

NRC Observations (Data/Examples)

	Process Observations	Technical Observations
<u>Topical Report (TR)</u> <u>Staff Turnover Rates</u>	New staff, promotions, retirements, office reorganizations: These transitions can prolong the review schedule and cause inconsistent staff expectations for those assigned to complete TR reviews. Specifically for technically complex TRs that involve several branches – or even NRC offices.	Frequent turnover raises the potential to identify new technical issues if the new reviewer has a different perspective - Or if the new reviewer did not “trust” the level of review that the prior reviewer performed. Similar questions that have already been resolved, or may be raised again, result in delays. Depending upon the transition between the new and prior reviewer, the new reviewer may not realize that their questions have already been reviewed, evaluated, and resolved.
<u>TR Acceptance Reviews</u>	Questions have been raised regarding the NRC staff's acceptance or rejection of a TR, and the timing of these steps. NRC proposed guidance has been included in Section 4.2.4 of LIC-500, Draft Rev. 4, “Topical Report Process.”	
<u>Request For Additional Information</u>	RAI Timeliness. An emergent technical issue(s) may divert industry focus from a TR review. The NRC staff are then placed in a position where they are waiting for months for an RAI response. By the time the RAI's arrive, the time that the technical staff allotted toward support of the TR review, has been filled with other workload obligations. NRC proposed guidance has been included in Section 4.2.6 of LIC-500, Draft Rev. 4.”	Multiple rounds of RAI's may be necessary depending upon the complexity of the issue. The responses to the first round of RAI's may raise additional questions.
<u>TR Submission</u>	A consistent process should be developed for the submission of all TRs, regardless of the owners group or	

	<p>vendor. Some TRs are submitted using electronic submission to the Document Control Desk. If it's not done correctly that creates delays in the PM's ability to obtain an ADAMS Accession number for the TR. The ADAMS Accession number for the TR is needed to request a TAC.</p> <p>NRC proposed guidance has been included in Section 4.2.2 of LIC-500, Draft Rev. 4.</p>	
<u>TR Review Fees (Fee Waivers)</u>	<p>Applicability of a fee waiver to TRs that had previously been withdrawn and later resubmitted for NRC review. Updated guidance should be developed regarding the process to coordinate the review of a TR which requests a fee waiver – or is relying upon a previously approved fee waiver request.</p> <p>NRC proposed guidance has been included in Section 4.1.2 of LIC-500, Draft Rev. 4.</p>	
<u>*Topical Report (TR) Objective Is Ambiguous/Unclear</u>	<p>It is not always clear what the NRC staff is being asked to approve in a TR. When the scope of the TR is not clear (or changes during the staff's review of the TR), this impacts the acceptance review process as well as the preparation and issuance of the RAI's {multiple rounds} and Safety Evaluation (SE).</p>	<p>A poorly defined objective in the TR can result in multiple rounds of RAI's, or SE's which don't address the technical issues that the owners group expected.</p>
<u>Role of Lead Technical Branch</u>	<p>LIC-500 refers to a lead technical branch. For TRs that involve multiple branches, additional guidance should be developed to ensure that the role of a lead technical branch is clearly defined. This role may vary based upon the technical issue and scope of the review.</p>	
<u>*Draft SE's (General Comment)</u>	<p>Vendors/owners groups use this as an opportunity to provide additional information/debate, or negotiate parts of the Draft or Final SE.</p> <p>NRC proposed guidance is provided in Section 4.2.8 of LIC-500, Draft Rev. 4.</p>	<p>The SE should not be the place to debate the merits of the staff's review. Frequent discussions should be taking place long before the Draft SE is issued, to support issue resolution. In the event that there are technical differences that can't be</p>

		resolved, a standard process should be developed to ensure that senior management is informed early in the review of the staff's recommendations/findings.
<u>Draft/Final SE (limitations and conditions)</u>	<p>The limitations and conditions located within the SE may be interpreted by licensees as too high-level. This leads to different interpretations by industry. The limitations and conditions need to be explicit.</p> <p>NRC proposed guidance is provided in Section 4.2.7 of LIC 500, Draft Rev. 4.</p>	
<u>TR and TSTF Coordination</u>	<p>TSTFs are being submitted to the NRC long after the TR SE is issued. That doesn't provide enough time to ensure coordination between the TR and TSTF technical reviewer(s). In addition, some TSTFs contain new information that was not considered during the TR review.</p> <p>NRC proposed guidance is provided in Section 4.2.1 and 4.2.3 of LIC-500, Draft Rev. 4.</p>	
<u>*TR Changes (prior to approval vs. after approval)</u>	<p>Inconsistent approach among owners groups and vendors. Agreed upon changes to a TR are not always formally submitted to the NRC in the form of a revised TR before NRC staff approval via an SE.</p>	