



Oklo Responses to NRC Requests for Additional Information for the Oklo Quality Assurance Program Description, Rev. 0

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Oklo Inc, Non-Proprietary



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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 46) 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.

Response to RAI 1.1

It is acknowledged that there are more requirements for a combined license as described in 10 CFR 52.79(a)(25) and elsewhere, than there are for a design certification exclusively as described in 10 CFR 52.47(a)(19) and elsewhere. The requirements for a combined license include all of those for a design certification as well as other requirements in addition to those for a design certification.

Oklo agrees that it is beneficial to clarify the scope of the Oklo QAPD. The scope of the QAPD is further clarified to be comprehensive for activities for a design certification application as well as consistent with the NEI 11-04A template for a non-operations phase, non-ESP only, COL for design and construction.

Oklo is in the design phase, however, it is anticipated that it is more efficient for both NRC and Oklo to be comprehensive for design related activities but to also include elements beyond just design related elements, such as fabrication, and other construction-related elements into this QAPD rather than submit an update in the relative near term (within approximately a year of the submission of the original Rev. 0 QAPD).

Wording is being revised in all locations mentioning an application type to ensure that the scope is clarified. There are 6 locations in the Oklo QAPD where an application type is mentioned and each is revised in the Revision 1 being submitted along with this response.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 1.1

Changes to clarify scope are shown in the attached markup version. Changes included striking specific mention to “DC Project” or “DC phase,” as well as adding sections to make the QAPD comprehensive to all sections needed for a pre-operational phase COL to better follow the NEI template and for efficiency for the NRC and Oklo staff. Relevant changes are listed below by section:

- Addition of terms “fabrication, construction, and testing” in Section 2 (as given in NEI 11-04A),
- Addition of Section 2.3, Site-Specific Safety-Related Design Basis Activities (as given in NEI 11-04A),
- Addition of terms “manufacture, construction” in Section 3.1 (as given in NEI 11-04A)
- Addition of Section 3.4, Setpoint Control (as given in NEI 11-04A),
- Modification of Section 4.1 to align with NEI 11-04A,
- Addition of terms “design, fabrication, and construction” in Section 7.1 (as given in NEI 11-04A),
- Removal of terms “during the DC phase” in Section 7.2 (to align with NEI 11-04A),
- Removal of terms “the DC phase” and addition of “COL design and construction” in Section 15.1 (to align with NEI 11-04A),
- Removal of terms “the DC phase” and addition of “COL design and construction” in Section 16.1 (to align with NEI 11-04A),
- Removal of terms “the DC Project” and addition of “manufacturing, construction” and “design and construction” in Section 17.1 (to align with NEI 11-04A), and
- Addition of terms “construction and fabrication” in Section 18.2 (as given in NEI 11-04A).

RAI 1.2

Section 1.1 (page 6 of 46), “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.

Response to RAI 1.2

As described in the Response to RAI 1.1, Oklo agrees that the scope needed to be better defined and implemented the changes outlined above, and can be seen in their entirety in the attached Rev. 1. Specific to this RAI 1.2, Oklo is including sections regarding fabricating, cleaning, receiving, handling and shipping, in case these are items needed for quality assured testing. Revisions to ensure that these items are adequately addressed as initially indicated are included in Rev. 1 attached to this response.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 1.2

Changes for these sections are shown in the attached markup version, and the summary of changes are listed by section below:



- Additions related to fabrication: Sections 2, 7.1, 8, 14, and 18.2;
- Additions related to cleaning: Sections 13, 13.1, and 1.13; and
- Added sections for handling, storage and shipping: Section 13 and Section 1.13.

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 46), "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.

Response to RAI 2

Oklo reiterates that this language is consistent with NEI 11-04A, "Nuclear Generation Quality Assurance Program Description," dated May 2011 (ADAMS Accession No. ML13164A017), as well as NEI 11-04A, "Nuclear Generation Quality Assurance Program Description," dated August 2013 (ADAMS Accession No. ML13235A267).¹ While it is true that NEI 11-04A is guidance, it is also true that the NRC staff issued a safety evaluation report (SER) on the NEI documents, concluding, in part, "that the QAPD template can be used by applicants of 10 CFR Part 52 permits or licenses, as applicable, for establishing a quality assurance program that complies with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Parts 50 and 52." (Final Safety Evaluation for Technical Report NEI 11-04, "Quality Assurance Program Description," Revision 0, ADAMS Accession Number ML13023A051). The SER did not take any

¹ NEI 11-04A was originally transmitted in June 2013 as shown in ML13164A017 (NEI 11-04A) and ML13164A016 (NEI cover letter). Subsequently, a corrected NEI 11-04A was transmitted in August 2013 to provide a corrected version (ML13235A267 and ML13235A266). Oklo notes that the superseded version still appears on the NRC website at <https://www.nrc.gov/docs/ML1316/ML131640033.html> and displays as the first option in an NRC website search for the term "NEI 11-04A," and both are labeled as Rev. 0. A clarification on the website would be useful, i.e., that this version is incorrect and has been superseded.



exception to the NEI language. Oklo requests clarification of why NRC-approved language is no longer considered acceptable.

The latest revision of Regulatory Guide 1.28, Rev. 5, (issued since the submission of the Oklo QAPD) similarly states: "The triennial period begins when an audit is performed."

Oklo does not see a conflict between initiating timing for a triennial schedule between stating when performed versus defining a month of the performance of an audit, given that audits are not performed instantaneously but over a period of time.

However, with respect to this response to the RAI 2, "when an audit is performed" could be considered the date of the conclusion of the audit. Oklo is not opposed to establishing the "performance" of the audit as the completion day of an audit and specifies this clarification to the commitment to the RG 1.28. Oklo also agrees to any other date preferred by NRC, such as initiation date.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 2

Regulatory Guide 1.28: U.S. Nuclear Regulatory Commission, "Quality Assurance Program Requirements (Design and Construction)," Regulatory Guide 1.28, Revision 4⁵, ADAMS Accession No. ML100160003ML17207A293

Oklo identifies conformance and exceptions for the applicable regulatory position guidance as indicated in the Oklo regulatory submissions. Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of 10 CFR Part 50 Appendix B with regard to establishing and implementing the requisite quality assurance program for the design of nuclear power plants. Oklo commits to the applicable regulatory position guidance as indicated in Oklo regulatory submissions.

Clarification: For the purposes of this QAPD, "performance" of an audit as described in RG 1.28 is defined as the date of conclusion of an audit, provided that the conclusion of an audit is not more than a month after the date of commencement of an audit, in which case the date of thirty (30) days after the beginning of the audit shall be the beginning of the triennial period.

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 46), 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.

Response to RAI 3

Oklo will update the QAPD reflecting the most recent RG 1.28, Rev. 5 exceptions/clarifications on this topic and throughout. Please see below for the relevant changes.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 3

Section 2.7 will be revised as follows, to incorporate RG 1.28, Rev. 5 language:

2.7 NQA-1 Commitment / Exceptions

In establishing qualification and training programs, Oklo commits to compliance with NQA-1-2008, Requirement 2, Sections 100 through 500 with the following clarification:

- ~~NQA-1-2008, Requirement 2, Section 303.3~~

~~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 qualification."~~

1. QA Program (NQA-1 Requirement 2)

a. Audit Participation

(1) Prospective lead auditors, with comparable industry experience, may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization.

Other sections affected by the release of RG 1.28, Rev. 5 include the below:

- References to RG 1.28, Rev. 4 have been updated to RG 1.28, Rev. 5,
- Because RG 1.28, Rev. 5 endorsed NQA-1b-2011 as the most recent addenda to NQA-1-2008, this terminology was added where relevant,
- The following addition to Section 7.2:
 - It is also noted that according to the RG 1.28, Rev. 5, the NRC finds that Nuclear Energy Institute (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 (Ref. 13), provides an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 for using laboratory accreditation by Accreditation Bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing commercial-grade surveys as part of

the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

- And the addition of the following addition to Section 17.2:

For guidance to establish the appropriate quality controls that incorporates the implementation of enterprise content management systems, web-based technologies, and higher capacity LAN/WAN networks, Oklo will utilize The Nuclear Information and Records Management Association (NIRMA) technical guides (TGs), as listed below:

- NIRMA TG 11, “Authentication of Records and Media”;
- NIRMA TG 15, “Management of Electronic Records”;
- NIRMA TG 16, “Software Configuration Management and Quality Assurance”; and
- NIRMA TG 21, “Electronic Records Protection and Restoration”.

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 expecting to be commercially dedicated (e.g., computer software, digital equipment, consulting services related to design and analysis, etc.).

Response to RAI 4.1

As described in the RAI, commercial-grade dedication is used for structures, systems, or components not designed and manufactured specifically as a basic component, and “basic component” includes safety-related design, analysis, and consulting services associated with design development. Accordingly, during design development, Oklo anticipates the possibility of using commercial-grade dedication for computer software, information, and other possible items/services. The full scope of what items or services will require dedication cannot be specified at this time, but Oklo also anticipates possible need to dedicate certain procurements from national labs.

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 46), 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.

Response to RAI 5

Oklo agrees that the clarification is unnecessary. This clarification has been removed in the attached Rev. 1, and shown below.

Additional changes to bring the Oklo QAPD in line with the revised NEI 11-04A, Rev. 0 are shown in the attached Rev. 1 and include the following:

- Added text in Section 3.6, NQA-1 Commitment,
- Added text regarding procedure adherence in cases of emergency, Section 5.1,
- Revised portion of Section 7.2 regarding NRC approved supplier accreditation,
- Revised Section 10.3, NQA-1 Commitment/Exceptions, and
- Added text in Section 12.2 NQA-1 Commitment/Exceptions.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 5

Section 4.1 will be amended as follows to bring it in line with the revised NEI 11-04A, Rev. 0:

4.1 NQA-1 Commitment/ Exceptions

In establishing controls for procurement, Oklo commits to compliance with NQA-1-2008, Requirement 4, Sections 100 through 400, with the following clarifications and exceptions:

- NQA-1-2008, Requirement 4

~~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 item 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.

Section 300 and 400 of Requirement 4 require the review of technical and Quality Assurance Program requirements of procurement documents prior to award of a contract and for procurement document changes. Oklo may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and quality assurance requirements 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 item can be appropriately dedicated in accordance with the Oklo QAPD, Section 7, "Control of Purchased Material, Equipment and Services."

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 46), "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.

Response to RAI 6.1

Oklo agrees that operations and maintenance do not fit in the current scope of the Oklo QAPD. Operations and maintenance has been removed in the referenced sentence in Section 5.2 as shown in the attached Rev. 1.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 6.1

Section 5.2 will be amended as follows:

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, and inspections, ~~operational activities and maintenance~~ will include as applicable, initial conditions and prerequisites for the performance of the activity.

RAI 6.2

The third bullet of Section 7.1 (page 21 of 46), "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.

Response to RAI 6.2

The scope of the QAPD has been revised to align with the NEI 11-04A template as pre-operations, non-ESP, COL applicant. The term "such as" was meant to indicate examples as opposed to definitive use. Oklo intends to be an NRC licensed entity, and as such may utilize industry programs as input or basis as described. However, such programs will not likely be used in the near term for acceptance of an item or service.

RAI 6.3

Section 7.1 (page 21 of 46), "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.

Response to RAI 6.3

The intent of the QAPD was to state that the majority of testing would be performed by suppliers or contractors as necessary as stated in Section 11, not that Oklo would not perform any testing as stated in Section 1.11 of Part III (Nonsafety-Related), which was in error. This language will be corrected and made consistent in the applicable sections. Suppliers and contractors will work under the Oklo QA program, or under their own programs, as indicated in Section 11.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 6.3

Part III, Section 1.11 is amended as follows:

1.11 Test Control

~~Oklo does not perform test activities in the early licensing phase, except for Computer Software testing described in Part II, Section 11.2 of this document. Suppliers may perform testing services in support of early licensing phase activities and where required~~



~~in contracts. Suppliers will be required to either have a test control program meeting the following requirements or conduct testing under the Oklo Quality Program.~~

Oklo employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

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 46), "Identification and Control of Materials, Parts, and Components" and Section 9 (page 25 of 46), "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.

Response to RAI 6.4

Oklo agrees that these sections should be addressed. Section 8 and Section 9 have been updated to address testing in the attached Rev. 1. As discussed in the Response to RAI 1.1, the Oklo QAPD is intended to be comprehensive for activities for a design certification application as well as consistent with the NEI 11-04A template for a non-operations phase, non-ESP only, COL for design and construction.

In addition to Section 8 and Section 9, it was determined that revisions to Section 10 ("Inspection") and other sections needed to be performed, as described in the Response to RAI 6.5.

RAI 6.5

Section 11 (page 28 of 46), "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.

Response to RAI 6.5

The response to RAI 6.3 clarified that section 11 states that the majority of testing may be performed by suppliers or contractors, and it was not intended that Oklo would not do any testing. As discussed in the response to RAI 1.1, 6.3, and 6.4, the scope of the QAPD is further



clarified to be comprehensive for activities for a design certification application as well as consistent with the NEI 11-04A template for a non-operations phase, non-ESP only, COL for design and construction.

Section 11, "Test Control," as well as Section 12, "Control of Measuring and Test Equipment," Section 13, "Handling, Storage, and Shipping," Section 14, "Inspection, Test, and Operating Status," were revised as shown in the attached Rev. 1. In addition, the corollary sections 1.11, 1.12, 1.13, and 1.14 were revised. Revisions used NEI 11-04A template language directly.

RAI 7

As an alternative to NQA-1-2008, Requirement 7, Section 501 (page 22 of 46), 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

Response to RAI 7

Oklo agrees with the inclusion of the cited portion of NEI 11-04A, Rev. 0. This portion is now incorporated into the Rev. 1 attached to this response. Because the scope of the Oklo QAPD is being further clarified to be comprehensive for activities for a design certification application as well as consistent with the NEI 11-04A template for a non-operations phase, non-ESP only, COL for design and construction, this latter clarification is applicable.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 7

Section 7.2 will be revised as follows:

- NQA-1-2008, NQA-1a, 2009, Requirement 7, Section 501
For Section 501, Oklo considers documents that may be stored in approved electronic media under Oklo or vendor control, not physically located on the plant site, but accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. 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.

RAI 8

As an exception to the NQA-1-2008 (page 29 of 46), 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.

Response to RAI 8

Similar to the NEI 11-04A template update, Section 12.2 will be revised to identify the following exception:

- NQA-1-2008, Subpart 2.4 refers to ANSI/IEEE Std. 336-1985 for the installation, inspection, and testing requirements for power, instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std. 336-1985 makes reference to the use of IEEE Std. 498-1985 for measuring and test equipment control, Oklo will implement the QA requirements of NQA-1-2008, Requirement 12.

Please see the attached Rev. 1 or the markup of changes below.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 8

Section 12.1 is amended as follows:

In establishing provisions for control of measuring and test equipment, Oklo commits to compliance with NQA-1-2008, Requirement 12, Sections 100 through 400, with the following clarification and exception:

- ~~The out of calibration conditions described in Section 303.2 refers to when the M&TE is found out of the required accuracy limits (i.e., out of tolerance) during calibration and not overdue for calibration.~~
- ~~Measuring and test equipment are not required to be marked with the calibration status, as described in section 303.6, where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the~~

device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-2008, Subpart 2.4 (See Section 7.2.1 of ANSI/IEEE Std. 336-1985).

- NQA-1-2008, Subpart 2.4 refers to ANSI/IEEE Std. 336-1985 for the installation, inspection, and testing requirements for power, instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std. 336-1985 makes reference to the use of IEEE Std. 498-1985 for measuring and test equipment control, Oklo will implement the QA requirements of NQA-1-2008, Requirement 12.

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.

Response to RAI 9

The Oklo QAPD has been revised to include this new Section 2 of Part III. Please see the attached Rev. 1 or the markup of changes below.

Associated Changes to Oklo QAPD as a Result of the Response to RAI 9

The following section has been added using language from the NEI template 11-04:

Section 2 – Non-Safety-Related SSCs Credited for Regulatory Events



The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related:

- Oklo implements quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Nuclear Power Plants". While the majority of RG 1.189 assumes LWR design, Section 8.5 provides guidance for non-LWRs, specifically:

"FPPs for proposed new non-light-water reactor designs should meet the overall fire protection objectives and guidance in the applicable regulations and this regulatory guide as they relate to safe shutdown and radiological release, as well as the specific fire protection requirements that apply. Fire hazards should be identified and evaluated, and an appropriate level of protection provided to meet these objectives. Design reviews and testing programs should confirm the safe-shutdown capability. SSCs important to safe shutdown should be protected in accordance with the enhanced criteria described above for light-water reactors."

- Oklo implements the quality requirements for ATWS equipment in accordance with Part III, Section 1.
- Oklo implements quality requirements for SBO equipment in accordance with Part III, Section 1.

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.

Response to RAI 10

The Oklo QAPD has been updated to remove this Regulatory Guide 1.29 as far as a holistic committal, as well as Regulatory Guide 1.26 and 1.8. The reason is that all three are LWR-specific and that guidance for the Oklo reactor will have to differ substantively. Please see Rev. 1 for these changes to Part IV.