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U.S. Nuclear Regulatory Commission **ATTN: Document Control Desk** 11555 Rockville Pike Rockville, MD 20852-2738

Subject: Oklo Inc.

Performance-Based Licensing Methodology Topical Report

Oklo Inc. (Oklo) submitted to the U.S. Nuclear Regulatory Commission (NRC) a Maximum Credible Accident (MCA) Methodology Topical Report and Performance-Based Licensing Methodology Topical Report on July 2, 2021. These reports outline the key methodological approaches that Oklo used for designing and preparing the license application for Oklo's Aurora at Idaho National Laboratory (Aurora-INL) Combined License Application (COLA) which was ultimately accepted for review. NRC staff's completeness determination reviews¹ documented certain supplemental information the staff determined should be included in each topical report prior to beginning NRC staff review. Oklo supplemented and resubmitted a revised MCA Topical Report on October 5, 2021, to address the NRC staff comments. Oklo is submitting its revision to the Performance-Based Licensing Methodology Topical Report as Enclosure 1 of this letter.

It is worth restating that, in preparation for the Aurora-INL COLA, Oklo considered both the requirements in Title 10 of the Code of Federal Regulations and numerous existing guidance documents that support implementation of those requirements for licensing nuclear power plants. While substantial guidance exists to support licensing and regulation of existing operating nuclear technologies, it is generally not suitable to be used for advanced fission technologies, which take far greater advantage of inherent design features.² Even recently developed technology-neutral guidance does not fully incorporate means of assessing the inherent features of new and advanced fission technology. And while regulatory guidance is a tool for demonstrating previous implementations of the requirements, it is the requirements themselves that have assured adequate protection of the public health and safety over the decades. With this in mind, Oklo is proposing a new approach that showcases addressing the regulations directly, while accounting for important functions and features of advanced fission.

The licensing approach outlined in the Performance-based Licensing Methodology Topical Report offers a flexible, performance-based approach for assessing the safety relevance of a design's functions and features. It further designates functions and features for regulatory controls and indicates which of those functions and features must be classified as safety-related. Although the Performance-Based Licensing Methodology designates where regulatory controls must be applied, it generally does not prescribe specifics on how they must be applied, to remain truly technology-inclusive. Design bases are both common regulatory controls and required by the regulations, and their application is described within the topical report. Design commitments uphold the design bases, which are then validated through prescribed programmatic controls; however, the development of design-specific programmatic controls is outside the scope of this methodology. This flexibility is a conscious methodological choice to offer critical flexibility for the allowance of unique considerations required in a technology-inclusive approach. Ultimately, the Performance-Based Licensing Methodology Topical Report guides the

¹ Forms 898, U.S. NRC staff completeness determinations for the topical report Oklo-2021-R19-NP, Rev. 2, "Maximum Credible Accident Methodology" (ML21184A002) and Oklo-2021-R20-NP, Rev. 0, "Performance-Based Licensing Methodology" (ML21187A001)

² When used in these methodologies, "functions" are usually passive or active (e.g., valve actuation, shutdown rod insertion) and "features" are typically inherent or intrinsic system characteristics (e.g., reactivity feedback, heat transfer properties, structural configurations).



development and tracking of the appropriate regulatory controls to assure safety from design to construction, and into operation. This results in a better framework for assuring safety and regulatory compliance, while also facilitating the commercialization of advanced nuclear power.

In the NRC staff's completeness determination forms for the Performance-based Licensing Methodology Topical Report, the staff provided three high level comments. Below is a brief description of the changes made to the topical report in response to the staff's comments.

- Comment I Comment I provided a comprehensive request for clarification on certain regulatory requirements that did not appear to be explicitly addressed within the Performance-Based Licensing Methodology. Oklo supplemented the topical report to be clearer about the intent of the methodology with respect to how it is intended to meet certain regulatory requirements. For the specific comments identified in the completeness determination form:
 - Comment I.A Oklo supplemented Section 3.5, "Assigning design bases and commitments," to assure that design bases and design commitments for new or novel features should include programmatic controls that ensure the performance of those safety features have been appropriately demonstrated for acceptability and are sufficiently understood, as needed per 10 CFR 50.43, "Additional standards and provisions affecting class 103 licenses and certifications for commercial power," paragraph (e).
 - Comment I.B Appendix A, "Performance-based structure" Section A.4.1, "Description and analysis of SSCs," discusses the development of Chapter 2 of the Final Safety Analysis Report, which for Oklo designs, includes a discussion of the regulatory requirement 10 CFR 52.79, "Contents of applications; technical information in final safety analysis report," paragraph (a)(2). Therefore, Oklo supplemented Section A.4.1 to include the need to address all of the elements of 10 CFR 52.79(a)(2) when submitting an application for a combined license.
 - Comment I.C Oklo supplemented Section 3.6.2, "Application of quality assurance," to explain how the methodology requires that functions and features are assigned to systems, sub-systems, components (SSCs) or portions of components, but does not prescribe a specific method for this assignment, as this must be done at the discretion of the designer. However, the creation of design bases, design commitments, and programmatic controls used to uphold functions or features inherently must provide specificity with regards to which SSCs or portions of components will be used to perform each function or embody each feature. Specifically, these assignments should be clear in an NRC application and the corresponding quality assurance requirements for the purpose of identifying those SSCs having importance to safety, as required by Criterion II of Appendix B to 10 CFR Part 50 and 10 CFR 50.34, "Contents of applications; technical information," paragraph (f)(3).
 - Ocomment I.D Oklo revised the topical report to focus on the safety-by-design approach utilized by this methodology. A key characteristic of this methodology is the ability to iterate, alongside a licensing basis event analysis methodology, to cover the full spectrum of events, including uncertainties associated with the design and the selection process. The licensing basis event analysis methodology is a separate methodology from the Performance-Based Licensing Methodology and is the basis for the acceptance criteria the Performance-Based Licensing Methodology does not define the acceptance criteria and does not use a single acceptance criterion of dose. Since this Performance-Based Licensing Methodology is technology-inclusive and intended for designers of new plants, it is flexible in its implementation and does not prescribe which functions and features must be classified as safety-related. Instead, this methodology provides one approach to evaluating the safety relevance of those functions and features to the licensing basis event analysis. Oklo has further revised the topical report to clarify this point, as well as that Oklo is not requesting an exemption for NRC applicants who



choose to use this methodology. Oklo also revised the topical report to reiterate the requirements of 10 CFR related to NRC applicants who choose to deviate from the 10 CFR requirements where they are not necessary to achieve the underlying purpose of the rule, and when NRC applicants choose to do so, they should evaluate whether exemptions from requirements are necessary in accordance with 10 CFR 50.12, "Specific exemptions."

- Comment I.E Oklo supplemented Appendix A, Section A.4.4, "Principal design criteria," to clarify it is not the purpose of the topical report to prescribe how principal design criteria are developed. Rather, an NRC applicant using this methodology is free to use methods from existing guidance, follow the approach taken by Oklo, or to develop their own methodology for identifying principal design criteria. Furthermore, principal design criteria need not be developed in advance of the implementation of this methodology.
- Comment II Oklo supplemented Section 1, "Purpose and scope," to address the need to pursue exemptions when application of the methodology, combined with a specific technology, demonstrates the need.
- Comment III Oklo supplemented throughout the topical report that the specific purpose of the Performance-Based Licensing Methodology is to describe a method for assessing the safety of functions and features on the licensing basis event analysis and for designating regulatory controls, by assigning design bases and design commitments to uphold those functions and features. However, the development of the full suite of programmatic controls (outside of quality assurance) is beyond the scope of this methodology. This allows for key flexibility in the design of programmatic controls to allow for the unique design-specific considerations. The topical report was supplemented, where appropriate, to discuss the need to account for the points raised by the NRC staff in the sub-bullets of Comment III.

Oklo participated in numerous public meetings with NRC staff to understand the intent of the NRC staff's comments. In doing so, it became apparent that additional clarification was necessary to better articulate how this methodology was intended to interface with other design and operation requirements. Therefore, to support the acceptance and review of the topical report, supplemental information was incorporated throughout to make the implementation language clearer and strengthen the methodology. Specifically, Oklo added two paragraphs that explained key interfacing interfaces between the Performance-Based Licensing Methodology and that of both the analysis of licensing basis event(s) (Section 3.2, "Identifying licensing basis event(s)") and an NRC applicant's Quality Assurance Program Description (Section 3.6, "The role of quality assurance as a programmatic control: assigning quality assurance requirements").

Oklo is preparing an illustrative example, as a companion to the Performance-Based Licensing Methodology, that provides a walk-through of the implementation of these methodologies from event analysis and identification of a potential safety function and how it would be expected to be incorporated into the design, analyzed and iterated upon, and then subsequently designated with a design basis, design commitments, and regulatory controls. While it is expected that this example will aid in understanding the implementation of the Performance-Based Licensing Methodology and its interface with the MCA Methodology, it should be viewed as a supporting document and therefore was not incorporated into the topical report itself. Oklo will be make this companion example available shortly following this submittal.



Oklo is confident that the incorporations to the revised Performance-Based Licensing Methodology Topical Report will help properly scope the intent and usefulness of the methodology, allowing the NRC staff to move forward with the review. Oklo looks forward to continued discussions on both the MCA Methodology Topical Report and the Performance-Based Licensing Methodology Topical Report.

If you have any questions or need any additional information, please contact us at regulatory@oklo.com or (650) 550-0127.

Sincerely,

Ross Moore

Director of Regulatory Affairs

Oklo Inc.

Enclosure: (1) Oklo Performance-Based Licensing Methodology Topical Report, Revision 1

CC (with enclosure):

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