

October 23, 2017

Ms. Caroline Cochran
Co-Founder, COO
Oklo, Inc.
230 E. Caribbean Dr.
Sunnyvale, CA 94089

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE OKLO,
INC. QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL
REPORT FOR DESIGN CERTIFICATION APPLICATION, CAC NO. RA9300

Dear Ms. Cochran:

By letter dated April 21, 2017 (Agencywide Documents Access and Management System) Accession No. ML17114A468, Oklo, Inc. submitted a Quality Assurance Program Description Topical Report to the U.S. Nuclear Regulatory Commission (NRC) for review and approval to be used in its design certification application. The NRC staff is performing a detailed review of this topical report to enable the staff to reach a conclusion on the safety of the proposed application. The NRC staff has identified that additional information is needed to continue portions of the review. On October 10, 2017, NRC staff held a conference call with Oklo to discuss, "Draft Request for Additional Information Regarding Review of the Quality Assurance Program Description Topical Report, Oklo-2017-01-NP," (ML17290A020). The staff modified some of the draft request for additional information (RAI) questions as a result of the conference call. The staffs final version of the RAI is contained in the enclosure to this letter.

Consistent with the NRC letter dated, May 24, 2017 (ML17143A321), to support the review schedule, you are requested to respond by November 24, 2017. If changes are needed to the topical report, the staff requests that a revision to, "Quality Assurance Program Description Topical Report," be submitted with the RAI responses.

If you have any questions regarding this matter, please contact me at (301) 415-0498 or via email at jan.mazza@nrc.gov.

Sincerely,

/RA/

Jan M. Mazza, Project Manager
Advanced Reactor and Policy Branch
Division of Safety Systems, Risk Assessment and
Advanced Reactors
Office of New Reactors

REQUEST FOR ADDITIONAL INFORMATION REGARDING THE OKLO, INC. QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT FOR DESIGN CERTIFICATION APPLICATION, CAC NO. RA9300 October 23, 2017

DISTRIBUTION:

Public
RidAcrsAcnw_MailCTRResource
RidsNroDsraArpb Resource
RidsOgcMailCenter Resource
RidsOpaMailResource
JMonninger, NRO
TMcGinty, NRO
MFranovich, NRO
KKavanaugh, NRO
JSegala, NRO

ENCLOSURE:

Request for Additional Information Regarding Review of the Quality Assurance Program Description Topical Report, OKLO-2017-01-NP

ADAMS Accession No.: ML17276B791

***via email**

NRO-002

OFFICE	NRO/DCIP/QVIB3	NRO/DSRA/ARPB	NRO/DSRA/ARPB*	NRO/DCIP/QVIB3
NAME	TLamb	JMazza	JSegala	KKavanagh
DATE	10/23/2017	10 /19/ 2017	10 /23/ 2017	10/23/2017

OFFICIAL RECORD COPY

REQUEST FOR ADDITIONAL INFORMATION
REGARDING REVIEW OF THE QUALITY ASSURANCE
PROGRAM DESCRIPTION TOPICAL REPORT, OKLO-2017-01-NP

OKLO, INC.
DOCKET NO. PROJ0823

By letter dated April 21, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17114A468), Oklo, Inc. (Oklo) submitted a Quality Assurance Program Description (QAPD) Topical Report to the U.S. Nuclear Regulatory Commission (NRC) for review and approval to be used in its design certification (DC) application. To complete its review, the NRC staff requests a response to the Request for Additional Information (RAI) below.

RAI 1

Each regulation related to licensing has an individual requirement regarding quality assurance programs (QAPs). For example, 10 CFR 52.17(a)(1)(xi) discusses the QAP requirements for early site permit applications, 10 CFR 52.47(a)(19) discusses the QAP requirements for design certification applications, and 10 CFR 52.79(a)(25) discusses the QAP requirements for combined licenses.

RAI 1.1

The "Executive Summary" (page 4 of 42) of the Oklo QAPD states (emphasis added), "The report scope is limited to the program activities associated with work in support of licensing activities (e.g., design certification, standard design approval, **combined license**, etc.)." However, in the cover letter of the QAPD, the following is stated, in part:

Oklo is currently completing the conceptual design of the facility and anticipates entering into the preliminary design phase of the process soon. The application of the Quality Assurance Program Description (QAPD) to the preliminary design is important to providing appropriate quality to the safety-related aspects of the design.

As written, the current scope of the Oklo QAPD only addresses design certification activities. As such, clarify the licensing scope of the application of the QAPD, and revise as necessary.

RAI 1.2

Section 1.1 (page 6 of 42), "Scope/Applicability," of Part I, "Introduction," to the Oklo QAPD discusses the specific activities to which the QAPD applies, to include fabricating, cleaning, receiving, handling, and shipping.

As written, the current scope of the Oklo QAPD only addresses design certification activities. Therefore, clarify and justify the scope of the activities related to the Oklo Power Reactor design certification.

RAI 2

Appendix B to 10 CFR Part 50 requires, in part, that the applicant establishes a quality assurance program which complies with the requirements of the appendix. Furthermore, as stated in Criterion II, "Quality Assurance Program," of Appendix B, the applicant shall regularly review the status and adequacy of the quality assurance program.

Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)" Revision 4, dated June 2010 (ADAMS Accession No. ML100160003), Paragraph C.2.b.2 states, "The applicant or licensee should either audit its supplier's QA [quality assurance] program on a triennial basis or arrange for such an audit. The triennial period begins when an audit is performed."

Section 2 (page 12 of 42), "Quality Assurance Program," of the Oklo QAPD states "Audit schedules are based on the month in which the audit starts." In Part IV, "Regulatory Commitments," of the Oklo QAPD, it also states that Oklo commits to using RG 1.28.

During the clarification call held with Oklo on October 10, 2017, Oklo stated that they utilized the template Nuclear Energy Institute (NEI) 11-04A, "Nuclear Generation Quality Assurance Program Description," dated May 2011 (ADAMS Accession No. ML13164A017). However, NEI 11-04A is strictly a guidance document. Oklo is committed to RG 1.28, which provides the NRC staff's formal position for the review of the Oklo QAPD.

As such, update the Oklo QAPD to remain consistent with RG 1.28.

RAI 3

The Oklo QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 2, Sections 100 through 500 (page 13 of 42), with the following clarification:

The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following, "The prospective lead auditor shall demonstrate his or her ability to properly implement the audit process, as implemented by Oklo, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of the qualification."

However, NQA-1-2008, Requirement 2, Section 303.3 provides for participation in independent assessments as another means to satisfy the requisite number of quality assurance audits, and supplies the acceptance criteria for use of these activities toward lead auditor qualification.

As such, the NRC staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for Oklo given that NQA-1-2008, Requirement 2, Section 303.3, already contains an alternative means for qualifying prospective lead auditors beyond participation in a minimum of five audits in the previous three years. Provide a justification for this clarification.

RAI 4

The regulations in Section 21.3, “Definitions,” of 10 CFR states, in part, the following regarding the definition of “basic component”:

In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

Additionally, the definition of “commercial grade item” states, in part:

When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed, and manufactured as a basic component.

The definition of “dedication” states, in part:

...dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function, and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program.

Section 3.3, “Commercial Grade Items,” of the Oklo QAPD states:

The use of commercial-grade equipment in safety-related applications shall be reviewed to ensure that it can adequately perform its intended function. Procedures shall be implemented to provide guidance on how to review and evaluate commercial grade items for suitability in applications covered by the QAPD. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier’s published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

The regulations in 10 CFR 52.47(a) discuss the contents of applications as they pertain to design certification applications. Specifically, the regulations in 10 CFR 52.47(a)(19) outline the contents to design certification applications specific to the quality assurance program, and state, in part, that a description of the quality assurance program applied to the design of the structures, systems, and components of the facility shall be included.

RAI 4.1

Based on Revision 0 of the Oklo QAPD, clarify if other basic components are expected to be commercially dedicated (e.g., computer software, digital equipment, consulting services related to design and analysis, etc.).

RAI 5

The Oklo QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 4, Sections 100 through 400 (page 17 of 42), as endorsed by RG 1.28, with the following clarifications and exceptions:

Section 203 requires the purchaser to specify the quality assurance requirements in the procurement documents. To meet this requirement, Oklo may require suppliers to have a documented QAP that meets the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of the procurement. Procurement documents for Commercial Grade Items that will be procured by Oklo for use as safety-related items shall contain technical and quality requirements such that the procured items can be appropriately dedicated.

With regard to services performed by a supplier, Oklo procurement documents may allow the supplier to work under the Oklo QAP, including implementing procedures, in lieu of the supplier having its own QAP.

It is unclear to the NRC staff as to whether the above statements are clarifications or exceptions to NQA-1-2008, Requirement 4, Section 203. Technical and quality requirements are provided in Sections 202 and 203, respectively, and would be applicable to the dedication of commercial grade items for use as safety-related equipment. In addition, commercial grade items and services are addressed by NQA-1a-2009, Requirement 7, Section 700, and Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services."

As such, it is not clear to the staff why an exception or clarification to NQA-1-2008, Requirement 4, Section 203, is necessary given that provisions regarding the information contained in the clarifications/exceptions are contained elsewhere in NQA-1-2008 and its addenda. Provide a justification for this clarification.

RAI 6

The regulations in 10 CFR 52.47(a) discuss the contents of applications as they pertain to design certification applications. Specifically, Section 52.47(a)(19) of 10 CFR states, in part, that a description of the quality assurance program applied to the design of the structures, systems, and components of the facility shall be included. Additionally, a description of the quality assurance program shall include a discussion of how applicable requirements of Appendix B to 10 CFR Part 50 were satisfied shall also be included.

RAI 6.1

Section 5.2 (page 18 of 42), "Procedure Content," of the Oklo QAPD states (emphasis added):

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2008. In addition, procedures governing tests, inspections, **operational activities** and **maintenance** will include as applicable, initial conditions and prerequisites for the performance of the activity.

Operational activities and maintenance fall under the scope of operations. Under the basis that the Oklo QAPD is only applicable to activities associated with the design certification of an Oklo Power Reactor, provide justification for requiring procedures for operational activities and maintenance during design certification, and update the QAPD as necessary.

RAI 6.2

The third bullet of Section 7.1 (page 21 of 42), "Acceptance of Item or Service," states:

Industry programs, such as those applied by ASME [American Society of Mechanical Engineers], Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate.

Under the basis that the Oklo QAPD is only applicable to activities associated with the design certification of an Oklo Power Reactor, and that Oklo is not currently and will not be an NRC licensed entity, provide justification for the above statement as it relates to ASME and NUPIC, and update the QAPD as necessary.

RAI 6.3

Section 7.1 (page 21 of 42), "Acceptance of Item or Service," of the Oklo QAPD states that for the design certification project, verification actions include testing, as appropriate. However, Section 11, "Test Control," of the QAPD notes that Oklo does not perform test activities in the design certification phase, except for computer software testing. Instead, testing services will be performed by suppliers and contractors as necessary.

As such, clarify if the intent is that suppliers and contractors work under the Oklo QAPD. Additionally, clarify the scope of testing services envisioned for procurement during the Oklo Power Reactor Design certification project, as well as the role Oklo will play in testing associated with design verification, including the control of measuring and test equipment (M&TE), and update the QAPD as necessary.

RAI 6.4

In multiple locations within the Oklo QAPD, testing is discussed. However, two sections of the Oklo QAPD have not been addressed that may be required for testing: Section 8 (page 24 of 42), "Identification and Control of Materials, Parts, and Components" and Section 9 (page 25 of 42), "Control of Special Processes."

Under the basis that the Oklo QAPD is only applicable to activities associated with the design certification of an Oklo Power Reactor, clarify the activities that will be performed within the intended scope of the design certification application, and update the QAPD as necessary.

RAI 6.5

Section 11 (page 28 of 42), "Test Control," of the Oklo QAPD addresses, in part:

...the necessary measures and governing procedures to demonstrate that design concepts will perform satisfactorily in service. These measures and governing procedures include criteria for determining when testing is required to demonstrate that performance of plant systems is in accordance with design.

Under the basis that the Oklo QAPD is only applicable to activities associated with the design certification of an Oklo Power Reactor and that testing services will be performed by suppliers and contractors, clarify the intended scope of the Oklo design certification project and how the activities described in Section 11 apply. Update the Oklo QAPD as necessary.

RAI 7

As an alternative to NQA-1-2008, Requirement 7, Section 501 (page 22 of 42), in terms of the requirement that documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use, the Oklo QAPD proposes that documents may be stored in approved electronic media under the applicant's or supplier's control and not physically located at the plant site, as long as they are accessible from the respective facility.

However, the NRC staff notes that Oklo did not include the latter part of the previously NRC approved alternative in NEI 11-04A, "Nuclear Generation Quality Assurance Program Description," Revision 0, dated May 2011 (ADAMS Accession No. ML13164A017), as approved by NRC safety evaluation dated May 9, 2013 (ADAMS Accession No. ML13023A051). The latter portion states that "following completion of the construction period, sufficient as-built documentation will be turned over to [Oklo] to support operations. The [Oklo] records management system will provide for timely retrieval of necessary records." Under the basis that the Oklo QAPD is only applicable to activities associated with the design certification of an Oklo Power Reactor, further clarification is necessary regarding the applicability of the latter part of the alternative.

As such, provide verification and/or clarification of whether the latter clarification stated above is applicable to the Oklo design certification project.

RAI 8

As an exception to the NQA-1-2008 (page 29 of 42), Requirement 12, Section 303.6 calibration labeling requirements, the Oklo QAPD proposes that M&TE are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as when the label will interfere with operation of the device), provided that the required information is maintained in suitable documentation traceable to the device.

However, the NRC staff notes that NQA-1-2008, Requirement 12, Section 303.6, as written, already provides for M&TE to be "otherwise identified" to indicate calibration status and establish traceability to calibration records.

As such, it is not clear to the staff why an exception to NQA-1-2008, Requirement 12, Section 303.6 is necessary. Clarify the use of this exception.

RAI 9

The regulations in 10 CFR Section 52.47, “Contents of applications; technical information,” outline the types of information that must be included in applications for design certification. Specifically, the regulations in 10 CFR 52.47(a)(15) state:

Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram events in § 50.62;

The regulations in 10 CFR 52.47(a)(16) state:

A coping analysis, and any design features necessary to address station blackout, as required by 10 CFR 50.63;

The regulations in 10 CFR 52.47(a)(18) state:

A description and analysis of the fire protection design features for the standard plant necessary to comply with 10 CFR part 50, appendix A, GDC 3, and § 50.48 of this chapter;

The NRC staff notes that specific quality controls for nonsafety-related structures, systems, and components (SSCs) that are credited for regulatory events as related to the above regulations are not addressed in the Oklo QAPD. However, the NRC staff notes that Part III, “Nonsafety-Related SSC Quality Control,” of the Oklo QAPD addresses nonsafety-related SSCs that are significant contributors to safety. Clarify not addressing nonsafety-related SSCs credited for regulated events.

RAI 10

The regulations in 10 CFR Section 52.47(a)(9) state, in part, that an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application must be included.

Standard Review Plan Chapter 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applications” (ADAMS Accession No. ML15037A441) in NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” outlines the specific review criteria for the NRC staff regarding QAPDs submitted in support of design certification applications. Section II.V.1 discusses the applicable regulatory guides and generic letters (GLs) specifically stating that the reviewer shall verify that the applicant or holder commits to the most recent revision of the RGs and GLs listed, to include RG 1.29, “Seismic Design Classification.”

The Oklo QAPD specifically identifies RG 1.29. However, the Oklo QAPD specifically commits to use of RG 1.29, Revision 4, dated March 2007 (ADAMS Accession No. ML070310052). The most recent revision of RG 1.29 is Revision 5, dated July 2016 (ADAMS Accession No. ML16118A148).

Under the basis that the Oklo QAPD is applicable to design certification activities and an application will be submitted under 10 CFR Part 52, update the Oklo QAPD to reflect the most recent revision of RG 1.29.