

November 5, 2003

The Honorable James C. Greenwood  
United States House of Representatives  
Washington, DC 20515-3808

Dear Congressman Greenwood:

On behalf of the Nuclear Regulatory Commission (NRC), I am writing in response to your September 2, 2003, letter to Chairman Diaz regarding the CFC Logistics, Inc. cobalt-60 irradiator in Milford Township, Bucks County, Pennsylvania. As noted in your letter, residents of Milford Township have expressed numerous concerns about the irradiator. On October 3, 2003, two senior officials from our Region I office in King of Prussia, Pennsylvania, George Pangburn and John Kinneman, met with you and members of your staff to discuss those concerns and NRC's licensing and inspection of the CFC irradiator. The following paragraphs respond to the specific points raised in your letter, many of which were discussed during the October 3<sup>rd</sup> meeting.

Your letter raised general questions about the CFC irradiator and NRC's actions in licensing and oversight of the CFC irradiator. You asked about NRC's continuing oversight of the facility and enforcement powers, security for the facility from natural disasters and terrorism, public participation, risk assessment for irradiators, and contingency plans in the event of leak at the facility.

Our staff reviewed the license application against the regulations in 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," as well as the guidance contained in NUREG-1556, Volume 6, "Program-Specific Guidance About Licensing Part 36 Irradiators." The regulations in Part 36 were developed in the early 1990s and established specific design, construction and operational requirements for irradiators including underwater irradiators. These requirements, along with the Commission's standards for protection against radiation contained in 10 CFR Part 20, provide a substantial and well-defined basis for a licensing decision.

Our review of the CFC license application was extensive. It included: 1) an acceptance review to ensure that the application contained the necessary information; 2) technical reviews and numerous onsite inspections by health physics, electrical engineering and geotechnical engineering experts; 3) several visits by senior Region I management; and 4) a peer review by an internal panel that focused on unique engineering aspects of the irradiator's design. In short, we applied substantial staff and management resources to review this application to ensure that the health and safety standards contained in our regulations were met. Based on this review, we issued a materials license to CFC Logistics for the Quakertown irradiator facility on August 27, 2003.

With regard to continuing oversight and enforcement powers, NRC conducted robust oversight of the CFC facility throughout construction and the initial stages of testing. For example, Region I inspectors recently observed and evaluated the receipt and loading of the cobalt-60 sources. We will continue this oversight during subsequent operation consistent with our regulatory program, which includes periodic onsite inspections. If we identify violations of our requirements, we will take appropriate action under our Enforcement Policy, issuing sanctions if necessary.

With regard to natural disasters, we specifically considered the impact that a seismic event might have on the facility. Our conclusion was that given the type of seismic event that might be realized in this part of the United States, and the robust structure of the pool itself, the potential for a significant loss of shielding water or release of radioactivity to the environment is very low. We did not specifically analyze the effect of an aircraft crash. However, because of the small footprint of the irradiator pool and the location of the sources deep within the pool, we believe that the likelihood of an aircraft crash resulting in a release of radioactivity to the environment is very remote.

On the subject of security from terrorism, in June 2003, the NRC staff issued Orders requiring certain compensatory measures to enhance security at irradiator facilities to address the current threat environment. The NRC staff ensured that CFC Logistics, as part of the irradiator community, was kept informed of the compensatory measures under consideration and has issued an Order to CFC Logistics imposing the same compensatory measures as were required for other licensed pool irradiators. CFC has already incorporated applicable security measures into the design of and operational procedures for the Quakertown facility, including, among other things, background checks for authorized users of radioactive material.

With respect to public participation, NRC policy is to proactively address public questions and concerns about its regulatory programs. This promotes public confidence that our regulatory decisions are protecting public health and safety. When the Milford Township Board of Supervisors held an informational meeting at the Quakertown High School on July 16, 2003, Region I management made presentations and answered questions about our licensing review. On August 21, 2003, the NRC staff held a public meeting at the same location to provide the public with an update on the licensing review and to describe how NRC took into account public concerns in that review. During both meetings, NRC managers responded to numerous questions raised by members of the public; many similar to those in your letter. We have carefully considered the issues raised at these meetings and believe they have been addressed in our review of the license application.

In addition, as you are aware, on June 23, 2003, counsel for Concerned Citizens of Milford Township requested a hearing on this application. In accordance with NRC's procedures regarding the conduct of adjudicatory proceedings for this type of facility, contained in 10 CFR Part 2, Subpart L, the Chairman of the Agency's Atomic Safety Licensing Board Panel has appointed a Presiding Officer to determine whether that request should be granted.

On September 23, 2003, the Presiding Officer issued an order denying a request to stay the effectiveness of the NRC license issued to CFC Logistics, Inc. The Presiding Officer has not yet issued an opinion on the issues of the petitioner's standing or the germaneness of the concerns they raised. Regarding the preparation of an Environmental Impact Statement (EIS), the Commission, in issuing its regulations for implementing the National Environmental Policy Act of 1969, included pool irradiators in 10 CFR Part 51 as "categorical exclusions" from EIS preparation. A "categorical exclusion" is provided by NRC regulations for agency actions that do not have a significant effect on the environment and for which neither an environmental assessment nor an environmental impact statement is required. This was done for irradiator licenses because these facilities, under normal and anticipated accident conditions, do not have significant environmental impacts. They do not release radioactive material in effluents, radiation levels outside the facility are not higher than background, the radioactive material is contained in doubly encapsulated sealed sources and the disturbance from construction is small.

Irradiators have been operated safely in this country for many years. There have been worker fatalities from acute radiation exposure at irradiators outside the United States; however, the only domestic worker fatalities associated with this type of facility have been from industrial-type accidents. As noted above, in 1993 the Commission issued new regulations for licensing of irradiators which considered the operational history of these facilities worldwide. The new regulations contained in 10 CFR Part 36 served to improve performance at domestically-licensed irradiators and are directly reflected in specific design features of the CFC facility, such as the stainless steel pool liner.

The design of the CFC irradiator has inherent safety features which reduce the risk of radiation exposure during operations. For example, the sources remain in a fixed position inside a closed plenum which is air- and water-tight, rather than being in a rack which is raised above the pool to irradiate product. To protect groundwater and keep the cobalt-60 from entering the environment, operation and design of the facility involves multiple containment barriers and control features. These include measures such as double encapsulation of the sources and constant monitoring for radioactive contamination in the air around the sources and in the pool water.

Finally, with regard to contingency planning for potential events at the irradiator facility, this issue was considered during the development of 10 CFR Part 36 and the Commission determined that due to the extremely low probability of an event that would lead to off-site consequences, no special regulatory requirements were needed in this area. NRC expects that licensees will inform offsite emergency responders of and provide training regarding the hazards associated with responding to emergencies, such as fires, at the irradiator facility. CFC has coordinated with offsite responders and NRC has confirmed that this coordination has taken place.

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I trust this information is responsive to your request. If you have additional questions regarding this matter, please feel free to contact me or Dennis Rathbun, Director, Office of Congressional Affairs, at (301) 415-1776.

Sincerely,

**/RA/**

William D. Travers  
Executive Director  
for Operations

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William D. Travers  
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