Orano Enrichment USA, LLC License Application
U.S. Nuclear Regulatory Commission Staff Observations

On March 9, 2026, the U.S. Nuclear Regulatory Commission (NRC) staff completed its audit of the draft application chapters. The draft chapters Orano provided were:

- Chapter 01: General Information
- Chapter 02: Organization and Administration
- Chapter 03: Integrated Safety Analysis
- Chapter 04: Radiation Protection
- Chapter 05: Nuclear Criticality Safety
- Chapter 06: Chemical Safety
- Chapter 07: Fire Safety
- Chapter 08: Emergency Management
- Chapter 09: Environmental Protection
- Chapter 10: Decommissioning
- Chapter 11: Management Measures (including Quality Assurance Program Description - QAPD)
- Chapter 12: Material Control and Accounting (including Fundamental Nuclear Material Control Plan - FMNCP)
- Chapter 13: Physical Protection
- Human Factors Program (HFP)
- Structural/External Events (S-EE)
- Electrical Distribution/Instrumentation and Controls (ED/I&Cs)

Additional draft information provided included:

- Decommissioning Funding Plan (DFP)
- Emergency Plan (EP)
- Fire Hazards Analysis (FHA)

This enclosure (1) provides the NRC staff's observations on the draft chapters of the Orano license application as listed below. Note that, of all of the draft chapters and draft information provided by Orano, those discussed below (e.i., 1, 2, 3, 5, 6, 7, 9, 11,v12, DFP, S-EE, and ED/I&Cs) were the only ones where the NRC staff had observations to provide. There were no observations for those chapters not discussed below (i.e., 4, 8, 10, FHA, and EP). The observations fall into the following three categories:

- Major – A gap in the application that needs to be resolved for the acceptance review.
- Moderate – An issue likely to result in the development of requests for additional information.
- Minor – Clarifications or lessons learned that would contribute to an improved review of the application.

A. Draft Chapter 1: General Information

1. Controlled area boundary description (Moderate):

In the application, the discussion of the facility layout does not define or describe the controlled area boundary, nor does it explain the relationship between the controlled area boundary and the facility buildings.

Per 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), applicants must describe the facility, including its layout and safety related design information, in sufficient detail to support the technical basis of the application. Consistent with NUREG 1520, section 1.1.4.3.1 (Facility Layout Description, item 3) and section 1.3.3 (Areas of Review, item 1a), the applicant should clearly identify the controlled area boundary, describe its extent, and explain how it interfaces with buildings and operational areas important to safety.

The application should therefore define and describe the controlled area boundary and explain its relationship to the facility buildings, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG 1520. This information is necessary to determine whether Orano has provided an adequate description of controlled areas consistent with regulatory expectations for fuel cycle facilities.

2. Cross-references to ISA Summary (Moderate)

In the application, the discussion of the facility layout does not provide specific cross-references to other sections of the application, including the Integrated Safety Analysis (ISA) Summary, for facility layout and process descriptions.

Per 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), applicants must describe the facility, including its layout and safety related design information, in sufficient detail to support the technical basis of the application. Consistent with NUREG 1520, section 1.1.6 (Evaluation Findings, page 1-5, last paragraph), the applicant should provide clear and traceable cross-references that link facility layout information to corresponding process descriptions and ISA Summary content.

The application should therefore provide specific cross-references elsewhere in the application, including the ISA Summary, for facility layout and process descriptions, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG 1520. This information is necessary to determine whether Orano has provided sufficient traceability to support an adequate understanding of facility layout and associated safety information.

3. Building-specific SNM inventories (Moderate)

In the application, the discussion of licensed material does not provide maximum quantities of special nuclear material (SNM) by major building or process area.

Per 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), applicants must describe the facility, including the type, form, and quantity of licensed material present, in sufficient detail to support the technical basis of the application.

Consistent with NUREG 1520, section 1.1.3 (Areas of Review, item 4, “Descriptive Summary of Licensed Material”) and section 1.1.4.3.4 (“Descriptive Summary of Licensed Material,” item 1), the applicant should identify the maximum quantities of SNM by building or process area to support an understanding of material distribution and associated safety considerations.

The application should therefore provide maximum SNM quantities by major building or process area, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG 1520. This information is necessary to determine whether Orano has provided an adequate description of licensed material to support the safety basis for the facility.

4. Meteorological and flood values (Moderate)

In the application, the discussion of natural phenomena hazards does not summarize or cross-reference the design-basis flood and meteorological values used to support the facility’s safety analyses.

Per 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), applicants must describe the facility, including safety related design information and the environmental conditions considered in the safety basis, in sufficient detail to support the technical basis of the application. Consistent with NUREG 1520, section 1.3.4.3 (“Regulatory Acceptance Criteria,” items 3 and 4), the applicant should identify or reference the design-basis flood levels and design-basis meteorological values used to evaluate external hazards and demonstrate that safety functions can be performed under those conditions.

The application should therefore summarize or cross-reference the design-basis flood and meteorological values, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG 1520. This information is necessary to determine whether Orano has provided an adequate description of external hazard design bases to support the facility’s safety basis.

5. Moderators or reflectors (Moderate)

In the application, the discussion of licensed material does not explicitly identify whether moderators or reflectors are present or absent.

Per 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), applicants must describe the facility, including safety related design information and characteristics of licensed material, in sufficient detail to support the technical basis of the application. Consistent with NUREG 1520, section 1.1.4.3.4 (“Descriptive Summary of Licensed Material,” item 2), the applicant should clearly indicate the presence or absence of moderators or reflectors to support an understanding of potential criticality safety considerations.

The application should therefore explicitly identify whether moderators or reflectors are present or absent, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG 1520. This information is necessary to determine whether Orano has adequately described the characteristics of licensed material important to criticality safety.

6. **Waste discharge points (Major)**

   In the application, the discussion of licensed material does not summarize the types of waste generated nor identify any environmental discharge points or confirm that none exist.

   Per 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), applicants must describe the facility, including safety related design information and the characteristics and disposition of licensed material, in sufficient detail to support the technical basis of the application. Consistent with NUREG 1520, section 1.1.4.3.4 (“Descriptive Summary of Licensed Material,” item 1), the applicant should identify the types of waste generated and indicate whether any environmental discharge points exist or confirm if no such discharge points are present.

   The application should therefore summarize waste types and identify any environmental discharge points or confirm that none exist, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG 1520. This information is necessary to determine whether Orano has adequately described waste streams and potential environmental discharges associated with licensed material.

Principal Contributor:

Osiris Siurano-Pérez

B. Draft Chapter 2: Organization and Administration

Overall Determination

The information contained in the Chapter 2 Word document substantially meets the acceptance criteria in NUREG-1520, Revision 2, Chapter 2. The application provides sufficient information to support an NRC detailed technical review. No major deficiencies were identified.

However, several criteria are only partially met and require clarification or additional specificity. These items would reasonably result in Requests for Additional Information but do not prevent the NRC from proceeding with a detailed review.

The following acceptance criteria are not fully satisfied

1. Management qualification specificity (Moderate)

In the draft chapter, qualification requirements for some management positions are described in general terms and do not consistently specify minimum education or experience levels.

Per Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22 and 10 CFR 70.65(b)(1)–(2), applicants must describe organizational structure and management responsibilities in sufficient detail to support the technical basis of the application. Consistent with NUREG-1520, sections 2.4.3 (“Regulatory Acceptance Criteria,” A.3 and B.2), applicants should identify qualification requirements—including minimum education and experience—for management positions that perform safety-significant functions.

Orano should provide specific qualification requirements for management positions, including minimum education and experience levels, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and the expectations in NUREG-1520. This information is necessary to determine whether Orano has adequately described management qualifications important to safety.

2. Accessibility of position descriptions (Moderate)

The draft chapter does not explicitly state that formal position descriptions—including qualifications, responsibilities, and authorities—are maintained and available to the NRC upon request.

Per 10 CFR 70.22 and 10 CFR 70.65(b)(1)–(2), applicants must provide sufficient detail regarding organizational responsibilities to support the facility’s safety basis. Consistent with NUREG-1520, section 2.4.3 (“Regulatory Acceptance Criteria,” B.2), applicants should identify where formal position descriptions are maintained and ensure that they can be provided to the NRC for inspection.

The application should therefore indicate that formal position descriptions are maintained and will be made available to the NRC upon request, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and NUREG-1520. This information is necessary to determine whether Orano has adequately documented and preserved role definitions important to safety.

3. **Employee safety-concern reporting mechanism (Moderate)**

   Although corrective action programs are described, the draft chapter does not provide an explicit commitment to a simple, facility-wide mechanism for all workers to report unsafe conditions.

   Per 10 CFR 70.22 and 10 CFR 70.65(b)(1)–(2), applicants must describe programs and processes that ensure workers can identify and report safety issues. Consistent with NUREG-1520, section 2.4.3 (“Regulatory Acceptance Criteria,” B.6), applicants should describe a safety-concern reporting mechanism that is accessible to all employees.

   The application should therefore identify a facility-wide safety-concern reporting mechanism available to all workers, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and NUREG-1520. This information is necessary to determine whether Orano has established adequate processes for reporting and addressing safety concerns.

4. **Written offsite emergency response agreements (Moderate)**

   The draft chapter references interfaces with offsite emergency organizations but does not clearly state that written agreements exist or will be established.

   Per 10 CFR 70.22 and 10 CFR 70.65(b)(1)–(2), applicants must describe arrangements with offsite organizations supporting facility emergency preparedness. Consistent with NUREG-1520, section 2.4.3 (“Regulatory Acceptance Criteria,” B.9), applicants should document written agreements with offsite emergency response organizations.

   The application should clearly state that written agreements with offsite emergency response organizations exist or will be developed, consistent with 10 CFR 70.22, 10 CFR 70.65(b)(1)–(2), and NUREG-1520. This information is necessary to determine whether Orano has established appropriate offsite support arrangements for emergency preparedness.

Principal Contributor

Osiris Siurano-Pérez

C. Draft Chapter 3: Integrated Safety Analysis

1. Descriptive List of IROFS (Major)

In the application, Orano does not include the list of items relied on for safety (IROFS) required by 10 CFR 70.65(b)(6). Specifically, the ISA Summary lacks the descriptions, in sufficient detail, necessary to understand each IROFS's function in relation to the performance requirements of 10 CFR 70.61. Also, the application does not provide the typical categorization of each IROFS as passive engineered, active engineered, enhanced administrative, or administrative control.

NUREG-1520, Chapter 3, Appendix A, provides acceptable formatting for the IROFS description in Table A-13. Additional context on the required content is found on page 3-A-14 of Appendix A. These references clarify that the applicant must describe each IROFS in sufficient detail to support staff review of its function, safety role, and associated management measures. These requirements directly support compliance with 10 CFR 70.65(b)(6) and the performance standards of 10 CFR 70.61.

Orano must provide a complete list of IROFS with concise descriptions of their safety functions, consistent with NUREG-1520 guidance. This information is necessary for NRC staff to evaluate whether the applicant has provided sufficient detail to understand the function of each IROFS to evaluate its adequacy, determine whether the identified IROFS meet the performance requirements of 10 CFR Part 70, Subpart H, and that the information provided supports a finding of reasonable assurance of adequate protection.

2. Descriptive List of IROFS that are the Sole Item Preventing or Mitigating an Accident Sequence (Major)

In the ISA Summary, Orano does not include the descriptive list of IROFS required by 10 CFR 70.65(b)(8). Specifically, the ISA Summary lacks identification of those IROFS that serve as the sole item preventing or mitigating an accident sequence that would otherwise exceed the performance requirements of 10 CFR 70.61. Without this information the NRC staff cannot determine whether the applicant has provided sufficient detail to support a finding of reasonable assurance of adequate protection.

NUREG-1520, Chapter 3, Appendix A, provides guidance on the level of detail and content necessary for describing IROFS that are credited as sole items preventing or mitigating accident sequences. This includes clear identification of their safety function, role in meeting the performance requirements of 10 CFR 70.61 and supporting management measures. These requirements directly support compliance with 10 CFR 70.65(b)(8) and the performance standards of 10 CFR 70.61.

Orano must clearly identify all IROFS that serve as the sole credited item preventing or mitigating accident sequences that could exceed the performance requirements, along with concise descriptions of their safety functions, consistent with NUREG-1520 guidance. This information is necessary for NRC staff to evaluate whether the applicant has provided sufficient detail to understand the function and adequacy of each sole IROFS, determine whether the identified controls meet the performance requirements of 10 CFR Part 70, Subpart H, and ensure that the information supports a finding of reasonable assurance of adequate protection.

3. Detail on Use of Demand Rates for Initiating Events Caused by Failure of an IROFS (Moderate)

Orano does not provide sufficient information to demonstrate that initiating event frequencies derived using Tables A-9, A-10, and A-11 of NUREG-1520 appropriately account for demand rate when the initiating event is associated with a P-type event (e.g., failure of an administrative control). Specifically, the ISA Summary assigns an initiating event frequency index of –2 to accident identifier CL1-2, which appears to be based on failure of IROFS 98, without providing information on the demand rate associated with this control.

NUREG-1520 provides context regarding the proper consideration of demand rate when evaluating initiating event frequencies. Pages 3-B-6 and 3-AA-3 through 3-AA-5 explain that P-type failures must incorporate frequency of required actions when determining the likelihood index, because controls required multiple times per year result in significantly higher initiating event frequencies than controls required only once per year. These requirements directly support the proper application of Tables A-9 through A-11 and are necessary to ensure compliance with the performance standards of 10 CFR 70.61.

Orano must clearly describe how initiating event frequencies were determined for P-type failures, including the demand rate associated with each credited administrative control, consistent with NUREG-1520 guidance. This information is necessary for NRC staff to evaluate whether the applicant has provided sufficient detail to understand the likelihood assigned to each initiating event, determine whether the assigned frequencies appropriately support compliance with 10 CFR Part 70, Subpart H, reflect actual operating conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

4. Detail on the Description of Accident Sequences (Moderate)

Orano does not provide sufficient information in the ISA Summary to demonstrate that the description of accident sequences meets the requirements of 10 CFR 70.65(b). Specifically, while the ISA Summary includes general discussions of accident sequences, it does not provide sufficient detail to understand the safety function of the IROFS within the context of each accident sequence or how the IROFS support meeting the performance requirements of 10 CFR 70.61.

NUREG-1520 provides guidance on the level of detail necessary for describing accident sequences and the associated IROFS. This includes identifying the sequence of events, describing the credited IROFS and their safety functions, and explaining how those functions prevent or mitigate the consequences of each accident sequence to meet the performance requirements. These requirements directly support accurate and complete ISA documentation and are necessary to demonstrate compliance with 10 CFR 70.65(b) and the performance standards of 10 CFR 70.61.

Orano must clearly describe each accident sequence with sufficient detail to explain the safety function of each credited IROFS, consistent with NUREG-1520 guidance. This information is necessary for NRC staff to evaluate whether the applicant has provided adequate detail to understand each accident sequence, determine whether the identified IROFS appropriately meet the performance requirements of 10 CFR Part 70, Subpart H,

reflect actual operating conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

5. Description of Each Process (Moderate)

Orano does not provide sufficient information in the ISA Summary to demonstrate that the description of the site, facility, and each process analyzed in the ISA meets the requirements of 10 CFR 70.65(b). Specifically, while section 2.1 of the ISA Summary lists several systems, the application does not provide further descriptions of these systems, leaving insufficient detail to understand their functions or their relevance to the processes analyzed in the ISA.

NUREG-1520 provides guidance on the level of detail necessary for describing the site, facility, and processes evaluated in the ISA. This includes providing clear descriptions of system functions, boundaries, and relationships to the processes analyzed, as well as any safety-significant aspects of those systems. These requirements directly support accurate and complete ISA documentation and are necessary to demonstrate compliance with 10 CFR 70.65(b) and to support evaluations conducted under the performance standards of 10 CFR 70.61.

Orano must clearly describe the systems identified in section 2.1, including their functions and relevance to each process analyzed in the ISA, consistent with NUREG-1520 guidance. This information is necessary for NRC staff to evaluate whether the applicant has provided sufficient detail to understand the systems and their roles in the ISA, determine whether the information appropriately supports compliance with 10 CFR Part 70, Subpart H, reflect actual operating conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

Principle Contributor

Langston Lewis

D. Draft Chapter 5: Nuclear Criticality Safety

1. Technical Practice for Nuclear Criticality Safety (NCS) Missing Information (Major)

Section 5.7, “Technical Practices for NCS,” of the OE Facility License Application does not include the information necessary to complete an acceptance review consistent with the regulatory acceptance criteria in NUREG-1520, Rev. 2, Section 5.4.3. While compliance with NUREG-1520 is not required to meet the regulatory requirements of 10 CFR Part 70, applicants that do not follow applicable guidance must describe and justify alternative approaches. The application does not provide such justifications for the areas identified below, and the absence of this information limits the staff’s ability to determine whether the regulatory requirements have been met. The following issues are not exhaustive, and providing the information described below does not guarantee acceptance.

Per 10 CFR 70.61 and 70.62, applicants must identify and analyze credible criticality accident sequences and establish IROFS and management measures to ensure that criticality safety is maintained. In accordance with 10 CFR 70.65(b), the application must provide sufficient detail to enable the NRC to determine whether the requirements for criticality safety have been met. NUREG-1520, Chapter 5, provides detailed acceptance criteria for calculational methods, criticality safety evaluations (CSEs), and control methods that, when followed, demonstrate compliance with regulatory requirements. Applicants deviating from this guidance must provide alternative technical bases and justification.

To meet regulatory requirements, Orano must address the following:

- 5.7.1 Calculational Method Validation
    - Provide the full validation report and supporting details required by NUREG-1520 Section 5.4.3.1.7.1(A) and (B), including documentation of the quality assurance applied to the development of the validation report.
    - Identify the method and value of the upper subcritical limit (USL). The only reference to a Keff value is within the Geometry/Volume section (0.95), and no supporting basis or USL determination is provided.
    - Demonstrate how the validation report supports the USL and how the USL informs the margin of subcriticality used in criticality safety evaluations (CSEs).
- 5.7.2 Nuclear Criticality Safety Evaluations (CSEs)
    - Provide detail demonstrating that CSEs will adhere to the principles outlined in NUREG-1520 section 5.4.3.1.7.2, including documentation of methods, assumptions, controlled parameters, and safety bases.
- 5.7.3 Control Methods for Prevention of Criticality
    - Clarify the facility’s commitment to the double-contingency principle (DCP) within CSEs.
    - Provide a detailed description of the hierarchy of controls. The current statement—“Where possible, passive engineered controls are used”—is insufficient.

- Address missing commitments related to NUREG-1520 Section 5.4.3.1.7.3. For example, enrichment CSEs are stated to be analyzed at 11% U-235 while geometry and volume assumptions use 10% U-235. When parameters are not controlled, the highest credible (worst-case) value must be assumed; the application does not justify deviation from this principle.
- Establish safety limits for controlled parameters within the application.
- Address acceptance criteria in Sections 4, 5, 7, 8, 9, 11, and 13 of NUREG-1520 Section 5.4.3.1.7.3 or justify acceptable alternatives.

This information is necessary to determine whether Orano has adequately described its technical practices for NCS, provided a sufficient basis for its calculational methods and controls, and met the requirements of 10 CFR 70.61, 70.62, and 70.65.

2. Standard Commitment Clarifications (Moderate)

Orano cites three ANSI/ANS standards—8.1, 8.3, and 8.24—as committed standards for NCS. However, in several portions of the application, the applicant states that certain plans were “developed consistently with” additional ANSI/ANS standards (i.e., 8.23, 8.19, and 8.20) without formally committing to them. While referencing standards in this manner may be acceptable, the application does not provide sufficient detail to demonstrate how the associated plans meet the intent of the regulations or how they align with applicable NCS practices described in these standards.

Per 10 CFR 70.61 and 70.62, applicants must identify and describe the IROFS, management measures, and technical practices necessary to ensure that accident sequences with potential criticality consequences are prevented or mitigated. Under 10 CFR 70.65(b), the application must include sufficient detail for the NRC to evaluate the adequacy of the applicant’s NCS program. NUREG-1520, Chapter 5, provides guidance for evaluating an applicant’s criticality safety practices and notes that when applicants choose not to commit to certain industry standards, they must clearly describe and justify alternative practices or provide sufficient detail to demonstrate alignment with regulatory requirements.

To meet regulatory requirements, Orano must:

- Clarify whether ANSI/ANS-8.23, 8.19, and 8.20 are formally committed standards or whether alternative approaches are being used.
- If these standards are not being committed to, provide detailed descriptions of the associated plans to demonstrate how they meet regulatory intent and support compliance with 10 CFR Part 70 criticality safety requirements.
- Provide justification for any deviations from applicable ANSI/ANS standards or describe alternative practices used to ensure safety.
- Ensure that descriptions are detailed enough to allow the NRC to evaluate the adequacy of the NCS technical practices without requiring additional information during acceptance review.

This information is necessary to determine whether the applicant’s use of ANSI/ANS standards—or alternative approaches—is sufficient to meet the regulatory requirements for nuclear criticality safety in accordance with 10 CFR 70.61, 70.62, and 70.65.

Principal Contributors

Logan Crevelt, Criticality Safety Engineer
Zee St. Hilaire, Criticality Safety Engineer

E. Draft Chapter 6: Chemical Processes Safety

1. Reasonableness/Conservatism of Consequence Analysis (Moderate)

Section 6.3.2.1.1 “Worker Exposure Assumptions”, of Orano’s draft chapter 6 states that “UF_6 is assumed to instantaneously mix in the room free volume, with no leakage producing a constantly increasing concentration until the release stops. The worker exposure duration is independent of the release duration, and the consequences are computed on the time-averaged concentration. Sufficient time is available for the worker to reliably detect and evacuate the area of concern prior to release.” The assumption of instantaneous mixing is conservative in some cases but not in others. For example, if a worker is located near the point of release, the concentration could be significantly higher than estimated under instantaneous mixing assumption. The application does not discuss how it supports the assessment that the consequence estimates are reasonable/conservative when there are multiple assumptions, some of which might be non-conservative.

The general and additional requirements regarding the contents of an application with respect to chemical process safety are in 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65 respectively. General information that must be included in the license application appears in 10 CFR 70.22. Information that must be included in the ISA summary appears in 10 CFR 70.65. The guidance in NUREG-1520, section 6.4.3.3(2), state that applicants should identify and use appropriate techniques and [conservative][1] assumptions in estimating concentrations of hazardous chemicals produced from licensed material or abnormal plant conditions that could affect the safety of licensed materials. The current application does not describe how the applicant evaluates the combined effect of conservative and non-conservative assumptions or how it verifies that the final consequence estimates meet the intent of this guidance.

Orano must clearly describe how it provides assurance that chemical consequence estimates are reasonable and conservative when some assumptions may be non-conservative, such as the use of instantaneous mixing when a worker may be located near the release point. The applicant should also describe whether an independent review or assessment is performed to evaluate the overall reasonableness of chemical consequence estimates. This information is necessary for NRC staff to determine whether the applicant has provided sufficient detail to support the chemical hazard evaluation, assess compliance with 10 CFR Part 70, Subpart H, ensure that analyses reflect realistic operating conditions, and support a finding of reasonable assurance of adequate protection.

2. Description of IROFS for Mitigation of HF Leaks/Release (Major)

Sections 6.3.2.1.1, “Worker Exposure Assumptions”, 6.5.2, “System Designs”, and 6.5.2.2, “Mitigative Features” of draft chapter 6 reference alarming within chemical processes and leak detection for UF_6/HF but do not explicitly state whether HF-specific detectors are utilized. Under section 6.5.2.2, Alarm Systems, it is noted that: “Leak detection is also provided to detect the release of UF_6/HF in the facility GEVS systems and other ventilation systems.” The ISA Summary references sensors for weight,

[1] Per NUREG-1520 section 3.4.3.2, “*The reviewer should verify that the applicant has used conservative assumptions and bounding conditions in the ISA to ensure that the performance requirements of 10 CFR 70.61 are met.”*

pressure, and temperature that initiate alarms when parameters are exceeded (e.g., pressure transducers are noted in ISAS section 2.1.2.7 as monitoring loss of feed supply). However, it is unclear whether these sensors provide timely and reliable HF detection, or whether this function is designated as an applied IROFS. Additionally, there are no descriptions for the applied IROFS listed in Table 2-2 and 2-3 of the ISA summary that would assist the reviewer in understanding the functions of the IROFS to mitigate an HF release.

Pursuant to 10 CFR 70.62(c)(1)(ii), (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies: (ii) chemical hazards of licensed material and hazardous chemicals produced from licensed material. Additionally, 10 CFR 70.65(b)(6) states that the integrated safety analysis summary must contain: (6) A list briefly describing each item relied on for safety which is identified pursuant to 10 CFR 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of 10 CFR 70.61.

Per NUREG-1520, section 6.4.3.4. The applicant must provide in the ISA summary a list of chemical process safety controls (i.e., IROFS) that are necessary to meet the performance requirements of 10 CFR 70.61. The applicant should identify IROFS for any unmitigated hazardous chemical accident sequences that would lead to consequences that exceed the performance requirements. The applicant should describe the IROFS in sufficient detail to permit an understanding of their safety functions.

Orano needs to identify and provide descriptions for any IROFS required for timely worker action (e.g., IROFS 95 for worker evacuation). The final ISAS must show IROFS, their descriptions, and the Management Measures.

3. Clarification of Chemical Dose Values, Uranium Intake Designation, and Inclusion of Standards (Minor)

Several tables in the License Application lack sufficient detail to verify compliance with performance requirements:

- Table 6-8 cites NUREG-1391 for renal damage thresholds instead of providing numeric values.
- UF_6 and HF doses reference AEGL levels without listing quantities, and AEGL units are missing in Tables 6-9 and 6-10.
- The source of acute chemical exposure values used for Table 6-12 high and intermediate consequences is unclear.
- Table 6-11 lists both “Uranium (mg) in 70 kg person” and “Uranium intake (mg) by 70 kg person” without clarifying the distinction. NUREG-1391 explains that 49% of intake is excreted via kidneys, but this clarification is not included in the application.

The requirements in 10 CFR 70.65(b)(7) state that the integrated safety analysis summary must contain: (7) “A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site or expected to be on-site.” This information is necessary to confirm that dose thresholds, AEGL values, and uranium intake assumptions are correctly applied and documented.

Orano needs to:

- Provide the actual numeric values for chemical dose thresholds (e.g., permanent renal damage, transient renal injury) and AEGL levels cited in Tables 6-8, 6-9, and 6-10. Include appropriate units for all AEGL values.
- Identify the source(s) for the acute chemical exposure values used for the Table 6-12 high and intermediate consequences.
- Clarify the difference between “Uranium (mg) in 70 kg person” and “Uranium intake (mg) by 70 kg person” in Table 6-11. Include explanatory notes consistent with NUREG-1391.
- Ensure that all tables include standards, units, and references for the values provided to support regulatory compliance and transparency.

The information is necessary to confirm that the assumptions and standards applied are appropriate and conservative.

4. Clarification of contents of application (Minor)

The updated License Application (LA) now contains sections 6.1, 6.3, 6.5 and 6.6. Please confirm whether additional information will be provided to address sections 6.2 and 6.4 (currently missing).

5. Detailed discussion of consequence analysis methodology

The NRC staff plans to review the consequence analysis calculations in the ISA documentation (referred to in section 2.3.2.2, “Blending Donor Station Heater Controller Failure and Heater Run Away (No IROFS Credited,” of draft application chapter 6) as part of the horizontal and vertical slice review process. The NRC staff will perform this review once the supporting documentation and calculation packages are ready and available.

Principal Contributor

Nicole D. Cortés Medina

F. Draft Chapter 7: Fire Safety

NOTE: due to time constraints, the FHA was not evaluated. The NRC staff will conduct this review after the application is submitted.

1. Facility Construction (Major)

Orano does not provide sufficient information in section 7.3.1 of the LA to demonstrate that the description of the proposed facility construction meets the expectations necessary to support an acceptance review under 10 CFR Part 70. Instead of providing a description of the construction features of the proposed facility, section 7.3.1 simply states that "Chapter 1 of the ISA describes the proposed facility construction, functional areas and process-related buildings that make up the proposed facility." This does not provide the level of detail needed for the U.S. NRC staff to understand the construction characteristics relevant to fire protection, confinement, and overall safety-significant design features.

The guidance in NUREG-1520 state that applicants should provide sufficient detail regarding facility construction and structural features to support evaluation of accident sequences, fire protection capabilities, and interactions with safety controls credited in the ISA. This includes describing construction materials, structural characteristics, fire ratings, barriers, ventilation configurations, and detection systems. These details are necessary to support the evaluation of compliance with 10 CFR Part 70 performance requirements.

Orano must clearly describe the construction features of the proposed facility in section 7.3.1, consistent with NUREG-1520 guidance. Information may include, but is not limited to:

- building/room (wall, ceiling, floor, door, window) in structure, material, insulation, weight support, and thickness,
- ventilation system and exhaust air/particulate systems (number, locations, and discharge rates of air/effluent outlet ducts),
- temperature detector and smoke detector, and fire alarm system,
- spacer, barriers, walls, windows, or other means to contain fire within the area, and
- hour ratings of wall, floor, ceiling, doors, and windows per International Building Code.

This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand construction characteristics relevant to safety, determine whether the information supports compliance with 10 CFR Part 70, Subpart H, reflect actual facility conditions, and ensure that the information supports a finding of reasonable assurance of adequate protection.

2. Power Supply and Distribution Systems (Major)

Orano does not provide sufficient information in section 7.3.3 of the LA to demonstrate that the electrical systems at the proposed facility meet the expectations necessary to support an acceptance review under 10 CFR Part 70. While the LA states that all electrical systems will be installed in accordance with National Fire Protection

Association (NFPA) 70, National Electrical Code, it does not describe the power supply and distribution systems for the proposed facility.

The guidance in NUREG-1520 state that applicants should provide descriptions of electrical power supply and distribution systems, including information on system configuration, redundancy, distribution architecture, and major components, to support evaluations of facility reliability and interactions with safety-significant systems.

Orano must clearly describe the facility power supply and distribution systems in section 7.3.3, including components such as control centers, panel boards, transformers, capacitors, and other major distribution equipment, consistent with the guidance in NUREG-1520. This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand the reliability of electrical systems, determine whether the systems support compliance with 10 CFR Part 70, Subpart H, reflect actual facility conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

3. Ventilation, Containment, Filtration and Exhaust systems (Major)

Orano does not provide sufficient information in section 7.3.5 of the LA to demonstrate that the description of the ventilation systems meets the expectations necessary to support an acceptance review under 10 CFR Part 70. Instead of providing only a brief statement, the LA must describe the ventilation systems in enough detail for the NRC staff to evaluate how the systems function to control smoke, fire, and combustible gases during onsite, external, or internal fire events.

The guidance in NUREG-1520 state that applicants should describe ventilation features and associated support systems that are relied upon for fire protection, confinement, and mitigation of hazardous conditions. This includes describing equipment and design features such as dampers, filters, containment boundaries, and HVAC components that influence the facility's ability to protect workers and maintain control of licensed material during fire events.

Orano must clearly describe the proposed facility ventilation systems in section 7.3.5, consistent with the guidance in NUREG-1520. Information should include, but is not limited to:

- fire/smoke dampers and detectors
- filtration systems (e.g., high-efficiency particulate air filtration systems and high-efficiency gas absorption systems
- containment systems
- supporting systems such as ductwork and HVAC

This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand ventilation system capabilities, determine whether the systems support compliance with 10 CFR Part 70, Subpart H, reflect actual facility conditions, and ensure that the information supports a finding of reasonable assurance of adequate protection.

4. Water Control Considerations (Major)

Orano does not provide sufficient information in section 7.3.6 of the LA to demonstrate that the drainage and containment system design will meet the expectations necessary to support an acceptance review under 10 CFR Part 70. Section 7.3.6 states that the drainage and containment system design and configuration will be addressed during the detailed design phase; however, the LA does not describe the basic methods the facility will use to control water, drainage, or contaminated runoff during fire protection activities.

The guidance in NUREG-1520 state that applicants should provide sufficient detail regarding drainage, containment, and water management practices to ensure that firefighting water, fire suppression discharges, or other emergency response activities do not compromise safety controls credited in the ISA. This includes describing water-reactive materials, water routing strategies, and emergency response plans that address use of water in areas where nuclear criticality safety concerns may exist.

Orano must clearly describe the basic methods it will use to control water, drainage, and contaminated runoff at the facility, consistent with the guidance in NUREG-1520. The LA may discuss water-reactive materials and their quantities and packaging, pre-incident plans that guide the use or restriction of water in specific areas, and emergency response activities that ensure firefighting water does not create a credible criticality event. This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand water-management practices, determine whether the proposed measures support compliance with 10 CFR Part 70, Subpart H, reflect actual facility conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

5. Lightning Protection (Moderate)

Orano does not provide sufficient information in section 7.3.7 of the LA to demonstrate that the lightning protection system for the proposed facility meets the expectations necessary to support an acceptance review under 10 CFR Part 70. While the LA states that lightning protection will be installed as necessary in accordance with NFPA 780, Standard for the Installation of Lightning Protection Systems, section A.1.1.5 of the FHA notes that lightning strikes account for approximately one-eighth of wildland fires. The LA does not clearly describe the safety significance of the lightning protection system or the basis for determining whether the system is relied upon for safety or requires ongoing maintenance to ensure reliability.

The guidance in NUREG-1520 state that applicants should provide sufficient detail regarding systems that protect the facility from external hazards, including lightning-initiated fire events, to support evaluations under the performance requirements of 10 CFR Part 70. This includes identifying whether such systems are credited to prevent or mitigate accident sequences, describing their design basis, and demonstrating alignment with applicable standards such as NFPA 780.

Orano must clearly address the following in section 7.3.7, consistent with the guidance in NUREG-1520 state:

- Clarify whether the lightning protection system is an IROFS or whether a maintenance program will be implemented to ensure that the system remains available and reliable.

- Provide the calculated expected lightning frequency (Nd) and tolerable lightning frequency (Nc) in the FHA, as required by NFPA 780, to support the design and installation of the lightning protection system at the proposed facility.

This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand the safety significance and design basis of the lightning protection system, determine whether the proposed approach supports compliance with 10 CFR Part 70, Subpart H, reflect actual site conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

6. Process Fire Safety (Major)

Orano does not provide sufficient information in section 7.4 of the LA to demonstrate that the discussion of process-related fire hazards meets the expectations necessary to support an acceptance review under 10 CFR Part 70. Section 7.4 states that the primary process chemical of concern is uranium hexafluoride (UF_6) and explains that UF_6 is not flammable and does not decompose into flammable constituents under conditions expected at the facility. The section also notes that the two byproducts of a UF_6 release—hydrogen fluoride (HF) and uranyl fluoride (UO_2F_2)—do not present process fire safety hazards. However, this discussion does not address other potential fire hazards associated with process equipment, combustible liquids used as cooling media or lubricants, or transient combustibles present in the facility.

The guidance in NUREG-1520 state that applicants should identify and describe all potential fire hazards that could affect safety-related equipment or challenge controls credited in the ISA. This includes hazards associated with facility processes, combustible materials, equipment-related fire sources, and transient fire loads. Providing only information related to the primary chemical of concern does not satisfy this expectation, as fire hazards may originate from non-process materials and equipment interactions.

Orano must clearly discuss, in section 7.4, the potential fire hazards associated with process equipment, combustible liquids used as cooling media or lubricants, and transient combustibles at the facility, consistent with the guidance in NUREG-1520. This information is necessary for the NRC staff to evaluate whether Orano has identified all relevant fire hazards, determine whether the LA supports compliance with 10 CFR Part 70, Subpart H, reflect actual facility conditions, and ensure that the information supports a finding of reasonable assurance of adequate protection.

7. Physical Security Concerns (Moderate)

Orano does not provide sufficient information in Chapter 7 of the LA to demonstrate that physical security concerns associated with potential fire events have been adequately addressed to support an acceptance review under 10 CFR Part 70. The LA does not describe how physical security requirements interface with fire safety considerations, including safe egress, emergency response, and coordination between onsite and offsite personnel during a fire event.

The guidance in NUREG-1520 state that applicants should identify and describe interactions between safety systems and physical security features when those interactions may influence the ability of personnel to evacuate or respond to emergencies. NFPA 101, Life Safety Code, requires that security measures must not prevent or obstruct safe means of egress during emergency conditions. Accordingly, the LA must provide sufficient detail to demonstrate that physical security provisions will not hinder fire response or evacuation capabilities.

Orano must clearly describe the physical security concerns relevant to fire events, including safe egress plans or methodologies and the roles of onsite and offsite emergency response personnel, consistent with the guidance in NUREG-1520. The LA must also ensure that security requirements do not prevent safe emergency egress as required by NFPA 101. This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand how security measures may affect fire response and evacuation, determine whether the LA supports compliance with 10 CFR Part 70, Subpart H, reflect actual facility conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

8. NFPA Codes (Moderate)

Orano does not provide sufficient information in the LA or related documents to demonstrate that the NFPA codes cited for fire protection compliance meet the expectations necessary to support an acceptance review under 10 CFR 70.64(a)(3). The LA references various NFPA codes but does not specify the edition of each code being applied. Because NFPA code requirements can vary by edition and the applicable edition is often based on the year of construction, the omission of this information prevents the NRC staff from determining whether the cited guidelines are current, effective, and applicable to the proposed facility.

The guidance in NUREG-1520 state that applicants should identify the specific versions of industry codes and standards credited in the safety analysis so that the NRC staff can evaluate their applicability and consistency with regulatory expectations.

Orano must clearly specify, in the LA and related documents (e.g., ISA Summary, FHA), the edition of each NFPA code cited for fire protection and confirm that the guidelines from these editions remain effective and applicable to the proposed facility. This information is necessary for the NRC staff to evaluate whether Orano has provided sufficient detail to understand the fire protection basis, determine whether the cited standards support compliance with 10 CFR 70.64(a)(3) and 10 CFR Part 70, Subpart H, reflects actual facility design conditions, and ensure that the information provided supports a finding of reasonable assurance of adequate protection.

Principal Contributor

Jimmy Chang

G. Draft Chapter 9: Environmental Protection

1. Missing/Incomplete Information (Minor)

Orano's information on Environmental Protection generally follows the guidance in NUREG-1520, Chapter 9, but it does not clearly address several gaps that affect the completeness and internal consistency of the information provided. In Section 9.1.1.4.2, the draft chapter references Section 9.1.5; however, no Section 9.1.5 exists in the draft chapter. In addition, Table 9-1, "Effluent Monitoring Program," includes gross beta monitoring and gross alpha/beta monitoring for liquid condensate samples, but Table 9-2 does not include minimum detectable concentrations (MDCs) for gross beta in gaseous effluents or gross alpha/beta in liquid effluents. Without this information, it is not possible to determine whether Orano's environmental monitoring program is fully described or aligned with regulatory expectations.

Per NUREG-1520, Chapter 9, the applicant must provide a clear and internally consistent description of its environmental protection program, including effluent monitoring strategies, analytical capabilities, and detection limits. In addition, Title 10 of the *Code of Federal Regulations* (10 CFR) 70.65(b)(9) and (10) require the applicant to describe its environmental protection and effluent monitoring programs in sufficient detail to demonstrate compliance with applicable requirements under 10 CFR Part 20, including public dose limits in Subpart D. Further, 10 CFR 70.59 requires the applicant to maintain effluent monitoring systems capable of identifying and reporting abnormal releases. These requirements ensure the NRC can verify that effluent characterization methods, monitoring parameters, and MDC values are adequate to support regulatory compliance.

To meet regulatory requirements, Orano must address the following:

- Correct the reference in Section 9.1.1.4.2 to Section 9.1.5 or include and describe Section 9.1.5 if it is intended to exist.
- Ensure consistency between Table 9-1 and Table 9-2 by including MDC values for gross beta monitoring in gaseous effluents and gross alpha/beta monitoring in liquid effluents, consistent with the monitoring parameters listed in Table 9-1.

This information is necessary to determine whether Orano's environmental protection program aligns with the guidance in NUREG-1520 and the requirements of 10 CFR Part 20 and Part 70 and provides reasonable assurance that effluent monitoring methods and detection limits are adequately characterized.

Principal Contributor:

Sunita Kambo

H. Draft Chapter 11: Management Measures

1. ISA Maintenance and Update Triggers (Major)

In sections 11.2.1 -11.2.4 the application states that corrective maintenance results, surveillance and monitoring activities, and preventive maintenance activities related to IROFS will be evaluated by the applicable safety disciplines to determine any impact on the ISA and any necessary updates. However, the application does not describe how, when, or by whom the ISA is updated before changes are implemented. Without this information, it is not possible to determine whether the applicant's configuration management and change-control processes meet regulatory requirements.

Per NUREG-1520, Rev. 2, Section 3.3.1, "Safety Program and Integrated Safety Analysis Commitments," the applicant must describe and commit to management procedures for conducting and maintaining the ISA. Section 3.4.3.1, "Safety Program and Integrated Safety Analysis Commitments," item (2)(b) of NUREG-1520 further states that the applicant must keep the ISA and its supporting documentation accurate and up to date through a suitable configuration management system, and must submit changes to the ISA Summary to the NRC in accordance with 10 CFR 70.72(d)(1) and (3). Section 3.4.3.1, item (2)(d) requires the applicant to evaluate proposed changes to the facility or its operations using ISA methods, designate new or additional IROFS and associated management measures as needed, and promptly evaluate the adequacy of existing IROFS when changes could affect their performance. If a proposed change results in a revised accident sequence in the ISA Summary or increases the consequences or likelihood of a previously analyzed accident sequence under 10 CFR 70.61, the applicant must promptly evaluate the adequacy of existing IROFS and management measures and make necessary changes.

The application must clearly describe the process by which ISA updates occur, including the timing of evaluations, the responsible organizations, or how ISA revisions are incorporated prior to implementing changes. This information is necessary to determine whether the applicant's commitments to maintain the ISA and evaluate changes are consistent with the requirements of 10 CFR Part 70, Subpart H.

2. Graded Approach (Major)

In section 11.0, the application states that management measures are implemented through a graded approach under the OE's Quality Assurance Program Description (QAPD), and that the QAPD provides additional measures to ensure that the design, construction, operation, and decommissioning of IROFS are controlled commensurate with the complexity of the service, the level of significance, and importance to safety. However, the application does not describe how the assigned Quality Levels (QLs) link to specific management measures such as configuration management, maintenance, training and qualification, procedures, or other controls necessary to ensure IROFS reliability. Without this linkage, it is not possible to determine whether the graded approach is applied in a manner consistent with regulatory expectations for safety-significant items.

Per NUREG-1520, Rev. 2, Section 3.4.3.2(6), "List Describing Items Relied on for Safety," the list required by 10 CFR 70.62(c)(1)(vi) is acceptable only if it meets certain conditions. Specifically:

- The list must include all IROFS associated with identified high- and intermediate-consequence accident sequences.

- The description of each IROFS may include the management measures applied (including safety grading), should include the characteristics of its preventive, mitigative, or other safety function, and may include assumptions or conditions—such as safety limits or margins—necessary to understand how the item achieves compliance with 10 CFR Part 70, Subpart H.

The application does not explain how QLs correspond to the management measures applied to each IROFS, nor does it describe how the graded approach ensures that management measures are commensurate with the safety significance of the item. Without this information, it is not possible to determine whether the applicant's approach to identifying, grading, and controlling IROFS aligns with the requirements of 10 CFR Part 70, Subpart H and the guidance in NUREG-1520, Rev. 2.

3. Audit Program Coverage (Major)

In section 11.5, the application states that audits and assessments are addressed through the OE's QAPD, noting that "Audits and Assessments are covered in the OE QAPD, section 18, Audits." The QAPD further commits that internal audits of organizational units performing QA activities are conducted at a frequency commensurate with the status and importance of the activity, and that regularly scheduled audits are supplemented by additional audits of specific subjects to ensure comprehensive program oversight at least annually. However, the application does not describe the scope or coverage of audits as they relate to all management measures, including configuration management, maintenance, training and qualification, procedures, and other controls applied to IROFS. Without this information, it is not possible to determine whether the audit program provides adequate oversight of safety-significant activities.

Per NUREG-1520, Rev. 2, section 11.5.7, "Audits and Assessments," the applicant should demonstrate that audits and assessments are adequately planned and that necessary programs, personnel, and procedures will be established to accomplish them. Section 11.6.5, "Evaluation Findings – Audits and Assessments," states that the NRC staff's conclusion that an applicant's audit and assessment program meets the requirements of 10 CFR Part 70 is based on evidence that the program provides reasonable assurance of protection of public health and safety, worker safety, and the environment.

The application does not describe how audits will encompass all management measures applied to IROFS, nor does it identify how audit scope, frequency, or methodology ensures adequate oversight of safety-significant activities. Without this information, it is not possible to determine whether the applicant's audit and assessment program aligns with the requirements of 10 CFR Part 70, Subpart H and the guidance in NUREG-1520, Rev. 2.

4. Configuration Management Assessment Criteria (Major)

In sections 11.1.1 and 11.1.5, the application states that the Configuration Management Program will be periodically assessed to ensure that the design remains consistent with the design and safety bases. However, the application does not identify the criteria for

determining whether configuration management is effective. The measures to be evaluated, the performance indicators to be used, and the thresholds for determining success are not described. Without defined criteria, it is not possible to determine whether the applicant's periodic assessments will meaningfully evaluate configuration management performance or ensure continued alignment with the design and safety bases.

Per NUREG-1520, Rev. 2, section 11.5.3, "Configuration Management," configuration management encompasses six key areas that must be effectively controlled to ensure that the facility's design and safety bases remain accurate and current. Section 11.6.1, "Evaluation Findings – Configuration Management," describes the basis on which the NRC staff determines whether an applicant's configuration management program is acceptable, including whether the applicant has established adequate criteria for evaluating configuration management effectiveness.

The application does not describe the criteria, metrics, or evaluation methods that will be used to assess configuration management effectiveness, nor does it identify how the applicant will determine whether the program continues to maintain consistency between the physical configuration, the design requirements, and the safety bases. Without this information, it is not possible to determine whether the applicant's approach to configuration management assessments aligns with the requirements of 10 CFR Part 70, Subpart H, and the guidance in NUREG-1520, Rev. 2.

5. Functional Testing (Moderate)

In section 11.2.4, the application states that functional testing of IROFS is performed following installation, during periodic surveillance, and after corrective or preventive maintenance or calibration to ensure that the configuration item is available and reliable to perform its intended function when needed. However, the application does not describe what measures are taken when an IROFS is out of service, nor does it identify any backup, compensatory, or interim controls that would be applied during periods when an IROFS is unavailable. Without this information, it is not possible to determine whether the applicant's maintenance and testing program ensures continuous protection consistent with the facility's safety basis.

Per NUREG-1520, Rev. 2, Section 11.5.4, "Maintenance," the applicant should describe how the maintenance function coordinates with and uses other management measures to ensure that safety-significant items remain capable of performing their intended functions. Section 3.4.3.2(6)(c), "List Describing Items Relied on for Safety," states that the essential features of each IROFS should be described and that sufficient information must be provided about engineered hardware controls to allow an evaluation that the controls will have adequate reliability.

The application does not identify how maintenance activities interface with other management measures to ensure safety when an IROFS is temporarily unavailable, nor does it describe any compensatory measures, backup controls, or interim protections that would be applied during such periods. Without this information, it is not possible to determine whether the applicant's approach to maintaining IROFS reliability aligns with the requirements of 10 CFR Part 70, Subpart H and the guidance in NUREG-1520, Rev. 2.

6. Training Effectiveness & Frequency (Moderate)

In section 11.3.6, the application states that the Training Program "shall be assessed periodically per QAPD, section 18, Audits." However, the application does not identify the interval at which training assessments will occur or the criteria that will be used to evaluate training effectiveness. The absence of defined evaluation criteria, performance indicators, or assessment frequency makes it impossible to determine whether the applicant's training and qualification program will ensure that personnel remain competent to perform safety-significant activities.

Per NUREG-1520, Rev. 2, Section 11.6.3, "Evaluation Findings – Training and Qualification," reasonable assurance exists only when the applicant's training and qualification program is sufficient to ensure that personnel are qualified and competent to design, construct, start up, operate, maintain, modify, and decommission the facility safely. The NRC staff's conclusion that an applicant meets the requirements of 10 CFR Part 70 is based on evidence that the training program includes adequate provisions for evaluating training effectiveness.

The application does not describe the criteria, metrics, or methods that will be used to assess training effectiveness, nor does it specify the frequency of such assessments. Without this information, it is not possible to determine whether the applicant's training and qualification program aligns with the requirements of 10 CFR Part 70, Subpart H and the guidance in NUREG-1520, Rev. 2.

7. Definition of Configuration Items (CIs) (Major)

The application states that management measures are applied to configuration items (CIs) that perform or support functions necessary to meet the performance requirements of 10 CFR 70.61, and that such CIs are IROFS. The application further states that CIs are items or services that are part of or support the Facility, and that management measures are applied in a graded approach to provide reasonable assurance that they are available and reliable to perform their intended function(s) when needed." However, the application does not provide a clear definition of what constitutes a CI or how CIs are identified for inclusion as IROFS.

Per 10 CFR 70.4, IROFS are defined as structures, systems, equipment, components, and personnel activities relied upon to prevent accidents that could exceed the performance requirements of 10 CFR 70.61 or to mitigate their consequences. The regulation also allows licensees to identify additional structures, systems, equipment, components, or personnel activities beyond the minimum required for compliance as IROFS.

Consistent with NUREG-1520, Rev. 2, Section 3.4.3.2(6), the description of IROFS should include the characteristics of their preventive or mitigative safety functions, the management measures applied to them (including safety grading), and any assumptions or conditions necessary to understand how the item achieves compliance with 10 CFR Part 70, Subpart H. Without a clear definition of CIs and their relationship to IROFS, it is not possible to determine whether the applicant's identification of safety-significant items and application of management measures is consistent with regulatory expectations.

Orano needs to clearly define what CIs are, how they are selected, and how they relate to or differ from IROFS to demonstrate that management measures are applied appropriately and in accordance with 10 CFR Part 70, Subpart H.

8. Initial Assessment (Moderate)

In section 11.1.5, “Assessments,” Orano does not address whether an initial assessment of the configuration management (CM) function will be conducted. The discussion in this section focuses on periodic assessments but does not describe how Orano intends to establish a baseline evaluation of CM effectiveness at program implementation.

Per 10 CFR 70.4, CM is a management measure that provides oversight and control of design information, safety information, and records of temporary and permanent modifications that may affect the ability of IROFS to perform their intended safety functions. Because CM directly supports the reliability and availability of IROFS, the effectiveness of the CM program must be demonstrated from its inception.

Consistent with NUREG-1520, Rev. 2, Section 11.4.3.1, item 11, the application should confirm that both initial and periodic assessments of the CM function are performed to evaluate program effectiveness and identify deficiencies. The guidance explicitly states that the applicant should address initial assessments, not only recurring ones, to ensure that the CM program is capable of supporting compliance with 10 CFR Part 70, Subpart H.

Orano should clarify whether it plans to conduct an initial assessment of the CM function to establish baseline program effectiveness and to demonstrate that CM processes are capable of supporting the safe performance of IROFS.

9. Management Measures and Quality Levels (Major)

The application identifies management measures and states that they are applied using a graded approach; however, it does not describe how this graded approach is implemented for each management-measure element. The application does not explain how management measures are adjusted based on the safety significance of the IROFS, nor does it describe how quality levels (QLs) relate to the grading of management measures.

Per 10 CFR 70.4, management measures include CM, maintenance, training and qualification, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements. These measures ensure that IROFS remain available and reliable to perform their intended safety functions. When a graded approach is used, the applicant must demonstrate how each management measure is tailored to the safety significance of the associated IROFS.

Consistent with NUREG-1520, Rev. 2, Section 11.4.3, when proposing a graded system of management measures, the applicant must: ensure the system maintains IROFS design integrity and reliability; describe how the graded system ensures compliance with 10 CFR 70.61 performance requirements; include a process for categorizing IROFS by safety significance and grading each management measure accordingly; and treat performance monitoring and corrective action elements as high-significance activities that are not subject to grading. Because performance monitoring and corrective action are

essential to verifying the continued effectiveness of IROFS, these activities must be controlled at the highest safety significance level regardless of the IROFS category.

The application should explain how IROFS have been classified, how management measures have been graded, and how the grading is commensurate with the reduction in risk that each IROFS is designed to achieve. If a particular management measure is applied differently to IROFS of varying importance, the application should describe those variations. The graded application of management measures must not result in changes to the design, configuration, or technical requirements of IROFS that could reduce confidence in their ability to perform their designated safety functions. The grading of QA elements and assignment of QLs should align with the same risk levels used for maintenance and other management measures.

Orano should provide the methodology used to implement the graded approach, describe how QLs are associated with the graded application of management measures, and explain the linkage between QLs and the specific management measures applied to items assigned those QLs.

10. Proposed Procedures to Protect Health (Major)

In section 11.4.1, the application states that activities involving licensed materials or IROFS are conducted in accordance with approved procedures intended to minimize danger to life or property and to prevent errors associated with on-the-spot judgments. However, the application does not describe the processes Orano will use to develop, implement, control, or maintain these procedures, nor does it explain how procedural controls will ensure protection of health and safety.

Per 10 CFR 70.22(a)(8), applicants must provide proposed procedures that protect health and minimize danger to life or property, including procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, and emergency procedures following a criticality accident. These procedures form part of the management measures necessary to ensure that IROFS remain capable of performing their intended safety functions.

Consistent with NUREG-1520, Rev. 2, Section 11.4.3.4, the application should describe the procedural program used to ensure safe operation of systems and activities involving licensed materials. This includes the processes for developing, reviewing, approving, revising, and controlling procedures; ensuring personnel are trained to the procedures; and verifying that procedures reflect current facility configuration, safety basis information, and IROFS requirements. The guidance also emphasizes that procedures must be sufficiently detailed to ensure consistent performance of safety-significant activities and must be maintained under CM controls.

The application should therefore describe Orano’s proposed processes for implementing procedures that protect health and safety, including how procedures are generated, how changes are controlled, how compliance is verified, and how procedural adequacy is ensured for activities involving IROFS and other safety-significant operations.

11. Management measures for administrative controls (Major)

In sections 11.3.1 and 11.4.1 the application states that each discipline maintains its own curated training modules or guides, and that minimum training requirements are developed for positions whose activities are relied on for safety. The application also states that administrative procedures are written by each department as necessary to control activities that support process operations, including management measures. However, the application does not clearly describe how administrative controls that are identified as IROFS are managed to ensure they remain available and reliable, nor does it explain how such administrative controls are identified, classified, or maintained under the management-measures framework.

Per 10 CFR 70.62(d), applicants must establish management measures that ensure both engineered and administrative controls identified as IROFS are designed, implemented, and maintained such that they remain available and reliable to perform their safety functions when needed. The regulation also allows management measures to be graded, but only to the extent that the grading remains commensurate with the reduction in risk attributable to the control or control system. Administrative controls that serve as IROFS must therefore be subject to management measures that ensure their continued effectiveness, including training, procedures, CM, assessments, and corrective action processes.

Consistent with NUREG-1520, Rev. 2, Chapter 11, the application should describe how administrative controls are identified as IROFS, how they are categorized by safety significance, and how management measures are applied to ensure their reliability. Administrative controls that function as IROFS typically include procedural steps, operator actions, surveillance activities, or other human-performance-based controls that prevent or mitigate accident sequences. Because their reliability depends on procedural adequacy, training, qualification, and oversight, the application must demonstrate how these elements are controlled under the management-measures program.

The application should therefore identify Orano’s administrative controls, describe the criteria used to determine when an administrative control is designated as an IROFS, and explain how Orano ensures the reliability of such controls through training, procedural controls, performance monitoring, and corrective action processes.

12. IROFS design, implementation and maintenance records (Major)

In section 11.7, “Records management,” the application references records management but does not commit to retaining IROFS-specific records for the life of the facility, nor does it identify the types of IROFS-related records that will be maintained. Without this information, it is not possible to determine whether Orano’s records management program provides adequate assurance that safety-significant information will be preserved to support long-term compliance with 10 CFR Part 70 requirements.

Per 10 CFR 70.64(a)(1), the design must be developed and implemented in accordance with management measures that ensure IROFS will be available and reliable to perform their safety functions when needed. The regulation further requires that appropriate records of these items be maintained by or under the control of the licensee throughout the life of the facility. These records typically include design basis information, CM documentation, maintenance and surveillance records, qualification and training records

for personnel performing IROFS-related activities, and documentation of changes affecting IROFS performance.

Consistent with NUREG-1520, Rev. 2, Chapter 11, the application should describe the record types associated with IROFS, the retention periods for each record category, and the controls used to ensure that IROFS-related records remain complete, accurate, and retrievable for the life of the facility. Long-term retention is essential to maintaining the safety basis, supporting CM, and demonstrating continued compliance with the performance requirements of 10 CFR 70.61.

Orano should clarify its approach for retaining IROFS-related records, including the specific record types to be maintained and the commitment to preserve these records for the life of the facility.

13. Facility Changes (Major)

In section 11.1.4 the application states that procedures control changes to the technical baseline and that interdisciplinary reviews provide a primary mechanism for ensuring consistency of the design with the design and safety basis. However, the application does not describe how Orano's change-control process meets the regulatory requirements for evaluating, documenting, and tracking changes in accordance with 10 CFR 70.72, nor does it explain how the process aligns with the methods endorsed in NRC Regulatory Guide 3.74 for fuel cycle facility change processes.

Per 10 CFR 70.72, licensees must evaluate proposed changes using ISA methods before implementation, document the basis for each change, and maintain records that demonstrate continued compliance with the performance requirements of 10 CFR 70.61. The regulation also requires that changes be reviewed to determine whether they require prior NRC approval and that all changes be tracked to support NRC inspection and oversight. These requirements ensure that modifications do not degrade the safety basis or the capability of IROFS to perform their intended functions.

Regulatory Guide 3.74 provides an acceptable method for implementing a compliant change-control process. The guidance describes expectations for screening changes, performing safety evaluations, documenting analyses, maintaining configuration control, and ensuring that changes affecting IROFS or safety-significant assumptions are appropriately reviewed and approved. Alignment with this guidance helps demonstrate that the licensee's change-control program provides adequate assurance of continued safety.

The application should therefore describe how Orano's change-control process conforms to the requirements of 10 CFR 70.72, including how changes are screened, evaluated using ISA methodologies, documented, tracked, and reviewed for potential NRC approval. The application should also explain how the process aligns with the methods described in Regulatory Guide 3.74 to ensure that changes do not adversely affect the design or safety basis of the facility.

14. Incident Investigation and Reporting (Major)

In section 11.6.1 the application states that the incident investigation process is a simple mechanism available for use by any person at the facility for reporting deficiencies,

abnormal events and potentially unsafe conditions or activities. Abnormal events that potentially threaten or lessen the effectiveness of health, safety or environmental protection will be identified and reported to and investigated by the EHS&L Manager. Each event will be considered in terms of its requirements for reporting in accordance with regulations and will be evaluated to determine the Level of investigation required. The application further notes that incident identification, investigation, root-cause analysis, environmental protection analysis, documentation, and follow-up are performed under Corrective Action Program (CAP) procedures. Radiological, criticality, hazardous chemical, and industrial safety requirements are addressed. Guidance for classifying occurrences are contained in CAP procedures, including examples of threshold off-normal occurrences. The depth of the investigation will depend upon the severity of the classified incident in terms of the Levels of uranium released and/or the degree of potential for exposure of workers, the public or the environment." However, the application does not describe how Orano will meet the NRC's immediate and follow-up reporting requirements, nor does it explain the process for making notifications to the NRC in accordance with 10 CFR 70.50 and 10 CFR 70.74.

Per 10 CFR 70.74(a) and (b), certain events must be reported immediately to the NRC Operations Center, including criticality accidents, loss or degradation of IROFS that could lead to high-consequence events, and other conditions specified in Appendix A to Part 70. These requirements are in addition to the written reports required under 10 CFR 70.50. Timely reporting ensures that the NRC is informed of significant safety-related events and can take appropriate regulatory action.

Consistent with NUREG-1520, Rev. 2, Section 11.4.3.6.1, the applicant must establish a formal procedure for investigating abnormal events to determine root causes, assess generic implications, evaluate risk significance, recommend corrective actions, and ensure reporting to the NRC as required by 10 CFR 70.50 and 10 CFR 70.74. The guidance emphasizes that the reporting process must be clearly defined, including criteria for determining reportability, timelines for notifications, and responsibilities for communicating with the NRC.

The application should therefore describe Orano's process for making required reports and notifications to the NRC, including how reportability determinations are made, who is responsible for contacting the NRC Operations Center, how timelines for immediate and written reports are met, and how CAP procedures interface with regulatory reporting requirements.

15. Identification of Sole Engineered IROFS, Basic components (Major)

In section 3.2, Table 3.2, "Sole Items Relied on for Safety," the ISA Summary identifies a set of sole items relied on for safety (sole IROFS). However, the QAPD states that failure of an IROFS does not create a substantial safety hazard. This creates an inconsistency, because sole IROFS—by definition—are the only items preventing or mitigating an accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61. Such items, if defective or noncompliant, could reasonably be expected to create a substantial safety hazard.

The requirement in 10 CFR 21.3.3, states that, when applied to facilities under 70, 71, or 72 of 10 CFR, *basic component* means a structure, system, or component or part thereof, that affects their safety function, that is directly procured by the licensee of a

facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

Sole IROFS are those that are the sole item preventing or mitigating an accident for which the consequences could exceed the performance requirements of 10 CFR 70.61, “Performance Requirements. Per 10 CFR 70.65(b)(8), applicants must provide a descriptive list identifying all IROFS that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of 10 CFR 70.61. These sole IROFS represent the minimum set of controls necessary to meet Subpart H performance requirements and therefore carry the highest safety significance.

Consistent with NUREG-1520, Rev. 2, section 11.4.3.8, “Other Quality Assurance Elements,” procurement documents for IROFS must address the applicability of Part 21 basic-component requirements. This includes ensuring that items whose failure could create a substantial safety hazard are procured, controlled, and maintained under a Part 21-compliant process. For sole IROFS, this expectation is particularly important because their failure directly affects the facility’s ability to meet 10 CFR 70.61 performance requirements.

The application should therefore clarify whether any of the sole IROFS listed in Table 3.2 are considered basic components under the definition in 10 CFR Part 21, and if so, how Orano’s QAPD and procurement processes ensure compliance with Part 21 reporting and defect-evaluation requirements.

Principal Contributor

Yilia Vega Claudio

I. Draft Chapter 12: Material Control and Accounting

1. Clarification of Facility Description (Minor)

The facility description provided in the Introduction section of the Fundamental Nuclear Material Control Plan (FNMCP, page 1-ix) includes the statement that “The Cylinder Receipt and Shipping Building (CRSB) contains equipment to receive, send, inspect, weigh, and enrichment cylinders.” However, this description is unclear and could lead to misinterpretation regarding the functions performed in the CRSB. In particular, the phrase “receive, send, inspect, weigh, and enrichment cylinders” is grammatically ambiguous and does not clearly distinguish whether enrichment activities occur within the CRSB or whether the intent is to describe the handling of enrichment plant cylinders.

Per 10 CFR 70.65(b)(9), applicants must clearly describe the facility and the processes involving SNM to support the safety program and material control and accounting system. NUREG-1520, Section 1.3 (“Facility and Process Description”), specifies that applicants should ensure that facility descriptions are unambiguous and accurately convey the functions of each building to allow the NRC to evaluate whether the proposed material control measures are appropriate and sufficient.

To meet regulatory requirements, Orano must:

- Clarify the intended meaning of the CRSB description, including whether enrichment activities occur within the building or whether the statement is intended to describe the handling of enrichment plant cylinders.
- Revise the sentence to clearly and grammatically identify the functions performed in the CRSB.
- Ensure that updated wording is consistent with descriptions elsewhere in the application and associated plans.

This information is necessary to ensure that the facility description in the FNMCP is accurate, unambiguous, and sufficient to support the U.S. NRC staff’s evaluation of the applicant’s material control and accounting program in accordance with 10 CFR 70.65(b).

2. Reporting Loss, Theft, or Diversion of Special Nuclear Material (Moderate)

In the “Reporting of Loss, Theft, or Diversion” section of the Introduction of the FNMCP (page 1-xiii), the applicant states that any anomaly or indicator resulting in a determination that an actual loss, theft, or diversion has occurred will be reported to the NRC in accordance with 10 CFR 74.11. However, this information does not provide a complete description of required reporting obligations. Under 10 CFR 74.11, reporting is also required for any incident in which an attempt has been made to commit a theft or unlawful diversion of SNM. The current wording does not clearly capture this requirement and could lead to an under-reporting of events that must be communicated to the NRC.

Per 10 CFR 70.65(b)(9), applicants must clearly describe their programs for compliance with applicable regulatory requirements, including reporting obligations for the protection and control of special nuclear material. Additionally, 10 CFR 74.11 requires prompt notification not only of actual losses, thefts, or diversions, but also of any attempts to

commit such acts. NUREG-1520, Chapter 5 (“Material Control and Accounting”), states that applicants should ensure all reporting requirements are fully described to allow the NRC to evaluate the adequacy of the proposed material control and accounting program.

To meet regulatory requirements, Orano must:

- Clarify that 10 CFR 74.11 requires reporting of actual losses, thefts, and diversions, as well as any attempts to commit theft or unlawful diversion.
- Revise the reporting description to explicitly include attempted theft or diversion of SNM.
- Ensure the updated language is consistent with 10 CFR 74.11 and the remainder of the FNMCP.

This information is necessary to ensure that the FNMCP accurately reflects NRC reporting requirements and provides a complete and technically sufficient basis for compliance with 10 CFR 74.11 and 10 CFR 70.65(b).

3. **Nuclear Material Custodians (Minor)**

Section 1.3, “Organization” (page 1-6), of the FNMCP describes the responsibilities and authority of Nuclear Material (NM) Custodians. However, in other sections of the FNMCP—such as Section 1.4, “Training and Qualification”—responsibilities for MCA Custodians are described. The application does not clarify whether NM Custodians and MCA Custodians refer to the same position or represent distinct roles with different responsibilities and is ambiguous regarding custodial responsibilities for NM, which could affect the NRC’s ability to evaluate the adequacy of the applicant’s material control and accounting program.

Per 10 CFR 70.65(b)(9), applicants must clearly describe organizational roles and responsibilities that support nuclear material control and accounting. NUREG-1520, Chapter 5 (“Material Control and Accounting”), states that applicants should ensure consistency across sections of the FNMCP, including clear identification of personnel responsible for custody, accounting, and control of SNM. Ambiguities in the identification of custodial roles can impact the NRC’s assessment of whether responsibilities are clearly assigned and adequately supported.

To meet regulatory requirements, Orano must:

- Clarify whether NM Custodians and MCA Custodians refer to the same position or represent different roles.
- If they are different positions, clearly delineate the responsibilities, authorities, and training requirements for each.
- Ensure consistent terminology across all sections of the FNMCP.
- Revise the relevant sections as needed to eliminate ambiguity and ensure alignment with organizational responsibilities described in Section 1.3.

This information is necessary to ensure that custodial responsibilities for NM are clearly defined and consistently presented throughout the FNMCP, enabling the NRC to evaluate the adequacy of the material control and accounting program in accordance with 10 CFR 70.65(b).

4. Determination of Active Inventory (Moderate)

Section 4.1.3, “Determination of Systematic Variance” (page 4-38), describes the process for determining active inventory. However, in several locations within the FNMCP, the term “annual inventory” is used in contexts where “active inventory” appears to be the more appropriate term. The inconsistent terminology creates ambiguity regarding the type of inventory being referenced and may lead to misinterpretation of inventory requirements and methods.

Per 10 CFR 70.65(b)(9), applicants must clearly describe the processes and methodologies used to support the material control and accounting program. NUREG-1520, Chapter 5 (“Material Control and Accounting”), specifies that terminology used to describe inventory types and inventory determination methods should be consistent and unambiguous to allow the NRC to evaluate whether the proposed program is technically sound and compliant with regulatory expectations.

To meet regulatory requirements, Orano must:

- Review the FNMCP to identify locations where “annual inventory” is used in place of “active inventory.”
- Clarify whether these uses of “annual inventory” refer to active inventory or to a different inventory type.
- Revise terminology as needed to ensure consistent and accurate use of inventory terms throughout the document.
- Ensure that definitions and inventory descriptions remain aligned with the methodology presented in Section 4.1.3.

This information is necessary to ensure that the terminology used to describe inventory processes relied upon for material control and accounting is accurate, consistent, and sufficient to support the NRC’s evaluation of the material control and accounting program in accordance with 10 CFR 70.65(b).

5. Shipper-Receiver Comparisons (Moderate)

Section 7 of the FNMCP (page 7-1) describes the applicant’s program for shipper-receiver comparisons. The application states that the facility meets the requirements of 10 CFR 74.31(c)(7) by establishing a program capable of detecting and resolving all significant shipper-receiver differences (SRDs). However, the cited regulation is incorrect; the applicable requirement for uranium enrichment facilities is 10 CFR 74.33(c)(7). In addition, 10 CFR 74.33(c)(7) specifies that shipper-receiver differences must be determined and resolved on both an individual batch basis and a total shipment basis. The applicant’s description does not clearly address both determinations.

Per 10 CFR 70.65(b)(9), applicants must clearly describe programs and controls that ensure compliance with NRC regulations for material control and accounting. The requirements of 10 CFR 74.33(c)(7) mandate that licensees implement a shipper-receiver comparison program that identifies and resolves significant SRDs on an individual batch basis and on a total shipment basis. NUREG-1520, Chapter 5 (“Material Control and Accounting”), further specifies that applicants must ensure their FNMCP descriptions clearly address all regulatory elements, including SRD evaluation methods.

To meet regulatory requirements, Orano must:

- Correct the regulatory citation in section 7 from 10 CFR 74.31(c)(7) to the applicable regulation, 10 CFR 74.33(c)(7).
- Describe how the shipper-receiver comparison program determines and resolves SRDs on both an individual batch basis and a total shipment basis.
- Ensure that the program description clearly aligns with all requirements of 10 CFR 74.33(c)(7).
- Revise Section 7 as needed to provide a complete and technically accurate description of the shipper-receiver comparisons process.

This information is necessary to ensure that the applicant's shipper-receiver comparison program is described accurately, is consistent with 10 CFR 74.33(c)(7), provides sufficient information to demonstrate compliance with applicable regulatory requirements, and provides a defensible basis for demonstrating compliance with NRC material control and accounting requirements in accordance with 10 CFR 70.65(b).

Principal Contributor

Glenn Tuttle

J. Draft Chapter on Structural/External Events

1. Incomplete Meteorological Information in the LA (Major)

In section 1.3.3 of its LA, Orano provides a high-level summary of meteorological conditions but does not include the design-basis values or supporting analyses required to establish the basis for each credible natural phenomena hazard (NPH) event. The submittal does not identify the type, frequency, or magnitude of meteorological design-basis events, nor does it describe the historical site-specific meteorological information or the sources used to determine bounding conditions.

Per 10 CFR 70.65(b)(9) and (10), the applicant must provide a description of site characteristics—including meteorological conditions—relevant to safety and accident analysis. These descriptions must support the safety program established under 10 CFR 70.62 and provide the basis for evaluating accident sequences and the performance of IROFS. NUREG-1520, Chapter 3 (Site Description) and Section 3.3 ("Site Characteristics") state that applicants must identify design-basis NPHs and include design-basis values for each credible event, including their type, frequency, and magnitude. NUREG-1520 further directs applicants to provide historical meteorological data, the most severe site-specific events on record, and the sources of meteorological information used to establish design-basis values. These requirements ensure the NRC can evaluate whether the proposed facility's safety basis appropriately accounts for credible meteorological hazards.

To meet regulatory requirements, Orano must address the following:

- Provide design-basis values for each credible NPH event, consistent with the type, frequency, and magnitude guidance in NUREG-1520.
- Include the most severe documented historical meteorological events applicable to each credible NPH hazard.
- Identify the source(s) of the meteorological data used to characterize each NPH event and justify how these sources support design-basis selections.

This information is necessary to determine whether Orano has adequately characterized meteorological hazards or established appropriate design-basis values consistent with the requirements of 10 CFR 70.65(b) and aligns with the expectations in NUREG-1520 for establishing credible and defensible design-basis NPH conditions.

2. Incomplete Hydrology Information in the LA for Design Basis Flood Events (Major)

Orano provides limited hydrological information. The LA does not include the design-basis flood (DBF) values or supporting analyses required to establish the basis for each credible flood-related NPH. While section 1.3.4.4 references the Environmental Report, the LA itself lacks the detailed hydrology information necessary to support safety analyses and the development of IROFS. Without this information, it is not possible to determine whether Orano has adequately characterized flood hazards or established design-basis values consistent with regulatory expectations.

Per 10 CFR 70.65(b)(9) and (10), applicants must describe site characteristics—including hydrology—relevant to safety and accident analysis and provide sufficient design-basis information to support the safety program required under 10 CFR 70.62.

NUREG-1520, section 3.3 (“Site Characteristics”) specifies that applicants must identify and describe design-basis NPH events, including the type, frequency, and magnitude of credible flood hazards, and present supporting hydrological data and methodologies. NUREG-1520 further directs applicants to identify the sources of hydrological information used to establish design-basis flood values, consider all relevant flood mechanisms (e.g., local intense precipitation, dam failures), and describe any standards, studies, or methodologies used. The guidance in NUREG/CR-7046 is also recognized by the NRC as an acceptable approach for evaluating design-basis flood levels caused by local intense precipitation and other site-specific hydrological events.

To meet regulatory requirements, Orano must address the following:

- Provide design-basis values for all credible flood-related NPH events, including their type, frequency, and magnitude, consistent with NUREG-1520.
- Identify and describe the hydrological data sources and the methodology used to determine the design-basis flood levels.
- Include a discussion of applicable flood hazards such as local intense precipitation, upstream dam failures, and other relevant mechanisms.
- Describe any studies, standards, or guidance documents used in establishing design-basis flood events, including methodologies consistent with documents such as NUREG/CR-7046.

This information is necessary to determine whether Orano’s hydrological hazard characterization meets the requirements of 10 CFR 70.65(b) and aligns with the expectations in NUREG-1520 for establishing credible and defensible design-basis flood conditions.

3. Incomplete Geology Information in the LA for Design Basis Seismic Events (Major)

Orano provides limited geological and seismic information and does not include the design-basis seismic values or supporting analyses required to establish the basis for credible seismic NPH events. The submittal does not specify peak ground acceleration (PGA), design spectral response accelerations, or the associated recurrence intervals for seismic design, nor does it identify the geological data sources or the methodologies used to derive these values.

Per 10 CFR 70.65(b)(9) and (10), applicants must describe site characteristics—including geology and seismology—that are relevant to safety analysis and the development of IROFS. These descriptions must include design-basis NPHs and must support the safety program requirements of 10 CFR 70.62. NUREG-1520, Section 3.3 (“Site Characteristics”), specifies that the application must identify and describe design-basis seismic events, including the type, frequency, and magnitude of seismic hazards, and must include the PGA, spectral response accelerations, return periods, and the supporting geological and seismological data. The guidance states that applicants should identify data sources, demonstrate that the seismic design basis reflects site-specific conditions, and document the methodology used to evaluate seismic hazards. These requirements ensure the NRC can evaluate the adequacy of the applicant’s seismic hazard characterization and the basis for seismic-related safety analyses.

Orano must address the following:

- Provide the design-basis seismic values, including the PGA, design spectral response accelerations, and corresponding recurrence intervals.
- Describe the geological and seismological data sources used to establish design-basis seismic parameters.
- Identify the methodology applied to determine seismic design-basis values, consistent with the expectations in NUREG-1520.

This information is necessary to determine whether Orano has adequately characterized seismic hazards or established seismic design-basis parameters consistent with the requirements of 10 CFR 70.65(b) and aligns with NUREG-1520 guidance for establishing credible and defensible design-basis seismic conditions.

4. Landslide hazard (Moderate)

In section 1.3.5.3 of the LA Orano states that slope stability analyses completed during the geotechnical investigation were used to determine the embankment outslope ratio to mitigate the risk of landslides. However, the application does not describe how the results of the geotechnical investigation were incorporated into the facility's design or identify the specific design features, analyses, or engineering measures used to prevent or mitigate potential landslide hazards.

Per 10 CFR 70.65(b)(9) and (10), applicants must describe site characteristics relevant to safety, including geologic and geotechnical conditions that could affect accident analyses or the performance of IROFS. These descriptions must support the safety program established under 10 CFR 70.62 by identifying NPH and demonstrating that the facility is appropriately designed to withstand such hazards. NUREG-1520, section 3.3 ("Site Characteristics"), specifies that applicants must evaluate site-specific geologic and soil stability conditions, including the potential for landslides, slope instability, and related geotechnical hazards. The guidance further indicates that applicants should describe how geotechnical investigations inform design-basis values and the engineering measures used to ensure stability of embankments, slopes, and foundations.

To meet regulatory requirements, Orano must:

- Clearly describe how the results of slope stability analyses and geotechnical investigations were incorporated into the facility design.
- Identify the specific design features or engineering measures implemented to mitigate or prevent potential landslide hazards.
- Demonstrate that these considerations align with the design-basis NPH requirements described in NUREG-1520.

This information is necessary to determine whether Orano has adequately evaluated landslide risks and geotechnical hazards consistent with the requirements in 10 CFR 70.65(b) and provides reasonable assurance that landslide risks have been appropriately addressed in the facility design.

5. Incomplete Information for the Design Criteria Against NPH Event (Major)

In section 1.2.1.2 of the ISA Summary, Orano states that the "design criteria meet the applicable baseline design criteria (BDC) established in 10 CFR 70.64," and that the SBM, BSPB, CRSB, and TSB structures "shall be designed to withstand the effects of external events (i.e., seismic, wind, snow, and local intense precipitation)." However, the application does not describe the design criteria for each credible external event or provide sufficient supporting information to demonstrate how these design criteria were established.

Per 10 CFR 70.65(b)(9) and (10), applicants must describe site characteristics and external hazards relevant to safety, including NPH events that could affect accident analyses or the performance of IROFS. These descriptions support the safety program under 10 CFR 70.62 by identifying credible NPH events and demonstrating that structures, systems, and components are appropriately designed to withstand them. NUREG-1520, section 3.3 ("Site Characteristics"), further specifies that applicants must identify and evaluate site-specific NPH hazards, establish design criteria informed by appropriate historical data and engineering standards, and describe the basis for these criteria, including return periods, exceedance frequencies, or design basis events.

To meet regulatory requirements, Orano must:

- Identify the established design criteria for each credible NPH event, including specific design basis values, return periods, exceedance frequencies, and/or defined design basis events.
- Describe the methodology used to develop these design criteria, including referenced standards, guidance, and any design parameters used to establish applicable design basis values for the facility.
- Provide a description of the most severe documented historical events for each credible NPH (e.g., precipitation, tornado, lightning, flood elevation from nearby water bodies) and explain how these events informed the development of design criteria.

    - Note that the most severe documented historical events have not been consistently or fully described for all credible NPHs.

This information is necessary to verify and determine whether Orano has adequately defined and justified the design criteria for each NPH event consistent with the requirements of 10 CFR 70.65(b), and whether the facility design provides reasonable assurance that external hazards have been appropriately evaluated and addressed.

6. No Information for the Design Criteria Against Other External Event (Major)

In section 2.4 and Appendix 2 of the ISA, Orano evaluates accident sequences for several external events that are not fully or clearly described in the ISA Summary or the LA.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify and describe external hazards relevant to facility safety, including those that may influence accident sequences or the performance of IROFS. These descriptions support the safety program under 10 CFR 70.62 by ensuring that credible external events are adequately evaluated, and that

design basis criteria are established using appropriate historical, technical, and methodological information. NUREG-1520, Section 3.3 (“Site Characteristics”), further specifies that applicants must identify, characterize, and evaluate credible external hazards such as volcanic activity, volcanic ash, aircraft impact hazards, and other site-specific external events, and must describe the engineering basis used to establish design criteria for each.

To meet regulatory requirements, Orano must:

- Identify the established design criteria for each credible external event (e.g., volcanic activity, volcanic ashfall, aircraft hazards), including specific design basis values, return periods, exceedance frequencies, or defined design basis events.
- Describe the methodology used to develop these design criteria, including referenced standards, guidance documents, and any design parameters used to establish the applicable design basis values.
- Provide a description of the most severe documented historical events relevant to each type of external hazard and explain how these events were used to inform the development of design criteria, as applicable.

This information is necessary to determine whether Orano has adequately identified and evaluated all credible external hazards in accordance with 10 CFR 70.65(b) and whether the design basis for these events provides reasonable assurance that such hazards have been appropriately considered in the development of the facility’s safety design.

7. Additional justification is required to demonstrate that certain external events are not credible (Moderate)

Appendix 2 identifies several external events as non-credible; however, the bases provided for these determinations are insufficient. For example, the accident identifier for “EE-OTHER NEARBY FACILITIES” states that “no such facilities were identified within close proximity to the facility,” but does not provide supporting information, defined criteria, or technical justification. This statement also appears inconsistent with other sections of the ISA Summary and the LA (e.g., Section 1.3.2.4), which identify nearby industrial facilities—both nuclear and non-nuclear—as being located in close proximity to the site.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify and describe external hazards that could affect facility safety, including hazards associated with nearby industrial activities, pipelines, railroads, or other offsite facilities. These evaluations support the safety program under 10 CFR 70.62 by ensuring that credible external hazards are properly identified and that the basis for dismissing hazards as non-credible is technically justified. NUREG-1520, Section 3.3 (“Site Characteristics”), further specifies that applicants should provide a defensible basis for determining hazard credibility, including the use of defined criteria, relevant distances, and site-specific information for facilities or activities that could pose an external event risk.

To meet regulatory requirements, Orano must:

- Provide the technical basis for determining that identified external events associated with nearby facilities are non-credible.

- Define safe-distance criteria applicable to nearby facilities, pipelines, rail corridors, and similar external hazards.
- Provide the actual measured distances to these nearby facilities and explain how these distances were evaluated against the defined criteria.
- Reconcile inconsistencies between Appendix 2 and other parts of the ISA Summary and LA regarding the presence and proximity of nearby industrial facilities.

This information is necessary to determine whether Orano has appropriately evaluated external hazards associated with nearby facilities in accordance with 10 CFR 70.65(b) and to provide reasonable assurance that determinations of non-credibility are supported by a defensible and technically sound basis.

8. Section 1.10.B, "Natural Phenomena Hazards" (Moderate)

The information provided in this section is insufficient to demonstrate compliance with the applicable baseline design criteria (BDC) requirements. The statement appears to simply restate the regulatory language of 10 CFR 70.64(a)(4), which addresses "environmental and dynamic effects," rather than providing the BDC for NPH required under 10 CFR 70.64(a)(2). As a result, the application does not clearly describe how the facility meets the NPH-related BDC, as intended for Section 1.10.B.

Per 10 CFR 70.64(a)(2), applicants must identify and establish BDC for natural phenomena hazards to ensure that structures, systems, and components relied on for safety are designed to withstand NPH events. This requirement supports the safety program under 10 CFR 70.62 by ensuring that credible hazards are evaluated and that the facility's design basis accounts for the effects of these hazards. Consistent with NUREG-1520, Sections 3.3 ("Site Characteristics") and 3.4 ("Baseline Design Criteria"), applicants must describe the design basis criteria, technical approach, and supporting information used to demonstrate compliance with 10 CFR 70.64(a)(2), rather than merely restating the regulatory text.

To meet regulatory requirements, Orano must:

- Provide the BDC established for NPHs consistent with 10 CFR 70.64(a)(2), rather than citing only the requirements of 10 CFR 70.64(a)(4).
- Describe the approach used to meet these NPH-related design criteria, including the analyses, standards, methodologies, or evaluations relied upon.
- Identify where supporting information is located in the LA, ISA Summary, or associated documentation to demonstrate compliance.

This information is necessary to determine whether Orano has adequately identified and described the BDC for natural phenomena hazards in accordance with 10 CFR 70.64(a)(2) and to provide reasonable assurance that the facility design meets the requirements for NPH resilience.

9. Tornados Events (Major)

The probability-based approach used in section 1.1.1.13.1 of the ISA Summary to establish the type, frequency, and magnitude of tornado events applicable to the site is inconsistent with standard industry methodologies. NUREG/CR-4461, Rev. 2, provides a well-established technical basis for determining tornado strike probabilities and

associated maximum wind speeds using site location, facility dimensions (based on a 200-ft building), and the selected annual probability of exceedance. For example, at an exceedance probability of 10^{-5} per year, the recommended design wind speed for a facility located near latitude 36° and longitude 85° is approximately 149 mph, with an average tornado design wind speed of 160 mph for that region. ANSI/ANS-2.3 provides comparable criteria across a broader regional scale. The application does not demonstrate how the probability approach used aligns with these established methodologies or provides an equivalent technical basis.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify and describe NPH relevant to safety, including tornado hazards, and must establish design criteria that support the safety program under 10 CFR 70.62. NUREG-1520, section 3.3 ("Site Characteristics"), specifies that applicants should use established industry standards and technical references, such as NUREG/CR-4461 and ANSI/ANS-2.3, to define tornado hazard design basis values. The guidance also indicates that applicants must describe the technical basis for these criteria, including historical data for the site and regional hazard characteristics.

To meet regulatory requirements, Orano must:

- Demonstrate how the tornado hazard design criteria were developed using an accepted methodology consistent with NUREG/CR-4461, ANSI/ANS-2.3, or equivalent technical bases.
- Identify the design basis tornado wind speeds, associated exceedance probabilities, and supporting technical justification.
- Provide a description of the most severe documented historical tornado events for the site and explain how these events were considered in establishing the design criteria.

This information is necessary to determine whether Orano has established tornado hazard design basis criteria consistent with 10 CFR 70.65(b) and whether the facility design provides reasonable assurance that tornado hazards have been appropriately evaluated and addressed.

10. Seismic Events (Major)

The seismology discussion following Section 1.1.1.17 of the ISA Summary does not provide a sufficiently comprehensive evaluation of seismic activity near the site. The application does not describe the seismic characteristics of the East Tennessee Seismic Zone or assess the potential severity of seismic events in terms of Modified Mercalli Intensity (MMI), both of which are important for informing facility design considerations. The section also does not identify or reference where the seismic design-basis event and associated design criteria are addressed within the ISA. Key seismic design parameters—such as the PGA, design spectral response accelerations, and the associated return period or recurrence interval—are not provided. As a result, the application does not demonstrate how the selected design-basis event accounts for the most severe historic seismic events applicable to the site.

Per 10 CFR 70.65(b)(9), applicants must describe site characteristics relevant to safety, including seismic hazards, and must identify how these characteristics inform the facility's design. This requirement supports the safety program established under 10

CFR 70.62 by ensuring that NPH, such as seismic events, are adequately identified and evaluated. NUREG-1520, Section 3.3 (“Site Characteristics”), specifies that applicants must describe local and regional seismicity, identify seismic sources such as the East Tennessee Seismic Zone, and provide design-basis seismic parameters including PGA, design response spectra, and the return period or recurrence interval. The guidance also indicates that applicants must demonstrate how the selected design-basis event accounts for the most severe historic seismic events for the site.

To meet regulatory requirements, Orano must:

- Provide a comprehensive description of seismic activity near the site, including characteristics of the East Tennessee Seismic Zone and expected impacts correlated to the MMI scale.
- Identify or reference where the seismic design-basis event and associated design criteria are addressed within the ISA.
- Provide the design-basis seismic parameters, including PGA, design spectral response accelerations, and the associated return period or recurrence interval.
- Demonstrate how the selected design-basis event accounts for the most severe historic seismic event applicable to the site.

This information is necessary to determine whether Orano has adequately evaluated seismic hazards consistent with 10 CFR 70.65(b) and to provide reasonable assurance that the facility design appropriately considers regional and site-specific seismic risks.

11. High-wind Events (Major)

Section 1.1.1.11 provides a general description of local wind patterns; however, the application does not clearly define or evaluate extreme wind events relevant to hazard assessment. The section does not describe the most severe documented historical high-wind event for the site, nor does it identify or reference where in the ISA the high-wind design-basis event and associated design criteria are established. Without this information, the application does not provide sufficient technical basis to demonstrate that high-wind hazards have been adequately evaluated or that the facility design accounts for the effects of extreme wind events.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify NPH, including extreme wind hazards, that could impact facility safety or the performance of IROFS, and must describe the basis for the design criteria used to withstand such hazards. These requirements support the safety program under 10 CFR 70.62 by ensuring that credible wind hazards are evaluated using historical data and appropriate design-basis parameters. NUREG-1520, Section 3.3 (“Site Characteristics”), specifies that applicants must identify site-specific extreme wind hazards, establish design-basis wind values, and demonstrate the technical basis for these criteria, including the consideration of the most severe historical events.

To meet regulatory requirements, Orano must:

- Provide a description of the most severe documented historical high-wind event for the site and explain how this event informed the development of the high-wind design-basis criteria.

- Identify or reference where the high-wind design-basis event and associated design criteria are addressed within the ISA.
- Provide the design-basis wind parameters—including wind speed values, associated exceedance probabilities or return periods, and supporting methodological justification.

This information is necessary to determine whether Orano has adequately evaluated high-wind hazards consistent with 10 CFR 70.65(b) and to provide reasonable assurance that the facility design appropriately considers extreme wind events.

12. Wind-Generated Missiles (Major)

The ISA Summary identifies an accident scenario related to wind-generated missiles; however, the application does not specify the missile criteria used in the facility's design to address these hazards. Missile criteria must be established in accordance with applicable guidance and industry standards, and the application should demonstrate how the facility's design is capable of withstanding the impact of wind-generated missiles consistent with these criteria. Without this information, the application does not provide a sufficient technical basis to show that missile hazards have been adequately evaluated. Additionally, the accident identifier for "EE-High Wind" describes an approach for concluding that wind-generated missiles will not pose a concern to EREF structures or internal components. This approach is inconsistent with NRC guidance, including Regulatory Guide (RG) 1.76, Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants, which identifies the onset of tornado-generated missile hazards at wind speeds exceeding 34 m/s (75 mph), rather than only above 111 mph. Proper characterization of applicable missile criteria must also account for the design-basis tornado events for the site, which may involve wind speeds greater than those considered in the current high-wind design basis.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify NPH, including high-wind and tornado-generated missile hazards, and must provide the bases for associated design criteria that support the safety program under 10 CFR 70.62. NUREG-1520, section 3.3 ("Site Characteristics"), specifies that applicants must identify credible missile-generating hazards, define missile impact criteria consistent with relevant standards and guidance (e.g., Regulatory Guide 1.76), and demonstrate that structures, systems, and components relied on for safety are adequately designed to withstand these hazards.

To meet regulatory requirements, Orano must:

- Identify and clearly describe the missile criteria used in the facility design to address wind-generated and tornado-generated missiles, consistent with applicable standards and NRC guidance.
- Demonstrate how the facility's structures and components are designed to withstand missile impacts based on these criteria.
- Revise the evaluation of "EE-High Wind" to ensure consistency with RG 1.76 and other relevant guidance, including recognition that missile hazards begin at wind speeds exceeding 34 m/s (75 mph).
- Ensure that missile hazard characterization accounts for the design-basis tornado events for the site, which may involve wind speeds greater than those considered in the high-wind design basis.

This information is necessary to determine whether Orano has adequately evaluated and addressed wind-generated and tornado-generated missile hazards consistent with 10 CFR 70.65(b) and to provide reasonable assurance that missile impacts have been appropriately considered in the facility's safety design.

13. Intense Precipitation Events (Major)

Section 1.1.1.12 describes general precipitation patterns for the region; however, the discussion focuses primarily on annual precipitation totals and average values and does not address extreme precipitation hazards relevant to facility safety. Eastern Tennessee experiences varied precipitation due to its humid subtropical climate, local Appalachian topography, and seasonal weather patterns, including intense convective thunderstorms, prolonged frontal systems, and remnants of tropical cyclones capable of producing heavy rainfall and localized flooding. The application does not describe the most severe documented historical precipitation events for the site—including rainfall, snowfall, and ice events—which are necessary for establishing design-basis precipitation criteria.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify NPH, including extreme precipitation events, that could impact facility safety or the performance of IROFS. These evaluations support the safety program established under 10 CFR 70.62 by ensuring that credible precipitation hazards are adequately characterized and incorporated into the design basis. NUREG-1520, Section 3.3 ("Site Characteristics"), specifies that applicants must describe site-specific extreme precipitation hazards, including the most severe historical storm events, and establish design-basis precipitation criteria informed by these events.

To meet regulatory requirements, Orano must:

- Provide a description of the most severe documented historical precipitation events for the site, including rainfall, snowfall, and ice events, and explain how these events informed the development of design-basis precipitation criteria.
- Identify or reference where the design-basis precipitation event and associated design criteria are addressed in the ISA.
- Provide the design-basis precipitation parameters—such as rainfall intensity, total accumulation, snow/ice loads, and associated return periods or exceedance frequencies—along with supporting justification.

This information is necessary to determine whether Orano has adequately evaluated extreme precipitation hazards consistent with 10 CFR 70.65(b) and to provide reasonable assurance that these hazards are properly addressed in the facility's design basis.

14. Extreme Temperature Events (Major)

Although eastern Tennessee generally experiences moderate seasonal conditions, the region can be subject to significant high and low temperature extremes influenced by its humid subtropical climate, regional topography, and seasonal variability. The application does not describe the most severe recorded minimum and maximum wet-bulb and dry-bulb temperatures applicable to the site based on historical data, nor does it identify the applicable design-basis event or corresponding extreme temperature values.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify NPH, including extreme temperature events, that could affect facility safety or the performance of IROFS, and must describe the basis for the associated design criteria. These evaluations support the safety program under 10 CFR 70.62 by ensuring that credible temperature extremes are identified, characterized, and incorporated into the design basis. NUREG-1520, Section 3.3 (“Site Characteristics”), specifies that applicants must identify site-specific extreme temperatures, establish design-basis temperature values informed by the most severe historical events, and describe how these events are considered in facility design and safety analyses.

To meet regulatory requirements, Orano must:

- Provide a description of the most severe recorded wet-bulb and dry-bulb minimum and maximum temperatures for the site, based on historical data.
- Identify the design-basis event for extreme temperatures and specify the corresponding design-basis temperature values.
- Describe how extreme temperature initiating events are considered in the facility’s design and the measures implemented to prevent or mitigate potential consequences, consistent with applicable performance requirements.

This information is necessary to determine whether Orano has adequately evaluated extreme temperature hazards consistent with 10 CFR 70.65(b), that the ISA demonstrate how extreme temperature initiating events are considered in the facility’s design or how potential consequences are prevented or mitigated, and to provide reasonable assurance that temperature-related hazards have been appropriately addressed in the facility’s safety design.

15. Thunderstorm/Lightning Events (Major)

Eastern Tennessee experiences moderate to high lightning density and frequent thunderstorms, which pose a potential hazard to the site. Section 1.1.1.13.2 of the ISA Summary identifies the database and methodology used to obtain lightning information; however, the application does not provide sufficient detail to demonstrate that lightning hazards have been adequately characterized or that the facility design meets the performance requirements of 10 CFR 70.61. The application does not identify the design-basis lightning strike frequency for the site, the maximum recorded lightning events for the region, or the specific design features and protective measures implemented to address lightning hazards.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify NPH that could affect facility safety, including lightning, and must describe how associated design-basis criteria support the safety program under 10 CFR 70.62. In addition, 10 CFR 70.61 requires that engineered and administrative controls be sufficient to prevent or mitigate the consequences of credible initiating events, including external hazards. NUREG-1520, Section 3.3 (“Site Characteristics”), specifies that applicants must identify lightning hazard characteristics for the site—such as maximum historical lightning events and lightning strike frequency—and describe the protective measures, codes, and standards used to mitigate these hazards.

To meet regulatory requirements, Orano must:

- Identify the design-basis lightning strike frequency for the site and provide supporting justification.
- Describe the most severe recorded lightning events for the region and explain how these events informed the development of lightning design-basis criteria.
- Describe the facility's lightning protection design, including protective measures, engineering features, and applicable codes and standards (e.g., NFPA 780, IEEE guidance).
- Explain how these measures are sufficient to prevent or mitigate potential consequences from lightning strikes consistent with the performance requirements of 10 CFR 70.61.

This information is necessary to determine whether Orano has adequately evaluated and addressed lightning hazards consistent with 10 CFR 70.65(b) and to provide reasonable assurance that the facility design sufficiently mitigates lightning-related risks.

16. Improper or Inadequate basis for accident identifiers associated with NPH events (Major)

Several accident identifiers in the ISA Summary conclude that no IROFS are necessary while relying on explicit building design features to prevent accident progression from external events and asserting that it is "highly unlikely" to exceed the performance requirements in 10 CFR 70.61. However, reliance on building design as a preventive measure without designating those engineered controls as IROFS is inconsistent with 10 CFR 70.61(e). Proper building design to withstand external events performs a safety function and therefore meets the definition of an IROFS. Without designating these features as IROFS, the analysis does not demonstrate how the structural features will reliably prevent the initiating event sequence from progressing to consequences that exceed 10 CFR 70.61 performance requirements. Additionally, the approach used to adjust initiating event likelihoods based on building design features is inconsistent with the intent of the regulations and with guidance in NUREG-1520. As described in Appendix B of NUREG-1520, external initiating events—such as high winds, seismic events, and other natural phenomena—are outside the control of the facility and therefore must be characterized solely by their frequency of occurrence based on site-specific hazard information. Engineering features cannot be used to modify the initiating event frequency; rather, they function to prevent or mitigate the consequences *after* the initiating event occurs. For external events, the building structure serves as an engineered feature intended to prevent hazards from impacting SNM or other IROFS and to prevent structural failure that could lead to consequences exceeding 10 CFR 70.61 performance requirements. The accident identifier for EE-High Wind references the NRC Interim Staff Guidance (ISG) for NPH regarding the use of building codes as consistent with the accident identifier approach. However, the ISG approach is mischaracterized and does not provide an adequate technical basis. Other external events, such as Extreme Temperature Events, are not addressed and should be included. Finally, certain accident identifiers (e.g., EE-SEISMIC-1a for the UF_6 area) conclude that an IROFS is required because failure could result in consequences of concern, such as building collapse, breach of UF_6 systems, and a potential UF_6 release. However, the application does not describe the IROFS or explain how it ensures compliance with the performance requirements in 10 CFR 70.61.

Per 10 CFR 70.61(b)–(e), applicants must identify IROFS necessary to meet the performance requirements and must ensure that these controls are clearly described, functionally justified, and capable of preventing or mitigating the consequences of credible accident sequences. The regulation in 10 CFR 70.65(b) requires that accident analyses and IROFS descriptions be sufficiently detailed to demonstrate how the performance requirements of 10 CFR 70.61 are met. NUREG-1520, Chapter 3 and Appendix B, further emphasize that engineered features credited for preventing or mitigating the progression of externally initiated accident sequences must be designated as IROFS and described with adequate detail to support their safety function.

To meet regulatory requirements, Orano must:

- Clearly identify engineered design features used to prevent or mitigate external event accident sequences and designate them as IROFS consistent with 10 CFR 70.61(e).
- Ensure that external initiating event frequencies are based solely on site-specific NPH hazard information and not modified by facility design features.
- Correctly apply NRC guidance, including ISG for NPH, and provide accurate technical bases for accident evaluations.
- Evaluate and include all applicable external hazards, including Extreme Temperature Events, in accordance with NUREG-1520.
- For accident identifiers that conclude an IROFS is required, describe the IROFS and explain how it ensures compliance with the 10 CFR 70.61 performance requirements.

This information is necessary to determine whether Orano has adequately identified, designated, and described IROFS for externally initiated accident sequences consistent with 10 CFR 70.61 and 10 CFR 70.65, and to provide reasonable assurance that the facility design appropriately prevents or mitigates the consequences of external hazards.

17. Missing Results from Unmitigated Consequences Analysis (Moderate)

The ISA Summary does not present the results of the unmitigated consequences analysis for accident sequences initiated by external events. These results are essential for establishing the applicable design criteria for NPH events based on the facility's risk profile. Unmitigated consequences analysis results also provide the technical basis for determining whether commercial codes and standards are appropriate substitutes for nuclear-facility-specific standards. Without including these results or providing sufficient justification for the use of commercial codes and standards, the application does not demonstrate that the selected design approach is appropriate considering the potential consequences associated with externally initiated events.

Per 10 CFR 70.65(b)(6)–(10), applicants must provide a description of accident sequences, including unmitigated consequences, and must describe the basis for the design criteria and controls necessary to meet the performance requirements of 10 CFR 70.61. The unmitigated consequences analysis provides the foundation for determining whether the potential consequences of an external event could challenge the performance requirements and therefore informs the selection of applicable design standards. NUREG-1520, Chapter 3, and industry standards such as ANSI/ANS-2.26 ("Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design") provide guidance on establishing the appropriate design category and associated design criteria based on the severity of unmitigated consequences.

To meet regulatory requirements, Orano must:

- Provide the unmitigated consequences analysis results for externally initiated accident sequences that form the basis for selecting the applicable NPH design criteria.
- Demonstrate how these results support the determination that commercial codes and standards are appropriate for the facility's design or provide justification for the selection of alternative standards.
- Reference applicable standards and guidance (e.g., ANSI/ANS-2.26) and explain how the chosen design requirements correspond to the potential consequences identified in the unmitigated analyses.
- Ensure that the design-basis criteria for NPH events are supported by a documented, technically sound justification aligned with the facility's risk profile.

This information is necessary to determine whether Orano has provided an adequate technical basis for its selection of design criteria and whether the facility's design appropriately accounts for the potential consequences of external events consistent with the requirements of 10 CFR 70.61 and 10 CFR 70.65.

18. Missing Definition of "Highly Unlikely" for NPH Events (Major)

The ISA Summary does not include a definition of "Highly Unlikely" for NPH events. Without a clear definition, it is not possible to determine whether likelihood assignments for NPH-initiated accident sequences are applied consistently or aligned with regulatory expectations. The absence of this definition limits the staff's ability to assess whether the likelihood categories used in the ISA appropriately reflect the characteristics of external initiating events.

Per ISG FCSE-15 (FCSE-ISG-15), Natural Phenomena Hazards in Fuel Cycle Facilities, the NRC staff review of ISA methodologies must include an assessment of how likelihood definitions—such as "Highly Unlikely"—are implemented for natural phenomena events. In accordance with 10 CFR 70.65(b), applicants must provide sufficient information to enable the NRC to evaluate the methods used to categorize accident likelihoods. NUREG-1520, Appendix B, further emphasizes that likelihood categories must be clearly defined and consistently applied, particularly for external events whose frequencies are determined by site-specific hazard data.

To meet regulatory requirements, Orano must:

- Provide a clear and explicit definition of the likelihood category "Highly Unlikely" as applied to NPHs.
- Demonstrate how this definition is used in the evaluation of NPH-initiated accident sequences in the ISA.
- Ensure that the likelihood definition is consistent with applicable guidance, including FCSS-ISG-15 and NUREG-1520.

This information is necessary to determine whether Orano has applied likelihood categories for natural phenomena hazards in a manner consistent with regulatory expectations and to provide reasonable assurance that the ISA methodology appropriately characterizes NPH-initiated accident sequences.

General Items to Consider

- **Buildings Physical Separation**

  - Further clarify how the four identical Separations Building Modules (SBM) will be physically separated, including structural design, if any, that prevent or mitigate an internal or external imitated event affecting one module to impact another module.

- **Comprehensiveness of Historical Event Evaluation**

  - Has the design appropriately considered all documented historical events? Are these events adequately bounded by the design basis event?

  - Does the ISA provide sufficient justification that the documented historical events considered as the design basis events are adequate for the design, based on the facility's overall risk?

- **Characterization of Design-Basis Events**

  - Each credible external event may result in different intensity levels or magnitudes that correspond to a different probability of occurrence for the site. For example, for a particular site an EF4 tornado or 180 mph high-wind wind event may be consider rare base on its likelihood of occurrence, but a lower intensity event (i.e., EF3 tornado or 160 mph high-wind wind event) may result in higher likelihood of occurrence for the site.

  - Design of the facility needs to properly define and address those external events at the magnitudes or intensity applicable to the site and not default to a general concluding of the initiating event is rare.

Principle Contributor

Juan López

K. Human Factors

Note: The Human Factors Engineering (HFE) Program Plan is typically housed in the ISA Chapter. Below are the staff's comments/observations on Orano's information on this program in that draft chapter.

1. Missing Human Factors Engineering Program Plan (Major)

Orano references regulatory requirements and guidance related to personnel activities, HFE, and management measures but does not provide a HFE Program Plan or describe how HFE principles, such as identification of personnel activities; HFE design review planning; operating experience review; functional allocation analysis and task analysis; human-system interface design, inventory and characterization; staffing; procedure development; training program development; and verification and validation are incorporated into its safety program. Moreover, Orano should describe the methodology and/or implementation for the proposed IROFS (see Observation No. 2 below) to ensure that each IROFS will be available and reliable to perform its intended function when needed.

Per 10 CFR 70.61(e), Orano must maintain a safety program that ensures each IROFS is available and reliable to perform its intended function when needed, which includes identifying personnel activities that serve as IROFS or support the performance of IROFS. Additionally, 10 CFR 70.62(d) requires the establishment of management measures that ensure compliance with the performance requirements of 10 CFR 70.61, including the design, implementation, and maintenance of administrative IROFS. NUREG-1520, Revision 2, provides the following, further guidance:

- Section 3.4.3.1 - states that HFE should generally be incorporated into the safety program to ensure that IROFS and related management measures function as intended.
- Chapter 11 of NUREG-1520 - describes expectations for management measures supporting IROFS performance.
- Appendix E of NUREG-1520 - provides guidance for incorporating HFE into safety-significant personnel activities using a graded approach.

The above discussed requirements and guidance ensure that the applicant appropriately evaluates human performance, human-system interfaces, staffing, training, and procedural adequacy to support safety.

To meet regulatory requirements, Orano must submit a HFE Program Plan that:

- Identifies safety-significant personnel activities;
- Describes HFE design review planning;
- Evaluates operating experience;
- Conducts functional allocation and task analyses;
- Characterizes human-system interfaces; and
- Addresses staffing, procedure development, training program development, and verification and validation.

Orano must also describe how HFE principles will be applied to IROFS (as referenced in Observation No. 2 below) to ensure each IROFS remains available and reliable to

perform its intended function when needed. This information is necessary for the staff to make an acceptability and safety determination consistent with 10 CFR Part 70 and NUREG-1520 guidance.

2. **Missing List of IROFS (Major)**

   The application does not include the information required to demonstrate compliance with 10 CFR 70.65(b)(6), which requires that license applications include a description of the safety program established under 10 CFR 70.62 and the Integrated Safety Analysis (ISA) Summary. The ISA Summary must include, among other elements, a list of IROFS that prevent or mitigate accident sequences with consequences exceeding the performance requirements of 10 CFR 70.61. The applicant did not provide this information in the proposed application. As a result, the application does not identify the "personnel activities" that constitute IROFS or the personnel activities that support safety (e.g., maintenance activities) as required under 10 CFR 70.61(e).

   Per 10 CFR 70.62(c) and (d), applicants must identify IROFS and describe the characteristics of their preventive, mitigative, or other safety functions, including the assumptions and conditions under which each IROFS is relied upon. These descriptions form the basis for evaluating whether the performance requirements of 10 CFR 70.61 will be met. NUREG-1520, Chapter 3, further specifies that applicants must clearly identify personnel activities that are credited as IROFS and describe the management measures necessary to ensure their reliability.

   To meet regulatory requirements, Orano must:

   - Provide the required list of IROFS in accordance with 10 CFR 70.65(b)(6), including personnel activities credited as IROFS under 10 CFR 70.61(e).
   - Describe the preventive, mitigative, or other safety function performed by each personnel-activity IROFS.
   - Identify the assumptions and conditions under which each IROFS is relied upon to meet the performance requirements of 10 CFR 70.61.
   - Provide sufficient detail for NRC staff to determine whether personnel-activity-based IROFS will be available and reliable when needed.

   This information is necessary for the NRC staff to determine whether Orano has identified all necessary IROFS or whether the associated personnel activities have been adequately characterized to ensure that each IROFS will be available and reliable to perform its intended safety function. The information is also necessary to determine whether the information provided in the application meets the requirements of 10 CFR 70.61, 70.62, and 70.65.

Principal Contributor

DaBin Gibbs

L. Electrical Distribution and Instrumentation and Controls

1. Missing list of IROFS (Major)

The application does not include the list of IROFS required to demonstrate compliance with 10 CFR 70.62(c)(vi). This regulation requires that the safety analysis identify each IROFS and describe the characteristics of its preventive, mitigative, or other safety function, along with the assumptions and conditions under which the item is relied upon to ensure compliance with the performance requirements of 10 CFR 70.61.

Per 10 CFR 70.62(c)(vi), applicants must provide a complete identification of each IROFS, including a description of its safety function and reliance conditions. This requirement supports the safety program established under 10 CFR 70.62 by ensuring that all engineered and administrative controls necessary to prevent or mitigate credible accident sequences are clearly defined. NUREG-1520, Chapter 3, further specifies that applicants must present a comprehensive list of IROFS along with sufficient detail to demonstrate how these controls satisfy the applicable performance requirements of 10 CFR 70.61.

To meet regulatory requirements, Orano must:

- Provide a complete list of all IROFS relied upon in the safety analysis.
- Describe the preventive, mitigative, or other safety function associated with each IROFS.
- Identify the assumptions and operating conditions under which each IROFS is credited to meet the performance requirements of 10 CFR 70.61.
- Ensure that the information is presented with sufficient detail to support NRC review and verification of safety-function adequacy.

This information is necessary to determine whether Orano has identified and described all required IROFS consistent with 10 CFR 70.62(c)(vi), to determine if a sufficient basis for understanding how the facility ensures that credible accident sequences are prevented or mitigated, and to provide reasonable assurance that the facility's safety controls are adequate to meet the performance requirements of 10 CFR 70.61.

2. Design Basis for IROFS (Major)

Several subsections of the application state that the principle of independence will be applied to IROFS and that periodic surveillance will be performed. However, the descriptions provided in Chapters 3 and 11 of the ISA Summary do not offer sufficient detail to demonstrate how IROFS will be designed, implemented, or maintained to ensure availability and reliability. The brief descriptions indicate that IROFS will generally consist of standalone devices (e.g., sensors, trip units controlling heaters or valves) that do not communicate with digital technologies to perform required safety actions, and that IROFS functionality will be monitored by a non-safety-related digital process control system. Aside from these statements and a reference to Regulatory Guide 1.75, the application does not describe the management measures or engineering practices that will be applied to ensure IROFS reliability and performance when needed. There is also no description of how process safety setpoints will be determined or which industry codes, standards, or methodologies will be used in the design, implementation, and maintenance of IROFS.

Per 10 CFR 70.62(d), applicants must identify and apply appropriate management measures to ensure that IROFS are designed, implemented, and maintained such that they are available and reliable when needed to meet the performance requirements of 10 CFR 70.61. These management measures must be described with sufficient detail to allow the NRC to evaluate their adequacy. NUREG-1520, Chapter 3, specifies that applicants must describe how design principles, engineering practices, setpoint methodologies, and applicable industry codes and standards are used to establish and maintain IROFS reliability. The guidance also notes that NRC review should be supported by documentation that can later be audited—such as boundary diagrams, design drawings, calculations, calibration procedures, and maintenance procedures—to verify that the design principles described in the application are implemented.

To meet regulatory requirements, Orano must:

- Provide detailed descriptions of the management measures that will be applied to ensure that IROFS are designed, implemented, and maintained to be available and reliable when required.
- Describe the engineering practices, industry codes, standards, and methodologies that will be used to establish IROFS functionality, including processes for developing and verifying process safety setpoints.
- Identify how independence and periodic surveillance of IROFS will be implemented and controlled.
- Provide sufficient information to allow the NRC to assess whether the design principles described in the application will be verifiable through future audits of design documents, calculations, drawings, and maintenance procedures.

This information is necessary to determine whether Orano has adequately described the management measures required by 10 CFR 70.62(d) and to provide reasonable assurance that IROFS will perform their credited safety functions when needed to meet the performance requirements of 10 CFR 70.61.

3. Electrical Power System (Moderate)

The application does not specify whether the electrical power system is classified as an IROFS or whether any IROFS depend on electrical power to perform their safety functions. For example, it is unclear whether any IROFS require continuous electrical power under normal operating conditions, or whether backup power sources such as batteries or uninterruptible power supplies (UPS) will be used to support safety-related functions. The ISA Summary appears to imply that IROFS do not require electrical power to complete their protective actions; however, the application provides no description of how electrical power availability, quality, or failure modes will be prevented from adversely affecting IROFS performance. Additionally, the application does not describe the electrical distribution design basis or how IROFS will be protected from electrical hazards such as lightning, ground faults, or surge conditions. The term “electrical” appears only in the context of equipment descriptions or fire protection ignition sources, with no corresponding electrical design criteria, codes, or standards identified. The only referenced Institute of Electrical and Electronics Engineers (IEEE) standard pertains to cable splicing practices, which is insufficient to establish the adequacy of the electrical design.

Per 10 CFR 70.62(c) and (d), applicants must identify each IROFS, describe its safety function, and apply appropriate management measures to ensure that IROFS are available and reliable when needed. This includes identifying dependencies—such as electrical power—that are necessary for IROFS to perform their safety functions. In addition, 10 CFR 70.65(b)(6) requires that the safety program described in the application provide sufficient detail to allow the NRC to determine whether the design is adequate to meet the performance requirements of 10 CFR 70.61. NUREG-1520, Chapters 3 and 11, specify that applicants must identify design criteria, codes, and standards for safety-related electrical systems and must describe how these systems support or interface with IROFS. The guidance further emphasizes that electrical design attributes—such as grounding, surge protection, lightning protection, and power quality—must be described when they are necessary to ensure IROFS reliability.

To meet regulatory requirements, Orano must:

- Specify whether the electrical power system, or portions of it, are classified as IROFS or support the operation of IROFS.
- Identify any IROFS that rely on electrical power, including whether continuous power, batteries, or UPS systems are needed for their safety functions.
- Describe how the electrical distribution system is designed to ensure IROFS are not adversely affected by electrical failures, including lightning, surges, ground faults, or other electrical hazards.
- Identify the applicable electrical design criteria, codes, and industry standards [e.g., IEEE, National Fire Protection Association (NFPA), International Electrotechnical Commission (IEC)] used in the facility design.
- Provide sufficient detail to allow the NRC to evaluate the adequacy of the electrical design as part of the overall safety basis and to verify IROFS reliability.

This information is necessary to determine whether Orano has adequately identified electrical dependencies and provided sufficient detail on the electrical design to demonstrate compliance with the performance requirements of 10 CFR 70.61 and the safety program requirements of 10 CFR 70.62 and 70.65.

4. Digital I&C IROFS (Major)

The application does not specify whether any instrumentation and control (I&C) IROFS rely on digital technologies, nor does it describe the associated management measures needed to ensure that digital I&C IROFS are designed, implemented, and maintained to be reliable and available when required. If any IROFS incorporate digital components—such as weighing scales, local temperature indicators, or other active engineered or administrative controls—then the application must identify the applicable design criteria, system development life cycle processes, and industry codes and standards used to establish reliability and prevent failures on demand.

Per 10 CFR 70.62(c) and (d), applicants must identify each IROFS and the management measures applied to ensure its availability and reliability to meet the performance requirements of 10 CFR 70.61. These requirements apply equally to digital and analog IROFS. NUREG-1520, Chapter 3, specifies that applicants must describe the engineering design criteria, software and hardware quality controls, verification and validation practices, and applicable industry standards (e.g., IEEE, ISA/IEC 61511, or other digital safety system standards) used to establish the safety basis for digital I&C

IROFS. The guidance further emphasizes that digital systems credited with safety functions must be supported by documented processes that control design, implementation, testing, maintenance, and CM.

To meet regulatory requirements, Orano must:

- Identify whether any I&C IROFS (engineered or administrative) rely on digital technologies.
- Describe the management measures and system development life cycle processes that will be applied to ensure digital IROFS are designed, implemented, and maintained to be reliable and available when needed.
- Identify the design criteria, verification and validation practices, and software and hardware quality measures that will be used to ensure reliability and low probability of failure on demand.
- Specify the applicable industry codes and standards—such as IEEE standards, IEC/ISA 61511, or equivalent—and describe how these standards will be implemented for each digital IROFS.
- Describe any dependencies on digital power, communications, or interfaces and how these will be controlled to ensure digital IROFS performance.

This information is necessary to determine whether Orano has adequately described the design, reliability, and management measures associated with digital I&C IROFS consistent with 10 CFR 70.62 and to provide reasonable assurance that these digital systems will perform their safety functions when needed to meet the performance requirements of 10 CFR 70.61.

5. Electrical and I&C IROFS Architecture and Design Characteristics (Major)

The application does not provide a high-level description of the electrical and I&C architecture or associated design features that demonstrate compliance with the performance requirements of 10 CFR 70.61, the BDC in 10 CFR 70.64, or the defense-in-depth expectations described in NUREG-1520. The information necessary to evaluate independence, isolation, redundancy, diversity, and protection against common-cause failures is not included. The application also does not identify the industry codes and standards governing the design, implementation, surveillance, calibration, and corrective maintenance of electrical and I&C IROFS. Without this information, the staff cannot determine whether the electrical and I&C systems credited as IROFS will be available and reliable when needed.

Per 10 CFR 70.62(c) and (d), applicants must identify IROFS and apply appropriate management measures to ensure that IROFS are designed, implemented, and maintained to be available and reliable to meet the performance requirements of 10 CFR 70.61. In addition, 10 CFR 70.64 requires that the design of new facilities incorporate BDC, including independence, reliability, and protection against common-cause failures for safety-related systems. NUREG-1520 (particularly Chapters 3 and 11) specifies that applicants must describe the overall safety-related electrical and I&C architecture, identify the design features that support independence and defense-in-depth, and reference applicable industry standards such as IEEE, NFPA, ISA/IEC 61511, or equivalent. The guidance further notes that electrical and I&C IROFS must be supported by documented design criteria, engineering practices, and management measures to ensure reliability and proper performance.

To meet regulatory requirements, Orano must:

- Provide a high-level description of the electrical and I&C architecture, including design features that address independence, isolation, redundancy, diversity, and protection against common-cause failures.
- Identify the industry codes and standards governing the design, implementation, testing, surveillance, calibration, and maintenance of electrical and I&C IROFS.
- Describe the management measures that will be applied to ensure electrical and I&C IROFS are available and reliable when needed, consistent with 10 CFR 70.62(d).
- Identify how defense-in-depth is achieved within the electrical and I&C design and how these features support compliance with 10 CFR 70.61 and 10 CFR 70.64.
- Provide sufficient information to allow the NRC to determine whether the electrical and I&C safety basis is complete and technically adequate.

This information is necessary to determine whether Orano has adequately described the electrical and I&C design features, associated management measures, and applicable industry standards to support IROFS availability and reliability consistent with 10 CFR 70.61, 70.62, and 70.64.

Principal Contributors

Gilberto Blas
Ming Li
David Rahn

M. Observations on Decommissioning Funding Plan

1. Decommissioning Cost Estimate (DCE) and Decommissioning Funding Plan (DFP) (Major)

The application includes an incomplete, blank template copied from guidance rather than a completed DCE/DFP. This does not meet the requirements of 10 CFR 70.25(e), which mandates that applicants submit a complete DCE/DFP that provides the basis for the facility's decommissioning funding mechanism.

Per 10 CFR 70.25(e), applicants must provide a detailed decommissioning funding plan that includes a site-specific cost estimate, identification of the funding mechanism, and supporting assumptions. This plan must demonstrate that sufficient financial resources will be available to complete decommissioning in accordance with regulatory requirements. NUREG-1520, Chapter 8, further specifies that DCE/DFP submittals must include a complete and technically justified cost estimate rather than placeholders or templates.

To meet regulatory requirements, Orano must:

- Submit a complete DCE consistent with the requirements of 10 CFR 70.25(e).
- Provide the full DFP, including cost basis, assumptions, funding mechanism, and supporting analysis.
- Remove blank templates and replace them with fully developed content that reflects facility-specific decommissioning obligations.

This information is necessary for the NRC staff to determine whether Orano has established adequate financial assurance for decommissioning in accordance with 10 CFR 70.25.

2. Eight factors are not addressed (Major)

The DFP does not address the eight factors required by 10 CFR 70.25(e)(2). These factors must be evaluated to ensure that the DCE accounts for potential conditions that could increase decommissioning liabilities. Without addressing these required elements, the staff cannot determine whether the applicant has provided an adequate basis for the decommissioning funding mechanism or whether the DFP meets the regulatory requirements of 10 CFR 70.25.

Per 10 CFR 70.25(e)(2), applicants must consider the following factors when preparing a DFP:

(i) spills of radioactive material producing additional residual radioactivity in onsite subsurface material;
(ii) waste inventory increases above previously estimated amounts;
(iii) waste disposal cost increases above previously estimated amounts;
(iv) facility modifications;
(v) changes in authorized possession limits;
(vi) remediation costs that exceed the previous cost estimate;
(vii) onsite disposal; and
(viii) the use of a settling pond.

NUREG-1520, Chapter 8, further specifies that applicants must explicitly address each factor or provide a justified explanation for why it does not apply.

To meet regulatory requirements, Orano must:

- Address each of the eight factors required by 10 CFR 70.25(e)(2) within the DFP, including a discussion of potential impacts on decommissioning cost estimates.
- Update the DCE/DFP to incorporate additional cost considerations or provide justification for why specific factors are not applicable.
- Provide supporting assumptions, methodologies, and cost bases to demonstrate that the DFP adequately reflects the potential range of decommissioning liabilities.

This information is necessary to determine whether Orano's DFP meets the requirements of 10 CFR 70.25 and provides reasonable assurance that adequate financial resources will be available to complete decommissioning.

3. No justification on how inventory is to be handled (Moderate)

The application references section 1, "DCE Reflecting Current Facility Conditions," of the Draft ISG on Decommissioning Funding Plans for Materials Licensees (June 2018, ADAMS Accession No. ML18161A087), which outlines acceptable justifications for how decommissioning inventory should be addressed. However, the LA does not include information demonstrating how the applicant evaluated its decommissioning inventory in accordance with this guidance, nor does it provide justification for any alternative approach.

Per 10 CFR 70.25(e), applicants must submit a Decommissioning Funding Plan (DFP) that includes a detailed, facility-specific cost estimate based on the current radiological and hazardous materials inventory. The guidance in the Draft ISG provides an acceptable method for ensuring that the DCE reflects current facility conditions; applicants that do not follow this method must provide alternative justification. NUREG-1520, Chapter 8, further specifies that applicants must clearly describe how inventory characterization, assumptions, and cost bases support the DFP.

To meet regulatory requirements, Orano must:

- Address how the decommissioning inventory was evaluated in accordance with section 1 of the Draft ISG (ML18161A087), or justify an alternative approach.
- Demonstrate that the DCE reflects current facility conditions, including site-specific inventory and contamination assumptions.
- Provide sufficient detail to support the radiological and hazardous materials assumptions used in the DCE and ensure consistency with regulatory requirements.

This information is necessary to determine whether Orano's DFP and decommissioning cost basis appropriately reflects current facility conditions as required by regulation and meets the requirements of 10 CFR 70.25.

4. Blank reference to U.S. Department of Energy Agreement (Moderate)

The cost basis for depleted uranium hexafluoride (DUF_6) disposal relies on two elements; however, the application does not provide sufficient technical justification to

support the validity of these inputs. Specifically, the estimated disposal cost is derived from (1) an agreement between the U.S. Department of Energy (DOE) and Orano Enrichment USA, LLC (OE), which specifies a disposal rate of $x.xx per kilogram of uranium hexafluoride (UF_6), and (2) the projected volume of DUF_6 generated through facility shutdown. The application does not include the referenced agreement, describe the underlying assumptions used to establish the disposal rate, or provide supporting analysis showing how the projected DUF_6 inventory was calculated. Without this information, the basis for the DUF_6 disposal cost estimate is not adequately supported.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify and describe factors affecting facility safety and must provide sufficient detail to support the assumptions and technical bases underlying cost-related safety program elements. Consistent with NUREG-1520 guidance, applicants are expected to present a transparent and defendable basis for cost assumptions when such assumptions influence safety-related planning or programmatic commitments, including the use of documented agreements, validated cost inputs, and traceable inventory calculations.

To meet regulatory requirements, the applicant must:

- Provide the referenced DOE–OE agreement or otherwise describe the technical basis used to establish the disposal rate of $x.xx per kilogram of UF_6.
- Describe the methodology and assumptions used to estimate the total DUF_6 volume generated through facility shutdown.
- Provide supporting calculations or source information demonstrating how DUF_6 quantities were determined.
- Explain how the disposal rate and DUF_6 volume estimates were validated and how uncertainties were considered.

This information is necessary to determine whether the DUF_6 disposal cost estimate is based on a defensible and technically sound foundation and to ensure that all cost-related assumptions influencing safety-related planning are adequately justified in accordance with 10 CFR 70.65(b).

5. Submittal of executed financial documents (Moderate)

At least 45 days prior to the receipt of licensed material Orano must submit executed decommissioning financial assurance instruments to the U.S. NRC for review and approval. Orano does not provide sufficient information describing how this requirement will be implemented, what specific instruments will be provided, or how it will ensure the instruments meet NRC regulatory criteria. Without identifying the types of financial assurance mechanisms to be used, their expected values, or the process for verifying their adequacy, the application does not establish a clear or defensible basis for ensuring compliance with decommissioning financial assurance requirements.

Per 10 CFR 70.65(b)(9) and (10), applicants must identify and describe commitments that relate to facility safety, including the methods and financial mechanisms used to ensure safe decommissioning. NRC guidance in NUREG-1520, section 6 (“Financial Assurance and Decommissioning”), specifies that applicants should clearly identify the planned financial assurance instruments, demonstrate that they will meet the requirements of 10 CFR Part 30, Appendix E (as applicable), and describe how the

applicant will ensure these instruments are executed and maintained in accordance with NRC regulations.
To meet regulatory requirements, Orano must:

- Identify the specific decommissioning financial assurance instruments that will be executed (e.g., surety bond, letter of credit, escrow agreement, trust fund).
- Describe the estimated value of each instrument and how the value was derived.
- Explain the process and timeline for preparing, executing, and submitting the final instruments at least 45 days before receipt of licensed material.
- Demonstrate how the selected instruments will meet the applicable criteria in NRC regulations and guidance.
- Describe how the applicant will ensure continued validity and sufficiency of the instruments once executed.

This information is necessary to determine whether the applicant has provided a defensible and technically adequate basis for meeting decommissioning financial assurance requirements consistent with 10 CFR 70.65(b) and applicable NRC guidance.

6. Other financial areas to be reviewed (Major)

Section 1.2.2, “Financial Qualifications,” of the application provides only high-level, generic statements and does not include the detailed information necessary to demonstrate compliance with 10 CFR 70.23(a)(5) and 10 CFR 140.13b. The section does not identify the source of financial assurance, provide the required financial plan, or include the firm contract information and evidence of offsite liability insurance needed to support the applicant’s financial qualifications. Further, the application does not reference where detailed financial statements are located or provide a summary of such information. Without these elements, the application lacks an adequate basis for establishing that the applicant meets NRC’s financial qualification requirements.

Per 10 CFR 70.23(a)(5), applicants must provide information demonstrating that they possess or have access to sufficient funding to conduct licensed activities safely. Additionally, 10 CFR 140.13b requires applicants to maintain appropriate levels of offsite liability insurance for the authorized operations. NRC guidance in NUREG-1520, section 1 (“General Information”), specifies that applicants should provide detailed financial statements, identify contractual mechanisms supporting financial assurance, and describe the insurance arrangements that ensure continued regulatory compliance.

To meet regulatory requirements, the applicant must:

- Provide the financial plan required by 10 CFR 70.23(a)(5), including firm contract information supporting access to necessary financial resources.
- Provide documentation or a description of the offsite liability insurance required under 10 CFR 140.13b.
- Identify where detailed financial statements are included in the application or, alternatively, provide a summary of such information within section 1.2.2.
- Demonstrate how the financial information provided satisfies NRC regulatory requirements and establishes adequate financial qualifications.

This information is necessary to determine whether the applicant has provided a complete, defensible, and technically adequate demonstration of financial qualifications in accordance with 10 CFR 70.23(a)(5) and 10 CFR 140.13b.

Principal Contributor

Kenneth Kline