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

January 06, 2022

Dr. Jacob DeWitte, Co-Founder
Chief Executive Officer
Oklo Inc.
230 East Caribbean Drive
Sunnyvale, CA 94089

SUBJECT: OKLO INC. - DENIAL OF THE AURORA COMBINED OPERATING LICENSE APPLICATION FOR FAILURE TO SUPPLY INFORMATION (EPID L-2020-NEW-0004 AND EPID L-2020-NEW-0005)

Dear Dr. DeWitte:

The purpose of this letter is to inform Oklo Inc. (Oklo) of the U.S. Nuclear Regulatory Commission (NRC) staff's decision to deny the custom combined license application for the Aurora micro-reactor pursuant to the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 2, "Agency Rules of Practice and Procedure," Section 2.108, "Denial of application for failure to supply information." Because Oklo has provided insufficient information, as discussed below, for the NRC staff to establish a schedule to review key safety and design aspects of Aurora, the agency is ending its custom combined license application review and denying the application without prejudice. Oklo is free to resubmit its application supplemented by additional information in the areas described below.

The NRC staff has determined that between March 2020, when Oklo submitted its custom combined license application under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," and the present, Oklo has repeatedly failed to provide substantive information in response to NRC staff requests for additional information (RAIs) on the maximum credible accident (MCA) for the Aurora design, the safety classification of structures, systems, and components (SSCs), and other issues needed for the NRC staff to establish a schedule and complete its technical review. A custom combined license application must contain all design information as well as site-specific information needed for licensing. Under 10 CFR 2.108 the Director, Office of Nuclear Reactor Regulation, may deny an application if an applicant fails to respond to a RAI within thirty (30) days from the date of the request, or within such other time as may be specified.

These information needs were identified and communicated to Oklo during (1) the custom combined license application acceptance review on June 5, 2020, (2) the Step 1 custom combined license application review, including RAIs and a letter dated November 17, 2020, (3) the completeness reviews for topical reports Oklo-2021-R-19-NP, "Maximum Credible Accident Methodology," (hereafter referred to as MCA) and Oklo-2021-R-20-NP, "Performance-Based Licensing Methodology" (hereafter referred to as PBLM), including emails dated August 5, 2021, and letter dated January 06, 2022, and (4) several public meetings held in 2020, and in 2021 prior to the submittal of the revised MCA and PBLM topical reports.

The NRC staff's decision to deny the Aurora custom combined license application is based on the following: Oklo has repeatedly failed to submit the information needed to complete the Step 1 review of its MCA analysis and safety classification SSCs; Oklo's October 30, 2020, RAI responses did not contain sufficient technical information; and the topical reports Oklo submitted, in part, to address Step 1 of the review to support a predictable review schedule, contained information that is conceptual in nature and does not adequately describe Oklo's methodologies for the Aurora's MCA or for safety classification of SSCs. Because of Oklo's repeated failures to provide necessary information to demonstrate the safety of its design, the NRC staff cannot establish a schedule for conducting an efficient technical review and the NRC's review of the Aurora custom combined license application cannot move forward. Details regarding these considerations are discussed below.

Because of certain information gaps in Oklo's application, the Aurora custom combined license application was docketed using a novel, two-step process

After providing limited information about its final design to the NRC staff in pre-application engagement, Oklo submitted a custom combined license application for one micro-reactor, designated as the Aurora, to be located at the Idaho National Laboratory in Idaho, by letter dated March 11, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20075A000). A custom combined license application submitted under 10 CFR Part 52 must contain complete design information and all site-specific information necessary for the NRC staff to reach safety and environmental findings for licensing.

The NRC staff's docketing acceptance review of the Aurora custom combined license application revealed many areas where Oklo provided insufficient information about its reactor for the NRC staff to determine a predictable schedule for an efficient safety review. As specified in 10 CFR 2.101, "Filing of application," before the NRC staff begins a full technical review of an application, it determines whether the application "is complete and acceptable for docketing." As described in the Office of Nuclear Reactor Regulation's Office Instruction LIC-117, "Acceptance Review Process for New Nuclear Facility Licensing Applications," (ADAMS Accession No. ML20283A182), the purpose of this docketing review is to ensure that the application contains sufficient information in scope and depth for the NRC staff to conduct its detailed technical review within a predictable timeframe. Because of information gaps in the Aurora custom combined license application, the NRC staff was not able to establish a full review schedule. Instead, the NRC staff developed a novel, two-step process for the review, and informed Oklo by letter dated June 5, 2020 (ADAMS Accession No. ML20149K616), that the application would be docketed and reviewed under this two-step process. In Step 1 of the process, the NRC staff would focus on obtaining from Oklo additional information on key safety and design aspects of the Aurora licensing basis; the NRC staff estimated that this activity would take five months. At the conclusion of Step 1, the NRC staff expected to have defined the scope of and schedule for the full, detailed technical review that would be conducted in Step 2.[1] In establishing the two-step review process, the NRC staff noted its commitment to completing its safety review of the Aurora application within the established generic 36-month NRC schedule for such reviews in accordance with the Nuclear Energy Innovation and Modernization Act (NEIMA). The two-step review process was intended to support that goal.

[1] The June 5, 2020 letter also noted that the NRC would begin portions of the environmental review during the five-month period for openness and to protect the overall review schedule. The full environmental review would begin after the Step 1 review was completed.

The two-step review process for the Aurora custom combined license application is a novel approach to licensing reviews. As specified in Office Instruction LIC-117, the usual process when significant information gaps are identified during a docketing review is to inform the applicant by letter of all the specific gaps in the application that preclude docketing. In cases where an application is not accepted for docketing, but the identified insufficiencies can be remedied (e.g., the applicant can provide the needed supplementary information within 6 months), the application can remain in a "tendered" state until the applicant addresses the identified information gaps, but generally not longer than 6 months from the date of the NRC letter informing the applicant of the gaps. If an applicant cannot address the information gaps in a timely manner, the applicant will be given the opportunity to withdraw the application. However, Office Instruction LIC-117 recognizes that the NRC staff has flexibility in deciding whether to accept an application for docketing based on consideration of other factors and circumstances, and the NRC demonstrated its flexibility in developing a novel approach for accepting the Aurora application.

To complete Step 1 of the review, the NRC staff engaged with Oklo in numerous public meetings, conducted regulatory audits, and issued RAIs on four key aspects of the application. The NRC's letter dated June 5, 2020, communicated the need to address four foundational aspects of the Aurora licensing basis during Step 1 of the review, before a reliable and efficient schedule for the entire detailed technical review could be established. These foundational aspects were (1) maximum credible accident, (2) safety classification of SSCs, (3) scope of quality assurance program, and (4) applicability of regulations. As described in the June 5, 2020, letter and the Step 1 review extension letter dated November 17, 2020 (ADAMS Accession No. ML20308A677), the NRC staff required additional information about the safety and design of the Aurora reactor to be able to define the scope and schedule for the full detailed review that was planned to be conducted in Step 2.

Oklo has repeatedly failed to submit the information needed to complete the Step 1 review of its MCA analysis and safety classification of SSCs

Of the four issues identified for resolution in Step 1 of the custom combined license application review, Oklo's MCA analysis and safety classification of SSCs remain open. Oklo proposed a novel approach to determining the spectrum of potential accidents deemed credible for the Aurora design and the selection of the MCA. Similarly, Oklo proposed a new methodology for determining the safety classification of SSCs within its design. Both topics are foundational in the NRC staffs review of the Aurora design for reasonable assurance of adequate protection of public health and safety and would significantly shape the scope and depth of other areas of the NRC staff's review. As such, it is essential that Oklo fully explain its novel approaches and the NRC staff evaluate their reasonableness prior to expending significant resources on other portions of the review. Although Oklo has been provided several opportunities to provide necessary technical information, it has failed to do so. The history of interactions between Oklo and the NRC is summarized in the following paragraphs.

After the issuing the June 5, 2020, docketing decision describing the four key areas of the application that must be supplemented before the NRC staff could establish a schedule for or begin a detailed review, the NRC staff proposed a series of public meetings with Oklo to obtain additional information on the Aurora beginning in early July 2020. Oklo was not able to support public meetings until early August 2020 and on August 4-5, 2020, the NRC staff held public meetings with Oklo to discuss the topics of MCA and safety classification of SSCs (ADAMS Accession No. ML20240A228). During the meeting, NRC staff highlighted the need for more

information on the application of the MCA approach[2] and safety classification of SSCs that performed the functions of reactivity control, heat removal, and confinement of radioactive material.[3] Oklo's presentations on these topics described their method for developing the MCA and the safety classification and treatment of SSCs. Oklo provided conceptual information consistent with the information already contained in the Aurora custom combined license application but did not provide detailed technical information responsive to the staff's requests for details about the safety of the Aurora design. Specifically, Oklo did not provide sufficiently detailed technical information to explain how Oklo arrived at the results of its MCA analysis or Oklo's assertion that safety-related SSCs are not required to control reactivity, remove heat, and retain radioactive material.

On September 18 and 23, 2020, the NRC staff transmitted to Oklo RAIs on the topics of MCA, SSC classification, and quality assurance (ADAMS Accession Nos. ML20265A123, ML20267A529, and ML20265A121). Additionally, on October 2 and 5, 2020, the NRC staff opened audits in the areas of MCA and SSC classification.[4] The purpose of these audits was to gain a better understanding of the information in the Aurora custom combined license application, identify any additional information that may be needed on the docket, and potentially formulate additional RAIs to aid in the closure of Step 1 (ADAMS Accession Nos. ML20265A273 and ML20275A060). Audit discussions occurred between NRC staff and Oklo in accordance with the audit plans until October 30, 2020.[5] By letter dated October 30, 2020 (ADAMS Accession No. ML20305A582) Oklo submitted its Step 1 RAI responses on the topics of MCA, safety classification of SSCs, and the scope of the quality assurance program.

By letter dated November 17, 2020 (ADAMS Accession No. ML20308A677), the NRC staff informed Oklo that the RAI responses, audit documents, and audit discussions enhanced the NRC staff's understanding of Oklo's novel approach to the Aurora design but did not provide sufficient information to define the scope of the full technical review of the custom combined license application. This letter informed Oklo that (1) resolution on several aspects of the MCA was needed, (2) resolution on several aspects of classification of SSCs was needed, and (3) the topic of quality assurance was being tracked as part of the safety classification of SSCs rather than as a separate issue. The letter also informed Oklo that the topic of applicability of

[2] The NRC staff presentation (ADAMS Accession No. ML20204A932) provided example event scenarios and related phenomena where more information was needed to support the Aurora COL application review.

[3] The NRC staff presentation (ADAMS Accession No. ML20204A933) concluded with a summary of items for which additional information was needed to support the Aurora custom combined license application review.

[4] The NRC staff also completed audits on the topics of MCA-heat transfer in the reactor system and regulatory applicability (ADAMS Accession Nos. ML20262G985 and ML20332A178). The MCA-heat transfer in the reactor system audit resulted in the issuance of an additional RAI on the topic of MCA on September 21, 2020 (ADAMS Accession No. ML20265A346).

[5] The MCA audit included an examination of Oklo's internal documents, regarding the MCA methodology and results of the event down selection. The NRC staff was unable to close the MCA and SSC classification audits because Oklo did not provide sufficient technical information on its MCA analysis, safety classification of SSCs, or the scope of its quality assurance program for the staff to develop a fulsome understanding of the topics. The staff's denial of the application and the termination of the review also closes the audits on these topics.

regulations was closed[6] and that Step 1 of the review was being extended to allow time for Oklo to address the topics of MCA and safety classification of SSCs.

On December 2, 2020, during a routine scheduling call, Oklo requested that the NRC staff temporarily pause its review and stop developing additional RAIs for the Aurora custom combined license application; Oklo confirmed its request in a follow-up email dated December 3, 2020 (ADAMS Accession No. ML20338A510). By letter dated December 21, 2020 (ADAMS Accession No. ML20357A001), Oklo informed the NRC staff that it was reviewing the specific items outlined by the NRC staff in the Step 1 extension letter for the topics of MCA and classification of SSCs, and that it would propose next steps for the Step 1 review. Discussions with Oklo on the next steps for the review took place with NRC management in early 2021. Ultimately, Oklo decided to submit generic topical reports to address the topics of MCA and safety classification of SSCs for the Step 1 review of these topics, including the specific questions in the RAIs.

Topical reports for the MCA methodology and safety classification of SSCs did not resolve the open Step 1 issues

By letter dated July 2, 2021 (ADAMS Accession No. ML21184A001), Oklo submitted two topical reports that contained insufficient technical information to address the open Step 1 issues for NRC staff review. The first, "Maximum Credible Accident Methodology," Revision 2[7] (ADAMS Accession No. ML21184A002), described Oklo's approach to the MCA analysis. The second, "Performance Based Licensing Methodology," Revision 0 (ADAMS Accession No. ML21187A001), attempted to describe, in part, Oklo's process for safety classification of SSCs. The NRC staff performed completeness reviews of the topical reports using the Office of Nuclear Reactor Regulation's Office Instruction LIC-500, "Topical Report Process" (ADAMS Accession No. ML19123A252). The staff determined that neither topical report contained sufficient information to initiate detailed technical reviews. Each report contained conceptual information, rather than repeatable methodologies, and each left many issues unresolved and open for future potential applicants referencing the topical reports to address. The NRC staff informed Oklo of the insufficiency of the topical reports by two emails dated August 5, 2021 (ADAMS Accession Nos. ML21201A079 and ML21201A111), that included attachments describing in detail the supplemental information Oklo must provide 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 identified five areas where additional information was needed for the MCA methodology and three areas where additional information was needed for the PBLM methodology. 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). During these meetings NRC staff responded to Oklo's requests for clarification on the information needed to address

[6] By letter dated November 17, 2020 (ADAMS Accession No. ML20300A593), the NRC staff informed Oklo that Step 1 was completed for the area of applicability of regulations. The NRC staff's Step 1 review focused on regulations Oklo identified as not applicable to its Aurora design and did not evaluate the acceptability of requested exemptions. By letter dated December 21, 2020 (ADAMS Accession No. ML20357A002) Oklo informed the NRC staff that they intend to pursue further engagement on the topic of applicability of regulations.

[7] "Maximum Credible Accident Methodology," Revision 0 was examined by NRC staff during the Step 1 MCA audit (ADAMS Accession No ML20265A273), and Revision 1 was submitted to NRC staff in response to an RAI (ADAMS Accession No. ML20305A582).

the information gaps identified during the completeness reviews of the topical reports. The NRC staff also clarified that some of Oklo's planned revisions appeared inadequate to address the information gaps.[8]

By letters dated October 5, 2021 (ADAMS Accession No. ML21278B096), and October 19, 2021 (ADAMS Accession No. ML21292A325), Oklo submitted revised topical reports for the MCA and PBLM methodologies. The NRC staff conducted a completeness review of the revised topical reports and determined that Oklo provided no new substantive information and failed to fully address the information gaps identified during the original completeness review and discussed during public meetings. By letter dated January 06, 2022 (ADAMS Accession No. ML21307A107), and its enclosures (ADAMS Accession Nos. ML21307A113 and ML21307A116), the NRC staff notified Oklo of its decision to not accept the topical reports for technical review on the basis that they were not sufficiently complete to initiate a detailed review.

Because of Oklo's repeated failures to provide necessary information about its reactor, the NRC's review of the Aurora custom combined license application cannot move forward

The NRC staff identified significant information gaps in the Aurora custom combined license application in its June 5, 2020, docketing decision, and has engaged with Oklo since August 2020 in sustained efforts to provide Oklo with options for providing the information needed on the topics of MCA and safety classification of SSCs to close Step 1 of the docketing review, establish a predictable schedule, and conduct an efficient safety review. The NRC staff used public meetings, audits, RAIs, and conducted two completeness reviews of the topical reports to provide Oklo with clear descriptions of the information Oklo must provide to obtain a combined license for the Aurora. However, the NRC staff has been unable from March 11, 2020, to the present to obtain necessary information from Oklo to support the completion of the Step 1 review, and preparation of a predictable schedule for the full review.

By letter dated June 5, 2020, the NRC staff committed to completing its review of the Aurora custom combined license application in the most efficient and effective manner possible and within the established generic 36-month NRC schedule for such applications in accordance with NEIMA. The NRC's docketing decision for the Aurora custom combined license application was designed to obtain the necessary additional design information from Oklo and complete Step 1 activities within five (5) months. The NRC staff engaged extensively with Oklo to complete Step 1 through numerous meetings and by conducting audits, requesting additional information, and clarifying its information needs. More than a year has passed since the application review commenced, during half of which the technical review was paused at the applicant's request. Oklo's proposal to develop generic methodologies to address the topics of MCA and classification of SSCs was not successful in closing Step 1 of the review, and foundational issues identified during the Aurora custom combined license application acceptance review remain unresolved. Accordingly, the NRC staff is unable to complete Step 1 of the two-step review, or establish a reliable and predictable schedule.

[8] For example, Oklo proposed revising the MCA topical report to add an approved NRC quality assurance program as a condition to address the identified information gap on conditions and interfaces. NRC staff informed Oklo that a quality assurance program alone does not appear to provide enough specificity, making it difficult for a user to implement the methodology. This is noted in the September 1, 2021 Meeting Summary (ADAMS Accession No. ML21259A260)

Oklo engaged in very limited pre-application interactions with the NRC staff

Prior to submitting its custom combined license application for the Aurora or its initial or revised topical reports, Oklo chose to conduct limited pre-application discussions with the NRC staff regarding its MCA methodology and safety classification of SSCs. Oklo met with the NRC staff to discuss various topics, such as core design (ADAMS Accession No. ML18032A757), risk analysis and source term (ADAMS Accession No. ML18032A761), principal design criteria (ADAMS Accession No. ML18248A167), the pilot use of the Licensing Modernization Project (LMP) methodology (ADAMS Accession No. ML19085A398), security and emergency planning (ADAMS Accession No. ML19232A187), radiation protection and automatic controls (ADAMS Accession No. ML19240A379), and safety case and external hazards (ADAMS Accession No. ML20003D837), prior to submitting the Aurora custom combined license application. Additionally, the NRC staff reviewed and approved the Oklo Quality Assurance Program Description (QAPD) (ADAMS Accession No. ML20205L415)[9], and the safeguards information protection and handling plan (ADAMS Accession No. ML19270F012). Oklo covered a broad range of topics in pre-application engagement with the staff, but, the effectiveness and relevance of the pre-application engagement was limited because (1) NRC staff feedback from the pre-application engagement was not incorporated into the Aurora custom combined license application, and (2) Oklo made other changes to the Aurora design and/or design basis after these interactions that limited the applicability of prior discussions to the Aurora custom combined license application.

One example of pre-application interactions that were not reflected in the custom combined license application is Oklo's pilot of the LMP methodology. The LMP methodology was developed by the Nuclear Energy Institute (NEI) in NEI 18-04, Revision 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactors" (ADAMS Accession No. ML19241A472), and endorsed by the NRC in Regulatory Guide 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (June 2020) (ADAMS Accession No. ML20091L698). This methodology provides one possible approach for selection of licensing-basis events for a non-light-water reactor design, classification and special regulatory treatments of SSCs, and assessment of defense in depth. Although Oklo participated in a pilot for an early version of the LMP methodology (ADAMS Accession No. ML19085A398), Oklo ultimately chose to base the Aurora custom combined license application and MCA and PBLM topical reports on a different approach (the MCA methodology) to determine licensing basis events and safety classification of SSCs. This serves as one example of how Oklo's limited pre-application interactions did not contribute to resolving the issues in Step 1 of the two-step review.

Conclusion

Based on Oklo's failure to provide the NRC with necessary information on its reactor, as described above, the NRC staff has insufficient information to establish a schedule or conduct a full review of the Aurora custom combined license application and therefore denies the application for failure to supply information. In accordance with the requirements of

[9] The applicability of Oklo's QAPD to the Aurora combined license remains an unresolved issue. On September 18, 2020, the NRC staff issued an RAI seeking clarification on the applicability of the QAPD to the Aurora combined license application (ADAMS Accession No. ML20267A529). Oklo's response, dated October 30, 2020 (ADAMS Accession No. ML20305A582), did not resolve the issue.

10 CFR 2.108, the NRC staff's Notice of Denial will be published in the *Federal Register* and within thirty (30) days after the date of publication in the *Federal Register*:

(1) Oklo may demand a hearing, and
(2) Any person whose interest may be affected by the proceeding may file a petition for leave to intervene.

The NRC staff has ceased all review activities on the Aurora custom combined license application and the associated charge numbers have been closed. The NRC staff has made no findings regarding the safety of the design; the NRC staff's denial of the Aurora custom combined license application is not a determination on the safety, security, or merits of the application. The NRC staff's denial of the Aurora custom combined license application is without prejudice and does not preclude Oklo from addressing the information gaps the NRC staff has identified and resubmitting a license application in the future. A new application will be subject to a completeness determination at the time of submittal. An incomplete application 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 email at William.Kennedy@nrc.gov.

Sincerely,

Andrea D. Veil

Digitally signed by Andrea D. Veil
Date: 2022.01.06 12:12:32 -05'00'

Andrea D. Veil, Director
Office of Nuclear Reactor Regulation

cc: Listserv

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ADAMS Accession No.: **ML21357A034**

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