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REGULATORY ISSUE RESOLUTION PROTOCOL

A Methodology for Resolving Regulatory Issues with Generic Implications for Fuel Cycle Facilities

December 2014

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Nuclear Energy Institute

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A Methodology for Resolving Regulatory Issues with Generic Implications for Fuel Cycle Facilities

December 2014

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ABSTRACT

This guideline describes a Regulatory Issue Resolution Protocol (RIRP or protocol) that may be used by the fuel cycle industry and the U.S. Nuclear Regulatory Commission (NRC) to identify, evaluate, resolve and close out selected generic regulatory issues that may impact operating or future fuel cycle facilities. The protocol is a framework for communication and using existing processes, as appropriate, for timely resolution of issues. The protocol bridges the gap between issue identification and final resolution in situations where a success path is not readily apparent. Regardless of whether NRC or industry identifies or proposes a generic issue, all resolution paths should lead to documenting industry and/or NRC commitment to implementing actions and solutions identified through this resolution protocol.

This protocol does not in any way limit the NRC's regulatory options should new information come to light that would change the safety or security significance or urgency of an issue. Additionally, use of the regulatory issue resolution protocol is not a replacement for taking immediate action as necessary to address nuclear safety, security or compliance matters, and does not alleviate the responsibility of licensees to comply with all applicable regulatory requirements.

For simplicity, both industry and NRC are referred to as "organization" for the purposes of this document. The protocol includes five phases, briefly summarized below and discussed in more detail in the body of this document:

1. **Identification Phase** – Either organization identifies a potential regulatory issue that has generic implications for operating or future fuel cycle facilities. The generic issue is defined consistent with the Regulatory Evaluation Summary described in Appendix A. The Regulatory Evaluation Summary should describe the potential generic issue and promptly be brought to the attention of the other organization to ensure mutual understanding prior to advancing to the "screening phase" described herein.
2. **Screening Phase –** The potential generic regulatory issue is discussed to ensure its full scope and impacts are described and documented, e.g., creation of a "problem statement." The issue is then "screened" for acceptance by both organizations using the specific questions outlined in the screening criteria. Issues that do not meet the screening criteria would likely be dispositioned through an alternative course of action. Issues that satisfy the screening criteria move into the planning phase.
3. **Planning Phase –** Collectively, the organizations identify specific actions required to resolve the potential generic issue, an approximate timeline with milestones, responsible organization and communication tools. The projected milestones are tracked to completion.
4. **Implementation Phase –** The tasks identified in the planning phase are executed in accordance with the timeline and milestones, and a desired outcome is agreed upon by both organizations.
5. **Closure Phase –** The resolution is documented by both organizations based on the results of the implementation phase, e.g., issuance of generic guidance or communication, endorsement of industry approach.

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REGULATORY ISSUE RESOLUTION PROTOCOL

A METHODOLOGY FOR RESOLVING REGULATORY ISSUES WITH GENERIC IMPLICATIONS FOR FUEL CYCLE FACILITIES

1 OBJECTIVES

The Nuclear Energy Institute (NEI) developed this resolution protocol to govern the identification, screening, evaluation, resolution, and closeout of regulatory issues (e.g., guidance, generic communications, NUREGs, interim staff guidance) with generic implications that apply to operating or future fuel cycle facilities. This protocol is similar to others in use today in such NRC regulatory program areas as the Independent Spent Fuel Storage Installations, (i.e., NEI 10-03).

The objectives of the protocol are to:

- Identify generic issues and provide early engagement between NRC and industry
- Agree on a common problem statement prior to issue resolution
- Establish success criteria to highlight attributes of resolution
- Identify and promote understanding of relevant regulatory requirements and associated existing or new guidance
- Ensure the durability of issue closure through the use of established regulatory processes

Documents generated by or submitted to NRC under this protocol will be made publicly available in ADAMS, consistent with agency policy. NRC meetings with NEI to discuss resolution will also be public meetings, consistent with agency policy.

2 ISSUE RESOLUTION PROTOCOL

The Regulatory Issue Resolution Protocol (RIRP or protocol) provides a framework for promoting timely identification, screening, evaluation and resolution of regulatory issues with generic implications (i.e., regulatory issues that apply to multiple licensees, certificate holders or applicants). The protocol provides a structure to consistently identify, screen, evaluate and resolve regulatory issues that are not consistent with current industry practice, previous NRC positions or expectations, or for emergent conditions for which no current regulatory guidance exist. Issues within the scope of the protocol apply to multiple licensees or applicants and warrant further industry-NRC interaction to determine and implement the most expeditious path to achieve resolution.

The protocol is not a new regulatory process. It is a framework for communication and for using existing processes, as appropriate, for timely resolution of issues. The protocol bridges the gap between issue identification and final resolution in situations where a success path is not readily apparent. Regardless of what organization identifies or proposes a generic issue, all resolution paths should point to achieving industry and/or NRC commitment to implementing actions and solutions identified by this resolution protocol.

3 ISSUE RESOLUTION PRTOCOL PRINCIPLES

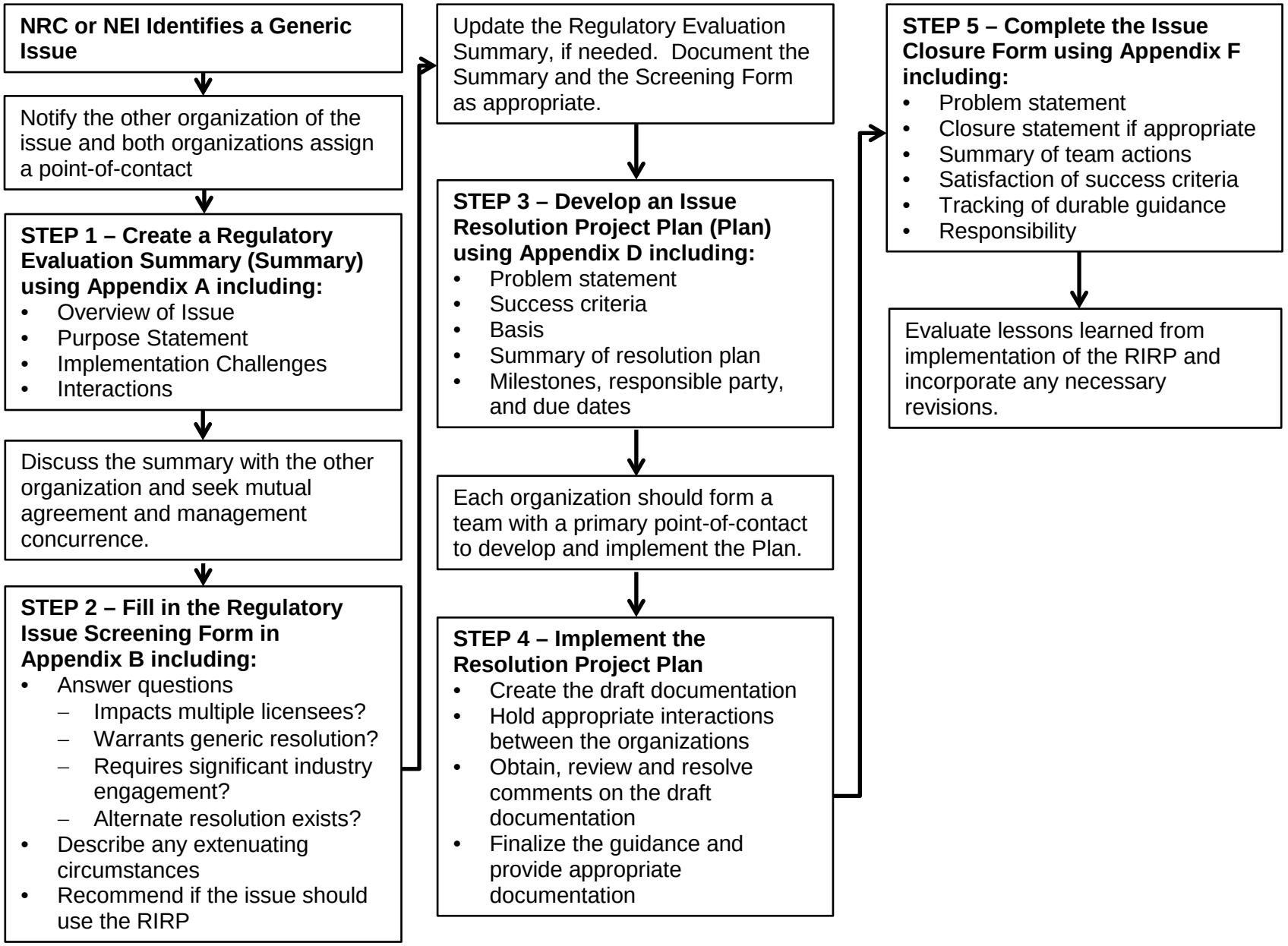
3.1 PRINCIPLES

The principles underlying the identification, screening, evaluation, and resolution of issues within this protocol are provided below.

1. Clear and concise communications are used throughout the protocol
    a. Define the problem to be resolved
    b. Develop success criteria for evaluating progress
    c. Identify key terms and definitions needed to resolve differing interpretations or positions, when warranted
    d. Identify and explain the regulatory baseline to establish a well-understood foundation for the issue resolution
    e. Seek legal counsel early in the process when needed, e.g., rule interpretation
    f. Document NRC staff positions and industry commitments
    g. Track and manage new information or issues that emerge during any phase of the protocol
    h. Determine how pertinent information will be communicated in a timely manner to affected organizations
    i. Keep NRC management and NEI informed and elevate stalled issues as appropriate
2. Durable guidance is issued and maintained by NRC to ensure longevity of the resolution. In some cases, NRC may opt to endorse industry-generated guidance to resolve the issue.
3. Lessons learned from application of the protocol are documented by NEI and NRC, when indicated, to capture feedback for continuous improvement and possible modification of the protocol.

3.2 PHASES

This protocol has five phases: 1) Identification; 2) Screening; 3) Planning; 4) Implementation; and 5) Closure. These five phases are introduced in the following flow chart entitled, “Flowchart with Major Steps in the Regulatory Issue Resolution Protocol.”


NRC or NEI Identifies a Generic Issue
Notify the other organization of the issue and both organizations assign a point-of-contact
STEP 1 – Create a Regulatory Evaluation Summary (Summary) using Appendix A including:
• Overview of Issue
• Purpose Statement
• Implementation Challenges
• Interactions
Discuss the summary with the other organization and seek mutual agreement and management concurrence.
STEP 2 – Fill in the Regulatory Issue Screening Form in Appendix B including:
• Answer questions
– Impacts multiple licensees?
– Warrants generic resolution?
– Requires significant industry engagement?
– Alternate resolution exists?
• Describe any extenuating circumstances
• Recommend if the issue should use the RIRP
Update the Regulatory Evaluation Summary, if needed. Document the Summary and the Screening Form as appropriate.
STEP 3 – Develop an Issue Resolution Project Plan (Plan) using Appendix D including:
• Problem statement
• Success criteria
• Basis
• Summary of resolution plan
• Milestones, responsible party, and due dates
Each organization should form a team with a primary point-of-contact to develop and implement the Plan.
STEP 4 – Implement the Resolution Project Plan
• Create the draft documentation
• Hold appropriate interactions between the organizations
• Obtain, review and resolve comments on the draft documentation
• Finalize the guidance and provide appropriate documentation
STEP 5 – Complete the Issue Closure Form using Appendix F including:
• Problem statement
• Closure statement if appropriate
• Summary of team actions
• Satisfaction of success criteria
• Tracking of durable guidance
• Responsibility
Evaluate lessons learned from implementation of the RIRP and incorporate any necessary revisions.

3.2.1 Identification Phase

1. Once a generic issue is identified, the Regulatory Evaluation Summary (Appendix A) is used to develop a description of the preliminary issue and share it with the other organization.
2. A point-of-contact (hereafter referred to as the POC) from each organization should be assigned to oversee development of this issue.

3.2.2 Screening Phase

1. The POCs from both organizations conduct the "screening" using the "Regulatory Issue Screening Form" (Appendix B). The POCs then discuss the issue with the organizations to ensure that the full scope of the issue and its potential impact are identified and clearly understood at the appropriate management level, e.g., NRC Division Director and NEI Director.
2. If the screening process determines that the screening criteria (see Appendix B) are not satisfied or mutual agreement cannot be reached, the issue should be documented as "closed" for the purposes of this RIRP. The reasons for rejection and a proposed alternative path for resolution are summarized on the "Issue Closure Form" (Appendix F) within 30 days of the "rejection" decision.
3. If all screening criteria are satisfied, the issue is granted preliminary acceptance for consideration under the RIRP and the findings of the screening are documented with the "Regulatory Issue Screening Form" (Appendix B) accordingly.
4. Within 60 days of a decision to "accept" the issue under this protocol, the NRC and industry interact as necessary to understand the information in the Regulatory Evaluation Summary and the "Regulatory Issue Screening Form" including proposed problem statement, background information, and the answers to the screening criteria questions.

Upon acceptance, both organizations will commit necessary resources to resolve the issue in a timely manner commensurate with its potential significance. Once screening is completed, the issue moves to the planning phase.

3.2.3 Planning Phase

1. Industry and the NRC form separate issue teams when practicable, each comprised of regulatory and technical specialists organized by an issue team leader, who acts as the primary POC and protocol facilitator. A responsible manager is identified to oversee the project development for each organization, e.g., NRC Division Director, NEI Director.
2. Within 60 days from entering the planning phase, the team leaders jointly develop the "Issue Resolution Project Plan" (resolution plan) with guidance from NRC and NEI management. The level of detail in the resolution plan should be commensurate with the complexity of the issue. The goal is to resolve the issue in a relatively short time frame. See Appendix D for a sample template of the resolution plan and Appendix E for guidance on its development.
3. As a normal course of action, the resolution plan should contain as complete as possible a problem statement and success criteria. The resolution plan should receive mutual agreement from both organizations at the management level prior to beginning problem solving.
4. The resolution plan should include a detailed description of the regulatory justification that is driving the issue resolution effort. When indicated, industry will provide written comments for NRC's consideration on the justification. Prior to finalizing the resolution plan, both organizations should seek mutual understanding and agreement of the regulatory issues and the regulatory justification since this information forms the basis for addressing the issue.
5. The resolution plan is considered final when both organizations agree on the scope of activities, the regulatory justification, and the milestone schedule. The relative priority of the issue will determine the schedule. The resolution plan should be completed prior to the implementation phase although it should be considered a living document that is modified as needed.
6. The resolution plan should be modified, if needed, based on the emergence of new information that changes the significance or urgency of the issues as identified by the NRC and industry.

3.2.4 Implementation Phase

1. Industry and NRC implement the resolution plan (Appendix D) through the following steps: 1) creation of draft documentation, 2) interactions as necessary in a transparent manner consistent with NRC policies and procedures, 3) resolution of comments on the draft documentation, and 4) conclusion of the regulatory issue with appropriate documentation.
2. During implementation the NRC and industry should periodically review the resolution plan to assess the status of the project and update the tasks and/or schedule, as appropriate. These reviews should be documented to track progress toward resolution.
3. The implementation phase should result in a durable, documented product. These products may include, but are not limited to:
    a. NRC Rulemaking
    b. Commission Direction
    c. NRC policy statement or staff position
    d. New or revised NRC inspection procedure
    e. New or revised NRC guidance (e.g., Regulatory Guide, Standard Review Plan)
    f. New or revised NEI guidance endorsed by NRC
    g. New NRC generic communications
    h. New or revised guidance drafted by external organizations, e.g., ANS

3.2.5 Closure Phase

1. The approved resolution is documented on the Issue Closure Form (Appendix E) and includes a clear description of any existing process and durable guidance that was utilized to produce a final resolution.
2. The Issue Closure Form should define the problem closure statement, identify the regulatory process to capture the resolution, and describe the completion of the success criteria.
3. If any additional actions are required for final close out, the process used to track the issue to resolution is agreed upon by both organizations.

3.3 REVISION TO REGULATORY ISSUES FORMS

A change in the regulatory issue as the project progresses may result in a need to revisit the Regulatory Evaluation Summary and Regulatory Issue Screening information. When this occurs, consideration should be given to creating a new separate regulatory issue. If revising the existing regulatory issue forms is determined to be the appropriate action, the team leads may coordinate such a revision. The same process should be used for a revised issue as for the original issue and receive the same level of review and concurrence as the original issue up to and including NRC and NEI management concurrence. The basis for any changes to the form should be documented along with the revised forms.

3.4 LESSONS LEARNED

At the conclusion of the resolution phase, both organizations should gather lessons learned, as appropriate, to improve the NEI RIRP. The lessons learned should be communicated to both organizations with the goal of reaching alignment and incorporating improvements into the protocol.

APPENDIX A: PROCESS FOR CREATION OF THE REGULATORY EVALUATION SUMMARY

The Regulatory Evaluation Summary should consist of a brief, i.e., 1-3 pages, overview of the proposed regulatory initiative. Its purpose is to provide a synopsis of the new regulatory initiative including overview, purpose, challenges, and estimate of opportunities for stakeholder interactions. The document is intended to serve as a communications tool to define the scope of the project early-on and communicate the information to stakeholders. The document should address the four following topics.

1. **Overview of the Issue:**

   The overview should provide information which includes:

   - A summary of the background which led the organization to conclude the need for the regulatory initiative.
   - A description of the problem or challenge that the regulatory initiative is intended to address with examples, if appropriate.

2. **Purpose Statement:**

   The purpose statement should clearly define the proposed outcomes that the organization hopes to accomplish with the regulatory initiative. The stated purpose should be succinct and as accurate as possible. The goals may evolve based on feedback from stakeholders, the concurrence process, input from the Commission, etc.

3. **Implementation Challenges:**

   The implementation challenges sections should summarize the anticipated impact the regulatory initiative may have on the organizations if implemented as described in the purpose statement. The section should address both the anticipated improvements and challenges industry and the NRC may experience. This section should not be construed as a cost benefit analysis but a general recognition of the benefits and challenges which may occur due to implementation of the regulatory initiative.

4. **Interactions:**

   The interactions section should provide a list of the potential internal and external stakeholders, expected meetings, public comment periods, major documents, etc., expected for the regulatory initiative. If appropriate, the NRC staff should provide a draft schedule describing the projected timeline for the regulatory initiative. This may be provided by referencing the Fuel Cycle Integrated Schedule, if appropriate. The section should note that the information is preliminary and may change as the project progresses.

Once completed, the draft Regulatory Evaluation Summary should be shared with the participating organizations for comment. Following successful completion of the screening criteria, described in Appendices B and C, the Regulatory Evaluation Summary should be updated, receive management concurrence, and be docketed by both organizations.

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APPENDIX B: REGULATORY ISSUE SCREENING FORM

Title: _____

I. Information on the generic regulatory issue

1. Problem Statement (Provide a clear, concise description of the issue.)

2. Background Information (Summarize industry events, licensing actions, inspection information, correspondence, and other documents germane to the issue. Attach documents and reference the Regulatory Evaluation Summary as appropriate.)

II. Screening Criteria (Provide an explanation as to how the issue meets each of the screening criteria to be considered for generic issue resolution.)

1. Does the proposed issue involve and affect multiple licensees (provide basis)?

2. Does the proposed issue warrant generic resolution with tangible benefits (provide basis)?

3. Does the issue warrant engagement between the industry and NRC (provide basis)?

4. Is there an alternate regulatory process for resolving the issue (provide basis)?

III. Are all screening criteria satisfied?

Yes _____

No____

IV. Are there extenuating circumstances indicating an alternate approach from the finding of the screening criteria and is there general agreement on a path forward (provide basis)?

V. Should the issue be processed using the RIRP process

NMSS staff recommendation (yes/no) _____

Industry/NEI representative (yes/no) _____

Other [Name:_____], (yes/no) _____

VI. Date _____

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APPENDIX C: REGULATORY ISSUE RESOULTION SCREENING FORM GUIDANCE

This appendix provides additional detail to be used as guidance in completing the Regulatory Issue Screening Form in Appendix B. The wording used in the problem statement and responses to the screening criteria questions need to be precise enough to clearly define the problem and guide the resolution process, but also flexible enough to allow the issue resolution team to explore various solutions. Ambiguous language in the problem statement and screening criteria responses, and overly prescriptive language in the success criteria should be avoided. On the other hand, legitimate restrictions on the resolution path should be identified, as appropriate.

Section I - Problem Statement and Background Information

The problem statement required for Section I of the Screening Form should be a concise summary of the issue proposed for generic resolution requiring industry-NRC interaction. The objective of the problem statement on the Screening Form is to provide sufficient information for the screener to understand the regulatory significance and the generic applicability in order to answer the screening criteria questions in Section II of the form.

The problem statement is a one or two sentence statement that identifies the issue to be resolved. It is not a description of the misunderstanding but rather the issue over which the misunderstanding originates.

The key elements of the problem statement at this stage are the description of the generic nature of the problem and its regulatory significance. Supporting documents that will help the reader better understand the problem (e.g., regulation, NRC or industry guidance document, NRC inspection report, operating event report, NRC generic communication, etc.) should be cited in the Background Information but not repeated in detail. A more detailed problem description will be developed by the issue team included in the Issue Resolution Project Plan.

Section II - Screening Criteria

Provide an answer to each of the screening criteria questions as described below. In order for the issue to be accepted into the protocol for resolution, Questions 1 through 3 require a “yes” answer and Question 4 requires a “no” answer.

1. **Does the proposed issue involve multiple licensees, certificate holders and/or applicants?**

   Provide an explanation of the type and number of regulated entities affected by the issues

   (e.g., all licensees, multiple 10 CFR Part 40 or 10 CFR Part 70 licensees).

2. **Does the proposed issue warrant generic resolution with tangible benefits and, if so, why and when?**

   Provide a summary of why the issue should be resolved generically rather than each affected entity addressing the issue individually. Describe how resolving the issue using this protocol will provide benefits to industry and/or the NRC that are commensurate with the effort involved. For example, will rulemaking significantly decrease NRC and/or industry burden without reducing safety? Will expediting the resolution serve to increase public confidence?

3. **Does the issue warrant engagement between the industry and NRC and, if so, why?**

   Provide an explanation of why the issue should be resolved through interaction between industry and the NRC. Industry may request NRC action to clarify the staff's position on an issue. The NRC may desire industry guidance to ensure a consistent approach to an issue. The consequences of doing nothing should also be clearly stated.

4. **Can a regulatory approach be identified to resolve the issue (provide basis)?**

   Provide an explanation of the existing regulatory process addressing the issue. For example, the industry may believe that an existing regulation does not adequately address all circumstances of a particular situation that commonly arises. The NRC may believe that existing industry guidance needs modification to help ensure the desired results in the licensees' products.

   Identify the generic regulatory approach that should be used to address the issue, e.g., interim staff guidance, NUREG, generic letter. In evaluating the regulatory approach, consider timeliness needs, the relative priority, and the assignment of resources. If the issue is more appropriately addressed in rulemaking, the regulatory issue resolution protocol should be transitioned to that process.

Section IV – Additional Considerations

Document the final determination made by each organization and any other relevant stakeholders (e.g., Regions, Agreement states) on whether or not the RIRP process should be used. Note: In the event of a disagreement of one or more parties, the NRC will make the final determination on the best approach to resolve the regulatory issue consistent with NRC policy and values.

Section VI – Date

After the team leads and respective NRC and NEI management review the issue, the problem statement and screening criteria should be revised, as necessary, to incorporate any clarifications resulting from the screening.

The date is entered upon finalization of the screening form. This date indicates that the problem statement has been developed and the screening criteria are completed. Once the date is entered, the Regulatory Evaluation Summary and the screening criteria should be docketed in the organizations' databases.

APPENDIX D: ISSUE RESOLUTION PROJECT PLAN

Title:_____

I. Problem Statement

II. Success criteria

III. Regulatory Justification

IV. Summary of Resolution Plan

V. Milestones, Responsible Party, and Due Date

MILESTONES	RESPONSIBLE PARTY	DUE DATE

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APPENDIX E: ISSUE RESOULTION PROJECT PLAN GUIDANCE

Guidance for the Issue Resolution Project Plan is intended not to be prescriptive but rather to provide guidance on organizing a project plan to resolve a regulatory issue. The detail included in the Issue Resolution Project Plan should be commensurate with the complexity of the issue.

Issue Team Pre-Work

Before developing the issue resolution project plan, the organization team members should research the regulatory topic to gain an understanding of the issue. The following elements should be considered in evaluating the background:

- Detailed Problem Statement
- History
- Affected Entities
- Relevant Field Experience
- Source and Reference Documents
- Burden Created
- Regulatory Significance
- Safety or security significance
- Risk-insights
- Cost burden
- Schedule impact
- Precedent or current accepted practice

I. Problem Statement

The organizations' teams should discuss and reach agreement on the problem statement. While the iterations should not be extensive, getting the problem statement right prior to problem solving ensures that the correct problem is being solved. The management sponsors' inputs are important to ensure the correct problem is being solved with the appropriate strategic perspective.

II. Success Criteria

The success criteria proposed for any issue needs to be specific, measurable, realistic, tangible and directed toward moving the issue to an existing process for final resolution in a timely manner. Achievement of the success criteria is the objective of the issue resolution project plan.

The industry and NRC issue teams should discuss and reach agreement on the success criteria. While the iterations should not be extensive, the success criteria should help the team start with the "end in mind" to know when the problem solving is finished. The management sponsors' inputs are important to ensure the resolution will address the problem being solved.

III. Regulatory Justification

The NRC will develop a draft regulatory justification for discussion with industry. The draft regulatory justification document will include a detailed description of the applicable regulatory requirements, as well as a description of how those requirements apply to the specific issue at hand. The organizations' teams will discuss the draft regulatory justification and the industry will provide written comments on the draft. The NRC will provide a written response addressing the comments along with the final regulatory justification for the relevant issue. While the iterations should not be extensive, a clear understanding of which regulations apply as well as how and when those regulations apply will provide the base for the resolution and enable the organizations to determine acceptance criteria that will result in or ensure continued compliance.

IV. Summary of Resolution Plan

The summary of the resolution plan should be developed with oversight from the organization's management. The summary should be recorded and tracked consistent with the cumulative effects of regulation efforts. The resolution plan should be updated periodically, as needed.

In addition to maintaining the schedule, the plan should describe the actions to be taken to resolve the issue and any resources needed. The plan should be detailed commensurate with the complexity of the issue.

V. Milestones, Responsible Parties, and Due Dates

Periodically, the organizations' management, (e.g., Division Director and NEI) should review the issue resolution project plan and provide feedback on the path forward; request additional action; or propose a course correction up to and including project modification or cancellation. Milestone actions and due dates should be outlined consistent with the level of detail commensurate with the complexity of the issue.

Reviews should be scheduled periodically to communicate progress; to discuss challenges; and to solicit management feedback and concurrence. Consider scheduling such reviews based on milestone completion as opposed to calendar date.

APPENDIX F: ISSUE CLOSURE FORM

Title: _____

I. Problem Statement

Provide a summary of the problem statement drawn from the Regulatory Evaluation Summary and the Issue Resolution Project Plan. This section is provided for completeness to ensure the issue is understood.

II. Closure Statement

For rejected issues, summarize the reason(s) for issue rejection and forward to the identifying organization. For resolved issues, summarize the resolution and any action items required by NRC and/or industry to be tracked in order to bring final resolution to the issue. List any remaining tracking items and the responsible party in Section V and VI below.

III. Summary of Teams' Actions

Provide a brief chronology of actions taken to bring the issue to resolution.

IV. Satisfaction of Success Criteria

Discuss how the success criteria were satisfied.

V. Tracking of Durable Guidance

Identify the specific documents that were created, revised or endorsed.

VI. Responsibility

Each organization is responsible for maintaining records of issues addressed under this protocol including durable guidance

Date: _____

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APPENDIX G: KEY TERMS AND DEFINITIONS

APPLICABLE STAFF POSITION

"Applicable staff position" is an NRC staff position that is a documented, approved, explicit interpretation of the regulations and is contained in a document such as the Standard Review Plan (SRP), a branch technical position, a regulatory guide, a generic letter, or a bulletin; and to which a licensee or an applicant has previously committed to or relied upon. [Reference: NRC Management Directive 8.4, page G-1]

BACKFITTING

"Backfitting" refers to the modification of, or addition to structures, systems, or components of a facility; or the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position. (The Commission recognized the importance of "backfitting" controls when it approved 10 CFR 70.76 to establish administrative standards for NRC imposition of new regulations or new interpretations of existing regulations.)

DURABLE GUIDANCE

"Durable guidance" is contained in any document that represents a formal position or commitment and is retrievable in the future. Durable guidance should transcend changes in personnel in industry or the NRC. Examples of durable guidance include regulatory guides, standard review plans, NRC regulatory issue summaries, and NEI reports.

ISSUE RESOLUTION PROJECT PLAN

"Issue resolution project plan" describes the issue background, reviews, actions, and milestone schedule to be executed to resolve and close an issue. The industry team leader prepares, maintains and ensures implementation of the issue resolution project plan.

LICENSING PROCESS

"Licensing process" is the collection of industry and NRC staff activities that are necessary to prepare, submit, review, approve, and maintain a license granted by the NRC staff pursuant to Title 10 of the Code of Federal Regulations. The overall licensing process is comprised of several sub-processes, such as the license amendment process, various reporting processes, change-management processes, the backfitting process, the inspection process, and others. Some sub-processes are broken down further. For example, the license process includes the acceptance review process and the request for additional information (RAI) process.

PRECEDENT

"Precedent" is defined as something that may serve as an example or rule to be followed in a subsequent act of the same kind. In a regulatory context, a precedent licensing action could be used to aid the evaluation of similar future requests for licensing actions.

PROBLEM STATEMENT

"Problem statement" is a one or two sentence statement that identifies the issue to be resolved. It is not the misunderstanding of the issue but rather the issue over which the misunderstanding originates. It should convey to a knowledgeable reader the nature and extent of a potential deficiency or non-compliance. The organization that identifies the issue prepares a draft problem statement as part of the issue identification portion of the protocol. The problem statement is refined as part of the screening portion of the protocol, and finalized between industry and the NRC.

PROTOCOL

"Protocol" is defined as an administrative methodology for inter-organizational coordination and communications.

REGULATORY ISSUE

A generic situation or topic (involving multiple events or licensees) that involves NRC oversight where the NRC and NEI agree there is a need for improved definition, direction, documentation, or guidance. Use of this protocol to resolve the generic item may result in development of guidance, NUREGs, interim staff guidance, standards, generic communications, rulemaking, Commission direction, etc. [Note: Although a regulatory issue may result in rulemaking, rulemakings are not a regulatory issue processed under this protocol.]

ISSUE TEAM

The industry and the NRC each establish a multi-discipline team of regulatory and technical specialists for each regulatory issue that enters the evaluation phase. Each issue team has a designated team leader.