September 13, 2006

MEMORANDUM TO: Joseph Giitter, Chief
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Division of Fuel Cycle Safety
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SUBJECT: RESPONSE TO AUGUST 4, 2006, MEMORANDUM ENTITLED "UNITED STATES ENRICHMENT CORPORATION LICENSE DETAIL REGARDING THE LEVEL OF INFORMATION NEEDED FOR 10 CFR PART 70 LICENSING"

This memorandum is in response to your recent request for comments on the subject Division policy statement of August 4, 2006 (ML062160073). We'd like to thank you for the opportunity to comment on such an important regulatory and safety matter. This is a very important issue that will affect future applications for new Part 70 licenses, and it is therefore important that all staff in Fuel Cycle Safety and Safeguards (FCSS) have a shared understanding of the regulatory basis for licensing new facilities. With regard specifically to the United States Enrichment Corporation (USEC), we believe that the Division should take the initiative to make the final version of this policy available to the Hearing Board, since this was the basis for licensing the facility. Doing so will demonstrate that we are in full support of this policy and are taking the Agency's Strategic Goal of Openness seriously.

We believe there are significant shortcomings with both the policy statement and the policy itself. In particular, we believe that the policy as stated in the subject memo is inconsistent with the requirements of 10 CFR Part 70, Subpart H. The use of such a policy for licensing new fuel facilities would therefore likely require a rule change, as explained below. We hope that you will give these comments due consideration. Should this not be resolved satisfactorily, we may be required to use the mechanisms provided in Management Directive 10.159, "Differing Professional Views or Opinions," to achieve a satisfactory outcome.

DISCUSSION

The subject memo itself discusses the Division's plans for performing the Integrated Safety Analysis (ISA) Summary update reviews and the Operational Readiness Review (ORR). We believe that this represents a sound plan for ensuring the facility will be built and operated safely and in accordance with NRC requirements.

However, we do have many substantive comments on the memo's enclosure entitled "Level of Information Needed for 10 CFR Part 70 Licensing." We have divided the enclosure into four sections: (1) a summary of applicable regulations, (2) a discussion of the reasonable assurance standard and level of detail needed for licensing, (3) a discussion of other regulatory requirements such as the ISA Summary updates, the 10 CFR 70.72 change process, and the ORR, and (4) an overall summary discussion. For convenience, these are discussed separately below:

Summary of Applicable Regulations

The first section of the enclosure to the subject memo is a summary of some of the applicable regulatory requirements. Our major comment on this section is that it is an incomplete list of the applicable regulations, and does not provide a full picture of what is required for licensing. Two of what we believe are key provisions, included in the memo, are:

10 CFR 70.65(b)(3) and 70.65(b)(6) require that the ISA Summary must contain:

> A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to §70.62(c)(1)(i)–(iii) and a general description of the types of accident sequences.
>
> A list briefly describing each item relied on for safety which is identified pursuant to §70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of §70.61. (Underlined for emphasis)

The key provision, which was not included in the memo, is 10 CFR 70.66(a):

> An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of §70.21, 70.22, 70.23, and 70.60 through 70.65.

The significance of this is that it provides a complete list of *all* requirements that must be met for licensing, and makes it clear that they must be met *prior to* the NRC granting a license. The licensing review, as can be seen from 10 CFR 70.66(a), includes review of a license application and an ISA Summary (among other documents). Both portions of the licensing review involve the review of both programmatic commitments and technical (i.e., facility- and process-specific) information. Historically, before the revision to Part 70, licenses typically consisted of two parts:

Part I contained enforceable commitments, mainly programmatic but also some technical, and Part II contained a Safety Demonstration. Under the new Subpart H requirements, the amount of technical information that must be reviewed has only increased, including review of the ISA Summary. The memo suggests that a licensing review is purely programmatic, which was not before and is not now a correct statement.

The memo's conclusion that 10 CFR Part 70 licensing "focuses on the programmatic provisions of the applicant's proposed activities" is contradicted by 10 CFR 70.22(a)(7) and 70.23(a)(3), to which the memo actually makes reference, as well as 10 CFR 70.22(a)(8) and 70.23(a)(4). These are:

> Each application for a license shall contain the following information...(7) A description of equipment and facilities which will be used by the applicant to protect health and minimize danger to life or property...(8) Proposed procedures to protect health and minimize danger to life or property [10 CFR 70.22(a)]

> (a) An application for a license will be approved if the Commission determines that: (3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property...(4) The applicant's proposed procedures to protect health and to minimize danger to life or property are adequate. [10 CFR 70.23(a)]

To these requirements have been added those of from Subpart H, including 10 CFR 70.61:

> (b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely...

> (c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed so that, upon implementation of such controls, the event is unlikely...

> (d) ...The risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical...

> (e) Each engineered or administrative control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program...shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements.

In addition to those paragraphs you listed in 10 CFR 70.65, paragraph 70.65(b)(4) states that the ISA Summary must contain:

> (4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61...

Taking these various regulations together, the staff must find that the applicant "has complied" with the various requirements listed in 10 CFR 70.66(a). These include 70.61(b), (c), and (d), as emphasized in 10 CFR 70.65(b)(4), as well as 70.65(b)(3) and (b)(6). Because the phrase "has complied with" is in the present perfect tense, these regulations must have been met prior to granting a license. This is also true in 10 CFR 70.23(a), which states that an application for a license will be approved if the Commission determines that "the applicant's proposed equipment and facilities are adequate." As indicated in the underlined text above, these contain the word "each" numerous times: "each process," "each item relied on for safety," "each credible...event," "each engineered or administrative control system," or, equivalently, "all nuclear processes." The use of this terminology in the rule, on so many occasions, and the use of the past tense in 10 CFR 70.23(a) and 70.66(a), indicates that the staff must find that the applicant has identified each credible event, each item relied on for safety, etc., and described equipment and facilities in sufficient detail prior to granting a license.

We therefore believe that the memo in its current form, by selectively citing only certain parts of the regulations, mistakenly de-emphasizes the importance of the technical review, which relies on review of the design, and over-emphasizes the review of programmatic commitments.

Reasonable Assurance Standard and Level of Detail

The second section of the attachment extrapolates from this summary of the regulations to make conclusions about the level of detail required for granting a license. The key portion is the first paragraph to this section, which is reproduced in full below, along with our comments interspersed throughout, in italics:

(1) "In 10 CFR Part 70 licensing, the staff uses a reasonable assurance standard and focuses on the programmatic provisions of the applicant's proposed activities. This is reflected in the above licensing requirements that talk about, 'sufficient detail to understand the theory of operation,' or a list 'briefly describing each item relied on for safety ... in sufficient detail to understand their functions in relation to the performance requirements.'"

We discussed the mis-characterization of the licensing review as being purely programmatic earlier. The phrases cited in this subsection are taken from 10 CFR 70.65(b)(3), which deals with the ISA review, not the review of programmatic commitments in the license application, and therefore this subsection is self-contradictory.

The phrase "sufficient detail to understand their functions" means that sufficient information must be submitted for the staff to perform a technical review to determine the adequacy of each IROFS (more than just a review focused on programmatic provisions). Thus, our view is that each IROFS must be identified, and that it must be described in sufficient detail to understand how it works and meets 10 CFR 70.61.

(2) "This is also reflected in the various chapters of the standard review plan, NUREG-1520, 'Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility'" (SRP).

We disagree that the SRP supports a staff review focusing solely on programmatic provisions. The SRP discusses both programmatic and technical aspects of the review in detail. (See our discussion on the intent of the SRP below.)

(3) "Based on this understanding, the licensing review needs to focus on the applicant's programmatic commitments and, consequently, the licensing decision is ultimately based on a sufficient level of detail to understand process system functions and functionally how items relied on for safety can perform their intended function and be reliable."

We discussed the mis-characterization of the licensing review as being purely programmatic earlier. This is an even more egregious example of this, because the reference to "process system functions" and "items relied on for safety" does not flow logically from the direction to "focus on the applicant's programmatic commitments."

(4) "The reasonable assurance standard is applied such that the staff decision pertains to a reasonable assurance that the integrated safety analysis summary is complete and the licensee will follow its integrated safety analysis approach and maintain it consistent with the regulations."

We agree with this statement. The staff must make a reasonable assurance finding that the ISA Summary is complete. This is also borne out by the use of the terms "each" and "all" numerous times in the regulations.

(5) "The level of detail required for a licensing decision, therefore, does not require a final facility design or an absolutely complete identification of all items relied on for safety and accident sequences,"

This directly contradicts the preceding sentence. Part (4) says the staff must have reasonable assurance that the ISA Summary is complete. Part (5), however, says that it does not have to be "absolutely complete." We do not understand the distinction between being "complete" and "absolutely complete."

In order to perform a complete ISA (which the memo states twice is required), the facility design must be sufficiently developed so that a comprehensive accident analysis can be performed; a "complete" ISA involves, as stated in the aforementioned regulations, both the identification and description of each hazard, accident sequence, IROFS, and management measure. In order to describe these items "in sufficient detail" (or in any detail), they must first be identified.

[This paragraph redacted]

the integrity of pigtails and piping connections, increasing the likelihood of a chemical release. Or the refrigerant could be a source of moderator or some uranium might get trapped in the cooling system. With this level of design, the staff cannot determine whether these potential accident sequences are credible and should be included in the ISA Summary. Until the staff has assurance that all credible accident sequences have been identified, the staff cannot

determine whether each IROFS has been identified.

In addition, there must a complete design at a sufficient level of detail for the staff to be able to determine adequacy of the IROFS. Until the staff has assurance that all IROFS have been identified and described in sufficient detail, the staff cannot determine that the ISA is complete and the design is adequate, which must occur to permit licensing.

(6) "but instead sufficient information has to be provided to understand the process and functions of items relied on for safety and reasonable assurance that the integrated safety analysis summary is complete."

This agrees with Part (4) above, but does not agree with Part (5). Part (4) says that the ISA Summary must be complete. Part (5) says that it does not have to be "absolutely complete" (since the IROFS description is part of the ISA Summary). Part (6) says that it does have to be complete. We do not understand the Agency's position on this question, but note you used the term "reasonable assurance that the integrated safety analysis summary is complete" twice.

Our view is that we agree with Parts (4) and (6) above, but do not agree with Part (5), which is inconsistent with the rest of the paragraph and with the regulations. To summarize, the major flaws in this paragraph are listed below:

- The discussion over-emphasizes the programmatic review, which does not alone answer the question of whether the applicant has met the requirements of 10 CFR 70.66(a), etc. The applicant must identify each IROFS and describe them in sufficient detail for the staff to conclude that the equipment and facility (which includes its IROFS) are adequate.

- The "sufficient detail" phrase and "reasonable assurance" standard are inappropriately used to justify why all accident sequences and IROFS do not need to be identified and adequately described.

- The discussion contradicts itself several times, first saying that the ISA Summary must be complete, then saying that it does not have to be complete, then saying that it must be complete. The distinction between "complete" and "absolutely complete" is unclear.

Other Regulatory Requirements

The third section of the enclosure to your memorandum mentions other regulatory requirements that must be considered. These include the ORR pursuant to 10 CFR 70.32(k) and the 10 CFR 70.72 change process. With regard to the ORR, we believe the intent of 10 CFR 70.32(k) is to confirm that the plant is constructed in accordance with the license, which should have included a description of the completed design. Its intent was not to allow the staff to the review of the design completed after the license was issued as an inspection activity. With regard to 10 CFR 70.72, this cannot be meaningfully applied until there is a completed baseline design from which future incremental changes are made. For example, it is unclear

how one would apply the “equivalent replacement” criterion if all of the IROFS have not been identified and described in sufficient detail at the time of licensing. In addition, the 70.72 process does not take effect until, as the memo noted, “after receiving its license,” and therefore does not help the staff determine that 10 CFR 70.66(a) is met prior to issuance of the license.

Summary Discussion

The fourth and final section of the enclosure to your memorandum makes several statements with regard to the licensing of the Louisiana Energy Services (LES) facility. A similar approach was used for both LES and for USEC. However, one important distinction that must be made is that LES was based on an existing facility, whereas USEC is not (though there was a partially completed centrifuge of earlier vintage in Portsmouth, Ohio, and a lead cascade facility that has limited chemical hazards and no criticality hazards). This is an important distinction, because it means that LES had a much better idea of exactly how the processes would be conducted and the equipment that would be used. (We understand the LES facility will be very similar to the plant in Almelo, Netherlands.) This fact provides much greater assurance that all accident sequences and IROFS have been identified. In addition, this discussion is not convincing because, to our knowledge, the staff has not made a detailed comparison between the two licensing actions with regard to completeness of the design. There is therefore no basis on which to judge whether the same licensing process can be adequately applied to both facilities or, if applied, will result in the same outcome.

The summary states:

> The Atomic Safety and Licensing Board (ASLB) concluded that based on its review the staff had adequately performed its environmental and safety reviews and a license could be issued. The ASLB decisions confirm that the above approach meets the legal requirements in 10 CFR Parts 40 and 70. Therefore, the approach can be directly applied to the USEC Inc. American Centrifuge Plant.

This is a non sequitur. The fact that ASLB did not identify any problems with the licensing does not mean that none exist. This would only be a relevant statement if the ASLB made some definite pronouncement on the design issue; it is our understanding from discussions with GCFLS and OGC that there is nothing in the record that definitively addresses this. It could simply be that the ASLB did not focus on this issue or realize the level of design. Our review of the LES SER indicates that the wording was chosen carefully, and was significantly revised during management review, so as to not draw attention to this issue. And as stated above, even if the correct outcome was achieved on LES, this does not necessarily mean that it can be applied to USEC. It could simply be that the LES design was substantially more complete than the USEC design.

Your summary also states:

> The fact that the LES plant is based on a facility currently operating in Europe has no effect on the licensing basis used to issue the LES license. The licensing bases for a

> uranium enrichment facility are solely the regulations in 10 CFR Part 40 and 70 and are not dependent on operations of similar facilities located elsewhere.

We disagree with this, based on discussions with technical staff involved in the LES review. Considerable weight was given to the fact that LES was based on an existing facility. Also, if the Almelo facility had no bearing on the LES licensing decision, then there is no justification for expending resources to send staff to the Netherlands. We take the position that the existence of the Almelo facility was important to reaching a licensing decision. At a minimum, it gave the staff a clearer picture of how the facility would operate and provided assurance that a nearly identical facility would be operated safely. Beyond that, the personnel involved in the performing the ISA had experience with those other facilities, and this experience, presumably, facilitated their safety analysis; we are aware of instances in which "operational experience" was used as justification for some issue by the applicant. It would be irresponsible of staff to disregard this valuable information, which would not be consistent with risk-informed and performance-based regulation. It would likewise be irresponsible for the staff to rely on "solely the regulations in 10 CFR Parts 40 and 70" and not to use their expertise and knowledge gained in reviewing other fuel cycle facilities or other experiences. We therefore do not consider this statement to be accurate.

Much discussion has been made concerning the intent of 10 CFR Part 70 and the SRP. In the following section, we provide some additional background from the SRP that contradicts some of the assertions in the policy memo.

Intent of NUREG-1520

The SRP contains a considerable amount of detail on the issue of completeness of the ISA Summary. NUREG-1520, Section 3.4.3.2, "ISA Summary and ISA Documentation," contains acceptance criteria for the staff's review of the ISA Summary. SRP Section 3.4.3.2 contains a list of nine items, which is identical to the list in 10 CFR 70.65(b), many of which have been discussed above.

The sections of 10 CFR 70.65(b) cited earlier were paragraphs (3), (4), and (6). With regard to paragraph 70.65(b)(3), page 3-13 (all page numbers refer to the SRP) states:

> The description of the processes analyzed as part of the ISA...is considered acceptable if it describes the following features in sufficient detail to permit an understanding of the theory of operation, and to assess compliance with the performance requirements of 10 CFR 70.61. A description at a systems level is acceptable, provided it permits the NRC reviewer to adequately evaluate (1) the completeness of the hazard and accident identification tasks, and (2) the likelihood and consequences of the accidents identified.

Clearly, the phrase "in sufficient detail" is not understood to mean that there can be incomplete identification of the hazards and accident sequences. Also, a system-level description may be acceptable, but is not automatically acceptable (it is only acceptable if it permits the findings in the paragraph above to be made). Finally, there is an expectation that all hazards and accident sequences have been identified.

Note that information listed on page 3-13 as appropriate process information includes: general arrangement, function, and operation of major components in the process; drawings; process schematics; chemical flow sheets; location and geometry of fissile and other materials; and process operating ranges and limits for measured process variables. This represents a level of design exceeding what was available to the staff during the USEC review, for certain portions of the facility.

Page 3-13 goes on to state:

> The description of process hazards provided in the ISA Summary is acceptable if it identifies, for each process, all types of hazards that are relevant to determine compliance with the performance criteria of 10 CFR 70.61. That is, the acceptance criterion is completeness. All hazards that could result in an accident sequence in which the consequences could exceed the performance requirements of 10 CFR 70.61 should be listed, even if later analysis of a particular hazard shows that resulting accident sequences do not exceed these limits. Otherwise the reviewer(s) cannot determine completeness.

This is very emphatic in explaining that, in determining whether the applicant has complied with 10 CFR 70.65(b)(4), there must be complete identification of hazards and accident sequences; the determination of this completeness is the main objective of this part of the review.

With regard to the completeness of accident sequences, page 3-14 states:

> The general description of types of accident sequences in the ISA Summary is acceptable if the reviewer can determine the following considerations:
>
> a. The applicant has identified all accidents for which the consequences could exceed the performance requirements of 10 CFR 70.61;
>
> b. The applicant has identified how the IROFS listed in the ISA Summary protect against each such type of accident.

Again, there is an expectation of completeness. “General types of accident sequences” differ if they consist of a different set of IROFS or failures (page 3-14). Completeness is expanded on at the bottom of this page.

> To demonstrate completeness, the description of general types of accident sequences must be identified using systematic methods and consistent references. Therefore, each description of a general type of accident sequence is acceptable if it meets the following criteria:
>
> a. An acceptable method of hazard identification and process hazard analysis was used in accordance with the criteria of NUREG-1513.
>
> b. The selected method was correctly applied.
>
> c. The applicant did not overlook any accident sequence for which the consequences

could exceed the performance requirements of 10 CFR 70.61.

d. The applicant used a method of identifying facility processes that ensures identification of all processes.

With regard to paragraph 70.65(b)(4), page 3-15 states that there are three elements to the performance requirements: (a) completeness, (b) consequences, and (c) likelihood. This is what the SRP says about completeness:

> Completeness refers to the fact that the ISA must address each [emphasis contained in original] credible event....Completeness is demonstrated by correctly applying an appropriate accident identification method, as described in NUREG-1513, "Integrated Safety Analysis Guidance Document." Completeness can be effectively displayed by using an appropriate diagram or description of the identified accidents. Specific acceptance criteria for completeness are covered in item 3 above.

Some staff has taken the position that completeness is defined by following an approved and systematic method. We believe this addresses only the first of the four criteria that have to be met, however. The method must also be "correctly applied." Of primary importance are the last two items; the last, in particular, underscores the necessity of having a complete understanding of the process as a prerequisite to performing a complete ISA.

With regard to paragraph 70.65(b)(6), page 3-21 states:

> The 'list describing items relied on for safety' required by 10 CFR 70.62(c)(vi) is acceptable, provided the following conditions are met:
>
> a. The list includes all IROFS in the identified high and intermediate consequence accident sequences. [emphasis included in the original]
>
> b. The description of the IROFS includes management measures applied to the IROFS (including the safety grading), characteristics of its preventive, mitigative, or other safety function, and assumptions and conditions under which the item is relied on to support compliance with the performance requirements of 10 CFR 70.61. If information on any safety limits and safety margins associated with an IROFS is not provided in the ISA Summary, it must be available for review in ISA documentation onsite.

This is expanded on below, also on page 3-21:

> a. All items: The primary function of the list describing each IROFS is to document the safety basis of all processes in the facility...Thus, the key feature of this list is that all [emphasis included in the original] IROFS are included. To be acceptable, no item, aspect, feature, or property of a process that is needed to show compliance with the safety performance requirements of the regulation may be left off the list.

This then discusses the level of detail for the description of all IROFS:

...the ISA documentation maintained onsite, such as system schematics and/or descriptive lists,

should contain sufficient detail about items within a hardware IROFS, such that it is clear to the reviewer(s) and the applicant, what structure, system, equipment, or component is included within the hardware IROFS' boundary and would, therefore, be subject to management measures specified by the applicant. Some examples of items within a hardware IROFS are detectors, sensors, electronics, cables, valves, piping, tanks, dykes [sic], etc. In addition, ISA documentation should also identify essential utilities and support systems on which the IROFS depend to perform its intended functions. Some examples of these are backup batteries, air supply, steam supply, etc.

> b. Description of items: The essential features of each IROFS should be described. Sufficient information should be provided about engineered hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability...For IROFS that are administrative controls, the nature of the action or the prohibition involved must be described sufficiently to permit an understanding that, in principle, adherence to it should be reliable.

The above excerpts from the SRP indicate that the applicant should identify all hazards and accident sequences, all IROFS needed to protect against them, with sufficiently detailed descriptions for the staff to determine adequacy, and must provide a good description of process equipment and flow in order to provide assurance that the ISA Summary is complete. Considerable additional guidance follows in the SRP, both for engineered and administrative controls, but clearly all IROFS have to be identified and the expectation is there is a reasonable amount of design information available to allow staff to make its determinations.

In addition, from a technical standpoint, it is simply not possible to perform a complete ISA without a complete understanding of the facility processes and a complete process design. While this is not explicitly stated in the regulation, it flows as a practical necessity that flows from the rule and underlies all the aforementioned quotes from the SRP.

Summary

In summary, we consider the policy in the subject memo to be self-contradictory and in conflict with both the rule and the SRP, and needs to be significantly revised. We would be available to assist in this effort. In addition, given the fact that the design and construction of a facility takes a number of years and there is an apparent desire to not delay the licensing until the end of this process, we urge you to consider a rule change. Either way, the policy must be consistent with the rule.

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