

THE U.S. NUCLEAR REGULATORY COMMISSION RESPONSE TO
APRIL 16, 2010 BACKFITTING CLAIM OF LOUISIANCA ENERGY SERVICES AS
SUPPLEMENTED ON MAY 4, 2010

INTRODUCTION

On April 16, 2010, Louisiana Energy Services, LLC (LES) submitted a backfitting claim to the U.S. Nuclear Regulatory Commission (NRC) concerning the National Enrichment Facility (NEF) located in Eunice, New Mexico (Agencywide Document Access and Management System [ADAMS] No. ML101380179). On May 4, 2010, LES submitted supplemental information pertaining to its backfit claim (ADAMS No. ML101260131). LES contends that the NRC staff (staff) has taken a new position with respect to the definition of boundaries for certain administrative controls which are categorized as items relied on for safety (IROFS). Specifically, LES contends that the NRC staff position, that certain monitoring equipment necessary to perform the administrative operator action must be categorized as within the IROFS boundary for IROFS C6, 38 and 42, is a new position constituting backfitting under The *Code of Federal Regulations* (10 CFR) 70.76. According to LES, imposing this “new” staff position would require that these processes, instruments or controls meet the applicable industry codes and standards imposed on such IROFS under the LES materials license, SNM-2010. LES states its belief that the staff position constitutes a backfit for which a backfit analysis has not been undertaken as required by § 70.76.

This document presents the NRC staff’s analysis and basis for its conclusion that the staff’s position on the two IROFS does not constitute backfitting under § 70.76.¹ In addition, this

¹ LES’s backfitting claim addresses three specific IROFS that it identified in its SAR and ISA Summary: IROFS C6, IROFS 38, and IROFS 42. Because the NRC staff (staff) has not performed an inspection of IROFS 42, and this IROFS is not necessary for initial plant operations, this document is limited solely to IROFS C6 and 38.

document presents the staff's basis for its determination that LES is not in compliance with IROFS C6 and 38, and License Condition 20.

BACKGROUND

A. LES's License Application and the NRC Staff's Review

On December 12, 2003, LES submitted an application to the NRC requesting a license under 10 CFR Parts 30, 40, and 70, to possess and use byproduct, source, and special nuclear material (SNM) in a uranium enrichment facility, namely the NEF (ML040020256). In June 2005, the NRC staff issued its Safety Evaluation Report (SER) for the NEF in which it documented its review and safety and safeguards evaluation of the application.² As part of the licensing review, the NRC staff reviewed the safety program as detailed in the Integrated Safety Analysis (ISA) Summary submitted by LES in accordance with 10 CFR 70.62(c)(3)(ii) and 70.65,³ along with portions of LES's ISA and Safety Analysis Report (SAR).⁴ As the proposed facility design was not complete at the time of the staff's review, the staff's review was based on a conceptual construct provided by the licensee. In recognition of this fact, the SER issued by the staff stated the staff's understanding of the preliminary design basis and established contingencies in the event that some of the design elements contemplated were modified prior to finalization.

In section 3.8 of its SAR, LES listed all IROFS designated for high- and intermediate-consequence accident sequences for the proposed facility based on the preliminary design. LES also committed to designing, constructing, testing and maintaining all IROFS to Quality Assurance (QA) Level 1. Given the preliminary nature of the design upon which the IROFS were designated and summarily described, the staff expressed a specific concern regarding

² Safety Evaluation Report for the National Enrichment Facility in Lea County, New Mexico, NUREG-1827, June 2005 (ADAMS No. ML051780290).

³ National Enrichment Facility Integrated Safety Analysis, Revision 4, 2005.

⁴ National Enrichment Facility Safety Analysis Report, Revision 6, 2005.

modification of the IROFS to include, among other things, digital controls and instrumentation, without prior NRC approval. Accordingly, the SER provides,

Since the proposed design, which is not complete at the time of this review, does not include IROFS that use software, firmware, microcode, [programmable logic controllers (PLCs)], and/or any digital device, including hardware devices which implement data communication protocols, the staff finds the current applicant commitments satisfactory. However, should the applicant choose to implement design changes to include any of the preceding features, prior NRC approval will be necessary (see License Condition No.1 in Section 3.4 of this SER).

In the facility SAR, the applicant provided preliminary design basis information for [Instrumentation and Control (I&C)] systems that it identified as IROFS for the facility. The design information is at the system functional level. Individual components and vendors had not yet been selected. Based on the staff's review of the SAR, supporting information provided by the applicant, and the applicant's commitments to the industry standards and guidance cited in the sections above for I&C systems, the staff finds that the preliminary design meets the requirements of 10 CFR 70.61 and 70.64(a)(10).

Given that these conclusions are based on preliminary design information and the possibility that the applicant may choose to implement design changes as discussed in the previous section on I&C, the staff is imposing a license condition to ensure that the final design is adequate and acceptable to the staff.

Safety Evaluation Report, NUREG-1827, pg. 3-35.

In response to a staff issued request for additional information (ML042950558), LES further clarified that,

[T]he IROFS are defined at the functional level. Upon completion of the design of each of the IROFS, the IROFS boundaries will be defined. In defining the boundaries for each IROFS, LES procedure DP-ISA-1.1, "IROFS Boundary Definition," will be used. This procedure requires the identification of each of the components necessary to ensure the IROFS is capable of performing its specified safety function, including support systems and components. As such, if after final design any software, firmware, microcode, PLCs, etc., is used for IROFS it will be identified at that time. For IROFS identified as using software, firmware, microcode, PLCs, etc., the applicable guidance . . .

including the endorsed IEEE standards, and industry standards will be used for implementing these features.⁵

Specifically, LES's response indicated that if the final design included software, firmware, microcode, PLCs, etc., those components would be compliant with NQA-1 Quality Assurance requirements of computer software for nuclear facility applications.

Additionally, as the facility was still in a preliminary design state, the licensing application for the proposed facility *did not contain definitions of the boundaries for each IROFS identified by the licensee*. Nonetheless, the staff concluded, based upon the procedures for development of the IROFS boundary descriptions and the provisions to be included in License Conditions 19 and 20 (discussed below), that,

[T]he preliminary design bases of the IROFS evaluated in this SER section will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. Given that these conclusions are based on preliminary design information, the staff is imposing a license condition to ensure that the final design is adequate and acceptable to the staff. Specifically, the following condition will be included in the license: The applicant shall utilize its procedure, "IROFS Boundary Definitions," to define the boundaries of each IROFS. Completed IROFS boundaries for all IROFS shall be available for inspection at the time of the operational readiness review.

Id. at 3-51. Consistent with the NRC staff's recommendations in the SER, the materials license issued to LES for the NEF, SNM-2010 (ML061740476), contained the recommended license conditions, which conditions remain unmodified today.

License Conditions 19 and 20

License Condition 19 to SNM-2010 states:

To define the boundaries of each item relied on for safety (IROFS), the licensee shall utilize its procedure, "IROFS Boundary

⁵ LES "Response to NRC Request for Additional Information Regarding National Enrichment Facility Safety Analysis Report and Emergency Plan," dated May 19, 2004 (ML042950558; ISA-20(b)).

Definitions.” Completed IROFS boundaries for all IROFS shall be available for inspect at the time of the operation readiness review.

License Condition 20 states:

Currently, there are no IROFS that have been specified as using software, firmware, microcode, programmable logic controllers, and/or any digital device, including hardware devices which implement data communication protocols (such as fieldbus devices and Local Area Network controllers), etc. Should the design of any IROFS be changed to include any of the preceding features, the licensee shall obtain Commission approval prior to implementing the change(s). The licensee’s design change(s) shall adhere to accepted best practices in software and hardware engineering, including software quality assurance controls as discussed in the Quality Assurance Program Description throughout the development process and the applicable guidance of the following industry standards and regulatory guides as specified in Safety Analysis Report Chapter 3:

a. American Society of Mechanical Engineers (ASME) NQA-1-1994, Part II, subpart Part 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,” as revised by NQA-1a-1995 Addenda of NQA-1-1994 and ASME NQA-1-1994, Part 1, Supplement 11S-2, “Supplementary Requirements for Computer Program Testing.” (Refer to SAR Chapter 11, Appendix A, Section 3.) (*emphasis added*)

IROFS C6 and 38

IROFS C6 pertains to controlling the cascade enrichment, and is currently described in the ISA

Summary as,

Administratively calculate and set the cascade enrichment control device in accordance with the calculation to ensure ^{235}U enrichment $< 5\%$ to ensure subcriticality within the designed process and analyzed activities. This is implemented by ensuring the calculation performed accurately, and the associated cascade enrichment control device setting is implemented in accordance with the calculation: the 5% limit is based on the NEF Materials License limit and consistent with the Nuclear Criticality Safety Analyses to ensure subcriticality within the designed process and analyzed activities. If the acceptance criterion is not met and the cascade enrichment control device setting has not been changed, then the cascade enrichment control device setting shall not be changed. If the acceptance criterion is not met and the cascade enrichment control device setting has been changed, then the

associated cascade shall be isolated such that no additional UF₆ can enter or exit the cascade.

The enhanced (i.e., Index of "-3") administrative control to calculate and set the cascade enrichment control device in accordance with the calculation to ensure ²³⁵U enrichment < 5 % to ensure subcriticality within the designed process and analyzed activities is based on the following factors: exceeding the ²³⁵U enrichment license limit of 5 % will be precluded by independent verification of the cascade enrichment control device setting calculation prior to changing the cascade enrichment control device setting and independent verification of implementation of the enrichment control device setting within 1 hour after changing the cascade enrichment control setting. This enhancement shall meet the requirements for independent verification identified in Section 3.8.1.⁶

IROFS 38 concerns the filling of the cylinder with uranium hexafluoride (UF₆), and is currently described in the ISA Summary as,

Administratively limit the cylinder fill mass to ensure cylinder integrity. This is implemented at Tails Low Temperature Take-off Stations, Feed Purification Low Temperature Take-off Stations, Product Low Temperature Take-off Stations, and Product Blending Receiver Stations by verifying that cylinder weight is within specified trending limits once per shift during filling of the cylinder. Weight limit conservative with respect to assuring cylinder integrity. If the acceptance criterion is not met, then fill of the associated cylinder shall be terminated.

The enhanced (i.e., Index of "-3") administrative control to limit the cylinder fill mass to ensure cylinder integrity is based on the following factors: Exceeding the cylinder fill mass limit will be precluded by independent verification (i.e., second verification) performed on the next shift following the completion of the IROFS38 periodic verification on the previous shift (i.e., first verification). This enhancement shall meet the requirements for independent verification identified in Section 3.8.1.

Staff Identification of Non-Compliance with License Condition 20

Prior to commencement of operations at the NEF, the facility is required to undergo an operational readiness review (ORR) and a construction inspection so that the NRC may verify that the facility has been constructed in accordance with the terms of its license. 10 CFR

⁶ National Enrichment Facility Integrated Safety Analysis Summary, Version 15, dated March 31, 2010, Section 3.8.3.C6 and Table 3.8-1.

70.32(k). During a recent inspection at the NEF (NRC Inspection Report No. 70-3103/2010-006), the staff identified a deficiency concerning the LES's failure to include equipment necessary for IROFS C6 and 38 to accomplish their safety functions within the boundaries for these IROFS, which LES has defined and had available for inspection at the ORR. The staff discovered that although both IROFS C6 and 38 were accomplished through the use of digital controls or instrumentation (i.e., the PCS, scales, monitoring instruments, valves, etc.) these controls were not included within the IROFS boundary definitions and were not qualified in accordance with LES's license commitments. The staff notified LES of this finding, and in response, LES has filed a backfit claim under 10 CFR 70.76.

DISCUSSION

A. LES is Not in Compliance with Applicable Requirements

10 CFR 70.62(c)(1)(vi) requires LES to conduct and maintain an ISA, that is of appropriate detail for the complexity of the process and that identifies each IROFS identified pursuant to § 70.61(e), the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of § 70.61. As discussed above and as described in the LES Boundary Definition Document for IROFS C6 or 38, safety function of the operator includes actions to prevent inadvertent criticality due to over-enrichment or overfill and potential rupture of the product cylinder and involves the use of hardware, instrumentation, and the plant control system (PCS) as a routine course of action during operation. LES believes § 70.62 is met because the digital software is not "relied on" for either IROFS C6 or 38 to perform its intended safety function. Thus, LES's implicit argument is that digital software is not "relied on" because the operator could determine cylinder fill using a methodology which does not utilize instrumentation or the PCS. LES appears to rely upon this same logic as a basis for its claim

that License Condition 20 is not contravened. See the first full paragraph of p.9 of the Attachment to the April 16, 2010, LES Letter.

The staff does not agree with LES's interpretation of § 70.62(c)(1)(vi). If a licensee's procedure describes a routine and ongoing course of actions to accomplish a safety function, in this case, prevention of inadvertent criticality due to over-enrichment or cylinder rupture due to overfill, then those routine described actions are "relied on," in the ordinary meaning of this word, to accomplish those safety functions. The staff's regulatory practices in other areas, e.g., nuclear power plants, are consistent with this interpretation of the word "relied on."⁷ The staff has long understood that if a design or operational activity does not "rely upon" structures, systems, and components (SSCs) or action to accomplish a safety function or meet a regulatory requirement, then the licensee may not use that SSC or action as part of normal operation or to meet regulatory requirements with respect to preventing or mitigating intermediate - or high-consequence accident sequences or events. Accordingly, it is the staff's position that LES is in non-compliance with § 70.62 because the boundary descriptions for IROFS C6 and 38 do not include a sufficient description of how instrumentation or the PCS is used, despite the fact that LES's procedures for routine operation relies upon the operator's use of instrumentation and the PCS to implement IROFS C6 and 38 safety function(s) in order to prevent over-enrichment or cylinder overfill, respectively.

License Condition 20 requires that if the design of any IROFS is changed to include software, firmware, microcode, programmable logic controllers, and/or any digital device, including hardware devices which implement data communication protocols, then the licensee shall

⁷ For example, the staff would not treat an SSC, otherwise described in an FSAR as required to perform a required safety function, e.g., a safety function described in the one of the general design criteria of 10 CFR Part 50, Appendix A, as a non-safety related SSC if the licensee's operating procedures would require the use of non-safety related SSCs as a routine matter to accomplish the GDC-mandated safety function.

obtain Commission approval prior to implementing the change(s). LES appears to argue that it did not breach License Condition 20, because License Condition 19 allows LES to change any IROFS's boundary description without limitation - including the limitation in License Condition 20. The staff disagrees with LES's position, for several reasons. There is nothing in the explicit language of License Condition 19 indicating that its terms supersede or are controlling if there is a conflict with another license condition. Furthermore, there is nothing in the language of Conditions 19 or 20 precluding LES from complying with the mandates of both license conditions. LES presents no technical, regulatory or policy basis as to why these two license conditions should not be interpreted in a manner that gives both license conditions legal effect and force. Additionally, the terms of License Condition 19 merely requires that the boundary definitions be available for staff inspection during the ORR. As indicated in the SER, this inspection will enable the staff to ensure that the IROFS are adequate. In this instance, the staff inspection revealed that the boundary definitions for IROFS C6 and 38 were inadequate due to LES's non-compliance with License Condition 20. Finally, License Condition 20 appears to be a more comprehensive and specific regulatory limitation as compared with the much shorter regulatory provision of License Condition 19. Ordinarily, a specific legal provision supersedes or acts to modify the dictates of a more general legal provision. Applying this principle, the staff concludes that the specific regulatory direction in License Condition 20 controls over the general regulatory provisions of License Condition 19. For these reasons, it is the staff's position that LES is in non-compliance with License Condition 20, inasmuch as its routine operating procedures requires the operator to use the hardware, instrumentation, and the PCS to perform the safety function(s) of preventing over-enrichment and cylinder overfill, but the boundary descriptions for IROFS C6 and 38 do not include the instrumentation or the PCS within the IROFS's boundary.

B. The Staff Position on IROFS C6 and 38 Does Not Constitute Backfitting

1. *The Staff Did Not Review or Approve the Boundary Definitions for IROFS C6 and 38.*

As discussed above, the boundary definitions for IROFS C6 and 38 were developed *after* the NRC issued the LES license. This is consistent with the understanding by both LES and the staff that the IROFS boundary definitions were to be developed after issuance of the license once the facility design was finalized, and were to be developed in accordance with the IROFS Boundary Definition Procedure, License Conditions 19 and 20, and consistent with the summary descriptions in the ISA.⁸ The absence of the actual definitions of the IROFS boundaries at the time of LES license issuance precludes any LES claim of backfitting based upon an argument that the staff reviewed and approved the actual boundary definitions. Accordingly, any valid backfitting claim raised by LES must be based upon a demonstration that the staff changed its interpretation of the IROFS Boundary Definition Procedure, the summary descriptions of these IROFS in the ISA Summary, the summary description of the PCS, or the intended effect of License Conditions 19 and 20.

2. *The Staff's Interpretation of the IROFS Boundary Definition Procedure, the Summary Descriptions of IROFS C6 and 38 in the ISA Summary, or the Summary Description of the PCS in the ISA Summary Have Not Changed.*

LES argues that although it did not submit a list of all components included in each IROFS boundary before the ISA Summary was approved, the NRC staff was informed that certain instruments and digital based controls, e.g., the PCS, were not included within the IROFS boundary. LES states that IROFS C6 and 38 use administrative controls, i.e., human oversight or monitoring of physical devices or systems, to reduce the likelihood of specific accident sequences. With respect to IROFS C6, LES acknowledges that the valves that operate the

⁸ See, "February 26, 2004, Meeting Summary: Louisiana Energy Services' Approach for Preparing the Integrated Safety Analysis," dated March 3, 2004 (ML040630042).

enrichment controls are monitored by the PLC in the PCS, but that human operators compare the setting in the PCS and arguably are able to respond within sufficient time if deviations in performance of the PLC or PCS are noticed. As for IROFS 38, LES admits that during the licensing process the NRC staff submitted a request for additional information in which it asked LES whether instrumentation was used to measure cylinder weight, to which LES responded that “IROFS 38 did require instrumentation for the operator to monitor cylinder weight and noted that the calibration of this weight monitor was in the boundary.”⁹ LES argues in its response that during the licensing process it consistently applied its IROFS boundary definition approach to IROFS 38, and 42, such that that these IROFS were not specific with regard to the components used.¹⁰

In the staff’s view, these arguments in support of LES’s backfitting claim are misplaced and irrelevant. They focus solely on the content of LES’s representations to the NRC – which the staff does not dispute. In the staff’s view, the real issue to be determined – inasmuch as the backfitting concept depends upon a change in the *NRC’s position* – is *the staff’s understanding and interpretation at the time that the staff reviewed and approved LES’s ISA Summary and the IROFS Boundary Description Procedure regarding LES’s representations on the use of the instrumentation, hardware, and the PCS during normal operations*. There is manifest information demonstrating that the staff understood that if the boundary description of an IROFS involving operator action excluded digital software controlled instrumentation, then that operator would not utilize that instrumentation in implementing the IROFS function, i.e., during normal operation on a day-to-day basis as reflected in an operating procedure.

⁹ LES Backfit Claim, dated April 16, 2010, at Attachment, pg. 3.

¹⁰ *Id.*

Moreover, the licensing history of the NEF clearly shows that the staff was concerned about the use of digital controls and software to accomplish the performance requirements in 10 CFR 70.61, and ultimately imposed License Condition 20 in order to preclude LES from using digital software controls in implementing IROFS without first complying with the terms of License Condition 20. During the licensing process, the NRC staff understood that an operator would observe the trending weight of a cylinder being filled, and if the weight of the cylinder is getting close to a maximum limit, the operator would take action to stop the flow of UF₆ into the cylinder. In fact, as LES noted in its submittal, the NRC staff issued a request for additional information in which the staff specifically asked whether for IROFS 38 “instrumentation [is] used by the operators to measure the cylinder weight,” and if so, whether the instrumentation is part of IROFS38. During the licensing proceeding, LES responded to the request for additional information that

IROFS38 does require instrumentation for the operator to monitor cylinder weight. This instrumentation would be considered to be included in the IROFS boundary. As such, the identification of the components that comprise the IROFS boundary and the associated management measures for assuring reliability and availability per 10 CFR 70.62(d) will be performed as described in the response to RAI ISA-21b.¹¹

Instead of limiting the boundary at calibration as LES alleges in its backfit claim, the response directly states that the instrumentation shall be included in the boundary. During the ORR, the staff found that IROFS 38 was actually defined and implemented in such a manner that the weight of the cylinder was captured by a scale that input data into the PCS. The PCS, through the use of software and digital instrumentation, would use the captured information to create and display the weight and the trending data for the cylinder fill for the operator. The operator would then base his/her response on the displayed data, and, if the weight exceeds a threshold or the trending data indicates a problem, the operator would take action through the PCS to stop

¹¹ LES “Response to NRC Request for Additional Information Regarding National Enrichment Facility Safety Analysis Report and Emergency Plan,” dated May 19, 2004 (ML042950558; ISA-21(c)).

the flow of UF₆ through the affected cascade. The SER clearly set forth staff's understanding that none of the IROFS designated by LES in its license application included the use of digital controls. It was only upon inspecting the IROFS Boundary Definitions that the licensee made available during the ORR in accordance with License Condition 19, that the NRC staff learned otherwise.

Furthermore, during the licensing proceeding, the NRC staff understood IROFS C6 as only involving human interactions and a manual enrichment control device, i.e., valve. Specifically, the staff understood that the first operator would perform a calculation to determine the enrichment setting, and would manually change the setting on the valve that controlled the enrichment setting for the cascade. Thereafter a second operator would perform an independent calculation to determine the enrichment setting and compare with the values derived by the first operator. The second operator would then compare the independently derived setting to the settings of the valve. At no time did staff understand that digital controls or implementation would be used in this process as a routine, operational matter, i.e., described as a routine, day-to-day activity necessary to comply with the NRC requirements in an operating procedure.

The staff reviewed the documents referred to by LES in its April 16, 2010, backfitting claim, as well as the documents attached to LES's May 4, 2010, letter supplementing the earlier backfitting claim. The two affidavits presented by LES as enclosures to its May 4, 2010, letter do not refer to any written or oral communications from LES to the staff indicating that LES made it known to the staff that IROFS C6 and 38 were to be performed as an operational matter or routine, i.e., set forth in an operating procedure for use on a day-to-day basis, using hardware, instruments, or the PCS. The staff's review of the remaining documents enclosed with the May 4, 2010, letter disclose no information which suggest that LES's position in this

regard were communicated to the staff, and none of the NRC-generated materials enclosed with the May 4, 2010, letter reflects NRC knowledge or approval of LES's position that digital software-controlled systems can be excluded from the IROFS boundary description even when used on a routine basis in an operating procedure to implement the IROFS, so long as the IROFS can also be implemented without the use of a digital software-controlled system. A review of the staff's SER on the ISA Summary also disclosed no discussion suggesting that the staff knew of, understood, or approved of the LES position in this regard.

In sum, the staff finds no information presented or referenced by LES supporting a determination that the staff understood, at the time of its review and approval of the ISA Summary, that digital software-controlled instrumentation – even though excluded by the licensee from its definition of the boundaries of IROFS C6 and 38 – would be relied upon during normal operation, i.e., used on a routine, day-to-day basis as described in an operating procedure, to accomplish the necessary safety functions required by § 70.61. Hence, imposition of the staff position in this regard would not constitute backfitting under § 70.76.

3. The Staff's Interpretation of License Conditions 19 and 20 Has Not Changed.

As described above in section A of the "Discussion," LES appears to argue that it did not breach License Condition 20, because License Condition 19 allows LES to change any IROFS's boundary description without limitation - including the limitation in License Condition 20. Apart from the relative merits of this argument, LES has not demonstrated that the staff was aware of the LES position on the meaning of License Conditions 19 and 20 prior to issuance of the LES license – in particular LES's apparent position at this time that changes to the boundary definitions in IROFS C6 and 38 could be made without regard to the limitations in Condition 20. The two affidavits presented by LES as enclosures to its May 4, 2010, letter do not refer to any

written or oral communications from LES to the staff making LES's position on the meaning of License Conditions 19 and 20 known to the staff. The staff's review of the remaining documents enclosed with the May 4, 2010, letter disclose no information to suggest that LES's position on the meaning of License Conditions 19 and 20 were communicated to the staff, and none of the NRC-generated materials enclosed with the May 4, 2010, letter reflects NRC knowledge or approval of LES's position on the meaning of License Conditions 19 and 20. A review of the staff's SER on the ISA Summary also discloses no discussion suggesting that the staff knew of, understood, or approved of the LES position in this regard.

License Condition 20, which provides the basis for staff's concerns with IROFS C6 and 38, is based on representations made by LES during the licensing proceeding, confirms staff's understanding of LES's designated IROFS at the time of licensing, and establishes the procedures that LES is to follow should it change the design of its IROFS to include certain digital instrumentation or controls. As such, the terms of License Condition 20 are very specific. In section 11.8 of the SAR included in its initial application, LES committed to maintaining a QA Level 1 Program that conforms to the criteria established in 10 CFR 50, Appendix B and the guidelines of ASME NQA-1 as specified in the QA Program Description. The QA Level 1 QA Program shall be applied to those structures, systems, components, and administrative controls that have been determined to be IROFS (except IROFS 27e to which QA Level 1 Graded applies), items that are essential to the functions of the IROFS, and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied. In addition, as previously noted, LES's commitment was reconfirmed in its May 19, 2004, response to a staff inquiry about the role that software, hardware, and code would play and what were the limitations with IROFS, wherein LES affirmed that if any IROFS were identified after final design as using software, firmware, microcode, PLCs, etc., it would implement these features in accordance with the QA-Level 1 Program.

Based upon the commitments made in LES's license application and ISA Summary, as well as the preliminary descriptions of the IROFS, the schematic drawing of the PCS architecture, verbal interactions between LES representative and staff, e.g., technical meetings, and LES's responses to the staff's RAIs, the staff was satisfied with the preliminary concepts of the IROFS being independent of digital instrumentation or controls. For example, among other things, LES indicated that,

- the PCS PLC has no direct, hardwired interface for the actuation, control, or reset of IROFS;
- the software running in the PLC has no interface with the IROFS for the actuation, control, or reset of the IROFS;
- none of the IROFS identified during the licensing process relied on software for performance of their specified safety function;
- the safety function of the identified IROFS are carried out locally;
- the only interface between the PCS and these IROFS is related to the monitoring of IROFS status and operation; and
- IROFS systems will be designed such that process control system failures will not affect the ability of the IROFS systems to perform their required safety functions and that control systems will not be used to perform IROFS functions.

However, notwithstanding these representations, the staff was also mindful of the fact that the preliminary concepts were subject to change, and that LES might choose to integrate digital control of systems after NRC issued it a license for NEF. License Condition 20 was put in place to require NRC approval of the use of such digital controls, instrumentation, or systems so that the NRC would have an opportunity to consider whether their use impermissibly impacts the intended safety function(s) of the affected IROFS, and to determine whether any requirements should be imposed on the use of such system to ensure quality, availability, or reliability.¹²

¹² SER § 3.4, NUREG-1827.

In sum, there is no evidence, at the time the staff issued LES's license, of either staff knowledge or approval of the LES position of the meaning of License Conditions 19 and 20. Accordingly, there is no staff position contemporaneous to the issuance of the LES license which may form the basis for a backfitting claim that there is a "new" or "changed" staff position on the meaning of License Conditions 19 or 20.¹³

CONCLUSION

LES is in non-compliance with License Condition 20 because the boundary descriptions for IROFS C6 and 38 do not include sufficient descriptions of the hardware, instrumentation, and PCS, *despite the fact that LES operational procedures for IROFS C6 and 38 require the use of digital software-controlled systems as a routine operational matter in implementing the IROFS.*

The staff never reviewed or approved the specific IROFS boundary descriptions for IROFS C6 and 38, either prior to issuance of the LES license or thereafter. Accordingly, there was no staff approval of the specific IROFS C6 or 38 boundary description, which may serve as a valid basis for a backfitting claim that there is a subsequent "new" or "changed" staff position on the actual boundary descriptions for IROFS C6 and 38.

LES has not identified any new or changed staff position with respect to the interpretation of the LES procedure for describing boundaries of IROFS C6 and 38, the meaning of IROFS summary descriptions in the ISA Summary, or the description of the PCS in the ISA Summary. The NRC staff's position is that the boundary definition procedure, *properly implemented in accord with*

¹³ On the contrary, the sequence of events on this matter suggests that, *after* the NRC safety review (as documented in the SER) and issuance of the LES materials license, LES adopted a new interpretation or position of License Conditions 19 and 20 to effectively redefine the boundaries of the IROFS, thereby achieving LES's goal to exclude the computer software and digital controls and instrumentation from the qualification requirements/commitments contained in License Condition 20 and LES's licensing documents.

License Conditions 19 and 20, would result in acceptable boundary definitions for IROFS C6 and 38. LES has not presented any information suggesting that LES had made known to the staff, prior to receipt of the NEF license LES's position that the primary, day-to-day activities of the operator to monitor and control cylinder fill or enrichment control, would be done, as required by an operating procedure, using the PCS, or any other digital software-controlled system, controls or instrumentation, consistent with its representations in the ISA Summary and License Condition 20. Nor has LES presented any information that the staff specifically knew and approved the LES position. The staff does not believe that the LES position can be inferred from LES's boundary definition procedure or the ISA Summary, and in any event is untenable in light of the explicit provisions of License Condition 20. Accordingly, there was no staff approval of: (i) LES's intent that the primary, day-to-day activities of the operator to monitor and control cylinder fill or enrichment control would be done using the PCS, or any other digital software-controlled system, controls or instrumentation; or (ii) LES's interpretation of the IROFS Boundary Definition procedure and the relevant ISA Summary descriptions; which could have served as a valid basis for a backfitting claim that there is a subsequent "new or "changed" staff position on what is necessary to comply with § 70.62.

LES has not identified any new or changed staff interpretation of License Conditions 19 and 20. Nor has LES shown that LES's understanding of the meaning and effect of License Conditions 19 and 20 were presented to the staff prior to issuance of the LES license, much less any statement by the staff reflecting their knowledge or approval of the LES view in this regard. Accordingly, there was no staff approval of LES's view of the meaning and effect of License Conditions 19 and 20, which could have served as a valid basis for a backfitting claim that there is a subsequent "new" or "changed" staff position with respect to the meaning of License Conditions 19 and 20.