

February 27, 2004

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED
USNRC

February 27, 2004 (4:06PM)

BEFORE THE PRESIDING OFFICER

In the Matter of)	
)	Docket No. 30-36239-ML
CFC LOGISTICS, INC.)	
)	ASLBP No. 03-814-01-ML
(Materials License))	
)	

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

NRC STAFF RESPONSE TO PENDING MOTIONS

INTRODUCTION

On February 17, 2004 the Presiding Officer issued a "Prehearing Order (Regarding NRC Staff Participation and Other Matters)," (Prehearing Order). The Presiding Officer, pursuant to his authority under 10 C.F.R. § 2.1213,¹ directed the NRC Staff (Staff) to furnish its views on the Intervenor² "Renewed Motion for Stay," dated November 13, 2003 (Stay Motion) and their "Request for Reference to Commission," dated December 1, 2003 (Reference Request). More specifically, the Presiding Officer stated: "...the Staff should in its brief address, in addition to any other matters it wishes to discuss, the matters listed in the Appendix to this Order (pp. 7-9, below)." Prehearing Order at 3, *emphasis in original*. The Appendix contained questions for the Staff to address in its brief. The first three groups of questions represent the Presiding Officer's distillation and restatement of proposed questions submitted by the Intervenor and the Licensee,

¹ 10 C.F.R. § 2.1213, "Role of the NRC staff," provides, in pertinent part:

...upon a determination by the presiding officer that the resolution of any issue in the proceeding would be aided materially by the staff's participation in the proceeding as a party, the presiding officer may order or permit the NRC staff to participate as a party with respect to that particular issue.

² The Intervenor is 25 residents of Milford Township, Pennsylvania. See letter from Robert Sugarman, Esq. to John Kinneman, dated June 23, 2003, and "Designation of Presiding Officer," dated July 14, 2004.

CFC Logistics, Inc. (CFC-L). In paragraph D of the Appendix, the Presiding Officer listed four additional questions proposed by the Intervenors that the Staff was requested to address. Prehearing Order at 9. Finally, the Presiding Officer requested the Staff to review the remaining proposed questions of the parties to determine if answers to any of them were necessary to put on the record the bases for the Staff's actions with respect to the application and the license. *Id.*

Pursuant to the directions and invitation of the Presiding Officer, the Staff addresses below all of the questions set forth in the Appendix to the Prehearing Order. As permitted by the Presiding Officer, the Staff has combined Questions 1 and 2 on page 9 of the Appendix, with related questions in the Appendix. Questions 3 and 4 on page 9 of the Appendix are addressed separately in this response. In accordance with the option provided by the Presiding Officer (Prehearing Order at 3), the Staff has no further matters it believes necessary to provide in response to the two pending motions.

RESPONSES TO QUESTIONS

APPENDIX A

BACKGROUND

"In support of a stay, the intervenors assert that the terms of the sales contract refer to the irradiator as a 'prototype' and thus render its operation 'experimental.'"

QUESTION 1 Was the Staff aware of all of the terms of that contract when it approved the license?

ANSWER

The Staff reviewers of the CFC-L application had not seen the sales contract between CFC-L and the designer of the GENESIS I irradiator, GrayStar, at the time that the Staff approved and issued the license. Therefore, the Staff was not aware of its terms.

QUESTION 2 If so, why did the Staff conclude that those contract terms did not require denial or conditioning of the license (and by extension thus do not now support the grant of the requested stay motion)?

ANSWER

Not applicable. See Answer to A.1, above.

QUESTION 3 If not, does the Staff believe that those contract terms do support the grant of the requested stay motion?

ANSWER

The Staff does not believe that the terms of the sales contract describing the GENESIS I irradiator as a "prototype" provide any basis for a stay of the license. According to Webster's Third New International Dictionary (unabridged) (1986), the first meaning of "prototype" is "an original on which a thing is modeled." With respect to science and engineering, the definition is "the first full-scale model of a new type or design of ... machinery" The Staff believes that the Intervenor place more significance upon GrayStar's use of the term "prototype" in the contract than the term can bear. The simple fact that a facility for which an NRC license is sought contains some "prototypical" aspects does not mean that the applicant cannot demonstrate compliance with NRC licensing requirements. The Intervenor's position is not made more persuasive by characterizing the GENESIS I irradiator as "experimental." That characterization does not appear to be a fair reflection of the evolutionary state of the art regarding irradiators. The GENESIS I irradiator had to stand on its own merits with respect to NRC's review, irrespective of whether it was a new or an older design.

Further, from a regulatory perspective, what matters is whether the proposed facility met NRC licensing requirements. The application provided a description of any distinctive aspects of the proposed facility, so that the Staff was able to perform an informed review. See the February 19, 2003 application (ML030630036). To the extent that the Staff had remaining questions after reviewing the application, formal and informal requests for additional information were made of the applicant, and amendatory information was submitted by CFC-L. See CFC-L's letters amending the license application (ML031210348, letter dated April 22, 2003), (ML031960588, letter dated

June 30, 2003), (ML031900700, letter dated July 8, 2003), and (ML032030333, letter dated July 22, 2003). The distinctive aspects of the GENESIS I include principally the use of the dry plenum as the structure housing the sources; and the heavy, but thin-walled, bells to contain product. However, it is common for an application for an NRC license to contain some “new” or “unique” aspects. The Staff is accustomed to reviewing new or unique designs. There is nothing inherent in an application having “prototypical” aspects that prevents the applicant from meeting the NRC licensing requirements. Based upon its review of the application, as amended, the Staff concluded that the application met the NRC’s licensing requirements and that the new design aspects did not represent a radiological health and safety issue. See Inspection Report dated August 27, 2003, issued in support of the license approval (ML032390328).

APPENDIX B

BACKGROUND

“The intervenors assert that certain statements by the irradiator designer and by a Company contractor indicate that a particular aspect of the irradiator created an unsafe condition. See, e.g., Exhibit C to stay motion. Prior to the receipt of any cobalt sources, the Company arranged for that condition to be changed to eliminate the assertedly unsafe condition. The NRC Staff rejected as inadequately supported, however, the Company’s application for a license amendment to incorporate that change. The Company thereupon undid the change, putting the irradiator back in its original, assertedly unsafe, condition.”

QUESTION 1 At what point was the Staff aware of the Company contractors’ and the irradiator designer’s expressed safety concerns?

ANSWER

The Staff was not the recipient of any information directly from REVISS (the contractor who manufactured and supplied the sealed sources) regarding the check valve. The Staff originally heard about an issue regarding the check valve through a telephone conversation with CFC-L on

September 25, 2003 (ML032760410). Also, according to a record of a September 30, 2003 telephone conversation between Dr. Sattar Lodhi (NRC) and Dr. Russell Stein (GrayStar) (ML032760410), Dr. Stein characterized the plenum without the check valve, and with a plug in its place, as being "much better and safer." Thus, the Staff first became aware of the issue on September 25, 2003 and first heard it described as a "safety" issue on September 30, 2003.

QUESTION 2 What is the Staff's current position as to the safety of the above-mentioned condition and what is the basis for that position? (See also Tr. 299-300, where the Staff at one point agreed to address similar matters.)

ANSWER

The operation of the GENESIS I irradiator, with the submitted design of the check valve installed on the bottom of the plenum, does not present a safety problem. The Staff discussed these matters with representatives of CFC-L and C. H. Landis, CFC-L's engineering consultant. See telephone log at ML032760410. CFC-L and Landis reported that they had removed the check valve because REVISS had expressed a concern that leakage of the valve might cause deposits on the sources which, in turn, might affect the cladding over time. The Staff evaluated the concern, as presented during conversations with the licensee by telephone and during an inspection associated with the first delivery of the sources. See ML032760410 and ML033080387.

The sources are qualified for in-air and in-water storage and CFC-L must maintain the water in the pool at the high level of purity required by 10 C.F.R. § 36.63. For these reasons, operation of the irradiator with the installed check valve, rather than a plug, provides the requisite protection of the public health and safety from radiological hazards.

The staff is combining with its Answer B.2, its response to Question D.1 ("Was a record made of Reviss' expressed concerns about irradiator safety; if not, why not?") and Question D.2 ("Did the Staff address the merits of Reviss' concerns and, if so, what determinations were made thereon and where are those determinations reflected? If not, do those concerns now need to be

addressed?"). The REVISS concern was recorded by the Staff and it was addressed on the merits. The recording of the concern and the Staff's evaluation thereof are found the telephone logs and the Inspection Report referenced earlier in this Answer. See ML032760410 and ML033080387.

APPENDIX C

BACKGROUND

"The Rules of Practice prohibit discovery in proceedings of this nature. In lieu thereof, the NRC Staff prepares and files a "hearing record" presumably containing the documents upon which the Staff based its determination to award the license."

QUESTION 1 Were any of the documents and/or information now sought by the intervenors considered by the NRC Staff when it passed on the validity of the license?

ANSWER

In licensing the CFC-L irradiator, the members of the Staff who performed the application review did not consider any documents and/or information that are not either publicly available in ADAMS or have been provided to the Intervenors under Protective Order.

QUESTION 2 If so, why are they not part of the hearing file? If not, why are they not relevant to a determination of the validity of the license?

ANSWER

All non-proprietary and non-Safeguards documents related to the licensing of the CFC-L irradiator are in the publicly available hearing file. Proprietary documents that bear upon the facility's licensing were previously provided to the Intervenors under Protective Order. The documents and/or information now requested by the Intervenors go beyond the scope of information required by the Staff in connection with licensing. The licensing requirements are principally set forth in 10 C.F.R. Parts 20, 30, and 36. These Parts of the Commission's regulations establish the information that CFC-L was required to submit. The Staff's findings as to the application are set forth in the Inspection Report, dated August 27, 2003 (ML032390328). Thus,

the documents now requested by the Intervenors are not relevant to the Staff's determination as to the issuance of the license.

QUESTION 3 Based upon the answers to the above questions, what action does the Staff urge us to taken the intervenors' document-related motion, given the language and purpose of the rules applicable to proceedings of this nature?

ANSWER

The Commission's "Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings," Subpart L to 10 C.F.R. Part 2 expressly prohibit discovery. See 10 C.F.R. § 2.1231(d): "A party ... may not seek discovery from any other party ... or the NRC or its personnel, whether by document production, deposition, interrogatories, or otherwise." Instead, the Staff is required to establish and maintain a "hearing file." See 10 C.F.R. § 2.1231(a). The hearing file shall contain:

... the application and any amendment thereto, any environmental impact statement or assessment relating to the application, and any NRC report and any correspondence between the applicant and the NRC that is relevant to the application.

See 10 C.F.R. § 2.1231(b). As reflected in previous responses, above, the Staff *has* established a hearing file for this proceeding.

The Intervenors seek in their Reference Request to have the Presiding Officer refer to the Commission for determination the matter of whether the circumstances of this case mandate that the prohibition on discovery be waived in this proceeding. Reference Request at 1. In order for the Presiding Officer to certify such a question to the Commission, the Intervenors must demonstrate that: "... special circumstances exist so that application of the regulation to the subject matter of the proceeding would not serve the purpose for which the regulation was adopted." See 10 C.F.R. § 2.1239(b). That paragraph of the regulations further provides that: "In the absence of a *prima facie* showing of special circumstances, the Presiding Officer may not further consider the matter."

The Intervenors state in their Reference Request, at 1, that: "The basis of the request includes the disclosure that the facility is still 'developmental', while in operation. Moreover, the nuclear vendor, Reviss, objected to the facility layout, fearing that it might cause concerns for accidents through corrosion of plenum." As discussed, above, in Answer B.2, it is common for a facility that is the subject of a license application to have some new or unique aspects to it. That fact does not, however, bear upon whether the applicant demonstrates that it meets the NRC's licensing requirements. The CFC-L application, as amended in response to the Staff's requests for additional information, provided the requisite basis for the Staff to grant the requested license. The Staff had all of the design information needed to determine compliance with licensing requirements. The additional documents now requested by Intervenors do not contain any new information that causes the Staff to change its licensing decision.

Answer B.2 also addresses the concern raised by REVISS about the long-term effect on the cladding enclosing the sealed sources of unexpected exposure to water as a result of postulated leakage through the check valve. This matter has been fully addressed by the Staff, as reflected in telephone logs and an Inspection Report referenced in Answer B.2.

Intervenors also assert as basis for their Reference Request (at 2) that:

The National Environmental Policy Act ("NEPA") 42 USC § 4321 requires that full disclosure be made of environmental impacts and documents considered or utilized in evaluating environmental impacts. Full disclosure is required under this section and case law authority. Regulation 10 CFR § 2.1231 stands in the way of NEPA and the Commission should reverse them so they are consistent.

As stated, the Intervenors here are requesting a change to 10 C.F.R. § 2.1231, more specifically, the removal of 10 C.F.R. § 2.1231(d) from the NRC's regulations. A request of this type must be made through a petition for rulemaking. Were the Staff to consider the wording as support for the waiver request, the mere reference to a statute as requiring full disclosure of environmental impacts does not support waiver of regulations that provide for such full disclosure through the hearing file, and prohibit discovery on that basis.

In summary, the Intervenors have failed to demonstrate “special circumstances” supporting the waiver of the Commission’s regulations that do not provide for discovery in Subart L proceedings.

APPENDIX D

BACKGROUND

In Section D of the Appendix, the Staff was also asked to address four additional questions from those suggested by the Intervenors. Questions D.1 and D.2 have been answered above.

QUESTION 3 What consequences should flow from an irradiator licensee’s unapproved modification of its facility when no source is present and what steps does the Staff take to approve the return of the facility to its original condition?

ANSWER

With respect to this facility, License Condition 18 provides that: “The licensee is not authorized to make modifications to the source plenum described in the application dated February 19, 2003, without specific authorization by the Commission.” The so-called “test” involving removing the check valve at the bottom of the plenum and replacing it with a plug took place sometime during September 2003. Consequently, that action was undertaken by CFC-L after the license was issued and was inconsistent with the License Condition. The Staff did, however, take into consideration the fact that the sources had not yet been delivered when the alteration of the plenum was undertaken. After reviewing the removal of the check valve and CFC-L’s reinstallation of the valve as soon as the Staff advised CFC-L that such an activity was prohibited by the license, the Staff concluded it would not cite CFC-L for a violation. A decision not to take enforcement action does not, however, mean that the Staff is not requiring a licensee to take actions to avoid repetition of an identified problem. In this case, the Staff requested that CFC-L address in writing how it would strengthen management controls to assure that required procedures are followed, and CFC-L provided a response considered acceptable by the Staff. See letter and inspection report at ML033080387 and licensee response at ML033350161.

QUESTION 4

Where is the heat calculation for the full load of sources in operation? Are you willing to release it? Please advise whether you will release all assumptions and input which formed the basis of the calculation.

ANSWER

In an April 18, 2003 response to a Staff request for additional information, GrayStar provided source temperature calculations based upon an assumed "full licensed capacity of 1,000,000 curies." See ML031210348 (specifically, the April 18, 2003 letter). This letter includes a statement of all of the assumptions, methodologies, equation references, and results. It also contains the calculations performed and graphs generated. The Staff reviewed this material and found it acceptable for licensing. Accordingly, the requested heat calculations have already been provided.

CONCLUSION

The Staff submits the above responses to questions as its brief in reply to the Stay Motion and the Referral Request.

Respectfully submitted,



Stephen H. Lewis
Counsel for NRC Staff

Dated at Rockville, Maryland
this 27th day of February, 2004

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE PRESIDING OFFICER

In the matter)	
)	Docket No. 302-362339-ML
CFC LOGISTICS, INC.)	
)	ASLBP No. 03-814-01-ML
(Materials License))	
)	

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing "NRC STAFF RESPONSE TO PENDING MOTIONS" have been served upon the persons listed below by 1st class U.S. mail, or through deposit in the Nuclear Regulatory Commission's internal mail system, as indicated with an asterisk, and by electronic mail, as indicated with a double asterisk, this 27th day of February, 2004.

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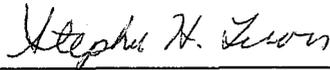
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