

RAS 2411

November 22, 2000
DOCKETED 11/22/00

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE PRESIDING OFFICER

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

NRC STAFF'S REPLY TO GRAYSTAR'S NOVEMBER 15 FILING

INTRODUCTION

In this proceeding concerning the denial of an application for a certificate of registration regarding a sealed source, GRAY*STAR, Inc. (GrayStar) and the Staff filed their initial written presentations on September 25, 2000. See "Gray*Star, Inc.'s Brief in Support of Application for Registration of Model GS-42 Sealed Source" (GrayStar's Presentation), and "NRC Staff's Initial Written Presentation" (Staff's Presentation), respectively. On October 30, 2000, GrayStar and the Staff filed their responses to the September 25 filings. See "Gray*Star, Inc.'s Response to NRC Staff's Brief Regarding the Application for Registration of Model GS-42 Sealed Source" (GrayStar's October 30 Response), and "NRC Staff's Response to GrayStar's Written Presentation" (Staff's October 30 Response), respectively. During a November 8, 2000, telephone conference, the Presiding Officer authorized GrayStar, by November 15, to file a ten-page reply to the Staff's October 30 Response. See unpublished Order dated November 13, 2000 ("Confirming Matters Addressed at November 8, 2000, Telephone Conference") (November 13 Order), at 1-2. On November 15, 2000, GrayStar filed "Gray*Star, Inc.'s

Reply to NRC Staff's Response Brief" (GrayStar's November 15 Reply). During the November 8 conference, the Presiding Officer authorized the Staff to reply to GrayStar's November 15 Reply by November 22, 2000. See November 13 Order, at 2. The Staff's reply follows.

DISCUSSION

I. GrayStar Fails to Carry its Burden Showing Use of Cesium is Justified

GrayStar has known from the beginning of this proceeding that it carried the burden of showing a proper technical justification for using radioactive cesium as the sealed source material in its Model 1 irradiator. The Presiding Officer made this clear in her unpublished order dated August 17, 2000 ("Setting Schedule for Proceedings and Addressing Other Matters Considered at August 15, 2000, Telephone Conference") (August 17 Order), stating as follows:

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

August 17 Order, at 1. Since then, in neither GrayStar's Presentation, GrayStar's October 30 Response, nor GrayStar's November 15 Reply -- arguments which total more than 120 pages -- has GrayStar adequately justified its proposed use of cesium in the Model GS-42 sealed sources.

This failure is particularly evident in Section C of GrayStar's most recent filing (see GrayStar's November 15 Reply, at 10-11, and nn. 3-4, regarding the necessary level of justification to be provided), in which GrayStar argues in part that the Staff must explain

why using cobalt-60 in irradiator sealed sources would be safer than using cesium. *Id.*, at n.4. On the contrary, as is evident in the following excerpt from the Commission's 1993 Statement of Considerations (SOC) published with the 10 C.F.R. Part 36 rules, it is GrayStar which must justify the use of cesium (rather than cobalt-60) in its Model GS-42 sealed sources:

The NRC has decided not to approve further use of cesium sources, although the term "as practical" [in 10 C.F.R. § 36.21(a)(3)] would allow the NRC to make an exception where justified to the NRC.

58 Fed. Reg. 7715, 7718, col. 2 (February 9, 1993). As previously discussed (*see* Staff's October 30 Response, at 20-21), 10 C.F.R. § 36.21(a)(3) and the SOC make clear that the Commission was concerned about the use of cesium chloride in commercial irradiators, and that -- regardless of capsule design -- cobalt-60 would be the preferred material for irradiator use, due to its lower dispersibility.

GrayStar complains that the hearing record contains no evidence of dispersibility problems caused by the use of cesium in dry irradiators. *See* GrayStar's November 15 Reply, at 7. But GrayStar addresses neither the safety issues arising from the proposed use of cesium in the GS-42 sealed sources, nor the related safety concerns pertaining to the large amounts of cesium which would be present in each Model 1 irradiator. As previously discussed by the Staff, these issues include the dispersal of cesium should an accident occur in a Model 1 irradiator. *See* Staff's October 30 Response, at 7, and 32-34. The fact that a serious dispersion accident has not occurred at a dry Category I irradiator, or the fact that the potential risk for dry irradiators in general may be lower than the risk for wet irradiators, does not mean that safety hazards would not exist at dry Category II irradiators such as GrayStar's Model 1. Thus, to properly evaluate the use in Category II

irradiators of hazardous radioactive materials such as cesium-137, the Staff must consider potential accident scenarios, and not focus only on the operating experience of Category I irradiators using smaller amounts of cesium as the sealed source material. The Staff would be derelict in its duty to do otherwise.

Rather than addressing the Staff's concerns about the consequences of potential accidents in the Model 1 irradiator, GrayStar merely points out that "in the past," registration requests regarding sealed sources containing cesium were approved. GrayStar's November 15 Reply, at 2, *citing* a 1984 registration approval.¹ Even assuming this sealed source approval is technically similar to the approval GrayStar now seeks, the 1984 action was obviously taken before the 10 C.F.R. Part 36 rules became effective in 1993. *See* 10 C.F.R. § 36.21(a) (regulations applicable only to sealed sources installed after July 1, 1993). Accordingly, the California registration action cited by GrayStar is not relevant here.

In further questioning the technical validity of the Staff's evaluation, GrayStar states that 10 C.F.R. § 36.21 only governs "sealed sources," and not radioactive material "isolated

¹ The cited 1984 approval regards registration number CA598D115S, a California registration which apparently pertains to Staff Exhibit 1, attached to Staff's Presentation dated September 25, 2000. GrayStar emphasizes that this 1984 approval applied to a "Category II" irradiator. GrayStar's November 15 Reply, at 2. Staff Exhibit 1 is not clear on this point. Page one of Exhibit 1 states that this approval applied to a "Category I" irradiator, but page two of Exhibit 1 refers to a "Category 2" irradiator. Regardless of its category in California's regulatory program, there are significant differences between this California irradiator and GrayStar's Model 1 irradiator. *See* Staff's Presentation, at 12.

from a sealed source.” GrayStar’s November 15 Reply, at 2, n.1.² NRC regulations define the term “sealed source” as meaning “any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.” 10 C.F.R. § 30.4. Consistent with this meaning of “sealed source,” the Staff considered the intended use of cesium-137 not in isolation, but in the context of GrayStar’s requested use of this material in the GS-42 sealed sources. Accordingly, the Staff’s evaluation was entirely proper.

In contending that it has met all of the applicable requirements set forth in 10 C.F.R. § 36.21, GrayStar offers to work with the Staff to resolve the technical issues on which GrayStar and the Staff differ. See GrayStar’s November 15 Reply, at 9, and n. 2. As to whether there should be further interaction to resolve technical issues (a question also raised by the Presiding Officer during the November 8, 2000, telephone conference), the Staff’s position is that absent a legally binding determination that GrayStar’s proposed use of cesium meets the non-dispersibility requirements of 10 C.F.R. § 36.21(a)(3), further technical review of GrayStar’s registration application would not be warranted.

Finally, the Staff briefly addresses GrayStar’s question as to whether the Staff “is now arguing that the Commission intended for all the requirements of Part 36 to apply to dry-source storage irradiators.” GrayStar’s November 15 Reply, at 7, *citing* Staff’s October 30 Response, at 20. On the contrary, the Staff made clear in its October 30 filing that many

² On this point, GrayStar cites NRC Regulatory Guide 10.10, and International Atomic Energy Agency (IAEA) Safety Series No. 107. As previously discussed, NRC regulatory guides and other documents apart from NRC regulations are of no legal effect in applying the requirements of 10 C.F.R. § 36.21, or any other NRC regulation. See Staff’s October 30 Response, at 13-16. However, this distinction appears to be of no consequence here, as the 10 C.F.R. § 30.4 sealed source definition quoted in the text above is consistent with both NRC Regulatory Guide 10.10, and the IAEA provision relied upon by GrayStar.

of the specific 10 C.F.R. Part 36 provisions apply only to situations involving the use of wet-storage irradiators. See Staff's October 30 Response, at 14, and n.13. The Staff did not focus on these provisions, since they are not relevant in this proceeding due to the fact that the GrayStar Model 1 irradiator is a dry-storage irradiator.

As established above, in Staff's Presentation, and in Staff's October 30 Response, GrayStar has failed to carry its burden of showing that a proper justification exists for allowing GrayStar to use radioactive cesium as the sealed source material in its Model 1 irradiator. Accordingly, the Presiding Officer should affirm the Staff's denial of GrayStar's application for registration of its Model GS-42 sealed source.

II. Use of GrayStar's Proffered Video Tape

The Staff has viewed the video tape provided by GrayStar's attorneys. Most of the tape, and the accompanying narration, covers the GrayStar Model 1 irradiator, rather than the GS-42 sealed sources to be used in the irradiator. The tape provides only a brief, and very general, reference to the use of cesium 137 material, and lacks any detail regarding how this material will be loaded into capsules. In fact, the Model GS-42 sealed sources are neither depicted nor discussed anywhere in the video tape. This proceeding covers only the registration of the Model GS-42 sealed sources. Therefore, the relevance of the video tape has not been established.

Apart from its lack of relevance, the tape's contents would be repetitive of what is already part of the record in this proceeding. Specifically, the photographs and pictures attached to GrayStar's November 15 Reply depict the irradiator and sealed source components in sufficient detail to obviate the need for any additional pictorial evidence. In fact, Figure 22 attached to GrayStar's November 15 Reply appears to be a still frame taken

from the video tape. Additionally, the promotional nature of the tape is evident, and the Staff is unsure whether this is the same tape that was submitted sometime prior to the April 1999 registration application. While the Staff has not reviewed the statements made in the recently-submitted video tape in any detail, the Staff in general disagrees with the statements therein regarding the purported safety of the irradiator, and the references to regulatory approval.

However, the Staff notes that presiding officers have a large amount of discretion in conducting 10 C.F.R. Part 2, Subpart L proceedings (see 10 C.F.R. § 2.1209), and that strict rules of evidence do not apply in such proceedings. See 10 C.F.R. §§ 2.1233(e), and 2.1235(c). Thus, the Presiding Officer may find here that viewing GrayStar's video tape for its background information about the irradiator, and how GrayStar intends that the irradiator would be used, will help to provide a more complete record for decision. Should the Presiding Officer make such a finding, the Staff would not object.

CONCLUSION

GrayStar has failed to show that its GS-42 sealed sources meet the safety requirements of 10 C.F.R. §§ 32.210(c) and 36.21. GrayStar has failed to provide reasonable assurance that the radiation safety properties of its proposed sealed source, when used in the proposed GrayStar Model 1 irradiator, would be adequate to protect health and minimize danger to life and property. Accordingly, the Presiding Officer should

affirm the Staff's denial of GrayStar's application for registration of its Model GS-42 sealed source.

Respectfully submitted,

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

Dated at Rockville, Maryland
this 22nd day of November 2000

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CERTIFICATE OF SERVICE

I hereby certify that signed copies of "NRC STAFF'S REPLY TO GRAYSTAR'S NOVEMBER 15 FILING" have been served on those listed below either by U.S. Mail, first class, or by internal distribution, this 22nd day of November 2000. Additionally, electronic copies have been transmitted this date to those listed below and marked by single asterisks.

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