

**To continue its review, the staff submits the following request for additional information (RAI).**

RAI-1. For accident sequence EC3-1 describes the accident sequence and respective redundant IROFS please clarify the following:

- Provide more detail on the independence of each IROFS. It is not clear how they are individually performed.
- Under what specific circumstances the isolation of the flow is the action.
- Given that the IROFS are independent of each other, describe how the failure of one of the IROFS leads to the isolation of the process or if a double failure is needed for the isolation.

Regulatory Basis

The staff must have reasonable assurance that IROFS identified in the ISA Summary have the capability to mitigate or prevent the accident sequence identified in the ISA. Title 10 CFR 70.62(c)(vi) states in part, that the ISA should identify "...each item relied on for safety identified pursuant to 70.61 (e) of this subpart, the characteristics of its preventive, mitigative, or other safety functions, and the assumptions and conditions under which the items relied upon to support compliance with the performance requirements."

RAI-2. Clarify the safety function for IROFS59 and IROFS22 and specify what parts would be under QL-1? Clarify what portion of each IROFS will be under QL-3 and describe for each IROFS what is considered "Operated Support Equipment" or "Other Equipment"?

Regulatory Basis

The staff must have reasonable assurance that the licensee safety program is graded in such a manner that management measures applied to IROFS are commensurate with the reduction in risk attributed to that item as stated in 10 CFR 70.62 (a).

RAI-3. For IROFS59 and IROFSC22 define "Operated Support Equipment" or "Other Equipment" in terms of whether they represent valves, controllers and controller set points. Specify what quality level will be applied to calibrating the equipment bounded under these IROFS?

- a. Clarify how commitments to RG 1.105, "Set Points for Safety Related Instrumentation" will be incorporated for the controllers associated with these IROFS.
- b. Specify applicable management measures to IROFS559 and IROFSC22 as Redundant IROFS, including the support or other equipment associated with them.

Regulatory Basis

The staff must have reasonable assurance that, as stated in 10 CFR 70.62 (d), management measures are established to ensure compliance with performance requirements in 10 CFR 70.61.

- RAI-4. Justify excluding the definition and discussion of redundant IROFS in the QAPD or revise it to define and clarify the quality level applicable to redundant IROFS.

Regulatory Basis

10 CFR 70.62 (d), states in part, that the measures applied to a particular engineer or administrative control or control system may be graded commensurate with the reduction in risk attributed to the control or control systems.

- RAI-5. Provide a sample of five other IROFS that will be defined as “redundant administrative controls.” For each example, justify its classification as “redundant,” and describe the associated accident sequence and the QL-3 support equipment intended to support the prevention or mitigation of the accident.

Regulatory Basis

The staff must have reasonable assurance that the licensee’s ISA demonstrates the licensee appropriately applied an acceptable ISA methodology to identify those items delineated in 10 CFR 70.62(c)(1)(i) – (vi).

- RAI-6. According to the LES Quality Assurance Program Description (QAPD), Revision 39, QA requirements such as inspection, test, and operating status; corrective action; QA records, and audits are not applicable to QL-3 equipment. Provide a justification for maintaining the performance requirements of redundant IROFS supported by QL-3 equipment without adhering to QA requirements similar to QL-1 or QL-2AC.

Regulatory Basis

10 CFR 70.4 defines items relied on for safety 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.

10 CFR 70.61(e) requires, in part, each engineered or administrative control or control system necessary to comply with performance requirements be designated as an item relied on for safety.

- RAI-7. According to the LES QAPD, Revision 39, the loss of support equipment subject to Section 19, “Provisions for Change,” ...must not represent a loss of a specified safety function of the IROFS.” Will this same criterion apply to the QL-3 support equipment for IROFS like IROFSC22 and IROFS59?

Regulatory Basis

The staff must have reasonable assurance that the licensee's ISA demonstrates the licensee appropriately applied an acceptable ISA methodology to identify those items delineated in 10 CFR 70.62(c)(1)(i) – (vi).

RAI-8. According to the revised ISA Summary, the licensee credits IROFSC22 and IROFS59 each with a failure probability of 0.001 based on independent verification. Provide further justification for concluding that independent verification is robust enough to warrant a failure probability of 0.001, i.e. the independent verification will fail one time out of a thousand.

NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," states that the IROFS boundary for an enhanced administrative control includes all instrumentation (sensors, annunciators, circuitry, any controls activated by the operator) relied on to trigger the operator action. Independent verification is generally not equated to instrumentation. Furthermore, NUREG-1520 places the failure probability index of an enhanced administrative control into context through correlation with a failure frequency qualitatively described as a few failures in the facility's lifetime. In terms of human reliability in plant operations, there is little evidence that supports such a failure frequency for independent verification.

#### Regulatory Basis

The staff must have reasonable assurance that the licensee's ISA demonstrates the licensee appropriately applied an acceptable ISA methodology to identify those items delineated in 10 CFR 70.62(c)(1)(i) – (vi).

10 CFR 70.65(b) states, in part, that the licensee's ISA Summary should list IROFS in sufficient detail to understand their functions in relation to the performance requirements of 10 CFR 70.61;