

June 28, 2016

MEMORANDUM TO: Kevin Hsueh, Chief  
Licensing Processes Branch  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

FROM: Brian Benney, Senior Project Manager */RA/*  
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SUBJECT: SUMMARY OF APRIL 11, 2016, MEETING WITH THE NUCLEAR  
ENERGY INSTITUTE TO DISCUSS LOW RISK AND LOW SAFETY  
SIGNIFICANT COMPLIANCE ISSUES

On April 11, 2016, a Category 2 public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) and representatives of the Nuclear Energy Institute (NEI) at NRC Headquarters, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland. The purpose of the meeting was to discuss improving the efficiency of handling low risk compliance issues. The meeting notice and agenda are available in the Agencywide Documents Access and Management System (ADAMS) under Package Accession No. ML16109A106.

In its opening remarks, the NRC staff shared the following draft problem statement and definitions for discussion.

“The NRC staff is looking to develop a risk-informed approach for low risk and low safety significance design compliance issues that are related to technical specification operability, while providing adequate protection and timely corrective action.

**Draft Definitions:**

- Design Compliance Issue: the licensee has a technical specification related structure, system or component (SSC) or a non-technical specification support SSC that fails to meet a current licensing basis design requirement (e.g., an environmental qualification, a design requirement necessary to meet the accident analysis, or GDC 2/plant-specific equivalent design requirement, etc.).

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- Timely Corrective Action: the time for corrective action should be minimized to the extent practicable because enforcement discretion is being exercised for the current licensing basis (CLB) design requirement. Accordingly, the licensee should restore compliance with the current licensing basis at the first available opportunity. Restoration can be through hardware modification or by changing the licensing basis through applicable regulatory processes (e.g., license amendment, exemption, 50.59, etc.).

- Low risk and low safety significance: proposed definitions under development.”

During the discussion, the following questions and issues were discussed:

- On the problem statement/definitions – would the process apply to low risk non-conforming conditions?
  - The staff noted that the non-conforming condition must have a nexus to operability, or else the process would not be needed, since the licensee could simply handle it through their corrective action program. The staff also noted that it does not matter who discovers the condition (licensee or NRC) for the process to apply.
  - If interpretation of the current licensing basis (CLB) is the issue, then is corrective action required or not? The staff indicated that clarification of the CLB may be needed to resolve the issue. Clarification could be accomplished using the appropriate regulatory process (e.g., 50.59, licensing amendment, etc.)
  - It was noted that if the licensee disagrees that the issue is part of its CLB, then the process would probably not work until the NRC had done its due diligence and determined that the issue in the licensee’s CLB (e.g., completing a Task Interface Agreement (TIA)).
  - The staff is still working to define the terms low risk and low safety significance. Defining these terms will be an agenda item on the next workshop/meeting.
- NEI asked, “What would be entry point and what would be the process and how often would this process be used?”
  - Although there is no bases for this number, Region 2 added that the process is expected to be used 5-10 times a year.
  - Ultimately, it was concluded that the entry point would probably be when either the licensee or the NRC concluded that the SSC was inoperable.
- Can any individual raise an issue? If either the NRC or the licensee believes the SSC is inoperable, the process could be applicable. The licensee does not have to agree with NRC to enter this process, but the licensee would have to agree to take corrective action.
- If the licensee is in a Technical Specification (TS) Limiting Condition for Operations (LCO) due to the non-conformance with a CLB design requirement, then what would the NRC be exercising discretion against? The NRC would be exercising discretion against design requirement. Frequently, these design issues only affect a specific set of circumstances (e.g., tornado missile hitting a specific part, like an exhaust stack, of a SSC), so the most effective way for the staff to give discretion is by granting it against the design requirement for the SSC (or part of the SSC) in question. Granting discretion against the TS LCO or Completion Time (CT) would require specific clarification by the staff as to when and how the discretion is being applied. This could be potentially more confusing to operators. The process would only apply to a question on operability related to a nonconformance with a design requirement.

**Case Studies Discussion:** Significant discussion was held around the case studies and how the process might work for the example cases. Some of the insights identified include:

- The licensee would have to make a case for low risk/low safety significance and the associated basis for that conclusion.
  - May need a two-step process: If LCO has a 72 hour CT, then it gives licensee some time to make decision whether to enter this process, and to develop the technical basis for demonstrating low risk and low safety significance. However, a licensee may need to request enforcement discretion to gain sufficient time to perform the analysis for an LCO with a short duration CT.
  - Similarly, the licensee may also need additional time to determine the path forward for corrective action.
  - Compensatory measures will likely need to be implemented to manage risk.
- What is the time frame or when does the clock start? The clock starts at the time of discovery from (i.e., the time licensee decides the SSC is inoperable).
- The staff indicated that the purpose of this process is for the licensee to focus on taking timely corrective action, instead of putting extensive resources into trying to reach agreement with the regulator.
- When licensee and/or NRC agrees a violation exist would that be one entry point to this process?
- The NRC staff are thinking that the process would be a form of long term enforcement discretion. It will likely be documented similarly to the current NOED process.
- Some issues may not be low risk/low safety significance initially; however, If the licensee can show that a procedure, placement of additional equipment, or other compensatory measures can lower the risk below the threshold level, then this process can be entered.
- To receive discretion, the licensee must restore compliance with original requirement, or utilize the appropriate regulatory process (e.g., exemption, license amendment, etc.) to change the requirement.
- The process would allow for separation of past risk from future risk. Specifically, if the risk going forward is low (e.g., due to interim corrective actions or compensatory measures), then the process would be applicable even though the risk in the past may have been high.
- The NRC staff indicated that timely corrective action should be at the earliest opportunity due to the fact that discretion is being exercised.
- Can the process be entered before declaring SSC inoperable or only after declaring SSC inoperable? The staff noted that the process only applies if the issue affects operability. Design issues do not necessarily create an operability issue. The design issue is not of immediate concern, as long as the SSC is capable of performing its specified safety function.

Some challenges to the new process that need to be addressed were highlighted in the discussion. These challenges included:

- A licensee may need to review the licensing bases to determine if they meet the criteria for the process (which could require some time prior to entry into this process). At the end of the review, the licensee may determine that this process cannot be applied, and as a result, they lost time that should have been applied to taking adequate action.
- Regarding the NRC's forward fit policy, would license amendments submitted to take corrective action under this process be considered voluntary? The staff stated that they would not. The goal is to restore compliance with the current licensing basis in a timely manner, not to upgrade the licensee to current standards.

- How is time needed for corrective action determined?
- How cumulative risk is tracked needs to be addressed. Licensees can monitor this using its online risk model.
- Could this create a process that circumvents the TIA process and back-fit cost benefit analysis? The staff acknowledged that resources would be saved by not conducting a TIA and licensees could be forced to fix things that are not required by its licensing basis if the staff does not perform the full evaluation up front.
- Could corrective action be based solely on risk? The staff noted that this is a risk-informed process not risk-based. Regulatory Guides 1.174 would apply to any license amendments received.
- How would the process address the denial of a license amendment that was submitted as the corrective action? What would happen to the corrective action timeline, and what would be the licensee's status? An additional concern is that the licensee is losing time.

It was agreed to hold another meeting/workshop within two months. The focus of the next workshop will be the low risk and low safety significance definitions and an outline of how the process will work. A discussion will also need to be held about the risk threshold.

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