

March 5, 2001

MEMORANDUM TO: Martin J. Virgilio, Director
Office of Nuclear Material Safety and Safeguards

FROM: Dennis C. Dambly
Assistant General Counsel
Materials Litigation and Enforcement

SUBJECT: PRESIDING OFFICER'S INITIAL DECISION IN GRAYSTAR
PROCEEDING

On February 27, 2001, the presiding officer in the subject proceeding issued her initial decision (LBP-01-07) (copy attached), upholding the Staff's denial of an application for a certificate of registration regarding a sealed source, intended for use in devices to irradiate food. The applicant, GrayStar, Inc., sought approval to use cesium-137 as the radioactive source material in its sealed sources (designated by GrayStar as the GS-42 sealed sources). Each food irradiator (designated by GrayStar as the Model 1) would have had a total strength of three million curies, produced by 64 individual GS-42 sealed sources, each of which would contain 51,500 curies of cesium-137 in powder form. See LBP-01-07, at 4.

In upholding the Staff's denial, the presiding officer rejected all of GrayStar's arguments. In accordance with the Staff's position, the presiding officer made the following findings: (1) the licensing requirements for irradiators in 10 C.F.R. Part 36 are applicable to the GS-42 (see LBP-01-07, at 21-22); (2) the 10 C.F.R. § 36.21(a)(3) performance criterion for sealed sources used in irradiators, *i.e.*, that the radioactive material used in such sources must be "as nondispersible as practical," is applicable to the GS-42 (see LBP-01-07, at 25-26), and that the GS-42 fails to meet this requirement (*Id.*, at 40-42); (3) the product registration provisions for specifically licensed items are also applicable to the GS-42, and require GrayStar to show, pursuant to 10 C.F.R. § 32.210(c), that the radiation safety properties of the GS-42 are adequate to protect health and minimize danger to life and property (see LBP-01-07, at 20-22, and 48-49); (4) the GS-42 fails to meet the double encapsulation requirement of 10 C.F.R. § 36.21(a)(2) (see LBP-01-07, at 48); and (5) the GS-42 fails to meet the testing requirements of 10 C.F.R. § 36.21(a)(5). See LBP-01-07, at 47-48.

GrayStar has until March 19, 2001, to petition the Commission to review LBP-01-07. However, by letter dated March 2, 2001, GrayStar has informed the Staff that after considering LBP-01-07, GrayStar has decided to withdraw its registration applications regarding both the

GS-42 and the Model 1. We thus do not expect GrayStar to request that the Commission review LBP-01-07. Should you have any questions concerning this matter, please contact John Hull at 415-1573.

Attachment: As stated

cc w/att: W. Travers, EDO
S. Burns, OGC
L. Chandler, OGC
H. Miller, RI
B. Fewell, RI