



June 1, 2000

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards
US Nuclear Regulatory Commission
Washington, DC 20555

RE: NRC letter dated May 24, 2000: "TECHNICAL EVALUATION OF APPLICATION
FOR CERTIFICATE OF REGISTRATION"
Sealed Source and Device Evaluation Case Number SSD 99-27

Dear Dr. Cool:

This letter is in response to your denial letter of May 24, 2000 for the GRAY*STAR, Inc. application for a Sealed Source and Device Certificate of Registration. We request that the application be reconsidered and reopened based on arguments to follow. If it is not within your authority or judgement to reopen the evaluation, we request a hearing in accordance with 10 CFR 2.103 as soon as possible. We would appreciate a quick response because the **GRAY*STAR™** Model 1 is the only product of GRAY*STAR, Inc. and therefore, time is of the essence.

We are surprised by your action. Our initial application for the evaluation of the Sealed Source and Device was submitted to the NRC on September 5, 1996. Due to known deficiencies in the original application, an updated application was submitted on April 15, 1999. On July 26, 1999, we received a letter of deficiency (sixty questions) which we responded to in detail on September 27, 1999 [117 pages of response; 19 drawings; 2,370 pages of reference information]. The NRC's "Team Review" was completed on November 4, 1999 and the Office Director briefed on December 21, 1999. Between November 4, 1999 and May 2, 2000, Russell Stein of GRAY*STAR, Inc. and John Jankovich of the NRC had at least nine telephone conversations. As part of each conversation, Mr. Stein specifically asked Dr. Jankovich if any more information was necessary for the NRC to make its determination on the application. On each call, Dr. Jankovich professionally stated that no information is requested of GRAY*STAR and that he would let us know if any questions arose. On May 2, 2000, Mr. Stein was informed by Dr. Jankovich that there was no more NRC discussion that would require input from GRAY*STAR, Inc. and that the NRC had all the information it needed to make its determination which would follow in approximately two weeks. Thus, we did not anticipate any deficiencies as outlined in your May 24, 2000 letter.



We are also surprised that the reason for denial (dispersibility) in your May 24th. letter implies that other isotopes can be used in lieu of cesium-137, and yet this question was not raised in the July 26, 1999 deficiency letter. In other words, the denial is based on an issue which we were not notified of nor allowed to respond to prior to your denial letter of May 24, 2000. Therefore, we submit the following argument supporting that cesium-137 chloride is the only practical chemical and isotopic form for use in the **GRAY♦STAR** Model 1.

We recognize that it is the NRC's obligation to assure the health and safety of the public as well as to protect property from damage when considering an application of this type. And, that part of the process is to insure that all questions are adequately answered to provide that protection. Items 2, 3 and 4 of Enclosure 1 as well as all of Enclosure 2 of the May 24, 1999 Denial Letter are questions which would be typical of a letter of deficiency. Therefore, we have limited this response to Item 1; Dispersibility. Subsequent to an ultimate decision on the dispersibility issue, we will address all of the other items by providing information to the NRC for their further evaluation assuming the application is reopened.

The following is an analysis of the practicality of the use of various methods for which the **GRAY♦STAR** Model 1 is intended. The **GRAY♦STAR** Model 1's primary purpose is to destroy pathogens in food products and thus provide a safer food supply for the public.

ANALYSIS:

I. Use of Irradiation to Help Prevent Foodborne Disease.

The irradiation of food is one of the best methods of reducing pathogens without significantly changing the food's texture, taste or appearance. This is primarily due to the small amount of total energy utilized on the food (cold process) and the strong effect that irradiation has on microorganisms. Irradiation is a volume sterilent and is not restricted to the surface of the product, which is a major limitation of various chemical techniques as well as steam pasteurization.

One alternative would be to not use irradiation on food products. This alternative is not practical. Presently, the CDC estimates 76 million Americans suffer from food poisoning, 325,000 are hospitalized and 5,200 Americans die every year. Although other techniques will help reduce this figure, the only practical technique that will have a significant impact is irradiation. The USDA, FDA, the Codex Alimentarius Commission and many other domestic and international organizations recognize the importance of food irradiation. President Clinton recently mandated that listeria, a virulent pathogen, be reduced by a factor of two in the next five years on "ready to eat" foods. Without irradiation as a tool, it will be difficult, if not impossible, to achieve this goal.

Therefore, we believe that many more irradiators will be constructed in the near and long term future. If there is any probability of a radiological incident with an existing irradiator, that probability will be increased with the utilization of more irradiators of current design.

II. Self-Shielded Gamma Irradiators with No On-Site Source Transfer vs. Other Irradiators.

The **GRAY♦STAR** Model 1 is the only self-shielded commercial isotopic irradiator with no on-site transfer of sources. Therefore, all following discussions for a self-shielded irradiator with no on-site source transfer will be specific to the **GRAY♦STAR** Model 1.

The **GRAY♦STAR** Model 1 irradiator was conceived and designed to be an inherently practical irradiator for food processors. At the same time, it was conceived and designed to be radiologically “safer” as defined by the principles of ALARA (As Low As Reasonably Achievable) and to avoid specific accidents that have occurred in the past resulting in injury and death. The irradiator is designed to be inherently safe. As “inherently safe” we mean that the unit will not cause radiological injury to a worker or any member of the public, no matter what the operator does, or does not do, within reasonable conditions of use (it is not “determined man proof”). This is a very difficult design/engineering goal, which **GRAY*STAR**, Inc. believes it has achieved.

Research into all irradiator overexposures by **GRAY*STAR**, Inc. has indicated that almost all of the injuries were due to the operator entering the radiation chamber when the chamber was exposed to the source (or part of the source). Therefore, the key to the **GRAY♦STAR** Model 1's safety is to absolutely prevent this type of incident from happening. Present commercial irradiators rely on training and interlocks to mitigate against accidents. All previous incidents were caused by combinations of failures of equipment and operator error. Even with the best of training, redundant interlocks and excellent procedural controls, equipment will fail and operators will make errors. The **GRAY♦STAR** prevents overexposure by providing a simple, absolute coupling of the door/shield and the source (the source is part of the door/shield) so that no one can have access to the chamber when the source is exposed: To do so would require the individual to walk through 16 inches of solid steel which is not possible. There are no interlocks to fail, nor can an operator err in any way that would allow the operator to enter the chamber when the chamber is exposed to the source, even if the software or wiring were tampered with.

There have been at least two non-fatal overexposures in the United States and at least five fatal overexposures abroad due to a person or persons entering the chamber while the source is exposed. The probability of this type of incident occurring will increase as new irradiators of existing design are utilized. The **GRAY♦STAR** will totally avoid that possibility.

Another key feature of the **GRAY♦STAR** Model 1 is that it does not require on-site source transfer. This eliminates the possibility of a radiological incident during on-site transfer. Also, due to the long half-life of cesium-137, it will not require frequent transport of sources to the irradiator site. Existing transport casks for irradiator source material have a higher external surface dose rate than the Graysafe™ (the cask portion of the **GRAY♦STAR** Model 1). The number of transports, as well as the higher dose rates of existing casks, will expose the public to more radiation than the infrequent transport of the Graysafe™. Thus, the **GRAY♦STAR** is more in line with the principles of ALARA than presently licensed commercial irradiators.

The food industry has indicated that if irradiation is to be practical on a commercial basis, it must have the following features: The ability to irradiate product on a full 40" x 48" pallet. It must be on-site. And, it must have an economy of scale that is cost effective with a product volume of about 20 million pounds for disinfection. Larger irradiators such as cobalt-60 facilities may be cost effectively utilized if the production volumes are above 250 million pounds a year; however, this will limit the practical availability of irradiation to only large processors and will be prohibitive to smaller processors (a typical meat processing plant is between 20 to 100 million pounds a year). Only a self-shielded irradiator such as the **GRAY♦STAR** unit will meet these commercial practicalities.

The design of the **GRAY♦STAR** Model 1 allows for the use of new techniques that augment product safety including a real time electronic dosimetry system which is not possible on a cobalt-60 facility. Also, the **GRAY♦STAR** has the ability to permit remote access of raw processing data directly from the irradiator independent of the operator. This is a feature desired by customers and the USDA to assure that the product has been properly irradiated. This feature may also be included within the customer's By Product Material License to allow the NRC to monitor the unit remotely if desired.

A) Water Storage and/or Water Irradiation Irradiators:

To the knowledge of GRAY*STAR, Inc., these are the only types of irradiators used on a commercial basis for the same purpose as the **GRAY♦STAR** Model 1.

These types of irradiators rely on both comprehensive operator training and interlocks. There is documentation of both interlocks failing as well as operator errors that have led to several radiation injuries, including fatalities. These irradiators should not use cesium chloride as a source. Therefore, they are limited to cobalt-60 due to the solubility of cesium chloride and the presence of water as a dispersal medium. Due to the relatively short half-life of cobalt-60, the facilities constantly require new sources to be brought to the site. As mentioned above, this increases the potential for a radiological incident during transport. Also, the public will be exposed to some additional radiation since the allowable dose rates can be as high as 200 mR/hr while the sources are in transport. The Graysafe™ has a calculated accessible dose rate of only 0.011 mR/hr

while the unit is in transport. The lower surface doses of the Graysafe™ are designed to meet the more stringent shielding requirements of an irradiator than those of a shipping cask.

Because of the use of water in these irradiators, a medium exists to transport (disperse) any radioactive material released due to an encapsulation failure. Several failures have occurred in the past with water irradiators using both cesium and cobalt sources.

*NOTE: The management of GRAY*STAR, Inc. strongly believes that cesium chloride should not be used in a water irradiator and has protested the use of cesium in such units to the NRC in the past (prior to the WESF lease program).*

If the situation was reversed and the **GRAY♦STAR** was the approved norm, one could argue that the use of a water pool irradiator was not a practical alternative because there is a greater possibility of an accident and increased public radiation exposure. In keeping with ALARA, a water storage or water irradiation irradiator is not practical if a reasonable alternative exists which provides less potential exposure to either the worker or the public. The **GRAY♦STAR** is such an alternative.

B. Dry Storage On-Site Loading Irradiators:

This type of irradiator can be designed to meet the operational safety criteria of the **GRAY♦STAR** Model 1, but does not have the loading safety criteria of the **GRAY♦STAR** that minimizes potential exposure to workers and the public during transportation and installation. Also, due to the impractical nature of this type of irradiator, there are presently no commercial dry storage on-site loading irradiators in use.

Unlike the features of the **GRAY♦STAR** Model 1 mentioned above, this type of irradiator will have the possibility of a radiological incident while loading the sources. Also, if not performed properly, there is the potential for an unshielded source.

Another disadvantage of this type of irradiator is that if the unit requires supplemental sources due to decay, the old sources will have to be removed from the unit and stored (unproductively) at a storage facility which will increase the radioactive material burden of society as a whole.

In keeping with the policy of ALARA, this type of irradiator is not practical if a reasonable alternative exists, which provides less potential exposure to either the worker or the public.

- C. Dry Storage Irradiator with Interlocks (panoramic irradiator where the source is independent of the radiation chamber):

This type of irradiator relies on both comprehensive operator training and interlocks. There is documentation of interlocks on this type of irradiator having failed in the past (fortunately not leading to injury). A mistake by the operator and/or a failure of the interlocks can lead to a radiological incident.

In keeping with ALARA, this type of irradiator is not practical if a reasonable alternative exists, which provides for less potential exposure to either the worker or the public. The **GRAY♦STAR** irradiator is such a reasonable alternative.

- D. Machine Source Irradiators:

Irradiators which use machine sources include e-beam and X-ray units. Since they are not under the safety purview of the NRC, their safety will not be discussed in this section. The characteristics of these sources are addressed under the "Source Type" section below.

III. Source Type:

There are only four sources of radiation approved by the US Food and Drug Administration for the irradiation of food.

- A. Cesium-137:

Cesium-137 emits gamma rays with an energy of 0.662 MeV. It has a 30.2 year half-life (power loss of 2.3% per year) and is presently available both in the United States and abroad. The energy of cesium-137 is not sufficient to induce radioactivity in the food.

- B. Cobalt-60:

Cobalt-60 emits gamma rays with two photons with an average energy of 1.25 MeV. It has a 5.27 year half-life (power loss of 12.3% per year) and is presently available only from foreign sources. Cobalt-60 is presently used for the irradiation of food products. The energy of cobalt-60 is not sufficient to induce radioactivity in the food.

C. Electron Beams (e-beam):

E-beams are a non-nuclear source of irradiation. E-beams are produced by accelerating electrons to near the speed of light (beta particles). The FDA limits their energy to a maximum of 10 MeV so that they do not significantly induce radioactivity in the food product. They have a severe practical limitation because they have very limited penetration in typical food products (3.5 inches). Although they can be used, and are presently being used on some food products, they cannot be used on the bulk of foods produced.

D. Bremsstrahlung Radiation (X-rays):

X-rays are a non-nuclear source of irradiation. X-rays are produced by attenuating an e-beam (see above) in a high Z material such as tungsten or tantalum. The X-rays produced have a spread from 0 MeV to 5 MeV, which is the allowable limit for the maximum e-beam energy by the FDA so that they do not significantly induce radioactivity in the food product. The conversion of e-beam to X-rays is very inefficient and leads to unacceptably high processing costs. These costs are not practical as long as other, less expensive methods of irradiating food for elimination of pathogens exist (e.g. gamma, e-beam). X-rays are not currently being used for any commercial irradiation although there is one small experimental production facility being built for the eradication of fruit flies in papaya. This technology is not tested.

IV. Source Selection for Self-Shielded Isotopic Irradiators with no On-Site Source Loading:

As mentioned previously, the **GRAY♦STAR** Model 1 is the only present commercial food irradiator in this category, and thus all further discussion will refer to the **GRAY♦STAR** unit.

There are only two isotopic sources the FDA has approved for use: cobalt-60 and cesium-137. The use of cobalt-60 in this type of irradiator is impractical. Cobalt-60 requires significantly more shielding than cesium-137. The weight of the shipping cask portion of the unit would be prohibitive. As it is, the **GRAY♦STAR** Model 1 with cesium has a shipping cask of 167 tons which is at the upper limit of what is transportable on a practical basis (if the unit were to use cobalt-60 it would weigh approximately 145 tons more than the Graysafe™ or a total in excess of 300 tons, which cannot be shipped on a practical basis).

The use of cobalt-60 in this type of irradiator would require the unit to be transported back and forth on a nearly annual basis to a loading site due to the short half-life of the source. The used sources would have to be unproductively stored in a

licensed facility until they are disposed of as low level radioactive waste.

Cesium-137 is the only practical isotope for this type of unit because of its thinner shielding (vs. Cobalt-60) and its relatively long half-life. Two half-lives of cobalt-60 is 10.54 years vs. cesium-137 with two half-lives of 60.4 years.

V. Chemical / Physical Form of Cesium-137:

[Response to Question 2 in Amendment 1 - Vol. 1 of the "Response to NRC June 1999 Memo" dated September 27, 1999]

*GRAY*STAR, Inc. determined that cesium chloride was the only practical isotopic form of Cs-137 and that Cs-137 was the only practical isotope for this type of irradiator. The analysis follows:*

Most chemical forms of cesium are soluble in water. Those that are not are significantly lower in curies per gram than CsCl. If an insoluble compound (including glass) is used in lieu of CsCl, greater self-absorption will be realized. This causes two compounding problems.

- 1) To meet the production requirements of the user, more cesium would have to be used. The more cesium used, the greater the heat generated by the sources.*
- 2) The gamma photons absorbed by the greater mass of the non-cesium atoms would lead to greater heat generated by the sources. The net effect is that the sources would have a much higher heat output and would lead to prohibitive design complications. These complications might lead to a unit which is less safe than using CsCl.*
- 3) Further, the complexity of producing compounds other than CsCl would lead to major difficulties in the hot cell operations of source preparation. These complexities would generate far more waste and potential hazards than using CsCl.*

Cost and Operating History:

- 1) It is relatively easy to handle and cost effective to encapsulate compared with other compounds.*
- 2) It has a very long history of use in many types of irradiators.*

*Thus, the GRAY*STAR(tm) was specifically designed to address the soluble nature of CsCl.*

GRAY*STAR, Inc. maintains that cesium chloride is the only practical form of cesium-137 that can be used in a **GRAY♦STAR** Model 1, or a similar type of irradiator.

VI. The GRAY♦STAR is Specifically Designed to Minimize Dispersal of Cesium Chloride:

GRAY*STAR, Inc. has spent over \$4,500,000 of private capital and over ten years on the design and development of the **GRAY♦STAR** Model 1 including the GS-42 special form source. The management has no specific bias for or against any isotope. The choice of cesium chloride was mandated in order to achieve the overall safety and production goals of the unit (see section II above). To further improve safety, GRAY*STAR, Inc. volunteered to use its NRC approved Quality Assurance Plan for the design, fabrication and use of the GS-42 sources in the **GRAY♦STAR** Model 1. Due to the stringent requirements called for by this Plan, costs were substantially increased and time schedules for development of the source and device were significantly delayed. We know of no other source manufacturer who has performed their development under a full ASME NQA-1 program which was pre-approved by the NRC.

The GS-42 source encapsulations were specifically designed to overcome all known failure mechanisms. The design draws upon the histories of large and small cesium sources (as well as non-cesium source encapsulations). Size was a determining factor in the safety analysis incorporated into source design. The Denial Letter of May 24, 2000 implies that small source history is not applicable to the GS-42. GRAY*STAR, Inc. believes that all the history, especially that relating to safety performance, is important. Also, the Denial Letter implies that there is a bias against a large source by the NRC. GRAY*STAR, Inc. is unaware of any regulation or rationale for the NRC to discriminate on source size for non-exempt special form sources. GRAY*STAR, Inc. considered using many smaller sources. This was determined to be less safe because the probability of failure of any one encapsulation is greater the larger the number of sources used. This is particularly true for dispersibility. The specific activity of the GS-42 in curies per gram is the same for other cesium chloride sources. Therefore, a leak in a small source would have the same effect as that of a large source assuming they are stored and handled in the same fashion (e.g. Dry Storage / Dry Irradiation). Further, there are special form encapsulations larger than 30 curies as referenced in your letter. On November 9, 1998 a Certificate of Registration was granted for a special form encapsulation of cesium-137 in the form of cesium chloride at an activity of up to 14,000 curies per capsule (Re: CA0598S119S). Our initial application for the GS-42 was submitted on September 5, 1996.

The use of cesium chloride in the irradiator is unique when compared to other production irradiators, but is very widely used in research irradiators. Cesium chloride irradiators have to be designed specifically for the isotope and its chemical form. It is usually impractical to place cobalt-60 in a cesium-137 irradiator. Similarly, cobalt-60 irradiators have to be designed specifically for the isotope and its chemical form. It is usually impractical and not prudent to place cesium chloride in a cobalt-60 irradiator. (A case in point is the Decatur, Georgia incident where cesium chloride was used in a water storage irradiator specifically designed for cobalt-60.) There are many research, blood, and insect irradiators which specifically use cesium chloride due to the

impractical nature of cobalt-60 in such units. The application specifically asks for a Certificate of Registration for the use of the GS-42 source only in a **GRAY♦STAR** Model 1 irradiator. A partial list of unique design features to mitigate against encapsulation failure and dispersal of cesium chloride follows:

- 1) Grayfill™ source loading technique to allow for the encapsulation to undergo non-destructive examination prior to being loaded with cesium chloride. This will allow for greater source encapsulation integrity assurance. [Grayfill™ is a method for fabricating, assembling, welding and testing the integrity of both encapsulations prior to the introduction of the cesium chloride. The above steps are not performed in a “hot cell” and do not have the complications of being performed in a high radiation environment. After the encapsulations are manufactured and tested, they are placed in a “hot cell” and are “filled” with radioactive cesium chloride. After filling, both encapsulations are mechanically sealed and then the outer seal is welded. The method allows for a “closed” system to minimize “hot cell” contamination as well as source contamination.]
- 2) Unique encapsulation shape to minimize decay heat buildup in the source.
- 3) Unique end caps to minimize any transfer of stress to the source tubes.
- 4) Sources are only retained by their end caps to minimize stress, providing better cooling of the source tubes.
- 5) Dovetailed end caps to assure positive source location (cannot come free from the source rack).
- 6) Low density filling of the sources to prevent over pressure in the source in the event that the sources are heated beyond the phase transition point for cesium chloride (this heating is mitigated by the specific design of the source).
- 7) Helium purge of the cesium chloride to remove elements of ambient air which might interact with the cesium chloride and to provide better heat conduction within the source.
- 8) A filling technique designed to minimize possible contamination of the annulus (gap between the inner and outer encapsulations) or the outside of the source during the filling process.
- 9) The dry storage / dry irradiation nature of the irradiator. There is no medium for immediate dispersal of dangerous amounts of radioactive material (water). Further, there is no electrolytic corrosion of the source due to storage in a water pool which has actually led to cobalt-60 encapsulation failures in the past.
- 10) The isolation of the sources from the product chamber to prevent damage of the encapsulations by misaligned product.
- 11) The non-thermal cycling of the sources, in part, prevents the ability of the cesium chloride to be “aerosoled” should a leak occur.
- 12) If a source were to leak, the dispersal would be limited. Because part of the unit is also its shipping cask, the leaking sources are contained in the shipping cask and can be removed to an off-site facility for corrective action. This would mitigate against serious site contamination.

There is no perceived mechanism which would allow for catastrophic source failure. If there is an unforeseen failure, it would most likely be in the form of a "pin hole" leak. Because there is no transfer mechanism for the cesium chloride to rapidly disperse, the size of the source is irrelevant. (For example, if the sources were to be used in a water medium on a routine basis, it might be possible for such a leak to allow all of the contents to go into solution and be quickly dispersed.) The unit also incorporates the ability to monitor for a leak.

VII. Conclusion:

Food will be irradiated to help prevent foodborne disease, which will increase the number of irradiators in the United States.

With the increased number of irradiators in the United States, the probability of a radiological incident is increased, as well as exposure to the general public. With the best intentions of both industry and government regulators, overexposures can occur in facilities using present designs (e.g. cobalt-60 water storage / dry chamber irradiators).

There is a need for a unit which is self-shielded which also has no on-site source loading. The only practical way to fill this need is with a unit which incorporates cesium-137. The only practical form for the cesium-137 is cesium chloride.

GRAY*STAR, Inc. believes that the **GRAY♦STAR** Model 1 which incorporates the GS-42 source encapsulation fulfills this need, and that there is no other practical solution. In support of our belief, 18 units have already been ordered by the food industry and many other orders are pending. The customers made the decision to install **GRAY♦STAR** units because of their inherently safe design, production capabilities and cost. These customers have made business plans based on employing **GRAY♦STAR** units, which include serious financial commitments in addition to the ordering of the units themselves. The **GRAY♦STAR** Model 1 has no interlocks to fail, software that can be modified or interlocks that can be rewired that would lead to a potential overexposure due to a person entering the chamber when the chamber is exposed to radiation. If the **GRAY♦STAR** Model 1 had been used in lieu of existing facilities where injury and death have occurred, *no one would have been injured.*

If there had been a more practical solution, GRAY*STAR, Inc. would have pursued that path. Cobalt-60 cannot be used in a **GRAY♦STAR** Model 1. If cobalt-60 could have been used practically in the **GRAY♦STAR**, we would have done so.

We therefore ask that the NRC reconsider its denial based on the above information. We will fully address all requests for further information as outlined in the May 24, 2000 letter shortly after a reopening of the evaluation is granted. It is of utmost importance to provide the food industry with a practical method of irradiation as soon as it is diligently possible to prevent injury and loss of life due to foodborne pathogens.

Thank you for your time and attention.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Stein', with a long horizontal flourish extending to the right.

Russell N. Stein
Vice President

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3 Recipient's Name
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Company: Office of Nuclear Material Safety and Safeguards
Address: US Nuclear Regulatory Commission
City: Washington DC
State: DC ZIP: 20555

2 Your Internal Billing Reference Information
City: MOUNT ARLINGTON
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