

Audit questions related to AUR-PDD-001 Revision 0, “Nuclear Quality Assurance Program (N-QAP) for Aurora Powerhouses”

1. Sections II.1 through II.18 contain a subsection titled “ANSI/ANS-15.8 commitment.” In each of these subsections, Oklo Inc. (Oklo) includes a statement committing to compliance with American National Standards Institute (ANSI) and American Nuclear Society (ANS) standard ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors.” Since ANSI/ANS-15.8-1995 has not been endorsed by the U.S. Nuclear Regulatory Commission (NRC) as an acceptable way for meeting the quality assurance (QA) requirements of Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, this statement is unclear.

Please revise these statements to reflect how Oklo’s Nuclear Quality Assurance Program (N-QAP) is written to meet the regulatory requirements. In addition, the staff would like to understand how to interpret these statements committing to ANSI/ANS-15.8-1995 in light of the remainder of the description in the N-QAP.

2. The staff notes that the N-QAP does not describe how the QA requirements of Appendix B to 10 CFR Part 50 are met. Therefore, for each Appendix B criterion, please provide: (1) a justification for why ANSI/ANS-15.8-1995 satisfies Appendix B to 10 CFR Part 50; and/or (2) a gap analysis, as necessary, that identifies the specific measures, controls, and program elements that Oklo will implement to supplement ANSI/ANS-15.8-1995 to demonstrate compliance with Appendix B to 10 CFR Part 50.
3. Section I.1, “General,” states, in part, that “The Oklo Inc. (Oklo) Nuclear Quality Assurance Program (N-QAP) is the top-level policy document that establishes Oklo’s quality assurance policy and assigns major functional responsibilities for design, construction, and operation activities conducted by or for Oklo.” Section I.1.1 further states, in part, that “The N-QAP applies to activities that affect the quality and performance of safety-related structures, systems, and components (SSCs), including, but not limited to, designing, procuring, fabricating, cleaning, inspecting, receiving, handling, shipping, testing, and training.”

However, neither of these sections specify which type of application Oklo’s N-QAP is applicable to (e.g., standard design approval, design certification, manufacturing license, early site permit, limited work authorization, construction permit, operating license and/or combined operating license). Given that the QA requirements for a QA program vary depending on the type of application, please clarify which type(s) of application(s) for Aurora powerhouses that Oklo’s N-QAP is applicable to.

4. Section II.1, “Organization,” does not: (1) provide measures for maintaining independence between organizations performing checking functions from the organization performing the functions; and (2) does not describe the management structure during the construction and operation phases.

(1) Please clarify how Oklo’s N-QAP will provide measures for maintaining independence between organizations performing checking functions from the organization performing the functions; and (2) please provide a description in the N-QAP of Oklo’s management structure during the construction and operational phases.

5. Please describe the Oklo QA organization at various stages of the facility lifecycle from siting and construction, to startup testing and operations.
6. Section II.2.3, "Issuance and revision to Nuclear Quality Assurance Program" states, in part, that "Administrative control of the N-QAP is in accordance with 10 CFR 50.54, "Conditions of licenses," as applicable." As a non-licensee, Oklo would be subject to 10 CFR 50.4(b)(7)(ii), which states, that "A change to an NRC-accepted quality assurance topical report from non-licensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent."

Please confirm that any changes to Oklo's N-QAP will be submitted to the NRC for review and approval in accordance with 10 CFR 50.4(b)(7)(ii).

7. Oklo's N-QAP does not provide measures for the following activities:
 - a. management review of the N-QAP to assess the effectiveness and the adequacy of the scope and implementation.
 - b. establishing and maintaining a list of the structures, systems, and components (SSCs), and/or activities under the control of the N-QAP at the applicant's or holder's facility.

Please clarify how Oklo's N-QAP will provide measures to address items (a) and (b) above.

8. Oklo's N-QAP does not describe how training for positions identified in 10 CFR 50.120, "Training and qualification of nuclear power plant personnel," will be accomplished or how specific personnel will be trained. In addition, there is no information on the training requirements for QA and Quality Control (QC) personnel, including QA and QC management.

Please provide a description of how Oklo will accomplish training for positions identified in 10 CFR 50.120 and a description of the training requirements for QA and QC personnel, including QA and QC management.

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The description above is not sufficient for the NRC staff to determine how Oklo plans to implement its commercial-grade dedication program. Please provide a more detailed description of how Oklo intends to perform commercial-grade dedication. In addition, please provide the relevant procedures for commercial-grade dedication for the staff audit.

10. Section II.3, “Design control,” states, in part, that “The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within Oklo and with its suppliers.” In addition, Section II.4, “Procurement document control,” states, in part, that “Legacy technical information that is to be used in safety-related SSC design must be evaluated to meet quality assurance requirements.” However, Oklo’s N-QAP does not provide any description on how legacy data will be controlled and implemented.

Please provide a description of how Oklo’s N-QAP plans to control and implement the use of legacy data. The description should provide details on the data qualification process, the qualification methods, and how the results will be documented.

11. Subsection II.3.1 states, in part, that “The extent of the design verification required is a function of the complexity of the design, the degree of standardization, the state of the art, whether the item under consideration is safety-related, and the similarity with previously proven designs.”

How is the extent of design verification determined in practice? To help the staff understand how this will be implemented in practice, please provide the relevant implementing procedures.

12. Subsection II.3.3, “Computer application and digital equipment software,” states, in part, that

Computer programs are either pre-verified for acceptability before use or their results are verified as part of the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. Oklo and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

- a. ANSI/ANS-15.8-1995 does not cover software QA. What guidance will Oklo follow for software QA?
- b. What is the software configuration management process described in the second sentence above?
- c. Provide the software quality assurance and configuration management procedures, if developed, and indicate what software verification and validation tools or methods will be used.

13. Section II.3.5 “ANSI/ANS-15,8 commitment,” states, in part, that “[[

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14. Section C.4 of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/index>); Section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants,” Revision 1 (ML15037A441) addresses the documentation of design analyses. The staff does not see any provisions in ANSI/ANS-15.8-1995 or the N-QAP to address this topic. Please clarify Oklo’s plans in this area.

15. Section II.4, “Procurement document control,” states, in part, that

Applicable design bases and other requirements necessary to ensure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR Part 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under Oklo’s approved QA program).

Oklo’s N-QAP does not provide measures to ensure that the applicable technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, “Reporting of Defects and Noncompliance”) are invoked for the procurement of items and services.

Please clarify how Oklo’s N-QAP will provide these measures as described above.

16. Section II.4 does not provide measures for the following from NUREG-0800, Section 17.5 (Revision 1), Section D.3: “Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.”

Please clarify how Oklo’s N-QAP will provide measures to address the above.

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Please clarify how Oklo plans to address 10 CFR Part 21 reporting requirements through the procurement documents for suppliers.

18. Section II.6, “Document control,” does not: (1) define the scope of the document control program and/or provide a list of the types of documents that will be controlled; and (2) provide measures for the control of procedures during the operational phase, including temporary procedure changes.

Please (a) define the scope of the document control program and/or include a list in the N-QAP of the types of documents that will be controlled; and (b) clarify how Oklo’s N-QAP will provide measures for the control of procedures during the operational phase, including temporary procedure changes.

19. Section F.8 of NUREG-0800, Section 17.5, Revision 1, states, in part, that procedures used during the operational phase are reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every 2 years to determine if changes are necessary or desirable. Procedures do not have to be reviewed every 2 years provided that all of the following are met:
- a. Applicable procedures are reviewed following any modification to a system.
 - b. Applicable procedures are reviewed following an unusual incident, unexpected transient, significant operator error, or equipment failure.
 - c. Procedures are updated during use when discrepancies are found.
 - d. Procedures are reviewed by knowledgeable individuals prior to use if not used in the previous 2 years.
 - e. A QA program audit of procedures is conducted every 2 years.

The staff does not see any provisions in ANSI/ANS-15.8-1995 or the N-QAP to address this topic.

Please clarify how Oklo's N-QAP will provide these measures as described above.

20. Section II.7.2, "ANSI/ANS-15.8 commitment," states: "[[

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Please provide details on Oklo's approach in establishing intervals for assessments (audits) consistent with the importance, complexity, and quantity of products or services. To help the staff understand how this will be implemented in practice (including scope and frequency), please provide the relevant implementing procedures for audit.

21. Section II.7.1, "Acceptance of item or service," states, in part, that "Industry programs, such as those applied by ASME, Nuclear Procurement Issues Corporation (NUPIC), or other established utility groups, may be used as input or the basis for supplier qualification whenever appropriate."

Please explain Oklo's process, described in Section II.7.1, to utilize industry programs (including access to NUPIC audit reports and ASME surveys) as an input or basis for supplier qualification.

22. Section II.10, "Inspection," does not provide measures for inspection results to be documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

Please clarify how Oklo's N-QAP will provide these measures as described above.

23. Section II.10 states: "If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel is provided."

Please clarify what is intended by this statement. What types of situations is this referring to? What is the definition of “disadvantageous” in this context? Please provide relevant implementation procedures for the staff audit.

24. Section II.11, “Test control,” commits to additional language nearly identical to that in Appendix B to 10 CFR 50.

To help the staff understand how this will be implemented in practice, please provide the relevant implementing procedures for the staff audit.

25. Section II.12, “Control of measuring and test equipment,” does not provide measures for the following: (a) how will the calibration status be indicated and traceability maintained; (b) how often will the measuring and test equipment (M&TE) be calibrated and whether it will be against national standards; (c) what happens when there aren’t any nationally recognized standards; (d) what actions will Oklo take when M&TE is found to be out of calibration; and (e) how calibration will be performed and controlled during the operational phase.

Please clarify how Oklo’s N-QAP will provide measures to address items (a) through (e) above.

26. Section II.13, “Handling, storage, and shipping,” does not provide measures for the following activities:

- a. establishing controls for the packaging, shipping, handling and storage of items on a case-by-case basis with due regard for the item’s complexity, use, and sensitivity to damage.
- b. ensuring that prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could affect their function.
- c. establishing controls for hoisting, rigging, and transport activities that protect the integrity of the item involved as well as potentially affected nearby structures and components.

Please clarify how Oklo’s N-QAP will provide measures to address items (a) through (e) above.

27. Section II.13 does not describe the provisions for the storage of chemicals, reagents (including control of shelf-life), lubricants, and other consumable materials.

Please provide a description of how Oklo’s N-QAP will address storage of chemicals, reagents (including control of shelf-life), lubricants, and other consumable materials.

28. Section II.14, “Inspection, test, and operating status,” does not provide measures for temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point setting, to be controlled by approved procedures which include a requirement for independent verification.

Please clarify how Oklo’s N-QAP will provide these measures as described above.

29. Section II.15, “Nonconforming materials, parts, or components,” does not provide measures for the following activities:
- a. for items to be dispositioned as reviewed and accepted, or rejected.
 - b. for items that are reworked, repaired, and replacement items to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.
 - c. a nonconformance to design requirements dispositioned as use-as-is or repair to be subject to the design control measures commensurate with those applied to the original design. The as-built records, if such records are required, reflect the accepted deviation.
 - d. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

Please clarify how Oklo’s N-QAP will provide measures to address items (a) through (d) above.

30. Section II.15 does not describe any interfaces between the identification and control of nonconforming materials, parts, or components, and 10 CFR 50.55 and 10 CFR Part 21 during design, construction, and operations, as applicable.

Please provide a description of the interface between Oklo’s program for nonconforming materials, parts, or components, and 10 CFR 50.55 and 10 CFR Part 21 during the design, construction, and operations phases, as applicable.

31. Section II.16, “Corrective Action,” does not describe any interfaces between the corrective action program, and 10 CFR 50.55 and 10 CFR Part 21 during design, construction, and operations, as applicable.

Please provide a description of the interface between Oklo’s corrective action program, and 10 CFR 50.55 and 10 CFR Part 21 during the design, construction, and operations phases, as applicable.

32. Section II.17, “Quality assurance records,” does not provide measures for the following activities:

- a. establishing requirements concerning record retention (lifetime vs. nonpermanent records), such as duration, location, and assigned responsibility for protecting records from destruction by fire, flooding, tornadoes, insects, and rodents and from deterioration by extremes in temperature and humidity.
- b. committing to implementing NRC’s Generic Letter (GL) 88-18, “Plant Record Storage on Optical Disks.” GL 88-18 describes an acceptable method for storing QA documents in optical media in accordance with the criteria in Appendix B to 10 CFR Part 50.

- c. committing to following NRC's Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," and the following technical guidelines (TG) from the Nuclear Information and Records Management Association (NIRMA):
 - i. TG 11-2011, "Authentication of Records and Media"
 - ii. TG 15-2011, "Management of Electronic Records"
 - iii. TG 16-2011, "Software Configuration Management and Quality Assurance"
 - iv. TG 21-2011, "Electronic Records Protection and Restoration"

These TGs provide guidance to establish the appropriate quality controls that incorporate the implementation of enterprise content management systems, web-based technologies, and higher capacity local- and wide-area networks. The NRC approves for use the 2011 versions of the NIRMA TGs.

Please clarify how Oklo's N-QAP will provide measures to address items (a) through (c) above.

- 33. Section II.17 does not include pre-operation, start-up, modification, and audits as activities for which records should be controlled, and their retention times specified, as defined in appropriate procedures.

Please clarify how Oklo's N-QAP will address control and retention of records of the activities listed above.

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Section II.18 does not provide any clear distinction between audits and assessments.

Please update the N-QAP to ensure that the distinction between audits and assessments is clearly documented.

- 35. Section II.18, "Assessments," states in part: "Independent internal assessments of selected aspects of licensing, design, and construction activities are performed with a frequency commensurate with safety and in a manner that ensures completion of assessments for safety-related activities."

Please provide details on Oklo's process for establishing the frequency and scope of assessments (audits) commensurate with safety. To help the staff understand how this will be implemented in practice (including the scope and frequency of internal assessments), please provide the relevant implementing procedures for audit.

- 36. The staff understands that in Oklo's classification approach, non-safety-related with augmented quality (NSRAQ) SSCs are intended to be considered important to safety but not safety-related. Section II.2 states, in part, that "Specific program controls may be applied to non-safety related SSCs that are significant contributors to plant safety and for which 10 CFR Part 50, Appendix B does not apply. These controls, consistent with applicable

sections of the N-QAP, are applied selectively to those items and are focused on the characteristics or critical attributes that qualify the SSC as a significant contributor to plant safety.”

To help the staff understand how this will be implemented in practice, please provide the relevant implementing procedures for the staff’s audit or otherwise describe how QA requirements will be applied to NSRAQ SSCs.

37. Oklo’s N-QAP does not include a section describing how it addresses SSCs classified as non-safety-related but important to safety.

Please clarify how Oklo’s N-QAP will address SSCs related to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and station blackout (SBO) (10 CFR 50.63) that are not safety related.

38. Oklo’s N-QAP does not include a list of Regulatory Guides (RGs), Generic Letters, and other quality standards that Oklo commits to for the implementation of its N-QAP to ensure meeting the requirements of Appendix B to 10 CFR Part 50.

Oklo’s N-QAP should identify conformance with the RGs and other quality standards, as applicable. If conformance at this point is not practical, Oklo’s N-QAP should list these documents and explain that conformance and exceptions for the applicable regulatory position provided in the RGs and the other quality standards will be provided in the applicable license applications (e.g., safety analysis reports).

39. Part IV, “Additional controls for the plant operational phase,” states, in part, that “Part IV of the N-QAP establishes the measures and governing procedures for the operations phase of the plant through the following requirements.” Please clarify at what point in time the implementation of these additional controls becomes applicable.

40. Part IV does not include a “Definitions” section. Please provide a list of terms and their definitions to ensure consistency and uniform understanding.

41. Subsection IV.1.2, “Independent Review,” provides a list of the functions performed by the independent review program. One of the functions of the independent review program is the review of the adequacy of the internal audit program every 24 months per ANSI/ANS 3.2-2012, “Managerial, Administrative and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants” (which is endorsed in RG 1.33, “Quality Assurance Program Requirements (Operation),” Revision 3 (ML13109A458)). Please clarify if Oklo’s independent review programs plan to review the adequacy of the internal audit program every 24 months.

42. Subsection IV.1.2 states, in part, that “Activities during the operational phase are independently reviewed on a periodic basis by the Independent Review Body (IRB), which administers the independent review program and provides independent oversight.” Subsequently, that section states that “A group may function as an IRB. In discharging its review responsibilities, the IRB keeps safety considerations above cost or schedule considerations. One or more organizational units may collectively perform this function.” However, no other information is provided about the IRB. Specifically, the following information is missing:

- a. Who the IRB reports to.
- b. Composition of the IRB.
- c. Frequency of meetings during the period of initial operation and afterwards.
- d. Documentation and recording of meeting results.
- e. Use of contractors.
- f. Qualification of the members of the IRB.

Please clarify how Oklo’s N-QAP will address the information in (a) through (f) above.

43. Section IV.2, “Operation phase procedures,” does not provide the expected format and content of the operational phase procedures to be used during the design, operation, and maintenance of the Oklo nuclear power plants.

Please clarify how Oklo’s N-QAP will provide the expected format and content of the operational phase procedures.

44. Subsection IV.2.1, “Procedure types,” includes a description of the types of procedures Oklo plans to use to govern the operation and maintenance of its nuclear power plants. Not included on this list of procedures are (a) engineering; (b) configuration management; (c) installation; (d) calibration and test; and (e) test and inspection procedures.

Please clarify how Oklo’s N-QAP will include descriptions of the types of procedures (a) through (e) listed above.