March 9, 2001

ALL AGREEMENT STATES
MINNESOTA, PENNSYLVANIA, AND WISCONSIN

PROGRAM MANAGEMENT INFORMATION: GRAYSTAR, INC. - DENIAL OF APPLICATION FOR SEALED SOURCE REGISTRATION CERTIFICATE (STP-01-018)

This is to inform you that the Atomic Safety and Licensing Board Panel (ASLBP) of the U.S. Nuclear Regulatory Commission (NRC) has upheld the staff's decision which denied an application for a certificate of registration for a sealed source design, intended for use in devices to irradiate food. The sealed sources, Graystar, Inc. model GS-42, were designed to contain approximately 55,000 curies each of 137-Cesium in "caked powder form" for use in Graystar's model 1 irradiator. Enclosed is the ASLBP's Initial Decision on this case, issued on February 27, 2001.

Thank you for your attention to this matter. If you have any questions regarding this correspondence, please contact me or the individual named below.

POINT OF CONTACT:	Lloyd A. Bolling	INTERNET:	LAB@NRC.GOV
TELEPHONE:	(301) 415-2327	FAX:	(310) 415-3502

/RA by Spiros C. Droggitis, Acting for/

Janet R. Schlueter, Acting Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

STP-01-018 March 9, 2001

Distribution:
DIR RF (1-58) DCD (SP03) PDR YES
SDroggitis
BGUsilton
Agreement State File

DOCUMENT NAME: G:\LAB\STP-01-018.wpd

OFFICE	STP	STP:ADD		
NAME	LABolling	JRSchlueter (By SCDroggitis)		
DATE	3/09/01	03/09/01		

OFFICIAL RECORD COPY STP-A-4

LBP-01-07

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges:

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

In the Matter of	Docket No. SSD 99-27
GRAYSTAR, INC.	ASLBP No. 00-778-06-ML
(Suite 103, 200 Valley Road, Mt. Arlington, NJ 07856)	February 27, 2001

INITIAL DECISION

This 10 C.F.R. Part 2, Subpart L matter concerns the NRC Staff's denial of an application for a certificate of registration for a sealed source under 10 C.F.R. §§ 32.210 and 36.21. GrayStar, Inc. (GrayStar), the developer of the Model GS-42 sealed source (GS-42) at issue, has challenged the Staff's denial in this proceeding.

The GS-42 was developed for use in GrayStar's Model 1 irradiator,[1] which is intended primarily for use by food producers to irradiate large, pallet-sized quantities of food. The GS-42 as designed would use cesium-137 in the form of cesium chloride "caked powder" as the radiation source. The issues in this proceeding center on whether this use of cesium-137 chloride as a source for the GS-42 is justified. These issues include the following interrelated questions: (A) whether 10 C.F.R. Part 36, regarding "Licenses and Radiation Safety Requirements for Irradiators," and section 36.21(a)(3) in particular, are applicable to the GS-42; if so, (B) whether the GS-42 meets the requirement in section 36.21(a)(3) that a sealed source "use radioactive material that is as nondispersible as practical," and (C) whether the design and testing of the GS-42 meet the double encapsulation and testing requirements of sections 36.21(a)(2) and 36.21(a)(5); and finally, (D) whether GrayStar has "provide[d] reasonable

[1]GrayStar has also applied for registration of the Model 1 irradiator. The Staff has not denied registration of it, but has provided GrayStar with a list of deficiencies to address prior to a final determination on the request for registration. Further review of it is currently suspended, and the parties agreed during an August 15, 2000, telephone conference in this matter that registration of the Model 1 irradiator would not be part of this matter. *See* Transcript at 12-13 (Aug. 15, 2000).

assurance that the radiation safety properties of the source . . . are adequate to protect health and minimize danger to life and property," as required by 10 C.F.R. § 32.210(c).

The Staff contends that 10 C.F.R. Part 36 and section 36.21(a)(3) are applicable to the GS-42; that GrayStar has not justified the use of cesium-137 chloride powder sufficiently to overcome the "qualified ban" of section 36.21(a)(3); and that GrayStar has not performed sufficient testing or otherwise established that the GS-42 meets the requirements of 10 C.F.R. §§ 36.21(a)(2), 36.21(a)(5), and 32.210(c). GrayStar argues that 10 C.F.R. Part 36, and section 36.21(a)(3) in particular, do not apply to the GS-42; that even if they do GrayStar has shown that the cesium-137 chloride in the GS-42 sealed source would be "as nondispersible as practical"; that sufficient testing has been performed on the GS-42 to satisfy section 36.21(a)(2) and (a)(5), assuming the provisions apply; and that GS-42 is otherwise in all respects appropriate for registration under 10 C.F.R. § 32.210(c).

I conclude that the provisions of 10 C.F.R. Part 36, including section 36.21(a)(3), apply to the GS-42 sealed source.[2] I also conclude that GrayStar has not established that the GS-42 sealed source is designed, filled and/or tested in a manner sufficient to assure that its cesium-137 chloride source is "material that is as nondispersible as practical," as required under 10 C.F.R. § 36.21(a)(3). I further conclude that GrayStar has not established that the GS-42 meets the double encapsulation and testing requirements of section 36.21(a)(2) and (a)(5). Finally, I conclude that GrayStar has not provided 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, as required by 10 C.F.R. § 32.210(c). Based upon these conclusions, I uphold the Staff's denial of GrayStar's application for a certificate of registration.

I. BACKGROUND

Because this case involves a somewhat complex set of facts, as well as legal issues of first impression, the Background section of this decision includes, in addition to a recounting of general facts and a procedural history of the case, a chronological history of some of the

---

[2]There is at least one exception to the conclusion that the provisions of 10 C.F.R. Part 36 apply to the GS-42 sealed source. The parties agree that section 36.21(a)(4) does not apply, as it is limited in its terms to sources "for use in irradiator pools," and the Model 1 is designed to be a dry-source-storage irradiator.

interactions between GrayStar and the Staff that ultimately led up to the Staff's denial of GrayStar's application for a certificate of registration and GrayStar's request for a hearing. This historical recounting provides some additional context for the novel issues involved in this matter, as well as for the starkly opposing viewpoints of GrayStar and the Staff on the applicability and proper interpretation of 10 C.F.R. Part 36 and section 36.21(a)(3), their relationship to 10 C.F.R. § 32.210(c), and whether GrayStar has shown adequate factual and legal justification for using cesium-137 chloride in the GS-42 sealed source.

A. <u>General Facts</u>

Although neither party has submitted its written presentation under oath or affirmation as required by 10 C.F.R. § 2.1233(a), the basic facts in this case are not in dispute. The parties differ on the inferences to be drawn from many of the facts, however, and their written presentations and responses consist largely of argument on the significance and interpretation of such facts. Facts subject to this sort of dispute are discussed below in the Analysis section of this decision, in connection with the issues to which they relate. The following background facts, the significance of most of which is not contested, provide general context for the history and issues analysis portions of this decision.

1. GrayStar and Food Irradiation

GrayStar is a privately held company founded in 1989, with headquarters in Mt. Arlington, New Jersey. Its corporate objective is to manufacture and lease its Model 1 irradiator, a dry-source-storage irradiator designed to use the GS-42 sealed source at issue in this matter.[3] Each Model 1 would contain 64 of the GS-42 sealed sources, each of which would contain 51,500 Curies (Ci) of cesium-137 chloride in "caked powder" form, encapsulated in double stainless steel tubes, with a total strength of approximately 3 million Ci.[4] GrayStar presents the Model 1 irradiator, with its GS-42 sealed sources, as a new and unique means of irradiating food products on a wide scale.

The types of radiant energy typically used in food irradiation include microwave and infrared radiation, which heat food; visible light or ultraviolet light, which dries food or kills food

---

[3]*See* GrayStar, Inc.'s Corrected Brief in Support of Application for Registration of Model GS-42 Sealed Source (Oct. 3, 2000) [hereinafter GrayStar Brief], at 2.

[4]GrayStar Brief at 19, 20 n. 13; NRC Staff's Initial Written Presentation (Sept. 25, 2000) [hereinafter Staff Presentation], at 6.

surface microorganisms; and ionizing radiation, which penetrates into food without heating it, using cobalt-60, cesium-137, x-rays or electron acceleration.[5] It is not disputed that ionizing irradiation is an effective means of eliminating pathogenic bacteria, insects and parasites. It can also reduce spoilage and, in some fruits and vegetables, inhibit sprouting and delay the ripening process. It penetrates into food without significantly raising its temperature, making it radioactive, compromising its nutritional quality, or noticeably changing its taste, texture or appearance, so long as the radiation is applied properly to suitable products.[6] The Food and Drug Administration has officially endorsed the use of food irradiation using either cobalt-60 or cesium-137 radioactive sources.[7]

According to Graystar, cobalt irradiators cannot be used economically to irradiate large quantities of food, are not easily transportable because of their volume and weight, and have other disadvantages including water storage of sources.[8] In contrast, GrayStar asserts that its Model 1 irradiator, with its self-shielded, dry-source-storage GS-42 sealed sources, would be an economically viable technology that could be transported to and installed at individual food production facilities to irradiate large, pallet-scale volumes of food. GrayStar further asserts that the Model 1 would not require on-site source changing with its attendant risks, because of the longer, 30.2-year half-life of cesium-137, which results in a source strength loss of only 2.3% a year, as compared to cobalt-60's 5.27-year half-life and strength loss of 12.3% a year.[9]

2. Model 1 Irradiator Design and Operation

Even though registration of the Model 1 irradiator is not at issue in this proceeding, its design and operation as planned by GrayStar are relevant to an understanding of the GS-42 sealed source at issue. The Model 1 is the only irradiator in which the GS-42 is designed to be used, and GrayStar argues that aspects of its design and proposed operation help to assure the nondispersibility of the cesium-137 chloride proposed to be used in the GS-42 sealed source.

---

[5]GrayStar Brief at 3.

[6]GrayStar Brief at 2-3.

[7]*Id.* at 2-4, 20.

[8]*See id.* at 17, 22.

[9]*See id.* at 4, 21, 27.

The Model 1 irradiator design consists of two modular parts, one to be installed below the floor, on and within conventional concrete footings and retaining walls, and one to be installed at floor level above the below-floor part. The part that would be installed below the floor is a 165-ton cask (called a "Graysafe"), 8.5 feet by 10.5 feet by 12 feet high, which would be the storage container for the sources. The upper part would weigh approximately 32 tons, have approximately the same dimensions as the lower part, and have an irradiation chamber into which food to be irradiated would be placed. A power pack and computer console would be attached to the outside of the upper part next to the chamber doors, and three hydraulic cylinders would be attached to each outer side of the upper part.[10] The irradiation chamber is designed to be large enough to contain a 40-inch by 48-inch pallet of food 53 inches high, the size GrayStar asserts the food industry has indicated is necessary if the irradiator is to be commercially practical.[11] The two modular parts are designed so that each could be shipped commercially to food producers for use on-site, which GrayStar says the industry has indicated is also necessary if the irradiator is to be practical.[12] By comparison, cobalt irradiators are generally built and loaded at the site of operation because of their great size and weight.[13]

The door to the irradiation chamber of the Model 1 irradiator is designed so that it can be open only when the radiation sources are shielded below the floor. The 64 cesium sources would be arranged and contained in four panels set flush to the inside wall surfaces of a four-sided steel box (with no fixed top or bottom panel) contained within the Graysafe cask. This steel box (called the "door source") will weigh approximately 105 tons and have walls at least 16 inches thick; the containment of the sources within this box will, it is argued, prevent inadvertent access or exposure to the sources.[14] When this "door source" box containing the sources is in the below-floor position, it and the sources on its inside walls would surround a solid steel center column. After a pallet of food is rolled into the upper chamber, which would be done

---

[10] *See* Videotape, "The GrayStar Solution" [hereinafter GrayStar Videotape], filed with GrayStar Reply to NRC Staff's Response Brief (Nov. 15, 2000) [hereinafter GrayStar Reply].

[11] *See* GrayStar Videotape, and Figure 22, also filed with GrayStar Reply; GrayStar Brief at 29.

[12] GrayStar Brief at 29.

[13] *See* GrayStar Videotape.

[14] *See* GrayStar Brief at 22, 24; GrayStar Videotape.

without an operator entering the chamber,[15] the operator would close the chamber doors (which open to the outside) using two handle keys, one in each door, and then remove the handle keys from the doors, place them into the computer console, rotate them a quarter turn, and hold them in place long enough for the four-sided "door source" box containing the sources to rise to its complete upper position.

The six hydraulic cylinders are designed to raise the "door source" box all the way to the top of the upper part of the Model 1 irradiator, until the top of the source box completely surrounds a steel center column above the radiation chamber, and the source panels are centered around all four sides of the irradiation chamber. In this position, the chamber doors would be contained inside the "door source" box and there would be no operator access to open them. The irradiator is designed so that, during the hydraulic lifting process, the source panels will not emerge out of the lower shield until the upper part of the "door source" box surrounds the lower part of the upper steel center column. If the hydraulic cylinders fail or the handle keys are not held properly or are taken out of the console prematurely, the "door source" box is designed to lower itself automatically back into the below-floor storage cask.[16] When the "door source" box rises all the way to the top of the upper part of the Model 1 irradiator, the food on the pallet would be irradiated from four sides, according to preset dose amounts. When this is completed, the "door source" would automatically lower, taking the sources back into the below-floor storage cask.

The unit is designed to prevent radiation leakage by virtue of the steel columns above and below the radiation panels when they are in the operating position, the inability to raise the sources out of the Graysafe cask except when the chamber door is closed, and the four 16-inch-thick walls of the "door source" that contain the sources and prevent access to the chamber door and the internal chamber when the sources are in the raised position.[17]

GrayStar plans to have the Model 1 units fabricated at a site such as Babcock and Wilcox's plant in Indiana, where the steel components would be precision-milled. After assembly, the units would be sent to a government laboratory such as the Hanford site in

[15] *See* GrayStar Brief at 22; GrayStar Videotape.

[16] *See* GrayStar Videotape.

[17] *See* GrayStar Videotape.

Washington state or the Savannah River site in South Carolina, for loading of the cesium-137 chloride sources, which would come from material presently stored as high-level radioactive waste. After loading of the sources into the Graysafe, security welding would be done to make the sources inaccessible except for reopening at a source-loading site. The Graysafe and the upper portion of the Model 1 irradiator would be transported separately, by ship, rail or special truck, much as other overweight items are transported. GrayStar projects that maintenance would be routine only, since no bearings, conveyor belts or similar moving parts are to be used[18]; that only minimal, on-site training of operators would be required; and that some inspection and monitoring would be done by remote access, using a telephone line and a code number.[19]

B. Application History

GrayStar submitted its application for registration of the Model 1 irradiator and Model GS-42 sealed source on April 19, 1999. However, communication between GrayStar principals and the NRC Staff had begun as early as September 1996, when GrayStar first requested registration by the NRC of "a unique irradiator design." Although this request is not in the record, the record does contain the January 27, 1997, response to Martin Stein, President of GrayStar, from Larry W. Camper, Chief of the Medical, Academic, and Commercial Use Safety Branch of the NRC Office of Nuclear Material Safety and Safeguards (NMSS), Division of Industrial and Medical Nuclear Safety. In this letter, Mr. Camper noted the understanding that the first unit was likely to be located at a U. S. Department of Agriculture (USDA) facility near Philadelphia, Pennsylvania, and that there had been discussions between USDA personnel and representatives from NRC's Region 1 office.

Mr. Camper stressed the need "for a collaborative effort between all parties since this is a unique device design, as such, obstacles may surface during licensing and product registration that may be policy setting and require additional time to resolve." Noting that the NRC had done a "cursory review of the application to identify areas that we feel require more information or clarification," Mr. Camper specified fifteen issues in the January 27, 1997, letter, including the following as the first-numbered item:

---

[18] *See id;* GrayStar Brief at 22-23.

[19] *See* GrayStar Videotape.

> We are concerned with the choice of cesium-137 chloride from the Department of Energy (DOE) for use in the Gray Star source designs. Note: while 10 CFR Part 36 may not be directly applicable, use of soluble cesium is prohibited by that rule. While Gray Star does not plan to use the DOE supplied [Waste Encapsulation and Storage Facility (WESF)] capsules in the irradiator, the radioactive material purity is in question. Specifically, the [e]ffect of the cesium-137 chloride compound and its impurities on capsule wall integrity may be an issue. DOE reports involving destructive analysis of their source capsules show corrosion from the inside of the source capsule out. We request clarification on how the cesium-137 chloride will be purified, dried, and specifications on the chemical composition. Additionally, we request justification as to why an insoluble and nondispersable form of cesium cannot be used.[20]

By letter dated February 10, 1997, GrayStar Vice President Russell N. Stein responded to Mr. Camper, addressing the matter quoted above by arguing that since GrayStar's irradiator was not a wet-source-storage irradiator, the requirement relating to insoluble radioactive material was "NOT directly applicable"; Mr. Stein also addressed the issues of source purity and corrosion, and offered to review reports on cesium compounds other than cesium-137 chloride, and to meet with the NRC prior to formalizing the encapsulation program.[21]

Mr. Camper responded to Mr. Stein in a letter dated May 20, 1998, indicating that since "a large amount of significant technical data" was missing, the review process of the application was being terminated, albeit without prejudice to the resubmission of a complete application "fully addressing our concerns." No specific reference is made in this letter to cesium-137 chloride, but there is a reference to GrayStar's having indicated to Mr. Camper that it "would provide further information regarding the development and encapsulation tests of the special form source [GrayStar] intended to use as well as regarding the quality assurance (QA) program and prototype testing for the irradiator."[22]

On April 19, 1999, GrayStar submitted a new application dated April 15, 1999.[23] Thereafter, meetings were held with GrayStar on May 11 and July 13, 1999. On July 26, 1999, John P. Jankovich, Senior Engineer with the NMSS Division of Industrial and Medical Nuclear Safety, Materials Safety and Inspection Branch, sent GrayStar a "Request for Additional

---

[20] Hearing File, Vol. I, Tab I, at 1. The WESF sources were produced at DOE's Hanford facility and were leased to four commercial irradiators, until a leak occurred in an irradiator using WESF capsules in Georgia and the Commission subsequently required that all such sources be removed and returned to DOE. *See* 58 Fed. Reg. 7716 (Feb. 9, 1993).

[21] Hearing File, Vol. I, Tab II.A, at 1-2.

[22] Hearing File, Vol. I, Tab III.A, at 1.

[23] Hearing File, Vol. I, Tab IV.A *et seq.*

Information/GrayStar Model 1 Irradiator and Model GS-42 Sources" (RAI).[24] In a cover letter, Mr. Jankovich noted that the Model 1 was being evaluated as a Category II irradiator as defined by the American National Standards Institute (ANSI) at Standard N43.10, and that GrayStar's design fell within the scope of 10 C.F.R. Part 36, applicable to "panoramic irradiators that have either dry or wet storage."[25] Among the 60 listed information items in the RAI were requests relating to GrayStar's criteria for selecting the form of cesium-137 it had chosen for the GS-42, in the context of the requirement at 10 C.F.R. § 36.21(a)(3) "that the radioactive material be as nondispersible as practical"; the amount of cesium-137 chloride to be used in each source; the loading of the source; the failure of the inner seal of the source in testing; the axes used in vibration tests; and source integrity and corrosion issues, including the drying procedure to remove water from source tubes.

On August 11, 1999, a meeting was held at which GrayStar discussed several issues with NRC management, including various reasons GrayStar asserted for classifying the Model 1 as a Category I irradiator, to which the provisions of 10 C.F.R. Part 36 would not apply.[26] Thereafter, on August 12, 1999, GrayStar submitted a written request for additional time to respond, formally requesting that the Model 1 be classified as a Category I irradiator, and noting among other things the ways in which GrayStar contended the Model 1 fell within the criteria for Category I irradiators.[27]

By letter dated September 10, 1999, from Mr. Jankovich, Graystar was granted an extension of time and, among other things, notified that NMSS continued to maintain that the Model 1 was a Category II irradiator under ANSI 43.10 and a panoramic irradiator under 10 C.F.R. § 36.2.[28] Thereafter, GrayStar continued to assert that the Model 1 was not a panoramic

---

[24]Hearing File, Vol. II, Tab V.B.

[25]Hearing File, Vol. II, Tab V.A. at 1.

[26]Hearing File, Supplemental Documents filed by Staff Sept. 6, 2000, Item 7, Minutes of Meeting with GrayStar, Inc. (Aug. 11, 1999).

[27]*Id.*, Item 6, Letter from Stein to Jankovich (Aug. 12, 1999).

[28]*Id.*, Item 8, Letter from Jankovich to Stein (Sept. 10, 1999).

irradiator, but provided information relating to specific issues on the design, testing, filling and other aspects of the GS-42 sealed source and Model 1 irradiator.[29]

On May 24, 2000, Mr. Donald A. Cool, Director of the NMSS Division of Industrial and Medical Nuclear Safety, wrote to Mr. Stein, notifying him that GrayStar's request for registration of the GS-42 sealed source was denied and that the remainder of the application was being suspended.[30] Mr. Cool's letter states that the Staff found GrayStar's Model GS-42 design "not acceptable for registration and licensing under 10 C.F.R. 32.210 and 10 C.F.R. 36.21," and that GrayStar's application did "not adequately justify [the] choice of cesium-137 chloride powder, a dispersible material." An attachment to the May 24, 2000, letter provided a detailed statement of the basis for denial, which included discussions of dispersibility and testing issues.[31]

In its May 24, 2000, letter, the Staff notified GrayStar of its right to request a hearing under 10 C.F.R. § 2.103(b).[32] Thereafter, on June 1, 2000, GrayStar requested reconsideration of the denial and, in the alternative, sought an agency hearing.[33] In a June 8, 2000, letter to Mr. Stein, Mr. Cool declined to reconsider the application, noting that "[t]he proposed Model GS-42 sealed source and the Model 1 irradiator would involve the use of cesium-137 chloride powder, an unacceptably dispersible material," and stating that GrayStar had not adequately addressed this point and other matters, "in particular, [by failing] to demonstrate that [the] proposed model designs would adequately protect health and minimize danger to life and property."[34]

C. <u>Procedural History</u>

---

[29]Hearing File, Vol. II, Tab. VI.A, Letter from Stein to Jankovich (Sept. 27, 1999).

[30]*See* Hearing File, Vol. V, Tab VII.A, Letter from Donald A. Cool to Russell N. Stein (May 24, 2000).

[31]The attachment to the May 24, 2000, letter cited four factors as bases for the Staff's denial: "Dispersibility," "Testing of Sealed Sources," "Sealed Source Construction and Durability," and "The Design Has Not Been Finalized." Hearing File, Vol. V, Tab VII.A. The latter two of these issues were resolved during the course of the proceedings through GrayStar's provision of information that satisfied the Staff's concerns. *See* NRC Staff's Response to GrayStar's Written Presentation (Oct. 30, 2000) [hereinafter Staff Response] at 26.

[32]Section 2.103(b) provides that when the NRC Staff denies an application it must inform the applicant of "(1) [t]he nature of any deficiencies or the reason for the . . . denial, and (2) [t]he right . . . to demand a hearing within twenty (20) days from the date of the notice or such longer period as may be specified in the notice."

[33]Hearing File, Vol. V, Tab VIII.

[34]Hearing File, Vol. V, Tab IX.

In a Memorandum and Order served June 13, 2000, the Commission referred GrayStar's request for a hearing to the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, to designate a member of the Panel to rule on GrayStar's request for hearing and if necessary to serve as presiding officer to conduct a hearing pursuant to 10 C.F.R. Part 2, Subpart L. On June 16, the Chief Administrative Judge set a deadline for the Staff's answer to GrayStar's hearing request. On June 23, the NRC Staff filed an answer indicating that the Staff did not oppose the hearing request of GrayStar.

On July 10, 2000, the Chief Administrative Judge granted the hearing request of GrayStar and issued a Notice of Hearing, which was published in the July 14, 2000, *Federal Register*.[35] On July 31, 2000, the Chief Administrative Judge appointed the undersigned to serve as Presiding Officer, and on August 28, 2000, Judge Thomas D. Murphy was appointed as Special Assistant to the Presiding Officer. On August 1, 2000, the Staff filed the Hearing File in the matter, pursuant to 10 C.F.R. § 2.1231. On August 15, 2000, pursuant to an unpublished Order issued August 4, 2000, a telephone conference was held to discuss and clarify the issues to be addressed and determined in this proceeding and to set deadlines for the filing of written presentations by the parties.

Although no intervention petitions have been filed in this matter, prior to the August 15 conference, Donald W. Thayer, Ph.D, Research Leader for the USDA Agricultural Research Service (ARS), indicated some interest on the part of the ARS. Dr. Thayer declared in a letter that the Department's Eastern Regional Research Center in Wyndmoor, Pennsylvania, had signed a Cooperative Research and Development Agreement with GrayStar, Inc., for the evaluation of the GrayStar irradiator.[36] According to Dr. Thayer, "[t]he interest of the ARS is to obtain the use of a unique, pallet-scale, gamma irradiation source with precise irradiation dose and environmental controls for research on 1) a determination of the efficacy of gamma irradiation for the control or elimination of food borne pathogens, and 2) shelf-life extension of various fresh and processed meat, poultry, fruit, and vegetable products." The results of such research were to be published in peer-reviewed journals and were "expected to provide information that will be of value to the food processing industry and to the establishment of

---

[35]65 Fed. Reg. 43,789 (July 14, 2000).

[36]Aug. 11, 2000, Letter from Donald W. Thayer to Administrative Judge Ann M. Young.

regulations by the Food and Drug Administration and the USDA, Food Safety and Inspection Service for the irradiation of foods." Dr. Thayer stated that the ARS had expended $642,302.00 for renovation of a building and new laboratory space in anticipation of receiving the GrayStar irradiator.[37] Dr. Thayer subsequently indicated that his letter was intended to be treated only as a limited appearance under 10 C.F.R. § 2.1211(a).[38]

During the August 15, 2000, telephone conference, in addition to discussing the issues in the case and a common outline for addressing them, the parties agreed that the use of cesium-137 chloride was not absolutely foreclosed for use in the Model GS-42 sealed source, provided adequate justification for such use is demonstrated, with the burden being on GrayStar to show that the registration should be granted.[39]

On September 7, 2000, another telephone conference was held at the request of GrayStar, at which additional issues were raised by both parties, additional documents provided by Staff for the hearing file were noted, and certain deadline extension requests were granted

---

[37]In his Aug. 11, 2000, letter Dr. Thayer also declared:

> We currently are using a self-contained, dry-storage, irradiator with a rated capacity of 213,000 Ci strength of Cs-137 [, which was] constructed in 1969 and has been in continual use for research on the irradiation of food. The USDA currently has 22 irradiators on its inventory; 13 of these use Cs-137 as the radiation source and are self-contained, dry-storage types. These irradiators have contributed significantly to the progress of agricultural research and the control of insect vectors of disease. Cs-137 is ideally suited for self-contained irradiators because of it[s] 30 year half life. Though the unit described above at this facility has gone through one half-life it is still a very useful system for research. I recently was asked to determine the cost of recharging or replacing a Co-60 unit currently in use at the ARS Plum Island facility and learned that the cost to recharge or replace this unit would be very similar. Because of the 5 year half-life of its Co-60 source the activity of that unit has decayed to the point of being of little value. In order to recharge this irradiator it will have to be decontaminated, removed from the BL4 facility on the island, shipped to the mainland, and then to the Nordion facility in Canada. That unit is used to sterilize meat contaminated with exotic animal diseases such a hoof-an[d]-mouth disease virus or anthrax.
>
> I hope that the value of properly contained Cs-137 sources is not overlooked. Our Cs-137 radiation sources, and I believe all others, are cesium chloride (CsCl) powder doubly encapsulated within stainless steel. The only real limitation of such sources is a lower energy level than that of Co-60. Because of the solubility of the CsCl used in these sources, in the unlikely event of a leak in encapsulation, they probably should only be used in dry-storage irradiators such as the Gray*Star.

[38]Aug. 14, 2000, Letter from Donald W. Thayer to Office of the Secretary, NRC.

[39]*See* Presiding Officer's Order (Setting Schedule for Proceedings and Addressing Other Matters Considered at August 15, 2000, Telephone Conference) (Aug. 17, 2000) at 1 (unpublished); Transcript at 21 (Aug. 15, 2000).

to accommodate these new items.[40] Thereafter, on September 25, the parties filed their initial written presentations,[41] and on October 30, their responses to each other's written presentations.[42] On November 2, GrayStar filed a request for further proceedings,[43] specifically, an additional written filing, along with the presentation of certain visual information illustrating the operation of the Model 1 irradiator and Model GS-42 sealed sources. On November 8, a telephone conference was held to address GrayStar's request.[44] GrayStar was permitted to file one additional written reply to the NRC Staff, along with photographs and a videotape; the Staff was permitted to file a response;[45] and these items were timely filed on November 15 and 22, respectively.[46] Subsequently, the Presiding Officer viewed the videotape in question, and no further proceedings have been deemed necessary in the matter.

II. ANALYSIS

As indicated above, the issues in this proceeding include the following interrelated questions, all of which center on whether the use of cesium-137 chloride as a source for the GS-42 is justified: (A) whether 10 C.F.R. Part 36, and section 36.21(a)(3) in particular, are applicable to the GS-42; if so, (B) whether the GS-42 meets the nondispersibility requirement of section 36.21(a)(3), and (C) whether the design and testing of the GS-42 meet the requirements of 10 C.F.R. § 36.21(a)(2) and (a)(5); and lastly, (D) whether GrayStar has "provide[d] reasonable assurance that the radiation safety properties of the source . . . are adequate to protect health and minimize danger to life and property," as required by 10 C.F.R.

---

[40] *See* Presiding Officer's Order (Addressing Matters Considered at September 7, 2000, Telephone Conference) (Sept. 14, 2000, unpublished); Transcript at 58-80 (Sept. 7, 2000).

[41] GrayStar, Inc.'s Brief in Support of Application for Registration of Model GS-42 Sealed Source (Sept. 25, 2000) (Corrected GrayStar Brief filed Oct. 3, 2000); Staff Presentation.

[42] GrayStar, Inc.'s Response to NRC Staff's Brief Regarding the Application for Registration of Model GS-42 Sealed Source (Oct. 30, 2000) [hereinafter, GrayStar Response]; Staff Response.

[43] GrayStar, Inc.'s Request for Further Proceedings Regarding the Application for Registration of Model GS-42 Sealed Source (Nov. 2, 2000).

[44] See Transcript at 81-155 (Nov. 8, 2000).

[45] *See* Presiding Officer's Order (Confirming Matters addressed at November 8, 2000, Telephone Conference) (Nov. 13, 2000) (unpublished).

[46] GrayStar Reply; NRC Staff's Reply to GrayStar's November 15 Filing (Nov. 22, 2000) [hereinafter Staff Reply].

§ 32.210(c). In resolving these issues, which are addressed below in the order listed, a determination must be made for each whether the applicant has met its burden of proof,[47] by a preponderance of the evidence.[48]

Before addressing these issues, it is noted that GrayStar has challenged the Staff's denial not only on its merits, but also on the basis that the Staff has failed to articulate the reasons for the denial. Although the Staff's bases for denial have not always been stated with complete precision, its general position with regard to the matters at issue has been fairly consistent since the first interactions with GrayStar, as illustrated in the chronological history above. In this proceeding, based on its May 24, 2000, denial letter, its September 25, 2000, Written Presentation and its October 30 and November 22, 2000, responses to GrayStar's filings, the Staff's asserted reasons for denying approval and registration of the GS-42 are taken to be as follows: (1) The proposed use of cesium-137 chloride caked powder has not been justified under 10 C.F.R. § 36.21(a)(3)[49] and also does not meet the health and safety requirement of 10 C.F.R. § 32.210(c),[50] in that (a) GrayStar has not adequately shown how the filling process for the sources would avoid the potential for corrosion inside the source capsules, how the moisture content in the source capsules would be limited to 0.01 percent, how this would be measured and determined, or what quality control measures would be used to check for internal corrosion and to verify that the moisture content is below 0.01 percent;[51] (b) GrayStar has not shown that the six-month frequency of the radiation monitoring it proposes is adequate to identify any leak promptly;[52] (c) the leak testing of the GS-42 sealed source has not been sufficient to assure that the sources will not leak;[53] and (d) GrayStar has not presented a

[47] *See* 10 C.F.R. § 2.1237(b), which provides that "[u]nless otherwise ordered by the presiding officer, the applicant . . . has the burden of proof."

[48] *See Philadelphia Electric Co.* (Limerick Generating Station, Units 1 and 2), ALAB-819, 22 NRC 681, 720 (1985); *Hydro Resources, Inc.* (2929 Coors Road, Suite 101, Albuquerque, NM 87120), LBP-99-30, 50 NRC 77, 110 (1999).

[49] Staff Response at 30-34.

[50] *Id.* at 24.

[51] *Id.* at 27-29.

[52] *Id.* at 33.

[53] *Id.* at 31.

"set of physical parameters" or an adequate safety analysis or probabilistic risk assessment to address the long-term reliability of the GS-42 sealed sources, to identify and analyze the potential failure modes of the GS-42 sealed source, or to support its claim that the caked powder form of cesium-137 chloride it proposes to use is less likely to cause a breach than the block form used in the DOE WESF capsules;[54] and (2) the heat testing and vibration testing that have been performed on the GS-42 do not meet the double encapsulation and leak-testing requirements of 10 C.F.R. § 36.21(a)(2) and (a)(5), or the health and safety requirements of 10 C.F.R. § 32.210(c).[55]

A. Applicability of Regulatory Provisions

1. 10 C.F.R. Part 36

GrayStar argues that Part 36 is not applicable in this case because it does not by its terms apply to the category of irradiator that best fits the Model 1,[56] and because GrayStar is seeking not a license under Part 36 but merely a registration under 10 C.F.R. § 32.210.[57] GrayStar contends that the Model 1 is a Category I irradiator under ANSI Standard N43.10, in that (1) it is a "device" rather than a facility-type irradiator as defined under Categories II, III and IV of the ANSI standard; and (2) it is self-contained, with sources integral to the shielding, and relies primarily on physical design rather than on operator training and interlocks for safety, as in Category II, III and IV irradiators. This argument fails, however, because the ANSI definition for Category I irradiators indicates that they are devices in which "[h]uman access to the sealed sources and to the space subject to irradiation is not physically possible."[58] Notwithstanding Graystar's assertion that it would take conscious effort to gain access, human access to the Model 1 irradiation chamber is possible.

Looking to the terms of Part 36 itself, section 36.1(c) provides that "[t]he regulations in this part do not apply to self-contained dry-source irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible to

---

[54]Staff Presentation at 9, 20; Staff Response at 32-34.

[55]Staff Response at 22 n. 25, 31, 34-38.

[56]GrayStar Brief at 68-72.

[57]GrayStar Response at 2-3.

[58]*See* 58 Fed. Reg. 7715 (Feb. 9, 1993).

personnel)." On the other hand, section 36.1(b) provides that the Part 36 requirements do apply to both wet and dry-source-storage "panoramic" irradiators. Section 36.2 includes the following definition:

> *Panoramic dry-source-storage irradiator* means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Again, even if, as GrayStar argues, it would take some conscious effort for a human being to get or be placed into the irradiation chamber and then be irradiated, the chamber is certainly "potentially accessible to personnel," and there is nothing in the definition that would except the Model 1. I accordingly find that the Model 1 irradiator is a panoramic irradiator as defined at section 36.2.

GrayStar's argument that it seeks not a license but merely a registration under section 32.210 has some surface appeal, not only with regard to Part 36 generally but also with regard to section 36.21, the only section of Part 36 at issue in this matter. The title of Part 36 does contain the word "Licenses," and section 36.21(a)(1) does state that sealed sources installed after July 1, 1993, "[m]ust have a certificate of registration issued under 10 CFR 32.210," suggesting that registration under § 32.210 is a separate matter from the other requirements under section 36.21. However, the title of Part 36 also contains the words, "and Radiation Safety Requirements for Irradiators," and the heading for section 36.21 is "Performance criteria for sealed sources." Also, certain language in the Statement of Considerations (SOC) for the 1993 final rule adopting Part 36 leads to the conclusion that the requirements of sections 32.210 and 36.21 are to be read in conjunction with each other with regard to the performance criteria for sealed sources used in irradiators.

Specifically, in the discussion of section 36.21, the SOC states:

> This section lists performance criteria required for sealed sources used in irradiators. Normally the tests used to demonstrate that the criteria can be met are conducted by the source manufacturer, not the irradiator licensee. The manufacturer then applies to the NRC or an Agreement State agency for approval for use in irradiators. If this procedure has been followed, the licensee need only note the manufacturer's name and model of the sources in its license application to demonstrate that the requirement is met.
>
> . . . .
>
> The rule does not specify any requirements for sealed sources installed prior to July 1, 1993. Sources previously installed were approved by NRC on a case-by-case basis under § 32.210, a review which includes consideration of the criteria in American National Standard N542-1977. . . .

> Several commenters stated that the performance criteria in this section by themselves are not sufficient to establish the adequacy of the performance of sealed sources in irradiators. The NRC agrees with the comment but notes that the criteria in the section are not the only criteria that the sealed sources must meet. The adequacy of sealed sources is reviewed and approved by NRC under § 32.210 of its regulations. The § 32.210 review is very extensive and considers many factors that could affect the integrity of the sealed sources, including their manufacture and conditions of use, on a case-by-case basis. Because of the large number of factors that must be considered and the special circumstances that could arise, it is not possible to establish specific criteria beyond the basic framework in § 36.21. The NRC believes that this method of sealed source review is adequate. Therefore, no additional changes in § 36.21 were necessary.[59]

The first quoted paragraph suggests that the critical approval of a sealed source occurs when the manufacturer seeks approval, which is taken to mean registration as in this case, as distinguished from the licensing that is subsequently applied for by one other than the manufacturer, most logically the user. The first paragraph also suggests that once the approval is granted to the manufacturer, approval of the registered sealed source in a subsequent licensing proceeding would involve little if any substantive examination of the sealed source (barring user-specific problems),[60] at least insofar as the requirements at issue are concerned. Thus, registration of the source and approval of a license for its use go hand in hand.

Following the same analysis, GrayStar's argument that section 36.21 does not apply to the GS-42 because it has not yet been installed is also found to have no merit.[61] In light of the quoted language from the SOC, this argument -- in effect that GrayStar, the manufacturer of the GS-42, should not be required to address the same requirements applicable to a subsequent purchaser once GS-42 sources have been installed in the Model 1 irradiator, which GrayStar is also constructing -- is baseless. Finally, the last quoted paragraph of the 1993 SOC, when read in conjunction with the first, suggests that NRC approval of an application for registration of a sealed source by a source manufacturer (such as GrayStar) would encompass consideration of both the "basic framework" of requirements set forth at section 36.21, as well as the many factors unique to a given source that would be reviewed on a case-by-case basis under section 32.210.

---

[59]58 Fed. Reg. at 7718.

[60]GrayStar Reply at 9.

[61]*See* GrayStar Brief at 11 n. 7; GrayStar Response at 6 n. 2.

Based upon the preceding analysis, I conclude that Part 36 does apply to the Model 1 irradiator and GS-42 sealed source, except where provisions are clearly limited in their application to wet-source-storage irradiators.

2. Applicability of 10 C.F.R. § 36.21(a)(3)

GrayStar's first argument with regard to section 36.21(a)(3) is that it does not apply to the GS-42 as it would be used in the Model 1 irradiator, because according to its plain meaning the section applies only to wet-source-storage or wet-source-change irradiators.[62] The provision states:

> (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;
> . . . .

The plain meaning of this language is that *all* irradiators subject to the rule must use radioactive material that is as nondispersible as practical, and that, if the source is used in a wet-source-storage or wet-source-change irradiator, it must use radioactive material that is also as insoluble as practical. As the Staff argues, for the provision to have the meaning GrayStar would give it, it would instead have to read, "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."[63]

Despite the plain meaning of the regulation's wording, however, there are some NRC guidance documents containing essentially the interpretation argued by GrayStar. Specifically, in NUREG-1550, it is stated:

> Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21. One such requirement is that the licensed material be as insoluble and nondispersible as practicable if used in a wet-source-storage or wet-source-change irradiator.[64]

---

[62]GrayStar Brief at 73; GrayStar Response at 7-8; GrayStar Reply at 3.

[63]Staff Response at 14.

[64]NUREG-1550, *Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations* (Nov. 1996), at 16.

The same language also appears in NUREG-1556.[65] Additionally, the following language is found in Draft Regulatory Guide DG-0003:

> In general, the use of cesium-137 chloride is not acceptable in pool (Category III and Category IV) irradiators or (Category II) dry-source-storage irradiators that load or unload sources under water at the irradiator because it does not meet the requirements of 10 CFR 36.21(a)(3).[66]

GrayStar also relies on some of the regulatory history preceding the adoption of section 36.21(a)(3) to support its reading of the section, including comments by Commissioner Greta Dicus and then-Chairman Ivan Selin. During a 1991 meeting, Commissioner Dicus recommended that cesium-137 chloride not be excluded as a source material "so long as it is appropriately encapsulated in appropriate form for the kind of irradiator that it is going to be used in."[67] And in a 1992 meeting, then-Chairman Selin 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.[68]

GrayStar argues that the Staff's failure to follow up by providing justification for the requirement for dry irradiators in the final rule, which was changed from the originally-proposed, "[m]ust use radioactive material that is as insoluble and nondispersible as practical," to the present reading, supports its reading of the rule.

Although the language quoted above from the guidance documents illustrates some confusion around the issue of the applicability of section 36.21(a)(3) to dry-source-storage irradiators, and although no justification for or clarification of the prohibition for dry-source-storage irradiators was discussed in the 1993 SOC for Part 36 as directed by Chairman Selin, there has been no showing that interpreting the regulation according to its plain meaning would

---

[65]NUREG-1556, Vol. 3, *Consolidated Guidance About Materials Licenses - Applications for Sealed Source and Device Evaluation and Registration* (Sept. 1997), at 4-9.

[66]Draft Regulatory Guide DG-0003, "Guide for the Preparation of Applications for Licenses for Non-Self-Contained Irradiators," at 3-5.

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

[68]SRM-921027, Staff Requirements-Affirmation Session/Discussion and Vote, 10:30 a.m., Oct. 27, 1992, encl. 3, at 1 ("Chairman Selin's Comments on SECY-92-323").

produce an absurd or similar undesirable result. Moreover, interpretation from such guidance and history "may not conflict with the plain meaning of the wording used in [a] regulation," which in the end "of course must prevail."[69]

Based upon the preceding analysis, I find GrayStar's arguments to be without merit, and conclude that 10 C.F.R. § 36.21(a)(3) does apply to the GS-42 sealed source. GrayStar must therefore establish, under section 36.21(a)(3), that the GS-42 sealed source will use "radioactive material that is a nondispersible as practical."

With regard to what is required in making such a showing, the Staff argues that "[i]t 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 '<u>radioactive material</u> that is as nondispersible as practical'."[70] However, the Staff has agreed that the use of cesium-137 chloride is not absolutely foreclosed for use in the GS-42 sealed source, provided adequate justification for such use is demonstrated by GrayStar.[71] The Staff has given examples, in a telephone conference, of circumstances that might in its view constitute adequate justification for the use of cesium-137 chloride: first, if cobalt became unavailable because there was no cobalt to be found; and second, if a single irradiator needed replacement sources, in a limited circumstance.[72]

The Staff has also cited language in the 1993 SOC for Part 36 to the effect that "[t]he NRC has decided not to approve further use of cesium sources, although the term 'as practical'

---

[69]*See Long Island Lighting Company* (Shoreham Nuclear Power Station, Unit 1), ALAB-900, 28 NRC 275, 288-290 (1988), *review declined*, CLI-88-11, 28 NRC 603 (1988). It is noted that the Staff filed with its Oct. 30, 2000, Response, the affidavit of Stephen A. McGuire, who according to the affidavit was the principal author of Part 36, the SOC for it, and the 1994 Draft Regulatory Guide DG-0003, and who states that the statement in DG-0003 is "not accurate." McGuire further states in his affidavit that he does not recall why he included this statement in the Guide; that his erroneous statement was not included in Volume 6 of NUREG-1556, *Consolidated Guidance About Materials Licenses - Program-Specific Guidance About Materials Licenses, Final Report* (Jan. 1999), which states at page 8-5 that, for any sealed source not yet installed in an irradiator, the source "must meet the requirements" of 10 C.F.R. § 36.21; and that he views this statement as correcting his 1994 error. Although the corrective nature of this later statement is not completely self-evident, the words of the rule must prevail over all such guidance in any event, as indicated in the text.

[70]Staff Response at 21 (emphasis supplied by Staff).

[71]Transcript at 21 (Aug. 15, 2000).

[72]Transcript at 119-120, 129 (Nov. 8, 2000).

would allow the NRC to make an exception where justified to the NRC."[73] This language, although perhaps not the first interpretation of section 36.21(a)(3) that would spring to mind based upon its actual words, is not inconsistent with the words of the section. Therefore, having been endorsed by the Commission in its 1993 SOC, it is entitled to "special weight" under relevant case law.[74] As such, it supports the Staff's argument to the effect that section 36.21(a)(3) is to be construed to require a high level of justification for the use of any form of cesium -- a "very strong presentation . . . that it would be safe to use cesium chloride powder" in the GS-42.[75] At the same time, the use of the word "practical" in section 36.21(a)(3) suggests that considerations of the sealed source form, proposed usage, and encapsulation design, along with other relevant factors, are also appropriate in determining whether a sealed source meets the requirement of the section.

B. Whether the GS-42 Sealed Source Meets the "Nondispersible as Practical" Requirement of 10 C.F.R. § 36.21(a)(3)

GrayStar proposes that, as the source material for the GS-42, it will use cesium-137 chloride caked powder. Thus, as indicated above, it must meet a rigorous standard of showing that such use of cesium-137 chloride would be safe, and "as nondispersible as practical." Whether or not the standard of justification should be quite so stringent as illustrated by the Staff's two examples, the Staff's view that the primary concern is the hazard that would be posed by any leak of cesium-137 chloride because of its dispersibility[76] is found to be persuasive, especially in view of the very high radiological content of each GS-42 sealed source and of the Model 1 irradiator as designed, with its 64 sealed sources. Therefore, as the Staff contends,[77] in making the "nondispersibility" determination required under section 36.21(a)(3), it is appropriate to consider not only methods of preventing leaks in the GS-42, but also the manner in which any leak that did occur would be mitigated to prevent and limit any dispersion of the source.

---

[73] 58 Fed. Reg. at 7718.

[74] Shoreham, ALAB-900, 28 NRC at 290-291.

[75] *See* Transcript at 9 (Aug. 15, 2000).

[76] *See* Staff Response at 23.

[77] *Id.* at 33.

GrayStar asserts that the cesium-137 chloride to be used in the GS-42 meets the nondispersibility requirement of section 36.21(a)(3) by virtue of several factors. These may be grouped into two categories: (1) the properties of cesium-137 chloride caked powder as compared to other source materials; and (2) design features of the GS-42 sealed source. GrayStar's argument on both of these categories is presented in the context of the above-described design features of the Model 1 irradiator, which are asserted by GrayStar to assure the nondispersibility and safety of the cesium-137 chloride in the GS-42 even further.

1. GrayStar's Reasons for Choosing Cesium-137 Chloride for GS-42 Sealed Sources

GrayStar states that it chose cesium-137 chloride as the source for its irradiator over cobalt-60, which occurs as a solid metal and is used in irradiators in the form of metal rods (or, in times past, pieces of metal wire), "in order to obtain the health and safety advantages inherent in [the] Model 1 irradiator's modular, standardized design approach."[78] Because it emits gamma rays with lower energy than cobalt-60 (0.662 MeV as compared to an average 1.25 MeV), cesium-137 does not require as much heavy shielding and can be more easily transported than any irradiator using cobalt. In this regard, GrayStar asserts that the 167-ton weight of the GraySafe using cesium-137 chloride -- as compared to an estimated 300-ton weight if the Model 1 used cobalt-60 -- is the upper limit of what is commercially transportable to food producers on a practical basis.[79] In addition, cesium-137 was chosen because, as noted above, its longer half-life avoids the need for either frequent on-site loading of new sources or frequent transporting of the irradiator to be reloaded, both of which GrayStar argues would involve increased risk of radiation exposure to workers and the public in violation of the NRC's as low as reasonably achievable (ALARA) policy, as well as undermine the commercial utility and practicality of the irradiator.[80]

According to GrayStar, most injuries involving exposure to radiation in cobalt irradiators have occurred when a person walked into an irradiation chamber when the sources were exposed because interlock protection systems had failed. In contrast, says GrayStar, the Model 1 is "designed to make such accidents physically impossible," by making the sources

[78] GrayStar Brief at 27.

[79] *Id.* at 22, 27-30.

[80] *Id.* at 30.

integral with the shielding, so that they cannot be moved independently of the shielding material, and cannot physically be raised into the chamber when the chamber door is open.[81] GrayStar asserts that the only way that a human being could be exposed to the radiation sources in the Model 1 irradiator would be for a person to go or be placed into the chamber and for another person then intentionally to close the chamber doors, put the handle keys into the console and turn them to raise the “door source” box and sources until the sources surrounded and irradiated the chamber. As compared to a large cobalt-60 facility-type irradiator, because of the Model 1's small size there would be no way for an operator to miss seeing a person inside its irradiation chamber, no easy entry by a person at any time, and no room for such entry while a food product was in the chamber to be irradiated.[82]

In comparing cesium-137 chloride to cobalt as a source, GrayStar also cites NUREG/CR-6642 for the proposition that “[t]he accident risk for the Co-60 device is larger than that for the Cs-137 device because of the larger assumed source strength. While the form of the Cs-137 is more prone to spreading contamination if the encapsulation fails, this is not a major risk contributor.”[83] However, this statement is made in the context of evaluating cobalt systems with a typical source strength value of 9000 Ci and cesium-137 chloride systems with a typical source strength value of 2000 Ci. This is far lower than the 51,500 Ci strength of the GS-42 sealed source (double the highest licensed source strength of 22,500 Ci cited in the report),[84] which is proposed to be used in an irradiator with a total strength of approximately 3 million Ci. Therefore, the quoted statement cannot be given great weight in the context of this case, given that the consequences of a GS-42 capsule failure would be significantly greater than a failure of a 2000 Ci source or even a 22,500 Ci source.

GrayStar also chose to design an irradiator that uses cesium-137 as the source rather than one using either electron beam or X-ray radiation. According to GrayStar, it did not choose to use electron beams because they have limited ability to penetrate food, thus limiting

---

[81] *Id.* at 25-26.

[82] *Id.* at 23.

[83] GrayStar Response at 19; NUREG/CR-6642, *Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems,* Section 3.0, Vol. 2, SCIE-NRC-379-99, at 3-446 (Feb. 2000).

[84] NUREG/CR-6642, Vol. 2 at 3-440, 3-444.

the amount of food that could be irradiated at one time. Further, GrayStar determined that the use of X-ray technology is prohibitively costly.[85]

What GrayStar has chosen to use as a source, as indicated above, is cesium-137 chloride, which is used in some already-licensed irradiators. GrayStar chose to use this salt form over other forms of cesium, and also chose to use a particular form of cesium-137 chloride. Cesium is a metallic element that occurs naturally in the form of monovalent cesium salts and oxides; it does not, according to GrayStar, ever take the form of a solid metal.[86] Most forms of cesium are water soluble. At least one form -- cesium dispersed in glass by vitrification -- is not water soluble, but GrayStar chose not to use this because it would require a greater amount of material to achieve the same irradiation levels as cesium-137 chloride. This would, in turn, cause greater heat generation, resulting in thermal stresses on source encapsulations, operating temperatures beyond the Model 1 design basis, and possible shattering of the glass upon cooling with resulting small fragments available for leakage. Also, GrayStar states that the complexity of producing compounds other than cesium-137 chloride would cause "major difficulties and complexities in hot cell operations for source preparation."[87]

Cesium chloride takes the form of a crystalline solid, which can range in form from a block to coarse crystals to a fine powder.[88] The block form of cesium-137 chloride (formed by a melt-cast process) has been shown to swell with increased temperature, thereby placing potentially significant stress on steel encapsulation containers and actually causing a breach in one such container (the DOE WESF cannister[89]) in the 1980's. Based on these factors, GrayStar chose not to use the block form of cesium-137 chloride. Instead, it proposes to use cesium-137 chloride in a "caked powder" form, which, it argues, would be more "deformable" or flexible than the block form and have other advantages as well.

---

[85]GrayStar Brief at 28.

[86]*Id.* at 14.

[87]*Id* at 32.

[88]*Id.* at 14-15.

[89]See 58 Fed. Reg. at 7716. In the SOC for Part 36, the Commission discusses the failure of the WESF capsule (*see also* note 20 above), the subsequent removal of all such sources from irradiators, and concludes the discussion of this subject by noting that, "[a]s a consequence, this final rule was written to require that irradiators use radioactive materials that are as insoluble and nondispersible as practical (typically cobalt-60)." *Id.*

This caked-powder form would be produced by creating a cesium-137 chloride and distilled water solution and then evaporating the water by heating the solution in the source container, a doubly-encapsulated stainless steel tube that is described below in greater detail. GrayStar asserts that because this cake form would have the ability to flow and conform within the encapsulation, it would avoid the stresses caused by the block form of cesium-137 chloride used in the 1980's.[90] GrayStar argues that the solid cake form would also be less likely to be dispersed from any container breach or rupture than would occur with a granular crystal salt (in a state similar to table salt). It notes as well that even cobalt-60 sources can leak and thus be dispersed.[91] In addition, GrayStar states that any stressing temperature changes will be avoided by maintaining the sources in the GS-42 at a consistent temperature, in part through the dry-storage aspect of the design, which will prevent the sort of thermal cycling involved in water storage of sources with attendant cooling (and shrinking) of the source while in the water and heating up (and swelling) of the source while out of the water for irradiation. Dry storage is also asserted to exclude the potential for dispersal in water, and to reduce the potential for corrosion of the source capsules.[92] According to GrayStar, periodic radiation surveys, proposed to occur every six months, would detect any leakage that did occur and allow for remedial action to be taken.[93]

2. Staff Concerns on Use of Cesium-137 Chloride

The Staff acknowledges the drawbacks in the need for heavier shielding and more frequent source changes with cobalt irradiators as compared to irradiators using cesium, but contends that the Commission was aware of these factors and the weight-transportability issue with cobalt irradiators when it established the performance criteria of 10 C.F.R. § 36.21 in 1993, including its “qualified ban on any new use -- in panoramic irradiators [such as the Model 1] -- of

---

[90] *See* GrayStar Brief at 15-16.

[91] *See id.* at 15-17. GrayStar cites NUREG-1345, *Review of Events at Large Pool-Type Irradiators* (March 1989), at 11 for its reference to “several source leakage events [that] have been reported for cobalt-60 sources used in water pool irradiators.” *Id.* at 14, n. 10.

[92] *Id.* at 16-17, 21, 23-24.

[93] *Id.* at 18.

sealed sources containing dispersible cesium [without] substantial justification." [94] According to the Staff, "[t]he Commission determined that the safety hazards associated with leaks of dispersible cesium chloride, even though the leaks were infrequent, justified restricting its use."[95] The Staff asserts that GrayStar has not justified its proposed use of the dispersible cesium-137 chloride caked powder, stating that the primary safety concern with the use of cesium-137 chloride "is its dispersibility once a leak occurs, rather than [its] potential to <u>cause</u> a leak."[96]

The Staff argues that the longer half-life and decay time of cesium-137, combined with its dispersibility, could actually present an increased risk in comparison with cobalt-60 if a leak or other safety problem occurred, including the possible increased risks associated with a proliferation of smaller (non-cobalt) irradiators "in the vicinity of food processors, whose personnel have no previous training or experience with radiation safety."[97] The Staff has also questioned the adequacy of GrayStar's safety analysis and probability risk assessment, arguing that it has failed adequately to address the long-term reliability of the GS-42 sealed source, to identify and analyze potential failure modes, and to present a set of physical parameters in quantified terms to support its claim that the caked powder form of cesium-137 chloride would be less likely to cause a breach than the block form used in the WESF capsules.[98] And the Staff asserts that the six-month radiation monitoring schedule is not frequent enough to detect and address promptly any leaks that might occur.[99]

---

[94]Staff Presentation at 8-9; *see also* Staff Response at 30.

[95]Staff Response at 31. The Staff's assertions that GrayStar's arguments comparing cesium sources to cobalt are in effect a challenge to the regulations, *see* Staff Presentation at 9-10, Staff Response at 31, need not be addressed in this decision, as GrayStar's arguments are taken as challenging not the rule itself but rather the applicability of it to the GS-42 and, more specifically, as raising issues of what constitutes appropriate justification for the use of cesium-137 chloride under the "as nondispersible as practical" language of section 36.21(a)(3). To the degree GrayStar's arguments challenge the NRC interpretation of the rule as expressed in the SOC for Part 36, this may be raised with the Commission in any appeal that may be taken from this decision.

[96]Staff Response at 32 (emphasis in original).

[97]Staff Presentation at 9 n. 4.

[98]*Id.* at 9, 20; Staff Response at 32-34.

[99]*Id.*

The Staff contends that, notwithstanding all the factors GrayStar asserts to justify using cesium-137 chloride in the GS-42, cesium-137 chloride powder -- even in its “caked” form -- is dispersible, not only in water but also in air, by physical forces such as air turbulence, physical contact, fire or explosion, should there be a leak in any of the source capsules.[100] Indeed, the Staff asserts, the caked powder form of cesium is more likely to leak out of a breach than is the block form used in the WESF sealed sources, identified by the Commission as a safety concern in 1993 when Part 36 was adopted.[101] The Staff asserts that 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”.[102]

GrayStar’s argument that the irradiator could be moved off-site in its own cask if there were a radiation leak, and that this is a mitigating factor, is also viewed by the Staff as inadequate justification for using cesium-137 chloride because of the uncertainty of whether any leak would necessarily be confined to the irradiator, and of whether transportation of an irradiator with a leaking source could in fact be safely undertaken.[103] GrayStar has stated that the design of the Model 1 would allow for a leak to be addressed on-site, off-site, or both, as necessary,[104] but has not provided any specifics of how this would be accomplished.

3. Size of GS-42 Sealed Sources and Model 1 Irradiator

The issue of the size of the Model 1 and the GS-42 sealed sources and their radiological content in comparison with smaller cesium irradiators is a central issue for the Staff. As indicated above, each Model 1 irradiator is designed to contain 64 individually-sealed cesium-137 chloride sources, each encapsulated in double stainless steel tubes, with a total strength of 3 million Ci.[105] One example of the currently existing smaller NRC-licensed irradiators that use cesium-137 chloride (also in dry storage) is that used by the USDA/ARS in Pennsylvania, which

---

[100]Staff Response at 2-3.

[101]*Id.* at 32; *see also* 58 Fed. Reg. at 7716; Staff Response at 4; *supra* note 89.

[102]Staff Response at 32 (emphasis in original).

[103]Staff Presentation at 13.

[104]GrayStar Response at 16-17.

[105]GrayStar Brief at 19, 20 n. 13.

has a total licensed strength of 250,000 Ci.[106] Most smaller irradiators that use cesium-137 as a source contain 30 Ci per source, much less than the 51,500 Ci per source contemplated for the GS-42.[107]

Declaring that it has studied the operational history of existing and past irradiators that use cesium-137 as a source, GrayStar asserts that the GS-42 has been designed to take advantage of some of the better design features of smaller cesium irradiators, including making the sources integral parts of the irradiator devices, using self-shielding, and using a smaller irradiation chamber than cobalt irradiators use. GrayStar asserts that, just as with smaller cesium irradiators, any leak in a source in the GS-42 would be localized to that source alone, and the solid cake form of the source would prevent dispersal of the source.[108] According to GrayStar, there are no everyday mechanisms "with the obvious potential to cause a large breach or rupture" of multiple sources,[109] as evidenced by the hundreds of cesium chloride irradiators that have operated without problems for more than 30 years. Moreover, GrayStar contends, with the WESF sources, there was only one leak out of 766 sources in four irradiators with water storage of sources that were used for many years, and this leak ultimately released 8 Ci out of a source containing over 50,000 Ci in water, which was much less severe than several leaks in cobalt sources.[110]

While not discounting the importance of the operational history of smaller cesium irradiators, the Staff argues that it is not transferable to the GS-42, given the large difference between the 30 Ci sources generally utilized in the smaller irradiators, and the 51,500 Ci radiological activity of one GS-42 sealed source.[111] According to the Staff, because each GS-42 capsule would contain substantially more radioactive material than sources in the smaller cesium irradiators, "the potential exists that more material would disperse" from a single GS-42

---

[106]*Id.* at 18-19 (citing USDA Materials License (NRC), Amendment 55, Dkt. No. 030-06923).

[107]Staff Presentation at 6 (citing Staff's May 24, 2000, Denial Letter, Attachment 1, Hearing File Vol. V, Section VII.A).

[108]GrayStar Brief at 19.

[109]*Id.*

[110]GrayStar Response at 18.

[111]Staff Presentation at 7.

capsule than from a single smaller source capsule.[112] The Staff points out that the amount of material that leaks in any given situation also depends upon circumstances such as the size of a breach in a capsule; heat and pressure build-up in a defective source; the existence of air turbulence, fire or explosion in the irradiation chamber to disperse the material; and how long it takes before a leak is identified.[113]

GrayStar, however, contends that the encapsulation design for the GS-42 renders the cesium-137 chloride that is proposed to be used in it "as nondispersible as practical." It is thus appropriate to consider in some detail this design.

4. Design of GS-42 capsules

Each GS-42 sealed source is designed to be encapsulated in a stainless steel tube that is in turn encapsulated in another, slightly larger stainless steel tube. The overall length of the tubes would be either 46.47 inches or 38.47 inches long; the Model 1 irradiator would contain 32 capsule tubes of each size.[114] The shape of a cross section of each of these tubes is an elongated oval, with flat sides. The inner tube is approximately 2.75 inches across the long dimension of its cross section, and approximately 1 inch across the short dimension. The flat sides of the long dimension of the inner tube extend approximately 1.75 inches before rounding at each end into a curve with a radius of slightly less than .5 inch. The outer tube is approximately 3 inches across the long dimension of its cross section, and approximately 1.25 inches across the short dimension. The flat sides of the outer tube, corresponding with the flat sides of the inner tube, extend approximately 2 inches before rounding at each end into a curve with a radius of slightly more than .5 inch.[115] The thickness of the stainless steel of which the tubes are made is 0.049 inch.[116]

According to GrayStar, although the elongated oval tubes are more expensive and difficult to manufacture than are the cylindrical capsules that are traditionally used for irradiator

---

[112]Staff Response at 34.

[113]*Id.* at 33.

[114]Hearing File, Vol. V, Tab VI.F.1, September 1999 Application for Sealed Source and Device Evaluation and Registration, Revision 01, at 10.

[115]Hearing File, Vol. II, Tab IV.J.

[116]GrayStar Brief, Attachment A at 9.

sources, they are more efficient than cylindrical capsules, for the following reasons: (1) the radioactive material in the center of a cylindrical capsule is significantly shielded by the rest of the source material and thus more source material must be used to achieve the same levels of radiation; (2) there is more of the source material to leak out of a cylindrical capsule in the event of a breach in the capsule; and (3) increased decay heat build-up can lead to increased thermal stress and potential source failure in a cylindrical capsule. In contrast, the shape of the GS-42 capsules serves to decrease the amount of self-shielding, reduce the operating temperature, and reduce the total amount of source material required to provide a given level of radiation.[117]

GrayStar also contends that the end caps for the capsule tubes are designed to minimize any transfer of stress to the source tubes, first, by making the end caps the sole load-bearing point of the encapsulations and the only part of the capsule designed to retain the source, and second, by dovetailing the end caps with the source racks, thereby preventing the capsules from coming loose and falling from the racks.[118] These factors, together with the dry source storage and elimination of significant thermal cycling, the isolation of sources and containment of sources in their own shipping cask (the “Graysafe”) as described above, the use of stainless steel 316L even when not required for dry-source storage irradiators, and the GrayStar source filling methods described below, are asserted to make the cesium-137 chloride source in the GS-42 as “nondispersible as practical.”[119]

The assembling and filling process planned for the GS-42 capsules may be summarized as follows: All seams between the tubes and their respective end caps are welded, leaving only two small threaded penetrations, one through an end cap of the inner capsule and one through the corresponding end cap of the outer capsule. Weld inspection is performed using nondestructive examination methods such as dye-penetrant testing, under “full NQA-1 Quality Assurance requirements [as requested by NRC Staff] to further ensure the nondispersibility of the cesium-137 chloride.”[120] After testing has been performed, the capsules are to be introduced into a “hot cell” at a government laboratory, where they would be filled using a

---

[117]GrayStar Brief at 37-38.

[118]*Id.* at 38-39.

[119]*Id.* at 34-45.

[120]*Id.* at 34-36.

mechanism designed so that no radioactive material would come in contact with the threads of either of the penetrations left open, or with any part of the annulus between the two tubes.[121] The GS-42 capsules are to be partially, or "low density," filled, to allow for accommodation of any expansion of the cesium-137 chloride. The cesium-137 chloride solution would next be evaporated through a heat and vacuum process; GrayStar's quality assurance plan, designated as "ASME-NQA-1," is asserted to ensure a maximum moisture content of 0.01 percent by weight.[122] The sources would then be purged with dry helium to remove any elements of ambient air that might interact with the cesium-137 chloride. Helium's heat transfer properties are asserted to reduce material operating temperatures even further.[123] Two mechanical seals would then be "torqued down with high pressure to ensure the plug is permanent,"[124] followed by "an additional redundant step of adding a seal weld around the outside mechanical seal."[125]

GrayStar asserts that its examination, testing and filling procedures will ensure source capsule integrity, and that its double-encapsulation design will meet the NRC's defense-in-depth approach.[126] GrayStar further supports the safety of the GS-42 by pointing out that the GS-42 was designed in accordance with the IAEA Safety Standards, Safety Series No. 6, 1985 Edition (As Amended 1990), which states "[s]pecial form radioactive material shall mean either an indispersible solid radioactive material or a sealed capsule containing radioactive

---

[121] *Id.* at 34-36, 41.

[122] *Id.* at 62.

[123] *Id.* at 39-40.

[124] *Id.* at 36.

[125] *Id.* at 37.

[126] *Id.* at 34-35; 39-40.

material."[127] Finally, GrayStar notes that its quality assurance program for "radioactive material packages" has been approved by the NRC.[128]

5. Staff Concerns Related to Design of GS-42 Sealed Source

Acknowledging that "GrayStar made a 'good faith' effort to design its sources so that leaks are unlikely," the Staff nonetheless maintains that because all sources are required to be designed so that leaks are unlikely, its design process for the GS-42 does not relieve GrayStar from justifying "the use of dispersible cesium-137 chloride material."[129] According to the Staff, no matter how well-designed the GS-42 sealed source is, problems associated with the proposed use of cesium-137 chloride in it mandate that the requested registration be denied. In addition to problems of dispersibility in air if a leak occurred, radiation surveys that are too infrequent, and inadequate safety analysis and probability risk assessment, the Staff raises questions about the testing of the sources, and the potential for corrosion inside the capsules.[130]

Testing issues are discussed below. With regard to potential corrosion, the Staff challenges the filling process, noting that introducing a solution of chloride ions, which are corrosive, into stainless steel capsules "has the potential to compromise the structural integrity of the encapsulation."[131] Even though GrayStar proposes to analyze the moisture content in simulated encapsulations prior to filling of the actual capsules,[132] the Staff asserts that GrayStar

---

[127]GrayStar Response at 14 (citing IAEA Para. 502-504). GrayStar has also noted IAEA Safety Series No. 107, Radiation Safety of Gamma and Electron Irradiation Facilities (1992), which defines "sealed source" as "[r]adioactive material sealed in a capsule that is strong enough to prevent dispersion of the radioactive material under the conditions for which it was designed," and argues, vis a vis the Staff's position in the alternative that the fact of using cesium-137 chloride itself makes compliance with the nondispersibility requirements of 10 C.F.R. § 36.21(a)(3) essentially impossible, that "to regulate the use of CsCl based solely on the material itself and not the encapsulation defies the whole purpose of 'sealed source' designation." GrayStar Reply at 2-3 n. 1.

[128]GrayStar Response at 15.

[129]*See* Staff Response at 34.

[130]*Id.* at 22 n. 25; 26; 29.

[131]Staff Response at 27, 29.

[132]GrayStar Brief at 63.

has not established that there would be adequate quality control measures to assure that there would be no internal corrosion and that moisture content would be below 0.01 percent.[133]

6. Conclusions on Whether GS-42 Meets Requirement of 10 C.F.R. § 36.21(a)(3)

GrayStar has not justified the use of caked powder cesium-137 chloride in the GS-42 sealed source. This conclusion is based on GrayStar's failure to establish by a preponderance of the evidence that the cesium-137 chloride, as proposed to be used in the GS-42 sealed sources, is "as nondispersible as practical." First, GrayStar has not established by a preponderance of the evidence that there would be adequate quality control measures to assure that moisture in the capsules would be within the 0.01 percent limit. As argued by the Staff, absent such measures, the potential for corrosion within a capsule, which could occur if there is moisture in the capsules and which would increase the risk of a leak, is an unresolved issue directly related to dispersibility.

Second, GrayStar has not established by a preponderance of the evidence that the probability risk assessment it has done adequately addresses the unique circumstances related to the risks associated with the GS-42 as it would be used in the Model 1 irradiator. Specifically, GrayStar has not sufficiently addressed the concerns raised by the Staff relating to the use of cesium-137 chloride caked powder, the factors that could influence the dispersibility in air of the cesium-137 chloride powder if a breach occurred, the size and radiological strength of the GS-42 and the Model 1 irradiator in which it will be used, and the design of the GS-42 as related to source-filling and testing.

Third, GrayStar has not established by a preponderance of the evidence that radiation monitoring would be frequent enough to detect adequately and/or most effectively mitigate any leaks that might occur. It is evident that if a capsule failure did occur, cesium-137 chloride could leak out, even at a very slow rate, over the course of six months. Finally, although questions relating to testing of the sources are addressed in the next section, the findings and conclusions drawn therein are also relevant to the justification issue under section 36.21(a)(3), in that they relate to the potential for leaks and mitigation of any leak that could occur. In this regard, GrayStar has not established by a preponderance of the evidence that adequate testing has been completed to justify the use of cesium-137 chloride in the GS-42.

---

[133]Staff Presentation at 17 *et seq.*; Staff Response at 29.

All of the preceding conclusions are reached in the context of the very high radiological content of the GS-42 sealed sources as they are proposed to be used in the Model 1 irradiator, and of the proposed usage of the Model 1 irradiators in many food production facilities by relatively untrained personnel. In this context, although GrayStar has developed an innovative and unique design, it is appropriate to require a high standard of justification for the use of cesium, especially in the inherently dispersible form chosen by GrayStar. Although I do not conclude herein that the GS-42 could never meet such a high standard, I do conclude that GrayStar has not made such a showing in this proceeding.

C. Whether the Design and Testing of the GS-42 Meet the Requirements of 10 C.F.R. § 36.21(a)(2) and (a)(5)

10 C.F.R. § 36.21(a)(2) provides that sealed sources installed after July 1, 1993, "must be doubly encapsulated." 10 C.F.R. § 36.21(a)(5) provides that sealed sources "[i]n prototype testing . . . must have been leak tested and found leak-free after each of the tests described in paragraphs (b) through (g) of [section 36.21]." Paragraph (b) of section 36.21 concerns temperature testing, including a thermal shock test; paragraph (e) has to do with vibration testing. The Staff questions two aspects of GrayStar's testing of the GS-42 sealed source: (1) the failure of the inner seal plug of the GS-42 capsule during part of the thermal shock testing, which was not followed up by a correction to assure that the inner seal plug was leak-free after testing, and which the Staff asserts does not fulfill the requirements of subsections (a)(2) and (a)(5) of section 36.21; and (2) the failure to do vibration testing on the third axis of the capsule tubes, which the Staff asserts does not fulfill the requirement of section 36.21(a)(5).[134]

GrayStar has had various tests performed on the GS-42 sealed source capsules, including parameters for temperature, pressure, impact, vibration, puncture and bending.[135] The temperature and vibration parts of the testing were conducted by Smithers Scientific Services, Inc., of Akron, Ohio, or by its subcontractor, Peterson Heat Treating of Kent, Ohio.[136]

1. Temperature Testing

---

[134]Staff Presentation at 14-16; Staff Response at 34-38.

[135]GrayStar Brief at 50.

[136]Hearing File, Vol. I, Tab IV.E, "Exhibit 3 - Prototype Testing - Source," at page 7 of unnumbered pages.

During the heat testing of the GS-42 sealed sources, two outer capsule leaks developed, and one inner capsule failure occurred. The leaks in the outer tubes occurred during tests performed by Peterson Heat Treating. Prior to testing, stainless steel plugs were welded in the outer blind endcap test holes. A very large calibrated gas fire furnace was used to heat two source assemblies to 800°C. The source assemblies were stacked on top of each other in a horizontal configuration similar to the vertical position designed for the Model 1 irradiator. After one hour at temperature the assemblies were removed to cool prior to integrity testing. No leaks were detected at this point, despite some anticipated ballooning; the non-radioactive cesium chloride used during the test had become molten and flowed to the bottom of the source capsules where it solidified upon cooling. Plugs were again seal-welded into the outer blind endcap test holes, and the assemblies were reheated to 600°C for a thermal shock test designated as TRS-005. After holding at temperature for 15 minutes, the assemblies were removed and lowered into water at ambient temperature within 10 seconds; no bubbles were observed coming from the tubes while in the water. After the assemblies were allowed to cool, however, helium leaks were detected in the seal surfaces of both outer encapsulations. At this point there were no leaks in the inner capsules.[137]

Smithers Scientific Services did an additional integrity check to help determine the cause of the leaks in the outer capsules. After torquing in seal plugs and making sure that there were no leaks, the items were placed into a furnace, brought up to a temperature of 600°C, and then dropped into ambient temperature water within a few seconds. A leak was found on the inner seal plug. It was determined that the cause of the leaks in the thermal shock test “had to do with the seal itself”;[138] however, whether this reference is to the inner or outer seal plug, or both, is not specified. Two new test specimens were then prepared for additional testing by having their outer seals welded. Peterson Heating then redid the thermal shock test described above, and both specimens passed the leak test for both the inner and outer capsules. It was noted that there appeared to be no distortion between the outer end caps,

---

[137] *Id.* at 10-11.

[138] Hearing File, Vol. I, Tab IV.E, at 12.

indicating that no unusual loads would have occurred to cause source assembly distortion, had the capsules been mounted in a source rack.[139]

The conclusion drawn by GrayStar from this and additional leak testing was that only thermal test TSR-005 produced a helium leak in the outer encapsulation at the seal plug, but that after applying a seal weld to the outside of the outer seal plug, the source assemblies had passed the test. Thus, weld sealing of the outer plug was recommended, and it was concluded that "there is reason to believe that production GS-42 source assemblies will satisfy all of the performance specifications."[140]

The Staff asserts that the leaks in the seals of the outer and inner capsules indicate design deficiencies in the GS-42 and other violations of section 36.21 requirements, irrespective of the use of cesium-137 chloride, arguing as well that by virtue of its plans to use the dispersible cesium-137 chloride in the GS-42 sealed source, GrayStar must "demonstrate that a leak is substantially less likely for its sources, than would be the case for sources containing nondispersible material."[141] The Staff argues that the leak in the inner capsule, without subsequent modification, constitutes a failure to meet not only the requirement of 10 C.F.R. § 36.21(a)(5) that a source "must have been leak tested and found leak-free after each of the tests," but also the double encapsulation requirement of 10 C.F.R. § 36.21(a)(2).[142]

GrayStar asserts that the fact that the final testing yielded no failures in either the inner or outer source establishes that it met the requirement of the rule, citing ANSI Standard N43.6 (1997) 4.1.1, which states that "[a] source with more than one encapsulation shall be deemed to

---

[139]Hearing File, Vol. I, Tab IV.E, at 12-13.

[140]Hearing File, Vol. I, Section IV.E, at 13.

[141]Staff Presentation at 15; *see also* Staff Response at 35.

[142]Staff Response at 35-36. Noting that the testing was done using non-radioactive cesium, the Staff has also stated that it "has not yet taken a position on whether the use of non-radioactive cesium for testing purposes would be acceptable in this case." Staff Presentation at 15-16. In response, GrayStar points out dangers in using radioactive materials in testing and notes that 10 C.F.R. § 71.75 provides that "[e]ach solid radioactive material or capsule specimen to be tested must be manufactured or fabricated so that it is representative of the actual solid material or capsule that will be transported, with the proposed radioactive content duplicated as closely as practicable." GrayStar Response at 22. As noted by GrayStar, section 71.75 goes on to state, "Any difference between the material to be transported and the test material, such as the use of non-radioactive contents, must be taken into account in determining whether the test requirements have been met." *Id.* No ruling is made on this issue, however, as the Staff has not alleged any deficiency in this regard.

have complied with a test if it can be demonstrated that at least one encapsulation has maintained its integrity after the test."[143] The Staff, however, notes that this standard is "applicable only to sources containing a maximum activity level of 30 curies for cesium-137" under ANSI Standard N43.6-1997, Tables 2 and 3, making it inapplicable to the GS-42 sources.[144] The Staff argues that, even were the standard cited by GrayStar applicable, corrective action would still be needed for the inner seal in light of the test result showing a possible defect in it, given the "specific safety concern raised by the Commission with respect to the use of dispersible material."[145] The Staff disagrees with GrayStar's statement that "it is physically impossible for the inner seal plug. to be thermally shocked because the outer capsule thermally insulates the inner capsule,"[146] noting that since the inner cap is designed to be nested inside the outer end cap with direct metal-to-metal contact between the caps without thermal insulation, 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 would not necessarily provide isolation or complete thermal protection for the inner seal cap and seal plug, according to the Staff.[147]

2. Vibration Testing

The Staff also argues that relevant standards found in ANSI/HPS Standard N43.6-1997 require that sources like the GS-42 should be tested along three axes, rather than the two that were tested by GrayStar's contractor.[148] GrayStar does not contest the relevancy of these standards, but argues that it has met these requirements. Section 7.5.2 of this document requires that "each axis" be tested, with a note stating that "[a] spherical source has one axis taken at random. A source with an oval or disc-type cross-section has two axes: one of

---

[143]GrayStar Brief at 51.

[144]Staff Response at 36.

[145]*Id.* at 37.

[146]GrayStar Brief at 52.

[147]Staff Response at 37.

[148]Staff Presentation at 16, Exhibit II.

revolution and one taken at random in a plane perpendicular to the axis of revolution. Other sources have three axes taken parallel to the significant overall dimensions."[149]

The testing contracted by GrayStar was done on two axes of the source capsules, "in the longitudinal axis direction and in the operational vertical axis direction,"[150] which is taken to mean that the long axis perpendicular to the axis of revolution (along the length of the tube) was tested, and the longer axis of the cross section was tested, but that the shorter cross-section axis, i.e., from one flat side to the other flat side, was not tested. GrayStar argues that it was not necessary to test the sources across the shorter cross-section axis, because the GS-42 has "an oval or disc-type cross-section,"[151] which require only testing of two axes. The Staff contends that the shape of the GS-42 is not an "oval or disc-type cross-section," because of its flat sides -- that it falls rather into the "other" category, requiring testing along three axes.

3. Conclusions on Temperature and Vibration Testing of GS-42

GrayStar has failed to establish, by a preponderance of the evidence, that the thermal shock testing of the GS-42 satisfies 10 C.F.R. § 36.21(a)(5). This conclusion is based on GrayStar's failure to modify or correct the inner capsule seal plug after a leak was discovered in it during part of the testing. Although the outer seal failures were corrected, the failure of the inner seal was not, and thus it was not leak-free after each test. GrayStar's argument that the whole double capsule assembly passed the test that was performed after the inner seal plug failure occurred fails to take into account that, should there ever be a breach in the outer capsule, from whatever cause, it would then be possible for the inner seal plug to fail for the same reason it failed in the test. In addition, as the Staff points out, heat could be transferred to the inner endcap through the contact it has with the outer endcap. This could also potentially cause the inner capsule to fail within the outer capsule, which could result in eventual failure of the entire assembly. It is reasonable to require GrayStar to complete this part of the testing as Staff has suggested, particularly given the relatively large radiological content of each proposed GS-42 sealed source and the use to which it will be put.

---

[149] *Id.*

[150] Hearing File, Vol. II, Tab VI.B, at 13.

[151] Hearing File, Vol. II, Tab VI.B, GrayStar Application, Amendment 1-Vol. 1, at 13.

I also conclude that, by virtue of the inner seal plug leak, GrayStar has failed to establish, by a preponderance of the evidence, that the GS-42 meets the double encapsulation requirement of section 36.21(a)(2). If the inner seal plug has not been tested sufficiently to ensure that it will withstand relevant testing on its own, it stands to reason that what remains is a single capsule that has passed relevant testing requirements, i.e., only the outer capsule.

I further conclude that GrayStar has failed to establish, by a preponderance of the evidence, that the vibration testing of the GS-42 was sufficient to meet the requirements of section 36.21(a)(5). Although GrayStar argues that the cross section of the GS-42 capsule is an oval or disc-type cross-section, it is found that the two flat sides of the cross section make it not just a simple oval, but another shape, subject to the requirement to test in three axes. GrayStar, not having completed testing on all three axes, has therefore not met the requirement at section 36.21(a)(5) that "each of the tests" described in section 36.21(b) through (g), including subsection (e), be completed.

D. <u>Whether the GS-42 Meets the Requirements of 10 C.F.R. § 32.210(c)</u>

10 C.F.R. § 32.210(c) provides that a "request for review of a sealed source . . . must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing . . . to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property." The Staff asserts that, due to the problems, discussed above, associated with the proposed use of cesium-137 chloride caked powder, and due to the heat and vibration test deficiencies, GrayStar has failed to provide the reasonable assurance required by 10 C.F.R. § 32.210(c).[152]

By virtue of my previous conclusions (1) that GrayStar has not justified the use of cesium-137 chloride in the GS-42 sufficiently to fulfill the requirement of 10 C.F.R. § 36.21(a)(3), and (2) that GrayStar has failed to establish that the heat and vibration testing of the GS-42 fulfill the requirements of 10 C.F.R. § 36.21(a)(2) and (a)(5), I further conclude that GrayStar has failed to provide, by a preponderance of the evidence, the reasonable health and safety assurance required by 10 C.F.R. § 32.210(c). The purpose of the justification and testing at issue is to assure such protection of health and safety, and any omission to satisfy

[152] Staff Response at 22 n. 25.

fully the requirements of section 36.21 thus cannot be said to provide the "reasonable assurance" section 32.210(c) requires.

III. CONCLUSION

Although GrayStar has spent a great deal of time and resources developing an innovative design for its Model 1 irradiator and GS-42 sealed source, the dispersibility in air of the cesium-137 chloride caked powder proposed for use in the GS-42 presents significant health and safety issues. Notwithstanding the potential benefits presented by GrayStar, a potential for harm also exists, should there be weaknesses that are not fully addressed prior to any manufacture of the Model 1 and the GS-42 sealed sources. Any hazard would be multiplied by the planned use of the irradiators in many locations across the country within food producers' own sites, by operators who will likely not be as well-trained as are others who work with radiation. Therefore, as the Staff has argued, a high standard of justification for the use of cesium-137 chloride is appropriate and, in keeping with the NRC's defense in depth philosophy and primary concern with safety, all of the requirements of applicable rules must be fully satisfied.

In this context, and based on the failure of GrayStar to establish by a preponderance of the evidence, (1) that its proposed use of cesium-137 chloride is justified in the GS-42 sealed source under 10 C.F.R. § 36.21(a)(3); (2) that the testing and double encapsulation requirements of subsections (a)(5) and (a)(2) of section 36.21 have been met; and (3) that the health and safety requirements of section 32.210(c) have been fulfilled, I conclude that the Staff's denial of approval and registration of the GS-42 sealed source must be upheld.

For the foregoing reasons, it is, this 27th day of February, 2001, ORDERED that:

1. The registration of the GS-42 sealed source is denied;

2. This proceeding is terminated; and

3. In accordance with the provisions of 10 C.F.R. §§ 2.1251 and 2.1253, this Initial Decision may be appealed to the Commission by filing an appeal statement that complies with the provisions of 10 C.F.R. §2.786(b). To be timely, an appeal statement must be filed within 15 days after this Initial Decision is served (i.e., on or before Monday, March 19, 2001.)

BY THE PRESIDING OFFICER[153]

\S

Ann Marshall Young

ADMINISTRATIVE JUDGE

Rockville, Maryland

February 27, 2001

[153]Copies of this Memorandum and Order were sent this date by Internet e-mail transmission to all participants or counsel for participants.