



August 12, 1999

John Jankovich
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Dr. Jankovich:

This letter is in response to your letter dated July 26, 1999 responding to our Application of Sealed Source and Device Evaluation and Registration. Due to the nature of the questions, we will not be able to supply adequate answers within the thirty days requested. Therefore, we would like an extension and anticipate having the response to you by September 26, 1999. If we are unable to meet that time frame, I will let you know in writing as soon as a new schedule is in effect. Part of the difficulty is that some of the questions might require us to utilize outside consultants and under our Quality Assurance Plan, the accreditation of these consultants can be time consuming.

In the letter of July 26, 1999, you note that you have conducted the evaluation of our application as a Category II irradiator. We maintain that the review and subsequent regulatory processes (e.g. Byproduct Material Licenses) should be based on a Category I irradiator or perhaps on a modified Category I irradiator basis. This argument is detailed in Exhibit I (attached). Please let us know of your final determination as soon as practical so that we can assure that our response to your July 26th. letter incorporates the appropriate information.

Also, in Frederick Sturtz's letter to us dated June 22, 1999, it is stated that the Commission has determined that an Environmental Assessment is necessary and that we should supply an Environmental Report. We maintain that according to CFR regulations, a report is specifically excluded and is therefore not necessary. This argument is detailed in Exhibit II (attached). Once again, please let us know of your final determination as soon as practical.

We wish to thank you and your associates for the informative meetings yesterday. It was timely and helped facilitate the regulatory process.

Sincerely,

Russell N. Stein

Vice President



Exhibit I

Evaluation of the application for Device Review as a Category I versus a Category II irradiator.

NRC Comment (Jankovich Letter dated July 26, 1999):

"Please also note that we have conducted the evaluation of your application as a Category II irradiator. Your design fits the definition in ANSI N43.10: '[a] controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system."

"A number of questions in the Enclosure refer to provisions of 10 CFR 36, Licenses and Radiation Safety Requirements for Irradiators which states that '[t]he regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.'" Your design is within the scope of this regulation. our questions address those aspects of the design which apply generically to all locations where you may want to install the irradiator and, therefore, should be resolved at this time."

GRAY*STAR, Inc. Response:

The NRC has segregated irradiators into four categories based on ANSI Standard N13.10 to facilitate the type of review that should be performed on various irradiators. There is a question of whether the GRAY♦STAR™ irradiator should be classified as a Category I or Category II irradiator. The GRAY♦STAR™ irradiator does not technically fit into either category. GRAY*STAR, Inc. maintains that the GRAY♦STAR™ irradiator should be classified as a Category I irradiator for the following reasons:

I. The GRAY♦STAR™ irradiator is more closely aligned with Category I irradiators in form and function and intent than Category II irradiators. The Final rule RIN 3150-AC98, "Licenses and Radiation Safety Requirements for Irradiators" on which Part 36 is based outlines the segregation of Category I irradiators from Categories II, III and IV. The rule excludes "Category I - Self-Contained, Dry-source-storage Irradiators from Part 36:

"This rule does not cover self-contained dry-source-storage irradiators (Category I) for several reasons. First, they are devices that the licensee usually purchases without participating in their design and manufacture. Because safety features are designed into them, self-contained irradiators present less potential hazard and they are considered to be adequately addressed by existing requirements."

1. *"First, they are devices that the licensee usually purchases without participating in their design and manufacture."*

The GRAY♦STAR™ irradiator is a "device" that the licensee leases without participating in the design and manufacture.

2. *Because safety features are designed into them, self-contained irradiators present less potential hazard and they are considered to be adequately addressed by existing requirements.*

The GRAY♦STAR™ irradiator has all safety features designed into it to present less potential hazard than typical Category II, III and IV irradiators.

II. The GRAY♦STAR™ irradiator is a self-shielded irradiator. Radiation safety of the GRAY♦STAR™ irradiator is inherent in the irradiator itself. It does not rely on procedures and training to maintain its safety radiation safety. There are no irradiation interlocks used to prevent inadvertent irradiation exposure. This concept is true for Category I irradiators but not true for Categories II, III and IV.

There is only one area where the GRAY♦STAR™ irradiator does not fit the definition of a Category I irradiator. The similarities and variances of the GRAY♦STAR™ irradiator to a Category I irradiator are outlined as follows:

Category I - Self-Contained, dry source storage irradiator. [American National Standard N433.1]

1. *An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials,..."*

The GRAY♦STAR™ irradiator is an irradiator in which the sealed sources are completely contained in a dry container constructed of solid materials.

2. *"...the sealed source(s) is shielded at all times,..."*

The GRAY♦STAR™ irradiator shields the source at all times.

3. *"...and human access to the sealed source(s)...is not physically possible in its designed configuration."*

Human access to the sealed sources in the GRAY♦STAR™ irradiator is not physically possible.

4. *"...and human access to...the volume(s) undergoing irradiation is not physically possible in its designed configuration."*

Technically human access to the volume undergoing irradiation is physically possible in the GRAY♦STAR™ irradiator. However, access would not be routine and would not lead to an inadvertent exposure to irradiation in its designed configuration. The following discusses the design features that prevent inadvertent radiation exposure by raising the source with a human inside the chamber:

A. The irradiation chamber is an area roughly the size of a commercial pallet of product. It is not a "room". The operator would not enter this area during routine operations. No other person would enter this area during routine operations. The only time the area might be entered is for minor maintenance such as replacing the "visual alert" light bulb. The height of the chamber is approximately 55 inches. In essence, the chamber is similar to a chamber on a Category I irradiator except that it is larger. The only difference is the size of the individual who could gain access. [e.g. A newborn baby could be placed in many Category I irradiators.]

B. The irradiation chamber cannot be "inadvertently" accessed. The chamber is small and would be uncomfortable to spend any time in. For irradiation to occur, the doors to the chamber must be shut. There is no immediate method for closing the doors from the inside of the unit. [There are no handles or hand grips on the doors on the inside of the unit.] There is no immediate method for holding the doors closed from the inside of the unit. [The doors are spring loaded to return to the open position should the handle keys be located on the doors. There is no way to operate both handle keys from inside the unit.]

C. For the irradiator to be operated, both handle keys must be removed from the doors. The handle keys can only be removed from the doors with both doors closed and in the

latched position. This can only be performed by someone outside the chamber. This person would have direct line of site and be only inches away from the chamber itself. It is inconceivable that someone could hide in the chamber. If a full pallet of product is in the chamber, there is no room to also allow access for a human.

D. Should for some unknown and unanticipated reason, a person find themselves in the chamber with the chamber doors closed and latched, they can open either door independently by pressing a button on the inside of either door.

E. Prior to the irradiation cycle commencing, a visual alert (light bulb) is illuminated in the chamber. If the light bulb should not be functioning, the hydraulic system will not be able to raise the door/source. There is also an audible alert prior to the irradiation cycle commencing.

F. There is an emergency stop button located in the chamber.

G. The source cannot be raised when the handle keys are still in the unit.

H. The source cannot be raised if either of the chamber doors are not in the closed position for whatever reason.

A person cannot enter the chamber when the source is in the raised position because they are barred by 16 inch solid steel plate.

III. . By categorizing the GRAY♦STAR™ irradiator as a Category I irradiator versus a Category II irradiator does not make the irradiator any less safe. Further, it reduces the regulatory burden of GRAY*STAR, Inc., the user, and the regulatory agencies. Most importantly, it eliminates certain requirements that are part of Part 36 which are required for Category II, III and IV irradiators which would not make the GRAY♦STAR™ irradiator any more safe and perhaps less safe. [e.g. 10 CFR 36.67(b)(2)] If the NRC determines that the GRAY♦STAR™ irradiator is a Part 36 irradiator (Category II), then the application and subsequent applications for By Product Material will be filled with exemption requests. GRAY*STAR, Inc. believes that it would be less of a burden, and more accurate to categorize the unit as a Category I and make it incumbent upon GRAY*STAR, Inc. to provide answers to questions relating to the one item that does not make the unit categorically a category I irradiator. [i.e. Human access to the chamber.]

REQUEST:

GRAY*STAR, Inc. respectfully requests that the unit be defined by the NRC as a Category I irradiator not subject to all of the inapplicable regulations of Part 36. GRAY*STAR, Inc. will provide (has provided) design information which illustrates just how a human would be prevented from being inadvertently exposed to radiation.

Should the NRC designate the GRAY♦STAR™ irradiator as a Category II irradiator, GRAY*STAR, Inc. requests that it be exempt from any requirements of Category II which are not required of Category I irradiators with the exception of regulations specific to potential radiation exposure of a human being within the chamber during irradiation.

Exhibit II

Requirements for Environmental Report and Environmental Assessment
for the GRAY♦STAR™ irradiator

NRC Comment (Sturtz Letter dated June 22, 1999):

"Please also note that the Commission has determined to prepare an environmental assessment in accordance with 10 CFR 52.21. Further, in light of the GrayStar [sic] irradiator's innovative design, the Commission has determined in accordance with 10 CFR 51.60 that an environmental report is necessary."

GRAY*STAR, Inc. Response:

GRAY*STAR, Inc. maintains that 10 CFR 52.22(c)(14)(vii) categorically excludes "Irradiators" and thus neither an Environmental Report nor an Environmental Assessment is necessary.

Further, even though the irradiator is an "innovative design", to our knowledge, we are within the environmental boundaries of existing Category I and Category II irradiators and are well with the boundaries of existing Category III and Category IV irradiators.

Further, to our knowledge, no application for a Category I, II, III or IV irradiator has had to prepare an Environmental Report (per 10 CFR 51.60) in the past.

Further, environmental reports are site specific in nature and the pending application is for a device evaluation which is not site specific and therefore an Environmental Report is not appropriate.

Further, environmental assessment is usually reviewed at the time of the site specific By Product Materials License.

Further, all irradiators have a minimal environmental effect as compared to operations requiring Environmental Impact Statements as outlined in 10 CFR 51.20.

Therefore, GRAY*STAR, Inc. contends that an Environmental Report is not necessary for the Evaluation of the Sealed Source and Device and that an Environmental Assessment is not necessary for the Evaluation of the Sealed Source and Device.

We respectfully request the NRC to rescind its request for the Environmental Report and Environmental Assessment. If the NRC maintains its position, we request the following materials:

- 1) Examples of precedent of both Environmental Reports and Environmental Assessments performed on existing Irradiators of all categories.
- 2) Details of the "innovative design" which environmentally differ from existing irradiators of all categories.
- 3) If a generic Environmental Assessment has been performed in the past on irradiators by the NRC, a copy of this Assessment.
- 4) If a generic Environmental Assessment exists, the differences between the effects on the environment of the generic model versus potential effects of the "innovative design" of the GRAY♦STAR™ irradiator.