

January 8, 2010

MEMORANDUM TO: Nilesh C. Chokshi, Deputy Director  
Division of Site and Environment Reviews

Anthony H. Hsia, Deputy Director  
Division of Site and Environmental Reviews

Mark D. Lombard, Deputy Director  
Division of Safety System and Risk Assessment

Laura A. Dudes, Deputy Director  
Division of Engineering

John R. Tappert, Deputy Director  
Division of Construction Inspection  
and Operational Programs

Andy C. Campbell, Deputy Director  
Division of Construction Inspection  
and Operational Programs

FROM: Frank M. Akstulewicz, Deputy Director */RA/*  
Division of New Reactor Licensing

SUBJECT: PROCESS AND TIMELINE FOR CLOSURE OF OPEN ITEMS AND  
CONFIRMATORY ITEMS IN SAFETY EVALUATION REPORTS

Enclosed is a process for prompt closure of Open Items and Confirmatory Items in Safety Evaluation Reports. This memorandum describes a process that delineates timeliness and quality expectations. The feedback that you provided on November 30, 2009, and during the NRO Program Meeting held on December 1, 2009, has been incorporated into the process. When conflicts arise between competing priority projects that cannot be resolved promptly between the respective branch chiefs, those conflicts should be brought to my attention for resolution.

DNRL will begin to implement this procedure effective January 15, 2010. The enclosed process will be incorporated into the next update of the NRO Licensing Process Plan.

Enclosure:  
As stated

CONTACT: Serita Sanders, NRO/DNRL  
(301) 415-2956

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## **LICENSING PROCESS FOR RESOLUTION OF OPEN ITEMS AND CONFIRMATORY**

### **ITEMS**

#### I. Purpose

The purpose of this procedure is to outline a process and instructions for the prompt review and closure of an Open Item (OI) or a Confirmatory Item (CI). The process is essential to the Office's ability to effectively track receipt, review and closure of current open items and confirmatory items in the Phase 4 established schedules. Early review and development of associated safety evaluation input is intended to mitigate the need for late-developing requests for information that frequently happen as the technical staff prepares their safety evaluation inputs.

#### II. Roles and Responsibilities

Chapter Project Manager (PM) – The chapter PM will communicate with the applicant and the technical staff to ensure that responses to OIs are successful. The PM will use the staff's OI input to update the safety evaluation report (SER) with OI chapter issued to the applicant (chapter draft). The chapter PM, in consultation with the assigned technical staff, will review subsequent revisions of the document to determine if CIs can be closed and provide an update to the chapter draft, accordingly. The chapter PM will maintain and update the chapter draft to reflect the latest status of OIs and CIs.

Technical Reviewer – The technical reviewer assigned to the document review will work with the chapter PM and the applicant to achieve a successful response to the OI and then provide the chapter PM with appropriate closure wording and verify that CI commitments have been reflected in the final version of the document.

Licensing Branch Chief – The licensing branch chief will work with the PM and the technical branch chief in cases where schedule or other expectations are not met to establish alternate expectations.

Technical Review Branch Chief (TRBC) – The TRBC will monitor their staff's performance related to OIs and CIs closure to assure that they meet the timeliness and quality expectations stated below or provide remedial measures as needed. The TRBC will assist in establishing alternate timeliness expectations as needed.

Deputy Director of Licensing Operations (DDLO) – The DDLO will establish alternate due dates in consultation with other division deputy directors, in the event that alternate due dates cannot be established at the branch level.

Deputy Director of the Technical Review Division – The deputy director of the assigned technical division will assist in establishing alternate timeliness expectations in the event that timeliness expectations cannot be agreed upon at the branch chief level.

ENCLOSURE

### III. Expectations

#### A. Timeliness Expectations

The timeliness expectations are expressed, below, in business days where “T” is the day of the applicant’s response and the “number” is the total time elapsed in business days:

1. T-5 Five business days prior to the expected receipt of response to an OI, the chapter PM will alert the technical reviewer to expect a response.
2. T=0 Response to OI or CI received
3. T+3 Upon receipt of the OI response, the chapter PM will promptly provide the response to the technical reviewer. The planning expectation is that the chapter PM can provide the response within three business days.
4. T+18 Within the next 15 business days, or within a mutually established timeframe, the technical reviewer will complete a preliminary review of the OI response. The review should be of sufficient scope and depth to determine one of the following: (1) the response appears to be acceptable and expectations for OI closure have been met; (2) the response addresses some portion of the OI; however, expectations for OI closure have not been met; or (3) the OI response is unacceptable and expectations for OI closure have not been met. For cases (2) and (3) the technical reviewer will discuss any deficiencies with their branch chief and provide the PM with the deficiencies in writing via e-mail within the established 15 business days, or within a mutually established timeframe negotiated between the PM and the TRBC.
5. T+21 Following receipt of the technical branch assessment, within the next three business days, the chapter PM will either inform the applicant that the OI response is acceptable or reengage the applicant to resubmit another response to adequately address the staff’s concern such that there is a success path for resolution of the OI.
6. T+41 Within the next 20 business days, the technical reviewer will provide the chapter PM with a revised safety evaluation input with the new closeout language for the OI, following review by the TRBC, or establish an alternate submittal schedule for the safety evaluation input.
7. T+46 Within the next five business days, the chapter PM will update the chapter draft to include the closeout wording for the subject OI.
8. If timeliness expectations cannot be met, the licensing branch chief and DDLO (as needed) will promptly work with the technical staff to establish and monitor performance against alternate expectations.
9. If a contractor is involved in evaluating the response to the OI and they cannot support the above schedule, the chapter PM will promptly develop an alternate review schedule in consultation with the technical reviewer (and/or the TRBC), as appropriate for the situation, and communicate the alternate review schedule to all stakeholders.
10. For CIs, the chapter PM, in consultation with the technical reviewer, will promptly review the subsequent change to the document, provided in the latest revision, to ensure that the CI can be closed. The chapter PM shall promptly update the chapter draft upon CI closure.

## B. Quality Expectations

Quality expectations for the SE inputs have been previously established. Specifically, the OI closure input should provide the basis as to why the resolution meets the applicable requirements. OI safety evaluation input from the technical reviewer that doesn't meet quality expectations will be promptly returned to the responsible TRBC for remediation.

## IV. Procedure.

- 1 The chapter PM will engage the applicant on proper scope, content and schedule for response to an OI in cooperation with the technical reviewer via phone calls and meetings as needed. The chapter PM will be aware of, and comply with Office Instructions concerning the handling of draft information (COM-203, Revision 2). Public meetings to discuss OI responses should be considered to assure closure of OIs and expedite schedules.
- 2 The chapter PM will monitor progress on OI response schedules with the applicant frequently but not less than on a weekly basis.
- 3 Upon receipt of the OI response, the chapter PM will work with the technical staff to ensure that (1) the applicant is informed of the likely outcome (acceptable or not acceptable); (2) within four weeks of determining that the OI is resolved, a revised write-up of the respective SER section is obtained and SER input quality expectations have been met; and (3) the chapter draft is updated within the established schedules. The licensing branch chief will be promptly alerted if expectations are not met; the DDLO will be informed by the licensing branch chief, if expectations are not met. For unacceptable OI responses received from the applicant, the chapter PM will (1) reengage the applicant to obtain a submittal that adequately addresses the staff's concern and (2) determine the root cause(s) of the unsuccessful response, and (3) take preventive measures to prohibit reoccurrence.
- 4 If the technical reviewer is not able to meet the timeliness expectations, the chapter PM, and if necessary the licensing branch chief, will engage the cognizant TRBC to promptly establish alternate review schedules, which will be promptly communicated to the technical reviewer, the chapter PM, and the DDLO. The chapter PM, and the licensing branch chief if necessary, will monitor alternate expectations to ensure a successful outcome.
- 5 If decisions on an alternate review schedule cannot be reached at the branch chief level, the DDLO will promptly engage the deputy director of the technical review division to obtain resolution. The review schedule will be communicated to all stakeholders.
- 6 For CIs, the chapter PM, in consultation with the technical staff, will review the subsequent change to the DCD to ensure that the CI can be closed. If the CI can be closed, the chapter PM will update the chapter draft in a timely manner and obtain technical staff concurrence via final chapter close-out concurrence. If the CI cannot be closed, the chapter PM will promptly engage the applicant to initiate remedial actions.
7. Conflicts that arise between review resources and schedules for Group 1 applicants, which cannot be resolved by discussion between the affected licensing and technical review branch chiefs, should be elevated promptly to the deputy director for licensing operations for resolution.