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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges:

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

In the Matter of GRAY*STAR, INC. (Suite 103, 200 Valley Road, Mount Arlington, NJ 07856)	Dkt. No. SSD 99-27 ASLBP No. 00-778-06-ML September 25, 2000

GRAY*STAR, INC.'S BRIEF IN SUPPORT OF APPLICATION FOR REGISTRATION OF MODEL GS-42 SEALED SOURCE

I. INTRODUCTION

Gray*Star, Inc. hereby submits this brief in support of its application for registration pursuant to 10 C.F.R. § 32.210, of the Gray*Star Model GS-42 sealed source,[1] which is only employed in the Gray*Star Model 1 irradiator.[2]

1 "Sealed source" is defined in NRC's regulations as "any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material." 10 C.F.R. § 36.2.

2 "Irradiator" is defined in NRC's regulations as

> a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

10 C.F.R. § 36.2.

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By way of background, Gray*Star, Inc. is a privately held company founded in 1989 with its headquarters in Mt. Arlington, New Jersey. Gray*Star's corporate objective is to manufacture and sell its Model 1 irradiator, which is specifically designed to meet the needs of the food industry. With the increase of food-borne pathogens and food-borne illness, the food industry has looked to irradiation as a means to ensure the safety of food and food products. As a consequence, a greater interest in irradiation technologies has developed. Food irradiation, which is the process of exposing food to high levels of radiant energy, is now a multi-billion dollar market and has been recognized by several federal agencies, including the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Food Safety Inspection Service (FSIS), and many foreign countries as a viable means of combating many types of food-borne disease. See e.g. 64 Fed. Reg. 72149 (Dec. 23, 1999) ("Irradiation of Meat Products; Final Rule"); 62 Fed. Reg. 64108 (Dec. 3, 1997) ("Irradiation in the Production, Processing and Handling of Food"); see also, Letter from Dr. Donald W. Thayer, USDA, ARS to NRC Administrative Judge Ann M. Young (Aug. 11, 2000) ("USDA Letter").

With regard to FDA specifically, it has evaluated irradiation safety for 40 years and found the process safe and effective for many foods. Most recently, red meat irradiation was approved. During the course of FDA's review of this use, it reviewed research on the chemical effects of radiation on meat, the impact the process has on nutrient content, and potential toxicity concerns. In this most recent review and in previous reviews of the irradiation process, FDA scientists concluded that irradiation reduces or eliminates pathogenic bacteria, insects and parasites. Further, the agency concluded that irradiation reduces spoilage, and in certain fruits and vegetables, inhibits sprouting and delays the ripening process. Also, it does not make food radioactive, compromise nutritional quality, or noticeably change food taste, texture or appearance as long as it is applied properly to a suitable product.

Irradiation has also been lauded by health experts who say that in addition to reducing E. coli O157:H7 contamination, irradiation can help control the potentially harmful bacteria Salmonella and Campylobacter, two chief causes of food-borne illness. The Centers for Disease Control and Prevention estimates that Salmonella--commonly found in poultry, eggs, meat, and milk-- sickens as many as 4 million people, and kills 1,000 people, per year nationwide. Campylobacter, found mostly in poultry, is responsible for 6 million illnesses and 75 deaths per year in the United States alone. A May 1997 presidential report, "Food Safety from Farm to Table," estimates that millions of Americans are stricken by food-borne illness each year and some 9,000, mostly the very young and elderly, die as a result. See generally, J. Henkel, FDA Consumer, Irradiation: A Safe Measure for Safer Food (May-June 1998).

The types of radiant energy typically used in food irradiation include: microwave and infrared radiation that heat food during cooking; visible light or ultraviolet light used to dry food or kill food surface microorganisms; and ionizing radiation, resulting from cobalt-60, cesium-137, x-ray machines, or electron accelerators, that penetrates into food, killing insect pests and microorganisms without raising the temperature of the food significantly or leaving any radioactive residue behind. Food and food products are most often irradiated commercially to extend shelf-life, to eliminate insect pests, or to reduce pathogenic microorganisms. See 64 Fed. Reg. 72149.

Gray*Star's staff has worked in the radiation industry and in government for over 40 years. Gray*Star began developing its Model 1 irradiator, which is designed to use cesium-137 chloride ($Cs^{137}Cl$) as a source of radiation, over a decade ago to specifically meet the food industry's need to combat the rise in food-borne disease. The Model 1 is specifically designed to provide a uniform dose of radiation to products with varying densities, e.g. produce, meat, including bone, etc., to ensure near complete eradication of food-borne disease causing insects, parasites and pathogens.

Also, Gray*Star recognized that to date, irradiated products have a cost that is slightly higher than untreated products due to the extra step irradiation adds to food processing. Major food companies such as poultry processors, meat packers, and grocery chains have yet to embrace irradiation partially due to logistical reasons. For example, Food Technology Service Inc., located in Mulberry, Florida, is the only irradiation facility dedicated solely to treating agricultural products. More than 40 other facilities nationwide primarily handle sterilization of medical supplies, though these plants also claim that they irradiate food products. In fact, it was a New Jersey-based medical irradiation company, Isomedix Inc., that petitioned FDA to approve red meat irradiation. Beyond physical distances and lack of facilities, product volume makes it unlikely that irradiation will be widespread using currently employed technologies. Recognizing the need for a new economically viable technology that is readily available to the food industry, Gray*Star designed the Model 1 to be safe, as efficacious as practicable, and with the ability to be installed at individual food facilities.

II. PROCEDURAL HISTORY

On April 19, 1999, Gray*Star submitted an application, followed by a letter dated September 27, 1999, requesting registration of its Model 1 food irradiator and the Gray*Star Model GS-42 sealed source, which is employed in the Model 1. Following extensive discussions and correspondence between Gray*Star and the NRC Staff, on May 24, 2000, the NRC Staff issued a letter denying Gray*Star's request for registration of the Model GS-42 sealed source.

See Letter from Donald A. Cool, Director, Div. of Industrial and Medical Nuclear Safety, NMSS, to Russell N. Stein, Gray*Star, Inc. (May 24, 2000).

In its letter, the NRC staff stated that Gray*Star's Model GS-42 source design "is not acceptable for registration and licensing under 10 C.F.R. § 32.210 and 10 C.F.R. § 36.21" due to the alleged failure of Gray*Star's application to "adequately justify [its] choice of cesium-137 chloride powder, a dispersible material." Id. The NRC Staff enclosed a "detailed statement" supporting its denial. Id. at Encl. 1.

With regard to the Model 1 irradiator generally, the denial letter stated that the NRC staff was suspending its review of the irradiator, which would contain the Model GS-42 sealed source. Although review has been suspended, the letter states that Gray*Star's application contains deficiencies with respect to the Model 1 irradiator which "would have to be addressed before [NRC] would approve the design." Id. A discussion of the "deficiencies" was attached to the letter as Enclosure 2. Id. The letter indicates that Gray*Star need not address the "deficiencies" in Enclosure 2 at this time because the NRC staff has suspended further review. Id. Finally, the letter offered Gray*Star an opportunity for a hearing pursuant to 10 C.F.R. § 2.103(b).

By letter dated June 1, 2000, Gray*Star requested that the NRC staff reconsider its decision to deny the registration of the GS-42 sealed source and Model 1 irradiator. Following multiple telephone conversations between Gray*Star and members of the NRC staff regarding the denial letter, the NRC staff declined to reconsider its denial decision. Consequently, on June 1, 2000, in accordance with 10 C.F.R. § 2.103, Gray*Star requested a hearing with respect to the NRC staff's denial of the request for registration for the GS-42 sealed source and Model 1 irradiator. On June 13, 2000, the Commission referred the request for hearing to the Atomic

Safety and Licensing Board Panel and directed the panel to appoint a presiding officer to rule on the request for hearing, and if necessary, conduct the hearing pursuant to 10 C.F.R. Part 2, Subpart L, "Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings." In the Matter of Gray*Star, Inc., 2000 NRC LEXIS 68 (June 13, 2000). The Commission explained in its order that since Subpart L "ordinarily governs materials licensing cases, including the NRC staff denials of requested agency approvals," and because "Part 36 involves materials licenses," it is "sensible" to apply Subpart L to this case.[3] Id.

Following designation of the Presiding Officer, on August 15, 2000, a telephone conference was held with the parties and the Presiding Officer during which the issues to be addressed in the hearing were discussed and clarified. See Transcript of Aug. 15, 2000 Telephone Conference. During the telephone conference, the parties agreed that the registration of Gray*Star's Model 1 irradiator will not be part of this proceeding because the NRC Staff has not denied Gray*Star's request for registration of the Model 1, rather it merely has suspended further review of the request for registration of the Model 1 and has provided Gray*Star with a list of deficiencies that need to be addressed prior to a final determination. Id. Perhaps most

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3 The Commission further noted in the order that Subpart L "expressly covers agency licensing actions 'subject to' Part 30." Id., citing 10 C.F.R. § 2.1201(a). While Gray*Star does not contest the Commission's determination that Subpart L should govern Part 36 licensing cases, it respectfully submits that this is not a licensing case under Part 36. Rather, the matter at issue in this case is the registration, as opposed to the licensing, of the GS-42 sealed source pursuant to 10 C.F.R. § 32.210. Contrary to the Commission's (and the staff's) apparent understanding, Gray*Star has not requested a license under Part 36. The staff's misunderstanding of this fact is reflected in the denial letter where it states that the GS-42 source design is "not acceptable for registration and licensing under 10 C.F.R. § 32.210 and 10 C.F.R. 36.21." Denial Letter at 1 (emphasis added). While a specific license ultimately may be necessary in the future (e.g. for Gray*Star and its customers) for sealed sources in a Model GS-42, a license is not at issue here.

importantly, the parties agreed that the use of cesium-137 chloride in sealed sources generally, and in the Model GS-42 sealed source particularly, is not foreclosed by regulation. Id.

Following the telephone conference, the Presiding Officer issued an order setting the schedule for the proceeding and setting forth the issues to be addressed in the parties' written presentations. See Order (Setting Schedule for Proceedings and Addressing Other Matters Considered at August 15, 2000, Telephone Conference), (Aug. 17, 2000) ("Order"). In the Order, the Presiding Officer instructed the parties to conform their written presentations to the format and list of issues set forth in the Order. Order at 3.

Following issuance of the Order, on September 7, 2000, a transcribed telephone conference was held at the request of Gray*Star with the Presiding Officer, counsel for Gray*Star, and counsel for and members of the NRC staff participating. As a result of the conference, the Presiding Officer issued an order dated September 14, 2000, admitting two new issues into the hearing: the applicability of 10 C.F.R. Part 36 generally, and Gray*Star's compliance with 10 C.F.R. § 36.35. See Order (Addressing Matters Considered at September 7, 2000, Telephone Conference), Dkt. No. SSD 99-27 (Sept. 14, 2000) ("September 14 Order"). In addition, the September 14 Order extended the deadline for the filing initial briefs in this proceeding to September 25, 2000. The September 14 Order did not change the Presiding Officer's instruction to conform the written presentations to the numbering system used and issues raised in the Order. Accordingly, the following discussion employs the same numbering system used in the Order and addresses all of the issues raised therein.

III. STANDARD OF REVIEW[4]

When reviewing a decision of the Staff to issue a materials license, the presiding officer is required to review de novo all issues sufficiently established by the parties. Because the applicant bears the burden of proof, the adequacy of the Staff's review is not determinative of whether the application should be approved. See In the Matter of the Curators of the University of Missouri, 1995 NRC LEXIS at *104-6 (1995) (citations omitted). For the presiding officer "to deny a meritorious application for a license based on the staff's error would be "grossly unfair." Id. at *106. The "sole focus of the hearing is on whether the application satisfies NRC regulatory requirements, rather than the adequacy of the NRC staff performance." Id. at *105. An application is not to be denied simply on the basis of a deficiency or omission in the application. See In the Matter of the Curators of the University of Missouri, 41 NRC 71, 1995 NRC LEXIS 21, *43 (1995).

In addition, the Commission has adopted a policy of risk-informed, performance-based approaches to NRC regulatory oversight and licensing. This policy resulted directly from the request of the Chairman of the Commission that the NRC "staff explore ways to reduce the regulatory burden . . . without compromising protection of health and safety and the

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4 The standard of review set forth below is based on the Commission's determination that the staff's denial of the registration is a "licensing action" subject to Subpart L. It is important to note however, that as discussed in footnote 3, supra, Gray*Star has not requested a license, but merely the registration of the GS-42 sealed source. Section 32.210, which governs registration, does not specify which of the hearing processes set out in 10 C.F.R. Part 2 or more importantly, the standard of review that applies to registration adjudications. Moreover, a review of the NRC caselaw suggests that a challenge to a registration decision may be a case of first impression. Gray*Star notes, however, that as discussed in further detail below, section 32.210 sets forth a standard for sealed sources, which provides that the staff should formulate, with the assistance of the applicant, reasonable standards if the normally accepted industry standards do not readily apply. See 10 C.F.R. § 32.210(d).

environment." The NRC is moving to implement this policy through the adoption of risk-informed, performance-based standards. Generally speaking, a performance-based approach establishes standards of performance that must be achieved by a regulated entity, while allowing flexibility as to the methods the entity may employ to achieve those standards. NRC has articulated four key elements to its approach to performance-based regulation:

> (1) There are measurable parameters to monitor acceptable plant and licensee performance; (2) objective performance criteria are established to assess performance; (3) there is licensee flexibility to determine how to meet established performance criteria; and (4) failure to meet a performance criterion must not result in unacceptable consequences.

A risk-informed, performance-based approach to regulation uses risk insights and deterministic analyses and performance history to develop parameters for monitoring the performance of a regulated entity, as well as for developing criteria for performance assessment. The use of a risk-informed, performance-based approach theoretically results in NRC focusing on specific areas of greatest concern as the primary means of regulatory oversight. The approach is intended to permit the licensee enhanced flexibility in complying with regulatory requirements while at the same time focusing regulator and licensee resources on those areas of greatest potential significance to human health and the environment. In keeping with this approach, section 32.210, which was adopted prior to the risk-informed, performance-based policy initiative, includes a performance-based type standard in that it permits the staff and the applicant to work cooperatively to develop reasonable standards and criteria governing the sealed source to be registered if accepted industry standards "do not readily apply to a particular case." See 10 C.F.R. § 32.210(d).

IV. GRAY*STAR WRITTEN PRESENTATION

As discussed above, Gray*Star is seeking the registration of product information regarding its GS-42 sealed source, pursuant to 10 C.F.R. § 32.210.[5] Before turning to the issues raised in the Order specifically, it is useful to briefly review the regulations governing the registration of sealed sources, and the performance requirements applicable to a specific NRC licensed sealed source.

With regard to the registration of a sealed source, 10 C.F.R. § 32.210 provides that any manufacturer of a sealed source whose product is intended for use under a specific NRC license may request that the NRC evaluate the radiation safety information about the product for registration. 10 C.F.R. § 32.210(a). Section 32.210(c) requires that a request for review of a sealed source include "sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing . . . to provide reasonable assurance that the radiation safety properties of the source [ ] are adequate to protect human health and minimize danger to life and property."[6] 10 C.F.R. § 32.210(c) (emphasis added).

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[5] While the only issue in the current proceeding is the registration of the GS-42 sealed source, one cannot reach sound conclusions regarding the registration of GS-42 sealed source without also considering certain aspects of the Model 1 irradiator because the GS-42 sealed source was designed simultaneous with, and specifically and solely for use in, the Model 1 irradiator. Therefore, in the following discussion addressing the matters set forth in the Order, Gray*Star includes references to specific aspects of the Model 1 irradiator that are relevant to the registration of the sealed source. Counsel for the NRC Staff has agreed that it is appropriate to reference aspects of the Model 1 irradiator in support of the registration of the sealed source. Telephone conference with J. Hull, Counsel for NRC Staff and Anthony J. Thompson and David C. Lashway, Counsel for Gray*Star (Sept. 19, 2000).

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

Section 32.210(d) states that "[t]he NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor." 10 C.F.R. § 32.210(d) (emphasis added). Finally, if the registration application is deemed adequate, the Commission issues a certificate of registration which acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the sealed source. 10 C.F.R. § 32.210(e).

As discussed above, 10 C.F.R. § 32.210, which permits the registration of products, provides that the NRC evaluates a sealed source for registration purposes using radiation safety criteria in accepted industry standards or reasonable standards developed with the help of the manufacturer. In contrast, section 36.21 of the NRC's regulations specifies design and performance criteria for certain sealed sources that are subject to a NRC specific license[7]:

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

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

(2) Must be doubly encapsulated;

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

(3) Must use radioactive material that is nondispersible as practical and that is insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator[8];

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

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

10 C.F.R. § 36.21.

Thus, the requirements that manufacturers of sealed sources must meet to obtain a registration pursuant to section 32.210 differ from those that a party seeking a specific license for a sealed source pursuant to 10 C.F.R. § 36.21 must satisfy. Importantly, Gray*Star only requested the registration of, not a specific license for, its GS-42 sealed source. With this background in mind, we turn to the issues raised in the Order.

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

The first bases of denial asserted by the staff in its May 24 letter relates to the dispersibility of cesium-137 chloride powder as used in the GS-42 sealed source.

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

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

The two primary NRC licensed types of sources available for use in irradiators are cobalt-60 and cesium-137. See NUREG a/CR-6642 at 3-413, 3-439; See generally, 55 Fed.Reg. 50008 (Dec.4, 1990). The NRC Staff has acknowledged that both cobalt-60 and cesium-137 can be used in sealed sources for irradiators within the requirements of 10 C.F.R. Part 36. Order at 1. Moreover, the NRC Staff has acknowledged that cesium-137 in the form of cesium chloride can be used in sealed sources for irradiators within the requirements of 10 C.F.R. Part 36. Id. The NRC Staff maintains, however, that any material used in a sealed source, either cobalt-60 or cesium-137, must demonstrate compliance with the requirements of 10 C.F.R. § 36.21(a)(3), that is, that sealed sources use a radioactive material:

> that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator.

10 C.F.R. § 36.21(a)(3) (emphasis added). As is discussed in Section 3.5(a), infra, Gray*Star believes that, based on the plain language of the text of this regulation, the requirement of 10 C.F.R. § 36.21(a)(3) applies only where "the source is used in a wet-source-storage or wet-source-change irradiator." Since the GS-42 will be used only in a dry-source-storage irradiator (i.e. the Gray*Star Model 1 irradiator), and is not intended for, and Gray*Star does not request approval for, use in a wet-source-storage or wet-source-change irradiator, the requirement in 10 C.F.R. § 36.21(a)(3) does not apply to the GS-42 source.[9] Even assuming, arguendo, that 10

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9 This is not unusual. Many sections of 10 C.F.R. Part 36 apply only to wet-source-storage irradiators and do not apply to dry-source-storage irradiators, such as the GS-42 sealed source design used in the Gray*Star Model 1 irradiator. See, e.g., 10 C.F.R. § 36.21(a)(4) (specific materials), 36.23(i) (personnel barriers), 36.25(b) (dose over a water pool), 36.33 (pool design), 36.39(c) (pool integrity), 36.39(d) (water handling systems). In addition to the plain language of the regulations, this dichotomy of requirements has been recognized by NRC Staff. Draft

C.F.R. § 36.21(a)(3) somehow applies to dry-source-storage irradiators and their sealed sources, Gray*Star demonstrated that the GS-42 sealed sources, as designed for use in the Gray*Star Model 1 irradiator, would satisfy the "as nondispersible as practical" standard in 10 C.F.R. § 36.21(a)(3).

Cobalt is a metallic element. Cobalt-60 for irradiators is in the form of metal rods.[10] NUREG/CR-6642 at 3-413. All NRC-licensed irradiators using cobalt-60 as a source use the cobalt in a metallic form.

Cesium is a non-metallic element that occurs naturally in the form of covalent-bonded cesium salts. Unlike cobalt, cesium does not, and cannot, occur as a solid metal. Cesium-137 for irradiators is in the form of a salt, cesium chloride. Cesium chloride is the only practical commercially available form of cesium as a radioactive source. Every NRC-licensed irradiator using cesium-137 as a source that Gray*Star is aware of uses the cesium in the form of cesium chloride.

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Regulatory Analysis and Environmental Assessment of NRC Regulations on Licenses and Radiation Safety Requirements for Large Irradiators.

10 As a metal, cobalt can be made in various metallic forms. In the past, cobalt-60 for irradiators came in the form of one-millimeter cobalt wire cut into one millimeter lengths. These cobalt-60 wire segments for irradiators are referred to as "mini-pellets." While convenient to manufacture and flexible for use in different irradiators, these mini-pellets turned out to be highly dispersible in water storage. Several events of leakage from such cobalt-60 sources used in water pool storage irradiators, and dispersion by the water, were reported in the 1970s and 1980s. NUREG-1345 AT 11 (1989). Though the cobalt-60 mini-pellets were not "soluble," because they were a metallic element and thus not strictly soluble in water, they were, in fact, highly "dispersible" in water storage. As a result, the use of such "dispersible" cobalt-60 sources has been discontinued for use in water storage pools, and replaced by the use of metal rods. No concerns with dispersal of the Cobalt-60 mini-pellets were reported for dry source storage irradiators.

Cesium chloride is a salt and takes the form of a crystalline solid. As a salt, cesium chloride can range in forms from a block to a fine powder.[11] Cesium chloride in the form of a uncompressible block, formed by a melt-cast process, was used in the so-called "WESF" canisters developed by the U.S. Department of Energy (DOE) and used in irradiators in the 1980s. DOE/ORO-914 (DE91 008210) – Interim Report Of The DOE Type B Investigation Group; Cesium-137; A Systems Evaluation, Encapsulation To Release At radiation Sterilizers, Inc., Decatur, Georgia; July 1990. (hearing file index # VI.C.7). The uncompressible block form used in the WESF canisters exhibited the undesirable characteristic of swelling with increased temperature thereby placing potentially significant stress on the steel encapsulation (i.e., container) containing the cesium chloride. The uncompressible block form and repetitive swelling from thermal cycling in a water pool irradiator eventually contributed to the breaching of one WESF canister in a water pool storage facility. See id.

At the other extreme, cesium chloride in the form of a fine powder salt would have the potential to disperse more easily out of a breach in the same container. A coarser crystal form, like table salt, would have the ability to flow and avoid the stress concerns associated with the uncompressible blocks used in the WESF canisters and could be too large to flow out of a minor breach in the container. A cesium chloride and distilled water solution (that ultimately dries into a cake on the inside of the container) also would also have the ability to flow and conform, to avoid the stresses from a uncompressible block as in the WESF sources, and would be even more unlikely than the coarser crystal form to flow out of any breach or even a rupture in the container. The GS-42 source uses the cake form ("caked powder") of cesium chloride. The

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11 Common table salt is sodium chloride. Table salt, like cesium chloride, can range in sizes from large blocks, to large cakes (as used for farm animals), to coarse crystals (as in a salt

caked powder form provides the dual advantages of deformability, to avoid placing high stresses on the encapsulation, and to reduce the possibility, and minimize the extent, of potential leakage even if the container is breached.

In addition to the beneficial use of the cake form of cesium chloride, the Gray*Star Model 1 irradiator, in which the GS-42 source is to be used, is specifically designed to avoid thermal cycling of the sources, to avoid placing cyclical thermal expansion stresses on the source containers.

Any salt (in fact, any material, including cobalt-60) will expand to some degree when heated, and then contract again when cooled. Water storage irradiators cool the sources in the water pool, and then the sources significantly heat up when removed from the water for irradiation. In the process, the source swells up when out of the water and shrinks back down when returned to water storage. This cycle is repeated every time the source is taken out of the water for use in irradiation and then returned to the water. This thermal cycling, and repeated expansion and contraction of the source material, places repeated stress on the encapsulation. This thermal cycling is thought to be one of the principal causes of the failure of the WESF source encapsulation used in the water pool storage irradiator in Decatur, Georgia in the late 1980's. DOE/ORO-914 (DE91 008210) – Interim Report Of The DOE Type B Investigation Group; Cesium-137; A Systems Evaluation, Encapsulation to Release At Radiation Sterilizers, Inc., Decatur, Georgia; July 1990, pp. 101 (4.7.2 – Conclusions), 106 (4.9.2 (Conclusions). (hearing file index # VI.C.7).

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shaker), to a fine powder.

The Gray*Star Model 1 irradiator was designed to eliminate the harmful effects of thermal cycling on the encapsulation by maintaining the sources at a consistent temperature. In part, this is accomplished by using a dry storage medium rather than water. The GS-42 therefore avoids the problems of thermal cycling that can lead to problems with the use of cesium chloride in a water storage irradiator especially with the use of a non-compressible block of melt cast cesium chloride both of which GS-42 avoids by design.

In summary, the GS-42 source design uses one of the two primary irradiator source materials (cesium-137 as cesium chloride), in a form that minimizes the potential for breach and leakage (cesium chloride as caked powder), in an irradiator expressly designed to avoid the problems that could lead to breach of encapsulation for a cesium source (dry storage instead of wet storage, with no thermal cycling).

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

The leak potential/danger with regard to cesium-137 chloride relates to the use of water for source storage or source changeout. The principal cesium-137 chloride leakage event has involved the leakage of the WESF source at the water pool irradiator facility in Decatur, Georgia in the late 1980's. See 58 Fed.reg. 7715. Cesium chloride is soluble in water, which enhances its dispersibility following a leak if the source is stored in water. However, water also provides leak potential/danger with respect to cobalt-60 sources. Several source leakage events have been reported for cobalt-60 sources used in water pool irradiators. NUREG-1345 at 11. Like cesium-137, cobalt-60 was also dispersed by the water storage pool following the leaks. No source leakage events have been identified for cesium-137 chloride used in dry-source-storage irradiators.

The GS-42 source design and the Gray*Star irradiator are designed with many unique features to prevent a leak from occurring in a GS-42 source encapsulation. These features are discussed in section 1.d.vi, below. Even assuming hypothetically that a leak does somehow occur, the GS-42 source design and the Gray*Star Model 1 irradiator also incorporate several features to mitigate the consequences of any leak. First and foremost, the Model 1 irradiator was designed from the beginning as a dry-source-storage irradiator that requires no water for source storage or source changeout. This feature by design excludes the dominant mechanism for dispersal of radioactive material should a leak occur. Second, the cesium-137 chloride used in the GS-42 sources is in a caked powder form. The cake form prohibits the bulk of the source material from passing through a leak path. Third, even assuming hypothetically that a leak occurs and that some source material does leak, Model 1 operations require that periodic radiation surveys be performed in order to detect any leakage, which would allow any necessary remedial actions to be taken to protect health and safety.

More important than the design features taken to mitigate consequences of a hypothetical leak, however, are the numerous design features added to the GS-42 source encapsulation and Model 1 design to ensure that, by specific design components, the source material has been rendered as nondispersible as practical. These design features are discussed in more detail in the sections below.

c. Comparison to smaller irradiators and sealed sources using cesium-137 chloride

Smaller irradiators also use sealed sources with cesium-137 in the form of cesium chloride. Just like the GS-42, these sealed sources use dry storage, instead of wet storage, to eliminate concerns about the solubility of cesium chloride, as a salt, in water. Just like the GS-

42, with dry storage these sealed sources avoid the thermal cycling problems that are a primary concern with water storage irradiators.

One of these smaller irradiators is the Category I sealed source irradiator used by the Department of Agriculture's Agricultural Research Service in Pennsylvania. This irradiator, licensed by the NRC as a Category I sealed source irradiator, uses cesium-137 in the form of cesium chloride, just like the GS-42. The total licensed source strength for this irradiator is 250,000 curies. USDA Materials License (NRC), Amendment 55, Dkt. 030-06923. While this amount is lower than the Gray*Star Model 1 (3 million curies), this source strength is substantial enough to require careful attention to assure adequate protection of public health and safety. The cesium chloride sources, as well as their shielding, are integral parts of the irradiator devices, just like the GS-42 used in the Gray*Star Model 1 irradiator.[12] Like the Gray*Star Model 1, these smaller irradiators have an irradiation chamber that is much smaller than the building-sized chambers used in standard Category II-IV "facility-type" irradiators.

The breach of a cesium chloride source in one of the smaller irradiators would result in minor localized leakage at the site of the breach. The form of the cesium chloride, as a solid crystalline salt, reduces the amount of material that could leak out of a small breach or fracture. There is no everyday mechanism with the obvious potential to cause a large breach or rupture of such sources. Just like these sources, the result of a breach of a GS-42 source encapsulation would also lead to only a localized release of material at the site of the breach. Because of the

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[12] This is fundamentally different from standard Category II-IV irradiators in which the source is completely separate from the shielding, and the irradiator is not a <u>device</u>, but rather a <u>facility</u>. In standard irradiators, the shielding is in the form of water in a pool or concrete walls of a building, from which the source is completely separate and can be removed. For sealed sources in a Category I irradiator, and GS-42 sealed sources in the Gray*Star Model 1 irradiator, the sources are integral with the shielding and the entire <u>device</u>.

caked powder form of the cesium chloride used in the GS-42, there is no mechanism for cake to readily disperse through a small breach or fracture. Just like in the smaller cesium chloride sealed sources, without the presence of water, there is no real mechanism to remove the cesium chloride source from the GS-42, even if a breach were to occur. Because the result of a breach for dry source storage is just the potential for localized leakage in the immediate vicinity of the breach, the potential consequences of a breach in the GS-42 are essentially identical to those of a breach in a sealed cesium chloride source used in an irradiator that is smaller than the Gray*Star Model 1[13] - - a localized and limited release of material, independent of the overall size of the entire irradiator.

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

i. General value of irradiation to help prevent foodborne disease

Irradiation of food is acknowledged to be one of the best methods of reducing potentially dangerous pathogens without significantly changing the food's texture, taste or appearance. This is primarily due to the small amount of total energy utilized on the food (it is a cold process) and the strong effect that irradiation has on microorganisms. Irradiation is a volume sterilent and is not restricted to the surface of the product, which is a major limitation of various chemical techniques as well as steam pasteurization. Put simply, food irradiation offers the potential to eliminate the food-borne pathogens that not only spoil food, but also cause illness and death in people. Every year people from outbreaks of the bacteria e. coli break out at locations across the

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13 The fact that the total curies in the Model 1 irradiator is larger could be misleading because each Model 1 contains **x** individually sealed sources so the breach of one does not necessarily indicate any likelihood that others will be breached. So the results of a breach in a GS-42 are likely to be similar to that in other category I irradiators.

United States. The most susceptible people are small children, who have difficultly fighting off the bacteria's debilitating effects. The Food and Drug Administration ("FDA") has officially endorsed the use of food irradiation using either cobalt-60 or cesium-137 radioactive sources. In order to facilitate development of commercial food irradiators, the NRC promulgated a specific section devoted specifically to irradiators, 10 C.F.R. Part 36. Gray*Star now comes before the NRC with the Gray*Star Model 1 irradiator, the first new design concept developed to allow the life-saving benefits of food irradiation to be implemented efficiently on a commercial scale.

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

The design approach taken with the Gray*Star Model 1 irradiator was specifically selected to ensure that the GS-42 sources would be "as nondispersible as practical." The Gray*Star design team studied all of the past incidents of leaks at irradiators and designed the Model 1 irradiator and its GS-42 sources from the start to address these problems by avoiding the design approaches that had led to such leaks. Gray*Star recognized that the most successful irradiators with regard to source leak prevention are the dry-source-storage, self-shielded irradiators that include their sources and shielding as integral parts of a single dry storage device. Gray*Star then set out to develop a new and unique irradiator design that would retain all of these advantages but also provide a device with a large enough capacity to meet the needs of commercial food irradiation.

From the very beginning, the Gray*Star Model 1 irradiator was designed to eliminate any need for water storage of sources, or water shielding for changing sources. Water has been the bane of irradiators worldwide because the water simultaneously increases the potential for source failure, through thermal cycling and corrosion, and increases the potential for source material to be dispersed should the source encapsulation fail. Gray*Star therefore set out from the beginning to eliminate the use of water from the irradiator design, and instead to rely on the dry-source-storage approach that has proved so successful in smaller irradiators.

In the Gray*Star Model 1 irradiator, both the GS-42 sources and their shielding are integral to the device. The sources and the shielding are incorporated into the device under controlled factory conditions at the time the device is fabricated, and prior to its delivery to a user. This removes the need to perform radioactive material loading operations at users' commercial food processing plants all over the country. Moreover, the GS-42 sources are integral with their shielding material, so that the sources can never be inadvertently physically accessed by the user because the shielding material would have to be removed.

The Gray*Star Model 1 irradiator design specifically selected cesium-137 over cobalt-60 as a source material for the irradiator in order to ensure that the health and safety advantages of the Gray*Star device could be utilized cost effectively. While this is discussed in more detail in section 1.d.iii below, the fundamental difference in the two source materials is that the long half-life of cesium-137 means that the sources loaded at the factory can remain sealed inside the device for the lifetime of the irradiator's operation. In contrast, the short half-life of cobalt-60 requires that the sources be regularly and routinely handled and changed out at the customer's facility, which, at such times turns the customer's facility from a food processing facility into a radioactive material handling facility. This approach was fundamentally rejected in the Gray*Star Model 1 design, the object of which was to provide a sealed, standardized, modular device for food irradiation that does not require the customer to be involved with radioactive material handling operations.

The Gray*Star Model 1 was also designed from the beginning with an enclosed radiation chamber that is large enough to accept a loaded pallet of product (approximately four feet wide, four feet high, and four feet deep), but not be so large that human access would be easy, or worse yet, such that human access would be necessary and routine. All product loading operations for the Gray*Star are performed from outside the irradiator. Moreover, there are no moving conveyer belts or similar moving parts inside the irradiation chamber that could fail and require a person to enter the chamber for maintenance. Because the shielding is integral with the GS-42 sources, entry into the chamber is physically impossible while the sources are exposed. Areas outside of the irradiation chamber thus can never be exposed to irradiation, either intentionally or unintentionally. The Gray*Star Model 1 irradiator is designed such that human access to the irradiation chamber is not required. The radiation chamber is designed to accommodate a pallet with product such that no room is left for human access when the product is in the irradiator. Even without product in the chamber, access is uncomfortable and the sources cannot be raised while the doors are open and unlocked. It would effectively take the intentional act of a second party to close and lock the doors to the chamber and raise the source with a person inside since there would be no way to miss the fact that a person was in the chamber as with a facility type irradiator. While this unique safety feature of the Gray*Star Model 1 irradiator is not aimed at the nondispersibility of the source material, it is nonetheless a key safety design aspect of the Gray*Star Model 1 irradiator that demonstrates why the Gray*Star Model 1 irradiator design approach was selected.

The benefit of these fundamental decisions made in the Model 1 irradiator design that go to ensuring that source material remains as nondispersible as practical can be more readily understood in comparison to other available irradiator design approaches.

(A) Water storage and/or water irradiation irradiators

Water storage and/or water irradiation irradiators (i.e., wet-source-storage irradiators) subject their sources to water which creates an environment conducive to corrosion, significant potential stresses from thermal cycling, and the most dominant mechanism for dispersal of radioactive material, should a source leak occur. Each one of these is a dominant factor in increasing the dispersibility of source material and works directly against making the source design as nondispersible as practical. Water source storage has led to source failures and leakage with water irradiators using both cesium-137 sources and cobalt-60 sources. The Gray*Star Model 1 irradiator is specifically designed to avoid the use of wet-source-storage in order to remove the dominant mechanism for failure of irradiator sources and dispersal of source material. This is a principal factor that makes the GS-42 sources, as used in the Gray*Star Model 1 design, as nondispersible as practical.

(B) Dry storage on-site loading irradiators

Dry-source-storage irradiators with on-site loading of sources address part of the problem with dispersibility, by eliminating the use of water storage, but significant concerns still remain regarding source integrity and worker health and safety. On-site loading irradiators require the handling and loading of sources into the irradiator at the food processor's facility. On-site loading and handling operations create the potential for damage to source encapsulation, a radiological incident during on-site transfer, or undetected damage to the source encapsulation leading to failure of the source at a later time. Because the great variety of processor facilities cannot provide the same controlled, safety designed conditions as a single irradiator fabrication facility can, on-site source loading increases the likelihood of a problem with source loading, such as misplaced sources or mishandled sources, which could lead to stresses on the sources sufficient to increase the potential for source failure and leakage. This problem is particularly exacerbated if the sources use the short-half-life material cobalt-60, which will require such on-site loading and handling operations with some frequency. The Gray*Star Model 1 design eliminated these concerns by designing a single, integral device wherein the sources are loaded under controlled factory conditions at the time the irradiator is fabricated. The design eliminates the need for on-site source loading and handling at food processor facilities around the nation. This modular design approach considerably enhances the GS-42 sources' resistance to dispersibility.

On-site source loading and handling operations are not only not beneficial for nondispersibility purposes, such operations can pose the potential threat of additional, unnecessary radiation exposure to workers and perhaps even the public during on-site installation. This potential additional radiation exposure is eliminated with the Gray*Star Model 1 design. Reduction in potential radiation doses is a major goal of the Model 1 irradiator design, by eliminating the need for dose intensive source handling operations at food processor sites.

(C) Dry storage irradiators with interlocks (panoramic irradiators where the source is independent of the radiation chamber)

Dry-source-storage irradiators where the source is independent of the radiation chamber also address the fundamental problem with wet-source-storage irradiators, but still leave unresolved significant potential health and safety concerns. Where the source is independent of the radiation chamber, the potential exists for the source to be moved up into the chamber with no shielding in place to protect the users. For these designs, the irradiator must rely on interlocks provide shielding before the source is exposed. Research by Gray*Star into all irradiator overexposures indicates that almost all injuries were due to an operator entering the radiation chamber when the chamber was exposed to the source. Numerous accidents, several resulting in death of the operators, have occurred in such irradiators where the source was exposed but the interlock system failed, and an operator walked into the radiation chamber. See 55 Fed.Reg. 500008. Present commercial irradators must rely on training and interlocks to reduce the likelihood of such accidents. The Gray*Star Model 1 irradiator is designed to make such accidents physically impossible.

The Gray*Star Model 1 irradiator is designed to eliminate these types of accidents by designing the irradiator with the source encapsulations being integral with the shielding. Unlike irradiators with interlocks to prevent operator exposure, the GS-42 sources cannot be moved independently of the shielding material. When the source/shielding assembly is moved up to the level of the radiation chamber, the entrance to the radiation chamber is fully shielded and completely blocked by 16 inches of solid steel (the integral shield material). There are no interlocks to fail, nor could any operator error allow the operator to enter the radiation chamber while the chamber is exposed to the source because as soon as the chamber doors are unlocked the sources and shield material are automatically lowered into place below the radiation chamber. It is therefore impossible for an operator to enter the radiation chamber while the sources are up, which eliminates the cause of the exposure accidents that have occurred in the past with other irradiator designs.

This is a health and safety issue that is not directly related to nondispersibility of the source material, but it again demonstrates the basis and direction used in developing the design of the Gray*Star Model 1 irradiator and its integral GS-42 sealed sources.

(D) Machine source irradiators

Irradiators which use machine sources include e-beam and X-ray units. These types of irradiators do not use radioactive source material and are not licensed by the NRC. As a result, these devices shed no light on the requirements of 10 C.F.R. § 36.21(a)(3). Moreover, as is discussed in more detail below, each of these machine sources have significant practical limitations that effectively preclude their application for commercial food irradiation.

iii. Comparison of Cesium-137 with other source types

The only two radioactive source materials approved by the FDA for food irradation are cobalt-60 and cesium-137. The Gray*Star design team specifically selected cesium-137 as a source material over cobalt-60 in order to obtain the health and safety advantages inherent in the Gray*Star Model 1 irradiator's modular, standardized design approach, as described in the section above. Once cesium-137 was selected as the only appropriate source material for the Gray*Star Model 1 irradiator, the design team set about making the GS-42 source encapsulations, as used in the Gray*Star Model 1 irradiator, as nondispersible as practical. For the reasons discussed below, the Gray*Star Model 1 design objectives could not be achieved using cobalt-60 as a source material. For other reasons, Gray*Star design objectives also could not be achieved practically using either e-beam and X-ray machine sources.

Cesium-137 is a radioactive source material that emits gamma rays with an energy of 0.662 MeV. Cesium-137 has a half-life of 30.2 years, which results in a source power loss of only 2.3% per year. The energy of cesium-137 gamma radiation is not sufficient to induce radioactivity in the food. Cesium-137 is commercially available both in the United States and abroad.

(A) Cobalt-60

Cobalt-60 is a radioactive source material that emits two gamma rays with an average energy of 1.25 MeV, twice as high as that of cesium-137. Cobalt-60 has a half-life of 5.27 years, far shorter than that of cesium-137, which results in a source power loss of 12.3% per year and hence the need to change our sources more frequently. Like cesium-137, the energy of cobalt-60 gamma radiation is not sufficient to induce radioactivity in the food. Unlike cesium-137, cobalt-60 is only currently commercially available from a single supplier in Canada.

(B) Electron beams (e-beam)

Electron beams ("E-beams") are a non-nuclear, non-radioactive material source of irradiation. E-beams are produced by accelerating electrons to near the speed of light (such accelerated electrons are referred to as "beta particles"). These non-nuclear sources are regulated by the FDA, not the NRC. FDA regulations limit the maximum energy of e-beams to 10 MeV so that they do not significantly induce radioactivity in the food product. The severe practical limitation of e-beam sources is that beta particles have very limited penetration into typical food products (approximately 3.5 inches), and therefore the maximum volume of product that can be irradiated at any one time is severely limited. Although such devices can be used, and are currently being used on some food products, the limitations they place on product size and density effectively precludes their practical application to food irradiation on a commercial-scale.

(C) Bremsstrahlung Radiation (X-rays)

Like e-beams, Bremsstahlung radiation (X-rays) is a non-nuclear, non-radioactive material source of irradiation. Like e-beams, this non-nuclear source is also regulated by the FDA, and not the NRC. X-rays are produced by applying an e-beam (as discussed above) to a high density material such as tungsten or tantalum. The X-rays produced has a range of energies from essentially 0 MeV to 5 MeV, which is the maximum X-ray energy permitted by FDA regulations in order to preclude significantly inducing radioactivity in the food product. The severe practical limitation of X-ray sources their prohibitive cost. The creation of e-beams, and then conversion of the e-beams into X-rays is extremely energy intensive and inefficient, and results in impracticably high irradiation processing costs. No commercial irradiators use X-ray sources. Although such devices can be used, their prohibitive cost effectively precludes their practical application to food irradiation on a commercial-scale.

iv. Basis for selection of cesium-137 for GS-42 versus cobalt-60

The principal design goals of the Gray*Star Model 1 irradiator are to provide food processors with a commercially practical irradiator that is semi-modular and standardized, and does not require the food processor to become involved in irradiator design or source loading and handling. The goal, in essence, is to provide processors with a practical device for food processing, while leaving the design, fabrication, and radioactive source material handling to the device designer and fabricator. In order to achieve a commercially practical irradiator for food processors, the food processing industry indicated that the irradiator must be located at the food processor's site, and the radiation chamber must be large enough to irradiate product on a full 40" by 48" pallet. In order to locate the irradiator at a food processor's site, the Gray*Star Model 1 irradiator is designed as a semi-modular, self-contained device in which both the sources and the shielding are integral to the device. The irradiator is designed to permit full factory fabrication of a standardized, modular unit that can then be transported to the food processor's facility and located there without the need to design a new, separate facility for the irradiator. At the same time, to ensure the device is commercially practical, the Gray*Star

Model 1 radiation chamber is designed to be large enough to accept a full 40" by 48" pallet of product.

These fundamental design decisions directed the choice of cesium-137 as the only practical source material for use in the Gray*Star irradiator. First, the higher gamma ray energy of cobalt-60 would result in a device design that would be so heavy as to be effectively precluded from commercial shipment. The lower gamma ray energy of cesium-137 permits the irradiator to be of a weight that can be commercially transported even with full radiation shielding. The shipping weight of the Gray*Star Model 1 is 167 tons, which is the upper limit of what is transportable on a practical basis. The higher gamma ray energy of cobalt-60 would require far more shielding to achieve the same radiation protection. The additional shielding needed if cobalt-60 were used as the source material in the Gray*Star Model 1 would add approximately an additional 145 tons to the transportation weight of such a Gray*Star irradiator, for a total weight in excess of 300 tons, which would effectively preclude transportation of the Gray*Star irradiator to customer sites. [14]

Second, the short half-life of cobalt-60 (5.27 years) would require either performing frequent on-site source handling and loading operations, something the Gray*Star Model 1 irradiator is specifically designed to avoid, or removing the Model 1 irradiator from the food processor's facility and transporting the entire device back to the fabrication facility on a regular basis. Such routine source handling and transportation operations are potential problems for both radiological and commercial reasons. The potential for unnecessary additional radiation exposure to workers and the public on a regular basis (which is directly contrary to the NRC's

As Low As is Reasonably Achievable ("ALARA") policy), and unnecessary additional handling operations could result in accidents breaching the source encapsulations. Moreover, the unnecessary source removals or irradiator removals on a frequent basis would add cost, disrupt food processor operations, and effectively undermine the utility of the irradiator to the point that it might not be commercially practical. The protection of health and safety was a driving motivation to select cesium-137 as the source material for the Gray*Star Model 1 irradiator.

In order to achieve the objectives for which the Gray*Star Model 1 irradiator is designed, principally to enable the health and safety benefits of food irradiation to be practically implemented in commercial food processing, cesium-137 is the only practical source material available. Once Gray*Star determined that cesium-137 is the only practical source material that can be used in its irradiator, Gray*Star set about taking every practical step available to ensure that the cesium-137 source material, as sealed in the GS-42 sealed source encapsulation and used in the Gray*Star Model 1 irradiator, is rendered as nondispersible as practical. The unique design features incorporated into the GS-42 sources to ensure they are as nondispersible as practical are discussed in section 1.d.vi, below.

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

Cesium-137 source material is only commercially available in the form of cesium chloride. NRC licensed cesium-137 irradiators use cesium in the form of cesium chloride. Cesium is a nonmetallic element that occurs naturally in the form of a salt, cesium chloride.

Footnote continued from previous page

14 The other alternative would be to dramatically decrease the size of the Gray*Star's Model 1 radiation chamber, which would effectively preclude the device from commercial

Cesium is stable in the form of cesium chloride. While cesium chloride is soluble in water, because of the chemical nature of cesium, most other chemical forms of cesium are also soluble in water. There would be no benefit to using one of these other chemical forms because it would not address the wet-source-storage irradiator concerns about dispersibility of cesium chloride in water. The forms of cesium that are not water soluble are significantly lower in terms of radionuclide density (curies per gram) than cesium chloride, which would create significant collateral problems for the source encapsulation. If an insoluble compound is used in place of cesium chloride, such as cesium dispersed in glass (i.e., vitirification) the radionuclide density will be reduced and greater self-absorption of radiation will occur in the source material. This can result in several problems for the source encapsulation:

(1) To provide the same irradiation levels from the sources, more cesium will have to be used in each source to account for the additional self-absorption. The more cesium that is used, the greater the heat that is generated in the sources resulting in additional potential thermal stresses on the source encapsulations.

(2) The gamma photons absorbed by the greater mass of the non-cesium atoms will lead to greater heat generated by the sources. The net effect is that the sources will have a higher heat output, resulting in higher operating temperatures than the irradiator is designed for.

(3) The complexity of producing compounds other than cesium chloride could lead to major difficulties and complexities in hot cell operations for source preparation.

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applications

(4) Experience with cesium glass compounds has demonstrated that the glass typically shatters upon cooling, resulting in many small fragments available for leakage, and is without apparent benefit when compared to caked cesium chloride, where the cesium is to be used in a dry-source-storage irradiator and not immersed in a water storage.

For these practical reasons, every irradiator using cesium-137 source material uses the form of cesium chloride. Where, like the GS-42 sealed source, the source is intended solely for use in a dry-source-storage irradiator, and will not be used in a wet-source-storage irradiator, the use of cesium-137 in the form of cesium chloride as a source material is an appropriate alternative.

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

Assuming *arguendo* that this section of Part 36 applies to sealed sources like the GS-42 that are to be used exclusively in dry-source-storage irradiators, the only regulatory issue addressed in Question #1 of this filing is whether the GS-42 sealed source design complies with the requirement in 10 C.F.R. § 36.21(a)(3) that the source be "as nondispersible as practical."[15] The requirement is not that the source be "nondispersible," only that it be as nondispersible "as practical." The "as practical" nature of the requirement dictates that it can only be evaluated with respect to the source encapsulation design and the overall irradiator design. Since it is clear that NRC Staff permits the use of cesium-137 in the form of cesium chloride in irradiators, the

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15 The requirement continues on "if the source is used in a wet-source-storage or wet-source-change irradiator." Since the GS-42 as used in the Gray*Star is neither of these, Gray*Star maintains that 10 C.F.R. § 36.21(a)(3) does not apply to the GS-42 source design (as limited strictly to use only in the dry-source-storage Gray*Star Model 1 irradiator design).

"as practical" requirement thus requires a determination that Gray*Star has taken appropriate steps in the design of the source encapsulation and the irradiator to safeguard against the dispersal of the cesium chloride source to the extent practical.

Gray*Star has taken extensive steps in the design and function of both the Gray*Star Model 1 irradiator and the GS-42 sealed source encapsulation design to assure the nondispersibility of the cesium chloride to the extent practical. Gray*Stars design staff has spent literally decades in the irradiation design industry, and used all of that experience to identify the potential means of dispersal of source material and to develop innovative design approaches to make the GS-42 sources used in the Model 1 irradiator as nondispersible as practical.

The most important step in making the sources as nondispersible as practical is the most obvious – the Model 1 irradiator and the GS-42 sealed sources are designed to eliminate wet-source-storage and water-source-change, since water is by far the primary and dominant mechanism for the potential dispersal of cesium chloride source material. Moreover, water storage creates significant thermal cycling and thermal stress problems that challenge source encapsulations used in wet-source-storage irradiator designs. Instead, the Gray*Star Model 1 irradiator and GS-42 sealed source encapsulations are designed solely for use with dry-source-storage. The use of dry-source-storage instead of water storage is a significant design challenge which Gray*Star's designers took on and addressed in order to assure, to the extent practical, the nondispersibility of the cesium-137 chloride used in the GS-42 sealed sources.

In addition to principal nondispersibility design feature, eschewing the use of water for source storage or source changing, Gray*Star also incorporates numerous unique design features into the GS-42 sealed source design to ensure that the cesium-137 chloride source material used in the GS-42 sealed sources will be as nondispersible as practical. Twelve of these unique design features were raised in the Applicant's June 1, 2000 letter to the NRC Staff.[16] The twelve unique design features of the GS-42 to assure nondispersibility are discussed individually in the sections below.

(1) Source Loading Technique and Nondestructive Examination

Grayfill™ source loading technique allows the encapsulation to undergo nondestructive examination (NDE) prior to being loaded with cesium chloride. This allows for greater source encasulation integrity assurance. Grayfill™ is a method for fabricating, assembling, welding and testing the integrity of both encapsulations prior to the introduction of the cesium chloride. The above steps are not performed in a "hot cell" and therefore do not pose the potential problems associated with examination in a high radiation environment. After the encapsulations are manufactured and tested, they are placed in a "hot cell" and are then "filled" with radioactive cesium chloride. After filling, both encapsulations are mechanically sealed and then the outer seal is welded. The method allows for a "closed" system to minimize "hot cell" contamination as well as source contamination.

The most susceptible part of a source encapsulation to any type of leakage is where the encapsulation is welded or mechanically sealed - - that is, if a failure were to occur, it likely would be along a weld seam or the seat of a mechanical closure). In order to guard against dispersibility due to weld failure, the weld seams need to be inspected. Weld inspection is performed using NDE methods such as dye-penetrant testing. Because the source material is highly radioactive, it is extremely difficult to perform extensive NDE of weld seams on the

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16 The NRC Staff did not provide any specific response to these twelve design features raised in Applicant's June 1, 2000 letter to the Staff. Therefore, Gray*Star is currently unaware of any Staff concerns with these design features to the extent they address the "nondispersible as practical" requirement in 10 C.F.R. § 36.21(a)(3).

source encapsulation after the source material is loaded into the encapsulation. The GS-42 sealed sources have two separate encapsulations – and inner encapsulation and an outer encapsulation – to provide defense-in-depth.[17] Therefore, Gray*Star specifically designed the GS-42 sealed source encapsulation such that the seams of the encapsulation will be welded and NDE inspected in a controlled factory environment prior to any radioactive material being loaded into the encapsulation. This unique approach ensures that the encapsulation weld seams will preclude dispersibility to the extent practical. To Gray*Star's knowledge, the GS-42 encapsulation will be the only NRC-licensed sources fabricated, welded, and inspected under full NQA-1 Quality Assurance requirements. Gray*Star took this additional significant step (beyond the requirements of 10 C.F.R. Part 36) at the NRC staff's request to further ensure the nondispersibility of the cesium-137 chloride.

Of course, not every seal on the encapsulation can be closed and inspected before the radioactive source material is added, or else there would be no way to introduce the source material into the encapsulation. The GS-42 is therefore designed with the least number of penetrations (two, one for each encapsulation), of the smallest practical size, to allow the encapsulation to be filled while at the same time minimizing the sites where seal failure could occur. When it is introduced into the "hot cell," the GS-42 has only two small threaded penetrations (one through the inner encapsulation and one through the outer encapsulation) through which radioactive source material is added. The filling mechanism is specifically

[17] Although not required by 10 C.F.R. Part 36, both of the GS-42 sealed source encapsulations are fabricated from corrosion resistant material – stainless steel 316L. Under Part 36, only wet-source-storage irradiator sources are required to use a corrosion resistance material. See 10 C.F.R. § 36.21(a)(4). However, even though it is not required (since the GS-42 is solely for use in a dry-source-storage irradiator), Gray*Star took the extra step of using corrosion

designed such that no radioactive material comes into contact with the threads of either of the seal penetrations. After the radioactive source material is added into the inner encapsulation, a threaded mechanical seal is used to close each of the two penetrations. These mechanical seals are torqued down to with high pressure to ensure the plug is permanent. The mechanical seal is such that there is no reasonable apparent mechanism that would allow caked cesium chloride to escape through the seam.[18] Moreover, there are two redundant seams to provide defense-in-depth, even though there is no known mechanism for caked cesium leakage.

In addition to the two redundant mechanical seals on the source encapsulation, the Applicant added an additional redundant step of adding a seal weld around the outside mechanical seal after the radioactive material has been added.[19] Gray*Star has taken every reasonable step to ensure the integrity of the GS-42 source encapsulation in order to make the source material as nondispersible as practical.

(2) Source Encapsulation Shape

Unique encapsulation shape to minimize decay heat buildup in the source.

Footnote continued from previous page

resistant stainless steel 316L for the GS-42 source encapsulations, to ensure every practical step had been taken to assure the source material in the GS-42 is as nondispersible as practical.

18 During one of the many tests conducted on the mechanical seals for the GS-42, a slight leakage of pressurized helium gas was detected. Gray*Star's tests with helium gas went far beyond the testing methods required for sealed source encapsulations, which dictate the use of pressurized water. Helium gas was used because, as the lightest noble gas, it is the most likely material to leak from a weld seam. Non-pressurized caked cesium chloride is far less likely to leak through any seam that is pressurized helium gas. These is no indication that caked cesium chloride would have leaked from the seal.

19 There is no practical way to add an additional seal weld around the internal mechanical seal.

Traditional irradiator source encapsulations have used cylindrical encapsulation shapes.[20] Cylindrical encapsulations are easier and less expensive to manufacture. However, the cylindrical shape is less efficient for an irradiator because the radioactive material in the center of the cylinder is significantly shielded by the rest of the source material in the encapsulation. As a result, more source material must be used in a cylindrical source to achieve the same levels of irradiation. In addition to additional cost for source material, the cylindrical shape has two adverse design impacts. First, there is more decay heat buildup in the source, and higher peak temperatures in the source material in the middle of the cylinder. This can result in increased thermal stresses on the source encapsulation and increases the potential for source failure. Second, there is more source material in the encapsulation that may leak out. The GS-42 sealed source design specifically addresses these design concerns. Instead of using a cylindrical encapsulation, even though easier and less expensive, Gray*Star designed the GS-42 encapsulation with an oval cross section. This unique oval cross section decreases the amount of self-shielding in the radioactive source material, reduces the operating temperature (and therefore thermal stresses) of the source material, and requires less source material to provide the same level of irradiation. This unique design feature of the GS-42 source design contributes significantly towards making the GS-42 source as nondispersible as practical.

(3) Source Encapsulation End Caps

Unique end caps to minimize any transfer of stress to the source tubes.

The GS-42sealed source encapsulation is designed with thick billet end caps that are the sole load bearing point of the encapsulations when used in the Gray*Star irradiator. This design

[20] For example, the WESF cesium-137 chloride sources were cylindrical.

takes any load bearing stress off of the source tubes, which reduces the likelihood of source failure.

(4) Retention of Encapsulation End Caps

Sources are only retained by their end caps to minimize stress, providing better cooling of the source tubes.

As discussed in (3) above, the GS-42 sealed source is designed such that its thick end caps are the only load bearing surface of the source. In the Gray*Star Model 1 irradiator, the sources are only retained by their end caps. The end caps themselves do not contain radioactive material; the radioactive source material is all contained in the source tubes. By designing the GS-42 sources and Gray*Star Model 1 irradiator such that only the end caps are retained, the cooling of the sources is enhanced, which decreases source temperatures and reduces thermal stresses on the encapsulation. This design feature further enhances the nondispersibility of the GS-42 sources.

(5) Dovetailed End Caps to Assure Sources Cannot Fall

Dovetailed end caps to assure positive source location (cannot come free from the source rack).

The GS-42 sealed source encapsulations are located in the Gray*Star Model 1 irradiator source racks by dove tailing the source racks and the GS-42 end caps. As a result of this design feature, the GS-42 source encapsulations cannot come free from the source racks and therefore cannot be subject to impact stresses associated with a fall from the source racks. This design feature ensures the source encapsulations cannot undergo significant impact stresses and thus enhances the nondispersibility of the GS-42 sources.

(6) Low Density Source Filling

Low density filling of the sources prevents over pressure in the source in the event that the sources are heated beyond the phase transition point for cesium chloride.

As discussed earlier in the response to Question #1, earlier cesium chloride source designs have had problems with thermal stresses caused by heating and expansion of the cesium chloride inside the source encapsulation.[21] When cesium chloride is heated beyond a certain temperature, the material undergoes a phase change to a phase with a greater volume which can impart considerable stresses on the source encapsulation if the design does not allow sufficient room to accommodate the "growth" of the cesium chloride in the phase transition. In order to address this concern, Gray*Star added two unique aspects to the GS-42 sealed source design. First, the GS-42 sealed source is designed so that the encapsulation will only be partially filled with cesium chloride, the remaining space inside the encapsulation is available to accommodate expansion of the cesium chloride. Thus, even if the cesium chloride source material reaches the phase transition temperature in the Gray*Star Model 1 irradiator, the source is designed with sufficient room to accommodate the expansion without imparting any stress on the encapsulation. Second, as discussed earlier in the twelve unique design features, the GS-42 is designed to minimize the decay heat buildup in the source, and to maximize the cooling of the source tubes, in order to reduce the operating temperature of the GS-42 sealed sources. As a result, the operating temperature of the source material in the GS-42 source encapsulation is projected to remain well below the phase transition temperature of cesium chloride, and, thereby to eliminate thermal expansion concerns. These design features reduce the stresses on the GS-42 source design and therefore enhance the nondispersibility of the source.

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[21] In the WESF sources, these thermal stresses are believed to be the primary cause of failure of the source encapsulation in Decatur, Georgia.

(7) The helium Backfill of Sources

Helium purge of the cesium chloride removes elements of ambient air which might interact with the cesium chloride and provides better heat conduction within the source.

The void space left by design in the GS-42 sealed sources to allow room for expansion of the cesium chloride (as discussed in (6) above) are backfilled with helium gas. The helium gas backfill provides two advantages. First, helium is an inert gas and will not react with the cesium chloride. Second, helium has excellent heat transfer properties relative to other gases and will thereby reduce source material operating temperatures even further. While neither of these features is essential to the performance of the GS-42 sealed source design, they are yet additional features which reduce the potential for breach of the source encapsulations and thereby increase the nondispersibility of the source design.

(8) Filling Process to Minimize Contamination

The filling technique is designed to minimize possible contamination of the annulus (gap between the inner and outer encapsulations) or the outside of the source during the filling process.

The GS-42 sealed source uses a unique process to fill the source encapsulation which deposits the radioactive source material directly into the inner encapsulation, without contacting the outside of the inner encapsulation (the annulus between the two encapsulations) or the outside of the outer encapsulation. This unique process improves the nondispersibility of the source design. First, there is no radioactive source material that could leak outside of the encapsulation with a single failure (failure of the outside encapsulation). Thus, the only manner in which source material could leak out of the GS-42 sealed source would be two have two separate failures - - failure of both the inside and outside source encapsulation.

(9) Dry Source Storage

The dry storage / dry irradiation nature of the irradiator means that there is no medium for immediate dispersal of dangerous amounts of radioactive material (i.e.: water) and further, that there is no electrolytic corrosion of the source due to storage in a water pool which has led to cobalt-60 encapsulation failures in the past.

The designers of the GS-42 sealed source and the Gray*Star Model 1 irradiator studied all of the irradiator source encapsulation failures with loss of source material that have occurred in the past. In every case, the sources were stored in water, or the irradiation was done with the sources in the water, or both. The water acted as both a mechanism to corrode the encapsulation material to the point of failure, to impose severe cyclical thermal stresses from repeated cycles of in air followed by cooling in water, and provided a mechanism to disperse the source material in the event of an encapsulation failure. After studying all of the past encapsulation failures, Gray*Star made the decision to design the GS-42 sources and the Gray*Star Model 1 irradiator without any use of water for either source storage or irradiation. The use of dry-source-storage for the GS-42 source encapsulations eliminates the cause of all prior source material dispersal events. The elimination of water and use of dry-source-storage for the GS-42 sealed source and Gray*Star Model 1 irradiator is the primary and most significant aspect that makes the GS-42 sealed source design as nondispersible as practical. While this same approach has been used on numerous smaller irradiators licensed by the NRC, the Gray*Star Model 1 is the first practical irradiator (with a larger irradiation chamber designed for efficient use in food processing facilities) to make use of the dry-source-storage design approach that has proven effective in assuring that cesium chloride sources are as nondispersible as practical.

(10) Isolation of Sources from Product in the Radiation Chamber

The sources are isolated from the product in the radiation chamber to prevent damage of the encapsulations by misaligned product.

In traditional "facility-type" irradiators, the source is raised up into a large irradiation room and product moves around the source on a conveyer belt. These systems present the potential for moving product to come into contact with the source itself and thereby damage the source encapsulation. This increases the potential for dispersibility of the source material. Gray*Star designed the GS-42 source and the Gray*Star Model 1 irradiator to eliminate these risks. In the Gray*Star Model 1, the product is placed inside the irradiation chamber prior to irradiation. The GS-42 sealed sources are contained in the shielding walls which move up out of the floor integral with the sources after the doors of the chamber have been closed and locked. The product cannot be positioned over the location of the shield/source walls because walls of the chamber will not allow the product to be moved into the travel path of the shield/source for three of the walls, and for the fourth wall (where the doors to the chamber are located, the product must be fully within the chamber (and off of the travel path of the shield/source) in order for the doors to be closed. If the doors are not closed, the irradiator cannot be operated. Equally important, the Gray*Star Model 1 was designed without any conveyer belts to avoid the problems associated with such systems. For the Gray*Star Model 1 irradiatior, during irradiation when the GS-42 sealed sources are raised, there is no moving product inside the irradiation chamber. These design features remove the potential risk to sources in irradiators designed for moving products on conveyer belts, and thereby further enhance the nondispersibility of the GS-42 sealed source design, as implemented in the Gray*Star Model 1 irradiator.

(11) Elimination of Significant Thermal Cycling

The non-thermal cycling of the sources, in part, prevents the cesium chloride from being "aerosoled" should a leak occur.

In wet-source-storage dry chamber irradiators, the source encapsulations go through significant thermal cycling everytime the source is removed from its water-cooled storage pool and lifted up into an air-cooled irradiation chamber. Because the air cooling is much less effective than the water cooling, the source encapsulation experiences a significant increase in temperature every time the source is lifted into the chamber, followed by a rapid decrease in temperature when the source is lowered back down into the water pool. In addition to the potential deleterious effects of thermal stresses on the source encapsulation, the repeated expansion and contraction of the source material can result in fracturing of the source material, especially where cesium chloride is used. Fracturing of the source material can produce smaller and smaller source material particles, to the point where the particles could be small enough that they could be aerosolized in the event of a leak.

In light of the problems associated with frequent thermal cycling of source encapsulations, Gray*Star designed the GS-42 sealed source and Gray*Star Model 1 irradiator to eliminate thermal cycling. The source encapsulations in the Gray*Star Model 1 are in dry-source-storage and never subjected to the rapid cooldown by immersion in a water pool. The GS-42 sealed source encapsulations remain at a relatively constant temperature,[22] and never experience the significant thermal cycling endemic to wet-source-storage irradiators that can damage the source encapsulations and degrade the source material itself.

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22 Of course, the GS-42 spaced sources will experience slight variations in temperature as the ambient temperature in the building the Gray*Star Model 1 is housed in experiences the type of variation in heating and air condition load common to any home or business. This slight

(12) Irradiator is its own Shipping Cask

If a source were to leak, the dispersal would be limited. Because part of the unit is also its shipping cask, the leaking sources are contained in the shipping cask and can be removed to an off-site facility for corrective action. This mitigates against serious on-site contamination.

The Gray*Star Model 1 irradiator is designed as a semi-modular unit that can be shipped intact with its GS-42 sealed source encapsulations. This feature is unique to the Gray*Star Model 1 irradiator design, among commercial irradiators.[23] As discussed earlier, the primary benefit of this is that no source loading (with attendant potential radiation exposure concerns) need be performed at the user's site, and all source loading (and unloading) can be done in a carefully planned, designed, and controlled facility. At the same time, in the hypothetical event that a source leaks, the entire irradiator can be shipped back to a controlled facility in its shipping cask without any removal or handling of sources. While this feature does not, itself, reduce the potential for a GS-42 source to leak (all of the previous design features do just that), this design feature minimizes the potential extent of contamination, even if it is assumed to occur. Thus, by reducing the extent of contamination, the modular design used for the Gray*Star Model 1 further enhances the nondispersibility of the GS-42 sealed source design.

Taken together, these numerous design features of the GS-42 sealed source encapsulation demonstrate that Gray*Star has gone to great lengths to make the GS-42 sealed source design as

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variation in temperature (of a few degrees) is very different from the thermal cycling that has caused problems for irradiator sources (hundreds of degrees).

[23] This same advantage applies to many smaller Category I irradiators, but has never (before the Gray*Star Model 1) been applied to a commercial-sized irradiator. Gray*Star specifically designed the Gray*Star Model 1 and the GS-42 sealed sources to incorporate the significant safety advantages found in the smaller irradiators into a larger, commercial-scale irradiator.

nondispersible as practical. Every recognized failure mechanism with past cesium chloride sources has been taken into account by Gray*Star in the design of the GS-42 sealed source encapsulation to maximize, to the extent practical, the nondispersibility of the GS-42 sealed source design.

vii. Other

The Applicant has taken every practical, known step to assure that cesium-137 chloride as used in the GS-42 sealed source encapsulation and Gray*Star Model 1 irradiator is as nondispersible as practical. In all of its filings and correspondence with Gray*Star, NRC staff has failed to identify any practical feature that could be added to the GS-42 source design, as used in the Gray*Star Model 1 irradiator, to further improve its nondispersibility. Gray*Star is committed to meet or exceed every applicable NRC requirement for its irradiator GS-42 sealed source design. If any additional practical design features had been identified by the NRC staff, or any other party for that matter, such design features could have been considered for the GS-42 sealed source design. As Gray*Star points out in Section 1.f below, if the GS-42 source design cannot comply with the requirement of 10 C.F.R. § 36.21(a)(3), then no use of cesium-137 chloride can satisfy the requirement. Such a de facto prohibition of cesium-137 from use in any NRC-licensed irradiator cannot be the intent of 10 C.F.R. § 36.21(a)(3) (if it applies to dry-source-storage irradiators at all), or the "as practical" requirement in its text (even assuming it does apply to dry-source-storage irradiators).

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

Each of the sections a – d have something to relate to this inquiry. Section a identifies that cesium-137, in the form of cesium chloride, is one of the two source materials (the other is cobalt-60) available for use in irradiators licensed under 10 C.F.R. Part 36. Moreover, NRC staff has acknowledged that cesium-137, in the form of cesium chloride, can be licensed for use in irradiators under 10 C.F.R. Part 36.

Section b shows that the leak potential with regard to cesium-137 chloride concerns its use in wet-source-storage and wet-source-change irradiators, because water is the principal potential cause of source encapsulations failure, and the dominant mechanism for dispersal of any material that leaks from a source encapsulation. There has not been any leak potential or danger identified with regard to cesium-137 chloride used in dry-source-storage irradiators. The GS-42 sealed source is solely for use in a dry-source-storage irradiator.

Section c shows that smaller irradiators using cesium-137 chloride sources with dry-source-storage operate more like the GS-42 sealed source in the Gray*Star Model 1 irradiator than any large "facility-type" wet-source-storage, conveyer-belt type irradiator. These smaller dry-source-storage irradiators continue to be licensed by NRC with sources using cesium-137 chloride, and continue to have excellent safety records with regard to nondispersibility of the sources. Because both are dry-source-storage irradiators, these irradiators are more relevant to the performance and leak potential of the GS-42 sealed source encapsulations. Because they are dry, the potential risk from a leak for these smaller irradiators using cesium-137 chloride is similar to the risk associated with the GS-42 sources in the Gray*Star Model 1 irradiator. Which incorporates multiple separately sealed source units rather than past experience with irradiators storing cesium-137 chloride sources in water.

Section d demonstrates that cesium-137 chloride is the only practical source material for the GS-42 sealed sources, because the principal design objectives of the Gray*Star Model 1 irradiator (standard design with factory fabrication, user input on design not required, modular shippable one-piece package, size compatible with efficient commercial food facility operations, no on-site loading of sources, no frequent source changeouts required) can not be met with the forced use of cobalt-60. Mandating the use of cobalt-60 as the only permissible source material would, in practical effect, kill the Gray*Star Model 1 irradiator. The information in section d demonstrates that killing the Gray*Star Model 1 irradiator would also assure hundreds, if not thousands, of deaths that could be avoided by use of the Model 1. Section d demonstrates that Gray*Star has thoroughly studied the history of irradiator incidents and has specifically taken numerous unique design steps to eliminate the risk factors for source encapsulation leakage in order to ensure that the GS-42 sealed source design as "nondispersible as practical."

While each of the sections is important in terms of safety, and each aids in understanding of the motivation for the GS-42 sealed sources and development of their design, the most important section for this inquiry is the analysis in section d demonstrating that the design of the GS-42 sealed source encapsulation is "as nondispersible as practical." The regulatory question at issue, assuming arguendo that 10 C.F.R. § 36.21(a)(3) applies at all to dry-source-storage irradiators, is whether the GS-42 source is "as nondispersible as practical." Section d demonstrates that Gray*Star has taken every practical step to ensure that the GS-42 sealed source design, as used in the Gray*Star Model 1 dry-source-storage irradiator, is as non-dispersible as practical.

f. Other matters relating to dispersibility issue

A key threshold issue, which is raised in the response to 1.a. above, is the applicability, if at all, of the requirements of 10 C.F.R. § 36.21(a)(3) where the sealed source will not be "used in a <u>wet-source-storage</u> or <u>wet-source-change</u> irradiator." 10 C.F.R. § 36.21(a)(3) (emphasis added). The GS-42 sealed source design, that is the subject of this proceeding, is only intended for, and Gray*Star only requests registration for, use in a <u>dry-source storage</u> irradiator, the

Gray*Star Model 1 irradiator. This threshold question is addressed, pursuant to the Presiding Officer's Order, in section 3.5.a of this filing, infra.

The response to Question #1 above demonstrates is that, if 10 C.F.R. § 36.21(a)(3) applies at all to a dry-source-storage irradiator design, Gray*Star has taken every practical measure to assure the nondispersibility of the cesium-137 chloride source material. Certainly the staff fails to identify in any of its filings or submittals to Gray*Star any additional practical (in fact, even impractical) design features that could be added to the GS-42 sealed source or the Gray*Star Model 1 irradiator to improve the nondispersibility of the GS-42 sealed sources. The staff has acknowledged that cesium-137 chloride can be used in irradiators licensed under 10 C.F.R. Part 36. Order at 1. Thus, if the requirement of 10 C.F.R. § 36.21(a)(3) does apply to dry-source-storage irradiators (which Gray*Star maintains it does not, see discussion in section 3.5.a infra), then the GS-42 sealed source design, for exclusive use in the Gray*Star Model 1 irradiator complies with the requirement. If the GS-42 sealed source design cannot comply with this requirement, then no sealed source design using cesium-137 chloride can satisfy the requirement. Such an interpretation renders the "as practical" requirement in the text of 10 C.F.R. § 36.21(a)(3) a nullity, a conclusion which the NRC can not have intended in promulgating Part 36 of its regulations.[24] A conclusion that the GS-42 source design does not meet the requirement of 10 C.F.R. § 36.21(a)(3) without identifying any way in which the source can be practically made more nondispersible, practically speaking, concludes that cesium-137 chloride is prohibited from use in an irradiator licensed under 10 C.F.R. Part 36, which is directly

[24] Statutory construction directs that a law or regulation should be interpreted to give meaning to the literal text of the law or regulation, and not to ignore sections of the plain wording of a regulation.

contrary to the NRC staff's acknowledgement that cesium-137 chloride can, in fact, be used in irradiators licensed under Part 36.

2. Prototype Testing of GS-42 Sealed Sources Under 10 C.F.R. § 36.21(a)(5)

The second bases for denial referenced by the staff relates to prototype testing of the GS-42 sealed source.

a. Design of inner capsule relative to leak potential.

As indicated above, the NRC's performance criteria for sealed sources requires that prototype sealed sources be leak tested and found leak-free after each regulatorily prescribed test. See 10 C.F.R. § 36.21(a)(5) and (b)-(g). The parameters tested include temperature, pressure, impact, vibration, puncture and bend. 10 C.F.R. § 36.21(b)-(g). In its denial letter, the NRC staff asserts that Gray*Star's application reported that in some of the prototype tests on the GS-42 sealed source, "both the inner and outer capsules leaked." Denial Letter at Encl. 1, p. 1. The Staff goes on to state that "to resolve the problem, the applicant only modified the design of the outer capsule. However, because the inner capsule was not modified, the staff considers the inner capsule to be subject to leaks, and therefore, the design is unacceptable." Id. The NRC staff's assertions are simply incorrect: "both the inner and outer capsules" did not leak during any of the prototype testing (preliminary or final) of the GS-42 sealed source.

The prototype testing on the GS-42 sealed source was conducted in accordance with 10 C.F.R. § 36.21(a)(5) and (b)-(g), 10 C.F.R. § 71.75 (Qualification of special form radioactive material), 49 C.F.R. § 173.469, ISO-2919, ANSI N43.6, ANSI N433.1 and IAEA Safety Series

No. 6.[25] Notably, the final design assemblies of the GS-42 sealed sources passed all tests for both sealed sources and "special form radioactive material."[26] There were no leaks from either the inner or outer capsule in the final design assemblies of the GS-42.

Under the above testing requirements, a sealed source complies with a test if it is demonstrated that at least one encapsulation maintains integrity. See e.g., ANSI N43.6 (1997) 4.1.1 ("A source with more than one encapsulation shall be deemed to have complied with a test if it can be demonstrated that at least one encapsulation has maintained its integrity after the test."). Moreover, several of the specified testing methods[27] test the integrity of only the outer capsule and none of the testing methods insure that the inner capsule maintains its integrity when there is no breach of the outer capsule. Further, the NRC, in the Federal Register notice establishing Part 36,[28] recognized the importance of the double encapsulation: "[d]ouble encapsulation provides additional protection in case one of the welds in the source is defective."

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25 See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services Report, Sealed Source Qualification Testing – Overview, at 6. (Hearing File No. IV.E).

26 "Special form radioactive material" is any radioactive material that meets the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5mm; and

(3) It satisfies the requirements of section 71.75.

10 C.F.R. § 71.4. The GS-42 sealed source is a "special form radioactive material; therefore, it must meet the requirements set forth in section 71.75.

27 See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services Report, Sealed Source Qualification Testing – Overview, at 6 (Hearing File No. IV.E).

28 58 Fed. Reg. 25 (Feb. 9, 1993).

Double encapsulated sources, like the GS-42 sealed source, provide additional assurance that at least one of the capsules is performing its intended function and will not leak.

Turning to the testing completed on the GS-42 sealed source, the inner and outer capsules of the GS-42 were independently fabricated and independently tested for weld quality and leak tightness prior to the GS-42 being filled with representative non-radioactive cesium chloride (CsCl). After filling, the inner and outer seal plugs were installed, a seal weld was added to the outer seal plug, and the double encapsulation was tested in accordance with the regulatory requirements discussed above.[29] During the course of these tests on the preliminary design, at no time did both the inner and outer capsules leak.[30] While Gray*Star readily acknowledges that after thermal shock tests of the preliminary design, the outer seal plugs exhibited minute leakage but the inner capsule did not leak during these tests.[31]

Following these tests, as an additional safety precaution, the preliminary design was modified such that a seal weld was added to the outer seal plug to further ensure that the minute leaks which occurred during testing of the preliminary design would not occur in the final design. Following this modification, the final design GS-42 sealed source was thermally shocked. The results of these tests on the final design, which included independent testing of the inner and outer capsules, showed that both were leak free.[32]

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[29] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services Report, Sealed Source Qualification Testing – Overview, at 11, 18, and report attachment at 92 - 94. (Hearing File No. IV.E).

[30] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services Report, Sealed Source Qualification Testing – Overview, at 6 (Hearing File No. IV.E).

[31] Gray*Star employed a helium (He) leak test, which is the most sensitive.

[32] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services

Gray*Star, interested in determining whether the leak in the outer plug in the preliminary design noted above was due to mechanical or thermal failure, conducted thermal shock tests of the inner and outer end caps (which are merely a part of the encapsulations) used in the preliminary design. During the course of this testing, an inner seal plug showed signs of leaking using the most sensitive He leak detection test. The outer seal plug, however, did not leak.[33] Due to the fact that it is physically impossible for the inner seal plug of the GS-42 sealed source to be thermally shocked because the outer capsule thermally insulates the inner capsule, no design change to the inner seal plug was made by Gray*Star following these end cap tests on the preliminary design.

Finally, and perhaps most importantly, Gray*Star will perform tests on the assemblies and welds (including, but not limited to, visual inspection, dye penetrant testing, and He mass spectrophotometer leak testing), prior to the introduction of the WESF $Cs^{137}Cl$ in the "hot cell" to ensure that there are no leaks or defects in the encapsulation.. This additional step, which is not required by regulation, is in keeping with the NRC's "defense in depth" approach to safety. Notably, to Gray*Star's knowledge, no other sealed sources that are registered by NRC undergone such post-assembly testing.

In conclusion, the NRC staff's assertion that "in some of the prototype tests, both the inner and outer capsules leaked" is mistaken. The GS-42 sealed source is double encapsulated

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Footnote continued from previous page

Report, Sealed Source Qualification Testing – Overview at 11, 18 and report attachment at 92 - 94. (Hearing File No. IV.E).

33 See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services Report, Sealed Source Qualification Testing, at 17 and report attachment at 88 - 95. (Hearing File No. IV.E).

and has more than satisfied the prototype testing requirements set forth in 10 C.F.R. § 36.21(a)(5) for sealed sources.

b. Vibration testing

As discussed above, section 36.21(a)(5) requires that sealed sources be leak free after certain prototype tests. One such test is the vibration test. Specifically, section 36.21(e) provides:

> (e) *Vibration.* The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency sound.

The NRC staff wrongfully asserted in its denial letter that "[t]he vibration testing of the source is incomplete." Specifically, according to the staff, "the vibration testing . . . should be performed along the weakest axis (i.e. transverse axis) instead of the stronger two axes according to accepted vibration testing practices as described in industry standards." Moreover, the staff claims that the prototype was only tested in the vibration spectrum range of 25-100 Hz, while the regulations require a range of 25-500 Hz. As discussed below, the GS-42 sealed source was tested along the axis most susceptible to failure and, indeed, was tested in the vibration spectrum range of 25-500 Hz.

i. Along weakest axis.

The "industry standards" referenced by the staff specify that the testing of prototype sources shall be performed at ". . . two axes, one of revolution and one taken at random in a plane perpendicular to the axis of revolution." See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star^{tm} Model 1 Irradiator, Amendment 1, Vol. 1, Question 10 (Sept. 27, 1999) (Hearing File No. VI.B) (referencing ANSI/HPS N-43.6

1997, 7.5.2. ISO 2919-1980, 8.5.2). The GS-42 sealed sources were tested, with the prior agreement of the NRC staff,[34] with the axes positioned to best simulate their operational orientation under severe conditions. The tests performed on the GS-42 prototype sources were of vertical orientation because they were determined to have a greater probability of failure (i.e. they were more rigorous tests) than tests performed on the "transverse axis."[35] The vibration test protocol was written to provide the worst-case evaluation of the GS-42 double encapsulations. The GS-42s were tested in an orientation expected to result in maximum potential damage. Also, the tests were designed to emulate more realistically the stress on the sealed sources expected to occur when the GS-42 sealed sources are installed in an operational Model 1 irradiator. Further, instead of conducting the test with the GS-42 sealed sources positioned flat against the table and held rigidly along the entire length, the sealed sources were held by their end caps only, thereby allowing the centers of the GS-42s freedom to oscillate. Again, this testing methodology more closely models the manner in which the GS-42 sealed sources are to be used in the Model 1 irradiator and reflects the standards permitted under 10 C.F.R. § 32.210(d).[36]

Further, a "temperature correction factor" was included in the testing protocol to account for the higher than ambient operating temperature for the GS-42 sealed source.[37] In other words,

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[34] Meeting between R.N. Stein, Gray*Star, Inc. and John Jankovich and Larry Camper, NRC (Jan. 4, 1999).

[35] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services Report, Sealed Source Qualification Testing. (Hearing File No. IV.E).

[36] The sealed sources in the Model 1 irradiator are held by their end caps in a source rack with the center tubing portion is not supported by a source rack.

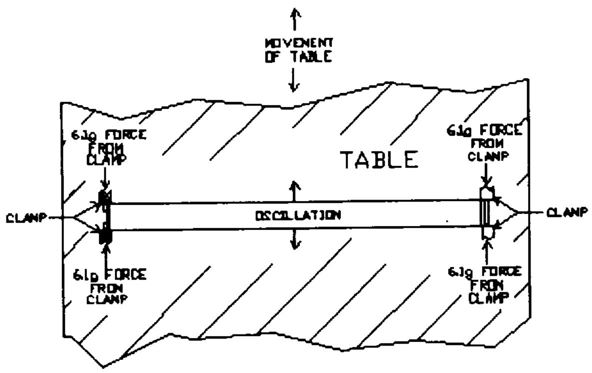
[37] A greater force of 6.1 g's was applied, rather than the standard force of 5 g's required under the regulation. Moreover, 400°C was chosen as the worst case scenario to account for the fact

to account for the potential for diminishing steel strength at higher temperatures, the forces were increased for testing. Although this conservative approach is not required by the "industry standards," Gray*Star used the more rigorous tests to ensure the integrity of the sealed source under normal operating conditions.

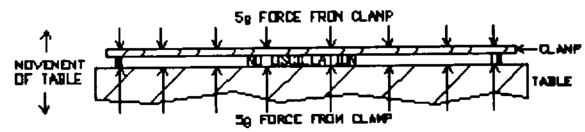
In summary, the testing protocol was designed, with the agreement of NRC staff, to create a more rigorous testing program than is required by the regulations for the GS-42 sealed sources (see diagram below), and to model the way the GS-42 sealed source actually is employed in the Model 1 irradiator. Notably, the GS-42 sealed sources passed each of the more rigorous vibration tests, readily exceeding all regulatory requirements.

Footnote continued from previous page

that 263°C is the actual maximum operating $Cs^{137}Cl$ / metal interface temperature of the Model 1 irradiator. Normal testing procedures call for only an ambient (20°C) test temperature to be used.



TOP VIEW OF ACTUAL VIBRATION TEST SET-UP
(NOT TO SCALE)



FRONT VIEW OF VIBRATION TEST SET-UP PER ISO-2919/ANSI-43.6
(SOURCE FULLY CLAMPED TO TABLE)
(NOT TO SCALE)

REPRESENTATIVE SKETCHES OF
ACTUAL VIBRATION TEST SET-UP vs.
TEST SET-UP PER ISO-2919/ANSI-43.6

ii. Range to 500 hertz.

With regard to the range of vibration tested, the NRC staff's assertion is incorrect because vibration tests were performed and the results reported to the staff at a range of 25-500 Hz. The test report prepared by Smithers Scientific Services, Inc. clearly documents compliance with the 25-500 Hz requirement.[38] As discussed in the report, "[d]ue to the vibration equipment controller limitations, the three sweeps were run in two segments: 25-100 Hz and 100-500 Hz." These sweeps satisfy the intent of the regulation as the purpose of the sweeps is not to test the integrity of the encapsulation, but merely to identify resonance frequencies that are the actual pass/fail tests. Resonance frequencies were found only at 46, 54, 201, and 203 Hz on the two sources tested. Thirty minute vibration tests at 6.1g at each resonant frequency were then run as

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[38] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 3; Smithers Scientific Services

required by the specifications. The encapsulations were then He leak tested and found to be leak-free. Therefore, the sources passed the vibration tests.

3. GS-42 sealed-source construction and durability

The third bases raised by the staff in support of the denial relates to the construction and durability of the GS-42 sealed-source.

Section 36.21(a)(4) requires that sealed sources installed after July 1, 1993:

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

(Emphasis added). The GS-42 sealed source is intended for use only in dry racks inside the Model 1 irradiator. Thus, because the GS-42 sealed source is not for use irradiator pools, a plain reading of section 36.21(a)(4) makes clear that it <u>does not apply</u>. Any other interpretation of the regulation would require a distortion of the English language. In its Denial Letter, however, the NRC staff asserts that Gray*Star's application for registration fails to satisfy section 36.21(a)(4) because it "did not demonstrate that chloride corrosion, which could lead to leaks, would not form in the encapsulations during either the filling process or during operation." As discussed, the NRC staff's reliance on section 36.21(a)(4) is misplaced. Because the GS-42 sealed source is not for use in an irradiator pool, but rather in dry racks in the Model 1 irradiator, the NRC staff's reliance on section 36.21(a)(4) as a basis for the denial is mistaken.

Footnote continued from previous page

Report, Sealed Source Qualification Testing , at 9 and report attachment at 41 - 46. (Hearing File No. IV.E).

Assuming, arguendo, that the Presiding Officer were to somehow interpret section 36.21(a)(4) to apply to the GS-42 sealed source, the GS-42 satisfies this requirement and the staff's arguments with regard to source construction and durability are incorrect.

3.1 Integrity of source housing

In its denial, the staff raises several concerns with regard to the integrity of the GS-42 source housing.

a. Relevance of historical evidence using different fabrication procedures

In its denial letter, the NRC Staff references their July 26, 1999 letter to Gray*Star wherein the staff requested that Gray*Star "show that chlorides were not likely to form pits in the encapsulation during either the filling process or during operation of the irradiator." In response to the NRC July 26 letter, Gray*Star cited historical evidence showing that pitting will not occur in 316L stainless steel and that "the time (in hours) involving the filling operation is not sufficient to significantly promote corrosion of the encapsulation material." The staff found this response insufficient stating "no data were provided showing that the conditions present during the filling process (i.e. pH, time, temperature, concentration of impurities, etc.) will be unlikely to cause corrosion of the stainless steel encapsulation."

During the design phase of the GS-42 sealed source, Gray*Star conducted extensive literature research into the corrosion of various materials when exposed to $Cs^{137}Cl$. Following review of the corrosion potentiality of various compounds, Gray*Star concluded that 316L stainless steel (as prescribed in section 36.21(a)(4)), was the best compound to use in the GS-42 sealed source. The rationale for Gray*Star's conclusion was included in Gray*Star's Application Addendum.[39]

In short, Gray*Star decided to employ 316L stainless steel because the NRC recommends its use in section 36.21(a)(4) and due to its well-known corrosion resistance, favorable structural properties, and its long history of use for encapsulation of $Cs^{137}Cl$. See DOE/ORO-914 (DE91 008210) – Interim Report Of The DOE Type B Investigation Group; Cesium-137; A Systems Evaluation, Encapsulation To Release At Radiation Sterilizers, Inc., Decatur, Georgia; July 1990, 00. 9, A3. (hearing file index # VI.C.7)

All of the research on, and use of, encapsulation materials employing $Cs^{137}Cl$ suggests that there is no better choice than 316L stainless steel. The public literature supports this conclusion. See Fullam, H., "Compatibility of Cesium Chloride and Strontium Fluoride with Containment Materials," Battelle-Nortwest Report No. BNWL-1673, p42 (Cesium Chloride Compatibility) (hearing file index # VI.e.4)

Notably, the NRC staff fails to cite any studies, reports, or analyses in support of its claim that 316L stainless steel is not resistant to corrosion when exposed to $Cs^{137}Cl$ under circumstances similar to those existing with the GS-42 sealed source. In fact, Gray*Star repeatedly requested that the staff provide it with any information relating to the corrosion potential of 316L stainless steel under similar circumstances and no information was provided. (May 25, 2000). Telephone conference between R. N. Stein, Gray*Star, Inc., and J. Jankovich, NRC.

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[39] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator, Amendment 1, Vol. 1 (Sept. 27, 1999) at Quest. 13. (Hearing File No. VI.B).

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

i. pH, ii. Time, and iii. Temperature.

In short, the pH, time, temperature, and solution strength during the filling procedure will be controlled using standard operation instructions pursuant to Gray*Star's Quality Assurance Plan (ASME-NQA-1). The Quality Assurance Plan (the "Plan") is a performance-based system. Under the Plan, Gray*Star will ensure that the detailed specifications in the engineering drawings are satisfied. Should deviations from the Plan be made, Gray*Star would expose itself to liability for failure to comply with the Plan.

With regard to the staff's concern about pH, as described in the application materials, an aqueous solution will be used during the filling procedure to transfer the WESF source material to the GS-42 sealed source encapsulations. With respect to pH of the filling solution, should the WESF material when dissolved in distilled water produce a pH that likely will cause corrosion during the filling process, the pH will be appropriately modified using a neutralizing agent such as CsOH, which will not significantly modify the impurity level of the CsCl source.

With respect to temperature, the temperature of the process will be controlled to maximize the efficiency of the process. After virtually all of the moisture is removed from the encapsulation, (the $Cs^{137}Cl$ is no longer in solution), the temperature will be raised to allow for the material to be "baked". The baking time and temperature will be sufficient to remove all residual moisture down to 0.01% by weight. At no time will the temperature be allowed to increase to a level which might cause sensitization to the stainless steel or a phase transition in the $Cs^{137}Cl$.

With regard to time, the estimated time to transfer the CsCl and distilled water solution into the GS-42 encapsulation and to complete the drying cycle is four (4) hours. This short period of time will mitigate corrosion, if any, to the stainless steel due to the solution to a level that is virtually undetectable. Importantly, Gray*Star has not found, nor has the staff produced, any reference material that details acute corrosive attack on 316L stainless steel upon the introduction of $Cs^{137}Cl$ in distilled water in such a short time period.

iv. Concentration of impurities.

The filing process to be used on the GS-42 sealed sources minimizes impurities which otherwise might be introduced into the encapsulation. For example, the BNL procedure introduced various organic impurities (see attached report). Gray*Star's process does not increase the type or quantities of impurities in the finished encapsulation. The pH of the solution might be dependent on some of the impurities of the original WESF material. Also, as free Barium ions in the WESF capsules interact with the water, it is anticipated that they will produce barium hydroxide. This barium hydroxide will move the pH to a more alkaline solution. If measurements indicate that the pH is excessively acidic, a neutralizing agent will be employed such as cesium hydroxide. The choice of cesium hydroxide is to assure that no impurities are added to the final product.

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

Next, the staff asserted that "moisture remaining in the source tube after fabrication could compromise the integrity of the stainless steel encapsulation." In support of this claim, the staff cites a "Corrosion Data Survey," Metals Section, 6th Edition, which allegedly provides that a 5-15% solution of CsCl in water at a temperature between 150-250°F can have a penetration rate of 0.002 to 0.020 inches per year in Type 316 stainless steel. Applying this data to the GS-42 sealed source, the staff concludes that the GS-42 sealed source's inner source tube would be compromised in 25 years, while the anticipated life of the Gray*Star™ Model 1 irradiator is 60 years. The staff's claim is faulty on several grounds.

First, as indicated in Gray*Star's application and acknowledged by the staff in the denial letter, "the CsCL source will be dry during the operational lifetime" of the Model 1 irradiator because the method for filling the sources involves dissolving CsCl in water, pouring the solution into the source tube, and evaporating water leaving a dry CsCl cake on the inner surface of the source tube. Since the source is dry during the operational lifetime of the Model 1, the corrosion rates used by the staff in their calculation of lifetime corrosion are inapplicable.[40]

Second, moisture will be removed from the encapsulation by a heat/vacuum evaporation process. Gray*Star will ensure under its Quality Assurance Plan (ASME-NQA-1) that the sources will have a maximum moisture content of 0.01% by weight. This maximum limit has been noted on engineering drawings AAI-403 and AAI-404. Therefore, again, the $Cs^{137}Cl$ will not be in solution during the operational lifetime of the sources. Further, following the construction of the actual filling equipment at the "hot-cell" facility, test runs using CsCl will be conducted. CsCl, with impurities like those found in the WESF materials, will be placed in "simulated" WESF containers. The WESF-type material will be removed from the WESF-type container and placed in an aqueous solution and transferred into GS-42 sealed sources using the same apparatus and procedures that will be employed on the actual CsCl from the WESF material. The "simulated" GS-42 sealed sources will then be destructively tested and analyzed to determine whether modifications are required to the apparatus and procedures to meet the design specifications. Only after the apparatus and procedures are finalized and validated will actual CsCl from the WESF materials be introduced for encapsulation. Perhaps most importantly, the

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40 With respect to the staff's concern about corrosion during filling (discussed above), if the amount of corrosion were calculated using the staff's data for the period during filling when the CsCl is in solution, (assuming the longest that the $Cs^{137}Cl$ will remain in solution in the GS-42 encapsulations will be four (4) hours), the amount of corrosion would be 0.000009 inches, which is insignificant.

final moisture content of the CsCl in the simulated encapsulations will be analyzed, pursuant to the Quality Assurance Plan, to ensure that it is at or below 0.01% by weight.

Third, as discussed, the Gray*Star filling process allows for the control of moisture level during filling and in the finished source capsule. This differs from other methods of encapsulation where the moisture content in the finished source capsule is largely dependent on the ambient moisture levels of the loading facility (i.e. the humidity in the "hot-cell" is not normally controlled). Thus, it is common practice to encapsulate $Cs^{137}Cl$ powder in 316L stainless steel sealed sources without controlling the resultant moisture levels in the finished source. For example, data developed using mass spectrographic analysis shows that five welded $Cs^{137}Cl$ powder storage cans that had been in storage for 18 months exhibited a moisture level of 0.07 - 0.16% water by weight.[41] In contrast, in a study completed using simulated non-radioactive WESF source material, "[t]he hermogravimetric analysis of the CsCl indicated less than 0.01% water in the product."[42] More importantly, there is no evidence in these reports that the moisture content in the CsCl material has led to corrosion problems. Gray*Star has not uncovered, nor has the staff provided, any reports on the BNL strip sources, or other $Cs^{137}Cl$ sources, that suggest that moisture content within a sealed source has contributed to the failure of the source due to corrosion of the encapsulation material.

3.2 Crevice corrosion

a. Relevance of historical evidence using different filling procedures.

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41 N. C. Bradley & C. L. Ottinger, Investigation of Deformation in Rectangular Cesium-137 Sources, Isotopes Development Center, ORNL-TM-3069, Oak Ridge National Laboratory; Oak Ridge, TN (Aug. 1970) at 20, Table 4. (Hearing File No. VI.C.4).

42 Fullam, H. T., Compatibility of Cesium Chloride and Strontium Fluoride with Containment Materials, BNWL-1673, Pacific Northwest Laboratories, Richland, WA (Oct. 1972) at 27. (Hearing File No. VI.E.4).

In its denial letter, the NRC Staff acknowledges that it requested that Gray*Star show that crevice corrosion could not be a problem in the GS-42 sealed sources. The staff provided no legal authority in support of its request for this information. Nevertheless, Gray*Star responded to the request with historical information showing that crevice corrosion has not traditionally posed a problem for sealed sources employing 316L stainless steel. See [**CITE WITH E.G. OF HISTORIAL REFERENCE**]. The staff in its denial, dismissed Gray*Star's response by baldly asserting that "due to the differences in the filling procedures between the cited encapsulations and the Gray*Star encapsulation design, the historical evidence is not applicable." The staff failed to provide any support for their claim or explain why the historical evidence is not applicable.

b. Special difficulty removing moisture from crevices

The staff also cites in its denial that "crevice corrosion is a concern, since it may be more difficult to remove moisture contained in these crevices." The staff ignores Gray*Star's replies to questions 14 and 16 in its Application Addendum.[43] Moreover, the staff fails to recognize that combined head and vacuum is the standard physical method for removing moisture from a salt. Further assurance of dryness is provided by baking out the resultant material under vacuum. Because the actual source encapsulation is the drying vessel, it is independent for ambient moisture in the hot cell. This method will assure the dryness of the final material far more than any other process used in the past or present.

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43 See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator, Amendment 1, Vol. 1 (Sept. 27, 1999), Quest. 14 and 16. (Hearing File No. VI.B).

More specifically, the combined head and vacuum will dry not only the moisture within the source material, but will also dry out any moisture from the inside of the inner encapsulation. This is true for crevices within the inner encapsulation.

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

On page 3 of the enclosure to the denial letter, the staff asserts that "effects that impurities in the CsCl source may have on pitting, crevice, and stress corrosion cracking mechanisms was not resolved." Gray*Star had cited historical evidence showing that any impurities in the source would have no effect on the corrosion mechanisms. The staff acknowledged Gray*Star's response in the denial letter. The staff, again claims, however, that the differences in the filling procedure between the encapsulations referenced in the historical citations and the GS-42 sealed source encapsulations renders "the historical evidence [] not applicable." Here again, the staff fails to explain why the alleged differences in the filling procedures renders the historical information inapplicable. In addition, there is no historical evidence that $Cs^{137}Cl$ with a moisture content of less than 0.01% and at an interface temperature below 263° C has resulted in or will result in corrosion of the encapsulations based on impurity content.

The Gray*Star fill process does not introduce any impurities that are not already present in the WESF capsules. Exhibit 2 of the Application[44] and the reply to Addendum Questions 14 -

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[44] See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator (April 15, 1999) at Exh. 2 - Chemical Composition of Source Material - Cesium Chloride. (Hearing File No. VI.D)

16[45] detail the effect of impurities present in the WESF material on the stainless steel as regards to pitting, crevice corrosion, and stress cracking. Based on the data from the WESF materials, which suggests that impurities may have a substantial effect on the corrosion rate, Gray*Star designed the GS-42 source encapsulations to have a maximum $Cs^{137}Cl$/metal interface temperature of 263° C which will mitigate the high temperature-high impurity affected corrosion rate increase as seen in the referenced text.

The Gray*Star fill technique will greatly limit impurities produced by the manufacture, filling, and testing of the encapsulation. The fill technique will eliminate the use of organic material in the testing of the capsules, thereby virtually eliminating the chance of the impurity-free WESF material becoming contaminated (all organic impurities were burned off during the melt-cast filling procedure). Unlike the filling of the BNL strip sources, the Gray*Star fill technique introduces no impurities, inorganic or organic, as the transfer medium is distilled water, which will not add impurities.

3.4 Long term reliability and failure modes

The staff stated in support of its denial that Gray*Star failed to adequately address the potential failure of the GS-42 sealed sources over the long-term. Specifically, the staff claimed that "due to the differences between the GS-42 and the WESF encapsulation, different failure mechanisms may occur, and the applicant did not adequately address such potential failure."

a. Relevance of historical experience with WESF sources.

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45 See Application for Sealed Source and Device Evaluation and Registration, GS-42 Sealed Source, Gray*Star™ Model 1 Irradiator, Amendment 1, Vol. 1; September 27, 1999, Quest. 14 and 16. (Hearing File No. VI.B).

NRC approved the WESF encapsulations as a sealed source for use in commercial irradiators on a probationary test basis. The test indicated that there were certain problems with such use. These problems led to a failed WESF source in Decatur, Georgia. The data received from these tests were incorporated into the design rationale of the GS-4Z for their exclusive use in the Model 1 irradiator. Gray*Star, Inc. reviewed the data and specifically mitigated against all known and suspected causes of deformation and failure of the WESF sources (as well as all other incidence of source deformation and failure know to Gray*Star). The history of WESF sources has also provided data on components of cesium sources which are positive in nature. For example, the use of 316L stainless steel has not been indicated in any of the deformations and failure of the WESF source, nor any other known cesium source.

Also, refer to the supplemental report (attached) for a detailed analysis of deformation/failure mechanisms and the techniques employed by Gray*Star to mitigate against these deformations and failure.

b. Potential failure modes specific to GS-42.

There are design differences between the GS-42 and other sealed sources. These design differences were specifically incorporated to mitigate known and hypothetical failure mechanisms. Attachment A is a summary report[46] that addresses the design factors of the GS-42 source encapsulations which mitigate possible problems and actual failures of other encapsulation designs and addresses hypothetical failure mechanisms relative to the unique

46 R.N. Stein, Mitigation Design Techniques Incorporated In GS-42 Sealed Sources For Use in Gray*Star™ Model 1 Self-Shielded Irradiators (July 24, 2000) (Attachment A).

aspects of the GS-42 design. It compares the GS-42 sealed source to the WESF and BNL Strips as well as other sealed sources.

3.5 .a Applicability of 10 C.F.R. Part 36

i. Applicability of 10 C.F.R. Part 36 to GS-42 Source Used in a Category I Irradiator

As a threshold matter, the requirements of 10 C.F.R. Part 36, including 10 C.F.R. § 36.21(a)(3) should not be applied to the GS-42 sealed source because the requirement of Part 36 do not apply to "Category I" irradiators. Irradiators have been divided up into four general categories by the American National Standards Institute. See, e.g., ASNI Standard N13.10, "Safe Design and Use of Panoramic Wet Source Storage Gamma Irradiators (Category IV)." The NRC adopted ANSI's four category classification system. See 58 Fed. Reg. 7,715, (1993) (final rulemaking for 10 C.F.R. Part 36). In the final rulemaking promulgating 10 C.F.R. Part 36, NRC made clear that the new rule "does not cover self-contained dry-source-storage irradiators (Category I) for several reasons." Id. The Gray*Star Model 1 irradiator fits best into Category I in the ANSI four-category system.[47] Moreover, the reasons given for why Part 36 does not apply to Category I irradiators also apply to the Model 1 irradiator. If the Model 1 irradiator is demonstrated to be a Category I irradiator, the requirements of 10 C.F.R. Part 36, including 10 C.F.R. § 36.21(a)(3), would not apply to the registration of the GS-42 sealed source design.

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[47] The ANSI four-category classification system was developed before the genesis of the Gray*Star Model 1 irradiator, and was based on the characteristics of then-exiting irradiator designs. As a result, the Gray*Star Model 1 irradiator does not fit cleanly into any of the categories developed by ANSI. Gray*Star believes, however, that the Model 1 irradiator is most closely aligned with the form, function, and intent of Category I irradiators.

The two reasons given by the NRC for excluding Category I irradiators from the requirements of 10 C.F.R. Part 36 also apply to the Gray*Star Model 1 irradiator. The first reason given by the NRC is that "they are devices that the licensee usually purchases without participating in their design and manufacture." This is fundamentally different from the "facility-type" irradiators in Categories II, III, and IV, in which the licensee is integrally involved in the design of the irradiator and the irradiator design is usually one-of-a-kind. The Gray*Star Model 1 irradiator is aligned with the Category I irradiators. Just like the Category I irradiators, the Model 1 irradiator is a "device" (not a "facility") that the licensee leases without participating in the design and manufacture of the irradiator. The Model 1 irradiator is a device, not a facility. Unlike Category II, III and IV irradiators, the Gray*Star Model 1 irradiator is a standardized device, not a one-of-a-kind facility.

The second reason given by the NRC is that "[b]ecause safety features are designed into them, self-contained irradiators present less potential hazard ...." The Gray*Star Model 1 is a self-contained irradiator (source and shield are integral to the device) that has numerous unique safety features designed into it to protects operators and the public. Many of these features are discussed in the response to Question #1, supra. Unlike Category II, III and IV irradiators, the Model 1 irradiator does not place primary reliance for safety on operator training and interlocks, but instead, like a Category I irradiator, uses the physical design of the device as the primary means of protecting health and safety.

The Gray*Star Model 1 irradiator fits within the ANSI definition of a Category I irradiator. The ANSI definition of a Category I irradiator is as follows:

> An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed

source(s) and the volume(s) undergoing irradiation is not
physically possible in its designed configuration.

ANSI Standard N433.1. The Gray*Star Model 1 irradiator meets the intent of the this definition.

First, a Category I irradiator is "[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials." ANSI Standard N433.1. The sealed GS-42 sources in the Gray*Star Model 1 irradiator are completely contained in a dry container of solid materials. As stated earlier in this filing, the Gray*Star Model 1 is a dry-source-storage irradiator, with no water pool for source storage or change-out. The sealed sources are an integral part of the Gray*Star Model 1 irradiator, and integral to the shielding of the irradiator. The Model 1 is fundamentally different from Category II, III and IV irradiators in which the source and shielding can move independently.

Second, a Category I irradiator is one in which "the sealed source(s) is shielded at all times." ANSI Standard N433.1. The GS-42 sealed sources are shielded in the Gray*Star Model 1 device at all times. There is no physical way for the GS-42 sealed sources in the Gray*Star Model 1 irradiator to irradiate any area outside the Gray*Star Model 1 device.

Third, a Category I irradiator is one in which "human access to the sealed source(s) … is not physically possible in its designed configuration." ANSI Standard N433.1. By design, the GS-42 sources are integral to the Gray*Star Model 1 irradiator and its shielding. Human access to the sealed sources is not physically possible.

Fourth, a Category I irradiator is one in which "human access to the … volume(s) undergoing irradiation is not physically possible in its designed configuration." ANSI Standard N433.1. This aspect of the Category I definition is the most difficult for the Gray*Star Model 1 to meet. Human access to the radiation chamber of the Gray*Star Model 1 is not required. Due to its low height (four and a half feet) and small volume, access to the small radiation chamber of the Gray*Star Model 1 irradiator would be difficult and extremely uncomfortable. Nonetheless, human access to the radiation chamber is not physically impossible.[48] This analysis, however, misses the point of the definition. Category II, III and IV irradiators are facility-type irradiators in which the radiation chamber is a very large facility-type room into which operators routinely enter and work. The concern with such irradiators is that an operator will enter the large radiation room while the room is exposed to the source. This type of "facility-type" irradiator is fundamentally different from the "device-type" irradiator typical of Category I and the Gray*Star Model 1 irradiator. Unlike Category II, III and IV irradiators, the radiation chamber in the Model 1 irradiator is not a large facility-type radiation room, the radiation chamber is not routinely entered by operators, and it is physically impossible to enter the radiation chamber while the chamber is exposed to the source (because of the integral shield/source used in the Model 1 irradiator device).

Therefore, the Gray*Star Model 1 irradiator fit best into the definition of a Category I irradiator, under the ANSI four-category classification system, and is clearly different from the Category II, III and IV irradiators in the ANSI classification system.[49] As a Category I irradiator, the Gray*Star Model 1 and its GS-42 sources would be exempted from the requirements of 10 C.F.R. Part 36, and would instead be licensed under the general requirements of 10 C.F.R. § 30.33 that are used to license Category I irradiators. If the Gray*Star Model 1

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[48] Gray*Star notes that human access is not physically impossible for other Category I irradiators. At least one Category I irradiator has a radiation chamber 14 inches high, 10 inches wide, and 10 inches deep. While human access may not be practical, a small human could physically access such a radiation chamber.

[49] If the ANSI classification system been created after the development of the Gray*Star Model 1 irradiator, it appears clear that the ANSI definitions would have been modified to cleanly encompass the Model 1 irradiator. The closest fit in the ANSI classification system for the Gray*Star Model 1 irradiator is ANSI Category I.

irradiator is determined to fit best as a Category I irradiator, the requirements of 10 C.F.R. Part 36 would not apply to the GS-42 sealed sources and the NRC staff's denial of registration based on the requirements of 10 C.F.R. Part 36 would be without merit.[50]

ii. **Applicability of 10 C.F.R. § 36.21(a)(3) GS-42 Source Used in a Dry-Source-Storage Irradiator**

The issue in Question #1 of this filing addresses the GS-42 source design's compliance with the requirement in 10 C.F.R. § 36.21(a)(3). If this section does not apply to the GS-42 source design, then the issue addressed in Question #1 is moot as a matter of law.

Even if 10 C.F.R. Part 36 is determined to apply to the Gray*Star Model 1 irradiator, it appears to be clear that § 36.21(a)(3) should not be applied to the GS-42 source design. It is clear from inspection of the text of Part 36, as well as its regulatory history, that not every section of Part 36 applies to every type of irradiator. Many of the requirements in Part 36 apply only to wet-source-storage water-pool type irradiators. See, e.g., 10 C.F.R. §§ 36.21(a)(4), 36.23(i), 36.25(b), 36.29(b), 36.33, 36.39(c), 36.39(d), 36.41(c), 36.41(d). NRC acknowledged from the beginning that only certain of the requirements of Part 36 are applicable to a given type of irradiator. For example, the regulatory impact analysis supporting the proposed rule for 10 C.F.R. Part 36 states clearly that "[s]ince the proposed rule covers several types of facilities, not all requirements apply to all types of irradiators." Draft Regulatory Analysis and Environmental Assessment of NRC Regulations on Licenses and Radiation Safety Requirements for Large Irradiators, SEA Report No. 87-288-09-A, Prepared for U.S. Nuclear Regulatory Commission at 5 (Feb. 1989). Directly on point for the matter at issue here, the regulatory impact analysis

[50] If this determination were made, the GS-42 sealed source registration request would be returned to the NRC Staff for review under the applicable requirements for sources used in

clearly stated that "not all regulations governing source storage pools apply to dry-source storage facilities." Id.

The plain text, regulatory guidance, and regulatory history of 10 C.F.R. § 36.21(a)(3) demonstrate that this section applies only to sources used in a wet-source-storage or wet-source-change irradiator. The GS-42 sealed source design will not be used in either a wet-source-storage or wet-source-change irradiator. The GS-42 sealed source is to be used solely and exclusively in a dry-source-storage irradiator, the Gray*Star Model 1 irradiator. If the requirement in 10 C.F.R. § 36.21(a)(3) does not apply to dry-source-storage irradiators, then the GS-42 sealed source design is not required to meet this requirement, and the issue raised in Question #1 is moot as a matter of law.[51]

Canons of construction, applicable to regulations as well as to statutes, direct that the first inquiry be made of the plain text of the regulation. Where the plain text is clear, the decision maker need look no further. The text of 10 C.F.R. § 36.21(a)(3) states that sealed sources:

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

10 C.F.R. § 36.21(a)(3) (emphasis added). The literal text therefore states that a sealed source must use material that is "as nondispersible as practical" and "as insoluble as practical" where "the source is used in a wet-source-storage or wet-source-change irradiator." There is nothing to indicate that only the second phrase is limited to wet-source-storage irradiators, or that the first phrase is not limited to wet-source-storage irradiators but is rather generally applicable to all

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Category I irradiators.

[51] Nonetheless, the Gray*Star's response demonstrates that the GS-42 source design, as used in the Gray*Star Model 1 irradiator, is designed to be as nondispersible as practical.

irradiators. If this were the intent, the drafters of the regulation could have set the two phrases apart using appropriate punctuation (i.e., a comma following the first phrase). There is no comma after the first phrase, or any other means to separate the two phrases with respect to the qualifying clause regarding wet-source-storage irradiators.

Moreover, this is consistent with structure of the rest of 10 C.F.R. § 36.21(a). 10 C.F.R. § 36.21(a) provides performance requirements for sealed sources, and has five subsections. Where a subsection of § 36.21(a) is of general applicability to all irradiators, no mention of irradiator type is used at all. This can be seen in 10 C.F.R. §§ 36.21(a)(1), (2) and (5). However, where a subsection of § 36.21(a) applies only to a specific category of irradiators, the subsection explicitly states a specific irradiator type. This can be seen in 10 C.F.R. § 36.21(a)(4), which explicitly states "if the sources are for use in irradiator pools." Just like 10 C.F.R. § 36.21(a)(4), 10 C.F.R. § 36.21(a)(3) also explicitly states a specific irradiator type, "if the source is used in a wet-source-storage or wet-source-change irradiator." The structure of § 36.21(a) indicates that requirements are only of general applicability where no specific irradiator type is provided. This is clearly not the case with 10 C.F.R. § 36.21(a)(3), and therefore the structure of the broader regulation also indicates that the "nondispersible as practical" phrase of 10 C.F.R. § 36.21(a)(3) is not a requirement of general applicability, but rather is limited, like is companion phrase "as insoluble as practical" specifically to "a wet-source-storage or wet-source-change irradiator." Nothing in the plain text of 10 C.F.R. § 36.21(a)(3) indicates that it also applies to dry-source-storage irradiators (i.e., irradiators like the Gray*Star irradiator).

The plain text interpretation of 10 C.F.R. § 36.21(a)(3) is fully consistent with the NRC Staff's published regulatory guidance concerning 10 C.F.R. § 36.21(a)(3). The NRC Staff has published two NUREGs to provide guidance to NRC staff reviewers and to license applicants that address this requirement. The staff's regulatory guidance to its reviewers and the public provides the NRC staff's published interpretation of NRC regulations. In NUREG-1550, "Standard Review Plant for Applications for Sealed Source and Device Evaluations and Registrations," the NRC staff provides guidance to its own staff reviewers regarding "the information and materials necessary to make a determination that the product is acceptable for licensing purposes." NUREG-1550 at iii (Nov. 1996). NUREG-1550 addresses 10 C.F.R. § 36.21(a)(3) with regard to licensing of irradiators. In NUREG-1550 the NRC staff states:

> Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21. One such requirement is that the licensed material be as insoluble and <u>nondispersible as practicable if used in a wet-source-storage or wet-source-change irradiator</u>.[52]

NUREG-1550 at 16 (emphasis added). There is no mistaking NRC staff's written meaning and intent in this statement - the "nondispersible" requirement in 10 C.F.R. § 36.21(a)(3) applies <u>only</u> to sources "used in a wet-source-storage or wet-source-change irradiator." This is fully consistent with the plain text reading of the regulation provided above.

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

[52] The NRC staff points out that "[t]he manufacturer or distributor of the sealed sources may demonstrate that the sealed sources meet the requirements as part of the evaluation and registration of the sealed source." NUREG-1550 at 16.

NUREG-1556 addresses 10 C.F.R. § 36.21(a)(3). In Volume 3 of NUREG-1556 the NRC staff again states:

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

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

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

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

Draft Reg. Guide DG-0003 at section 3.5 (emphasis added). This shows the same consistent NRC staff interpretation in its published guidance documents – the requirements in 10 C.F.R. § 36.21(a)(3) apply only to wet-source-storage and wet-source-change irradiators, and do not apply to dry-source-storage irradiators that do not use water pools for source storage or to load or unload sources at the irradiator. This published NRC staff interpretation of 10 C.F.R. § 36.21(a)(3) is once again consistent with the plain meaning of the text of the regulation.

The plain meaning of the text, as provided above, is also supported by the regulatory history of 10 C.F.R. § 36.21(a)(3). The proposed rulemaking for 10 C.F.R. Part 36 clearly demonstrates that the rulemaking was driven in response to a leaking source accident at a wet-source-storage irradiator in Decatur, Georgia, in 1988. See 55 Fed. Reg. 50,008, 50,010 (1990). The particular water pool irradiator that experienced the leak accident used cesium chloride sources in the outdated WESF encapsulations. There was no requirement like that final section 10 C.F.R. § 36.21(a)(3) in the proposed rule. During the rulemaking period, the issue of the continued use of cesium chloride and the WESF canisters was discussed and considered. On this subject, one key commenter, Greta Dicus, now a Commissioner of the NRC, while agreeing the outdated WESF source encapsulations should no longer be used, recommended that cesium-137 not be excluded as a source material "so long as it is appropriately encapsulated in appropriate form for the kind of irradiator that it is going to be used in."[53] Another commenter, Mr. Dietz, stated in the same meeting that "[c]esium is a pretty good source, and it's a good national asset. What is at fault is the encapsulation. I don't think it would be fair to bar cesium forever because we had an inappropriately encapsulated source which was designed for a totally different operation used in an irradiator and had this kind of problem."[54]

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

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

SECY-93-323, "Final Rule on 'Licenses and Radiation Safety Requirements for Irradiators," enclosure 1 at 70 (Sept. 18, 1992). The proposed final rule made no differentiation between types of irradiators and would therefore have been of generic applicability to all irradiator types.

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

The regulatory basis in the NRC staff's SECY supporting the proposed final rule (i.e., the proposed Statement of Considerations for the final rule) stated that "[t]he requirement that the radioactive material in the sources be as insoluble and nondispersible as practical not included in the proposed rule, although comment was sought on whether the use of cesium-137 should be permitted in irradiators in view of its solubility." Id. at 15. The staff's basis for this new requirement, however, only identified leakage events at water pool irradiators (particularly the WESF encapsulation failure at the water pool irradiator facility in Decatur, Georgia), and failed to identify even a single leakage event at a dry-source-storage irradiator.[55] Id. at 7. The Commission approved the NRC staff's proposed final rule, but in his approval NRC Chairman Selin made a comment specifically regarding the scope of 10 C.F.R. § 36.21(a)(3), as proposed by the staff. SRM-921027, "Staff Requirements – Affirmation Session/Discussion and Vote, 10:30 a.m., Tuesday, October 27, 1992," Encl. 3 at 1 ("Chairman Selin's Comments on SECY-92-323"). In his comments, NRC Chairman Selin recognized the disconnect between the general wording of the proposed 10 C.F.R. § 36.21(a)(3), and its regulatory basis, which applied only to water pool irradiators. Chairman Selin stated:

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

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[54] Id. at 50.

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

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

The plain language of 10 C.F.R. § 36.21(a)(3) agrees with the NRC staff's published interpretation of the regulation and the regulatory history of the development of the regulation. The requirement in 10 C.F.R. § 36.21(a)(3) applies only to wet-source-storage or wet-source-change irradiators, and does not apply to dry-source-storage irradiators. Since the GS-42 selaed source is to be use solely and exclusively in a dry-source-storage irradiator (the Gray*Star Model 1 irradiator), the requirement in 10 C.F.R. § 36.21(a)(3) does not apply to the GS-42 sealed source. As a result, registration of the GS-42 sealed source, for use solely in the Gray*Star Model 1 irradiator, cannot be denied on the grounds of 10 C.F.R. § 36.21(a)(3), and the demonstration that the GS-42 sealed source is "as nondispersible as practical" in Question #1 is moot.[56]

3.5.b Compliance with 10 C.F.R. § 36.35

During the September 7, 2000, telephone conference, counsel for the NRC staff indicated that it wished to raise Gray*Star's compliance with 10 C.F.R. § 36.35 ("Source rack protection") in further support of its denial of the application for registration. See September 14 Order at 2. Section 36.35 states:

> If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

Gray*Star's Model 1 irradiator, which is specifically designed to employ the GS-42 sealed source, does not call for the product to be irradiated to move on a product conveyor system; therefore, the barrier requirement in section 36.35 does not apply. Any assertion to the contrary would ignore the plain meaning of the regulation. Assuming, arguendo, the regulation did somehow apply, the staff raises compliance with section 36.35 for the first time now. Such a post-hoc rationalization cannot be the basis of the denial of the registration request. In any event,

[56] Of course, the demonstration that the GS-42 source, as used in the Gray*Star Model 1 irradiator is "as nondispersible as practical" adds even more defense-in-depth to the overall safety of the GS-42 sealed source and Gray*Star model irradiator design.

however, the camber walls within the Model ! are a protective barrier to prevent the product from contacting the source rack.

4. **Sufficiency of information about design of GS-42 "to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property" under 10-CFR-33.210(c) - i.e., finality and verifiability of design, generally.**

The final bases asserted by the staff in support of its denial relates to the sufficiency of the information provided by Gray*Star about the design of the GS-42 sealed source.

Section 32.210(c) provides that the request for a review of a sealed source seeking registration must include "sufficient information about the design, manufacture, and prototype testing . . . to provide reasonable assurance that the radiation safety properties of the source [ ] are adequate to protect health and minimize danger to life and property." 10 C.F.R. § 32.10(c). Citing this provision, the staff states in its denial letter that Gray*Star's application "did not provide finalized and verifiable design configuration for a number of safety issues." The staff has adopted an overly restrictive interpretation of the regulation, overlooking the fact that the regulation by its own words does not require that "finalized and verifiable design configuration" be provided, rather it only requires that "sufficient information" be provided to provide "reasonable assurance" that the "radiation safety properties of the source are adequate." As discussed below, Gray*Star provided specific data regarding the design, manufacture, and prototype testing of the GS-42 sealed source that is sufficient to provide assurance that its radiation safety properties are adequate.

4.1 Sufficiency of information about final design of source welding procedures.

The first issue the staff raises with regard to its claim that Gray*Star failed to provide "finalized and verifiable design information" relates to the welding of the sources. Specifically, on page 3 of Enclosure 1 to the denial letter, the staff claims that "since the welding method and appropriate quality standards have not been determined, we cannot reach a conclusion about the adequacy of the source welds." The attached drawings show the welding method and standards drawings;[1] these drawings provide ample information supporting the adequacy of the source welds. See Attachment B.

Gray*Star notes that should changes in the welds be necessary following the hot cell operator's pilot production runs,[57] Gray*Star will consult the NRC staff regarding the changes and, if necessary, will file a request for an amendment to the Certificate of Registration to account for any significant differences in the welding method between the initial Certificate of Registration application and the pilot run.

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

The second issue the staff raises with regard to its claim that Gray*Star failed to provide "finalized and verifiable design information" relates to the filling of the sources. The staff claims that Gray*Star failed to provide adequate information regarding the procedure by which CsCl is introduced into the stainless steel GS-42 encapsulations. Specifically, the staff asserts that evidence must be provided to show (1) that moisture is adequately removed from the inner and outer source tubes prior to sealing, and (2) corrosion did not occur in the source tube during the filling procedure such that the integrity of the source tube could be compromised. As discussed above, see supra, and further discussed below, the moisture content in the source tube will be well below any level sufficient to be of concern, and corrosion in the source tube during filling will, if at all, be minimal pursuant to the performance based commitment in Gray*Star's QA/QC plan.

a. Adequacy of moisture removal procedure

There appears to be some confusion by the staff regarding the filling process to be employed by Gray*Star. <u>See</u> Denial Letter Encl. 1 at 4. Gray*Star intends to use the evaporative process described in its application: a heat and a vacuum system to drive off the water from the source, which will ensure that the desired maximum moisture content is not exceeded. No other alternative filling process will be employed. Using this process, the maximum moisture level in the completed encapsulations will be 0.01% by weight.[58] This level will be controlled under Gray*Star's Quality Assurance Program (ASME-NQA-1). With respect to pitting, a literature search shows that pitting of the 316L material "within minutes" under the conditions at filling is highly improbable. With regard to uniformity, uniformity of filling will be maintained by filling the encapsulations in a horizontal orientation and will be confirmed using radiation measurement. Moreover, uniformity of the $Cs^{137}Cl$ in the source tubes will be measured using the actual dose rate assays after the filling process is complete.[59]

Further, the inner capsules and the $Cs^{137}Cl$ will be purged with dry helium gas during the process and prior to sealing. This unique method of filling prevents ambient gas and moisture to be introduced into the inner encapsulation. Thus, the method will allow tight control of what is in the encapsulation and the moisture level of both the $Cs^{137}Cl$ and the encapsulation itself.

Footnote continued from previous page

57 The filling and welding of the source capsules will be conducted by a contractor of Gray*Star, referred to here as the "hot cell operator," because the procedures will take place in a "hot cell" to ensure adequate protection of human health and the environment.

58 <u>See</u> DRAWINGS – AAI-403, rev 2 / AAI-404, rev 2, Note 1 ("The inner source tube is to be filled with radioactive cesium chloride. H_2O content in the cesium chloride must be 0.01% maximum (by weight) prior to installing the inner seal plug.").

59 This second control mechanism is consistent with NRC's "defense in depth" policy.

A maximum limit on percent water in the $Cs^{137}Cl$-filled source tubes, see supra at 3.1, per the NRC's request has been put directly on the engineering drawings. Notably, a review of other NRC-approved applications for registration for sealed sources, including sealed sources where Cobalt-60 is the source, shows that detailed information concerning how the source material is procedurally placed in the source tubes was not included. Under the NRC approved performance based Quality Assurance Program, Gray*Star is bound to ensure that all design parameters are met on the final GS-42 sealed source.

b. Prevention of corrosion

The NRC staff's denial letter states that: "[a]ccording to some technical references, pitting initiation times in stainless steel could occur within minutes if conditions (i.e. pH, temperature, chloride concentration) are severe enough." As discussed, previously, the staff does not, however, include any technical references. Gray*Star requested a copy of these document(s) referred to by the staff. Counsel for Gray*Star requested copies of the document(s) as well, but none were provided.

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

The $Cs^{137}Cl$ solution does not come into contact with the silver sealing surfaces during the wet fill process. The dry $Cs^{137}Cl$ does not come into contact with the silver sealing surfaces during the operational life of the sources.

The wet fill process includes tubing that is inserted into the inner encapsulation through the fill hole. It forms a seal with the inner endcap independent of the compression seal area. The tubing will be made of 316L stainless steel. The specific parameters of the tubing will be designed to optimize filling and to assure appropriate moisture removal. One of the key parameters of the tubing is that it must ensure that at no point does $Cs^{137}Cl$, either dry or in solution, come into contact with either sealing surface.

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

The uniformity of construction is specified on the drawings.[60] The "breakaway" diameter must be within 0.398 and 0.402 inches. Quality control checks under the Quality Assurance Plan will assure these dimensions.

The seal plugs are designed in such a way that they neck-down to a pre-determined diameter, providing an area large enough to ensure the minimum torque required for sealing is achieved prior to breaking off. Minimum torque requirements were determined experimentally under the Quality Assurance Plan. A maximum torque value is irrelevant (i.e. use whatever torque is necessary to break off the head of the plug). The breakaway seal plug method was specifically designed to provide appropriate pressure to the seal plugs without reliance on measuring equipment or human operator, both of which are subject to error. Further, the breakaway method was designed to be compliant with 10 C.F.R. § 71.4 which states: special form radioactive material means "...it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule."

V. CONCLUSION

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

Respectfully submitted this 25th day of September, 2000.

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60 See Attachment B.

By: _______________________
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ON BEHALF OF GRAY*STAR, INC.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judges:

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

In the Matter of	)	
GRAY*STAR, INC.	)	Dkt. No. SSD 99-27 ASLBP No. 00-778-06-ML
(Suite 103, 200 Valley Road, Mount Arlington, NJ 07856)	)	September 25, 2000

CERTIFICATE OF SERVICE

I hereby certify that I caused true and complete copies of the foregoing GRAY*STAR, INC.'S BRIEF IN SUPPORT OF ITS APPLICATION FOR REGISTRATION OF MODEL GS-42 SEALED SOURCE in the above-captioned matter to be served, via first class mail delivery and electronic mail on this 25th day of September, 2000 to:

Administrative Judge
Ann M. Young, Presiding Officer
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Mail Stop T-3 F23
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Adjudicatory File
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
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Office of the Secretary
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ATTACHMENT A

MITIGATION DESIGN TECHNIQUES INCORPORATED IN GS-42 SEALED SOURCES FOR USE IN **GRAY✦STAR™** MODEL 1 SELF-SHIELDED IRRADIATORS

[A Rationale for Design Criteria]

R.N. Stein

07/24/00

INTRODUCTION:

This report relies heavily on histories of both the WESF and BNL Strip sources. These source histories where chosen because of the wealth of documentation available. It is important that the reader reads the following references (attached) in their entirety to best understand the comparisons of the GS-42 and other source encapsulations.

Investigation of Deformation in Rectangular Cesium-137 Sources, N.C Bradley and C.L. Ottinger, Oak Ridge National Laboratory, ORNL-TM-3069, August 1970 [1]

Characterization of an Aged WESF Capsule, B.T. Kenna / F.J. Schultz, Sandia National Laboratories / Oak Ridge National Laboratory, SAND-83-0928 / TTC-0434, UC-71, July 1983 [2]

Interim Report of the DOE Type B Investigation Group, Cesium^{137}: A Systems Evaluation, Encapsulation to Release at Radiation Sterilizers, Inc., Decatur, Georgia; DOE/ORO-914 / DE-91-008210; July 1990 [3]

BACKGROUND:

This report will describe the various techniques used to improve upon the safety and reliability of $Cs^{137}Cl$ source encapsulations. These techniques were developed to avoid failure potentials in existing sources. Review of WESF and BNL Strip sources indicate that the method of encapsulation was a prime contributor to deformation and failure of existing sources. GRAY*STAR, Inc. has chosen to use a new type of encapsulation technique which benefits from the successes of the previous methods while mitigating against their failures and potential failures. This method is referred to as the "wet fill process".

There are two specific advantages to the wet fill process. First, the $Cs^{137}Cl$ material which is ultimately present in the final source is a dry, caked powder material containing insignificant organic impurities. Based on what was learned about the WESF and BNL source histories, a material in this form will not cause any known problems and has not been a contributor to source deformation or failure. Second, the process allows greater control of the material to achieve the previous advantage. In essence, the inner encapsulation itself becomes the processing chamber for the material. The system is independent of ambient conditions in the hot cell. For example, after filling, the $Cs^{137}Cl$ material and the encapsulation will be heated together to drive off any moisture within the encapsulation. Further, the final $Cs^{137}Cl$ will not be open to the hot cell environment which could allow reintroduction of ambient gas or moisture as is the case with other filling techniques.

A portion of the GRAY✦STAR Model 1 irradiator is a shipping package as defined in 10 CFR 71 and is subject to the stringent Quality Assurance provisions of that regulation. During a meeting with the U.S. Nuclear Regulatory Commission (NRC) on September 8, 1998, the NRC asked that GRAY*STAR, Inc. follow the same Quality Assurance Plan for both the sources and the device. We agreed to this provision even though it put GRAY*STAR, Inc. through hardship not required of our competition. The meeting was attended by Steve Baggett, John Jankovich, Patricia Eng, Kirk Lathrop, and Larry Camper of the NRC. Under the GRAY*STAR, Inc. Quality Assurance Plan, the engineering, testing, and construction of the source and device are tightly controlled and documented. Any knowledgeable violation of the GRAY*STAR, Inc. Quality Assurance Plan has severe criminal penalties independent and above that normally associated with the development and implementation of a source or device. During the same conversation, the NRC specifically stated that they were not concerned with how the encapsulations were filled, but, that the encapsulations are in compliance with the regulations of a "sealed source" [Steve Baggett].

GRAY*STAR, Inc. will manufacture the sources in compliance with their drawings as provided. This will be performed under the GRAY*STAR, Inc. Quality Assurance Plan and is subject to inspection by the NRC. To pre-define all of the steps required for the filling process within the Application for the sealed source would limit the ability of GRAY*STAR, Inc. to assure compliance with the drawings as provided. For example, if we were to outline a specific system to assure that the moisture level in the final encapsulation is at or below 0.01% by weight and the system were not capable to achieve this as outlined, the system would have to be modified to achieve the specified results under the GRAY*STAR, Inc. Quality Assurance Plan. This modification might be contradictory to the specifications of the application for the sealed sources. It is the contention of GRAY*STAR, Inc. that pre-definition of all of the steps required for the filling process within the Application of the sealed sources is impractical. Further, GRAY*STAR, Inc. believes this is beyond the scope of the review of an application for a Certificate of Registration of a sealed source and is not required of other sealed source manufacturers.

It is a well understood manufacturing principle that it is impractical to lock both the detailed methods of construction, and at the same time, require performance standards of the device. All manufacturing standards have provisions for appropriate modification to provide a specified end result.

SCOPE:

The GS-42 sealed source is specifically designed to mitigate all known failures of existing and previous $cesium^{137}$ chloride (as well as $cobalt^{60}$) sealed sources. Further, it is designed to reduce the probability of GS-42 source failure due to hypothetical mechanisms. In addition, the GS-42 has been designed and tested under the GRAY*STAR, Inc. NRC-approved Quality Assurance Plan.

$Cesium^{137}$ in the form of cesium chloride ($Cs^{137}Cl$) powder has been used for over 35 years in "category I" and "category II" irradiators. Its safety record is excellent. However, some deformations have been reported; mainly in the BNL Strip sources. Source encapsulations which are known to deform are still in use and are still being given Certificates of Registration by the NRC for use in both category I and category II irradiators. However, GS-42 is specifically designed to avoid these deformations.

$Cesium^{137}$ in the form of cesium chloride melt-cast has been used in the past in category II, category III, and category IV irradiators. Its safety records for categories II and III are excellent; however, there was one source failure in a category IV irradiator which is well documented. The GS-42 is specifically designed to mitigate against this type of failure.

This summary compares the design factors of the GS-42 with respect to the other $Cs^{137}Cl$ sources mentioned above. These design factors have led to unique features of the GS-42 which are also summarized to illustrate how they maintain a low probability of causing failure. Further, there are design features of the GS-42 which have been incorporated to reduce failure due to hypothetical possibilities.

DESIGN COMPARISONS:

Source Loading:

The cesium^{137} for the GS-42 is in the form of cesium chloride ($Cs^{137}Cl$). The initial material will be obtained from existing WESF sources (see below). The material will be extracted from the WESF encapsulations using a sealed system of dissolving the $Cs^{137}Cl$ in the WESF capsules using pure water, transferring this solution to the GS-42 through a closed system, and vacuum / heat evaporation of the solution directly within the GS-42 encapsulation. Therefore, the chemical composition of the initial material in the GS-42 will be identical to the WESF material with the exception of insoluble impurities, a portion of which will remain in the WESF encapsulation for appropriate disposal. Other techniques, such as those used for the WESF and BNL Strip source encapsulations referenced in the following two paragraphs, would lead to potentially higher contamination, radiation levels, and waste produced. GRAY*STAR's wet fill technique is highly desirable because it minimizes hot cell contamination and radioactive waste products and is therefore in accordance with the philosophy of ALARA (As Low As Reasonably Achievable). Further, it limits the introduction of ambient atmosphere from the hot cell into the final encapsulation providing better control of contaminants in the final sealed source. The GS-42 filling technique will also minimize surface contamination of the encapsulations as well as the shipping cask which is typical of conventional encapsulation methods.

The WESF sources were loaded by heating the $Cs^{137}Cl$ to above 730°C until it was molten. The molten material was then poured into a cascading series of seven inner source encapsulations. The advantage of this method was that it assured that the material is very dry. One of the hypothesized advantages was that the molten material would be introduced into the encapsulations at its maximum volume, and then allowed to cool to operating temperature. This would allow for a void space capable of accounting for future volumetric expansion. (In practice, many capsules were overfilled and did not have sufficient void space to accommodate volumetric expansion due to excessive heating.) The disadvantage of this method is that at molten temperatures, the $Cs^{137}Cl$ is highly corrosive to the stainless steel used, both to the encapsulations and the filling apparatus. Further, the molten pour created a non-compressible slug of $Cs^{137}Cl$.

The BNL sources were created by making wafers of highly compressed $Cs^{137}Cl$ powder. These wafers were physically placed in the encapsulations which were then sealed by remote welding. The manufacturing and testing procedures used introduced many organic contaminants into the inner capsule as well as into the annulus between capsules. The moisture content of the $Cs^{137}Cl$ was not controlled during filling as it will be with the GRAY*STAR, Inc. wet fill technique.

Impurities:

The GS-42 $Cs^{137}Cl$ contains the same (or fewer) impurities as the WESF material: there is no direct evidence that these impurities have contributed to failure or will lead to potential failure. Generally, reduction in impurities will raise the phase transition temperature of the $Cs^{137}Cl$ in the GS-42 capsules in comparison with the WESF capsules.

The GS-42 $Cs^{137}Cl$ contains less organic material than the BNL Strip material: There is evidence that the BNL Strip organic material has caused or contributed to BNL Strip source deformation. This organic material is minimized in the GS-42 because the material has been previously baked at high temperature during the WESF process and the wet technique does not introduce organic impurities (e.g. - steric acid as a lubricant or ethylene glycol as a leak testing medium) as does the BNL Strip process.

Moisture:

It has been hypothesized that relatively high moisture content may lead to, or contribute to, source deformation. The GS-42 $Cs^{137}Cl$ has a similar moisture content to the WESF melt-cast material, and a significantly lower moisture than the BNL Strip material. When employing the wet fill technique, moisture is simultaneously driven out of the $Cs^{137}Cl$ and the encapsulation. The capsules are protected from the introduction of ambient hot cell moisture into the GS-42s. Also, there is no need to introduce organic material to test the integrity of the capsules: The possibility that any organic material could contaminate the outer surface of the inner capsule is eliminated.

Physical Form:

The $Cs^{137}Cl$ will be in the form of a dry caked powder. This powder will have physical properties similar to the BNL Strip sources. The primary difference is that it is a caked powder at a packing density of only 2.0 g/cc; which is less than that of the BNL Strip sources (~3.2 g/cc), a loosely compressed "crumbly" powder. In any case, there is no evidence that $Cs^{137}Cl$ powder has contributed to failure or will lead to potential failure.

The WESF material has a packing density of about 4.0 g/cc and is the form of an incompressible slug. The lack of any local expansion space for the WESF "slug" lead to deformation and failure. The lack of expansion space of the BNL Strip sources might have lead to deformation. The low packing density of the GS-42 provides for both sufficient overall expansion space as well as heterogeneous localized expansion space. A maximum of fifty percent of the internal volume of the GS-42 inner capsule is filled with caked $Cs^{137}Cl$ as compared to approximately eighty percent for the BNL strip capsule or approximately eighty-two percent for the WESF capsule. Further the GS-42 material will be less corrosive than the WESF melt cast $Cs^{137}Cl$ during the filling procedure.

Specific Activity:

The specific activity of the $Cs^{137}Cl$ used in the BNL Strip sources is about 25 Ci/g. The WESF material at time of loading was approximately 20 Ci/g. Although there is no evidence that the specific activity of $Cs^{137}Cl$ has contributed to failure, the GS-42 has an initial specific activity of under 20 Ci/g. The fully loaded GS-42 achieves the maximum 2.0 g/cc packing density at an activity level of 12.5 Ci/g. Should the specific activity be greater, the packing density will be less, and there will be more void space in the encapsulation.

Capsule Material:

All three sources (GS-42, BNL Strip, and WESF) are fabricated out of 316L stainless steel and have undergone sealed source testing. All are double encapsulations, are comprised of relatively thin walled tubing, and have significantly thicker endcaps of 316L material. NRC regulation specifically states that 316 stainless steel is the material of choice due to its general corrosion resistance. There is no evidence that the use of 316L stainless steel has led to deformation or failure.

Capsule Design:

The WESF encapsulation is comprised of inner and outer cylindrical tubing. The inner tubing is welded to one endcap "cold" (not in a high radiation field). The inner tubing is then filled with the molten $Cs^{137}Cl$ and a second endcap is welded "hot" (in a high radiation field) to form the first seal. Leak and weld testing is performed on the inner capsule "hot". The inner tubing is inserted into an outer tube, welded, and tested in a similar method.

The BNL Strip encapsulation is comprised of inner and outer rectangular tubing. The sealing process is similar to that used by the WESF except that the $Cs^{137}Cl$ wafers are physically placed into the tubing prior to the welding (vs. molten pour).

The GS-42 encapsulation is comprised of inner and outer obround (oval) tubing. The inner tubing is welded to both endcaps "cold". The welds are inspected "cold" through both visual inspection and dye penetrant techniques. Also, both welds are leak checked using Helium Mass Spec. "cold". The inner tubing is placed in the outer tubing which is also welded and inspected in the same "cold" process as the inner tubing. *After the encapsulations are prepared and tested,* they are placed in a hot cell and the $Cs^{137}Cl$ is loaded through a fitting passing through the hole passing through both encapsulations. Once in place, a "seal plug" is torqued into the inner encapsulation which serves as a compression seal. This is followed by a second "seal plug" which is torqued into the outer encapsulation to provide a second compression seal. The torque applied is inherent in the "breakaway" nature of the plug and does not rely on the operator. Portions of the "seal plugs" are plated with metallic silver to provide both a lubricant and sealant. After sealing, a weld bead is applied around the juncture of the outer "seal plug" and the outer endcap to create a redundant third "seal". The inner encapsulation is held captive by the outer encapsulation's endcaps and not by the tubing itself.

The wet fill / seal plug process for filling the GS-42 avoids potential problems associated with hot cell welding and inspection. This includes the reprocessing of "false positive" weld tests due to the lower precision of in-hot cell testing. As a result, the disassembly of rejected filled capsules in the hot cell is eliminated, thus resulting in less contamination and material disposal problems. Further, it prevents contamination of the $Cs^{137}Cl$ from organic materials due to either inspection or compression as evidenced in the BNL Strip material. The wet fill technique allows overall better control of the quality of the encapsulation and the quality of the $Cs^{137}Cl$ fill material. The design, testing and manufacturing of the steel encapsulation and the design, testing and procedures of the fill process are performed under the Quality Assurance Program.

The interlocking of the inner to the outer encapsulations via the endcaps is unique to the GS-42. Under dynamic stress conditions to either the WESF or the BNL Strip sources, it is possible that the inner encapsulation can place unwanted stress directly on the relatively thin wall of the outer tubing. The GS-42 transmits any stress via the endcaps and prevents unwanted stress being placed on the relatively thin wall of the outer tubing. Although there is no evidence that inner to outer stress transmission has led to a failure, the interlocking of the GS-42 endcaps eliminates stress transmission.

Tubing Thickness:

The encapsulation of the GS-42 is made of 316L stainless steel which is also used by the other two sources referenced. The tubing wall thickness is 0.049 inches which is less than the 0.125 inch wall thickness of the WESF encapsulation and two and a half times greater than the 0.020 wall thickness of the BNL Strip encapsulation. There is no evidence that the thickness of the 316L stainless steel has contributed to failure. However, the thickness of the WESF walls is a contributor to self-absorption and therefore self-heating of the encapsulations. The GS-42 wall thickness is designed to minimize the self-heating and at the same time provide ample strength to the encapsulation. The GS-42's wall thickness is far thicker than that routinely used for Co^{60} encapsulations and other $Cs^{137}Cl$ sources now in use.

Source Shape:

The obround design of the GS-42 is as controllable as the cylindrical shape of the WESF capsules; it allows for a more controllable weld than that provided by the rectangular BNL Strip sources. There is no evidence that any welding technique used in either the WESF sources or the BNL Strip sources has contributed to failure or will lead to potential failure; however, it is possible that difficulties in welding around corners in the BNL Strip source could lead to source failure.

The obround design of the GS-42 lessens the probability for stress cracking experienced around the corners of a BNL Strip rectangular tube. There is no evidence that the shape of either the BNL Strip or the WESF tubing has contributed to failure. It is possible that the rectangular nature of the BNL Strip source might lead to stress cracking. The obround design of the GS-42 avoids this hypothetical failure.

Self Heating:

There is evidence that self heating of the WESF encapsulation did lead to source failure. (The self heating combined with the non-compressive nature of the $Cs^{137}Cl$, further combined with the thermal cycling of the sources, most likely led to the failure.) There is some evidence that self heating of the BNL Strip encapsulation led to source deformation. (Self heating combined with high pressures generated by the radiolysis of organic materials probably led to the deformation). Note: Neither in the case of the WESF source nor the BNL Strip source was decay heat the sole contributor to the deformations. The obround design of the GS-42 allows for better cooling and less self heating due to decay heat than the WESF encapsulations. The GS-42's shape is more similar to that of the BNL Strip source. Also, the GS-42 does not contain organic material or significant water to go through radiolysis and build up internal pressure.

Allowance For Deformation:

The WESF encapsulation design allows for little deformation prior to failure. The obround design of the GS-42, similar to the rectangular design of the BNL Strip sources, allows greater "forgiveness" of the tubing, which allows for greater deformation prior to failure if adverse conditions beyond normal usage should ever be present.

Welding And Inspection:

Although there is no evidence that a weld imperfection lead to a failure, welds are always suspect and can possibly lead to failure. The GS-42's ability to be welded and those welds tested on the "cold" encapsulations allows for more reliable welding and weld testing. This will lead to no filled sources requiring rework due to improper welds or "false tests" of welds. Rework of sources filled with $Cs^{137}Cl$ would lead to hot cell contamination and be against the principle of ALARA.

Sealing:

The GS-42 utilizes three seals vs. two for both the WESF and BNL Strip sources. There is no evidence that the sealing of the source has led to failure; however, the sealing of a source can possibly lead to failure.

The use of the "seal plugs" on the GS-42 is unique. They have been tested above and beyond the requirements of the "sealed source tests" and there is no reason to believe they would fail. However, the redundant third seal is a conventional weld and has the same high probability of non-failure as the welds utilized on both the WESF and BNL Strip sources.

The use of metallic silver on the GS-42 seal plugs is unique. Silver was specifically chosen due to its corrosion resistant properties: silver is almost identical in its corrosion properties to 316 stainless steel in an aqueous solution of $Cs^{137}Cl$. (Note: The $Cs^{137}Cl$ is not in an aqueous solution during operation or transit.) The GS-42 design eliminates contact of $Cs^{137}Cl$ with the silver, therefore corrosion of the silver is not a source of failure.

The torquing of the "seal plugs" will lead to counter rotational stresses on the inner encapsulation. To avoid this, there is a mating socket between encapsulations to transmit this force from the inner encapsulation to the outer encapsulation only through the relatively massive endcaps without putting any pressure on the relatively thin walled tubing.

Void Space:

There is evidence that the lack of localized void space in the WESF sources contributed to failure. Although there is little evidence that lack of void space led to BNL Strip source deformation it is possible that the void space is insufficient, and under high temperature, it could lead to deformation. The low packing density of the $Cs^{137}Cl$ in the GS-42 provides for greater total void space than either the WESF or BNL Strip sources. More importantly, it provides greater localized void space.

Dynamic Stress Loading:

Even C-188 (MDS Nordion, Inc.) $cobalt^{60}$ source outer encapsulations (the standard in the industry) have been known to fail under dynamic test conditions.[4] The GS-42 has undergone dynamic and static bend tests on the entire encapsulation without failure.

Capsule Placement And Orientation:

There are no published data on the orientation of BNL Strip sources, nor any analysis performed on any adverse effects because of their orientation. They are primarily used in dry storage / dry irradiation irradiators (categories I & II). In air, there is no medium for significant dispersal.

The WESF capsules were used in category II (Sandia), III (Lynchburg), and IV (Decatur, Westerville and Denver) irradiators. Their use in the category II irradiator did not indicate any problems. Further, some capsules that were used in the category II irradiator were destructively tested. No special problems were indicated.

WESF capsules used in the category III irradiator (Lynchburg) did not indicate any problems with their use. (Note: Presently the WESF capsules are stored under water and there are no reported problems with this indefinite storage. Some of the capsules have been stored since the early 1980s.)

The WESF capsules have also been used in three category IV irradiators. One of the three facilities used the capsules in a horizontal orientation and did not have any reported problems (Denver). Two of the facilities used the capsules in a vertical orientation. One facility (Decatur) reported deformation and confirmed leakage of one capsule.[5]

Vertical orientation of the WESF capsules is believed to be a primary contributor to the WESF failure. (Approximately 252 sources were subject to over 7,300 thermal cycles. One capsule leaked and one more was suspect to leakage. Several capsules had deformation. The deformed and leaking capsules were found to have most of the mass oriented at the bottom of the vertical encapsulation with a large amount of head space above the $Cs^{137}Cl$ "slug". The deformations were located radially around the large mass of material on towards the bottom of the encapsulation.) The GS-42 has a horizontal orientation as did one of the facilities that used the WESF capsules without incident (Denver).

The GS-42 is designed specifically to be mounted only in a horizontal orientation in a **GRAY✦STAR™** MODEL 1 irradiator. The sources are mounted in four source racks (16 sources to a rack). The irradiator is dry storage / dry irradiation. Only the endcaps of the GS-42 come into contact with any solid object.

Thermal Cycling:

Thermal cycling is attributed as the greatest contributor to the WESF encapsulation leak (>7,300 cycles). The GS-42s installed in the **GRAY✦STAR™** MODEL 1 irradiator do not go through repetitive thermal cycling. There are no data on BNL Strip thermal cycling performance.

As an additional precautionary measure, GS-42 endcaps successfully underwent thermal cycling tests as part of their sealed source testing to assure the performance of the "seal plugs", even though repetitive recycling will not be realized.

Environment (Water ¥ Air)

Water storage of the leaking WESF capsules allowed for dispersal through dissolution of the $Cs^{137}Cl$ in water. Further, thermal cycling in combination with water storage allowed $Cs^{137}Cl$ to be aerosoled out of the WESF failed capsule allowing dispersion.

The GS-42 encapsulations are used / stored in air and are not subject to repetitive thermal cycling between air use and water storage.

$Cobalt^{60}$ sources have failed in the past due to poor water conditions (e.g. electrolytic corrosion via impure water). The GS-42 is dry stored and not subject to electrolytic action.

Mounting In The Source Rack:

GS-42 mounting is specific to, and can only be used in, the **GRAY✦STAR™** Irradiator. The sources are held captive by their endcaps only. It has been hypothesized that over long periods of time, the endcaps might fuse together. To be able to separate the sources in the future (should fusing occur for any reason) the design of the endcaps minimize the contact surface of one to another. Thus, they would be fused with a weak juncture and any force used on the sources to "break" that fusion would be minimized and prevent hypothetical damage to the sources under the forces created during future separation.

The sources are held in place by their endcaps. This separation allows for free flow of air around all of the source tubing. It also eliminates any stresses or potential effects of another body in contact with the sources. To assure that the sources are strong enough to be supported solely by their endcaps, the sealed source vibration test was performed to amplify the testing stresses that the GS-42s will receive during operation.

$Cobalt^{60}$ sources are often held only by their endcaps. There is no evidence that this has caused a failure or might contribute to a failure.

MISCELLANEOUS:

Stainless Steel Sensitization:

Temperature tests performed on insulated test GS-42 sources[2] indicate that the GS-42 source encapsulation material will not exceed 263°C at the $Cs^{137}Cl$ interface. Therefore, they will not be susceptible to stainless steel sensitization when installed in the **GRAY✦STAR™** MODEL 1 irradiator during operation, storage, or during transport in the Graysafe™. (The Graysafe™ is the shipping cask portion of the unit.)

Physical Size:

The GS-42 is physically larger than a WESF source but contains less curie content than a fully loaded WESF source. The GS-42 is significantly larger in both physical size and curie content than a BNL Strip source. There is no evidence that size is a contributing factor in deformation, failure or $Cs^{137}Cl$ dispersion. There are more leaks reported in very small $Cs^{137}Cl$ sealed sources than in WESF or BNL Strip sources. (It is beyond the scope of this report to analyze very small $Cs^{137}Cl$ sealed sources for non-irradiator use.) With the exception of $Cs^{137}Cl$ sources which have been intentionally cut open, all leaks of $Cs^{137}Cl$ in air have had minimal dispersion independent of curie loading. Further, although the GS-42 has a relatively large curie loading, the specific activity is lower than that of most $Cs^{137}Cl$ sealed sources. The reported leak in the WESF source allowed for dispersion primarily because the source was stored in water. The water leaked into the "crack" and allowed for about 8 curies to go into solution. (It is notable that only a small fraction of the material went into solution.)

Further, due to the thermal cycling of the leaking source, some of the water entered into the encapsulation through the "crack" and was heated. This produced pressure which allowed $Cs^{137}Cl$ solution to be aerosoled out of the crack potentially onto equipment and product. (Note: The Decatur, GA facility did not continuously cycle the pool water through the water handling system and therefore did not continuously monitor water for radioactivity. This would have been unacceptable in an NRC state (Georgia is an Agreement State.)) If a leak had occurred with a dry stored WESF capsule, there would have been no medium for quick dispersion (water). Any contamination would have been minimal and not a direct radiological hazard prior to being detected during a routine six month leak test.

CONCLUSION:

The GS-42 using the wet fill technique mitigates against known causes of failure and potential failure. Factors leading to deformation and failures of the BNL Strip and WESF sources are specifically avoided. Conversely, the GS-42 takes advantage of design aspects of both the BNL Strip and WESF sources which have long histories of not contributing to deformation or failure, nor raise concerns of being suspect to failure. The GS-42 was also designed to circumvent problems which have not been known to fail, but still are suspect.

The wet fill technique is a new concept in source processing. The purpose of the wet fill technique is to produce a source which is more safe than those produced by previous methods in the past. Further, it is designed to provide safer hot cell operations and produce significantly less waste. Overall, the process is more in keeping with ALARA than all previous techniques.

REFERENCES

1 *Investigation of Deformation in Rectangular Cesium-137 Sources*, N.C Bradley and C.L. Ottinger, Oak Ridge National Laboratory, ORNL-TM-3069, August 1970

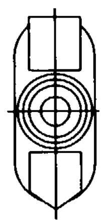
2 *Characterization of an Aged WESF Capsule*, B.T. Kenna / F.J. Schultz, Sandia National Laboratories / Oak Ridge National Laboratory, SAND-83-0928 / TTC-0434, UC-71, July 1983

3 *Interim Report of the DOE Type B Investigation Group, Cesium^{137}: A Systems Evaluation, Encapsulation to Release at Radiation Sterilizers, Inc., Decatur, Georgia*; DOE/ORO-914 / DE-91-008210; July 1990

4 *REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES; SAFETY EVALUATION OF SOURCE; No. NR-169-S-142-S*; December 23, 1985

5 *GRAY*STAR; APPLICATION FOR SEALED SOURCES AND DEVICE EVALUATION AND REGISTRATION; GS-42-SEALED SOURCE; GRAY✦STAR MODEL 1 IRRADIATOR*; APRIL 15, 1999; EXHIBIT 5 - THERMAL PROFILES - SOURCE

ATTACHMENT B



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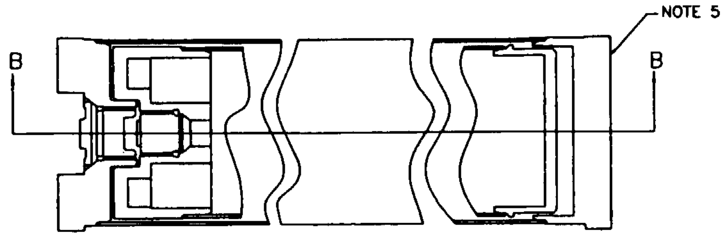
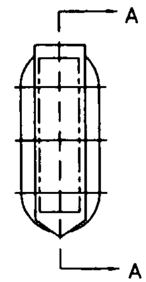


SECTION A-A



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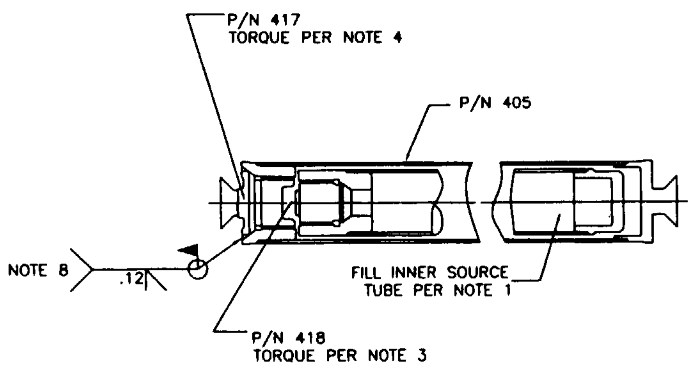

SECTION B-B

NOTES:

1 THE INNER SOURCE TUBE IS TO BE FILLED WITH RADIOACTIVE CESIUM CHLORIDE. H_2O CONTENT IN THE CESIUM CHLORIDE MUST BE 0.01% MAX (BY WEIGHT) PRIOR TO INSTALLING THE INNER SEAL PLUG.

2 DIMENSIONING AND TOLERANCING PER ASME Y14.5M-1994. ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SHOWN.

3 INSTALL AND TORQUE INNER SEAL PLUG UNTIL THE SHANK BREAKS IN THE V-NOTCH. DISCARD THE SHANK AFTER IT BREAKS.

4 AFTER COMPLETION OF INSTALLATION OF INNER PLUG PER NOTE 3, THE OUTER PLUG IS TO BE INSTALLED IN THE END OF THE OUTER SOURCE ASSEMBLY. APPLY TORQUE UNTIL THE SHANK BREAKS IN THE V NOTCH. DISCARD THE SHANK AFTER IT BREAKS.

5 MARK THE TREFOIL SYMBOL AND THE FOLLOWING DATA IN THE LOCATION SHOWN BY EITHER STAMPING OR LASER ETCH:
CAUTION RADIOACTIVE MATERIAL
GRAY*STAR, INC. MODEL GS-42
P/N 403 S/N XXXX
CESIUM 137

6 THE SERIAL NUMBER OF THIS ASSEMBLY SHALL BE THE SAME AS THE SERIAL NUMBER OF P/N 405.

7 ESTIMATED NOMINAL WEIGHT OF FINISHED PART IS 12 POUNDS EMPTY AND A MAXIMUM OF 8 POUNDS OF CESIUM CHLORIDE.

8 WELD PER ASME BOILER & PRESSURE VESSEL CODE SECTION IX. WELD FILLER METAL SHALL BE IN ACCORDANCE WITH SPECIFICATION SFA5.9 ER316L. FIELD SEAL WELD BY SOURCE LOADER.

REVISIONS

REV	SH	ZONE	DESCRIPTION	DATE	APPROVED
1	1		SEE REVISION	99-08-23	
2	1	A-2 C-2 B-4 B-8	UPDATED TITLE BLOCK AND PARTS LIST MODIFIED NOTE 8 MODIFIED NOTE 1 MODIFIED WELD CALLOUT	00-08-03	DRWN: AAS CHKD: DWK APRV: MCS

P/N	QTY	PART DESCRIPTION	MATERIAL	DWG.NO.	WEIGHT	REMARK
		CESIUM CHLORIDE			<8	
418	1	SEAL PLUG, INNER	SEE DRAWING	AAI-418	0.1	
417	1	SEAL PLUG, OUTER	SEE DRAWING	AAI-417	0.2	
405	1	LONG OUTER SOURCE TUBE ASSEMBLY	ASSEMBLY	AAI-405	11.4	

GRAY✦STAR — Gray*Star, Inc. Mt. Arlington Corporate Center, 200 Valley Rd. Suite 103, Mt. Arlington, NJ 07856

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DRAWN BY: AAS — DATE: 99-03-22
CHECKED BY: CDR — DATE: 99-03-22

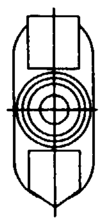
TITLE: SOURCE, LONG, CESIUM CHLORIDE, MODEL GS-42, ASSEMBLY OF

TOLERANCE UNLESS OTHERWISE SPECIFIED .XX = ±.01 .XXX = ±.005 ANGLE = ±10'

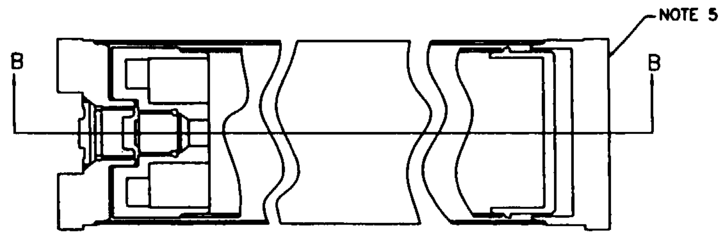
SIZE: D | FSCM NO. | DWG NO. AAI-403 | REV 2

SCALE 1/1 | SHEET 1 OF 1

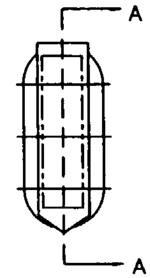
403S1R2.DWG



FILL END



SECTION A–A



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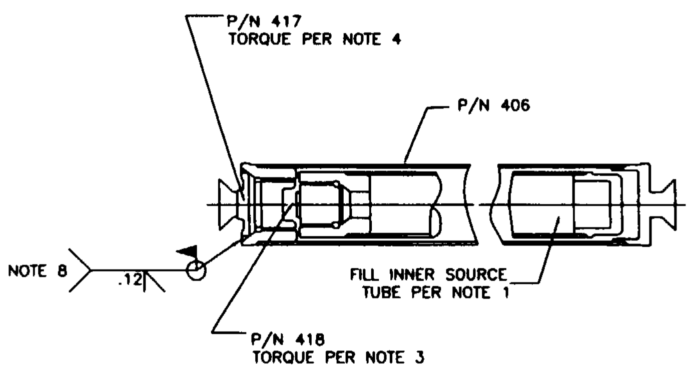

SECTION B–B

NOTES:

1 THE INNER SOURCE TUBE IS TO BE FILLED WITH RADIOACTIVE CESIUM CHLORIDE. H_2O CONTENT IN THE CESIUM CHLORIDE MUST BE 0.01% MAX (BY WEIGHT) PRIOR TO INSTALLING THE INNER SEAL PLUG.

2. DIMENSIONING AND TOLERANCING PER ASME Y14.5M–1994. ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SHOWN.

3 INSTALL AND TORQUE INNER SEAL PLUG UNTIL THE SHANK BREAKS IN THE V–NOTCH. DISCARD THE SHANK AFTER IT BREAKS.

4 AFTER COMPLETION OF INSTALLATION OF INNER PLUG PER NOTE 3, THE OUTER PLUG IS TO BE INSTALLED IN THE END OF THE OUTER SOURCE ASSEMBLY. APPLY TORQUE UNTIL THE SHANK BREAKS IN THE V NOTCH. DISCARD THE SHANK AFTER IT BREAKS.

5 MARK THE TREFOIL SYMBOL AND THE FOLLOWING DATA IN THE LOCATION SHOWN BY EITHER STAMPING OR LASER ETCH:
CAUTION RADIOACTIVE MATERIAL
GRAY*STAR, INC. MODEL GS–42
P/N 404 S/N XXXX
CESIUM 137

6 THE SERIAL NUMBER OF THIS ASSEMBLY SHALL BE THE SAME AS THE SERIAL NUMBER OF P/N 406.

7 ESTIMATED NOMINAL WEIGHT OF FINISHED PART IS 10 POUNDS EMPTY AND A MAXIMUM OF 6.5 POUNDS OF CESIUM CHLORIDE.

8 WELD PER ASME BOILER & PRESSURE VESSEL CODE SECTION IX. WELD FILLER METAL SHALL BE IN ACCORDANCE WITH SPECIFICATION SFA5.9 ER316L. FIELD SEAL WELD BY SOURCE LOADER.

REVISIONS

REV	SH	ZONE	DESCRIPTION	DATE	APPROVED
1	1		SEE PREVIOUS REVISION	99-03-23	
2	1	A–2 C–2 B–4 B–6	UPDATED TITLE BLOCK AND PARTS LIST MODIFIED NOTE 8 MODIFIED NOTE 1 MODIFIED WELD CALLOUT	00-08-03	DRWN: JAS CHKD: DMK APPR: MDS

P/N	QTY	PART DESCRIPTION	MATERIAL	DWG.NO.	WEIGHT	REMARK
		CESIUM CHLORIDE			<6.5	
418	1	SEAL PLUG, INNER	SEE DRAWING	AAI–418	0.1	
417	1	SEAL PLUG, OUTER	SEE DRAWING	AAI–417	0.2	
406	1	SHORT OUTER SOURCE TUBE ASSEMBLY	ASSEMBLY	AAI–406	9.8	

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Gray*Star, Inc. Mt. Arlington Corporate Center
200 Valley Rd. Suite 103, Mt. Arlington, NJ 07856

DRAWN BY: JAS — DATE: 99-03-22
CHECKED BY: — DATE: 99-03-22

TITLE: SOURCE, SHORT, CESIUM CHLORIDE, MODEL GS–42, ASSEMBLY OF

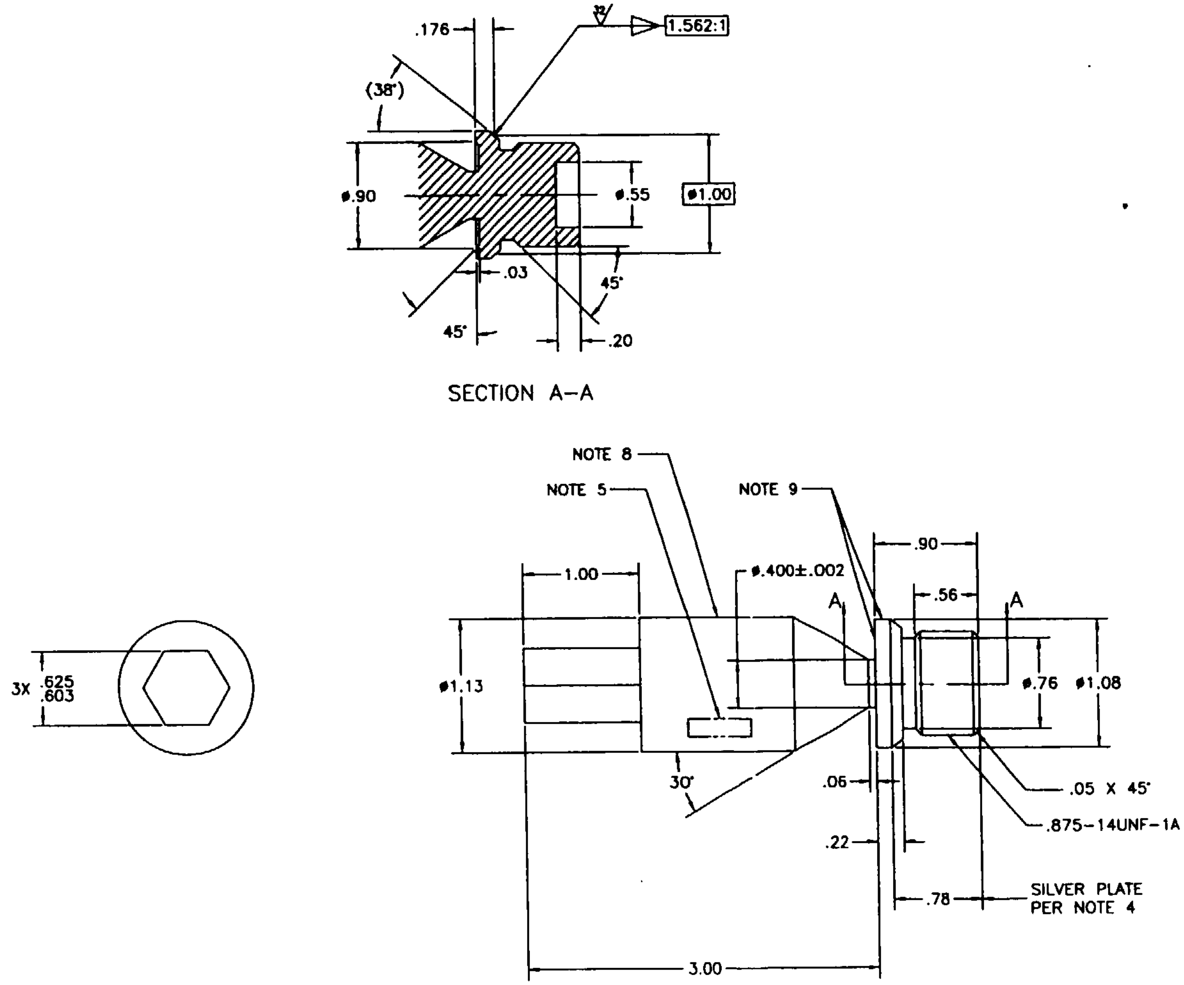
TOLERANCE UNLESS OTHERWISE SPECIFIED .XX = ±.01 .XXX = ±.005 ANGLE = ±10'

SIZE: D | FSCM NO. | DWG NO. AAI–404 | REV 2

SCALE 1/1 | SHEET 1 OF 1

404S1R2.DWG JMS

REV	SHEET	ZONE	DESCRIPTION	DATE	APPROVED
1,2,3			REDRAWN. PREVIOUS REVISIONS SEE FILE COPY.		
4	1	A,C-1,2 C-8	NOTES 4 & 9, MODIFIED NOTE 5, SYMBOL REMOVED SYMBOL CHANGED TO "NOTE 5"	99-09-23	DRWN: JMS CHKD: CDK APVD: MGS



NOTES:

1. ALL DIMENSIONING AND TOLERANCING IS IN ACCORD ACCORDANCE WITH ASME Y14.5M-1994. ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED.
2. ALL FILLETS ARE .02 R UNLESS OTHERWISE SHOWN. VISUAL INSPECTION ONLY.
3. MATERIAL, ASTM A276, TYPE 316-L, CONDITION A, STAINLESS STEEL ROUND BAR STOCK.
4. SILVER PLATE PER AMS 2412 IN THE AREA SHOWN, PLATE THICKNESS IS TO BE .003-.004. THREADS MAY BE CHASED AFTER PLATING TO MAINTAIN FIT-UP.
5. MARK PART NUMBER AND SERIAL NUMBER IN LOCATION SHOWN BY EITHER VIBRATOOL OR ELECTROCHEMICAL ETCH. THE CHARACTERS MUST BE AT LEAST .125 HIGH. EXAMPLE: 417-XXXX. (XXXX=SERIAL NO.)
6. BREAK CORNERS .005 MIN. VISUAL EXAMINATION ONLY.
7. SURFACE ROUGHNESS TO BE 125 RHR OR FINER UNLESS OTHERWISE SHOWN.
8. THIS SURFACE MAY BE MAINTAINED IN THE AS-RECEIVED CONDITION. THE STANDARD TOLERANCES ARE WAIVED FOR THIS FEATURE.
9. REMOVE SILVER PLATING FROM SURFACE.

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200 Valley Rd. Suite 103, Mt. Arlington, NJ 07856

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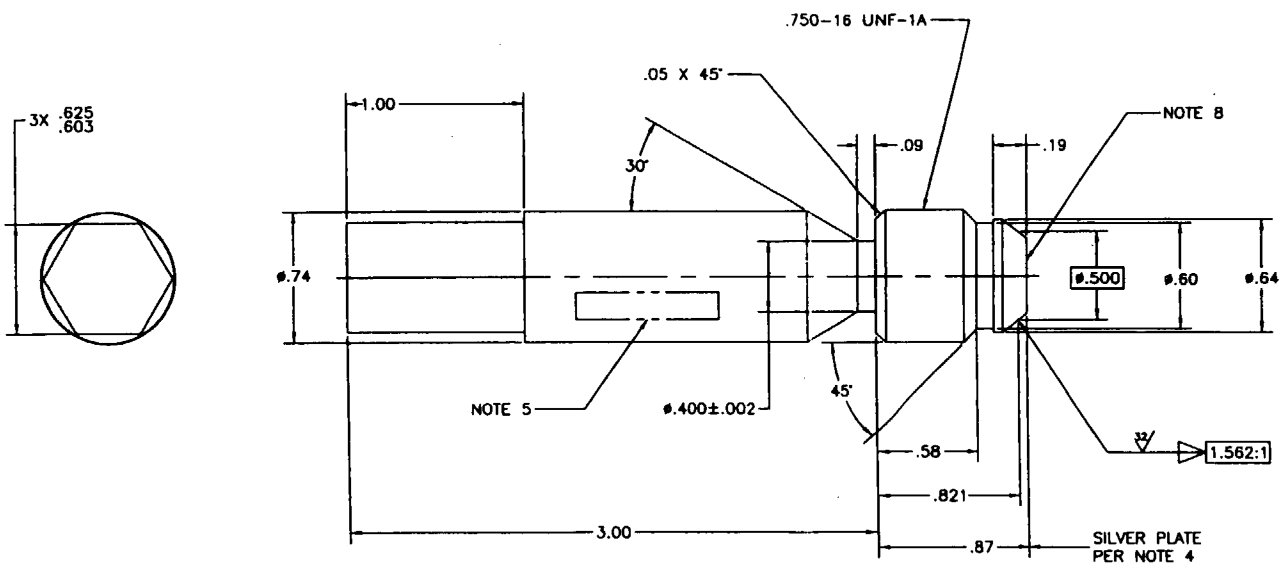
JHR	98-10-26	TITLE SEAL PLUG, OUTER
DWJ	98-10-26	
SIZE D	DWG NO. AAI-417	REV 4
SCALE 2/1		SHEET 1 of 1

USER: JMS 09/23/99 FILE: 417s1r4.DWG

REV	SHEET	ZONE	DESCRIPTION	DATE	APPROVED
1			REDRAWN, PREVIOUS REVISIONS SEE FILE COPY		
2	1	A,C-1,2 B-6	NOTES 4 MODIFIED NOTE 5 SYMBOL REMOVED NOTE 8 ADDED SYMBOL CHANGED TO "NOTE 8"	99-09-23	



NOTES:

1. ALL DIMENSIONING AND TOLERANCING IS IN ACCORDANCE WITH ASME Y14.5M-1994. ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED.
2. ALL FILLETS ARE .02 R UNLESS OTHERWISE SPECIFIED. VISUAL INSPECTION ONLY.
3. MATERIAL: STAINLESS STEEL ROUND BAR STOCK PER ASTM A-276, GRADE 316-L, CONDITION A.
4. SILVER PLATE PER AMS 2412 IN AREA SHOWN. PLATE THICKNESS TO BE .003-.004. THREADS MAYBE CHASED AFTER PLATING TO MAINTAIN FIT-UP.
5. MARK PART NUMBER AND SERIAL NUMBER IN LOCATION SHOWN BY EITHER VIBRATOOL OR ELECTRO-CHEMICAL ETCH. CHARACTERS MUST BE AT LEAST .125 HIGH. EXAMPLE: 418-XXXX. (XXXX=SERIAL NO.)
6. BREAK CORNERS .005 MIN. VISUAL INSPECTION ONLY.
7. SURFACE ROUGHNESS SHALL BE 125 RHR OR FINER UNLESS OTHERWISE SHOWN.
8. REMOVE SILVER PLATING FROM SURFACE.

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200 Valley Rd. Suite 103, Mt. Arlington, NJ 07856

JHR 98-10-28
DWJ 98-10-28

TITLE SEAL PLUG, INNER

SIZE D | DWG NO. AAI-418 | REV 2

SCALE 3/1 | SHEET 1 OF 1

JMS 09/23/99 FILE: 418S1R2.DWG
USER: