UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 6, 2022

Mr. Ross Moore
Director of Regulatory Affairs
Oklo Inc.
230 East Caribbean Drive
Sunnyvale, CA 94089

SUBJECT: COMPLETENESS DETERMINATION OF OKLO-2021-R19-NP, REVISION 3, "MAXIMUM CREDIBLE ACCIDENT METHODOLOGY," AND OKLO-2021-R20-NP, REVISION 1, "PERFORMANCE-BASED LICENSING METHODOLOGY" (EPIDS L-2021-TOP-0016 AND L-2021-TOP-0017)

Dear Mr. Moore:

The purpose of this letter is to inform you of the results of the completeness review of the subject topical reports. The U.S. Nuclear Regulatory Commission (NRC) staff have determined that the subject topical reports do not contain sufficiently complete information for the NRC to initiate detailed technical reviews.

By letter dated July 2, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21184A001), Oklo Inc. (Oklo) submitted topical reports, "Maximum Credible Accident Methodology," Revision 2 (ADAMS Accession No. ML21184A002), and "Performance Based Licensing Methodology," Revision 0 (ADAMS Accession No. ML21187A001), to support the NRC's review of the Oklo Aurora custom combined license application.[1] The NRC staff performed completeness reviews of the topical reports using the Office of Nuclear Reactor Regulation Office Instruction LIC-500, "Topical Report Process," Revision 8 (ADAMS Accession No. ML19123A252), and determined that the topical reports were not sufficiently complete for the NRC staff to initiate detailed technical reviews. The NRC staff informed Oklo of the decision by two emails dated August 5, 2021 (ADAMS Accession Nos. ML21201A079 and ML21201A111), that included attachments describing the

[1] As the NRC staff noted in its letter dated June 5, 2020, additional information on Oklo's maximum credible accident (MCA) was needed before the NRC staff could develop a schedule for reviewing the application (ADAMS Accession No. ML20149K616). On September 18, and 23, 2020, the NRC staff issued requests for additional information (RAIs) related to the MCA, structures, systems, and components (SSCs) classification, and quality assurance program for the Oklo Aurora custom combined license application (ADAMS Accession Nos. ML20265A123, ML20265A121, and ML20267A529). Oklo submitted responses to the RAIs on October 30, 2020. On November 17, 2020, the NRC staff informed Oklo that although its RAI responses and the associated NRC staff audits enhanced the NRC staff's understanding of Oklo's novel approach to the Aurora MCA, Oklo did not provide sufficient information to define the scope of the full technical review (ADAMS Accession No. ML20308A677). In response, Oklo requested that the NRC staff pause its review of the Aurora combined license application while Oklo refined its approach to addressing the MCA and other key areas in the step 1 review. Subsequently, Oklo informed NRC staff that it would submit two generic topical reports to address the MCA and SSC classification.

supplemental information needed for the NRC staff to begin the detailed review of each topical report (NRC Forms 898 – ADAMS Accession Nos. ML21201A094 and ML21201A113). The NRC staff held public meetings with Oklo on September 1, 16, and 28, 2021 (meeting summaries available at ADAMS Accession Nos. ML21259A260, ML21266A428, and ML21293A329, respectively), at Oklo's request to clarify the supplemental information needs. In response, Oklo submitted "Maximum Credible Accident Methodology," Revision 3 on October 5, 2021 (ADAMS Accession Nos. ML21278B097 and ML21278B098), and "Performance-Based Licensing Methodology," Revision 1 on October 19, 2021 (ADAMS Accession Nos. ML21292A326 and ML21292A327).

Using Office Instruction LIC-500, the NRC staff performed subsequent completeness reviews of the revised topical reports and supplemental information and finds that Oklo has not provided sufficient technical information to resolve the previously identified deficiencies in the topical reports. The primary purpose of the completeness review is to determine whether the applicant has submitted a sufficiently complete set of information for the NRC staff to initiate its detailed technical review of a topical report. The relevant criterion for completeness in Office Instruction LIC-500 states, in part, that, "the report should not exclude obvious necessary technical information such that the [NRC] technical staff could not be reasonably expected to complete the detailed technical review in an appropriate time frame." As noted above, the NRC staff described specific information gaps in the completeness determination forms sent to Oklo on August 5, 2021 and provided further clarification in the three related public meetings held in September 2021. Based on its completeness reviews of Oklo's October 2021 revised topical reports, the NRC staff finds that Oklo did not include adequate supplemental information to address the gaps identified in the NRC staff's August 2021 communications. The information gaps in the revised topical reports that were previously identified in August 2021 and discussed during the public meetings in September 2021 have been summarized in the enclosed NRC Forms 898.

The objective of the topical report process is to add value by improving the efficiency of other licensing processes. As stated, in part, in Office Instruction LIC-500, topical reports "improve the efficiency of the licensing process by allowing the staff to review proposed methodologies, designs, operational requirements, or other safety-related subjects on a generic basis so that they may be implemented by reference by multiple U.S. licensees, once acceptable for use and verified by the NRC staff." The methodologies proposed in Oklo's topical reports seem intended to fit within this description in that they represent generic analysis methods not previously used by applicants for nuclear power reactor licenses. However, the revised topical reports do not include sufficient information for the NRC staff to determine if the methodologies will improve the efficiency of the licensing process or whether the topical reports may be reliably implemented by multiple applicants for technologies that involve new and novel safety features. For example, the topical reports would leave the resolution of several important safety issues associated with a design's MCA to the discretion of an applicant that references the topical reports in a licensing action. Moreover, the topical reports include generalized concepts rather than rigorous, repeatable methodologies and lack specific guidelines and sufficient technical information. As a result, the NRC staff is unable to determine whether and how the topical reports or applicants that reference them would meet applicable safety requirements.

In addition, the topical reports continue to lack sufficient information in key areas necessary for the NRC staff to determine whether the methodologies will support regulatory findings of reasonable assurance of adequate protection of public health and safety when used by Oklo or other advanced reactor applicants. For example, the topical reports are vague about how to

determine and implement proper treatment of uncertainties, appropriate design margins, and adequate defense-in-depth. The topical reports do not commit to consensus codes or standards and do not provide alternate guidance for users to meet the regulatory requirement to consider codes and standards in the design. The MCA topical report states that it is acceptable not to use established methods to select a comprehensive set of accident initiators, but it does not provide a detailed methodology of its own as a substitute, leaving an open question how a user of the methodology will prepare a robust safety analysis that meets the regulatory requirements for the technical contents of applications. In the case of the performance-based licensing methodology (PBLM) topical report, overreliance on programmatic controls introduces significant uncertainty in the demonstration of safety features' performance and could lead an applicant to develop a licensing basis that is inconsistent with NRC safety requirements for technologies with new or novel features. Further, the PBLM topical report lacks detailed information about which regulatory requirements the methodology is intended to meet. Such omissions create uncertainty about whether applications using the methodology will be able to fill the gaps and include the information needed by the NRC staff to make the necessary findings, and therefore do not support efficient reviews of applications.

For the reasons discussed above and further described in the enclosed NRC Forms 898, the NRC staff finds that the topical reports do not adequately address previously identified gaps and are not sufficiently complete to support efficient, detailed technical reviews by the NRC staff. Allowing an additional opportunity to address the gaps in the topical reports will require substantial time and resources and would not support a timely, detailed technical review of either the topical reports or the custom combined license application they are intended to support. Therefore, the NRC staff has decided to not accept the revised topical reports for docketing or provide further opportunity to supplement them. The NRC staff activities on the reviews have ceased, and the associated charge numbers have been closed.

This decision is made without prejudice and does not convey any findings related to the general acceptability of the methodologies proposed in the revised topical reports. The NRC staff's rejection of these topical reports does not prevent Oklo from submitting other topical reports on these or other topics for NRC staff review. All topical reports will be subject to a completeness determination at the time of submittal. Incomplete submittals will not be accepted for docketing or a detailed technical review.

If you have any questions regarding this matter, please contact Mr. William Kennedy by telephone at (301) 415-2313, or e-mail at William.Kennedy@nrc.gov.

Sincerely,

Signed by Shams, Mohamed
on 01/06/22

Mohamed K. Shams, Director
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Enclosures:
As stated

Docket No. 52-049

cc: Listserv

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