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NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD

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Before Administrative Judges:

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Michael C. Farrar, Presiding Officer
Charles N. Kelber, Special Assistant

In the Matter of:
CFC Logistics, Inc.
(Materials License Application)

) Docket No.: 30-36239-ML
)
) ASLBP No.: 03-814-01-ML
)
) Date: September 5, 2003
)
) License Control No. 132825
)
)

**CFC LOGISTICS, INC.'S RESPONSE TO NRC STAFF'S BRIEF ON STANDING
AND PETITIONERS' AREAS OF CONCERN**

CFC Logistics, Inc., (CFC), by its undersigned counsel of record, hereby submits this Response to NRC Staff's Brief on Standing and Petitioners' Areas of Concern regarding CFC's Materials License No. 132825 allowing for the possession of cobalt-60 "sealed sources" for use in a Nuclear Regulatory Commission (NRC)-approved Category III underwater irradiator at its cold-storage facility in Quakertown, PA. For the reasons set forth below, CFC respectfully requests that the Presiding Officer deny Petitioners' request for a Subpart L hearing because they have failed to demonstrate standing for a Subpart L hearing and because they have failed to allege an area of concern which is "germane" to this proceeding.

I. BACKGROUND AND PROCEDURAL HISTORY

On January 27, 2003, CFC entered into a sales agreement to purchase and install a Category III underwater irradiator at its Quakertown, PA cold-storage facility. Under American National Standards Institute (ANSI) standards, a Category III irradiator is defined as a self-contained, wet source storage, gamma irradiator.¹

On February 19, 2003, CFC submitted a materials license application to NRC's Region I office requesting that NRC authorize CFC to possess cobalt-60 "sealed sources" when operating its Category III irradiator. Since NRC's review of CFC's license application began, NRC Region I officials have performed site visits/inspections on at least nine (9) separate occasions to ensure that the installation and operation of the Category III irradiator will satisfy relevant NRC regulations.² To the best of CFC's knowledge, this review has been the most extensive review of a Part 36 Category III irradiator license application to date.

By letter dated June 23, 2003, Petitioners submitted a letter to NRC Region I requesting a hearing regarding CFC's then-pending license application. On June 30, 2003, CFC became aware of this hearing request when it received a copy from NRC Region I via facsimile. CFC timely responded to this hearing request on July 11, 2003. After CFC filed its response, on July 15, 2003, Petitioners' filed a second hearing request in which Petitioners' again challenged CFC's then-pending license application and

¹ See ANSI/HPS N43.15-2001, New American National Standard: *Safe Design & Use of Self-Contained, Wet Source Storage Gamma Irradiators (Category III)* (June/July 2001).

² Indeed, NRC Staff has determined that the CFC Category III irradiator has been constructed in accordance with its license application and Part 36 regulations. See Letter from John D. Kinneman, Chief, Nuclear Materials Safety Branch 2, Division of Nuclear Materials Safety, to James Wood, President, CFC Logistics, Inc., *Inspection 03036239/2003001, CFC Logistics, Inc., Quakertown, Pennsylvania* (August 27, 2003). This inspection report is attached to this brief as Exhibit A.

responded to CFC's July 11, 2003 filing. Then, pursuant to an August 13, 2003, order from the Presiding Officer, on August 14, 2003, Petitioners filed an additional pleading in which they presented their areas of concern and affidavits regarding the proximity of petitioners to the CFC facility.

Pursuant to the Presiding Officer's August 13, 2003 order, on August 27, 2003, NRC Staff filed a brief regarding the legal standards for standing and "germane" areas of concern in Subpart L proceedings and its response to Petitioners' request for a hearing. Then, pursuant to an order from the Presiding Officer on September 3, 2003, NRC Staff was required to submit an additional filing addressing whether the CFC facility will be utilizing a significant source of radioactivity with an obvious potential for offsite consequences. NRC Staff submitted its brief on this subject the same day. In addition, on August 27, 2003, NRC Staff granted CFC a materials license in accordance with its license application.

In response to NRC Staff's brief and Petitioners' areas of concern, CFC herein submits this Response and respectfully requests that the Presiding Officer deny Petitioners request for a Subpart L hearing because they have failed to demonstrate the requisite standing to become intervenors in a Subpart L proceeding and because they have failed to present an area of concern which is "germane" to this proceeding.

II. NRC STAFF'S CHARACTERIZATION OF THE REQUIREMENTS FOR STANDING IS DEFICIENT

A. Requirements for Standing in Subpart L Proceedings

Initially, in its filing, NRC Staff presents a brief, cursory review of the requirements for standing in a Subpart L proceeding. However, while they correctly reference some of the requirements for standing, NRC Staff fails to completely describe

the requirements a petitioner must satisfy before standing is granted. As a result, CFC will present the requirements for standing in some detail below.

When the administrative action requested by a petitioner is made subject to a request for a Subpart L hearing and a petitioner's hearing request is deemed timely, the next concern is whether the petitioner has satisfied NRC's requirements for standing. As stated in 10 CFR § 2.1205(h):

The Presiding Officer...shall determine *that the requestor meets the judicial standards for standing* and shall consider, among other factors--,

The nature of the requestor's right under the Act ("AEA") to be made a party to the proceeding;

The nature and extent of the requestor's property, financial, or other interest in the proceeding; and

The possible effect of any order that may be entered in the proceeding upon the requestor's interest.

10 C.F.R. § 2.1205(h) (*emphasis added*).

Standing is not a mere legal technicality. It is, in fact, an essential element in determining whether there is any legitimate role for a court or an agency adjudicatory body to deal with a particular grievance. *Westinghouse Electric Corporation*, CLI-94-07, 39 NRC 322, 331-2 (1994). Judicial concepts of standing should be applied by adjudicatory boards in determining whether a petitioner is entitled to intervene. *Portland General Electric Co.*, ALAB-333, 3 NRC 804 (1976); *see also Niagra Mohawk Power Corp.*, LBP-83-45, 18 NRC 213, 215 (1983) (noting that contemporaneous judicial concepts should be used to determine whether petitioner has standing to intervene). Thus, the propriety of intervention involves both "constitutional limitations" on an adjudicatory body's jurisdiction and "prudential limitations" on its exercise. *Coalition of*

Arizona/New Mexico Counties for Stable Economic Growth v. Department of Interior, 1997 U.S. Dist. LEXIS 4212, *6 (10th Cir. 1997), citing *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

The “irreducible constitutional minimum” standing test requires a potential litigant to demonstrate that: 1) it has suffered *actual or threatened* injury, 2) that is caused by, or fairly traceable to, an act that the litigant challenges in the instant litigation, and 3) that is likely to be redressed by a favorable decision.” See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (emphasis added); *Georgia Institute of Technology*, CLI-95-12, 42 NRC 111, 115 (1995); *Envirocare of Utah, Inc.*, 35 NRC 167, 174-5 (1992). These three elements are commonly referred to as injury-in-fact, causation, and redressability. See *Coalition of Arizona/New Mexico Counties for Stable Economic Growth*, 1997 U.S. Dist. LEXIS at *6.

Beyond the constitutional standing test set forth above, “prudential limitations” are also imposed on a potential intervenor’s prospective standing. Prudential considerations include a party not being permitted to assert a generalized grievance and a party not being permitted to assert the rights of third parties. See *Warth*, 422 U.S. at 499. Specifically, prudential standing requirements require a showing that the injury is arguably within the “zone of interests” protected by statutes governing the proceeding. See *Assoc. of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150 (1970); *Metropolitan Edison Co.*, CLI-83-25, 18 NRC 327, 332 (1983); *Gulf States Utilities Co.*, CLI-94-10, 40 NRC 43, 47 (1994).

With regard to injury-in-fact, which may be either actual or threatened, it must be both *concrete* and *particularized*, not *conjectural* or *hypothetical*. See *Sequoyah Fuels*

Corp. and General Atomics, (Gore, Oklahoma Site), CLI-94-12, 40 NRC 64, 72 (1994) (emphasis added). There must be a *concrete demonstration* that harm could flow from a result of the proceeding. See *Nuclear Engineering Co., Inc., (Sheffield, Illinois Low-Level Radioactive Waste Disposal Site), ALAB-473, 7 NRC 737, 743 (1978)* (emphasis added). To show the required injury-in-fact based on an assertion of future harm, NRC has held that future harm “must be threatened, certainly impending, and real and immediate.” *Babcock & Wilcox, LBP-93-4, 1993 NRC LEXIS 6, **7-8 (1993)*. “A plaintiff must allege that he has or will in fact be perceptibly harmed by the challenged agency action, not that he can imagine circumstances in which he could be harmed.” *International Uranium (USA) Corp. (White Mesa Uranium Mill), LBP-01-15, 53 NRC 344, 349 (2001) citing United States v. Students Challenging Regulatory Agency Procedures (SCRAP), 412 U.S. 669, 688-89 (1973)*. An abstract, hypothetical injury is insufficient to establish standing to intervene. See *International Uranium Corp. (White Mesa Uranium Mill), CLI-98-6, 47 NRC 116, (1998)*. As a result, standing has been denied when the threat of injury is too speculative. See *Sequoyah Fuels Corp., CLI-94-12, 40 NRC at 72*.

B. NRC Staff's Characterization of Standing is Deficient

NRC Staff's characterization of the relevant standing requirements has failed to completely articulate such standing requirements. First, NRC Staff states that “injury in fact may be small and unlikely, yet satisfy the requirement for standing.” NRC Staff Brief at 3. On this point, NRC Staff cites the case of *Georgia Tech* in which the Commission affirmed a Licensing Board finding that “for threshold standing purposes, it was neither ‘extravagant’ nor ‘a stretch of the imagination’ to presume that some injury

'which wouldn't have to be very great,' could occur within ½ mile (800 meters) of the *research reactor*, based on the possibility that *noble gases* could disperse nuclear or radioactive materials beyond the reactor site boundary. See *Georgia Tech*, 42 NRC at 117 (emphasis added).

While NRC Staff is correct in stating that a *potential* and *plausible* injury-in-fact, which is not necessarily disastrous, may be sufficient to satisfy NRC standing requirements, the *Georgia Tech* case deals specifically with a non-power *reactor* and not with cobalt-60 "sealed sources." Cobalt-60 "sealed sources" do not involve the use of fissionable materials (i.e., materials capable of producing a nuclear criticality event) and do not involve "the possibility that noble gases could disperse beyond" the facility boundary and reach petitioners offsite. *Id.* Indeed, the Commission's Part 36 rulemaking states that comparisons between the radioactive material used in irradiators (cobalt-60) and that used in reactors "are not strictly relevant because the radioactive materials in irradiators are not volatile like the noble gases and iodines produced in a reactor and because irradiators do not have a driving force equivalent to the decay heat from a reactor to expel the materials from the facility." 58 Fed. Reg 7715, 7725 (February 9, 1993). Thus, NRC Staff's citation to the reasoning applied to standing in the *Georgia Tech* case is not relevant here.

Further, NRC Staff fails to focus on the fact that petitioners in the *Georgia Tech* case at least alleged a *viable pathway* for *potential* and *plausible* harm when submitting its bases for standing. (i.e., "noble gases" generated in a reactor which could be dispersed to a location within ½ mile of the facility as a result of the noble gases and decay heat generated at the reactor facility and cause actual injury-in-fact "if the wind is

blowing in [their]...direction.”) *Georgia Tech*, 42 NRC at *10. Without the allegation of a *viable pathway*, no *potential* or *plausible* injury-in-fact could exist since there would be no *plausible* way in which radioactive material could reach petitioners offsite. In some licensing proceedings, the Licensing Board has denied standing to intervenors who have failed to demonstrate that a viable pathway exists through which radioactive material could cause injury-in-fact in the face of testimony showing no such pathway exists. See *International Uranium (USA) Corp.* (White Mesa Uranium Mill), LBP-01-08, 53 NRC 204 (February 28, 2001). Therefore, NRC Staff’s characterization of standing requirements based on the *Georgia Tech* reactor case is deficient, because it fails to explain that even if a potential alleged injury which is “small and unlikely” could satisfy the criteria for injury-in-fact, it still must be based on a *viable pathway* to be considered *plausible* enough to grant standing

In a somewhat disjointed fashion, NRC Staff also makes the point that the potential harm alleged by Petitioners must be *possible*, although not certain, by citing the case of *Sequoyah Fuels* for the proposition that a “[p]etitioner need not establish certainty that injury will occur.” NRC Staff Brief at 3. In *Sequoyah Fuels*, petitioners alleged that it was *possible* that an unmeasured groundwater flow pathway not examined by the licensee could lead to the release of radioactive material from the licensee’s site. *Sequoyah Fuels Corp.*, 40 NRC at 74. Petitioners’ allegation was sufficient to grant them standing because, even though they could not establish that such groundwater pathway existed with *certainty*, the Commission determined that, “certainty is not required” for a threshold showing of standing. *Id.* However, while “certainty” is not required, even in *Sequoyah Fuels*, petitioners asserted the *possible* existence of a *viable pathway*

(unmeasured groundwater flow pathway) through which radioactive materials *plausibly* could be released from the licensee's facility to cause harm to petitioners. Thus, while NRC Staff's truncated discussion of the requirements for standing suggests that a small, unlikely potential injury can satisfy standing requirements, it fails to make clear that any such injury must be *possible and plausible* based on the allegation of a *viable pathway* to Petitioners. Therefore, to the extent that Petitioners fail to allege a *viable pathway* for *radioactive material* or *radiation* to reach them and cause them harm, they cannot satisfy the standing requirements for *concrete and particularized* injury-in-fact which is not *conjectural or hypothetical*.

III. THE "PROXIMITY PRESUMPTION" FOR STANDING REQUIRES A SIGNIFICANT SOURCE OF RADIOACTIVITY PRODUCING AN OBVIOUS POTENTIAL FOR OFFSITE CONSEQUENCES FROM A SOURCE WITHIN ITS NRC-APPROVED SHIELDING

A. NRC Requirements for Standing Under the "Proximity Presumption"

In some cases, potential intervenors have been granted standing in an NRC hearing based solely on their proximity to a facility utilizing nuclear or radioactive materials. In such a case, a petitioner/intervenor bases its standing upon a showing that his or her residence is within the geographical zone that might be affected by an accidental release of radioactive material. *See Houston Lighting & Power Co. (South Texas Project, Units 1 and 2)*, LBP-79-10, 9 NRC 439, 443 (1979).

With respect to proximity to a facility as a basis for standing, NRC has stated, "[i]n certain types of proceedings, the agency has recognized a proximity or geographical presumption that presumes a petitioner has standing to intervene without the need specifically to plead injury, causation, and redressability if the petitioner lives within, or otherwise has frequent contacts with, the zone of possible harm from the nuclear reactor

or other source of radioactivity.” *Florida Power & Light Co.* (Turkey Point, Units 3 and 4), LBP-01-06, 2001 NRC LEXIS 38 (February 26, 2001). However, the fact that a petitioner may reside even within a 50-mile radius of a *nuclear power reactor facility* will not always be sufficient to invoke the proximity presumption and establish standing to intervene. *Florida Power & Light Co.* (St. Lucie Nuclear Power Plant, Units 1 and 2), CLI-89-21, 30 NRC 325, 329 (1989) (emphasis added). For cases outside the nuclear power reactor context, a Licensing Board will consider the nature of the proceeding, and will apply different standing considerations depending upon the type of proceeding. See *Boston Edison Co.* (Pilgrim Nuclear Power Station), LBP-85-24, 22 NRC 97, 98-99 (1985), *aff’d on other grounds*, ALAB-816, 22 NRC 461 (1985).

On May 29, 1987, the Commission expressly rejected the application of a “proximity presumption” which was based *solely* on a petitioner’s distance from a facility utilizing nuclear or radioactive materials. See 52 Fed. Reg. 20089, 20090 (May 29, 1987). As a result, this “proximity presumption” has been applied to materials licensing proceedings only in cases where the licensing activity involved had “clear implications for the offsite environment, or major alterations of the facility with a clear potential for offsite consequences.” *Florida Power and Light Co.* 30 NRC at 329-30. When the licensing action does not involve such circumstances, the Commission has stated that, “[a]bsent situations involving such obvious potential for offsite consequences, a petitioner must allege some specific ‘injury in fact’” *Id.* at 329-30.

A presumption of standing based solely on geographic proximity (“proximity presumption”) may be applied in cases involving *non-power* reactors where there is a determination that the proposed action involves a *significant amount of radioactivity*

producing an obvious potential for off-site consequences. See Georgia Tech, 42 NRC at 116 (emphasis added). Whether and at what distance a petitioner can be presumed to be affected must be judged on a case-by-case basis, taking into account the nature of the proposed action and the significance of the radioactive source. See id.

With respect to licenses involving byproduct materials covered under 10 CFR Part 30 of NRC's regulations, such as the instant case, the Licensing Board has stated, "[t]he proximity of a person's home or property can be relevant to standing depending on the radiological materials and the potential hazard involved. *There must be sufficient information provided to determine that there is a possibility of injury. Northern States Power Company (Pathfinder Atomic Plant, Byproduct Material License), 30 NRC 311, *11 (October 24, 1989) (emphasis added). An additional important factor to be considered in this context is whether the petitioner can demonstrate that the risk of injury extends as far from the facility as petitioner resides. See e.g., Boston Edison Co. (Pilgrim Nuclear Power Station), LBP-85-24, 22 NRC 97, 98-99 (1985), aff'd on other grounds, ALAB-816, 22 NRC 461 (1985).*

B. The "Proximity Presumption" Standard Requires Evaluation of a Given Source In Its NRC-Approved Shielding and Protective Mechanisms

If a petitioner alleges that he/she should be granted standing merely as a result of his/her proximity to a facility utilizing nuclear or radioactive materials, then such an allegation must be evaluated in light of the standard articulated above: does the facility utilize a significant source of radioactivity with an obvious potential for offsite consequences? However, in order to apply this standard properly to a given facility, it is necessary to determine whether the nuclear or radioactive source is to be viewed in

“splendid isolation” (i.e., no shielding or protective mechanisms to prevent releases of nuclear or radioactive material) or within its NRC-approved shielding and protective mechanisms. CFC asserts that this standard must be applied to a given source within its NRC-approved shielding and protective mechanisms.

As a general proposition, the Commission has stated that “the interest of the petitioner must be assessed in terms of the *particular licensed facility or activity* at issue in the materials licensing proceeding.” 52 Fed. Reg. 20089, 20090 (May 29, 1987). (emphasis added). Therefore, it follows *logically* that an inquiry into a *licensed facility or activity* cannot be conducted without considering the shielding and protective measures which are required by the relevant regulations and the license.

For example, the above-referenced *Georgia Tech* case addresses this proposition. When discussing the petitioners’ allegations regarding standing based on proximity, the Commission noted that, “noble gases would *escape the steel containment building if the reactor core melted.*” *See Georgia Tech*, 42 NRC at *13 (emphasis added). Even though the Commission granted standing in this case, the inquiry into whether petitioners had standing based on geographic proximity was conducted in the context of a potential release of radioactive material from its containment building and the potential failure of safety systems.

Similarly, NRC’s Part 36 requirements for irradiators address “irradiators in which the *sealed sources* are always in a storage pool and are shielded at all times.....” 58 Fed Reg. at 7716 (emphasis added). These “sealed sources” are required to be doubly encapsulated and to satisfy the requirements of 10 CFR §§ 32.210 & 36.21 even before they are approved for use at a licensee’s facility. *See id.* Thus, it makes no logical sense

to evaluate “sealed sources” to be used in the CFC irradiator in “splendid isolation,” because the source manufacturer, not the licensee, assures that the “sealed source” requirements are satisfied and the “*sealed sources*” are only relevant as used in CFC’s Category III irradiator.

As a result, the Commission addressed these types of sources in the context of “shielding” pools in Part 36. When the Commission enacted its requirements for pool liners in 10 CFR § 36.33, it noted that such pools need not be back-fitted because cobalt-60 [in “sealed sources” in such pools] has very low solubility. *Id.* at 7720. Also, the Commission determined that leak detection systems which are more sensitive than those which merely detect water loss were not required, because leaks of cobalt-60 to pool water do not cause large increases in water contamination because cobalt-60 has very low water solubility. *Id.* Thus, since the cobalt-60 doubly-encapsulated “sealed source” will stay at the bottom of a “shielding pool” while in use, the potential for offsite consequences can only be evaluated on an *irradiator* rather than a “*sealed source*” basis.

IV. NRC STAFF’S CHARACTERIZATION OF GERMANE AREAS OF CONCERN IS DEFICIENT

A. NRC Requirements for “Germane” Areas of Concern

NRC Staff also includes a brief, cursory review of the requirement that Petitioners must adequately allege an area of concern which is “germane” to this proceeding, assuming, of course, that they have established standing. Although, NRC Staff does articulate portions of the Commission’s standards for “germane” areas of concern, they fail to address a fundamental question that must be evaluated when determining whether an area of concern is “germane” to a proceeding on a specific licensing action—that is,

has this area of concern been addressed previously and been decided in appropriate NRC proceedings (i.e., rulemaking, administrative hearing, etc.)?

Once standing has been established, a petitioner must allege at least one area of concern that is “germane” to the proceeding. *International Uranium (USA) Corporation (Receipt of Material from Tonawanda, New York)*, Docket No. 40-8681-MLA-4, (December 17, 1998); *International Uranium (USA) Corporation (Receipt of Additional Material from Tonawanda, New York)*, LBP-99-8, (February 19, 1999). According to NRC Staff, the standard for a “germane” area of concern is that it “must be relevant to whether the license should be denied or conditioned and need only be sufficient to establish that the issues a petitioner seeks to raise fall generally within the range of matters *properly subject to challenge* in the proceeding.” *See Sequoyah Fuels Corp. (Gore, Oklahoma Site Decommissioning)*, LBP-99-46, 50 NRC 386, 395 (1999) (emphasis added). Each such area of concern must be stated with enough specificity so that the Presiding Officer may determine whether the concerns are truly relevant to the licensing action at issue. *See Sequoyah Fuels Corp. (Gore, Oklahoma Site Decommissioning)*, CLI-01-2, 53 NRC 2, 6 n. 16 (2001).

Presumably, an area of concern is not “germane” if it has been addressed explicitly in NRC regulatory proceedings (i.e., rulemaking) or licensing proceedings (i.e., administrative hearings) on the basis of previously approved activities. That is to say, an area of concern is “germane” only if the petitioner alleges that the licensing action in question poses a significant, *incremental* threat above and beyond previously approved

activities.³ See e.g., *International Uranium (USA) Corp.* (White Mesa Uranium Mill), LBP-02-19, 56 NRC 113 (August 28, 2002). To proceed otherwise would allow potential petitioners to challenge activities which already have been deemed by NRC to adequately protect public health and safety through rulemaking, litigation or other administrative or judicial proceeding.

B. NRC's Part 36 Regulations for Irradiators

For an area of concern to be “germane” in the context of a Part 36 irradiator licensing proceeding, it must raise a potential concern that has not been decided in the Commission’s Part 36 rulemaking proceeding or a potential concern that demonstrates that the proposed licensing action poses a significant, *incremental* potential threat above and beyond what has been previously decided in such proceeding since the Part 36 regulations cannot now be challenged. See 10 CFR § 2.758.

1. Development and Environmental Assessment of Part 36 Regulations

Prior to 1993, NRC evaluated license applications for possession of “sealed sources” for use in irradiators on a case-by-case basis utilizing assessments of various types of potential health and safety issues such as air and water dispersion, performance criteria, fire protection, etc. In 1993, the Commission conducted a review of its irradiator radiation safety requirements and policies and decided to promulgate a formal set of regulations (10 CFR Part 36) to “specify radiation safety requirements and licensing

³ In general, previously approved NRC activities have undergone some type of environmental and technical review which demonstrates that the proposed activities satisfy relevant regulatory requirements and, therefore, adequately protected public health and safety. In the instant case, NRC’s Part 36 rulemaking was subject to an environmental assessment (EA) and NRC determined that no significant impacts would result from the activities authorized therein. See 58 Fed Reg. at 7727.

requirements for the use of licensed radioactive materials [sealed sources] in irradiators.” *See* 58 Fed. Reg at 7715. In this rulemaking, the Commission made clear that, “[t]he issue in the rulemaking is not whether irradiators should be licensed or whether they should continue to be licensed. Instead, the issue was whether to license them under a *formal, detailed, comprehensive* set of regulations as was proposed or to continue licensing on a case-by-case basis....” *Id.* (emphasis added). In the end, the Commission determined that a formal set of regulations governing the licensing and operation of irradiators *based on previous licensing experience* was the best course of action, and, as a result, a formal rulemaking was initiated which addressed most irradiators, including the CFC Category III underwater irradiator.

In the course of this rulemaking, the Commission determined that no environmental impact statement (EIS) was required because the promulgation of Part 36 was not a “major federal action” under the National Environmental Policy Act of 1969 (NEPA). NRC performed an environmental assessment (EA) for this rulemaking and concluded that a Finding of No Significant Impact (FONSI) was warranted demonstrating that compliance with the requirements delineated in Part 36 would not pose a significant, potential threat to public health and safety or the environment. *See id.* at 7727. Thus, similar to operating licenses in license amendment proceedings, Part 36 requirements have already been subject to scrutiny (rulemaking proceeding including public comment) and have been found to be adequately protective of public health and safety and the

environment. As a result, Part 36 requirements should not be, and indeed are not permitted to be,⁴ subject to litigation in a Subpart L proceeding.

2. Siting and Land Use Requirements for Part 36 Irradiators

As a general proposition, the Commission has determined that potential locations for Part 36 irradiators may encounter various local zoning, land use, and building code requirements. *See id.* at 7725. As part of its analysis on this subject, the Commission received a public comment in which a concern was raised about the large number of curies in radioactive material used at irradiator facilities and the potential locations at which such material could be sited. *See id.* This public comment compared the number of curies used in an irradiator operator's radioactive material inventory to that of a non-power research reactor such as the reactor described in the above-mentioned *Georgia Tech* case. However, the Commission dismissed this comment by stating, “[t]hese comparisons are not strictly relevant because the radioactive materials in irradiators *are not volatile like the noble gases and iodines produced in a reactor* and because *irradiators do not have a driving force equivalent to the decay heat from a reactor to expel the [radioactive] materials from the facility.*” 58 Fed. Reg. at 7725 (emphasis added). Thus, the Commission concluded that, “an irradiator meeting the requirements in the new Part 36 would present no greater hazard or nuisance to its neighbors than other industrial facilities, because there is little likelihood of such an irradiator causing radiation exposures offsite in excess of NRC’s [10 CFR] part 20 limits for unrestricted areas.” *Id.* at 7726. “Therefore, the NRC believes that, in general, irradiators can be

⁴ NRC’s 10 CFR Part 2 regulations prohibit challenges by petitioners to existing regulations barring extraordinary circumstances. *See* 10 CFR § 2.758.

located anywhere that local governments would permit an industrial facility to be built.”

Id.

The Commission’s siting analysis also included an inquiry into whether location of irradiators near airports or other facilities utilizing air transport should be prohibited.

Id. After examining the type of radioactive material utilized in an irradiator (typically cobalt-60), the Commission found that “[e]ven if a source were damaged as a result of an airplane crash, large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack [plenum] because the sources are not volatile.” 58 Fed. Reg. at 7726. As a result of this inquiry, the Commission concluded that, “a prohibition against placing an irradiator where other types of occupied buildings could be placed is not justified on safety grounds.” *Id.* Therefore, “NRC will allow the construction of an irradiator at any location at which local authorities would allow other occupied buildings to be built.” *Id.*

3. Performance Criteria for “Sealed Sources”

NRC’s Part 36 requirements address all potential radiation health and safety issues associated with the use of “sealed sources” in irradiators. For example, with respect to the particular radioactive material to be utilized in “sealed sources,” the Commission stated that “this final rule was written to require that irradiators use radioactive materials that are *as insoluble and nondispersable as practical* (typically cobalt-60).” *See id.* at 7716 (emphasis added). “Sealed sources” must meet stringent performance criteria set forth in 10 CFR § 32.210 and must include protective mechanisms to prevent the release of *radioactive material* to the environment such as double-encapsulation in corrosion-resistant materials like stainless steel. According to

the Commission, “[d]ouble encapsulation provides additional protection in case one of the welds in the source is defective.” 58 Fed. Reg. at 7718. As a result, the Commission determined that “[s]ince this has been a de facto requirement for meeting [10 CFR] § 32.210, this requirement should have no impact.” *Id.*

While the licensee seeking to obtain a Part 36 license will utilize the “sealed source” at its facility, “[n]ormally the tests used to demonstrate that the criteria can be met are conducted by the *source manufacturer, not the irradiator licensee.*” *Id.* (emphasis added). The source manufacturer is responsible for ensuring that all “sealed sources” meet NRC performance criteria for protection of public health and safety, including the aforementioned double encapsulation requirement. After demonstrating that such performance criteria have been met, source manufacturers must register (which effectively constitutes approval of) their “sealed sources” with NRC and obtain a registration number for such sources. Part 36 licensees are not permitted to utilize “sealed sources” for irradiation purposes that are not registered with NRC or an appropriate Agreement State. Therefore, use of a registered (i.e., NRC-approved) “sealed source,” by definition, satisfies the requirement for use of radioactive materials that are as *insoluble and nondispersable as practical.*

4. Irradiator Shielding Pool Requirements

NRC’s Part 36 requirements include design criteria for shielding pools in Category III underwater irradiators. For irradiators such as the CFC Category III underwater irradiator which utilize a “shielding” pool to prevent exposure to “sealed sources,” NRC requires that the licensee either (1) use a stainless steel pool liner (or a liner metallurgically compatible with other components in the pool) or (2) construct a

pool so that there is a low likelihood of substantial leakage. *See id.* at 7720. In promulgating this requirement, the Commission sought to minimize pool leakage in the unlikely event that the “shielding” water should become contaminated. 58 Fed Reg. at 7720. However, the Commission noted that “[b]ackfitting is not required because modifying an existing pool would be prohibitively expensive and any gain in safety would be marginal, *especially because cobalt-60 has very low solubility.*” *Id.* (emphasis added).

With respect to potential leakage of water from a “shielding pool,” Part 36 requires that irradiator operators have monitoring system to detect water loss from the “shielding” pool.⁵ A monitoring system which detects the presence of radioactive materials in pool water is not necessary because, as the Commission has stated, “[i]n normal circumstances, a pool leak is not a safety concern because pool water contains little or no radioactive material.” *Id.* Should any cobalt-60 enter the shielding pool, “[e]xperience with cobalt-60 has shown that pool contamination levels do not increase significantly because of the very low solubility in water of cobalt-60.” *Id.* Based on this, the Commission concluded “the NRC does not consider that a pool leak system more sensitive than that required in the rule is necessary.” 58 Fed. Reg. at 7720.

5. Operating and Emergency Procedures

10 CFR § 36.53 sets forth the specific operating and emergency procedures a Part 36 licensee must follow to operate a Category III irradiator. These procedures include but are not limited to requirements for operating personnel to be trained in the following:

⁵ Part 36 also requires a water purification to ensure that pool water remains clear and prevents corrosion of a source rack. Clear pool water also allows for visual inspection of a source rack to determine if damage has occurred. *See* 10 CFR § 36.63.

(1) monitoring of pool water for radioactive material, (2) leak testing of sources,⁶ (3) inspection and maintenance checks, (4) loading, unloading, and repositioning of “sealed sources,” and (5) emergency procedures for “sealed sources” in an unshielded position, (6) a prolonged loss of electrical power, and (7) detection of leaking sources. *See* 10 CFR § 36.53(a) et seq. Each of these requirements must be satisfied before an applicant may obtain a Part 36 license and all licensee personnel must be instructed on these procedures prior to using the irradiator.

6. Decommissioning and Financial Assurance Requirements

With respect to decommissioning Part 36 irradiators, NRC developed its design criteria for irradiators to allow for the safe and efficient facilitation of decommissioning. For example, leak detection requirements were included in Part 36 to allow licensees to detect leaking sources or pool water early enough to allow for the location and isolation of such leakage. 58 Fed. Reg. at 7726. Pool liner requirements in 10 CFR § 36.33 were implemented to prevent any contamination in pool water from leaking outside the irradiator, and the requirement for a “stainless steel” pool liner reflects NRC’s requirement that pool liner surfaces be easy to decontaminate. *Id.* Thus, the Commission determined that, “for an irradiator built in accordance with the rule, there should be no undue difficulty in decontamination.” *Id.* In addition, with respect to financial assurance requirements, 10 CFR § 30.35 prescribes the relevant financial amount applicable to Part 36 irradiators depending on the amount of curies of radioactive material used at the licensee’s facility. *See* 10 CFR § 30.35 (Table).

⁶ 10 CFR § 36.59 encompasses the requirements for monitoring systems to detect leaking “sealed sources.”

7. Use of HEPA Filters to Control Air Dispersion

During the Part 36 rulemaking, the Commission received a public comment which recommended that high efficiency particulate absolute (HEPA) filters be used on air exhaust ducts from radiation rooms in panoramic (not Category III underwater) irradiators to prevent the spread of radioactive materials. The Commission declined to adopt this recommendation because, even with panoramic irradiators, such filters are not necessary because “the comment was made in the context of the leaking cesium-137...source that occurred in Georgia in 1988. However, the NRC has decided that [such] sources should not be used in irradiators, and cobalt-60 is used in a far less dispersible form.”⁷ 58 Fed Reg. at 7727. Thus, the Commission concluded that the use of HEPA filters on air exhaust ducts from radiation rooms in panoramic irradiators is not required to protect public health and safety and, logically, would be even less necessary for a Category III irradiator.

C. Applications of Part 36 Requirements to “Germane” Areas of Concern

As noted above, NRC Staff has set forth generic standards for the demonstration of a “germane” area of concern by a petitioner. According to NRC Staff, the standards for a “germane” area of concern require that a petitioner (1) plead an area of concern which is relevant to whether the license should be conditioned or denied; which is (2) sufficient to establish that the issues a petitioner seeks to raise fall generally within the range of matters properly subject to challenge in the proceeding; (3) with enough

⁷ It is worth noting that the above-mentioned 1988 Georgia irradiator involved leaking of a *cesium-137* source was a Category IV irradiator and not a Category III underwater irradiator with a cobalt-60 “sealed source.” In addition, after examining the results of the Georgia leak incident, the Commission found that, “there was little escape of cesium-137 from the building and no known dose to the public.” 58 Fed. Reg. at 7727.

specificity so that the Presiding Officer may determine whether the concerns are truly relevant to the license amendment at issue. *See* NRC Staff Brief at 5. However, the aforementioned *International Uranium* case implicates one final fundamental requirement for an area of concern to be “germane” to a proceeding. The final requirement is that an area of concern must allege that the proposed licensing action poses a significant, *incremental* threat to public health and safety above and beyond that of previously approved activities. *See generally International Uranium (USA) Corp.* (White Mesa Uranium Mill), CLI-02-13, 55 NRC 269 (April 12, 2002).

When comparing all of the above-mentioned legal standards to licensing actions covered under Part 36, it is apparent that Part 36 requirements for irradiators serve as the “threshold” standard for applicants seeking to operate an irradiator. That is, as stated by the Commission in 10 CFR § 36.13, “[t]he Commission *will approve* an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section [Part 36].” 58 Fed. Reg. 7729 (emphasis added). These generic requirements apply to all Category III irradiators and, if an applicant meets each of these requirements, the Commission *must* grant the license. Therefore, Part 36 requirements are based on previously approved/licensed activities which have been codified in Part 36 so that if a potential concern was addressed and dismissed in the course of developing Part 36 requirements, it cannot now be “germane” unless such concern is based on some significant, incremental potential hazard not previously addressed and decided (i.e., it would make no sense to allow litigation to proceed on the issue of dispersion of cobalt-60 in water from a doubly-encapsulated “sealed source”

when the Commission already has specifically found that no such pathway exists because of Part 36 requirements and the insolubility of cobalt-60 in water).

V. PETITIONERS DO NOT HAVE STANDING TO INTERVENE IN THIS PROCEEDING AND HAVE NOT ALLEGED AN AREA OF CONCERN WHICH IS GERMANE TO THIS PROCEEDING

CFC agrees with NRC Staff's conclusion that the CFC Category III irradiator does not pose an obvious potential for off-site consequences and, thus, Petitioners' have not established that they have standing based solely on their proximity to the CFC facility. Petitioners' numerous hearing requests and specified areas of concern have failed to establish that they have established injury-in-fact necessary to have standing for a Subpart L hearing and have failed to allege an area of concern which is "germane" to this proceeding.

A. Petitioners Should Not Be Granted Standing Based on the "Proximity Presumption"

Petitioners have failed to demonstrate that they have standing to intervene for a Subpart L hearing solely on the basis of their proximity to the CFC facility. Petitioners allege that they live as close as 1/3rd of a mile from the CFC facility and, based on this factor alone, they possess standing. *See* Petitioners' August 14, 2003 Brief (Affidavits). However, as noted above, in order to be granted standing as a result of their proximity to the CFC facility, it must be demonstrated that the CFC Category III irradiator utilizes a *significant* source of radioactivity with an *obvious* potential for offsite consequences.

1. The CFC Category III Irradiator's Maximum Licensed Loading Capacity is Significantly Lower Than That of Previously Licensed Irradiators

Many NRC-approved irradiators in the United States currently utilize more radioactive material than the CFC Category III irradiator's maximum licensed loading

capacity of 1,000,000 curies, which is well within the parameters of previously approved irradiation activities contained in the Part 36 rulemaking, which the Commission has found poses no significant threat to public health and safety. *See* 58 Fed. Reg. at 7727. For example, one of the first major production irradiators ever constructed in the United States was the U.S. Army's Natick, Massachusetts facility that was built to hold up to 2,000,000 curies of radioactive material. In 1964, Johnson & Johnson's Ethicon facility also was built to hold up to 2,000,000 curies of radioactive material. In fact, some commercially operated irradiators are licensed to hold up to 10,000,000 curies. In total, there are more than 60 commercially operated irradiators in the U.S., and they average approximately 4,000,000 curies per unit, which is four (4) times greater than the maximum licensed loading capacity of the CFC Category III irradiator.

2. The CFC Category III Irradiator Does Not Pose An Obvious Potential for Offsite Consequences

CFC agrees with NRC Staff's conclusion that the irradiator does not pose an obvious potential for offsite consequences. As stated by NRC Staff, the CFC Category III irradiator primarily utilizes *passive* systems to prevent dispersion of cobalt-60⁸ outside the irradiator (i.e., doubly encapsulated sources, stainless steel plenum, and a "shielding" pool with redundant layers of stainless steel liners and concrete). NRC Staff is correct that the passive nature of these protective mechanisms make them more reliable than active systems which potentially could be subject to malfunction or to human error.

⁸ The "sealed source" requirements in Part 36 and 10 CFR § 32.210 are designed to prevent the dispersion of *radioactive material* (i.e., Cobalt-60). However, they are not designed to limit the gamma *radiation inside* the irradiator because, if they did, they would be useless in an irradiator. The "shielding" pool water is primarily designed to prevent exposure to gamma *radiation*. Based on a review of Petitioners' areas of concern and their experts' assessments, this distinction is clearly not understood by Petitioners.

NRC Staff also correctly notes that the CFC Category III irradiator does utilize *active* protective mechanisms for additional safety in the highly unlikely event that all of the passive systems fail to contain the cobalt-60. The CFC Category III irradiator utilizes a water purification system in accordance with NRC Part 36 requirements at 10 CFR § 36.63 so that potential corrosion of the stainless steel source rack (plenum) is minimized. Radiation alarms are also installed pursuant to Part 36 requirements to alert NRC-approved trained CFC irradiator personnel that radioactive material may have been dispersed at some point. However, due to the insolubility of cobalt-60 in water and the fact that it is, according to NRC, “as nondispersible as practical,” NRC Staff correctly concluded that “based upon the operational history of irradiators operating under Part 36, off-site consequences are not anticipated.” NRC Staff September 3, 2003 Brief at 2. Therefore, as NRC Staff concluded, “[t]he failure of any one active system, by itself, is not expected to cause exposures to workers, let alone to other members of the public off-site.” *Id.* at 3.

Additionally, unlike the fissionable materials used at reactor facilities, which are usually the facilities subject to a “proximity presumption” for standing, the 1,000,000 curies of cobalt-60 “sealed sources” to be used at the CFC facility is not volatile like that used at reactor facilities. The Commission has determined that “the radioactive materials in irradiators *are not volatile like the noble gases and iodines produced in a reactor and because irradiators do not have a driving force equivalent to the decay heat from a reactor to expel the [radioactive] materials from the facility.*” 58 Fed. Reg. at 7725 (emphasis added). Based on this, the CFC irradiator does not pose an obvious potential for offsite consequences sufficient to invoke the “proximity presumption.”

B. Petitioners Have Not Sufficiently Alleged Injury-In-Fact or a Germane Area of Concern to Be Granted Standing

Since it has not been demonstrated that the CFC Category III irradiator has an obvious potential for offsite consequences, Petitioners must sufficiently allege a *possible* and *plausible concrete and particularized* injury-in-fact in order to be granted standing in this proceeding.⁹ Petitioners must also allege an area of concern which is “germane” to this proceeding. That is, Petitioners must allege an area of concern which poses a significant, incremental threat to public health and safety or the environment above and beyond that of previously approved activities (i.e., Part 36 requirements). Petitioners have failed to do either.

1. Petitioners Have Not Alleged Injury-in-Fact or a Germane Area of Concern as a Result of Air Dispersion of Radioactive Material

Petitioners have failed to demonstrate that they will suffer injury-in-fact as a result of air dispersion of radioactive material. Petitioners allege that a cracking of the “vessel¹⁰ containing the cobalt-60 which require continual water cooling may crack from loss of coolant.” Petitioners’ August 14, 2003 Brief at 3. According to Petitioners, “*radiation* would be emitted into the air which would harm intervenors....” *Id.* (emphasis added). Petitioners claim that this allegation is substantiated by an expert who

⁹ It is worth noting that, as stated above in the *Northern States Power Co.* case, “[t]he proximity of a person’s home or property can be relevant to standing depending on the radiological materials and the potential hazard involved. *There must be sufficient information provided to determine that there is a possibility of injury.* *Northern States Power Co.*, 30 NRC at *11. Thus, in this proceeding, even if Petitioners can demonstrate that their proximity to the CFC facility is relevant, they still must demonstrate a *possible injury* before standing may be granted.

¹⁰ Petitioners make reference to a “vessel” containing cobalt-60 in their allegation. CFC cannot ascertain what Petitioners are referring to and, as such, assert that Petitioners have not alleged a *possible* and *plausible concrete and particularized* injury-in-fact but rather have used vague and confusing assertions as the basis of their alleged potential injury.

examined CFC's license application and found that "the loss of coolant or the failure of pumps to remove heat from the water may cause the water to boil, pressurization of the vessel causing the cobalt-60 rods to overheat and compromising the vessel." *Id.*

These allegations provide no rational basis on which standing should be granted. Initially, Petitioners' allegation rests on nothing more than misconceptions because neither the CFC Category III irradiator nor other underwater irradiators require the use of "cooling" water. The water located in the pool of the CFC irradiator is used for the purpose of "shielding" from gamma *radiation* and not for "cooling." *See* CFC License Application at 23. Indeed, as stated above, the Commission determined that irradiators do not generate decay heat similar to that generated by reactors which would require "cooling." *See* 58 Fed. Reg at 7725. Petitioners' so-called expert who allegedly examined CFC's license application could not possibly have concluded that the "shielding" water is required to "cool" the cobalt-60 "sealed sources" because neither the Part 36 regulations nor CFC's license application reference any such statement. Thus, since Petitioners allegation is based solely on the existence of "cooling" water for a heat source that the Commission has made plain does not exist, there can be no *possible and plausible concrete and particularized injury-in-fact* arising from an allegation based on "cooling" water.

Further, even if the facts cited by Petitioners in their allegation were accepted as true, the allegation still fails to allege a *viable pathway* through which *radioactive material* (i.e., cobalt-60) in an *underwater irradiator* will escape its NRC-approved nickel plating and double encapsulated source encapsulations, proceed out of the stainless steel source rack (plenum), travel through the "shielding pool" despite the fact that it is

insoluble, and disperse as *airborne particulates* out of the irradiator, through the CFC facility, and reach Petitioners causing them harm. Without more information regarding a *viable pathway* through which cobalt-60 will proceed and reach Petitioners, their allegation regarding air dispersion is insufficient for a grant of standing.

Further, Petitioners' area of concern regarding air dispersion is not "germane" to this proceeding. With respect to air dispersion, NRC's Part 36 rulemaking stated that air exhaust ducts from radiation rooms of panoramic irradiators need not be equipped with HEPA filters because they "are not necessary at irradiators to protect health and safety. 58 Fed. Reg. at 7727. This application was directed at panoramic irradiators because such irradiators utilize "sealed sources" *in air* unlike the CFC Category III irradiator which utilizes "sealed sources" *underwater and does not have a radiation room*. However, despite the fact that the Commission has found that HEPA filters are not necessary to filter air from panoramic irradiator radiation rooms, let alone underwater irradiators, the CFC Category III irradiator utilizes HEPA filters as an additional safety precaution. CFC License Application at 23. Thus, CFC not only has complied with Part 36 requirements for previously approved activities but has also *exceeded* such requirements. Further, Petitioners have not alleged that the potential for air dispersion from the CFC Category III irradiator represents a significant, *incremental* threat to public health and safety above and beyond previously approved Part 36 activities. Therefore, Petitioners' area of concern regarding air dispersion of cobalt-60 is not "germane" to this proceeding.

2. Petitioners Have Not Alleged Injury-in-Fact or a Germane Area of Concern as a Result of Air Circulation of Radioactive Material

Petitioners have failed to demonstrate that they will suffer injury-in-fact as a result of air circulation around the cobalt-60 source rack. Petitioners allege that “air circulation around the “vessel”¹¹ containing the cobalt-60 could emit [sic] radiation into the air.” Petitioners’ August 14, 2003 Brief at 4. Their allegation concludes that “[r]adiation emitted into the air would harm proposed intervenors, most of who live within a mile of the facility.”¹² *Id.* This allegation is substantiated by a so-called expert “who examined the [CFC] license application found air circulation around the vessel is a potential source of environmental contamination.” *Id.*

First and foremost, as a general matter, there is no “air stream” or “air circulation” flowing through the cobalt-60 source “pencils.” The source “pencils” are “sealed” in two 316L stainless steel casings which are hermetically sealed and leak tested. There is no method for external air flow within the source encapsulations to allow air to come into contact with the cobalt-60 metal. Further, the minute stagnant gas imprisoned in the doubly encapsulated “sealed source” *is not in contact with cobalt-60*, but rather is in contact with the source “pencils” non-radioactive nickel plating, which serves as an additional form of source encapsulation.

¹¹ Again, “vessel” is not a term used in the CFC license application, so CFC need not address what this reference means, but the “sealed sources” are underwater in a source rack (plenum).

¹² Once again, Petitioners fail to understand the difference between a release of *radioactive material* and a release of *radiation* from an underwater irradiator. Emissions of gamma *radiation* to workers are controlled by the 14 and 1/2 feet of water over the sources contained in the “shielding” pool and the potential for release of *radiation* from the irradiator to the public is remote, if not non-existent. So long as the irradiator meets Part 20 requirements for doses to workers (which is contained in Part 36), *radiation* is not escaping the irradiator to cause harm to workers, much less the public. With respect to potential releases of *radioactive material* (i.e., cobalt-60), NRC Staff already has determined that such material located in Category III irradiators meeting Part 36 requirements are as “*insoluble and nondispersible as practical.*”

While Petitioners go to great lengths to allege that CFC has not provided analyses regarding various aspects of the CFC facility's radiation safety procedures, they fail to allege a *viable pathway* through which cobalt-60 will escape the irradiator itself (nickel plating, doubly encapsulated source encapsulations, stainless steel source rack (plenum), "shielding" pool water, HEPA filters), travel outside the CFC facility, and reach Petitioners in concentrations sufficient to cause them harm. Without more, Petitioners have not alleged a *possible and plausible concrete and particularized injury-in-fact* sufficient to grant standing.

In addition, Petitioners' area of concern regarding air circulation is not "germane to this proceeding. The CFC Category III irradiator utilizes air to prevent water from the "shielding" pool from entering the source rack (plenum) and such air will not serve as a "driving force" to expel cobalt-60 from its doubly-encapsulated source casings, through the source rack (plenum) and the "shielding" pool, outside the CFC facility to reach Petitioners. Moreover, Petitioners have not alleged that the potential for dispersion of cobalt-60 from the CFC Category III irradiator as a result of air circulation near the "sealed source" represents a significant, incremental threat to public health and safety above and beyond previously approved Part 36 activities. Therefore, Petitioners' area of concern regarding air dispersion of cobalt-60 is not "germane" to this proceeding.

3. Petitioners Have Not Alleged Injury-in-Fact or a "Germane" Area of Concern as a Result of the Storage of Radioactive Waste

Petitioners have failed to demonstrate that they will suffer injury-in-fact as a result of the storage of radioactive waste at the CFC facility. Petitioners allege that the "[s]torage of radioactive waste at the [CFC] facility may emit radiation into the air."

Petitioners August 14, 2003 Brief at 5. Their allegation includes a claim that the “[e]mission of radiation into the air would harm proposed intervenors,” and is substantiated by so-called expert evaluation of CFC’s license application which claims that “the storage of radioactive waste in the form of resins collected from water chemistry controls is a potential source of environmental contamination.” *Id.*

This allegations falls short of fulfilling the requirements for standing. Petitioners’ allegation primarily relies on the fact that CFC will store radioactive waste at its facility during operation of the irradiator. However, nowhere in its license application does CFC indicate that radioactive waste will be stored on-site at any time. In fact, no radioactive waste will be stored at any time at the CFC facility. As stated above, an allegation based on incorrect information cannot form the basis for a *possible and plausible concrete and particularized injury-in-fact*.

Additionally, even if the facts in Petitioners’ allegation were taken as true, the allegation does not allege a *viable pathway* through which any cobalt-60 waste (which does not exist) in any form could escape the irradiator itself and the CFC facility and reach Petitioners thereby causing them harm. Petitioners do not even allege what type of harm they may incur as a result of the release of the so-called radioactive waste. Without more, Petitioners’ allegation does not present a *possible and plausible concrete and particularized injury-in-fact* sufficient for a grant of standing.

Further, Petitioners’ area of concern regarding storage of radioactive waste is not “germane” to this proceeding. At no time will CFC store radioactive waste on-site at its facility and, for that matter, Category III irradiators do not create radioactive waste which requires storage and/or disposal. Radioactive waste was not a public health and safety

issue in the Commission's Part 36 rulemaking and Petitioners have not alleged what type of harm they would suffer as a result of this hypothetical storage of radioactive waste and have not demonstrated that the CFC Category III irradiator poses a significant, incremental threat above and beyond previously approved Part 36 activities. Therefore, Petitioners' area of concern regarding storage of radioactive waste is not "germane" to this proceeding.

4. Petitioners Have Not Alleged Injury-in-Fact or a Germane Area of Concern as a Result of the Mishandling of Cobalt-60 Sources

Petitioners have failed to demonstrate that they will suffer injury-in-fact as a result of the mishandling of Cobalt-60 sources. Petitioners allege that "[m]ishandling of cobalt-60 rods could emit radiation into the air," which "would harm proposed intervenors..." Petitioners August 14, 2003 Brief at 5. This allegation is substantiated by so-called expert analysis that "found the mishandling of cobalt-60 rods during transportation, loading and discharge, cracking and leaks from the rods are potential sources of environmental contamination." *Id.*

This allegation falls short of fulfilling the requirements for standing. Petitioners again fail to allege a *viable pathway* through which cobalt-60 could travel and reach them causing harm. Petitioners merely allege that CFC has not provided any "dispersion analysis" or "emergency procedures" for loading and unloading sources, but they have not affirmatively alleged how the source "pencils" nickel plating and doubly encapsulated source encapsulation could crack and allow cobalt-60 to escape and migrate through the environment to cause them harm even if such sources were mishandled.

Without more, Petitioners have not alleged a *possible and plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Additionally, Petitioners' area of concern regarding the potential mishandling of cobalt-60 "rods" is not "germane" to this proceeding. Cobalt-60 "pencils" are handled during transport in accordance with relevant DOT regulations for the transportation of radioactive materials. When the cobalt-60 "pencils" reach the CFC facility, they are installed in the source rack either by an NRC-approved organization which has received appropriate training to install such "sealed sources" or by the licensee only after such licensee is approved by NRC. CFC has not proposed in its license application any other transportation or installation/handling procedures outside the scope of Part 36 requirements. In addition, Petitioners have not offered any allegations demonstrating that transportation or installation/handling procedures to be used by CFC pose a significant, incremental threat to public health and safety above and beyond previously approved Part 36 activities. Therefore, Petitioners' area of concern regarding the potential mishandling of cobalt-60 "pencils" is not "germane" to this proceeding.

5. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of A Loss of Electricity

Petitioners have failed to demonstrate that they will suffer injury-in-fact as a result of a loss of electricity at the CFC facility. Petitioners allege that "[a] loss of electricity could compromise cobalt-60 and emit radiation into the air," which would cause "harm to proposed intervenors." *Id.* This allegation claims that "[i]n the event of a loss of power while a bell containing cobalt-60 is underwater, the source could become water-logged, distribute itself within the pool, thereby clogging the filters. In changing the clogged filters, cobalt-60 may be released into the air." *Id.*

This allegation falls short of fulfilling the requirements for standing. Petitioners' allegation references a "bell containing cobalt-60" as the source of the potential release of cobalt-60. However, the CFC Category III irradiator utilizes "bells" to contain product to be irradiated underwater and not for the holding or storage of cobalt-60. As stated previously, the cobalt-60 "pencils" are plated with non-radioactive nickel and contained in doubly encapsulated stainless steel encapsulations to inhibit dispersion. So, it is not possible for such sources to become water-logged. This incorrect information is not sufficient to demonstrate a *possible and plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Further, even if the facts in Petitioners' allegation were accepted as true, the allegation still fails to allege how the cobalt-60, an insoluble material, will escape its nickel plating, its doubly encapsulated source encapsulations and its stainless steel source rack (plenum) and migrate through the "shielding" pool and reach any filters. Even if cobalt-60 were to escape its source casings, the CFC irradiator's "shielding" pool has no pipe fittings, plugs or other openings through which cobalt-60 could escape if it could dissolve in water, which it cannot. Petitioners do not allege any *viable pathway* through which such material will travel through the CFC facility and reach Petitioners causing them harm. Petitioners also do not allege what type of harm they will suffer as a result of a release of cobalt-60. This *vague and conjectural* allegation is insufficient to demonstrate a *possible and plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Petitioners' area of concern regarding a potential loss of electricity at the CFC facility is not "germane" to this proceeding. NRC's Part 36 rulemaking prescribes

requirements for automatic source retraction for panoramic irradiators, which raise their sources out of the storage pool. But such requirements are not necessary for Category III underwater irradiators, where the sources do not move, because the Commission has found that a loss of power is not a public health and safety issue. *See* 10 CFR § 36.37; *see also* 58 Fed. Reg. at 7720. The CFC Category III irradiator utilizes all relevant safety measures to prevent the release of cobalt-60 from the irradiator, and Petitioners have failed to offer any allegations demonstrating that CFC's irradiator poses a significant, incremental threat above and beyond previously approved Part 36 activities from a potential loss of power. Therefore, Petitioners' area of concern regarding a potential loss of power at the CFC facility is not "germane" to this proceeding.

6. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of A Damaged Air Line

Petitioners have failed to demonstrate that they will suffer injury-in-fact as a result of a damaged air line. Petitioners allege that "[a] damaged air line could compromise cobalt-60 and emit *radiation* into the air," which will cause "harm to proposed intervenors." Petitioners' August 14, 2003 Brief at 7 (emphasis added).¹³ This allegation is substantiated by a claim that "a break in the compressed air line...would allow water to enter the "bell" holding the cobalt-60 underwater, would degrade the source in the pool, clog the filters. In changing the clogged filters, cobalt-60 would be emitted into the air." *Id.*

This allegation is insufficient to demonstrate a *plausible concrete and particularized* injury-in-fact sufficient for a grant of standing. Petitioners' allegation

¹³ Once again, Petitioners have confused the emission of gamma *radiation* with a release of cobalt-60 *radioactive material*.

once again references a “bell containing cobalt-60” as the source of the potential release of cobalt-60 *radioactive material* and/or *radiation*. However, as stated above, the CFC Category III irradiator utilizes “bells” for containing product to be irradiated underwater and, at no time do these “bells” hold or contain cobalt-60 nor do they pose a threat after they are irradiated. *See* CFC License Application at 25. This incorrect information is not sufficient to demonstrate a *possible* and *plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Even if the facts in Petitioners’ allegation were accepted as true, this allegation still fails to allege how the cobalt-60 will escape its nickel plating and doubly encapsulated source encapsulations, migrate through the “shielding” pool and reach any filters as a result of damage to the air line. This allegation does not present a *viable basis* for damage to the air line to cause damage to the nickel-plated cobalt-60 in its doubly encapsulated stainless steel source encapsulation or how the cobalt-60, an insoluble material, will migrate through the stainless steel source rack (plenum) “shielding” pool water and reach an air filter. Even if cobalt-60 were to escape its source encapsulations and the source rack (plenum), the CFC irradiator’s “shielding” pool has no pipe fittings, plugs or other openings through which cobalt-60 could escape. Petitioners do not allege any *viable pathway* through which such material will travel through the CFC facility and reach Petitioners causing harm. Petitioners also do not allege what type of harm they will suffer as a result of a release of cobalt-60. This *vague and conjectural* allegation is insufficient to demonstrate a *possible* and *plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Additionally, Petitioners' area of concern regarding a damaged air line, which introduces air into the "bells" containing product to be irradiated as they enter the pool to keep such product dry, is not "germane" to this proceeding. Petitioners have not offered any allegations that CFC's Category III irradiator utilizes any mechanisms or procedures related to the use of an air line that pose a significant, incremental threat above and beyond previously approved Part 36 activities. Therefore, Petitioners area of concern regarding a damaged air line is not "germane" to this proceeding.

7. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of Ozone Dispersion

Petitioners have failed to allege that they will suffer injury-in-fact or a "germane" area of concern as a result of potential ozone dispersion. Petitioners allege that "[i]rradiation facilities generate high levels of ozone that is particularly harmful because of its close proximity to the ground." *Id.* at 7. According to Petitioners, this ozone dispersion would cause them to be harmed because a so-called expert has stated that "ozone harms the community surrounding an irradiation facility...." *Id.*

This allegation falls short of fulfilling the requirements for standing. Petitioners' allegation is a *generalized* grievance that appears to be addressed not only to the CFC irradiator, but to all irradiators across the country. Such generalized concerns are not sufficient to demonstrate injury-in-fact because, as the Licensing Board has found, "injury-in-fact cannot be asserted on the footing of nothing more than a broad interest shared with many others...." *International Uranium (USA) Corp.* (White Mesa Uranium Mill), LBP-02-3, 55 NRC 35, 39 (2002).

If Petitioners allegation was to be construed as applying only to the CFC irradiator, then it still would be insufficient to demonstrate injury-in-fact, since Category

III irradiators do not generate large concentrations of ozone because their sources are contained underwater. Category IV panoramic irradiators are the type of irradiators which irradiate in air that can generate levels of ozone requiring protective measures for workers in accordance with federal regulations (i.e., Occupational Safety and Health Administration (OSHA)). Thus, Petitioners' allegation that the CFC irradiator will generate "high levels of ozone" is incorrect and insufficient to demonstrate injury-in-fact.

Even if the CFC irradiator did create increased levels of ozone, Petitioners have not alleged a *viable pathway* through which such ozone could travel through the "shielding" pool water, through the irradiator itself, outside the CFC facility, and reach Petitioners causing them harm. Petitioners merely allege that ozone is a "very toxic atmospheric pollutant" when it is close to the ground. *Id.* This general allegation, without more, is insufficient to demonstrate a *possible and plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Petitioners' area of concern regarding potential ozone dispersion is not "germane" to this proceeding. As stated above, the production and potential release of ozone is not a health and safety issue at Category III irradiators because all irradiation activities and source storage take place underwater. In addition, Petitioners have not offered any allegations demonstrating that the CFC Category III irradiator is substantially different from previously licensed Part 36 activities that it would pose a significant, incremental threat as a result of ozone production and release. That is, Petitioners have not alleged that the CFC Category III irradiator will or likely will produce ozone in a manner different from that of previously license Part 36 activities. Thus, Petitioners' area of

concern regarding ozone production and potential release is not “germane” to this proceeding.

8. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of “New” and “Untried” Irradiator Designs

Petitioners have failed to allege injury-in-fact as a result of “new” and “untried” irradiator designs. Petitioners allege that “[p]lans for assembly and installation are new, untried on a large scale, and have not been made available for safety review.” Petitioners’ August 14, 2003 Brief at 8. According to Petitioners, these “assembly and installation plans” will cause air and water dispersion which will harm them. *Id.* Petitioners also allege that “[t]he facility is a ‘first of a kind’ (a scale up from an experimental operation of 17,000 curies of cobalt-60 to 1,000,000 curies), and is atypical of other radiation-source irradiators in the United States.” *Id.* at 13.

This allegation provides no *viable basis* for a *plausible concrete and particularized* injury-in-fact. Petitioners’ characterization of a traditional irradiator operation of 17,000 curies and an “experimental scale-up” of 1,000,000 curies is misinformed and incorrect. In Part 36 irradiators such as the CFC Category III irradiator, each cobalt-60 “pencil” can consist of up to 17,000 curies of cobalt-60, but usually contain approximately 10,000-12,000 curies. On the other hand, the *loading capacity* of an entire irradiator may utilize many of these “pencils” and is larger than that of one (1) source “pencil.” In fact, most commercial irradiators located in the United States have loading capacities greatly in excess of the CFC irradiator’s maximum licensed loading capacity of 1,000,000 curies. As stated above, the average loading capacity of commercially operated, NRC-licensed irradiators in the United States is approximately

4,000,000 curies. Thus, Petitioners' misinformed and incorrect characterization of the CFC irradiator as an "experimental scale-up" is incorrect and insufficient to demonstrate a *possible and plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Petitioners' statements that the CFC irradiator is "new" and "untried" or "atypical of other radiation-source irradiators in the United States" are utterly incorrect. CFC has constructed an irradiator that meets each of the requirements for a Category III irradiator under NRC's Part 36 requirements. CFC does not seek to install any mechanisms, propose any procedures or utilize any quantities of radioactive materials that are "new" and "untried." In fact, the CFC irradiator is well within the criteria used by previously approved Category III irradiators. Thus, the CFC irradiator is not assembled or installed based on any criteria that are "new" and "untried," with the exception of the design of certain redundant passive safety mechanisms such as the irradiator "shielding" pool (i.e., interior ¼ inch stainless steel liner, six (6) inches of concrete, a second ¼ inch steel liner, and three and one-half additional feet of concrete. *See* 10 CFR § 36.33.

Further, Petitioners merely allege that these so-called "new" and "untried" assembly and installation plans will cause "air and water dispersion." *Id.* Petitioners do not offer any allegations of how such air or water dispersion will occur nor do they offer any *viable pathway* through which such dispersion will travel and reach Petitioners causing them harm. Without more, this allegation does not demonstrate a *plausible concrete and particularized* injury-in-fact sufficient for a grant of standing.

Petitioners' area of concern claiming that the CFC Category III irradiator is an "experimental scale-up" design and that its installation/assembly is "new" and "untried"

is not “germane” to this proceeding. As stated above, Petitioners’ area of concern is based on substantial misinformation. Petitioners characterize a standard irradiator as possessing 17,000 curies of cobalt-60 and claims that the CFC maximum loading capacity of 1,000,000 curies is a “new” and “untried” design. However, as stated above, 17,000 curies is the maximum concentration of one (1) cobalt-60 “pencil” and CFC’s maximum licensed loading capacity of 1,000,000 curies is one-quarter the size of the average loading capacity licensed by NRC in the United States. Petitioners have not offered any allegations of how the CFC Category III irradiator’s maximum licensed loading capacity poses a significant, incremental threat above and beyond that posed by previously approved irradiators with much larger licensed loading capacities. Therefore, Petitioners’ area of concern claiming that the CFC Category III irradiator is an “experimental scale-up” is not “germane” to this proceeding.

9. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of Improper Security

Petitioners have failed to allege injury-in-fact as a result of improper security precautions at the CFC facility. Petitioners allege that “[b]ecause irradiation facilities are relatively small, they are often unregulated and lack adequate security.” *Id.* at 9.

Petitioners also allege that CFC’s security plans cannot be made adequate even though they have not yet assessed such plans. Petitioners’ August 14, 2003 Brief at 9.

As a general proposition, no irradiation facilities are unregulated. NRC or an appropriate Agreement State authority maintains regulatory authority over all irradiation facilities using licensed radioactive material for irradiation purposes. *See generally* 10 CFR Part 36. Moreover, Petitioners claim that such facilities often go unregulated is insufficient to demonstrate injury-in-fact, because it is well-settled that assertions of

broad public interest in regulatory matters do not establish the *particularized* interest necessary for participation by an individual in NRC adjudicatory processes such as Subpart L hearings. See *Long Island Lighting Co.* (Shoreham Nuclear Power Station, Unit 1), LBP-91-1, 33 NRC 15, 28 (1991); see also *Metropolitan Edison Co.* (Three Mile Island Nuclear Station, Unit 1), CLI-83-25, 18 NRC 327, 332 (1983).

With respect to Petitioners' allegation that CFC's security plans cannot be made "adequate," CFC has been issued a license by NRC in which one of the key requirements was compliance with NRC regulations regarding security. By approving CFC's license application, NRC has endorsed CFC's security plans as adequate to protect public health and safety. In addition, as mentioned by Mr. George Pangburn at the August 21, 2003 public meeting, the Commission has released new security requirements classified as "safeguards" with which irradiation facilities will be required to comply. CFC will complete all required actions to come into compliance with these new "safeguards" security requirements by September 12, 2003.¹⁴ Thus, Petitioners' allegation that CFC's security plans cannot be made adequate is incorrect.

In addition, Petitioners' area of concern regarding improper security precautions is not "germane" to this proceeding. CFC's facility complies with each of Part 36's requirements for security features at irradiation facilities. The relevant pages and procedures disclosed to Petitioners on August 28, 2003 simply illustrate how CFC has complied with relevant NRC requirements for security measures at its facility.

Petitioners have not and cannot present any allegations demonstrating that compliance with these regulations poses a significant, incremental threat to public health and safety

¹⁴ CFC will submit an affidavit from its RSO attesting to this in its response to Petitioners' request for a stay to be filed on September 9, 2003.

because CFC has complied with the Commission requirements as set forth in its Part 36 rulemaking and subsequent requirements. Since such requirements have been addressed during a formal rulemaking and have been found to adequately protect public health and safety, Petitioners' area of concern with respect to improper security measures at the CFC facility is not "germane" to this proceeding.¹⁵

10. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of Exposure of Workers to Radioactive Material

Petitioners have failed to allege injury-in-fact as a result of exposure of CFC facility workers to *radioactive material*. Petitioners allege that "[i]rradiation facility workers may be exposed to dangerous levels of *radiation*..." and "could spread radioactivity to locations outside the irradiation facility thereby harming proposed intervenors." *Id.* at 10 (emphasis added). This allegation is substantiated by the claim that the above-mentioned 1998 Decatur, Georgia incident involving a leak of cesium-137 from a Category IV irradiator resulted in the spread of radioactivity to location outside the irradiator facility. *Id.*

Petitioners' allegation here is insufficient to fulfill the requirements for standing. Their allegations that irradiation facility workers may be exposed to dangerous levels of radioactive material are insufficient for a grant of standing, because Petitioners do not have legal standing to raise concerns on behalf of workers who are not members of the group requesting a hearing. In fact, the Licensing Board has found that a petitioner cannot assert the rights of third parties as a basis for intervention. *See Detroit Edison Co.*

¹⁵ In addition to security measures implemented by the licensee, the Commission itself issues "irradiator orders" to Part 36 licensees instructing the Radiation Safety Officer (RSO) to implement additional security requirements which are distributed on a "need-to-know" basis. The entities that are permitted to view such orders are determined by the Commission.

(Enrico Fermi Atomic Power Plant, Unit 2), LBP-78-11, 7 NRC 381, 387 *aff'd* ALAB-470, 7 NRC 473 (1978).

Further, Petitioners' assertion that facility workers would be exposed to *radiation* and spread such *radiation* to locations outside the facility is insufficient to demonstrate injury-in-fact. Workers exposed to gamma *radiation* cannot carry such radiation and impact members of the public outside the CFC facility just like person who has just been x-rayed at a hospital cannot carry such radiation outside the hospital and impact the public.

Petitioners also have failed to allege a *viable pathway* through which *radioactive materials* (i.e., cobalt-60) will escape its nickel plating and doubly encapsulation source encapsulations, migrate through the source rack (plenum) and the "shielding" pool water, disperse as airborne particulates through the CFC facility, and reach facility workers causing them harm. In addition, Petitioners do not even allege that such workers will actually come into contact with them or that they will come into contact with any locations outside the facility that could be subject to radioactive material originating from facility workers. Without more, Petitioners allegation is insufficient to demonstrate a *possible and plausible concrete and particularized injury-in-fact* sufficient for a grant of standing.

Petitioners' area of concern with respect to exposure of facility workers to *radioactive materials* or *radiation* is not "germane" to this proceeding. This area of concern cannot be "germane" because Petitioners do not have the standing to raise such an area of concern as no Petitioner is a facility worker. Further, even if they could raise this area of concern, Petitioners have not offered any allegations demonstrating that the

CFC Category III irradiator poses a significant, incremental threat to facility workers or themselves as a result of potential exposure to facility workers above and beyond previously approved Part 36 irradiators. Additionally, Petitioners have not offered any allegations demonstrating how a facility worker contaminated with gamma *radiation* could transmit such radiation to Petitioners since, as stated above, transmitting such radiation is not possible. Therefore, this area of concern is not “germane” to this proceeding.

11. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of Water Dispersion

Petitioners have failed to allege injury-in-fact as a result of water dispersion from the CFC irradiator. Petitioners allege that the “[p]ublic water system may be accidentally, recklessly, or intentionally contaminated with cobalt-60 due to leakage to groundwater.” Petitioners’ August 14, 2003 Brief at 11. This allegation includes a claim that “[p]roposed intervenors health and safety would be jeopardized by contamination of drinking water...” and is substantiated by two alleged examples of incidents where workers released water containing cobalt-60 into the public sewer system. *Id.*

This allegation does not include any statements regarding how cobalt-60 potentially will be released from the irradiator or the CFC facility into public drinking water or the public sewer system, how cobalt-60 will reach Petitioners through drinking water or the public sewer system, and what specific potential harm the cobalt-60 will cause them. Indeed, the “shielding” pool water will not be contaminated with cobalt-60 because the “sealed sources” will be nickel plated and will be contained within doubly encapsulated source encapsulations, a stainless steel source rack (plenum), and a “shielding” pool tank with 14 feet of water above the sources reinforced by a ¼ inch

stainless steel liner, 6 inches of concrete, another ¼ inch stainless steel liner, and another encasement of three and one-half feet of concrete. Also, as stated above, the “shielding” pool does not contain any pipe fittings, plugs or other opening through which cobalt-60 potentially could escape if it could dissolve in water, which it cannot. Additionally, Petitioners examples of previous incidents involving the release of cobalt-60 from the facility by workers is not directly related to the CFC facility and merely serves as a *hypothetical* basis for which a potential release may be conceived. Thus, without more, this speculative allegation of a *hypothetical* potential release of cobalt-60 is insufficient to demonstrate a *possible and plausible concrete and particularized injury-in-fact* for a grant of standing.

Petitioners’ area of concern with respect to potential water dispersion is not “germane” to this proceeding. Petitioners offer no allegations that potential water dispersion from the CFC Category III irradiator poses a significant incremental threat above and beyond Part 36 requirements. There has been no allegation presented that demonstrates a greater potential risk of dispersion of cobalt-60 through water from the CFC facility than from other previously approved Part 36 irradiators. Further, as stated above, cobalt-60 is insoluble in water and Petitioners have not shown a *viable pathway* through which cobalt-60 could migrate through water to Petitioners and present a greater risk of a significant impact than that of previously approved Part 36 irradiators. Thus, this area of concern is not “germane” to this proceeding.

12. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of the Transportation of Cobalt-60

Petitioners have failed to allege injury-in-fact as a result of the transportation of cobalt-60 to the CFC facility. Petitioners allege that “[t]he irradiation facility must be

regularly replenished with cobalt-60, thereby increasing transportation hazards (locally and nationally.” *Id.* at 12. This allegation claims that “[a]n accident involving the transport of cobalt-60 or radioactive waste will expose proposed intervenors to radioactive materials. *Id.* Petitioners claim that these transportation hazards also have applications to potential terrorist activities. *Id.*

This allegation falls short of the requirements for a *plausible concrete and particularized injury-in-fact* for several reasons. Initially, Petitioners’ allegation regarding increases to transportation hazards from the shipment of cobalt-60 to the CFC facility or potential terrorism on a *national basis* is not sufficient for a grant of standing. In Commission practice, as stated above, a “generalized grievance” shared in substantially equal measure by all or a large class of citizens will not result in a *distinct and palpable* harm sufficient to support standing. *See Metropolitan Edison Co.* 18 NRC at 333. Thus, Petitioners’ cannot be granted standing solely on the basis of a *national interest* shared by a large class of citizens in transportation hazards.

In addition, Petitioners’ allegation regarding increases to transportation hazards resulting from the shipment of cobalt-60 to the CFC facility and potential terrorism on a *local basis* is not sufficient for a grant of standing. To the best of CFC’s knowledge, there has never been an instance where members of the public or property suffered harm as a result of the transportation of cobalt-60. While Petitioners go to great length to state that transportation of cobalt-60 will increase local transportation hazards, they do not specifically allege how such transportation hazards will harm them. Petitioners do not allege how cobalt-60 can be released from its DOT-approved transport containers, escape its nickel plating and doubly encapsulated source encapsulations, migrate from an

accident site and reach Petitioners causing them a *possible and plausible concrete and particularized* harm. Therefore, since Petitioners do not allege a *viable pathway* through which cobalt-60 could reach them as a result of a transportation accident, their allegation regarding transportation hazards on a *local basis* is insufficient to demonstrate a *plausible concrete and particularized injury-in-fact*.

Further, Petitioners' area of concern regarding transportation of cobalt-60 to the CFC facility is not "germane" to this proceeding. As stated above, nickel plated cobalt-60 is transported to the CFC facility in NRC-approved doubly encapsulated source encapsulations and in DOT-approved and NRC-reviewed transportation containers for the shipment of radioactive material. This type of transportation mechanism is identical those used by other Part 36 licensees receiving cobalt-60 for use in an irradiator. Petitioners have not presented any allegations showing that such transportation will be conducted in a manner that is different from previously approved methods for transporting cobalt-60 to licensed facilities. Thus, this area of concern is not "germane" to this proceeding.

13. Petitioners Have Not Alleged Injury-In-Fact or a Germane Area of Concern as a Result of Decommissioning and Financial Assurance

Petitioners' allegation that CFC has not set aside adequate financial assurance and has not proposed a decommissioning plan is insufficient for a grant of standing. Petitioners allege that "[t]he applicant has offered the minimum \$75,000 financial assurance, but has not come forward with a decommissioning plan." Petitioners' August 14, 2003 Brief at 14. According to Petitioners, "[p]roposed intervenors may be affected by serious air and water dispersion due to a lack of maintenance." *Id.*

This allegation falls short of fulfilling the requirements for standing. While Petitioners argue that CFC has not submitted a decommissioning plan, they do not allege what type of harm they might suffer as a result. The only allegation which remotely resembles potential harm in a general, conjectural statement that Petitioners “may be affected,” due to a lack of maintenance which has nothing whatsoever to do with a decommissioning plan or financial assurance. *Id.* In addition, CFC’s \$75,000 financial assurance package is submitted in accordance with Part 30 requirements. *See* 10 CFR § 35(d). Therefore, Petitioners’ allegation is insufficient to demonstrate a *plausible concrete and particularized injury-in-fact.*

Petitioners’ allegation also does not present a “germane” area of concern sufficient for the grant of a hearing. Petitioners’ allege that the \$75,000 financial assurance package presented to NRC by CFC is inadequate for decommissioning purposes. However, as stated above, 10 CFR § 30.35(d) requires \$75,000 for facilities using licensed radioactive materials such as CFC. If such requirements in the financial assurance regulations change, CFC and all other Part 36 licensees will have to comply with such changes. Additionally, Petitioners have not provided any allegations regarding how CFC’s compliance with existing NRC regulations will pose a significant, incremental threat above and beyond previously approved activities under Part 36. As such, Petitioners’ area of concern regarding decommissioning and financial assurance is not “germane” to this proceeding.

III. CONCLUSION

For the above-mentioned reasons, CFC respectfully requests that the Presiding Officer deny Petitioners standing because they have failed to demonstrate the requisite standing to intervene in this proceeding and because they have not presented an area of concern which is germane to this proceeding.

Respectfully Submitted,



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COUNSEL FOR CFC LOGISTICS, INC.

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
ATOMIC SAFETY AND LICENSING BOARD**

Before Administrative Judges:

**Michael C. Farrar, Presiding Officer
Charles N. Kelber, Special Assistant**

In the Matter of:
CFC Logistics, Inc.

(Materials License Application)

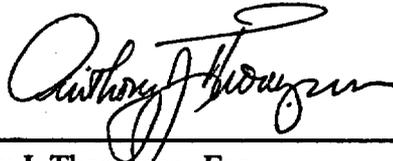
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) Docket No.: 30-36239-ML
)
) ASLBP No.: 03-814-01-ML
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) License No. 132825
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) Date: September 5, 2003
)

CERTIFICATE OF SERVICE

THIS IS TO CERTIFY that a copy of the foregoing CFC Logistics, Inc.'s Response to NRC Staff's Brief on Standing and Petitioners' Areas of Concern in the above-captioned matter has been served upon the following via electronic mail and U.S. First Class Mail on this 5th day of September, 2003.

- | | |
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Staff
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EXHIBIT A



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 27, 2003

Docket No. 03036239

License No. 37-30804-02

James Wood
President
CFC Logistics, Inc.
4000 AM Drive
Quakertown, PA 18951

SUBJECT: INSPECTION 03036239/2003001, CFC LOGISTICS, INC., QUAKERTOWN,
PENNSYLVANIA

Dear Mr. Wood:

From February 13, 2003 through August 6, 2003, Sattar Lodhi, of this office conducted inspections of your activities related to the construction of the Genesis I Irradiator at your facilities at the above address. On April 2, 2003, Surash Chaudhary, and on July 22, and August 6, 2003, Harold Gray of Division of Reactor Safety accompanied Dr. Lodhi to review and discuss various engineering specifications and aspects of the planned irradiator. Information provided during various telephone discussions was also considered during the inspection.

The inspection consisted of evaluation of site characteristics, appropriateness of materials used in the construction and fabrication of components, the procedures followed in the fabrication of various components, adequacy of equipment for the intended service, and discussions with your engineering staff involved in fabrication and installation of various components of the irradiator. The inspections were conducted to verify that the completed facility can be operated safely and meets the applicable NRC requirements. The findings of the inspection were discussed with you and/or members of your organization during various stages of the inspection. A report summarizing the findings of the inspection is enclosed.

Within the scope of this inspection, we conclude the facility has been constructed in accordance with your application for a license.

No reply to this letter is required. In accordance with 10 CFR 2.790, a copy of this letter and the enclosed report will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

J. Wood
CFC Logistics, Inc.

2

Your cooperation with us is appreciated.

Sincerely,

Original signed by John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 030-36239/03-001

cc:
Marie Turner, Radiation Safety Officer
Commonwealth of Pennsylvania

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03036239/2003001
Docket No. 03036239
Licensee: CFC Logistics, Inc.
Location: 4000 AM Drive
Quakertown, PA 18951
Inspection Dates: February 13, 2003 through August 6, 2003

Inspectors: Suresh K. Chaudhary 08/19/03
Suresh K. Chaudhary Date
Reactor Engineer

E. H. Gray 8/20/03
Harold Gray Date
Senior Reactor Engineer

Sattar Lodhi 8/27/03
Sattar Lodhi, Ph.D. Date
Health Physicist

Approved By: John D. Kinneman 8/27/2003
John D. Kinneman, Chief date
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

CFC Logistics, Inc.
NRC Inspection Report No. 03036239/2003001

CFC Logistics, Inc. has applied for an NRC materials license to possess and use sealed sources containing cobalt 60 in a pool irradiator at their Quakertown, Pennsylvania facility. The irradiator will be located at CFC's Quakertown refrigerated storage warehouse for storage of perishable food products. The application requests authorization to use sealed sources containing up to 1,000,000 curies of cobalt 60 in the irradiator. The irradiator will be used to irradiate food items, cosmetics, and pharmaceutical products.

The proposed irradiator is described in CFC's application dated February 19, 2003 (ML030630036). Inspection was conducted from February 13, 2003, to August 6, 2003, to review the fabrication, installation and testing of various components of the irradiator. Staff of the Division of Reactor Safety evaluated site preparation and the material and procedures used in the fabrication of the pool and other structures and found them to be in accordance with standard engineering practices. In addition, the seismic environment of the site and the effect of a seismic event on the facility were considered. The inspectors observed movement and operation of the irradiator components and the system functioned as expected. The inspectors also reviewed the hoists and load bearing components of the system.

The system is designed to meet applicable NRC requirements and has been built in accordance with specifications in the application. The completed concrete and steel structure conforms to the designs and drawings; construction procedures and process controls were adequately implemented to assure conformance to the design specified in the application. The irradiator installation appears to be well designed and well built. The system performed properly during pre-operational demonstrations and procedures appear to be adequate to assure safe operation.

While heavy load drops or seismic events are unlikely, engineering analyses indicate that such events will not result in a loss of source shielding or damage to the radioactive sources that would release cobalt 60 into the pool.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The scope of the inspection was to review the applicant's activities related to construction of a pool irradiator and plans for use of the irradiator upon completion.

b. Observations and Findings

CFC Logistics, Inc., (CFC) originally submitted an application dated January 30, 2003, for a license to construct and operate a pool irradiator at its facility in Quakertown, Pennsylvania. In the application, CFC stated that construction activities were underway. On February 6, 2003, during a telephone conversation with the proposed Radiation Safety Officer (RSO), and in a letter dated February 12, 2003 (ML030440043), Region I reiterated the provisions in 10 CFR 36.15 to CFC that any activities undertaken prior to issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license.

On February 13, 2003, an inspector visited the CFC facility in Quakertown, Pennsylvania, to discuss administrative deficiencies in its application dated January 30, 2003. During the visit the inspector noted that CFC had started preliminary construction work at the site.

Following the February 13 visit, the applicant withdrew the original application and submitted a revised application dated February 19, 2003 (ML030630036) that addressed the administrative deficiencies in its original application. The facility and CFC's activities have been reviewed against the February 19, 2003 application.

NRC inspectors visited the proposed facility on nine occasions to review construction activities and to evaluate various aspects of the design. Three of these visits included staff from the Division of Reactor Safety. Members of NRC Regional management were present during four visits.

II. Management Oversight of the Program

a. Inspection Scope

The scope of the inspection was to verify effective oversight of the program by the applicant's management.

b. Observations and Findings

CFC Logistics, Inc., is a part of Clemens Family Corporation, and James Wood is the President of CFC Logistics, Inc. Activities within CFC are divided into three operations, namely, Warehouse Operations, Administrative Operations, and Irradiator Operations, and each operation has a manager. Thomas Clemens is the Project Manager for the irradiator project and is responsible for all aspects of construction of the irradiator facility. Marie Turner is manager of Irradiator Operations, and is also proposed to be the Radiation Safety Officer (RSO) named on the license. Other members of the Irradiator Operations staff are irradiator operators and material handlers. The RSO reports to the President of CFC and irradiator operators report to the RSO. There will be a Radiation Safety Committee (RSC) to provide supervision to the radiation safety program. Membership of the RSC will include the RSO, an additional management representative and an irradiator operator.

c. Conclusions

The applicant's management structure and the proposed oversight of its activities meet NRC requirements and guidance provided in Section 3 of NUREG 1556, Volume 6.

III. Facilities and Equipment

a. Inspection Scope

The scope of the inspection was to verify that the facilities and equipment are constructed in accordance with the specifications described in the application and meet appropriate NRC requirements and that the applicant has appropriate operating and emergency procedures.

b. Observations and Findings

General Description

The facility is located in Quakertown, Pennsylvania. The facilities are described in the application dated February 19, 2003 (ML030630036), and letters dated April 22, 2003 (ML031210348), June 30, 2003 (ML031960588), July 8, 2003 (ML031900700), and

July 22, 2003 (ML032030333). These documents were reviewed by the NRC staff as part of the licensing process.

The irradiator (trade name GENESIS I) was designed by Gray*Star, Inc. Detailed engineering design and fabrication of all major components, including the electronic controls, were accomplished by Clayton H. Landis Company (CHL) at its Engineering Facility in Souderton, Pennsylvania. CHL contracted with an electrical engineer to develop the electronics and programmable logic controls associated with the irradiator and its operations, including the automated movements of product carriers (bells) into and out of the pool. In addition, CFC hired a third party engineer to witness and record key activities during construction and assembly of the irradiator.

The irradiator is located in an enclosed area within a large hall, one of several that comprise a cold storage facility, at the Quakertown site. The irradiator consists of a shielding pool which is largely below floor level. The radioactive sources will be placed in a source container (or plenum) at the bottom of the pool and will remain there during routine operation. A trolley and hoist system will lift product carriers, place them into the pool for irradiation and then remove them. The water quality in the pool is maintained by a circulating water purification system which draws water from the pool, runs it through a resin filtration system, and returns the water to the pool. The water circulation system is equipped to continuously monitor the conductivity of the pool water to assure compliance with 10 CFR 36.63. A radiation detector near the resin filter is designed to detect increases of radioactivity in the water.

The pool is a double-walled rectangular box prefabricated at CHL Engineering facilities. The application includes a diagram of the pool on page 47, and a copy of the diagram is shown in Figure 1 (also at ML03161057) of this report. The inner walls are made of ¼ inch thick stainless steel and the outer walls are made of ¼ inch thick carbon steel. The inner and outer walls are 6 inches apart and on each side of the pool structure the walls are joined by two 6-inch steel "I" beams welded lengthwise between them. The 6-inch wide space between the inner and outer walls was filled with concrete after the pool was placed on the concrete foundation. Within the emplacement at the site, the outer walls of the pool are surrounded by cement grout. The open edge of the pool is 42 inches above the floor which provides a barrier to prevent personnel from inadvertently falling into the pool. The main pool is connected to a smaller pool to hold water displaced by the product bells when they are lowered into the main pool.

The pool does not have any penetrations below the safe water limit level. Losses of water from evaporation and normal use will be made up by manually operating a valve. All connections to the pool are designed to prevent any loss of pool water due to siphoning. (10 CFR 36.33)

The source container or plenum is fixed at the bottom of the pool by a retaining mechanism. It is locked in place at the top of the pool by a locking bar and only authorized individuals have access to the key to unlock the retaining mechanism. The locking bar spans the width of the pool and divides the pool in half. The plenum

containing sealed sources remains fixed at the bottom of the pool during normal operations. Should it be necessary to raise the plenum, the sources will be removed from the plenum before it is raised. The plenum is lowered or raised mechanically only after unlocking the retaining mechanism and breaking a safety seal.

A diagram of the plenum is provided on page 49 of the application and Figure 2 (also at ML031610287) of this report. The plenum consists of 16-3 inch diameter vertical stainless steel tubes arranged in a vertical plane. Holders or racks containing the sources are inserted into these tubes. After loading, each tube is closed and sealed with a plug, and water is pushed from the tubes using compressed air, so that the sources are not in contact with pool water during operation. Then a pump continuously circulates air through the plenum tubes and a high efficiency particulate air (HEPA) filter. A radiation detector continuously monitors the air filter for radioactivity thereby providing a means to check for a leaking source. Another radiation detector monitors the radiation dose rate at the surface of the pool. The tubes that carry the air from the surface to the plenum and back to the surface are configured in such a way that there is no direct path for radiation from the sources to the surface. CFC plans to give particular attention to these tubes during the radiation survey after the sources are loaded.

Each of the three radiation monitors (air filter, resin filter and pool surface) have audio and visual alarms should the radiation level exceed the preset limit.

Procedures for operating the various systems, including the associated radiation safety and emergency procedures were reviewed.

Review of Construction Activities

An inspector observed the excavation for the pool on February 13, 2003. The field inspection report prepared by the applicant's independent engineering/geology company during excavation for the pool stated that the ground in the excavation was rocky and characterized the first 8 feet of excavation below floor surface as red/brown clayey gravel, followed by another 8 feet of layered red fractured shale in transition to penetrating 4 to 5 feet into the bedrock (red shale) at the bottom of excavation. The report also states that the bedrock is solid with no signs of fissure, and approved a bearing capacity of 2000 lbs/sq.ft.

Inspectors visited the both the irradiator facility and the fabrication shop at various times to verify the adequacy and acceptability of the construction material, techniques of construction, and conformance of the completed structure to design specification and drawings to those specified in the license application. An inspector reviewed the documentation for the foundation bearing capacity test, structural concrete inspection report, concrete mix design, and seven (7) and twenty-eight (28) day compressive strength tests for structural concrete and cement grout, and backfill concrete reports. The in-place pool, concrete floor around the pool, the pool upper structure, and the steel

frame for the mechanical hoist and monorail were also reviewed during assembly and when completed.

Inspectors also visited the nearby fabrication facility and observed various components being fabricated/assembled, including the completed double-walled pool, before it was placed in the excavation. An inspector reviewed the welding procedures and specifications, the nondestructive evaluation (NDE) of finished welds of the pool, and the qualifications of the welders, to verify conformance of the fabricated pool to the design specified in the application. The applicant's records indicated that the pool structure was successfully tested for leakage on July 11, 2002 (10 CFR 36.41(c)).

On July 22, 2003, and August 6, 2003, the inspectors visited the facility in Quakertown to review the performance of the completed mechanical components of the irradiator without radioactive sources installed. The inspectors observed complete cycles of the movements of the bells into and out of the pool and around the overhead monorail. An inspector observed a demonstration of response of the bell carriers in case of power failures on July 24, 2003, and noted that the bells came to a standstill when the electrical power to the system was turned off.

The inspectors reviewed operation of the water purification system on August 6, 2003, and noted that the conductivity of pool water was approximately 9.5 microsiemens/cm. 10 CFR 36.63 requires that the conductivity of the pool water remain less than 20 microsiemens/cm under normal circumstances.

c. Conclusions

Design, fabrication and assembly of irradiator components at CHL facilities, and construction at the site in Quakertown has been adequately supervised by the respective project managers.

Observations and comparisons of components to the engineering drawings and their description in the application confirmed the applicant's conclusions that the facility has been constructed in accordance with the specifications and drawings included in the application as supplemented by the additional submissions and in accordance with good engineering and construction practices. The completed concrete and steel structures conform to the design and drawings specified in the application; construction procedures and process controls were adequately implemented to assure conformance to the specified design.

Dry runs of the equipment observed during inspections demonstrated that the equipment functioned as designed.

IV. Radiation Safety Procedures

a. Inspection Scope

The scope of the inspection was to review the applicant's radiation safety procedures.

b. Observations and Findings

The inspectors discussed CFC's plans for conducting surveys during and following the loading of the sources and for evaluating the exposures of staff. The applicant plans to have a licensed organization supervise the source loading and provide training for their staff in the procedures for source handling and loading. The procedures for operating the pool water circulation system, the associated radiation monitor and the radiation monitors on the air system and near the pool were reviewed.

c. Conclusions

The applicant has adequate plans and procedures for conducting surveys during the loading of the sources and operation. The applicant's planned radiation survey instrumentation is adequate. Procedures for operating the pool water system and the radiation monitors are adequate.

V. Emergency Procedures

a. Inspection Scope

The scope of the inspection was to review the applicant's emergency procedures.

b. Observations and Findings

The applicant's emergency procedures and plans for implementation were reviewed and discussed with CFC staff. The applicant's procedures address the applicable issues required by 10 CFR 36.53, including loss of electrical power, abnormal radiation levels and suspected personnel overexposure. The inspectors determined that the RSO is knowledgeable of the trigger levels for emergency procedures and actions that need to take place. The inspectors also reviewed CFC's actions to familiarize and train police and emergency responders. CFC indicated that they have held at least three sessions with police, local fire fighters, emergency management personnel, other local government staff and emergency medical responders (ambulance). Sessions included review of the characteristics of radiation, tour of the facility, discussion of responsibilities of CFC staff (RSO and operators) and other appropriate topics. Training for fire fighters, ambulance and emergency responders was greater than two hours in length. Training

for police was somewhat shorter. An inspector contacted management representatives for the police and fire fighters and confirmed the training occurred as stated.

c. Conclusions

The applicant has adequate emergency procedures and plans for implementation. The applicant intends to assure that local emergency workers and first responders have appropriate information concerning the facility.

VI. Security Systems and Procedures

a. Inspection Scope

The scope of the inspection was to review the features of the facility associated with security and the applicant's procedures for assuring appropriate implementation of those features.

b. Observations and Findings

CFC included in the design specific features to provide for effective access control. Access to the irradiator enclosure is restricted and the facility is equipped with intrusion alarms. Inspectors reviewed the applicant's proposed security systems and access control procedures. The inspectors determined that representatives of the Pennsylvania State Police have visited the facility and discussed their capabilities for response, if needed.

c. Conclusions

The facility includes appropriate design features for a security program. The applicant's procedures are adequate to assure that only authorized individuals are allowed access to the irradiator and to detect attempted unauthorized access.

VII. Engineering and Design Evaluation

a. Inspection Scope

The inspectors evaluated the design, engineering practices, and material used in the fabrication of various components, and integrity and capacity of the assembled components to perform their respective tasks. This included a review of adequacy of the pool integrity, overhead crane-hoist supporting track and the hoist as-designed and as-built capability to handle working loads, plans for in-service maintenance and testing, and an evaluation of the response of the facility to load drops either from equipment

failure or a seismic event although the probability and the expected magnitude of a seismic event are low.

b. Observations and Findings

The inspectors reviewed the design parameters and adequacy of various equipment for service and held discussions with CHL engineers regarding the design.

Hoist Design and Heavy Load Handling

The inspectors discussed and reviewed: the design load limit for various components including the attachment lifting lugs; the cable and cable connector strength and test results; cable strength specification versus the load requirements, the hoist motor horsepower versus the load limitation for motor stalling before exceeding the load limit, safety considerations and control system response in case of a power failure during load lifting/moving sequence; and hoist and supporting structure susceptibility to a credible seismic event (earthquake). The inspectors discussed with CHL engineers the design of the overhead crane-hoist supporting track and the hoist as-designed and as-built capability to handle the working loads of placing loaded containers into and out of the pool. The inspectors also reviewed calculations related to the strength of various components of the system and their ability to withstand static and dynamic stresses during normal operation and those caused by a failure of the support cables.

The inspectors noted that the hoist cable test assembly, with lifting fittings part numbers 651 and 653, the two types used for lifting the bell assembly, was tested to failure and demonstrated a tensile strength of 24,410 pounds (lbs). This was over 3.2 times the maximum weight of the loaded bell, which is approximately 7,500 lbs. Because there are two lifting cables per bell, the hoist cables provide an overall safety factor on lifting of 6.5.

Load Drop

While a load drop is unlikely, the significance of such a drop was evaluated by the inspectors. The inspectors reviewed the features which assure pool integrity and the possible damage to the pool structure or the plenum and sources in the event that a loaded bell falls on the structure. This included discussions with CHL engineers and a review of drawings and calculations performed by CHL. Based on their review and discussions with the CHL engineers, the inspectors concluded that, due to the geometry of the product containers (or bells) and the pool, including the locking bar, the following scenarios involving a dropped bell needed to be examined further:

- (1) a dropped bell which strikes the edge of the pool directly or at an angle (as a result of a single cable failure);

- (2) a dropped bell directly over the pool which enters the pool perfectly upright within the constraints of the stainless steel guide rails;
- (3) a dropped bell that strikes the locking bar;
- (4) a dropped bell that falls away from the pool.

The inspectors' assessment of the impacts of a falling bell under these scenarios is as follows:

Scenario (1): The structural strength of the pool edges and its capability to resist impact is quite high since the upper pool edge is capped with ¼ inch thick stainless steel over a structure of ¼ inch thick stainless steel inner wall, 6 inches of 4,000 pounds per square inch (psi) strength concrete reinforced by twin steel I-beams on each side of the pool, and an outer carbon steel wall. Because of this robust structure, dropping a bell even from the maximum height of the hoist onto the pool edge is expected to result in only minor surface denting and/or scratching. The inspectors concluded that, under this scenario, damage to the pool liner resulting in loss of shielding and damage to the sources was not credible.

Scenario (2): The inspectors determined that, in the event of a potential crane failure or load drop directly over the pool, the bell would either fall straight into the pool following the guide rack or strike at an angle and not fully enter the pool. Because the clearances between the bell and the sides of the pool are very small - approximately ½ inch - the bell is much more likely to become stuck than to enter the pool unimpeded. However, if the bell were to enter the pool in free fall, its velocity would be impeded by the hydraulic dampening of the pool water flow reduction. The bell is not likely to have an adverse effect on the plenum because of this reduction in velocity, the stainless steel guide rails that are designed to prevent the bell hitting any part of the plenum or the pool liner, and the inherent strength of the plenum. In the event that the bell strikes the edge of the pool at an angle, only minor surface dents or surfaces is expected as noted in Scenario 1 above. In either case - a falling bell that becomes stuck in the pool opening or one that enters the pool itself - damage to the pool liner resulting in loss of shielding or to the sources in the plenum are not considered credible.

Scenario (3): Under the scenario, a dropped bell would impact on the locking bar that sits on top of the pool. The bar is made of 1/4 inch thick stainless steel plate formed to a 5 inch wide channel shape with 3.5 inch high edges spanning a pool inner width of 68 inches. Downward deformation of the lock bar approximately ½ inch would result in contact with other structural members in the pool effectively reducing the span distance to 58 inches. The lock bar is bolted to the pool edges at both ends by ½ inch diameter F593C-TME bolts and is boxed in at both ends by bolted stainless steel components that also provides support to bell guides. The span of the lock bar between the boxed in areas is 50.5 inches. This results in the lock bar being fixed and strengthened at both ends such that it is much stronger than a simple 5x3.5 inch channel.

Only considering the vertical sides (2x3.5 inch) and 1 inch of the horizontal section of the lock bar, there is (8" length x 1/4" thickness) 2 square inches of loadable cross-section of stainless steel in the lock bar. Stainless steel has a strength of 75,000 psi minimum. Using a safety factor of 4, two square inches would support a load of 37,000 lbs in tension or 18,750 lbs in shear. This compares favorably to the total weight of a load bell and its maximum load which is approximately 7,500 lbs or a loading of approximately 3750 lbs with one cable remaining functional.

CHL drawing No. 33248-205-242-001, Rev 1, shown in Figure 3, presents a calculation of the strength of the lock bar showing vertical strengths of the lock bar to be 5231 lbs at its center line and 11664 lbs at 8.75 inches inside the inner pool edge. The vertical strength of the lock bar at its center line (5231 lbs) is less than the maximum weight (7,500 lbs) of a loaded bell. However, this is not of safety concern because if only one cable fails, the bell will swing and one of its lower edges will strike the lock bar at a point away from the center line. On the other hand, if both cables fail, the weight of the bell will be at the ends of the lock bar because the bell is open at the bottom. Furthermore, the lock bar also has extra support at each end that effectively reduces the "free" length of the bar to approximately 58 inches, which is less than the length of the bell (approximately 66 inches). Therefore the weight of a fallen bell will be on the sections of the lock bar that have additional support. Accordingly, the inspectors concluded that, under this scenario, damage to the pool liner resulting in loss of shielding or damage to the sources was not credible.

Scenario (4): The inspectors concluded that if the bell were to fall away from the pool, striking the concrete floor or any ancillary equipment, the result would not be a loss of shielding or damage to the sources.

Seismic Event

10 CFR 36 applies certain design considerations for shielding walls at panoramic irradiators located in seismic areas. Although these considerations do not apply to underwater irradiators such as the one constructed by CFC, the staff evaluated seismic hazards for the CFC facility.

The staff consulted the U.S. Geological Survey (USGS) National Earthquake Information Center web site as well as the Limerick Generating Station Final Safety Analysis Report. Those sources indicated that the Quakertown area is physically located between the Piedmont Lowland section of the Piedmont physiographic province and the Reading Prong section of the New England physiographic province. A review of historic seismic events within 200 miles of the Quakertown area indicates that the highest intensity event recorded was a level VII on the Modified Mercalli Intensity Scale (MMIS). The USGS describes the effect of such an event as "Damage negligible in buildings of good design; slight to moderate in well-built ordinary structures; considerable damage in poorly built or badly designed structures; some chimneys broken." USGS data indicate that over a 50 year period in the Quakertown area, there is a 2% occurrence probability of a seismic

event with peak ground acceleration (PGA) of 0.16g (0.16 times the acceleration of gravity). Given that the projected operational life of the irradiator is less than 50 years, the likelihood of an event of this magnitude is considered low.

The staff's observations during visits to the facility, review of the design drawings, and conversations with the design engineers led to the conclusion that the final pool structure is a robust one. Accordingly, a seismic event that reaches the intensity described above is likely to result in negligible or no damage to the pool. Damage could occur to the support structure for the product delivery system as a result of ground acceleration, but the pool and the sources within the pool are expected to be unaffected. Based on review of the design and observation of the placement of the pool, seismic activity of the intensity typical of the region is not expected to adversely affect the sources in the pool.

If a seismic event were to occur while the bell was in the pool, the bell's lateral motion would be limited by the ½ inch clearance to the guide rails. The motion is not expected to have a significant effect on the pool structure. A seismic event while the bell is outside of the pool guide rails would result in the bell being fixed in space by inertia while the earth, building and crane move in the seismic wave. This would stress the hoist cables in the same way as an impact load; however, with a demonstrated safety factor of three on each of the two redundant cables, failure of either is not credible at the expected maximum seismic loading. This extra lifting safety factor discussed above is useful in evaluating the significance of a seismic event even in the more severe condition of having one lift cable severed. As noted above, the peak ground acceleration in the Quakertown area is projected to be 0.16g. This represents a maximum loading that is a small fraction of the loaded bell weight. In comparison to a seismic event magnitude of 0.16 g, the stress on the one remaining cable after severing of the other represents a bounding or maximum loading condition. In this case, the bell would be supported by the remaining cable with a safety factor of over 3, which is an acceptable condition. If a seismic event occurred while the bell was above the pool and caused a hoist or the load support failure, the dropping bell would have the same effect as discussed in the scenarios above.

c. Conclusions

The irradiator installation appears to be adequately designed and constructed. The system performed properly during operational demonstrations and procedures appear to be adequate to assure safe operation.

The motor hoist, cables and associated frame are adequate for carrying the intended loads. The system is designed against a motor driven component failure by having the motor stall horsepower below the torque level required to fail any component in the lifting train. Based on review of all the available information, a load drop is considered an unlikely event. In the event of a load drop under the four scenarios described above, the damage to the pool liner or irradiator assemblies are not credible results and damage to the pool's upper structure will be limited to minor dents or scratches on the top surfaces.



A crane failure or load drop anywhere in the building except directly over the pool would neither damage the sources nor lead to a loss of shielding.

These evaluations of the damage to the pool structure in case of a loaded bell falling on the structure, are in agreement with the applicant's evaluation described in its letter dated July 22, 2003 (ML032030333), in response to NRC's letter dated July 18, 2003 (ML032020137).

The pool structure and the plenum are also not expected to suffer any significant damage due to a seismic event of Level VII intensity on the modified Mercalli scale.

VIII. Exit Meeting

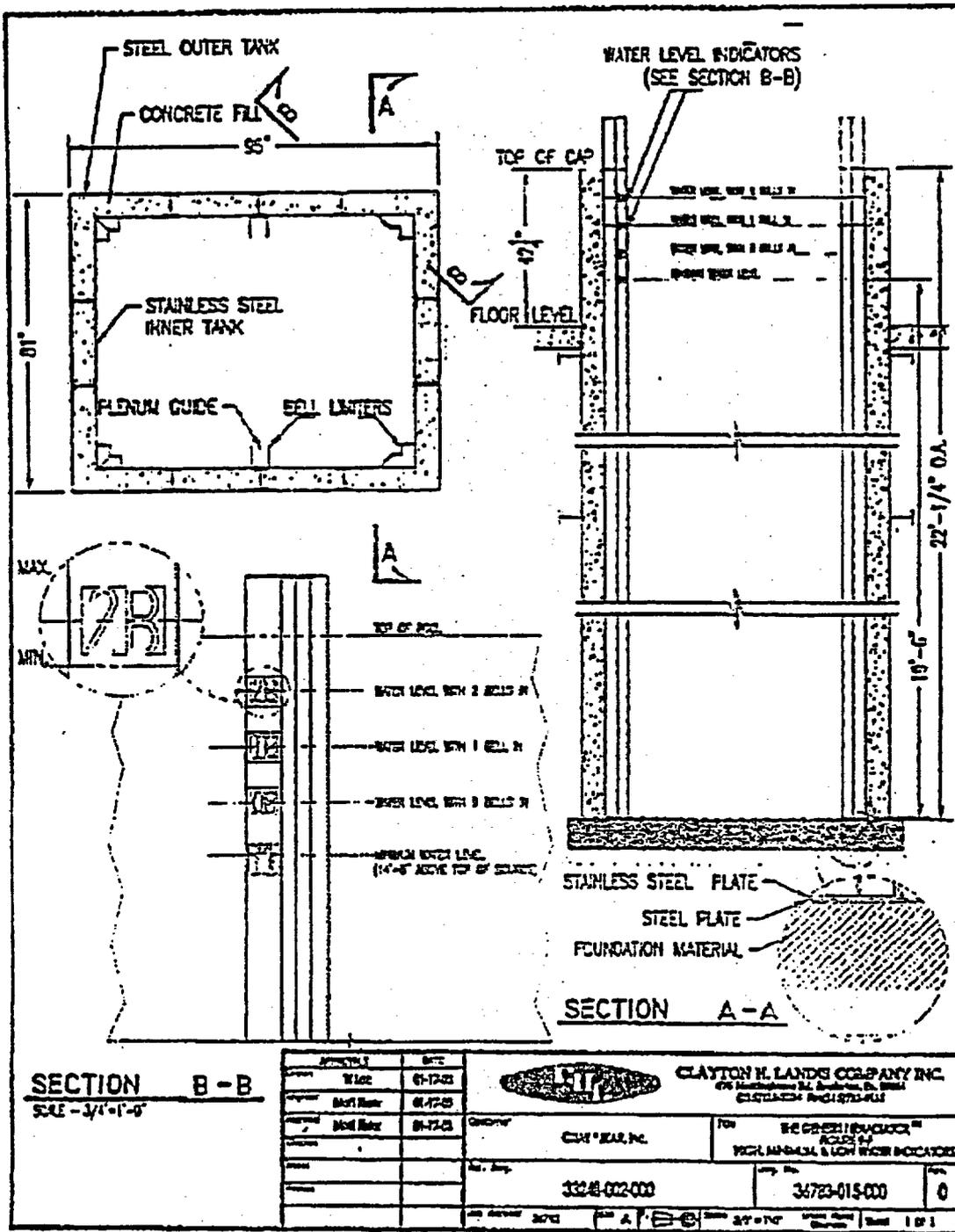
During each visit to the facility the inspector met with the applicant's management to discuss the various stages of construction of the irradiator. The inspector explained to the management NRC's procedure for review of a license application and its final disposition.

PARTIAL LIST OF PERSONS CONTACTED

Applicant

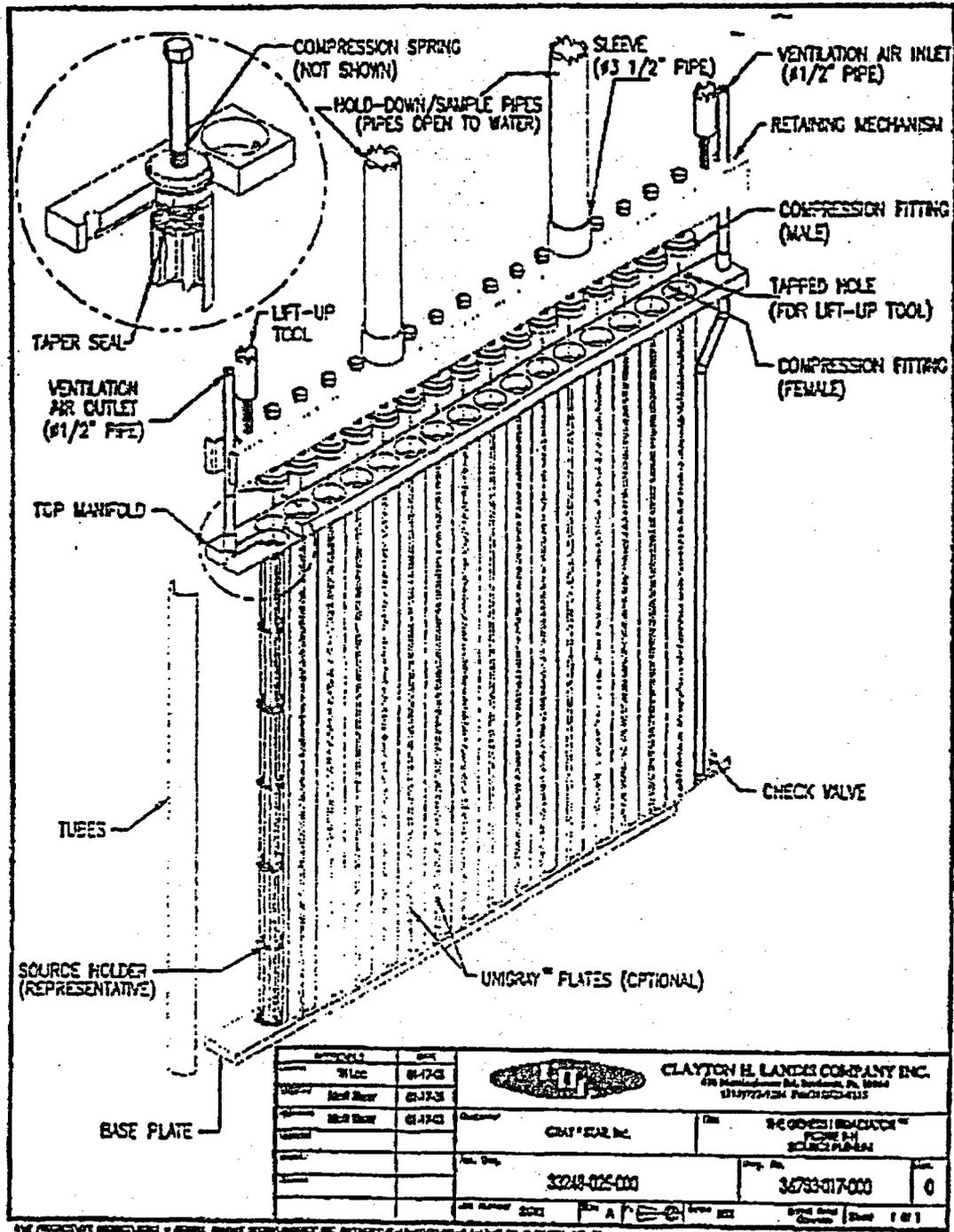
James Wood, President, CFC Logistics, Inc.
Marie Turner, Manager, Product Irradiations, CFC Logistics, Inc.
Thomas Clemens, Project Manager, CFC Logistics, Inc.
David Blattner, Irradiator Operator In Training, CFC Logistics, Inc.
Russell Stein, Vice President, Gray*Star, Inc.
Martin Stein, President/CEO, Gray*Star, Inc.
Rick Keiper, Project Manager, Clayton H. Landis Company, Inc.
Matthew Risser, Engineering Manager, Clayton H. Landis Company, Inc.
Kevin C. Landis, Engineer, Clayton H. Landis Company, Inc.
Andrew Landis, Engineer, Clayton H. Landis Company, Inc.
Joseph Paddock, Electrical Engineer, Clayton H. Landis Company, Inc.

FIGURE 1



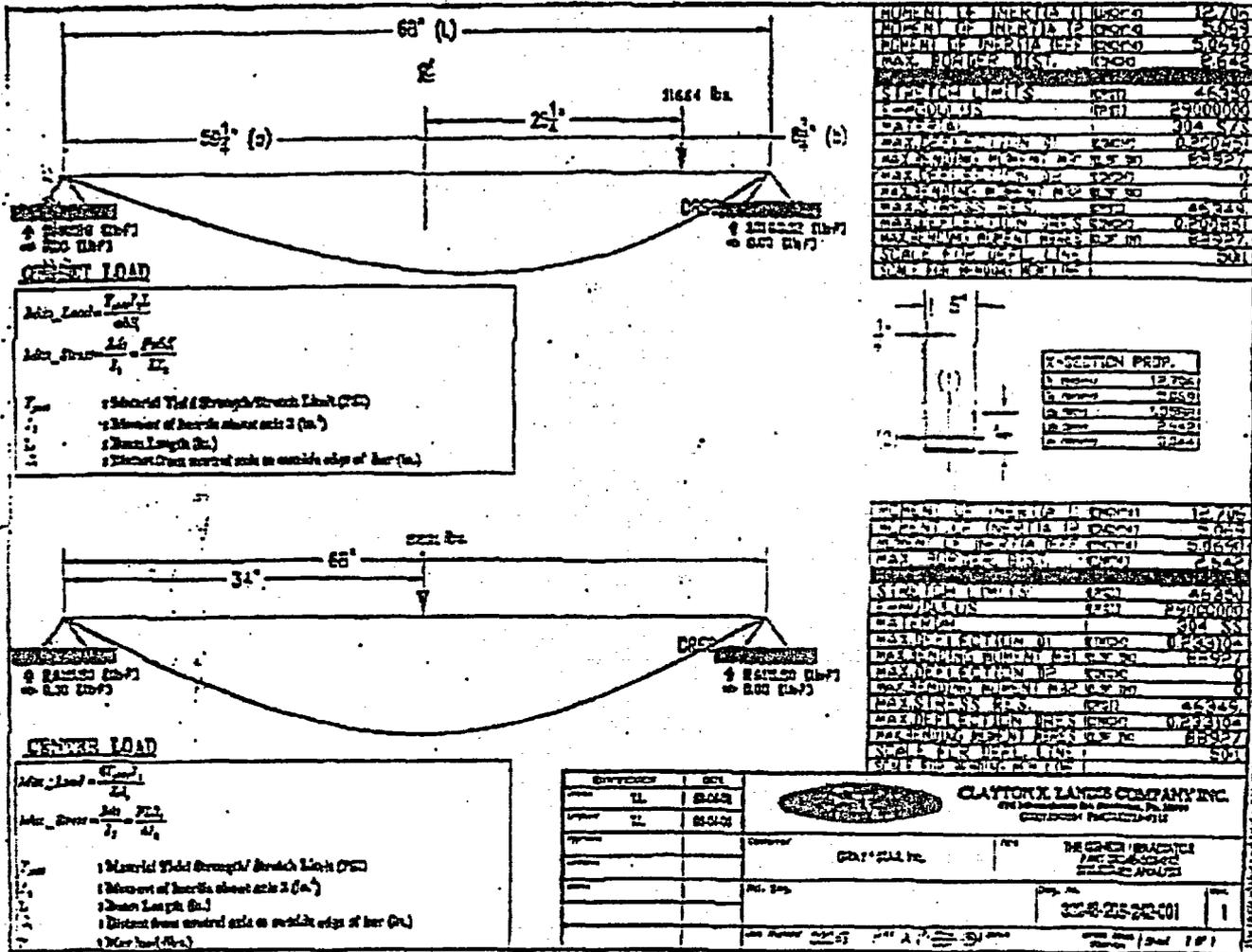
See also ML031610044

FIGURE 2



See also ML03160287

FIGURE 3



See also ML032250045

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September 5, 2003

BY ELECTRONIC, FACSIMILE AND U.S. FIRST CLASS MAIL

U.S. Nuclear Regulatory Commission
Office of the Secretary
Attn: Rulemaking and Adjudications Staff
One White Flint North
11555 Rockville Pike
Rockville, MD 20852

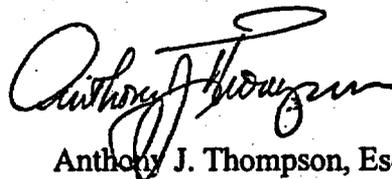
Re: In the Matter of: CFC Logistics, Inc.
Docket No: 3036239-ML
ASLBP No. 03-814-01-ML
License No. 132825

Dear Sir or Madam:

Please find attached for filing CFC Logistics, Inc.'s Response to NRC Staff's Brief on Standing and Petitioners' Areas of Concern in the above-captioned matter. Copies of the enclosed have been served on the parties indicated on the enclosed certificate of service. Additionally, please return a file-stamped copy in the self-addressed, postage prepaid envelope attached herewith.

If you have any questions, please feel free to contact me at (202) 496-0780. Thank you for your time and consideration in this matter.

Sincerely,



Anthony J. Thompson, Esq.
Christopher S. Pugsley, Esq.
Law Offices of Anthony J. Thompson, P.C.
Counsel of Record to IUSA

Enclosures

CFCCOVERLETTTER1.DOC)