding Officer should find that the dispersibility requirements of 10 C.F.R. § 36.21(a)(3) apply to sealed sources to be used in ANSI Category II dry irradiators, and that the Staff properly applied these requirements in reviewing and rejecting GrayStar's request to register the Model GS-42 sealed sources.²³

D. The Requirements of 10 C.F.R. § 32.210

The 10 C.F.R. § 32.210 requirements were added to the NRC's 10 C.F.R. Part 32 regulations in 1987²⁴ (*see* 52 Fed. Reg. 27782 *et seq.* (July 24, 1987)), and are incorporated by reference in the "Performance Criteria for Sealed Sources." *See* 10 C.F.R. § 36.21(a)(1). Part 32 of 10 C.F.R. sets forth the procedures and requirements applicable to the issuance of certificates

²³ Technical questions pertaining to 10 C.F.R. § 36.21(a)(3)'s non-dispersibility requirement, how this requirement is related to safety concerns about what happens if a leak occurs, and why measures to prevent leaks (*e.g.*, capsule design) do not constitute sufficient justification for using dispersible cesium chloride powder in ANSI Category II dry-storage irradiators, are discussed in Sections II.B-F, *infra*.

²⁴ The requirements of 10 C.F.R. § 32.210 are titled **Registration of product information**, and form Subpart D, **Specifically Licensed Items**, of 10 C.F.R. Part 32, **Specific Domestic Licenses To Manufacture Or Transfer Certain Items Containing ByProduct Material**.

of registration to manufacturers of sealed sources; and persons wanting to use the sealed sources must obtain 10 C.F.R. Part 30 licenses. See 10 C.F.R. § 32.1(a)(2). Issuance of a certificate of registration “acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.” 10 C.F.R. § 32.210(e).

With respect to the sealed sources at issue here, the most important requirements of 10 C.F.R. § 32.210 are found in subsection (c), which states in pertinent part as follows:

The request for review of a sealed source . . . must include sufficient information about the design . . . prototype testing . . . and leak testing . . . to provide reasonable assurance that the radiation safety properties of the source . . . are adequate to protect health and minimize danger to life and property.

10 C.F.R. § 32.210(c).²⁵ As explained in the 1987 SOC, Subpart D of 10 C.F.R. Part 32 was established to formalize the NRC’s long-standing practice of evaluating a manufacturer’s safety information for purposes of issuing specific licenses to users of the products, and to advance NRC policy objectives of ensuring the radiological safety of products containing radioactive material.

See Subpart D summary, which stated as follows:

The Nuclear Regulatory Commission is amending its regulations to formally endorse its current administrative practice under which manufacturers of radiation sources and devices containing radiation sources file safety information about their products with the NRC. The NRC evaluates and uses the information in its issuance of specific licenses to users of the products. Filing of information by a manufacturer (called registration) avoids multiple filings of the same information by the customers and thus expedites NRC’s issuance of licenses. The amendments, directed toward manufacturers, describe the information that the NRC needs for its evaluation of a

²⁵ GrayStar argues that the Staff “has adopted an overly restrictive interpretation” of 10 C.F.R. § 32.210(c). GrayStar’s Presentation, at 81. The Staff has made an engineering judgment that with respect to the leak testing and vibration testing information submitted by GrayStar, it fails to provide reasonable assurance that the radiation safety properties of the GS-42 sealed source are adequate to protect health and minimize danger to life and property. These technical issues are discussed in Sections II.G-H, *infra*.

source or device^[26] and state the registrant's responsibility to ensure that distributed products meet radiation safety specifications filed with the NRC.

52 Fed. Reg., *supra*, at 27782 (footnote added). Nothing in the 1993 SOC explaining why 10 C.F.R. Part 36 was added to the NRC's regulations indicated that these 1987 NRC policy objectives had been changed in any way. On the contrary, as noted above, the requirements of 10 C.F.R. § 32.210 are incorporated by reference in 10 C.F.R. § 36.21(a)(1).

GrayStar argues that the denial of its April 1999 registration application must be invalidated because the Staff improperly used 10 C.F.R. Part 36 licensing provisions on an application which was strictly for purposes of registering the Model GS-42 sealed source and Model I irradiator designs, and that only the requirements of 10 C.F.R. § 32.210 should therefore have been used. See GrayStar's Presentation, at 10-12, and nn. 6-7. GrayStar's basic premise here is that, for registration purposes, the GS-42 sealed sources need not meet the requirements set forth in 10 C.F.R. § 36.21. See GrayStar's Presentation, at 11 n. 7. This premise is erroneous, since it runs directly counter to 10 C.F.R. § 36.21(a)(1), which requires that sealed sources installed after July 1, 1993 must have a certificate of registration issued under 10 C.F.R. § 32.210. Moreover, contrary to GrayStar's statement that the denial of its request to register the Model GS-42 sealed sources was "based wholly on" failures to meet the requirements of 10 C.F.R. § 36.21 (GrayStar's Presentation, at 11 n. 7), this denial was also based on the Staff's finding that GrayStar's sealed source design failed to meet the requirements of 10 C.F.R. § 32.210(c). See the Denial Letter's Enclosure 1, at Section 4.

Additionally, GrayStar's argument, if accepted, would improperly divorce the requirements of 10 C.F.R. § 32.210 from the "Performance Criteria for Sealed Sources" contained in 10 C.F.R.

²⁶ In referring to any manufactured product which contains a sealed source, the word "device" is used in 10 C.F.R. § 32.210. "Device" is not a defined term, and insofar as it may cover irradiators, carries no special meaning distinguishing small irradiators from large ones, contrary to GrayStar's argument. See GrayStar's Presentation, at 19 n.12, and 69.

§ 36.21. These regulatory requirements are linked, and govern NRC's registration and licensing of sealed sources. In adopting Subpart D of 10 C.F.R. Part 32, the NRC recognized that an NRC certificate of registration, if issued, only constitutes a pre-marketing approval of the product, and its issuance "does not constitute a commitment to issue a specific license authorizing use of the source." 52 Fed. Reg., *supra*, at 27784, col. 1. Nonetheless, the connection between registration and licensing of sealed sources is clear. A manufacturer seeks to register product information so that its customers -- relying on the registered information -- will be able to apply for and obtain specific licenses authorizing installation and use of the manufacturer's registered product. While GrayStar maintains that it "only requested the registration of, not a specific license for, its GS-42 sealed source" (GrayStar's Presentation, at 12), it earlier correctly recognized that its application for an NRC certificate of registration represented a necessary "first step" in the licensing process. GrayStar's April 1999 application, at 3 (Hearing File Tab IV.B). Indeed, GrayStar's corporate objective "is to manufacture and lease its Model 1 irradiator." GrayStar's Presentation, at 2. The first step in meeting this objective is to show that the prototype GS-42 sealed sources -- containing cesium chloride powder -- have been successfully tested for leaks, and have otherwise been found safe, for use in GrayStar's Model 1 irradiator. See 10 C.F.R. § 32.210(c). GrayStar has failed to make this showing.

Thus, even if one accepts GrayStar's argument that only the requirements of 10 C.F.R. § 32.210 should apply to its April 1999 registration application, the result (*i.e.*, the denial of its application) would be the same. The Staff has found, pursuant to 10 C.F.R. § 32.210(c), that due to the proposed use of cesium chloride powder, the leak test failures, and the vibration test deficiencies, the radiation safety properties of the GS-42 sealed source are not adequate to protect health and minimize danger to life and property.

Accordingly, GrayStar's argument that the denial of its April 1999 registration application must be invalidated should be rejected.

E. The Requirements of 10 C.F.R. § 36.21(a)(4)

GrayStar argues that the Staff, in its Denial Letter and Enclosure 1 thereto, improperly applied the requirements of 10 C.F.R. § 36.21(a)(4), in evaluating corrosion issues connected with the construction and durability of GrayStar's Model GS-42 sealed source. See GrayStar's Presentation, at 57. The corrosion requirement at issue reads as follows:

Performance Criteria for Sealed Sources.

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

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

10 C.F.R. § 36.21(a)(4). It is evident from this wording that this corrosion requirement applies only to sealed sources intended for use in wet-storage irradiators. Cf. 10 C.F.R. § 36.21(a)(3) (dispersibility requirement applicable to wet and dry irradiators, as discussed in Section I.C, *supra*). The Staff therefore agrees that Section 3 of the Denial Letter's Enclosure 1 (see Hearing File Tab VII.B) erroneously cited 10 C.F.R. § 36.21(a)(4). This sealed source performance criterion addresses external corrosion problems, and applies only if the sealed source being evaluated is intended for use in a wet-storage irradiator. See 10 C.F.R. § 36.21(a)(4). Because GrayStar's Model 1 irradiator is a dry-storage irradiator, issues pertaining to external corrosion problems are absent, and 10 C.F.R. § 36.21(a)(4) is not applicable here. Section 3 of Enclosure 1 should have cited 10 C.F.R. § 32.210(c) instead. GrayStar recognizes the applicability here of 10 C.F.R. § 32.210(c). See GrayStar's Presentation, at 10-11.

As discussed in Section I.D, *supra*, a request for a sealed source registration certificate must include sufficient information about the prototype sealed source's test results to provide

reasonable assurance that the source's radiation safety properties "are adequate to protect health and minimize danger to life and property." 10 C.F.R. § 32.210(c). As discussed in Section II, *infra*, because of the leak test and vibration test deficiencies, and the problems associated with the proposed use of dispersible cesium chloride powder, the Staff's position remains that GrayStar's application for registration must be denied. The Presiding Officer should thus affirm the Staff's denial of GrayStar's application for registration of its Model GS-42 sealed source.

II. Technical Issues

After reviewing GrayStar's Presentation, and its Attachments A and B, the Staff is convinced that its technical reasons for denying GrayStar's April 1999 registration application remain valid. The following technical discussion reflects the consensus of the NRC team which reviewed GrayStar's April 1999 registration application,²⁷ and of the individuals who reviewed GrayStar's Presentation.²⁸ For the reasons discussed below, the Presiding Officer should sustain the Staff's denial decision.

The new technical information presented by GrayStar (summarized in Section II.A below) addresses in large part the Staff concerns stated in Section 3 ("Sealed Source Construction and Durability") and Section 4 ("The Design Has Not Been Finalized") of the Denial Letter's Enclosure 1. However, regarding the more significant safety issues stated in Section 1 ("Dispersibility") and Section 2 ("Testing of Sealed Sources") of the Denial Letter's Enclosure 1, GrayStar has still not adequately addressed these technical issues. Dispersibility issues are discussed in Sections II.B., C., D., E., and F., below. Testing issues are discussed in Sections II.G., and H., below.

²⁷ The following NRC employees reviewed GrayStar's April, 1999, registration application: John P. Jankovich (Team Leader); Keith D. Brown; John W. Hickey; Seung J. Lee; Cayatano G. Santos; Raeann M. Shane; and Frederick C. Sturz.

²⁸ The following NRC employees performed the technical review of GrayStar's Presentation: John W. Hickey; John P. Jankovich; Seung J. Lee; Cayatano G. Santos; and Frederick C. Sturz.

A. New Technical Information Submitted by GrayStar

In its filing dated September 25, 2000, GrayStar provided new information on a number of technical issues. A summary of the new information follows:

1. Helium Backfill

GrayStar characterizes the atmosphere inside the GS-42 sealed source as “backfilled with helium.” GrayStar’s Presentation, at 40. The April 1999 application had referred to the atmosphere as “purged with helium gas,” without explicitly addressing the absence of air. Hearing File Tab IV.B, page 11 of 38.

2. Integrity of Source Housing

GrayStar introduces the following new measures, aimed primarily to reduce the potential for internal corrosion:

2.1. GrayStar would use “distilled” water to dissolve the cesium-137 chloride. GrayStar’s Presentation, at 60.

2.2. The pH would be “appropriately modified using a neutralizing agent” such as cesium hydroxide. GrayStar’s Presentation, at 60. The April 1999 application did not discuss neutralizing agents.

2.3. The residual moisture content inside the GS-42 sealed source would be limited to 0.01% by weight. See GrayStar’s Presentation, at 60. Previously, such moisture content had not been defined. However, GrayStar did not provide the procedure on how the moisture content of 0.01% would be measured or determined, and does not identify the quality control measures which would be used to maintain the specification.

2.4. The time taken to place the cesium and distilled water mixture into the GS-42 sealed source capsules, and to complete the drying cycle, would be four hours. See GrayStar’s Presentation, at 60-61. Previously, the duration of this process was not defined.

2.5. GrayStar identifies new measures to minimize impurities in the cesium material, which could affect the pH, and describes how barium hydroxide, present from the WESF material, may reduce the potential for internal corrosion. See GrayStar's Presentation, at 61.

2.6. GrayStar introduces new revisions to four engineering drawings. See GrayStar's Presentation, at 66, and Attachment B. The revised drawings in Attachment B contain new information. In Drawing # AAI-403, Revision 2 (titled "Source, Long, Cesium Chloride, Model FS-42, Assembly of"), note 1 has been added to include a maximum water content of 0.01 weight percent prior to installing the inner seal plug. Note 8 of Drawing # AAI-403 has been modified. Previously, this note specified that the outer plug seal weld would be done in accordance with GrayStar's Technical Requirements specification TRS-025. The modified note specifies that this weld would be done in accordance with the ASME Boiler & Pressure Vessel Code. Additionally, note 8 now states that this weld would be done in the field by the source loader, and specifies the weld filler metal which would be used. These same specification changes are made in Drawing # AAI-404, Revision 2 (titled "Source, Short, Cesium Chloride, Model FS-42, Assembly of"). In Drawing # AAI-417, Revision 4 (titled "Seal Plug, Outer"), note 4 has been modified by deleting the sentence "Plating is optional on all other surfaces." Additionally, the areas to which note 9 of Drawing # AAI-417 (which states "Remove Silver Plating from Surface") applies, was modified. In Drawing AAI-418, Revision 2 (titled "Seal Plug, Inner"), note 4 has been modified by deleting the sentences "Plating is optional on all other surfaces"; and "Dimensional limits apply before plating." Additionally, note 8 of Drawing AAI-418 has been added, requiring that silver plating be removed from a particular surface on the seal plug.

2.7. In Attachment A of GrayStar's Presentation, GrayStar conducts a new analysis on the characteristics of the GS-42 sources in view of historical experience with other sources. The analysis, dated July 24, 2000, was conducted after the issuance of the Denial Letter.

In Attachment A, GrayStar states that inquiries regarding how the GS-42 sealed sources will be filled with cesium chloride are “beyond the scope of the review of an application for a Certificate of Registration.” Attachment A, at 4. The Staff disagrees. The NRC guidelines for conducting safety evaluations of registration requests state that “the reviewer must evaluate how the product is constructed and evaluate its integrity.” NUREG-1556, “Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration,” Volume 3, page 10-6. The GS-42 sealed source filling procedure introduces a solution of chloride anions to the stainless steel encapsulation. Chloride ions are corrosive. Therefore, GrayStar’s proposed filling procedure has the potential to compromise the structural integrity of the encapsulation. Thus, the filling procedure is properly within the scope of the Staff’s safety review.

2.8. GrayStar describes test runs that are to be done once the equipment used in the GS-42 sealed source filling process has been constructed, and how simulated sealed sources would then be destructively tested to determine if any changes are needed in the equipment or procedures. See GrayStar’s Presentation, at 62-63. However, it is not clarified whether this destructive test and analysis would include checking the encapsulation for internal corrosion, or whether this analysis would be used to verify that the moisture content is below 0.01 weight percent.

3. Torquing

GrayStar provides new information on the torquing of the seal plugs, contending that (1) the maximum torque is irrelevant; (2) there would be no reliance on measuring equipment or a human operator; and (3) the torquing process is designed to meet the requirements of 10 C.F.R. § 71.4. See GrayStar’s Presentation, at 85.

B. Inadequate Justification for Use of Dispersible Cesium Chloride Instead of Nondispersible Cobalt-60

In the 1993 SOC associated with Part 36, the Commission explicitly identified cobalt-60 as the insoluble and nondispersible radioactive material that would typically be approved for use in panoramic irradiators. See 58 Fed. Reg., *supra*, at 7716, col. 2. Furthermore, the Commission stated that it would not approve further use of cesium sources, but allowed for “an exception where justified to the NRC.” *Id.*, at 7718, col. 2. GrayStar provided additional information on why it chose cesium instead of cobalt, but did not provide any significant new arguments. The Staff continues to hold that GrayStar’s technical justification for using cesium is inadequate, as discussed below.

GrayStar’s technical justification for use of cesium-137 largely relies on two arguments: (1) Cesium-137 has a longer half-life than cobalt-60, so cesium requires less frequent source replacement; and (2) Cesium-137 requires less shielding, so the GrayStar irradiator would be lighter, and transportable as a complete unit. See GrayStar’s Presentation, at 22, 29, and 30.

The first argument is inadequate, because it could apply to any irradiator, and is based on a generic fact which was known to the Commission in 1993 when Part 36 was issued. If this argument were accepted for the GrayStar case, then it would have to be accepted for any case. An acceptable justification must be based on circumstances specific to the GrayStar case.

Similarly, the second argument is based on a generic fact which was known to the Commission when Part 36 was issued. However, in this instance, GrayStar is apparently arguing that the additional shielding required by cobalt-60 is not merely a hardship, but a prohibitive burden, because “fundamental design decisions” called for the irradiator to be transportable as a complete unit. GrayStar’s Presentation, at 29. The Staff acknowledges that GrayStar may view the use of cobalt-60 as impractical, given the design decisions it made. Nevertheless, as stated in its September 25 filing, the Staff concluded that the GrayStar justification is inadequate, because (1) GrayStar presented only the potential safety advantages of its proposed design, without discussing

or weighing potential safety disadvantages; and (2) the generic safety argument presented by GrayStar may be viewed as a challenge to the regulations, which should be addressed through rulemaking rather than in an adjudicatory hearing. See Staff's Presentation, at 8-10.

C. Past Use of Cesium-137 Chloride in Dry Irradiators

GrayStar refers to current and past use of cesium chloride sources in irradiators, apparently to support two contentions: (1) that the past performance of cesium chloride sources in dry irradiators has been satisfactory for the most part, and therefore constitutes a justification for approval of the proposed GS-42 sealed sources; and (2) that these GrayStar sources are unlikely to leak, because GrayStar considered the past history of cesium sources in designing the GrayStar sources. See GrayStar's Presentation, at 18-20, and Attachment A.

The first contention is invalid, because the Commission was aware that cesium chloride sources had been widely used in the past when it issued Part 36 in 1993, and these regulations were intended to prohibit the future use of cesium chloride in large irradiators unless appropriately justified. The Commission determined that the safety hazards associated with leaks of dispersible cesium chloride, even though the leaks were infrequent, justified restricting its use. Therefore, it is inadequate for GrayStar to merely cite as a justification a generalization that cesium chloride has been used in irradiators in the past.

With regard to the second contention, the Staff acknowledges that while GrayStar made a good faith effort to consider past experience in designing its GS-42 sealed sources, that is not enough to assure that these sources will not leak. The actual leak risk must be demonstrated by leak testing and other performance testing, and the testing done by GrayStar has not made the necessary showing in this regard. Moreover, to the extent that the GrayStar GS-42 sealed sources have different and unique design features, those features might or might not decrease the risk of

leaks. Therefore, the reference to historical data and experience does not constitute a sufficient demonstration that the GrayStar GS-42 sealed sources will not leak.

D. Relative Dispersibility of Different Forms of Cesium-137 Chloride

The following regards GrayStar's discussion of various forms of cesium-137, ranging from a block to a fine powder, and including a "caked powder" form. See GrayStar's Presentation, at 14-19.²⁹ GrayStar concludes that its caked powder form minimizes the potential for breach of the GS-42 sealed source encapsulation, and subsequent leakage. With respect to the potential for a source breach, GrayStar maintains that caked powder is less likely to cause a breach than the block form used in WESF capsules, because it is more deformable than the block form. GrayStar did not present a set of physical parameters in quantified terms which would support this claim. Moreover, even if GrayStar did provide such supporting data, this still would not address the justification for the use of dispersible material, as discussed below.

The safety concern with GrayStar's proposal to use cesium chloride is its dispersibility once a leak occurs, rather than cesium chloride's potential to cause a leak. The Commission's nondispersibility requirement reflects its general defense-in-depth philosophy, in that it assumes sealed sources will leak, and guards against the consequences caused by the spread of radioactive material after a breach occurs. In this respect, the caked powder form of cesium is more likely to leak out of a breach than is the block form, and it is the block form which the Commission identified in 1993 as a safety concern, in its discussion of the WESF sealed sources. See SOC, 58 Fed. Reg., *supra*, at 7716, col. 2; *see also* GrayStar's Presentation, at 14-15 (noting use of the block

²⁹ GrayStar's description of its caked powder form of cesium chloride differs somewhat from that given in GrayStar's April 1999 application, which referred to the cesium material as being "loose packed." Hearing File Tab IV.B, at page 11 of 38.

form in WESF sealed sources).³⁰ Thus, GrayStar's Presentation only serves to demonstrate that its caked powder form of cesium is more dispersible than the block form used in the WESF sealed sources, and that use of the caked powder form of cesium would be contrary to the Commission's defense-in-depth philosophy.

Since GrayStar's cesium material is dispersible, its use in a sealed source requires justification, in order to be authorized under 10 C.F.R. § 36.21(a)(3). It is not sufficient for GrayStar to demonstrate that its sources are unlikely to leak. GrayStar must demonstrate the justification for using dispersible material, because the Commission has expressed the safety concern that if dispersible material does leak, it poses a greater safety hazard than nondispersible material, due to the dispersible material's greater potential to spread.

E. Potential for Dispersion Following a Source Leak in a Dry Irradiator

GrayStar presents arguments that if a leak were to occur, not much radioactive cesium material would leak out (*see* GrayStar's Presentation, at 19), but the amount that leaks is a function of the circumstances when the leak occurred. Specifically, the leak amount depends on (1) the size of the breach in the capsule; (2) whether there is heat and pressure built up in the defective source; (3) whether there might be air turbulence, fire, or explosion in the irradiation chamber to disperse the material; and (4) how long it takes before the leak is identified. Regarding this last point, the proposed radiation surveys would be spaced at six-month intervals. *See* Exhibit 10 of April 1999 application (Hearing File Tab IV.L), at 1, *citing* 10 C.F.R. § 36.59(a). Consequently, any leaks might not be identified promptly. Factors (1) - (4) above are not addressed in GrayStar's Presentation.

³⁰ Without providing any cite, GrayStar states that the NRC "approved the WESF encapsulations as a sealed source for use in commercial irradiators on a probationary test basis." GrayStar's Presentation, at 67. This action apparently pre-dates the 1988 irradiator incident in Decatur, Georgia. Any such approval was superseded by the 1993 rulemaking. *See* SOC, 58 Fed. Reg., *supra*, at 7716, col. 2.

GrayStar also maintains that the potential consequences of a leak from a GS-42 sealed source would be the same as those from smaller sealed sources used in ANSI Category 1 irradiators. See GrayStar's Presentation, at 18-20. The large GrayStar sources contain substantially more radioactive material than is contained in ANSI Category 1 irradiators which use cesium-137 chloride (see Hearing File Tab VI.B., GrayStar's response to RAI Question 5), and, consequently, the potential exists that more material would disperse than would be the case if a leak occurred in an ANSI Category 1 irradiator.

F. Design Features to Prevent, Identify, and Mitigate Leaks

GrayStar's Presentation, at 17-18, and 33-46, describes design features to prevent leakage of the cesium-137 chloride. The majority of this information had been previously presented to the Staff in the April 1999 application, and in GrayStar's responses to the RAI questions. Moreover, these design features do not change the physical and chemical properties of the cesium-137 chloride, and are therefore not sufficient to resolve the issue of dispersibility. The Staff acknowledges that GrayStar made a "good faith" effort to design its sources so that leaks are unlikely. However, as stated in the Staff's September 25 filing, NRC regulations require that all sources be designed so that they are unlikely to leak, regardless of whether they contain dispersible or nondispersible material. See Staff's Presentation, at 11-12. The fact that GrayStar attempted to design the sources so that leaks are unlikely does not relieve them from the requirement to justify the use of dispersible cesium-137 chloride material.

G. Results of Leak Testing

GrayStar discusses the results of the prototype tests, and claims that the Staff misunderstood the test results. See GrayStar's Presentation, at 49-53. In the Denial Letter's Enclosure 1, the Staff summarized the results of the prototype tests by stating that "both the inner and outer capsules failed." Hearing File Tab VII.B, Section 2, at 1. As further specified in the

Staff's Presentation, at 14-15, 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.

In its September 25 filing, GrayStar claims that the Staff's Denial Letter incorrectly perceived the test results, and that the Staff implied there that the inner and outer capsules simultaneously failed on the same unit. The Denial Letter's Enclosure 1 stated that "in some of the prototype tests, both the inner and outer capsules leaked," and that to resolve the problem, GrayStar "only modified the design of the outer capsule." The Staff concluded in this regard that "because the inner capsule was not modified, the staff considers the inner capsule to be subject to leaks and, therefore, the design is unacceptable." Hearing File Tab VII.B, Section 2, at 1.

The Staff does in fact understand that in the prototype tests, the inner and outer seal failures occurred on different units. Since the inner capsule leaked during one of the tests, and its design was not subsequently modified, the Staff concludes (1) that the GS-42 sealed sources do not meet the testing requirements of 10 C.F.R. § 36.21(a)(5); and (2) that the GS-42 sealed

sources do not meet the double encapsulation requirement of 10 C.F.R. § 36.21(a)(2). This reiterates the Staff's previous findings in this regard. See Enclosure 1 of the Denial Letter (Hearing File Tab VII.B), Section 2, at 1; and Staff's Presentation, at 15. Additionally, as indicated by the previous finding that the GS-42 sealed source "design is unacceptable" (Enclosure 1 of the Denial Letter, Section 2, at 1), the Staff concludes that GrayStar did not meet the design requirements of 10 C.F.R. § 32.210(c).

GrayStar states that "there are two redundant seams to provide defense-in-depth," and that "an additional redundant step of adding a seal weld around the outside mechanical seal" is used on the outer capsule. GrayStar's Presentation, at 37. However, Exhibit 3 of GrayStar's April 1999 application ("Sealed Source Qualification Testing - Overview"), where "Day-5" of the testing was described, showed that only the outer capsule is closed with a weld seam; that a mechanical seal of the outer capsule failed on Day 3 of the prototype tests; and that due to this seal failure, an outer seal weld was added. See Hearing File Tab IV.E, at eleventh page (pages not numbered); see also GrayStar's Presentation, at 51-52. Therefore, contrary to what GrayStar now claims (see GrayStar's Presentation, at 37), the outer seal weld cannot be considered "redundant."

GrayStar also states that its GS-42 sealed source met the requirements of ANSI Standard N43.6-1997, Section 4.1.1. See GrayStar's Presentation, at 51. This ANSI standard states that a sealed source is acceptable when "at least one encapsulation has maintained its integrity after the test." However, this standard is applicable only to sources containing a maximum activity level of 30 curies for cesium-137. See ANSI Standard N43.6-1997, Tables 2 and 3. The maximum activity level in each GS-42 sealed source is over 51,500 curies. See Hearing File Tab VI.B., at 7 (response to RAI Question 5). This is a significantly higher activity level than what ANSI Standard N43.6-1997 covers. Moreover, cesium-137 chloride is highly dispersible. Since this ANSI standard was developed for much smaller sources than the GS-42 sealed source, compliance with

it does not assure safety of the GS-42 source. Furthermore, even if one assumes, *arguendo*, that this ANSI standard is applicable to larger sources, the Staff believes that, in light of the test result that showed a possible defect in the inner seal, corrective action is needed for the inner seal. This is because of the specific safety concern raised by the Commission with respect to the use of dispersible material.

GrayStar states that the seal plugs failed in the prototype tests due to thermal shock, and that "it is physically impossible for the inner seal plug of the GS-42 sealed source to be thermally shocked because the outer capsule thermally insulates the inner capsule." GrayStar's Presentation, at 52. The Staff disagrees with such a conclusion. In the Staff's view, the inner seal plug could well be subject to thermal shocks during its operational life. Specifically, the seal plug is located in the end cap of the inner encapsulation. This inner end cap is nested inside the outer end cap with direct metal to metal contact between the caps, without thermal insulation. Consequently, a thermal shock to the outer end cap could be directly transmitted to the inner end cap and to the seal plug. The air gap between the inner and outer plugs, which GrayStar referred to, would not necessarily provide isolation or complete thermal protection for the inner seal cap/seal plug.

H. Vibration Testing

GrayStar presents two diagrams of the test setup for vibration testing. See GrayStar's Presentation, at 55-56. The diagrams show that the test specimen was vibrated along the longer axis of the cross section on a horizontal shake table. The diagrams also illustrate how the test was conducted in conformance with ANSI Standard N43.6. The Staff had found this test acceptable, and it was not questioned in the Denial Letter. However, Enclosure 1 of the Denial Letter did cite the lack of vibration testing along the shorter axis of the cross section. See Hearing File Tab VII.B, Section 2, at 2. GrayStar's Presentation indicates that vibration testing along the shorter axis of the cross section has still not been done. In its response to RAI Question 10 (Hearing File Tab VI.B,

at 13), GrayStar stated that Footnote 3, Section 7.5.2, ANSI Standard N43.6-1997, was applicable. This ANSI standard specifies that, for sources with oval or disc-type cross-sections, testing along two axes is sufficient. The GS-42 source cross section has two flat surfaces, and is not circular or oval. Consequently, the Staff maintains that the limitation of the Standard does not apply to the GS-42 source, and that a vibration test along all three axes -- including the shorter axis of the cross section -- is necessary to meet the requirements of 10 C.F.R. § 36.21(e). GrayStar has still not conducted a vibration test along the shorter axis of the cross section.

CONCLUSION

GrayStar's Presentation fails to demonstrate that the GS-42 sealed sources meet the safety requirements of 10 C.F.R. §§ 32.210(c) and 36.21. 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 30th day of October 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 RESPONSE TO GRAYSTAR'S WRITTEN PRESENTATION," and Staff Exhibit 1 attached thereto, have been served on those listed below either by U.S. Mail, first class, or by internal distribution, this 30th day of October 2000. Additionally, electronic copies have been transmitted this date to those listed below and marked by single asterisks.

Administrative Judge
Ann M. Young, Presiding Officer *
Atomic Safety and Licensing Board
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Administrative Judge
Thomas D. Murphy, Special Assistant *
Atomic Safety and Licensing Board
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

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

Office of the Secretary *
ATTN: Rulemaking and Adjudications Staff
U.S. Nuclear Regulatory Commission
Mail Stop: O-16G15
Washington, D.C. 20555

Russell N. Stein, Vice President
Gray*Star, Inc.
Mt. Arlington Corporate Center
Suite 103
200 Valley Road
Mt. Arlington, NJ 07856

Anthony J. Thompson, Esq.*
Counsel for Gray*Star, Inc.
Shaw, Pittman
2300 N Street, N.W.
Washington, D.C. 20037-1128

Donald W. Thayer
U.S.D.A. Eastern Research Center
600 East Mermaid Lane
Wyndmoor, PA 19038

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