

RAS 2101

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD PANEL

DOCKETED 08/17/00

SERVED 08/17/00

Before Administrative Judges:

Ann Marshall Young, Presiding Officer
Frederick J. Shon, Special Assistant

In the Matter of

GRAYSTAR, INC.

(Suite 103, 200 Valley Road,
Mt. Arlington, NJ 07856)

Docket No. SSD 99-27

ASLBP No. 00-778-06-ML

August 17, 2000

ORDER

(Setting Schedule for Proceedings and Addressing Other Matters Considered at
August 15, 2000, Telephone Conference)

On August 15, 2000, a transcribed telephone conference was held in the above-captioned case, which concerns the request of GrayStar, Inc., (GrayStar) for a hearing to challenge the NRC staff's May 24, 2000, denial of its application to register its Model GS-42 sealed source and Model 1 irradiator. The following matters were considered and decided at this conference:

1. The parties agreed that registration of the Model 1 irradiator will not be a part of this case, in that the staff has not denied registration of it, but has merely provided GrayStar with a list of deficiencies that need to be addressed prior to a final determination on the request for its registration. 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.

2. It was noted that, pursuant to Dr. Donald W. Thayer's August 14, 2000, letter and e-mail, he and the U. S. Department of Agriculture, Agricultural Research Service (ARS), wish for his letter to be treated only as a limited appearance under 10 CFR §2.1211. However, the parties agreed that Dr. Thayer at the ARS will be served with copies of all orders and pleadings in this case, so that the ARS may be apprised of the progress and outcome of the case.

3. The parties were encouraged to consider engaging in mediation on as many issues as possible in this case, with a view to settling all or part of the case. If the parties wish to do this, they should contact the Presiding Officer as soon as possible so that the Chief Administrative Judge can assign a mediator to the case. Likewise, the parties were advised to make any requests that the Presiding Officer certify any novel policy issues to the Commission under 10 CFR § 2.1209(d) as soon as possible.

4. The following deadlines were set in the case, which shall be followed unless extended for good cause shown:

A. Counsel for the parties shall file simultaneous written presentations under 10 CFR § 2.1233 on or before September 11, 2000.

B. Both parties shall file responses to each other's written presentations on or before October 16, 2000.

C. Either party shall file any request for further proceedings in the case on or before October 23, 2000.

D. If the undersigned has any further questions of the parties after submission of their written presentations and responses and any other information provided to that point, she will provide these to counsel on or before November 6, 2000, with a response date stated therein.

E. Absent further proceedings in the case after receipt of the parties' October 16 written presentation responses, the Initial Decision in this case shall be entered on or before December 15, 2000.

5. The parties agreed to conform their written presentations under 10 CFR § 2.1233 to the following format and list of issues, using the same numbering system as used herein (all of which is drawn from the parties' correspondence on the denial of the registration at issue):

1. *Dispersibility of cesium 137 chloride powder in the Model GS-42 Sealed Source, under 10 CFR § 36.21(a)(3) and as discussed in Enclosure 1 to NRC Staff's May 24, 2000, letter*
 - a. *Appropriateness/inappropriateness/practicality of other sources as compared to cesium-137 chloride powder*
 - b. *Leak potential/danger with regard to cesium-137 chloride; unique design features to mitigate consequences of any leak*
 - c. *Comparison to smaller irradiators and sealed sources using cesium-137 chloride*
 - d. *Other unique circumstances relating to GS-42, including applicant's response numbers I-VII in June 1, 2000, letter from Russell N. Stein to Donald A. Cool*
 - i. *General value of irradiation to help prevent foodborne disease*
 - ii. *Comparison of GS-42, which is a self-shielded gamma irradiator with no on-site source transfer, vs. other irradiators*
 - (A) *Water storage and/or water irradiation irradiators*
 - (B) *Dry storage on-site loading irradiators*
 - (C) *Dry storage irradiators with interlocks (panoramic irradiators where the source is independent of the radiation chamber)*
 - (D) *Machine source irradiators*
 - iii. *Comparison of Cesium-137 with other source types:*
 - (A) *Cobalt-60*
 - (B) *Electron beams (e-beam)*
 - (C) *Bemsstrahlung Radiation (X-rays)*
 - iv. *Basis for selection of cesium-137 for GS-42 as compared to cobalt-60*
 - v. *Practicality and safety of using cesium-137 chloride as compared to other forms of cesium-137*

- vi. *Unique design features of GS-42 (numbered (1)-(12) in Russell Stein's June 1, 2000, letter)*
- vii. *Other*
- e. *Relation of a - d to each other, in terms of safety, relative importance, etc.*
- f. *Other matters relating to dispersibility issue*
- 2. *Prototype testing of GS-42 sealed sources under 10 CFR § 36.21(a)(5)*
 - a. *Design of inner capsule relative to leak potential*
 - b. *Vibration testing*
 - i. *Along weakest axis*
 - ii. *Range to 500 hertz*
 - c. *Other*
- 3. *GS-42 sealed-source construction and durability under 10 CFR § 36.21(4)*
 - 3.1. *Integrity of source housing*
 - a. *Relevance of historical evidence using different fabrication procedures*
 - b. *Possibility of corrosion during filling process based on conditions present during filling process*
 - i. *pH*
 - ii. *Time*
 - iii. *Temperature*
 - iv. *Concentration of impurities*
 - v. *Other*
 - c. *Possibility of corrosion during operation, based on adequacy of evaporation procedure to remove all moisture in source tube*
 - 3.2. *Crevice corrosion*
 - a. *Relevance of historical evidence using different filling procedures*
 - b. *Special difficulty removing moisture from crevices*
 - 3.3. *Role of materials impurities - relevance of historical evidence using different filling procedures*
 - 3.4. *Long-term reliability and failure modes*
 - a. *Relevance of historical experience with WESF sources*
 - b. *Potential failure modes specific to GS-42*
 - 3.5. *Other*

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.*
 - 4.1. *Sufficiency of information about final design of source welding procedures.*
 - 4.2. *Sufficiency of information about final design for source filling of GS-42.*
 - a. *Adequacy of moisture removal procedure.*
 - b. *Prevention of corrosion*
 - 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”*
 - 4.4. *Sufficiency of information about seal torquing, maximum allowable torque, and uniformity of construction.*
 - 4.5. *Other*

6. The NRC Staff is requested to augment the statements made in their May 24, 2000, letter to clarify which parts of the record provide specific bases for their denial. Both parties will address all of the issues outlined above, with provision of appropriate factual and/or legal basis for all statements and arguments put forth; failure to address any of the issues may result in an adverse inference being drawn with regard to any such issue(s). However, apart from citation of relevant law and regulations, counsel are requested to limit reference or incorporation by reference to materials not part of their written presentations as much as possible, and instead to quote relevant and appropriately identified portions and/or provide exhibit copies; where this is impossible or impractical, specific citations to sections and pages of materials in the hearing file should be provided.

It is so ORDERED.

BY THE PRESIDING OFFICER¹

/RA/

Ann Marshall Young
ADMINISTRATIVE JUDGE

Rockville, Maryland
August 17, 2000

¹Copies of this Order were sent this date by Internet e-mail transmission to counsel for GrayStar, Inc., counsel for the NRC staff, and Dr. Donald Thayer, U.S. Department of Agriculture, Agricultural Research Service.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)
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(Suite 103, 200 Valley Road,)
Mt. Arlington, NJ 07856))

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB ORDER (SETTING SCHEDULE FOR PROCEEDINGS AND ADDRESSING OTHER MATTERS CONSIDERED AT AUGUST 15, 2000, TELEPHONE CONFERENCE) have been served upon the following persons by U.S. mail, first class, or through NRC internal distribution.

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Washington, DC 20555-0001

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AUGUST 15, 2000, TELEPHONE CONFERENCE)

[Original signed by Adria T. Byrdsong]

Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 17th day of August 2000