

# Regulatory Issue Resolution Protocol

## Lessons Learned

### **BACKGROUND**

Based on a Nuclear Energy Institute (NEI) White Paper (Regulatory Issue Screening Process – RISP) provided to the Nuclear Regulatory Commission (NRC) in October 2008 (Agencywide Documents Access and Management System (ADAMS), Accession No. ML082840106), NEI submitted a letter to Eric Leeds on December 12, 2008 (Accession No. 083520100), describing and requesting support and co-sponsorship of an NEI sponsored pilot project titled Regulatory Issue Resolution Process (RIRP).

Eric Leeds responded on January 30, 2009 (Accession No. ML090070024), acknowledging that the NRC staff believed that NEI's proposed RIRP process had positive aspects warranting further discussion. The process outlined numerous potential options that could be employed by industry to identify issues, and NEI was encouraged to act as a clearinghouse to identify and inform commercial reactors of the issues and work to facilitate their resolution with NRC.

The NRC letter concluded that the staff believed that the described RIRP process was a logical endpoint that the RISP whitepaper sought to achieve, and that the NRR Office Director would be a co-executive sponsor of the effort.

The first public meeting was held in February 2009, and it was agreed that this would not be a new process, but would rely on existing NRC processes. As such, it was deemed to be a protocol to ensure issues were addressed within NRC processes.

From the December 12, 2008, letter from NEI, the problem and solution were described as follows:

**Problem:**

An untimely resolution of issues from the lack of a common understanding of the regulatory process within industry, as well as the lack of a defined process for achieving closure.

**Solution:**

Enhance the consistency in the regulatory process and achieve timely resolution and closure of generic issues by implementing a new process [protocol]. A resolution process [protocol] that includes a problem statement, objective, success criteria to achieve closure, action items, and milestones designed to manage an issue to timely resolution. To map the resolution approach through the regulatory process to ensure consistency. A new process [protocol] to drive existing issues to closure, manage newly identified generic issues more effectively, and enhance understanding of and consistency in the regulatory process.

## ***LESSONS LEARNED FROM THE RIRP***

The following paragraphs identify the lessons learned from establishing the RIRP. To date, seven public meetings have been held to interact on the development of NEI's proposed methodology for solving generic issues and facilitate NEI's ability to inform the NRC of guidance document development. On May 7, 2009, it was decided that submerged cables would be piloted to test and inform further protocol development.

1. The RIRP would best serve the primary objective of managing an issue to timely resolution by building an inclusive regulatory basis to address an issue. The regulatory basis applicable to the solution should initially be constructed by the protocol to be as broad as possible. This will substantially increase the likelihood that the solution will be tailorable to as many individual licensees as possible while accounting for variations in the licensing bases.
  - a) Specifically, with respect to the regulatory basis, it is the NRC's responsibility to establish the regulatory basis and explain it to the industry's working group and answer questions if there is any confusion.
  - b) NOTE: The staff recognizes that there will be instances when the regulatory basis may need to be focused on the most probable or likely set of regulations in order to develop and effect the best generic solution. However, it is crucial to protocol objectives that this not be a roadblock early in the protocol issue resolution.
  - c) The staff recommends that this approach be developed and tested by trial(s), for outcome-based consideration regarding the need for explicit inclusion in the protocol and its supporting documentation.
  
2. The RIRP needs decision points or criteria that allows either party to determine whether the potential benefits support continued engagement on an issue, or to propose exiting the protocol. A decision to exit the RIRP could be due to any number of factors, such as, reliance on an established path forward, or a determination that the chosen activity was not correct for the RIRP.
  - a) The staff recommends that this be developed and tested by trial(s), for outcome-based consideration regarding the need for explicit inclusion in the protocol and its supporting documentation.
  - b) Based upon the experiential results, create clearly delineated ground rules for engagement on such issues.
  
3. To demonstrate the potential value commensurate with the dedication of NRC staff and industry resources, there is a need for the RIRP to clearly incorporate a Nuclear Strategic Issues Advisory Committee-like agreement or process for the adoption of each issue and throughout the implementation phase of the issue resolution. It should address both short term and long term activities needed to support the resolution for the vast majority of licensees that are affected.
  - a) The staff recommends that this process be developed and tested by trial(s), for outcome-based consideration regarding the need for explicit inclusion in the protocol and its supporting documentation.

## ***OBSERVATIONS FROM THE RIRP***

The following identify observations were made by the NRC staff during the development of the lessons learned from the RIRP pilot effort on submerged cables.

Focus and rigor needs to be applied to individual steps within the RIRP. For instance, the time to develop the problem statement could have been condensed if discussions regarding regulatory bases or other topics had been delayed until completion of the problem statement. This holds for the individual activities that comprise the RIRP. Greater control by project managers (PMs) to stay on track and remain focused. Capture in roles and responsibility section of protocol document.

Pre-existing NRC actions may not be the best candidates for the RIRP. The existing regulatory history may increase difficulty in development of the problem statement or completion of other activities due to a preconceived understanding of the issue. Greater scrutiny employed to selection and screening of RIRP issues. Capture in the screening criteria.

If a pre-existing action is undertaken there should not be a rehashing of completed and defined activities, e.g., during the cable pilot, the regulatory bases should not have been a topic for discussion at several meetings. It should have been explained by the staff one time, with an opportunity for industry to ask clarifying questions. Once the questions have been answered, the group should move on the problem resolution phase. Create clearly delineated roles, responsibilities, and ground rules for engagement.

Resolution may or may not include actual issuance of the durable regulatory product and there could be multiple pathways to resolution. Durable regulatory guidance is mandated for complete closeout of an issue. Develop, capture, and define the differences between resolution and closeout.

There is a need to measure or demonstrate success or completion. Nearing the end of the pilot, Industry and NRC did not have the same level of understanding regarding project success or failure. Develop and incorporate measures of success or effectiveness. Tools should help ensure common understanding of issue completion and measure if the return on invested resources justified the expenditure. This could be multiple measures: short term and long term effectiveness.

The staff did not anticipate the impact on senior management resources to address the pilot project or for interaction on the overarching protocol. Staff and industry should plan to incorporate some appropriate level of senior management involvement in future protocol activities. In particular, senior levels of management should concur with the problem statement and regulatory basis early in the process, then stay informed of progress along the way.

There was some misunderstanding regarding what the expectations were associated with the working group team make up. Additional refinement is required for how protocol activities should be addressed by working groups and the make up of the working groups. The staff believes that the working group be established and the issue addressed at the lowest levels possible. If and only if, progress is not made should additional levels of management become involved to facilitate issue resolution. Incorporate clearly defined roles and responsibilities with corresponding expectations in the guidance document.

Prioritization of NRC resources; the RIRP has the capacity to dramatically alter how NRC resources will be expended. Staff should develop a better understanding and perhaps develop proposed resource impact statements. Resource impacts and projections should be shared with management before initiating an activity.

Staff needs to develop a methodology to ensure licensees are charged for the activities associated with resolution of protocol issues.

A single pilot is not sufficient to work out many of the complex inter-relations that must occur seamlessly for the protocol to provide a real return on investment. Means must be developed to overcome what would appear to be excessive interaction and resource expenditures to move the project forward. As such, the staff believes that lessons learned from the first pilot must be developed, addressed, and incorporated and the entire protocol reassessed before starting a new pilot. This iterative process would seem to be the most logical to continue to optimize this proposed methodology for addressing generic issues and instill the culture necessary for lasting success.

The staff observed knowledge transfer challenges associated with transfer of PM duties for the protocol. This exemplifies the need for a “stand alone” guidance document to provide sufficient detail for uninitiated personnel to use the protocol. Knowledge transfer challenges were observed when NEI presented its proposal for the next pilot project and identified that because the original author of the protocol document was no longer part of the team there was a knowledge gap regarding the intent and how to employ the original screening criteria. Another example identifying the challenge was the expectation that the NRC staff would provide an immediate acceptance/rejection of any proposed issue. Continue to define, build, and enhance the level of detail in the guidance document.

Realistic and achievable schedules and timeframes must be employed to address issues. Example, there was not consensus among the individual teams or jointly at the beginning of the pilot regarding what was an achievable meeting schedule. Unnecessarily aggressive, locked in schedules result in organizational stress and ultimately lost productivity. Schedule and resource projections should be well understood prior to accepting an issue for resolution.

Create clearly delineated roles and responsibilities and capture in the protocol documentation.

