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Louisiana Energy Services, LLC
NRC Docket No. 70-3103

Subject: Backfit Claim Concerning Definition of Boundaries for Administrative Control IROFS (Items Relied On For Safety)

Louisiana Energy Services, LLC (LES) appreciates the support that the NRC has provided to our project to date. Recently we have been engaged in a discussion with the NRC Staff which has the potential to significantly delay the project and result in an unacceptable cost. This issue is in our opinion one that should best be dealt with in accordance with NRC regulations and policy on backfitting. Therefore, pursuant to 10 C.F.R. 70.76, LES hereby submits a backfitting claim concerning an NRC Staff position related to the definition of boundaries for Administrative Control IROFS (Items Relied On For Safety). Specifically, the new Staff position would require that at least one set of monitoring instruments and other supporting components be required to support the safety function of certain administrative controls categorized as IROFS. As a result, such components would have to be Quality Level 1 (meeting 10 C.F.R. Part 50, Appendix B and ASME NQA-1 requirements) and further meet the applicable industry codes and standards imposed on such IROFS under the LES license. As explained in Attachment 1 to this letter, LES believes that the Staff position constitutes a backfit for which the Staff has not undertaken the requisite backfitting analysis set forth in 10 C.F.R. 70.76.

The imposition of this new Staff position would likely delay initial operation of LES's enrichment facility by several months or longer due to the need to qualify or replace the components to meet Quality Level 1 requirements and the associated design codes and standards without a demonstrated substantial increase in overall protection of public health and safety. Further, such replacements may not even be available for certain items.

LES submitted a license application to construct and operate a uranium enrichment facility (the National Enrichment Facility or URENCO USA Facility) on December 12, 2003. As part of its license application, LES submitted its Integrated Safety Analysis (ISA) Summary, as required by

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10 C.F.R. 70.61 and 70.62(c)(vi). In the ISA Summary, LES designated each administrative control necessary to reduce the likelihood of a credible high-consequence event as an IROFS¹ and further demonstrated that each IROFS would be available and reliable to perform its intended function when needed. LES's ISA Summary committed to defining the boundary of each IROFS (identifying all supporting systems, subsystems and components that are required to ensure the completion of the safety function) upon completion of the final design of the facility, and LES submitted its procedure for establishing such boundaries to the NRC. As described in Attachment 1, the ISA Summary and related correspondence also indicated that certain monitoring instruments and digital based controls (i.e., supporting components) were not themselves part of the boundary of the IROFS. For Administrative Control IROFS that use monitoring instruments, LES agrees that the IROFS boundary includes (1) the operator actions (based on procedures and training) required to take the administrative action, and (2) the calibration of the instruments that ensure accurate and reliable indication as presented on the docket in May 2004. LES's approach in this regard provides reasonable assurance that an appropriate level of nuclear and chemical safety is maintained.

The NRC undertook a thorough review of LES's ISA and ISA Summary as part of the licensing process. Based on a review of the full ISA for the facility, including "vertical-slice" reviews of high and intermediate consequence accident scenarios, the NRC issued a Safety Evaluation Report (SER) for the facility on June 15, 2005. The SER approved the ISA Summary including LES's approach to defining IROFS boundaries. Specifically, the SER stated (at 3.4):

The NRC staff has reviewed the ISA Summary and other information, and finds that it provides reasonable assurance that the applicant has identified IROFS and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61.

Recently, the NRC Staff informally notified LES that the boundary of an Administrative Control IROFS should include equipment necessary to perform the administrative operator action. Specifically, for IROFS 38, 42 and C6, the NRC has indicated that a set of the monitoring instruments and supporting equipment that could be used by operations personnel to take actions must be categorized as within the boundary of the IROFS. This position, if imposed, would constitute a new Staff position that departs from the Staff's approval in the SER. Further, if such supporting components are now determined to be IROFS, LES will be required to qualify the components to Quality Level 1 requirements (rather than the current Quality Level 2 or 3) and meet design codes and standards not originally applied, which would significantly delay startup of the facility by several months or longer.

As set forth in 10 C.F.R. 70.76, modifying or adding to systems, structures, or components of a facility or to the procedures or organization required to operate a facility after the date the NRC approves a licensee's ISA Summary is a backfit. In order to impose a backfit on a licensee,

¹ An IROFS is defined in 10 C.F.R. 70.4 as "structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as [IROFS]."

unless certain exceptions apply, the NRC must determine that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.² The NRC Staff has not undertaken the required analysis to justify a change in position with respect to the definition of boundaries for Administrative Control IROFS for the LES facility.

Accordingly, the NRC should identify the new Staff position as a backfit and not seek to impose the new position unless justified by a backfitting analysis meeting the standards of 10 C.F.R. 70.76. In view of LES's current schedule, LES respectfully requests that the NRC give expedited consideration to this backfit claim. Construction related to Cascade 1 and 2 is complete, and all onsite operational readiness reviews have been completed. The plant is ready to operate and awaits the NRC's final decision regarding the receipt of feedstock which is the only remaining activity prior to first cascade on line. In these circumstances, as provided in 10 C.F.R. 70.76(c), no licensing action or authorization should be withheld during the NRC's consideration of this matter.

LES has been in the past and continues to be prepared to work with the NRC to provide whatever support or information is necessary to help resolve this issue. Since first being apprised of Staff concerns in this area during an inspection the week of February 8, 2010 for the Operational Readiness Review, LES has been working diligently to identify alternatives to address NRC's concerns including the addition of new IROFS and graded quality and other approaches to expand administrative IROFS boundaries. During this time, LES has informally provided three white papers to the Staff, initiated condition reports to address issues as they have been raised, and developed justifications for the adequacy of LES positions. It was not until April 8, 2010 that the Staff provided its preliminary position to LES. Based on its review of the Staff's preliminary position, LES decided to submit this backfitting claim in an effort to achieve a resolution of the issue prior to the expected first cascade on line date.

Should you have any questions regarding this letter, please contact Gary Sanford, LES Director of Quality and Regulatory Affairs at 575.394.5407 or GSanford@nefnm.com. We look forward to your prompt reply and stand ready to assist the Staff in its evaluation of this backfitting claim.

Sincerely,

Out to RP for Gregory OD Smith

Gregory OD Smith

Chief Operating Officer and Chief Nuclear Officer

Attachments: 1) Backfit Claim

² 10 C.F.R. 70.76(a)(3).

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ATTACHMENT 1

BACKFITTING CLAIM CONCERNING DEFINITION OF BOUNDARIES FOR ADMINISTRATIVE CONTROL IROFS

INTRODUCTION

LES submitted a license application to construct and operate a uranium enrichment facility (the National Enrichment Facility (NEF) or URENCO USA Facility)¹ on December 12, 2003. The NRC undertook a thorough review process and approved LES's Integrated Safety Analysis (ISA) Summary in its Safety Evaluation Report, NUREG-1827, issued June 15, 2005. As part of the ISA Summary, LES identified as items relied on for safety (IROFS) administrative controls that are relied on to prevent potential accidents at the facility that could exceed performance requirements. As detailed below, the ISA Summary and related correspondence indicated that certain instruments and supporting components during the implementation of Administrative Control IROFS were *not* required to be designated as IROFS.

The NRC Staff has informally advised LES that a set of the processes, instruments or controls that could be utilized in an Administrative Control IROFS must also be designated as within the IROFS boundary. This position, if imposed, would represent a new Staff position – i.e., a backfit – for which the Staff has not undertaken the requisite backfitting analysis to demonstrate that there is a substantial increase in the overall protection of the public health and safety to be derived from the backfit and that the direct and indirect costs of implementation for the facility are justified in view of this increased protection. As LES has pointed out in discussions with the Staff on this issue, there are multiple means for monitoring and taking actions to accomplish an Administrative Control, and therefore it is not necessary to rely completely on one set of controls or approach to take operator action. In fact, such an approach is contrary to how the IROFS Boundary was defined as described on the docket in May 2004.

LES is submitting this claim of backfit so that the NRC Staff, in accordance with 10 C.F.R. 70.76 and the policy reflected in NUREG-1409, *Backfitting Guidelines*, can determine if the Staff position constitutes a backfit. If so, the Staff should not impose the position until it has performed the required backfitting analysis meeting the standards of 10 C.F.R. 70.76. As provided in 10 C.F.R. 70.76(c), the NRC should not delay or withhold any licensing action or authorization pending consideration of this claim.

BACKGROUND

A. ADMINISTRATIVE CONTROLS AS IROFS

NRC regulations recognize that administrative controls (i.e., human oversight or monitoring of physical devices or systems) may be utilized to reduce the likelihood of occurrence of a credible

¹The URENCO USA Facility was previously referred to as the National Enrichment Facility and therefore references to "NEF" herein or in supporting documentation refer to the URENCO USA Facility.

high-consequence event so that, upon implementation of the administrative control, the event is highly unlikely or its consequences are less severe than specifically-enumerated reactions.² An administrative control is an IROFS if it is the human action necessary to meet safety performance requirements, and it is supported by management measures (training, quality assurance, procedures, etc.) that ensure that the action will be taken if needed.³

B. IROFS 38, 42 and C6

The particular IROFS at issue here are IROFS 38, 42 and C6, each of which involves administrative controls that utilize processes, instruments or controls as supporting components.

1. IROFS 38

The safety function for IROFS 38 is described as:

Administratively limit the cylinder fill mass to ensure cylinder integrity.⁴

IROFS 38 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. Essentially, an operator observes the trending weight of a cylinder being filled by receiving data from the Plant Control System (PCS) displayed in the control room that is provided by the scale (load cells inside the stations). Independent verification is achieved for this IROFS over two shifts as the time to overfill a cylinder to the point it could rupture is extensive, and would require an abnormally high ambient temperature not present in the building, and would require the cylinder to be in place for an abnormally long period of time in the filling mode. Further, a second weight measurement of the cylinder is observed on a different scale once it is removed from the station. While in the station, the PCS automatically takes action based on a certain weight limit. This is not part of the Administrative IROFS but is a feature of the control system used at LES and the other URENCO sites as previously docketed. However, if the weight of the cylinder gets close to a higher, maximum limit, the operator will take action to stop the flow of UF₆ to the cylinder.

Multiple methods both using and not using the PCS are available to the operator to terminate station operation. The administrative control to shut down the station is identified as an IROFS but scales, monitoring instruments and equipment used to shut down the station (PCS, valves, breakers, etc.) are not included within the boundary for IROFS 38.

LES agrees that two basic elements are included within the IROFS boundary: (1) the operator actions (based on procedures and training) required to take the administrative action, and (2) the calibration of the instruments that ensure accurate and reliable indication. LES submitted evidence of actual operating experience for these types of features in URENCO centrifuge enrichment plants located in Europe to the NRC Staff on September 19, 2002 and March 2004.

² 10 C.F.R. 70.61(b). The reactions are set forth in (b)(1)-(4).

³ Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility (NUREG-1520) at 7.5.2.

⁴ ISA Summary, Revision 15 at page 3.8-29.

Such evidence demonstrated that over ten thousand cylinders have been filled using this approach without a single overpressure release event.

On April 19, 2004, the NRC Staff submitted requests for additional information (RAIs) to LES regarding the license application for the facility.⁵ RAI-21(c) noted that IROFS 38 was identified as an administrative control to prevent cylinder overfill and asked whether there was instrumentation used by the operators to measure the cylinder weight, and, if so, whether that instrumentation was part of IROFS 38. In response, LES stated that IROFS 38 did require instrumentation for the operator to monitor cylinder weight⁶ and noted that the calibration of this weight monitor was in the boundary. This position was supported in this same docketed submittal through the inclusion of the LES procedure for IROFS Boundary Definition as Attachment 4. This procedure requires identification of each component necessary to ensure the IROFS is capable of performing its specified safety function. It explicitly identified 'control cylinder over fill" as an example of BIN 3 "Administrative IROFS for Parameter Monitoring" which required the identification of operator actions and calibration requirements as within the IROFS Boundary but not the instrument itself as a QA Level 1 component. IROFS 38 was not considered an example of BIN 2 "Administrative IROFS Requiring Use of Components." Furthermore, two months prior to this RAI response, LES clarified via email attachment (ML040860203) that the load cell used to provide the weight indication was not QA Level 1 and not part of the IROFS. This same boundary definition approach was consistently applied to IROFS 42 and C6, i.e., the IROFS is not specific with regard to the components used.

2. IROFS 42

The safety function for IROFS 42 is described as:

Administratively limit the cylinder fill mass to ensure cylinder integrity.⁷

IROFS 42 is implemented by determining the weight of product cylinders before placement and heating in the Product Liquid Sampling Autoclave. As with IROFS 38, which also involves parameter monitoring, Administrative Control IROFS 42 uses monitoring instruments, including a scale which is not part of the PCS. These supporting components are not included within the boundary of the IROFS. LES agrees that two basic elements are included within the IROFS boundary: (1) the operator actions (based on procedures and training) required to take the administrative action, and (2) the calibration of the instruments that ensure accurate and reliable indication. Both this scale measurement, and the measurement taken in the station just prior to cylinder removal, are available to confirm cylinder fill quantity. Separate weight measurement of each product cylinder is also trended in the stations and recorded as noted in response to IROFS 38 above.

⁵ Letter to Rod Krich, Vice President, Louisiana Energy Services, Re: Request for Additional Information on Louisiana Energy Services Project License Application (Apr. 19, 2004) (ML041100816).

⁶ Letter to Director, Office of Nuclear Material Safety and Safeguards, Re: Response to NRC Request for Additional Information Regarding National Enrichment Facility Safety Analysis Report and Emergency Plan (May 19, 2004) (ML042950558).

⁷ ISA Summary, Revision 15 at page 3.8-31.

3. IROFS C6

The safety function for IROFS C6 is described as:

Administratively calculate and set the cascade enrichment control device in accordance with the calculation to ensure ^{235}U enrichment < 5 wt% to ensure subcriticality within the designed process and analyzed activities.⁸

IROFS C6 requires independent verification for both calculation and setting of the cascade enrichment controls. Specifically, implementation of IROFS C6 consists of calculating the parameters including feed flow, product flow and cascade header pressure with CASCAL software for input into the PCS. A second operator then independently performs the same calculations with CASCAL software and compares it to the first. The first operator then establishes the settings for the cascade enrichment control devices. The principal devices are the feed control valve and product control valve on the cascade valve frame. Both valves are mechanical valves monitored by the Programmable Logic Controller ("PLC") in the PCS, which controls the enrichment. A second operator then compares the settings in the PCS. Deviations in performance of the PCS or PLC are self-evident and there is a significant amount of time to respond.

LES understands that the Staff takes issue with the digital based processes, instruments and controls of the PCS not being included within the IROFS boundary. LES posed similar questions and issued a Condition Report in June 2009 to re-review the ISA and basis for use of IROFS C6 for enrichment control. This review concluded the technical basis for IROFS selection was sufficient to prevent criticality as originally determined in ISA development. These results have been shared and discussed with the NRC. During the September 19, 2002 meeting where URENCO operating experience was shared with the NRC, it was presented that there have been no criticality occurrences. Though not deemed required to comply with license and ISA requirements, LES continues to investigate the addition of another IROFS for enrichment level monitoring and operator action independent of PCS controls to address concerns expressed by the NRC.

ANALYSIS

I. NRC APPROVED THE ISA SUMMARY BASED ON LES'S IROFS BOUNDARY DEFINITIONS

A. ISA Summary

During the licensing process, LES indicated that certain instruments and digital based controls that support Administrative Control IROFS were not considered to be within the IROFS

⁸ ISA Summary, Revision 15 at page 3.8-33. The 5 wt% 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, although the URENCO USA Facility has been analyzed and shown to be safe operating at assays of 6 wt%.

boundary. In this regard, LES set forth the functions that the PCS was intended to perform and described the design of the PCS in its ISA Summary, which was submitted in accordance with 10 C.F.R. 70.61 and 70.62(c)(vi). The ISA Summary states that: "The PCS is required for remote operation, production protection and asset protection. Protection is carried out by the local control and protection systems of the individual process equipment. ***The PCS is not required and not relied upon for the protection of the public or environment; therefore, the PCS is not an IROFS.***"⁹

B. Claiborne Precedent

Due to the similarity in the design of the Cascade Hall at LES's facility and the earlier Louisiana Energy Services' Claiborne Enrichment Center, LES's Integrated Safety Analysis relied on the NRC Staff's review of the Claiborne Enrichment Center's license application relative to the Cascade System, where the Staff concluded that the descriptions, specifications or analyses provided an adequate basis for safety review of the facility operations and that the construction and operation of the facility would not pose an undue risk to public health and safety.¹⁰ In the SER for the Claiborne Enrichment Center, the Staff evaluated five abnormal operation scenarios in depth.¹¹ For example, its analysis for the abnormal condition of enrichment of the feed material above 5.02 wt % U-235 is as follows:

Abnormal operation (b) is the enrichment of normal feed material above 5.02 wt % U-235. During startup operations, the enrichment performance of each cascade hall is benchmarked against the controlling computer program. Then, whenever an enrichment campaign is established, the computer program monitors the controllers which control the enrichment. A second individual verifies the manual manipulation of the controllers. Gas samples of the UF product are taken within 24 hours to confirm the new enrichment level. If necessary, the controllers are readjusted to yield the desired enrichment. Samples are again taken to confirm the proper enrichment. The Cascade Protection System monitors pressure, temperature, and valve positions for cooling water, feed header, product take-off, and tails take-off systems and power for the centrifuges. Once an enrichment campaign is established, the monitoring data is used to verify that the enrichment level does not change.¹²

The Staff concluded:

The NRC staff agrees that the Cascade Protection System provides an adequate control system for enrichment control. While slightly higher enrichments might occur during an enrichment change, the quantity would be small and of no nuclear

⁹ ISA Summary 3.5.9.3 (emphasis added).

¹⁰ National Enrichment Facility Integrated Safety Analysis Summary, Rev. 3 at 3.4.3, page 3.4-14 (September 2004).

¹¹ Safety Evaluation Report for the Claiborne Enrichment Center, Homer, Louisiana, NUREG-1491 at 9.3.2, page 9-10 through 9-13 (February 1994).

¹² *Id.*

criticality safety consequence. The routine monitoring of the product provides further assurance that enrichments above 5.02 wt % U-235 do not occur.¹³

Based on the Claiborne SER, it is evident that the NRC was aware of how the plant operates and functions to prevent accident scenarios. The SER for the NEF, NUREG-1827, did not analyze each accident scenario, but rather it analyzed accident scenarios representative of potential facility events. In this regard, it analyzed a generic Inadvertent Nuclear Criticality, which would be representative of the accident scenario that requires IROFS C6.

C. NRC Site Visits

As part of the licensing process for the NEF, the NRC performed a thorough review of the ISA Summary, which included a “description of the safety function of each IROFS . . . along with the means by which the IROFS will be implemented.” As noted in the SER (3.3):

The staff reviewed the applicant’s Safety Analysis Report (SAR), portions of the Integrated Safety Analysis (ISA), and ISA Summary. Since the proposed facility has not been constructed, the staff visited a similar gas centrifuge uranium enrichment facility at Almelo, The Netherlands, to become familiar with the proposed processes and plant layout. The staff also conducted an in-office review of the ISA at the AREVA engineering offices in Marlborough, Massachusetts, and two in-office reviews of criticality, chemical safety, and other related documents at the applicant’s Washington, D.C. offices. . . . The staff also conducted detailed, vertical slice reviews of various accident scenarios, selected on a sampling basis, to confirm that the Safety Program and associated elements are adequately implemented by the applicant to achieve the performance requirements of 10 CFR 70.61.

D. NRC Approval in SER

The SER, NUREG-1827, approved the ISA Summary including LES’s approach to defining IROFS boundaries. Section 3.3.3.2.4 of the SER reviewed the descriptive list of IROFS identified in the ISA Summary. Although LES did not submit a list of all components included in each IROFS boundary before the ISA Summary was approved by the NRC, the Staff, as noted above, was informed that certain supporting components (e.g., the PCS) were not classified as IROFS. In addition, LES submitted its procedure for defining IROFS boundaries on the docket. In the SER (at section 3.3.3.2.4), the Staff noted that “Administrative control IROFS are adequately described to permit an understanding that adherence to it should be reliable.”

It is also important to note that the LES ISA is conservatively-based, as demonstrated by many years of operation resulting in an abundance of specific plant actions (such as filling over ten thousand cylinders) having occurred at Urenco’s facilities in Europe with this equipment, as well as analogous operating approaches at the three Urenco sites without the occurrence of the events postulated in the ISA for which these Administrative Control IROFS have been established.

¹³ *Id.*

Based on the Staff's review of the ISA, the SER concluded (at 3.4):

The NRC staff has reviewed the ISA Summary and other information, and finds that it provides reasonable assurance that the applicant has identified IROFS and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61.

The SER did note that the applicant's SAR provided only preliminary design basis information for Instrumentation and Control (I&C) systems that it identified as IFOFS for the facility, since the detailed design of the facility for construction and operation had not been completed. For that reason, the Staff included a condition in the NEF license as follows:

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.

Because Administrative Control IROFS rely on personnel actions and not engineered design features or hardware to accomplish the safety function, completion of the detailed design for the facility did not affect or substantively alter the approach previously docketed.

II. IMPOSITION OF A NEW STAFF POSITION WOULD BE A BACKFIT

As described above, the NRC's SER at the time of licensing found that LES's approach to defining IROFS boundaries was acceptable and provided reasonable assurance that the performance requirements of 10 C.F.R. 70.61 would be met. As a result, a new or changed Staff position would be a backfit. Under 10 C.F.R. 70.76, the NRC defines a backfit as a modification or addition to systems, structures, or components of a facility or to the procedures or organization required to operate a facility after the date the NRC approves a licensee's ISA Summary. Because the NRC approved LES's ISA Summary in the SER issued June 15, 2005, any changes to systems, structures or components imposed by the NRC after that date are potentially a backfit.

Although there are certain exceptions to the backfitting rule, generally the NRC must determine that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for the facility are justified in view of this increased protection.¹⁴ Before imposing a new position on LES, the backfitting rule and agency policy reflected in NUREG-1409, *Backfitting Guidelines*, indicate that the NRC should consider the backfitting implications of its position and classify its position as a backfit if appropriate.

Recently, the NRC Staff informally notified LES that the boundary of an Administrative Control IROFS should include equipment necessary to correctly perform the action. Specifically, for IROFS 38, 42 and C6, the NRC has indicated that the monitoring instruments and digital based

¹⁴ 10 C.F.R. 70.76(a)(3).

controls relied upon by operations personnel to take actions must be categorized as within the boundary of the IROFS. The basis for this position appears to be FCSS Interim Staff Guidance-01, Revision 0, "Qualitative Criteria for Evaluation of Likelihood," dated June 9, 2005. This same staff guidance establishes that ISA methods may be graded commensurate with the risk of the facility, including the type, number and robustness of IROFS. It is LES's position that the ISA conservatively established both the IROFS and their boundaries commensurate with facility risk while considering a large number of operating actions and significant operational experience for similar, if not identical, equipment in the European facilities. The informal Staff guidance in the ISG document was not used in the development of IROFS for the LES facility and does not appear to have been used in the Staff's review of LES's ISA Summary. In LES's view, the imposition of a new Staff position based on this informal guidance, and interpretation of this informal guidance in this manner, to call into question the Staff's prior approval of LES's definition of IROFS boundaries in the ISA Summary would constitute a backfit.

LES understands that, under the "compliance exception" to the backfitting rule (10 C.F.R. 70.76(a)(4)(ii)), the NRC does not undertake a backfit analysis if it determines that the modification is necessary to bring the facility into compliance with existing regulatory requirements or written commitments of the licensee. As detailed above, LES established IROFS to meet the performance requirements of 10 C.F.R. 70.61 and submitted its ISA Summary which identified each IROFS pursuant to 10 C.F.R. 70.62. The NRC reviewed LES's ISA Summary and concluded, in the SER, that LES provided reasonable assurance that it identified IROFS and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61. Similarly, as explained above, LES submitted its IROFS Boundary Definition procedure in 2004, and since that time LES has utilized that procedure to define the IROFS boundaries as required Condition 19 of its LES license. Thus LES has complied with the applicable regulatory requirements.

As the NRC's backfitting guidance recognizes, "once the [SER] is issued signifying the staff's acceptance of the programs described in the [SAR], the licensee should be able to conclude that its commitments in the SAR satisfy the NRC requirements in a particular area. If the staff was to subsequently require, after issuance of the license, that the licensee commit to additional action other than that specified in the SAR for the particular area, such action would be a backfit." Management Directive 8.4, *Management of Facility-specific Backfitting and Information Collection*, at page E1-4.

By e-mail on April 8, 2010, the Staff provided LES a preliminary Staff analysis entitled "IROFS Discussion." LES has considered that information and reviewed Administrative Control IROFS for parameter monitoring to confirm that the boundary is properly described and includes the established calibration requirements for any monitoring instrumentation.

Based on the Staff's preliminary analysis, LES understands that some of the Staff's conclusions derive from the view that certain Administrative Control IROFS, such as IROFS C6 and IROFS 38, require the use of supporting instrumentation/controls/devices to accomplish the safety function, along with operator action. While these IROFS use instrumentation for operators to carry out required proceduralized actions, they themselves are not a required part of the IROFS safety function nor are they included within the boundary with the exception of the calibration of

instrumentation for added assurance of accurate and reliable indication. Multiple methods are available both to monitor and control plant performance to prevent abnormal events as demonstrated through past operational history. For the administrative IROFS of concern, the 10 C.F.R. 70.61 performance criteria and health and safety of the public will be maintained even if the support instrumentation fails.

In addition, the Staff's preliminary analysis indicates that if digital instrumentation and controls are utilized as part of IROFS C6 and IROFS 38, then License Condition 20 would require a license amendment seeking approval of their use. License Condition 20 addresses IROFS 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. As of the time of licensing, LES had not identified any IROFS that relied on such features (see SER at 3-35). Again, although some Administrative Control IROFS, such as IROFS 38, may use digital monitoring instruments, the monitoring instruments provide data used by the operations personnel in performing the IROFS but are not essential in accomplishment of the IROFS safety function. In these cases, there are many methods for monitoring and considerable time – ranging from several hours to days – to accomplish the required action, and operations personnel have alternative means to achieve operational control besides digital based controls and are properly trained to take such actions. The LES Operations Requirements Manual (ORM), that has been available during the recent NRC operational readiness review inspections, provides required operator actions in the event process conditions cannot be verified within safe limits (e.g., in the case instrumentation is not available).

If such supporting components must now be included within the IROFS boundaries, LES will be required to qualify the components to Quality Level 1 requirements and meet industry codes and standards not part of the original design and manufacture of these devices, rather than the Quality Level 2 or 3 requirements that have been applied. To qualify and/or redesign these components could take several months to complete if possible. Any design changes would also have to be evaluated against a proven highly reliable design upon which the ISA is largely based. As a result, the first cascade on line date for the LES facility, currently scheduled for May 15, 2010, would be significantly delayed if not entirely prevented.