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August 11, 2003

George Pangburn
Director, Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

37-30804-02
03036239

SUBJECT: The CFC Logistics, Inc. License Application for a cobalt-60 irradiator, located in Quakertown, PA. Control No. 132825

Dear Mr. Pangburn:

As you know, my company, GRAY*STAR, Inc., is the manufacturer of the irradiator in question. Named the "Genesis", this installation at Quakertown is the first in what we hope will be many. It was specifically designed for use by the food industry. Food poisoning causes many deaths and much suffering in this country, and irradiation could do a great deal to alleviate this problem. However, The food industry had to wait over 40 years for the US FDA and the USDA to approve the process only after an extraordinary scientific safety review. But that approval was not enough to implement the process. The food industry needs equipment that is intrinsically safe and practical for their needs. For a number of reasons the present irradiators now in use for the sterilization of medical devices are not suitable. We therefore gave birth to the Genesis Irradiator(TM). We specifically chose to use a cobalt-60 underwater irradiator, because it is intrinsically safe and relatively easy to license. This is important to the food industry because of their concern over getting involved in nuclear regulatory complications. I have on many occasions (for over 40 years) assured them that although the U.S. NRC is very tough and demanding in their review and inspection, they are objective and fair. Unlike several other Federal Regulatory Agencies, they are resistant to political pressure and rely on sound science, competent engineering and adherence to well defined regulations. Under the Atomic Energy Act the NRC has been afforded extraordinary powers, because we cannot afford to have safety put in the hands of unqualified local towns.

That does not mean that I believe the public should not be well informed. Indeed, the NRC goes beyond most other Agencies by requiring all pertinent documents to be open for public review. But, I do not believe that public interest groups or individuals should be able to interfere with the legal regulatory process.

Sharon Turner, CFC's designated RSO, informed me that on last Thursday (August 7th) you told her that you were considering delaying the issuance of their license until after a public information meeting you wish to hold on August 21st. I do not know the reason for this delay. On repeated occasions CFC and GRAY*STAR have been told by you and other NRC staff officials that the issuance of the license is not affected by third party concerns. That the only thing that matters is whether the applicant successfully meets the NRC's regulatory requirements.

Has CFC done so? I know it would be the easiest thing in the world to say that more questions remain. We both know that this irradiator has undergone a precedent setting intensive review. I believe at this point that CFC has been inspected ten times! The NRC Staff has not notified us of any outstanding deficiencies. We, and CFC, have been as cooperative and responsive as possible. On July 17th you stated in your morning report, "The staff's review of the application is substantially complete and, as indicated at the meeting, a licensing decision is expected in the next few days." That was a few weeks ago. We understand that some additional information and documentation was then required. We complied. On August 8th your reviewer informed us that all known (pending) questions have been satisfactorily answered, and that he did not anticipate more, but that does not mean there will not be others. If this intensity of review was directed at our competitors' units many would not survive (the NRC might not survive either, considering your expenses).

GRAY*STAR, Inc. is now suffering severe financial hardship. I know CFC is also. We knew when we designed this unit that it would undergo additional scrutiny. We intend to provide equipment "above and beyond" regulatory requirements, both in terms of safety and quality. Unnecessary delays punish us for doing so. I have several pending sales that were based on the satisfactory performance of this unit in a timely manner. I am losing those sales. After all, if the NRC has that many questions, there must be something wrong with the Genesis, right? A few days may not matter to you but they do to us.

I am well aware that two US Senators and one State Senator have expressed concern that interested citizens should be granted a hearing. These citizens have been afforded that opportunity by filing a request on June 23rd for a Subpart L Hearing. If you wish to have a meeting to provide information to the public, so be it, but please do not punish us. The public may have the right to know, but we have our rights too. Please remember that although GRAY*STAR is a New Jersey company, Genesis units are entirely made by our fabricator, CHL Systems, located in Souderton, PA. If the Senators are concerned that the residents in that area be informed they should also be concerned with the rights of the employees whose jobs are at stake in that very region. Please don't insert yourself in that argument.

If you buckle to public pressure you will greatly weaken the NRC's position. Are you are waiting for a public meeting to see if there are any more questions (of course, there will be)? Will you then have to satisfy them with more answers? Are you now allowing a few residents of the town to decide on the merits of the unit? What is the purpose of the NRC, or for that matter, the Atomic Energy Act?

As I indicated earlier you could avoid the issue of delay by simply claiming that you have more questions. There is no way for me to refute that. The NRC by its very nature holds supreme power. We are at your mercy. I'm appealing to you and your staff as professionals. Speaking on behalf of the irradiation industry, the food industry and of the people of the United States who want to exercise a choice for the purchase of safer food, please don't let us down.

Sincerely,

A handwritten signature in dark ink, appearing to read "Martin H. Stein". The signature is fluid and cursive, with the first name "Martin" and last name "Stein" being more prominent.

Martin H. Stein
President; CEO

cc: William Travers
Martin Virgilio
Hubert Miller