

NRC Review Comments Concerning NEI's RIRP Rev 2

The NRC has completed its review of NEI's Regulatory Issue Resolution Protocol (RIRP) Flowchart, Rev 2 (ML091310067). The below comments and questions are consolidated as received from various NRC Divisions.

GENERAL COMMENTS

1. It is not clear what the industry is proposing. The flowchart needs a guidance document. The industry should provide the purpose of the RIRP and clearly define the scope of issues that would be subject to a RIRP. For example, inspections should only follow the Reactor Oversight Process for resolution, not both the ROP and the RIRP.
2. The existing ROP includes many, if not most of the steps included in the RIRP. The ROP has on-going working groups to resolve issues, and ensure regulatory authority. When inspection findings are considered, both the program office and the Region are engaged and working the issue. As needed, the ROP team may include other offices such as OE, etc. During recent working groups, there were no significant issues with the ROP identified by stakeholders. The staff believes the ROP is working, and there is no basis for implementing the proposed protocol for inspection findings.
3. The proposed RIRP protocol is intended for generic issues identified during plant-specific licensing reviews and inspections that have multi-unit applicability. For license renewal, generic issues identified during renewal reviews are currently resolved through the license renewal interim staff guidance (LR-ISG) process. A proposed revision to the LR-ISG process was recently submitted for public comment. Comments received did not identify any issues related to regulatory uncertainty and inefficiency of license renewal reviews. Additionally, this existing LR-ISG process includes many of the steps identified in the proposed RIRP process. Therefore, the staff believes there is no basis for the implementing the proposed protocol for license renewal reviews.
4. The proposed RIRP appears to be an additional process, independent of and to some degree superseding existing regulatory processes (e.g., Management Directives, Generic Safety Issue process, procedures for issuing orders, etc.); both internal and external. How this protocol fits within the NRC regulatory and internal operational framework needs to be further developed to ensure it does not conflict with the NRC regulatory authority, responsibilities, and efficient operations.
5. The potential issues areas identified as a partial listing is very broad and covers nearly every aspect of NRC licensing-related interactions with licensees. This approach is too broad and needs to be narrowed to a selected number of problematic areas, with a bases for why these areas cannot be resolved via the existing regulatory framework.
6. It is not at all clear what the real need of this process is. In discussion with DPR, this is to replace the Regulatory Issue SCREENING Process with a "resolution" protocol.

However, it remains an extra process, as we see it operating in parallel with other industry and NRC processes. In addition, there is no method described to insure industry commitment to any resolution, as is the case for existing processes.

7. Using this process the NRC will have to make special efforts to involve public stakeholders to avoid potential negative perceptions on favoritism (e.g. plenty of advance notice for public meetings, ensure the meeting purposes are well defined, explain terms, etc.) How the NRC's priorities on specific issues are defined needs to involve the public stakeholders to ensure that our value of independence is maintained. An unintended consequence is that this process may facilitate too close a working relationship between technical agency reviewers and licensees. We must ensure that the public is not excluded from these discussions and relationships.
8. While openness, clarity, and regulatory independence of the regulator are very important, the RIRP appears to compromise these principles of good regulation by involving industry group and licensee representation throughout the process; including a "joint" role in screening, prioritization, evaluation, and implementation. In addition, the protocol does not involve any other public stakeholders beyond individual licensees and industry groups. To achieve and maintain openness, this protocol needs to include other stakeholders throughout the process, including the ability to identify issues, screen issues, evaluate issues, and be represented in the ultimate resolution of issues. The protocol needs to establish how other stakeholders will be allowed active participation in all of these areas.
9. The RIRP identifies "attributes" that differ from the NRC Organizational Values. The staff cannot commit to performing regulatory activities in a manner using attributes that are not in alignment with the NRC Organizational Values.
10. The RIRP attributes should be defined.
11. Does industry plan to discuss the RIRP at the upcoming licensing forum?

GENERAL PROBLEM STATEMENT

1. The problem statement appears to focus on safety issues, and does not address risk or security. The problem statement should be updated to reflect the types of issues that may be considered by the RIRP.
2. The problem statement needs to address the need for the RIRP.
3. The first sentence under General Problem Statement: "The focus on nuclear safety can be affected when issues identified at one plant affect multiple plants ..." This statement appears to have no basis. It does not say how the focus is affected or whose focus is being discussed. (It could be argued that the NRC focus on an issue increases when multiple plants are affected - contrary to the implication in the statement.) In addition, "issues" should be changed to "regulatory issues" since that is the topic of the RIRP.

4. An initial important step is missing from the flow chart for this proposed process: issues should be screened to see if an existing agency process exists. The RIRP should not be used to by-pass existing processes that are more appropriate. An example would be if a licensee was not complying with an existing regulation.
5. The second paragraph clearly identifies the principles of good regulation, but emphasizes regulatory uncertainty and inefficiencies. This must be updated to ensure the regulatory aspect of NRC's independence and regulatory authority are clear. In all cases, the NRC has final decision-making authority.
6. The third paragraph identifies a need to establish "more effective use of existing processes to resolve issues" but does not provide an explanation of the problems or processes that are identified as being ineffective. Therefore, the staff cannot determine if the proposed protocol process would address and resolve the concerns.
7. The third paragraph discusses the protocol as a means for more effective use of existing processes to resolve issues. However, the flowcharts do not address any existing processes or ways to improve existing processes.
8. The problem statement should state why such a process is needed. It should also address what NRC programs are not needed because of the proposed protocol or why this is not duplicative of an existing regulatory process.
9. Recommend that for the list of issue-resolution attributes in the General Problem Statement: (1) adding "Nuclear Safety" at the top of the list and (2) deleting either "certainty" or "predictability" (or combining them). In addition, it is not clear that these attributes are complete and aligned directly with the NRC vision of good regulation.

RIRP LIFE CYCLE

1. The Life Cycle starts out with the identification of a regulatory issue. There needs to be more emphasis on the aspect of generic applicability to multiple plants and that current NRC processes are not efficiently resolving the issue.
2. What is a "larger implication?" This first "cloud" is too ambiguous.
3. The life cycle should more clearly denote at what point NRC involvement is required. The emphasis should be on industry developing solutions to generic issues.
4. The life cycle phases do not match the flowcharts. The life cycle has an evaluation phase and the flowcharts have an analysis phase.
5. The evaluation phase of the life cycle details gaining industry commitment, but the analysis phase flowchart is not clear on this. There must be industry commitment to any resolution from the RIRP.

RIRP TIMELINE

1. The timeline needs to detail at what point the NRC is engaged.
2. There needs to be a clearer distinction of the industry resolving issues before NRC engagement.
3. Recommend deleting "and memorialized" in two places. This is non-standard phrasing and is redundant to "institutionalize."
4. The box "sponsor concurrence" is ambiguous. Recommend changing to "concurrence by sponsor" if that is what is meant.

IDENTIFICATION PHASE (A)

1. Better definitions are needed for the sources of potential RIRP issues. Most of the sources have their own, well-defined course of action (NOEDs, 50.72 reports, etc). The flowchart does not clearly delineate when the RIRP process would be implemented in lieu of these other processes. In most instances, the RIRP should not be utilized.
2. There must be a defined method for industry to identify issues. If an issue is occurring at multiple plants, how is industry identifying this and determining it is generic? To date, industry has not been able to identify generic issues across the fleet.
3. Licensing reviews have a well-defined and working process. For license renewal, issues identified are resolved through the license renewal interim staff guidance (LR-ISG) process. The existing LR-ISG process includes many of the steps identified in the proposed RIRP process. The staff believes there is no basis for implementing the RIRP for license renewal reviews.
4. Inspection results have a well-defined and working process, the ROP. There are working groups currently in place to consider inspection issues, and the RIRP should not displace established processes that work. If industry has identified areas of the ROP that need adjusting, they should pursue this through the established process. Inspection results should not be a source to the RIRP.
5. The RIRP should consider inputs from other governmental bodies, such as DHS.
6. The box for a licensee to enter the appropriate process in parallel with the RIRP is misleading. If the answer to the question is that immediate action is necessary, the licensee should take that action immediately. The RIRP may not need to be entered, and if so, it should occur later, so as not to detract from the licensee's immediate action.
7. The "RIRP eligible" box needs some criteria for how to answer the question and what group provides this eligibility screening (i.e., the issue identifier, the NRC, a joint task

group). There is no guidance on what makes an item eligible for this protocol prior to its actual screening. Without established criteria, all identified issues will be forwarded to the screening phase.

8. Some of the logic paths terminate with an “END” block. It is not defined what that means to the user of the process.
9. There needs to be an issue problem statement developed in this phase. If an issue is identified, it must be defined and some scope applied to allow correct identification of the issue and to allow pass-through to the Screening Phase.
10. The identification phase should address the following:
 - what is eligible to enter this process
 - what should not enter this process
 - what other agency inputs are required
 - tracking
 - priority

SCREENING PHASE (B)

1. The early identification of potential joint problem solving should be removed in the Go/No Go block. The NRC is an independent regulator, and although the RIRP may allow both NRC and industry to present opposing viewpoints and resolutions for consideration, the RIRP should not be construed that the NRC and industry are “jointly” resolving problems. The NRC retains final decision-making authority.
2. There must be established screening criteria.
3. The protocol considers “cost-benefit” as a factor in the decision-making process. The staff makes its regulatory decisions based on safety. Therefore, a cost-benefit consideration should not be factored into the screening of regulatory issues.
4. The Prioritization point values need to be reviewed against real cases to ensure appropriate prioritization values as well as proper setting of the Priority value (the yes/no block).
5. No basis is given for the prioritization values and some seem to be contradictory to the NRC’s regulatory responsibilities (e.g., addressing compliance issues). For example, safety significance, shutdown issues, and cost-benefit are determined to be of greater value than risk significance, compliance, and operability with no explanation for these values. Further, there is a management override capability included that appears to allow various levels of NRC and/or industry management to decide to pursue lower priority issues without justification. It is not clear in what framework these values would be applied. Some sort of multi-attribute decision process is inferred, but a great deal of work would need to be done before a meaningful “priority” could be assigned.

6. The decision box "priority greater than or equal TBD" is a simplistic approach to decision making that appears to allow "resource availability" scores (which can be negative) to offset safety or risk significance.
7. The "yes" output of the "priority greater than or equal to TBD" box includes "problem statement (scope)." This seems out of place, as a good characterization of the problem is essential to enable proper screening. This problem statement should be determined prior to entering the screening phase.
8. There needs to be a clear definition and description of when and why NRC must be engaged.
9. The industry should clarify the details of the proposed "management override." This would include a discussion of the need for "management override" and when it could potentially be used. It must clearly state that NRC management has the final decision authority. NRC final decision-making authority should be defined and similar to the ROP issue resolution, at the NRC Division Director level.
10. The decision box "management concur" is ambiguous as it does not indicate (1) whose concurrence is needed (NRC, industry, and/or other stakeholders) and (2) does not indicate what is being concurred with.
11. Security issues need to be added to the protocol.
12. There needs to be consideration of proprietary, OUO, and SGI information.
13. The Problem Statement specific to this phase needs to include a defined endpoint. The problem statement for each issue must be properly scoped to maintain focus on the issue.
14. Some of the logic paths terminate with an "END" block. It is not defined what that means to the user of the process.
15. As described in the General Problem Statement, this phase should identify the inefficiencies of NRC processes that led the issue to the RIRP.
16. It may be useful to run the reviews that promulgated the development of this process through the screening phase to see how it works and whether it achieves its goal.
17. The Screening Phase should address the following:
 - The acronyms LATF and RPWG should be defined.
 - Lower level issues should be dropped or not
 - How the screening decisions are made
 - Identify the resources requirements and budget requirements
 - Identify the level of NRC management and staff review and approval required

ANALYSIS PHASE (C)

1. This phase appears to challenge NRC's independence. The analysis phase appears to assume that the NRC and industry will always agree on a resolution. It is not clear that this will always be the case. If a "consensus" cannot be reached, it would appear that the NRC is still responsible for making a safety decision. This is not reflected in the analysis phase.
2. Relies on NRC/NEI coordination to get to the same endpoints at the same time. This may not be feasible for most cases. A separate step may need to be included if one party cannot complete its work within a reasonable time of the other group.
3. This phase must have a clear and understandable scope defined and applied to every issue. Issues must not be allowed to expand during the analysis phase.
4. This phase must take a problem statement from the Identification Phase and ensure the operability and regulatory requirements are defined and met by licensees.
5. This phase (or possibly the Screening Phase) needs to ensure inclusion of regional input when appropriate for issues involving areas such as inspections, oversight, operability, etc.
6. This phase must identify all the documentation requirements and peer review required for the issue and for the analysis.
7. Because of the analysis phase, industry or NRC may close the issue. This option should be reflected as an outcome of this phase.
8. If this phase closes an issue, there must be some method to document and ensure knowledge management of the issue and reasons for closure. This phase needs a block that leads directly to the documentation phase.
9. The evaluation phase of the life cycle details gaining industry commitment, but the analysis phase flowchart is not clear on this. There must be industry commitment to any resolution from the RIRP.
10. The flow chart section between transfers "C" and "D" is missing a decision box(es) prior to the "resolution agreement" box. At this point in the protocol, NRC and the industry (and presumably other stakeholders) would interact to discuss their evaluations and decisions regarding the issue in pursuing an agreeable resolution.
11. The flow chart appears to put NRC and industry (and no other stakeholders) on equal footing to agree that a resolution has been reached. Leaving out other stakeholders violates the "openness" principle of good regulation and makes industry equal to NRC, which violates the "independence" principle.

12. The protocol presumes that ultimately an agreeable resolution is reached for all parties. In reality, there may be issues in which the participants will decide to agree to disagree and not reach a mutually agreeable resolution. However, if the RIRP is meant to close outstanding issues, the NRC must have final decision-making authority and industry must commit to the resolution.
13. This phase must identify the level of NRC management and staff review and approval required.
14. This phase must include some form of public interaction, such as posting the proposed resolution in the Federal Register.

IMPLEMENTATION PHASE (D)

1. Under the implementation phase, it is not clear what is meant by “Joint NRC/Industry agreement” on the changes to the durable guidance documents. Will the NRC be reviewing plant modifications and industry training modules? Will the industry be reviewing generic communications? Additional guidance should be provided on what this constitutes since it could be broadening NRC’s review responsibilities or potentially compromising our independence.
2. The last block indicates joint NRC/industry agreement. This should reflect NRC acceptance of an industry developed resolution implementation plan.
3. There should be a block for industry corrective actions.
4. There should be a block for the development of implementation guidance.
5. There should be a block for the development of a timeline for each issue. The RIRP should have goals set to measure performance and gain closure.
6. The protocol relies on NRC/NEI coordination to get to the same endpoints at the same time. This may not be feasible for most cases. A separate step may need to be included if one party cannot complete its work within a reasonable time of the other group.
7. There is no recognition in the process for the other NRC regulatory processes, both internal and external, that might impact the agreed upon resolution, such as stakeholder petitions, differing professional opinion, non-concurrence, etc. These processes need to be identified and addressed within this protocol, or at least identified as potential impacts on the protocol resolutions.
8. There are a number of elements that do not correspond with perceived resolutions. For example, NRC implementation is indicated as possibly including research programs but no research is identified in the parallel industry implementation block. Where these two blocks may actually involve parallel activities, both blocks should include the element.

9. The implementation lists are provided as examples and cover a wide range. It should be narrowed to those aspects in which real resolution results would be expected. Otherwise, there is the potential to create a burdensome, resource-intensive outcome that is not consistent with the original prioritization of the issue.
10. The box on joint NRC and industry agreement on changes appears to place the industry in a role of overseeing and approving of NRC changes to guidance documents without other stakeholder involvement and seems to undermine the "independence" principle of good regulation.
11. This phase should identify whether regulatory commitments or license conditions are required to implement the issue resolution. For the RIRP to work, there must be fleet-wide industry commitment.

DOCUMENTATION PHASE (E)

1. Relies on NRC/NEI coordination to get to the same endpoints at the same time. This may not be feasible for most cases. A separate step may need to be included if one party cannot complete its work within a reasonable time of the other group.
2. The potential documents that might be revised by this process include rulemaking, which is governed by a clear regulation. If the outcome of the resolution is to revise existing rules or develop new rules, then the process for proposing such changes should follow the established regulatory process and not be invoked by a separate process that would appear to gain NRC and industry agreement prior to and without the benefit of inputs from other stakeholders.
3. Use of the phrase "durable guidance document" is confusing - it is non-standard phrasing, and the definition provided (a document that is managed with a change process) is counter-intuitive. The concept appears to be a "living" document rather than "durable."

EDITORIAL REMARKS:

1. "Industry" should not be capitalized unless the first word of a sentence.
2. The first instance of "memorialize" on the "time line" page is misspelled.