Mazza, Jan

From: Mazza, Jan
Sent: Monday, December 16, 2019 2:51 PM
To: C Cochran; Alex Renner
Cc: Beasley, Benjamin; Vechioli Feliciano, Lucieann; Galletti, Greg
Subject: Draft RAIs - Oklo QAPD Topical Report
Attachments: Oklo QA RAIs_Draft_For_Meeting_12-18-2019.docx

Please see the attached draft RAIs for the Oklo QAPD topical report to be discussed on 12-18-2019.

Thanks - Jan

Jan Mazza
Project Manager, Advanced Reactor Licensing Branch
Division of Advanced Reactors and
Non-Power Production and Utilization Facilities
NRC Office of Nuclear Reactor Regulation
301-415-0498
Jan.Mazza@nrc.gov

REQUEST FOR ADDITIONAL INFORMATION

OKLO QUALITY ASSURANCE PROGRAM DESCRIPTION

OKLO-2019-14-NP, REVISION 0

EPID NO. L-2019-TOP-0024

DRAFT FOR MEETING 12-18-2019

The following requests for additional information (RAIs) are based on the U.S. Nuclear Regulatory Commission (NRC) staff's review of the Oklo, Incorporated (herein referred to as Oklo) Quality Assurance Program Description (QAPD). This requested information is necessary to demonstrate Oklo's compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

The NRC staff reviewed the Oklo QAPD based on Oklo's plans to submit a custom combined operating license (COL) that does not reference a previously-approved design certification (DC). 10 CFR 52.79(a)(25) states, in part, that "The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 have been and will be satisfied, including a discussion of how the quality assurance program will be implemented." Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction), Revision 5, dated October 2017, endorses NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," as one acceptable method to meeting the requirements of Appendix B to 10 CFR Part 50. NQA-1 provides the "how to" details to meet the requirements of 10 CFR 52.79(a)(25). When an applicant submits the QAPD as part of a licensing request, the NRC staff will determine if the applicant has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit, and New License Applicants," Revision 1, dated August 2015. Although NUREG 0800 is guidance for the NRC staff related to the review of light-water reactor (LWR) applications, the quality assurance program guidance in Section 17.5 can also be applied to non-LWRs, as the guidance is not design based.

The Oklo QAPD is based on the NRC-endorsed Nuclear Energy Institute (NEI) 11-04A, "Nuclear Generation Quality Assurance Program Description," template, that is based on the NQA-1 standard. In performing the review, the staff used the current NRC Standard Review Plan (SRP) Chapter 17.5 guidance as well as the NEI 11-04A QAPD template, and NRC staff final safety evaluation report (FSER) regarding the NEI template, dated May 9, 2013, to inform this evaluation.

General Question

RAI 1.0:
Regulations in 10 CFR 52.79(a)(25) requires a COL applicant to include a QAPD to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. The QAPD includes a discussion of how it satisfies applicable portions of Appendix B to 10 CFR Part 50.

In June 2010, the NRC issued Regulatory Guide (RG)1.28, Quality Assurance Program Criteria (Design and Construction), Revision 4. The issuance of RG 1.28, Revision 4 endorsed the Part

I and Part II requirements included in the American Society of Mechanical Engineers (ASME) Standard NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," for the implementation of a quality assurance (QA) program during the design and construction phases of nuclear power plants and fuel reprocessing plants as acceptable to the NRC staff and providing an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to specific additions and modifications of NQA-1-2008 and the NQA-1a-2009 Addenda and the regulatory positions in RG 1.28, Revision 4.

Subsequently, In January 2011 the ASME NQA-1 Committee and ASME approved a second Addenda to NQA-1-2008 (NQA-1b-2011), that provided additional revisions to NQA-1-2008/NQA-1a-2009 Addenda. The revised standard, NQA-1-2008//NQA-1a-2009/NQA-1b-2011, was evaluated and found acceptable to the NRC staff as providing an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to specific additions and modifications of NQA-1-2008, the NQA-1a-2009 Addenda, the NQA-1b-2011 Addenda, and the regulatory positions in RG 1.28, Revision 5, issued in October 2017.

The Oklo Quality Assurance Program Description (OKLO -2019-14-NP, Revision 0), Part 1, Section 1, "General," states in part, that the QAPD is based on the requirements and guidance of ASME NQA-1-2008 and NQA-1b, 2011 Addenda. However, the endorsed version of the ASME NQA-1-2008 standard also included NQA-1a-2009 Addenda, which is not referenced in the Oklo QAPD. Revisions made to the ASME NQA-1-2008 version resulting from inclusion of the ASME NQA-1a-2009 Addenda are, therefore, omitted from the Oklo QAPD, which is not consistent with the NRC endorsement of use of the ASME NQA-1-2008 standard. Furthermore 10 CFR Part 50.55a(1)(v)(B)(2-3) approves for incorporation by reference both NQA-1-2008 and NQA-1-2009A. This issue was discussed with the applicant in a telecom on September 30, 2019. The applicant stated the QAPD will be updated to reflect incorporation of ASME NQA-1-2009A.

Section 1 Organization

RAI 1.1
Criterion I, "Organization," 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, "Domestic Licensing of Production and Utilization Facilities," states in part, that "The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions."

Explain why Section 1.4, "Quality Assurance Manager," of the Oklo QAPD removed the statement in Section 1.5.2.1.1, "Quality Assurance Project Manager," of the NEI 11-04A template, that the "[Quality Assurance Manager] QAM may make recommendations to the management regarding improving the quality of work practices."

RAI 1.2
Criterion I, "Organization," of Appendix B to 10 CFR Part 50, states in part, that "The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing."

Explain why Figure 1-1, "Oklo Organization Structure," of the Oklo QAPD does not have line management for functions of Safety/Health and Information Technology.

Section 2 Quality Assurance Program

RAI 2.1
Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50, states in part, that "The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Section 2 of the Oklo QAPD states in part, that "Periodic audits or assessments of supplier QA programs are performed to ensure compliance with the Oklo QAPD and implementing procedures." Was the intent of this statement to ensure compliance with the suppliers' or principle contractors' QAP rather than the Oklo QAPD?

RAI 2.2
Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50, states in part, that "The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Section 2 of the Oklo QAPD omitted the final sentence of Section 2 of the NEI 11-04A template regarding audit schedules being based on the month in which the audit starts.
Please explain why this was omitted.

RAI 2.3
Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part, that "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Explain why Section 2.5, "Personnel Training and Qualification," of the Oklo QAPD lacks all discussion of minimum qualifications for directors, managers, and QA personnel charged with implementation of the QA program, consistent with Section 2.6, "Personnel Training and Qualification," of the NEI 11-04A template.

Section 3 Design Control

RAI 3.1
Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states in part, that "Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization."

Explain why Section 3 of the Oklo QAPD omitted the statement that, "Changes to design inputs, final designs, ... are justified and subject to design control measures commensurate with those applied to the original design," as described in Section 3, "Design Control," of the NEI 11-04A template.

RAI 3.2
Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states in part, that "Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions."

Explain why Section 3.1, "Design Verification," of the Oklo QAPD omitted the statement that, "Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use," as described in Section 3.1, "Design Verification," of the NEI 11-04A template.

RAI 3.3
Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states in part, that "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program."

Explain why Section 3.1, "Design Verification," of the Oklo QAPD omitted the statement that, "When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function," as described in Section 3.1, "Design Verification," of the NEI 11-04A template.

Section 6 Document Control

RAI 6.1
Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, states in part, that "Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality."

Explain why Section 6 of the Oklo QAPD omitted the statement that, "A method to ensure the correct documents are being used," as described in Section 6, "Document Control," of the NEI 11-04A template.

Section 7 Control of Purchased Material, Equipment, and Services

RAI 7.1
The staff considers this RAI to be editorial in nature. Section 7.1, "Acceptance of Item or Service," of the Oklo QAPD references the Nuclear Procurement Issues Committee." This should be revised to state, "Nuclear Procurement Issues Corporation."

RAI 7.2
The staff considers this RAI to be a recommendation. Section 7.2, "NQA-1 Commitment / Exceptions," contains a description of purchasing from a calibration laboratory and in lieu of performing the commercial grade survey, follows the guidance established in the Arizona Public Service (APS) SER and also notes the acceptance of NEI 14-05, "Guidelines for the use of Accreditation in lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1. While the APS SER regulatory position is still currently acceptable, the NRC has provisionally endorsed the current ISO-17025-2017 standard through the NEI 14-05 guideline and plans to formally endorse the current ISO-17025-2017 standard in

the near future. Therefore, the NRC staff highly recommends removing reference to the activities described in the APS SER, as they will be superseded through final endorsement of the NEI 14-05 guidance.

RAI 7.3
Section 7.2, "NQA-1 Commitment / Exceptions," of the Oklo QAPD contains a statement, in part, that "Regulatory Guide 1.28, Rev. 5, also stipulates other exceptions/clarifications with regard to audits which are mentioned in this section. See Section 18.3 for these additional exceptions/clarifications," which refers the reader to QAPD Section 18.3 for additional audit clarifications. Please explain why this was included in this section of the QAPD, and is it the intent of Oklo to implement those exceptions/clarifications as written?

Section 10 Inspection

RAI 10.1
Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part, that "The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Explain why Section 10.1, "Inspection Program," of the Oklo QAPD omitted the statement that, "Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers," as described in Section 10.1, "Inspection Program," of the NEI 11-04A template.

RAI 10.2
Criterion X, "Inspection," of Appendix B to 10 CFR Part 50, states in part, that "A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity."

Explain why Section 10.1, "Inspection Program," of the Oklo QAPD omitted the statement that, "Inspection results are documented by the inspectors, *reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results,* and controlled by instructions, procedures, and drawings," as described in Section 10.1, "Inspection Program," of the NEI 11-04A template.

RAI 10.3
Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part, that "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety."

Section 10.3, "NQA-1 Commitment / Exceptions," of the Oklo QAPD describes an exception to the commitment to IEE 336-1985 and IEEE 498-1995 with regard to the use of the definition of safety system. In lieu of committing to the definition of safety system, what definition is Oklo expecting to use to capture this important principle? What, if any, activities described in these standards is Oklo taking exception to as a result?

Section 11 Test Control

RAI 11.1
Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, states in part, that "Test results shall be documented and evaluated to assure that test requirements have been satisfied."

Explain why Section 11, "Introduction," of the Oklo QAPD omitted the italicized statement that "Test results are documented and evaluated by the organization performing the test, *and reviewed by a responsible authority*, to assure that the test requirements have been satisfied," as described in Section 11, "Test Control," of the NEI 11-04A template.

Section 15 Nonconforming Materials, Parts, or Components

RAI 15.1
Criteria XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, states in part, that "Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

Explain why Section 15 of the Oklo QAPD omitted a significant portion of the Section 15, "Nonconforming Materials, Parts, or Components," NEI 11-04A template, regarding conditional release of nonconforming items, nonconformances to design requirements, and review of nonconformances for adverse trends and for reporting to management.

Section 16 Corrective Action

RAI 16.1
Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50, states in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined, and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Section 16 of the Oklo QAPD omitted a significant portion of Section 16, "Corrective Actions," of the NEI 14-05 Template, regarding corrective action: documenting and classifying conditions adverse to quality, implementation of procedures following determination of conditions adverse to quality, and for the performance of timely evaluations and trending of significant conditions adverse to quality. Please explain why these discussions were omitted?

RAI 16.2
10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses," contains unique regulatory requirements pertaining to the reporting of defects.

Explain why Section 16.1, "Interface with reporting Program," of the Oklo QAPD lists references to 10 CFR 52 and 10 CFR 21, but does not list reference to 10 CFR 50.55.

Section 18 Audits

RAI 18.1

Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part, that "The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing."

Explain why Section 18.1, "Performance and Audits," of the Oklo QAPD omitted the italicized phrase below that, "Additional internal distribution is provided to responsible management levels *and to management of the internal audited organizations or activities in accordance with approved procedures.*"

Part III Non Safety-related SSC Quality Control

RAI Part III.1

Criterion I, "Organization," of Appendix B to 10 CFR Part 50, states in part, that "The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing."

Section 1.18, "Audits," of the Oklo QAPD introduces the term line management not used elsewhere in the document. Please explain why this term was used in this case.

RAI Part III.2

Criterion III "Design Control," of Appendix B to 10 CFR Part 50, states in part, that "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. Additionally, 52.79(a)(28) states in part, that "The final safety analysis report shall include the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license; Plans for preoperational testing and initial operations."

Section 2, "Non Safety-related SSCs Credited for Regulatory Events," of the Oklo QAPD commits Oklo to implement RG 1.189, Section 8.5, regarding application to non-LWRs. It further states, in part, that "testing programs may not be necessary for all non-light-water reactors to confirm safe-shutdown capability." What is the basis for this statement and why is it included since RG 1.189, already states that design reviews and testing programs should confirm safe shutdown capability?

Part IV Regulatory Commitments

RAI Part IV.1
10 CFR Part 52.79(a)(41) states in part, that "For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the SRP revision in effect 6 months before the docket date of the application."[1]

Section 1, "Nuclear Regulatory Commission Regulatory Guides," introduction, of the Oklo QAPD provides a statement that Oklo "complies with these standards to the extent described or referenced." Furthermore, as part of the description of RG 1.28, Revision 5, Oklo states, in part, that "Oklo identifies conformance and exceptions for the applicable regulatory position guidance as indicated in the Oklo regulatory submissions." Given the vagueness of these statements, the staff cannot determine Oklo's specific commitment to and/or exceptions taken to the specific RGs described in Section 1 of the Oklo QAPD. Provide a more definitive discussion regarding specific commitment and exceptions to the RGs identified in the submission.

RAI Part IV.2
10 CFR 52.79(a)(41) states in part, that "For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the SRP revision in effect 6 months before the docket date of the application."

Section 1, "Nuclear Regulatory Commission Regulatory Guides," of the Oklo QAPD provides an evaluation of the regulatory guidance described in NRC SRP Chapter 17, Section V, "Quality Assurance Program Commitments," and includes additional information for RG 1.164, regarding Dedication. However, the description contains significantly vague text regarding commitment to or exceptions taken to the regulatory guide and used terminology such as "plans to use," "as needed," with respect to implementation of the guidance. Describe specific commitments to and any exceptions taken to the regulatory guide.

RAI Part IV.3
10 CFR Part 52.79(a)(41) states in part, that "For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the SRP revision in effect 6 months before the docket date of the application."

Explain why the regulatory guide applicable to a QA program for a COL applicant, RG 1.231, "Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants," Revision 0, dated January 2017, was not evaluated as applicable to the applicant's scope of activities affecting quality.

RAI Part IV.4
10 CFR 52.79(a)(41) states in part, that "For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the SRP revision in effect 6 months before the docket date of the application."

The staff considers this RAI to be an observation that will require review beyond the QAPD.

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[1] NUREG-0800 "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," is specific to LWRs and 10 CFR Part 52.79(a)(41) does not apply to non-LWRs. However, Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit, and New License Applicants," is technology neutral and the QA staff will use this guidance document for the review of all QAPD Topical Reports regardless of the technology.

Section 1, "Nuclear Regulatory Commission Regulatory Guides," of the Oklo QAPD describes regulatory guidance that Oklo is not committing to, based on a general discussion focused on Oklo not being an LWR and therefore has substantive differences that inhibit commitment to the RGs directly. Specifically, RG 1.26, associated with safety classification of SSCs and RG 1.29, associated with seismic design criteria were determined to be not applicable. The review of the Oklo application will seek to affirm the technical basis for this determination, including why the concepts of safety classification of SSCs and seismic design criteria and the associated guidance provided in these RGs do not apply to the Oklo design.