



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

August 13, 1999

MEMORANDUM TO: Frederick Sturz, Section Leader  
Materials Safety and Inspection Branch, IMNS

FROM: John Jankovich *John Jankovich*  
Senior QA Engineer  
Materials Safety and Inspection Branch, IMNS

SUBJECT: MINUTES OF MEETING WITH GRAYSTAR, Inc.  
AUGUST 11, 1999

Representatives of GrayStar, Inc., requested a meeting with NRC management to discuss the classification of their irradiator design, submitted to NRC for approval as a sealed source and device. The meeting was held on August 11, 1999, at NRC headquarters in Rockville, Md. Messrs. Martin Stein, President/CEO and Russell Stein, VP represented GrayStar and presented the following issues for discussion:

1. Sealed Source and Device Issues

- GrayStar received and understands the questions in the NRC deficiency letter dated July 26, 1999;
- they stated that the design may not fit the classification of 10 CFR 36 as "panoramic" irradiator; GrayStar would prefer a classification of ANSI Category I in order to simplify the emergency response systems and the operator training requirements;
- human entry is limited to maintenance and cleaning;
- a number of generic issues (e.g. operating manual, operating procedures, personnel dose rates) contained in the NRC deficiency letter, should not be in the SSD registration but should be addressed in the site specific materials license.

2. Environmental Assessment Issues

- GrayStar needs additional information why the "categorical exclusion" from environmental reports (10 CFR 51.22) would not apply to their design;
- they would like to receive a copy of the generic (original) study which gave categorical exclusion to other irradiator designs;
- they will study the comparability of the GrayStar design to the ones in the generic report;
- GrayStar stated that approximately 600 irradiators are in use with Cs-137 as source material. Consequently, if GrayStar was to be required to prepare an environmental report, it would set a precedent.

NRC participants discussed the technical details of the issues presented by GrayStar.

In conclusion, the GrayStar representatives stated that they will write a letter to NRC asking for (1) classification as a non-panoramic irradiator; (2) delineation why they must prepare an environmental report; and (3) extension of the response period to NRC's deficiency letter.

NRC participants:

John Hickey/IMNS  
Charlotte Abrams/NMSS  
Frederick Sturz/IMNS

Seung Lee/IMNS  
Markley Au/IMNS  
John Jankovich/IMNS

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