



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

June 29, 2018

MEMORANDUM TO: Those on the Attached List

FROM: Anna Bradford, Deputy Director /RA/  
Division of Licensing, Siting, and Environmental Analysis  
Office of New Reactors

SUBJECT: OFFICE OF NEW REACTORS PHASE DISCIPLINE

This memorandum is an update to previously issued communications regarding the definitions and adherence to the phases used during the staff reviews of design certification (DC) and combined license (COL) applications. Over the last several years, these phases have been applied in multiple reviews in the Office of New Reactors (NRO) and have proven to be a practical approach. *Phase discipline* is the process of orderly completion of all activities within a review phase prior to transitioning to the subsequent phase. Phase discipline is critical because it assists the NRC in providing certainty and predictability to its review processes. Additionally, it decreases the risk that the late resolution of highly challenging issues will result in extended review times. A definition of each phase, and when each phase is considered complete, is provided in the Enclosure to this memorandum.

Staff should be especially judicious when determining whether a technical issue should be labeled as an Open Item within the draft Safety Evaluation Report during Phase 2. Open Items should be limited to those issues that have a well-defined scope and clear resolution path (e.g., a closure plan or other information), and that are likely to be resolved without the need for supplemental Requests for Additional Information (RAIs). Issues such as additional technical review of new design changes, substantive changes in the application that will need substantial review hours, or delayed RAI responses from the applicant should not be converted into Open Items. The incorrect conversion of technical issues into Open Items introduces substantial schedule risk in Phase 4 because: 1) the scope of the technical review, including schedule, remains undefined, 2) multiple rounds of RAIs may be still needed, and 3) a substantial expenditure of staff resources could result late in the review. To assist the staff with understanding phase discipline, attached to this memorandum are definitions for the phases, as well as a list of questions to use when determining whether the review is ready to move past Phase 2.

The project managers in the Division of Licensing, Siting, and Environmental Analysis (DLSE) in NRO will continue to review the safety evaluation inputs and test the bases supporting the conversion of technical issues into Open Items on a case-by-case basis. If DLSE staff members believe that a planned Open Item does not appear to be consistent with the phase discipline approach, they will initiate discussion with the appropriate staff and Division management to understand the basis for creating the Open Item, and to establish expectations for the applicant regarding what will be necessary to close the Open Item. Discussions with the applicant about these expectations are critical to facilitating the receipt of the necessary information to close the Open Item while minimizing the need for supplemental RAIs.

The use of phase discipline reflects our commitment to provide thorough and timely reviews, and acknowledges what is needed to successfully implement all the phases of the review

efficiently and effectively. Exceptions to the use of phase discipline should be limited and require Division management approval. For example, it may be reasonable to defer security reviews until Phase 4 for COL applications. In addition, judgement is required as to whether a revision to an application is minor and could be successfully accomplished during Phase 4 or whether it involves significant changes requiring a substantive new review and therefore should remain in Phase 2.

If you have any questions about the implementation of the phase discipline approach, please contact me at 301-415-1560.

Enclosures:

1. Definitions of the Phases of a Review
2. Phase 2 Completion Questions

## **Enclosure 1: Definitions of the Phases of a Review**

### **Phase 1: Preliminary Safety Evaluation Report and Requests for Additional Information (RAI) Preparation**

The staff conducts a thorough review of the information in the application and other supporting information using the regulations, regulatory guidance, and appropriate references. Requests for Additional Information (RAIs) are developed by the staff to address missing, incomplete, inconsistent, or unclear information within the application. The RAIs should be developed at the same time that the Preliminary Safety Evaluation Report (PSER) is being written to ensure that the information being requested is necessary for the safety finding. Once the Advance RAIs have been sent to the applicant, Phase 1 is complete<sup>1</sup>.

### **Phase 2: Safety Evaluation Report with Open Items**

The staff reviews the responses to the RAIs and develops the Safety Evaluation Report (SER) with Open Items. The RAI responses may be sufficient to close the RAI or may need to be supplemented or otherwise addressed. At this phase, the preliminary SER is updated based on the RAI responses. Phase 2 is not complete until unresolved technical issues discussed within the PSER are either fully resolved or meet the definition of an Open Item. Open Items are limited to those issues that have a well-defined scope and clear resolution path, and are likely to be resolved without the need for supplemental RAIs. Issues such as additional technical review of new design changes or substantive changes in the application that will need substantial review hours should not be converted into Open Items. A SER that includes these types of issues should be considered to be still in Phase 2.

In addition to Open Items, Phase 2 may include the development of Confirmatory Items. Confirmatory Items are those issues for which the staff and applicant have reached an understanding on the necessary information to resolve the issue, and for which the applicant has made a commitment to take an action (e.g., make a specific revision to the application).

The SER that has completed Phase 2 should be a complete and comprehensive product that documents the staff's review and conclusions, and can be issued on a chapter or section basis. The SER should clearly identify the Open Items and Confirmatory Items. Once this document has been completed and issued to the Advisory Committee on Reactor Safeguards (ACRS) for review, Phase 2 is complete.

### **Phase 3: Advisory Committee on Reactor Safeguards Subcommittee Review of Safety Evaluation Report with Open Items and Meetings**

The ACRS performs its review of the application as well as the staff's SER with Open Items. This phase provides the ACRS the opportunity to discuss the application and the staff's findings in meetings that include the applicant and are open to the public unless proprietary or security information will be discussed. Typically, separate meetings of both the Subcommittee and the

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<sup>1</sup> The RAIs should be shared with the applicant for proprietary review, etc. These RAIs are termed "Advance RAIs" and are the milestone for considering Phase 1 to be completed. See NRO-REG-101, Rev. 2, for more information on Advance RAIs.

Full Committee are held for each chapter of the SER with Open Items. Once the Subcommittee meeting has been held, Phase 3 is complete.

#### **Phase 4: Advance Safety Evaluation Reports and Meetings**

NRC staff evaluates the applicant's responses to each Open Item and, if it is acceptable, explicitly closes the Open Item in the Advance SER. Staff should also consider any comments formally received from the ACRS. The document should explain how the staff made its determinations along with the technical and legal basis for these determinations. Staff should also confirm and close the Confirmatory Items. Some Confirmatory Items may remain until a final application revision is issued in Phase 6. Once the Open Items have been closed and the Advance SER issued, Phase 4 is complete.

#### **Phase 5: ACRS Full Committee Review of Advance SER and Meetings**

The ACRS performs its review of the Advance SER in the same manner as discussed in Phase 3. This phase provides the ACRS the opportunity to discuss the application and the staff's findings in meetings that include the applicant and are open to the public unless proprietary or security information will be discussed. Typically, separate meetings of both the Subcommittee and the Full Committee are held for each chapter of the Advance SER. After the last Full Committee meeting, the ACRS provides a letter to the Chairman that either recommends approval of the application, or identifies unresolved issues associated with the application. The staff should consider the formal comments received from the ACRS and revise the Advance SER if necessary. Once the Full Committee meeting has been held, Phase 5 is complete for the individual sections and chapters. Phase 5 is complete for the application following receipt of the final ACRS letter and the staff's response to the ACRS letter is issued.

#### **Phase 6: Final Safety Evaluation Report with No Open Items**

After the staff incorporates any recommendations from the ACRS, the project manager and supporting staff develop the Final SER. The Final SER is issued to the applicant and issued publicly. Once the Final SER has been made publicly available, Phase 6 is complete.

## Enclosure 2: Phase 2 Completion Examples

### Questions to Consider when Determining Whether to Proceed to Phase 3

Phase 2 Question	If the Answer is “No”	If the Answer is “Yes”
Q1 - Could substantial review and/or additional RAIs still be needed?	Proceed to Q2	Hold in Phase 2
Q2 - Have all RAIs for the SER been addressed/closed?	Proceed to Q3	Proceed to Phase 3
Q3 – Is there a closure plan for this issue?	Hold in Phase 2	Proceed to Phase 3

### Examples of When to Hold in Phase 2

1. The applicant thinks it has completed its actions on an RAI response because the staff agreed with its RAI response during discussions. However, the applicant failed to provide application markups of the discussed documentation changes. This may occur because the applicant did not understand the need or because the applicant has not agreed to do so. Therefore, the staff has not agreed with the applicant on the specific information needed to close out the RAI.
2. An RAI response provides a general schedule of when the applicant will provide specific data the staff requested. The RAI response does not specify the specific type of data it will provide in one area, or commit to a reasonable delivery date to provide it, because it claims that it is dependent on the results of an unpredictable data analysis sequence. Therefore, there is no clear schedule or agreement on the specific information that is needed.
3. An RAI question was only partially addressed. The applicant states that the remaining portion of the RAI response will be addressed through testing or analysis. The applicant did not specify the testing or analysis protocol or strategy nor did the staff request that it be submitted. Therefore, substantive review or additional RAIs may still be needed.
4. The applicant provided all RAI responses except in one area. The future RAI response will be extensive because after the applicant evaluated the situation, it decided that it needed four additional months to provide a full response in the technical area. This additional information will not be received until after the Phase 2 due date and may need substantive review or additional RAIs to reach a finding. Therefore, substantive review or additional RAIs may be needed, and there may not be enough time to complete the Chapter SER development and processing before the due date.

### Examples of When to Proceed to Phase 3

1. The applicant has satisfactorily responded to RAIs, but has not updated the application. If the applicant and staff have agreed upon the content and scope of the application changes, then the review can proceed to Phase 3 and address the remaining items as confirmatory.

2. The applicant has not responded to all the RAIs; however, the path forward is clear and the applicant has provided a detailed closure plan and schedule that supports issuance of the Phase 2 SER with Open Items. The material to be submitted by the applicant is not expected to be complex or require substantive review. Staff may proceed to Phase 3 with Open Items.
3. The applicant has not responded to all the RAIs; however, the path forward is clear and the applicant has provided a detailed closure plan and schedule. The closure plan includes additional testing required to resolve the issue and it will not be performed until after the Phase 2 schedule. If there is high confidence that the testing can be completed successfully and on schedule, and the testing is not expected to produce new results or information (i.e., the testing is expected to be confirmatory) and a substantial staff review of the testing material and data is not expected, then staff may proceed to Phase 3 with an Open Item.

**MEMORANDUM TO THOSE ON THE ATTACHED LIST DATED JUNE 29, 2018**

SUBJECT: OFFICE OF NEW REACTORS PHASE DISCIPLINE

Director, Division of Engineering and Infrastructure, NRO

Director, Division of Safety Systems, Risk Assessment and Advanced Reactors, NRO

Director, Division of Construction Inspection and Operational Programs, NRO

Director, Division of Engineering, NRR

Director, Division of Safety Systems, NRR

Director, Division of Preparedness and Response, NSIR

Director, Division of Physical and Cyber Security, NSIR