

September 6, 2000

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

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

In the Matter of
GRAYSTAR, INC.
(Denial of Sealed Source Registration Application)
Docket No. SSD 99-27

Dear Administrative Judges:

Pursuant to 10 C.F.R. § 2.1231, the Staff is supplementing the GrayStar Hearing File established by letter dated August 1, 2000. Yesterday, additional documents were brought to my attention which should have been included in the Hearing File. Copies of these documents are enclosed, along with a revised Hearing File Index. The new documents are listed chronologically under the heading "Supplemental Documents" on the last page of the revised Hearing File Index.

Sincerely,

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

Enclosures: As stated

cc w/ encl: David Lashway, Esq.
Russell N. Stein

HEARING FILE INDEX (revised)

The Hearing File in this adjudicatory proceeding, regarding the NRC's denial of GrayStar's April 1999 sealed source registration request, contains the following items indexed below in chronological order. Correspondence between GrayStar and the NRC which pre-dates GrayStar's April 1999 filing (the three items designated below as tabs I, II, and III) provide relevant background information concerning an earlier GrayStar irradiator registration application submitted in 1996. Items I and II are referenced by GrayStar in support of its April 1999 filing. See enclosure within item IV.I. Other documents referenced by GrayStar -- but not submitted in support of its April 1999 filing -- are not being made part of the Hearing File.

<u>Tab Number</u>	<u>Description</u>
I.	Letter to GrayStar (M. Stein) from NRC (L. Camper) dated 1/27/97.
II.A	Letter to NRC (L. Camper) from GrayStar (R. Stein) dated 2/10/97.
II.B	Appendix A" attached to item II.A.
III.A	Letter to GrayStar (R. Stein) from NRC (L. Camper) dated 5/20/98.
III.B	Enclosure attached to item III.A: "Technical Issues to be Addressed in Application for Registration of the Model GrayStar Irradiator."
IV.A	Cover letter to NRC (J. Jankovich) from GrayStar (R. Stein) dated 4/19/99, regarding GrayStar's April 1999 registration application for the Model GS-42 Sealed Source, and Model 1 Irradiator.
IV.B	Cover sheet, summary data sheet, certification sheet, and 38-page application.
IV.C	Exhibit 1 of April 1999 registration application: Quality Assurance Program, and related implementing procedures.
IV.D	Exhibit 2 of April 1999 registration application: discussion of cesium chloride's chemical composition.
IV.E	Exhibit 3 of April 1999 registration application: documents regarding the testing of Model GS-42 Sealed Source (test results, plans, parameters, specifications and procedures). [END OF VOLUME I OF HEARING FILE]
IV.F	Exhibit 4 of April 1999 registration application: discussion of radiation profiles, and calculated flux patterns, for the Model 1 Irradiator.
IV.G	Exhibit 5 of April 1999 registration application: "Temperature Profile Analysis of the GS-42 Cesium-137 Source," and Test Specification TRS-012.

<u>Tab Number</u>	<u>Description</u>
IV.H	Exhibit 6 of April 1999 registration application: checklist for Model GS-42 Sealed Source.
IV.I	Exhibit 7 of April 1999 registration application: discussion of technical issues regarding applications for registration of irradiators.
IV.J	Exhibit 8 of April 1999 registration application: oversized drawings of Model GS-42 components.
IV.K	Exhibit 9 of April 1999 registration application: drawings of Model 1 Irradiator components.
IV.L	Exhibit 10 of April 1999 registration application: sample procedures regarding the Model 1 Irradiator.
IV.M	Exhibit 11 of April 1999 registration application: oversized label drawings.
V.A	Cover letter to GrayStar (R. Stein) from NRC (J. Jankovich) dated 7/26/99.
V.B	Enclosure attached to item V.A: Request For Additional Information (RAI).
VI.A	Cover letter to NRC (J. Jankovich) from GrayStar (R. Stein) dated 9/27/99, in response to RAI.
VI.B	Volume 1 of GrayStar's 9/99 filing: response to specific requests for information (page numbers added by NRC).
VI.C	Volume 2 of GrayStar's 9/99 filing:
VI.C.1	Soine, T. <i>et al.</i> , "An Evaluation of Strontium and Cesium Compounds for Waste Packaging," Battelle-Northwest Report No. BNWL-CC-1695, 1968.
VI.C.2	Procedure TRS-031: "Test: End Cap / Seal Plug Minimum Seal Torque Determination Test."
VI.C.3	Replacement pages to Smithers' 3/31/99 report (see Tab IV.E for copy of full report).
VI.C.4	Bradley, N. <i>et al.</i> , "Investigation of Deformation in Rectangular Cesium-137 Sources," Oak Ridge National Laboratory (ORNL), 1970.

<u>Tab Number</u>	<u>Description</u>
VI.C.5	Bryan, G., "Cesium Chloride Compatibility Testing Program - Annual Report Fiscal Year 1983," Report No. DE84 010574, Pacific Northwest Laboratory (PNL), 1984.
VI.C.6	Kenna, B. <i>et al.</i> , "Characterization of an Aged WESF Capsule," Sandia National Laboratories (SNL), 1983.
VI.C.7	"Interim Report of the DOE Type B Investigation Group, Cesium-137: A Systems Evaluation, Encapsulation to Release at Radiation Sterilizers, Inc., Decatur, Georgia," Department of Energy, 1990. [END OF VOLUME II OF HEARING FILE]
VI.C.8	"Welding Handbook," eighth edition, vol. 4, p. 357.
VI.C.9	"Welding Handbook," eighth edition, Figure 6.7.
VI.C.10	"CRC Handbook of Tables for Applied Engineering Science," second edition, Table 1-5.
VI.C.11	Procedure TRS-020: "Leaktightness - Helium Vacuum Annulus Test."
VI.C.12	Procedure TRS-021: "Visual Examination Procedure and Acceptance Standard of Welds."
VI.D	Volume 3 of GrayStar's 9/99 filing:
VI.D.1	Jones, J., "Fabrication of 137 Cs Sources," ORNL, 1964.
VI.D.2	[Not included in Hearing File: Duplicate copy of 1970 ORNL report, "Investigation of Deformation in Rectangular Cesium-137 Sources." See item VI.C.4, <i>supra</i>].
VI.D.3	[Not included in Hearing File: Duplicate copy of 1983 SNL report, "Characterization of an Aged WESF Capsule." See item VI.C.6, <i>supra</i>].
VI.D.4	Rimshaw, S. <i>et al.</i> , "Cesium-137 Data Sheets," ORNL, 1967.
VI.D.5	[Not included in Hearing File: Duplicate copy of 1990 DOE report, "Interim Report of the DOE Type B Investigation Group, Cesium-137: A Systems Evaluation, Encapsulation to Release at Radiation Sterilizers, Inc., Decatur, Georgia." See item VI.C.7, <i>supra</i>].
VI.D.6	Hammond, J., "Cesium Chloride Capsule Testing for Special Form Qualification," Atlantic Richfield Hanford Company, 1975.

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cont'd

Enclosure to letter dated September 6, 2000

<u>Tab Number</u>	<u>Description</u>
VI.D.7	[Not included in Hearing File: Duplicate copy of 1968 report, "An Evaluation of Strontium and Cesium Compounds for Waste Packaging." See item VI.C.1, <i>supra</i>].
VI.D.8	Fullam, H., "Compatibility Studies for the Waste Packaging Program - Interim Report," Battelle-Northwest Report No. BNWL-CC-2111, 1969.
VI.D.9	Fullam, H., <i>et al.</i> , "Interim Report on Low-Cost Cesium Radiation Sources from Hanford Waste Management Program," Battelle-Northwest Report No. BNWL-CC-2245, 1969.
VI.D.10	"Oral Statements about the RSI [Radiation Sterilizers, Inc.] Incident," Report No. DOE/ORO-914, Appendix C, Department of Energy, 1990. [END OF VOLUME III OF HEARING FILE]
VI.E	Volume 4 of GrayStar's 9/99 filing:
VI.E.1	"Interim Report of the DOE Type B Investigation Group, Licensing Correspondence," Report No. DOE/ORO-914, Appendix D, Department of Energy, 1990.
VI.E.2	Fullam, H., "Cesium Chloride Compatibility Testing Program - Annual Report Fiscal Year 1982," Report No. DE83006919, PNL, 1982.
VI.E.3	[Not included in Hearing File: Duplicate copy of PNL's 1984 report, "Cesium Chloride Compatibility Testing Program - Annual Report Fiscal Year 1983." See item VI.C.5, <i>supra</i>]. [END OF VOLUME IV OF HEARING FILE]
VI.E.4	Fullam, H., "Compatibility of Cesium Chloride and Strontium Fluoride with Containment Materials," Battelle-Northwest Report No. BNWL-1673, 1972.
VI.F	Volume 5 of GrayStar's 9/99 filing:
VI.F.1	GrayStar's revised registration application for the Model GS-42 Sealed Source, and Model 1 Irradiator.
VI.F.2	Procedure TRS-022: "Inspection and Rework Procedure for Outer Source Tube Assembly End Caps."
VI.F.3	Procedure TRS-023: "Inspection and Rework Procedure for Inner Source Tube Assembly End Caps."

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cont'd

Enclosure to letter dated September 6, 2000

Tab Number

Description

VI.F.4	Arthur, B., <i>et al.</i> , "Principles of Radiation Shielding," Prentice-Hall, 1984, pp. 158, and 209.
VI.F.5	Jaeger, R., <i>et al.</i> , "Engineering Compendium on Radiation Shielding," Springer-Verlag, 1968, pp. 170, 174, and 214-17.
VI.F.6	Chappell, D., "Handbook of Nuclear Research and Technology," McGraw-Hill, p. 192.
VI.F.7	Procedure 026: "Test: Wet Smear / Filter Test for Radioactive Contamination."
VI.F.8	Procedure 027: "Test: Sampling via Wash / Drain Pipe."
VI.F.9	Revised drawings of Model GS-42 components.
VI.F.10	Revised label drawings.

Copies of the following correspondence between GrayStar and the NRC (the three items designated below as tabs VII, VIII, and IX) were previously distributed, and should be inserted into the binders to complete the sets of Hearing File documents:

VII.A	Cover letter to GrayStar (R. Stein) from NRC (D. Cool) dated 5/24/2000, regarding denial of April 1999 application.
VII.B	Enclosure 1 attached to item VII.A: "Basis for Denial of Application for Registration of the Model GS-42 Sealed Source."
VII.C	Enclosure 2 attached to item VII.A: "Deficiencies in the Application for Registration of the GrayStar Model 1 Irradiator."
VIII.	Letter to NRC (D. Cool) from GrayStar (R. Stein) dated 6/1/2000, requesting reconsideration of registration denial, and alternatively requesting a hearing.
IX.	Letter to GrayStar (R. Stein) from NRC (D. Cool) dated 6/8/2000, denying June 1 request for reconsideration.

SUPPLEMENTAL DOCUMENTS

1. E-mail from GrayStar (R. Stein) to NRC (J. Jankovich) dated 5/4/99, regarding 5/11/99 meeting.
2. Telephone Conversation Record made by J. Jankovich of NRC summarizing 5/4/99 conversation with GrayStar (R. Stein).
3. Minutes of 5/11/99 meeting with GrayStar (Memorandum from J. Jankovich to F. Sturz dated 6/4/99).

Attachment to 6/4/99 Memorandum: Set of presentation slides used by M. Stein and R. Stein of GrayStar at 5/11/99 meeting.
4. Letter from NRC (F. Sturz) to GrayStar (R. Stein) dated 6/22/99, acknowledging NRC's receipt of GrayStar's 4/19/99 application requesting a certificate of registration for the irradiator and GS-42 sealed source.
5. Minutes of 7/13/99 meeting with GrayStar (Memorandum from J. Jankovich to F. Sturz dated 7/16/99).
6. Letter to NRC (J. Jankovich) from GrayStar (R. Stein) dated 8/12/99.

Exhibit 1 attached to 8/12/99 letter: "Evaluation of the application for Device Review as a Category I versus a Category II irradiator."

Exhibit 2 attached to 8/12/99 letter: "Requirements for Environmental Report and Environmental Assessment for the GrayStar irradiator".
7. Minutes of 8/11/99 meeting with Graystar (Memorandum from J. Jankovich to F. Sturz dated 8/13/99).
8. Letter from NRC (J. Jankovich) to GrayStar (R. Stein) dated 9/10/99, responding to GrayStar's 8/12/99 letter.
9. Fax from NRC (J. Jankovich) to GrayStar (R. Stein) dated 9/16/99, containing NRC's policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities.

September 6, 2000

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Sincerely,

John T. Hull */RA/*
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Russell N. Stein

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