



# Topical Report Completeness Determination

Topical Report Information		Review Information	
Report Number:	Oklo-2021-R20-NP, Rev. 1	Office/Division/ Branch:	NRR/DANU/UTB1
Title:	Oklo Topical Report Performance-Based Licensing Methodology		
ADAMS Accession Number:	ML21292A327	Project Manager:	Jan Mazza
EPID:	L-2021-TOP-0017	Reviewers:	Tim Lupold, Alex Siwy
Docket Number:	05200049		

Review Type:  Standard  Compressed

### ADAMS Accession Numbers (Top row is for transmittal of this form)

Package: <b>ML</b>	21307A108	E-mail: <b>ML</b>	21307A107	This Form: <b>ML</b>	21307A116
Withholding Determination: <b>ML</b>		Fee Waiver: <b>ML</b>			

### Topical Reports for Review

The NRC staff has performed an acceptance review of the subject topical report. We have found that the material presented is sufficient to begin our review. The dates below are based on current resources, if they change the NRC staff will contact you.

### Information for Topical Reports That Are Found Acceptable for Review

Issue Dates For Requests for Additional Information:	Issue Dates For Draft Safety Evaluation:
Review hours total includes project management and contractor time:	

### Topical Reports Not Acceptable for Review

- Based on its review of the information provided, the NRC staff cannot find sufficient details in the submittal to allow the staff to evaluate the proposed topical report.
- [Only for Use with Topical Reports in Standard Review Process]** Although the NRC staff has found the current topical report is not sufficiently detailed to begin our review, the sponsor can supplement the submittal with additional information. The additional information should be submitted within 60 days the date of this form.

**Basis for Nonacceptance:**

Oklo-2021-R20-NP, Rev. 1, "Performance-Based Licensing Methodology," (hereafter referred to as PBLM TR) did not provide technical information in sufficient detail to enable the NRC to commence its detailed technical review and make an efficient and timely assessment regarding the acceptability of the methodology.

**Additional Information Needed:**

The information needs were previously conveyed to Oklo in the original August 5, 2021, completeness determination as items I, II, and III (ADAMS Accession No. ML21201A113), and the staff held three public meetings with Oklo on September 1, 16, and 28, 2021 (meeting summaries available at ADAMS Accession Nos. ML21259A260, ML21266A428, and ML21293A329, respectively) to respond to Oklo's requests for clarification. Revision 1 of the PBLM TR made certain changes from Revision 0, but Oklo did not fully address the information needs previously identified during the original completeness review. The information needs that were not addressed are described below.



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I. The revised PBLM TR still does not appropriately address pertinent regulations.

A. The NRC informed Oklo that its PBLM TR did not address the provisions of 10 CFR 50.43(e)(1) for the use of simplified, inherent, passive, or other innovative means to accomplish safety functions and how the performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof. Oklo stated in the revised PBLM TR, "the programmatic controls developed to support the application of the methodology [PBLM] should ensure that the performance of each safety feature has been appropriately demonstrated for acceptability and is sufficiently understood, as needed when required by 10 CFR 50.43(e)." Programmatic controls may be used in certain circumstances to ensure that systems are built in accordance with the design and monitor the health of equipment following installation and throughout operational life. However, sole reliance on programmatic controls does not provide the information necessary for the NRC staff to make a regulatory finding on an application's compliance with 10 CFR 50.43(e)(1). In addition, sole reliance on programmatic controls does not provide a sufficient safety basis for a regulatory finding that the designs of safety functions and features provide reasonable assurance of acceptable performance prior to issuing a combined or operating license and commencing plant operation. Moreover, the PBLM TR defers determination of the necessary programmatic controls to future applicants without providing substantive guidance on how to ensure the appropriate programmatic controls are specified for functions and features relied on for safety.

B. The NRC informed Oklo that its PBLM TR did not address the provisions under 10 CFR 52.79(a)(2)(ii) that require the identification of generally accepted engineering standards for the design of the reactor. The PBLM TR does not provide the criteria for applying generally accepted engineering standards in the design of the facility. It also does not provide justification for not applying such engineering standards, nor does it provide acceptable, sufficiently detailed alternatives. Instead of providing guidelines for identifying generally accepted engineering standards to reference in an application, the PBLM TR proposes reliance on programmatic controls to demonstrate that design commitments are fulfilled. The NRC staff notes that codes and standards provide generally accepted engineering frameworks that have been developed in an open, collaborative manner and represent a collective judgement that following such frameworks lead to designs with appropriate safety margin (which, as an added benefit, enables more efficient NRC staff reviews). The PBLM TR does not provide sufficient detail to support programmatic controls as a substitute for the use of codes and standards. Without information about the use of codes and standards or sufficiently detailed alternatives, the NRC staff will not be able to make a regulatory finding on how the TR addresses the design commitments to comply with 10 CFR 52.79(a)(2)(ii).

C. The NRC informed Oklo that its PBLM TR did not address the provisions under 10 CFR 50.34(f)(3) that require sufficient information to demonstrate that the quality assurance list required by Criterion II, Appendix B, 10 CFR Part 50 includes all SSCs important to safety. The PBLM TR appears to conflict with this regulation by asserting that classification of SSCs is not required. Instead, the PBLM TR focuses on classifying functions and features of SSCs and states that the design bases, design commitments, and programmatic controls will specify which SSCs will be used to perform each function or embody each feature. The PBLM TR states that these assignments should be clearly outlined in an NRC application, along with corresponding quality assurance requirements. The language in both revisions of the PBLM TR may be construed in a manner to suggest that identifying SSCs important to safety is not required or is optional. Under 10 CFR 50.34(f)(3), the application is required to identify SSCs important to safety, or if an alternative approach is proposed, the applicant is required to seek an exemption and provide a requisite justification. The identification of SSCs important to safety is necessary to assure that those SSCs are subject to the appropriate regulatory controls in areas such as design, maintenance, and testing. Without this information, the NRC staff will not be able to make a regulatory finding on how the TR addresses the appropriateness of regulatory controls for all SSCs important to safety to comply with 10 CFR 50.34(f)(3).

D. The revised topical report still does not discuss the following requirements that are inherent in the current regulatory framework:

(1) The use of safety related equipment to shut down the reactor, as identified in the definition of "safety related SSCs" in 10 CFR 50.2, was not adequately addressed in Revision 0 and is still not adequately addressed in Revision 1. The PBLM TR does not provide a justification for why SSCs necessary to safely shut down the reactor should not be classified as safety related nor did it request and justify an exemption.

(2) The PBLM TR outlines a concept for defense-in-depth, rather than a methodology that can be applied consistently and predictably, and it does not explain how the user should ensure defense-in-depth in the design. Defense-in-depth provides that



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no single engineered design feature, human action, or programmatic control, no matter how robust, is exclusively relied upon to assure a necessary safety function. Defense-in-depth is usually achieved through a combination of conservative analyses, redundancy, and diversity. The TR does not specify how defense-in-depth is achieved through the PBLM.

(3) The PBLM TR does not address how the overall risk to the public from the operation of the facility under normal conditions, transients, and during and after accidents is acceptably low. The associated criteria in the TR are focused solely on design basis accidents (i.e., the PBLM TR exemplifies radiation dose as the sole criterion, which is specified in 10 CFR 50.34(a)(1)(ii) (D) or 52.79(a)(1)(vi)). These criteria are not the only criteria necessary to demonstrate reasonable assurance of adequate protection. The TR does not appear to address normal operations, anticipated operational occurrences (AOOs), beyond design basis events (BDBEs), severe accidents, etc. Applicants under 10 CFR Part 50 and 52 will have to address many specific regulations, such as 10 CFR 52.79(a)(5) for operational conditions and 10 CFR 52.79(a)(9) for station blackout, that apply to these plant states and events. Without this information, the NRC staff would not be able to make a regulatory finding on how the TR addresses the overall risk to the public of the operation of the facility.

E. The PBLM TR still does not address the development of the principal design criteria (PDC), in accordance with 10 CFR 52.79(a)(4), and instead the method to develop PDC is left to the applicant that references this TR. Development of PDC is essential for the application of the PBLM to ensure appropriate design bases and design commitments have been established. Without appropriate PDC development, the NRC staff would not be able to make a regulatory finding on how the TR addresses the acceptability of those design bases and design commitments.

II. The revised PBLM TR still does not adequately address and justify exemptions. As discussed in previous sections of this form, the revised PBLM TR either conflicts with or does not provide sufficient information to assure compliance with certain regulatory requirements in 10 CFR Parts 50 and 52. If the NRC were able to complete its review and find the PBLM TR acceptable, applicants using the PBLM TR would need to submit requests for exemptions with sufficient justification and receive NRC approval or demonstrate compliance with the regulatory requirements. However, the revised PBLM TR leaves the applicant to identify and address areas where the methodology may conflict with the regulations, and it lacks guidance for justifying those exemptions. This information is necessary because it may not be readily apparent to the user of the PBLM TR where and how the methodology is not in compliance with regulations. Without this information, the NRC staff would not be able to make a regulatory finding on whether the PBLM follows all relevant regulations and/or directs applicants to request exemptions from the appropriate regulations.

III. The revised PBLM TR does not fully address observations A through E from Section III of the August 5, 2021, completeness determination. The PBLM TR attempts to outline a complete performance-based licensing approach that is innovative in the way it demonstrates compliance with the regulations. A complete licensing approach has many components. One of those important components is sufficient information on the design, analysis, operation, and maintenance of SSCs that are important to safety. As previously communicated on August 5, 2021, Revision 0 of the PBLM TR was missing sufficient details regarding SSCs that are important to safety, including information on qualification for natural phenomena (earthquakes, floods, etc.), material degradation, and addressing reliability and capability for long-term operations. Revision 1 of the PBLM TR still does not address this information. Without this information, the staff will not be able to make a regulatory finding on how the TR addresses the performance of SSCs that maintain public safety throughout their full lifecycle.

## Approvals

Technical Branch Chief	
Projects Branch Chief	