

NEI 10-03, Draft Revision 0

REGULATORY ISSUE RESOLUTION PROTOCOL

*A Methodology for Resolving
Issues with Generic Implications*

February 2010

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Nuclear Energy Institute

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ACKNOWLEDGEMENTS

NEI acknowledges the assistance of the Dry Storage Task Force (DSTF) and the Regulatory Issue Resolution Protocol (RIRP) Team, a subset of the Licensing Action Task Force (LATF) in preparing this document. The teams' desired outcome was to have one guidance document for the Industry and the NRC to successfully use to effectively and efficiently resolve regulatory issues.

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ABSTRACT

This guideline describes a protocol that may be used by industry and the Nuclear Regulatory Commission (NRC) to evaluate, resolve and close out selected generic issues. It includes four phases, briefly summarized below and discussed in more detail in the body of this document:

1. Identification Phase – Any individual or group from the industry or the NRC identifies a potential issue for generic resolution.
2. Screening Phase – The issue is screened for acceptance based on specific criteria. Those issues that screen in move to the Evaluation phase. Those issues that do not meet the screening criteria are not accepted and closed to an alternative course of action.
3. Evaluation Phase – The issue is evaluated and tasks are executed until a final resolution is agreed upon between Industry and the NRC. This phase may involve public meetings between the industry and the NRC.
4. Implementation Phase – Implementation of the industry action is based on the results of the evaluation. NRC actions are implemented in accordance with existing regulatory processes. Closure of the issue is documented.

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REGULATORY ISSUE RESOLUTION PROTOCOL

1 OBJECTIVES

The Nuclear Energy Institute (NEI) has developed the Regulatory Issue Resolution Protocol (RIRP) to efficiently manage the identification, screening, evaluation and resolution of issues with generic implications that affect a significant number of licensees and Certificate of Compliance holders (hereafter referred to collectively as *licensees*).

The objectives of the protocol are to:

- Provide a systematic protocol for the identification, screening, evaluation, and resolution of generic regulatory issues.
- Promote effective communication between industry interests and NRC staff to ensure thorough and common understanding of the issues to be resolved.
- Promote the cooperative evaluation of all aspects of regulatory requirement and technical considerations prior to final determination of regulatory treatment and industry course of action.
- Develop issue resolutions that are timely, durable, and to the extent possible, consistently applicable throughout the industry.
- Support the consistent and effective regulation through reliance on existing regulatory processes for the communication and implementation of issue resolution.

To achieve these objectives, the protocol calls for the NRC and the industry to establish a mutual understanding of the detailed regulatory baseline early in the life of an issue. In the context of the protocol the *regulatory baseline* is comprised of a *licensing basis* and a *technical basis*. The licensing basis is the detailed set of requirements (i.e., laws, regulations, licenses, CoCs, and orders) with which a licensee must comply. The technical basis is the detailed set of formal guidance documents (e.g., codes and standards, Regulatory Guides, NUREGs, Standard Review Plan, generic correspondence, industry initiatives, etc.) that provide the procedures, methods, and other tools for establishing acceptable means for complying with the licensing basis.

Once the regulatory baseline has been established, the protocol calls for NRC and Industry to schedule Public Meetings to discuss the details of the issue and develop a mutually acceptable resolution path that meets the success criteria and ultimately achieves final issue resolution and closure. The documentation associated with the protocol and implementation by licensees, CoC holders, and the NRC staff provides a retrievable record for use in future activities.

2 RIRP DISCUSSION

The RIRP provides a framework for the thorough and timely resolution of regulatory issues with generic implications (i.e., regulatory issues that apply to multiple licensees). Issues to be addressed through the the protocol warrant cooperative evaluation, preferably including direct interaction between the industry and the NRC, in order to determine the most appropriate industry action and regulatory treatment.

The protocol is not intended to be a new regulatory process. It is a framework for the application of appropriate, established regulatory processes to ultimately resolve issues. For issues mutually selected by the industry and the NRC for RIRP application, this protocol bridges the gap between issue identification and final resolution, where an approach to addressing an issue or the particular existing regulatory process or processes to be used for final resolution may not be readily apparent.

The protocol includes an Issue Summary Form, an Issue Resolution Plan, and implementation and recordkeeping guidelines. The protocol includes development of a concise problem statement and success criteria for each issue, the preparation and execution of an Issue Resolution Plan, and documentation of issue closure with a reasonable degree of finality. "Resolution" in the context of this protocol may or may not be the final resolution of the issue itself, but could constitute entry of the issue into an existing regulatory process that will ultimately resolve the issue as a future work activity by industry and/or NRC. For instance, an issue moving through this resolution protocol may be considered "resolved" when an agreement is reached for industry to develop generic guidance that the NRC will endorse. Development and endorsement of that guidance would be normal work activities conducted outside of this protocol. On the other hand, this protocol could provide final resolution of the issue in the form of a documented closure statement on the Issue Summary Form (Appendix A) that confirms discussion between industry and the NRC to address an issue in a certain way. In this case, no further actions would be required other than for Industry and NRC to follow the agreed-upon approach.

It is recognized that standard project management tools are expected to be followed with any issue resolution. Furthermore, there are some issues that arise out of various programs and inspections that cross over several programs, disciplines, departments, etc. These issues rise to a level that resolution is best accomplished by multi-discipline teams of technical and licensing experts across both the NRC and the industry.

NOTE: Use of the regulatory issue resolution protocol is not a replacement for taking immediate action as necessary to address nuclear safety or compliance matters, and does not alleviate the responsibility of licensees and CoC holders to comply with all applicable regulatory requirements.

NRC/Industry agree on the actions required for final resolution.

4. Durable guidance is issued to enable long-term solutions.

3 RIRP APPLICATION

3.1 PHASES

The regulatory issue resolution protocol has four phases. The actions required to implement each are described in detail below.

3.1.1 Identification Phase - Any individual or group from industry or the NRC formally identifies a potential issue for generic resolution by completing the Problem Statement portion of the Issue Summary Form (Appendix A). The identifying individual may also suggest responses to the screening criteria questions and success criteria. The identifying organization (either Industry or NRC) owns the issue until closeout. NEI maintains a tracking log for all formally identified issues.

1. An individual or group identifies a potential issue and, at a minimum, someone from that organization fills out the Problem Statement in Section I of the Issue Summary Form (Appendix A). The identifier may initially answer the screening criteria questions and suggest success criteria. The problem statement should succinctly address the regulatory concern, generic applicability, and refer to relevant supporting documents (see Appendix B for additional guidance).
2. The Issue Summary Form is forwarded to the identifying organization's POC for the screening phase. The Industry's POC is typically from an existing NEI Task Force, i.e., Dry Storage Task Force, Licensing Action Task Force, etc. Alternatively, an issue specific NEI task force may be established subject to NEI management discretion.
3. The POC of the identifying organization obtains an issue number from the NEI POC and enters it in the appropriate location on the Issue Summary Form. The issue numbers are assigned as nnTF- X-YY-ZZ, where:
 - nnTF = NEI Task Force
 - X = "N" for NRC-identified issues or "I" for industry-identified issues
 - YY = The year the issue is identified, e.g., "10" for 2010
 - ZZ = The numeric identifier
4. The NEI log is updated to reflect the issue status.

3.1.2 Screening Phase – The issue owner organization point-of-contact (POC), or designee,¹ completes the screening criteria section of the Issue Summary Form. Based on the screening, the issue is preliminarily accepted and success criteria are developed. If the issue is preliminarily accepted, the Issue Summary Form is forwarded to the opposite organization for review and concurrence (e.g., NRC-owned issues are sent to industry, represented by NEI). Industry and the NRC

¹ Hereafter, "POC" means the point of contact or designee.

interact to reach final acceptance or rejection of the issue. If the issue reaches final acceptance, the issue moves to the Evaluation phase. If the issue is rejected, the Issue Summary Form is used to document the reason for rejection and any alternative course of action in the closure statement.

1. The POC answers each of the screening criteria questions in Section II of the Issue Summary Form, and makes a determination as to whether the issue meets all screening criteria. See Appendix B for additional guidance on answering the questions including use of appropriate technical and regulatory expertise. Two outcomes are possible in the initial part of the screening phase:
 - a) If all screening criteria for generic resolution are considered *not* met by the POC, “NA” for Not Accepted is entered in Section III of the Issue Summary Form, the reason(s) for closure are summarized in Section V of the Issue Summary Form, and the form is signed by the issue owner POC, on the last page. Section IV of the Issue Summary Form, “Concurrence” is left blank. The signed form is returned to the identifying individual, a copy of the form is retained for future reference by the identifying organization, a copy of the form is sent to the non-identifying organization’s POC, and the issue is considered closed. The NEI log status is updated to indicate the reason for closure and the date of closure.
 - b) If all screening criteria for generic resolution *are* considered to be met by the POC, the issue is preliminarily accepted. The issue owner POC proposes success criteria for resolving the issue in Section III of the Issue Summary Form, signs the Issue Summary Form in Section IV, and forwards the signed form to the non-identifying organization’s POC for concurrence. The NEI log status is updated to indicate that the issue is in concurrence and the date.
2. The NRC and industry interact as necessary to reach mutual agreement on the problem statement and the answers to the screening criteria questions. Two outcomes are possible in the final screening phase:
 - a) If mutual agreement cannot be reached that the issue meets all screening criteria, the issue is not accepted and resolved using this protocol. The reasons for rejection are summarized in Section V of the Issue Summary Form and the form is signed by the issue owner POC, on the last page of the form. The signed form is returned to the identifying individual, a copy of the form is sent to the non-identifying organization’s POC, a copy of the form is retained for future reference, and the issue is considered closed. The NEI log is updated to indicate closure of the issue and the date.
 - b) If Industry and NRC agree that all screening criteria are met for generic resolution involving NRC interaction, the issue is accepted as an issue to be resolved generically using this protocol. Industry and NRC agree on final Problem Statement wording, responses to the screening criteria questions, and success criteria, and the two organizations’ POCs sign the final version of the Issue Summary Form in Section IV, “Concurrence.” The final, signed Issue Summary

Form is retained by NEI with a copy provided to the NRC. The issue moves to the evaluation phase. The NEI log status is updated to indicate the issue is in the evaluation phase and the date.

3. Concurrence indicates NRC and Industry commitment of resources through to issue closure.

3.1.3 Evaluation Phase – Industry and the NRC commit resources for each issue, including an issue team leader from each organization to facilitate communication. An issue resolution plan is developed and maintained by the issue owner organization. The issue resolution plan is agreed to by both industry and the NRC and is executed in accordance with the schedule contained in the plan.

1. The evaluation phase begins with the Industry and NRC forming separate issue teams, each comprised of regulatory expertise and the technical specialists, and an issue team leader.
2. The issue team leader from the identifying organization owns the issue. The issue owner team leader develops an Issue Resolution Plan that includes the information and format delineated in Appendix E.
3. The Issue Resolution Plan should include any near term compensatory actions needed, if any, while the evaluation is ongoing.
4. The Issue Resolution Plan is executed in accordance with the schedule contained in the plan. Public Meetings between NRC and industry are conducted to discuss the issue and move toward resolution. The issue owner team leader maintains the plan throughout the evaluation phase. The issue resolution plan and/or another status document may be published and revised periodically to update the tasks and/or schedule, as appropriate, to indicate progress toward resolution.
5. The issue team leaders are responsible for communications and progress reports to the respective management in order to ensure appropriate management oversight.
6. An issue is considered resolved when agreements are reached and actions identified to : 1) resolve the issue immediately through documenting the agreements and actions in the Closure Section of the Issue Resolution Form, or 2) take specific actions to resolve the issue in the future under an existing regulatory process or processes. Those actions may include, but are not limited to:
 - a. Rulemaking
 - b. NRC policy statement or staff position
 - c. New or revised NRC inspection procedure
 - d. New or revised NRC guidance (e.g., Regulatory Guide, Standard Review Plan)
 - e. New or revised NEI guidance
 - f. CoC holder amendment requests or SAR changes

7. Any change management or stakeholder communications needed as part of the resolution should be discussed with the issue team.
8. When the issue resolution is mutually understood by both the industry and the NRC, the issue moves to the implementation phase. The NEI log status is updated to indicate the issue is in the implementation phase and the date.

3.1.4 Implementation Phase – The issue owner organization documents closure on the Issue Summary Form defining how the success criteria were met and what existing regulatory process or processes will provide final resolution, (e.g., NRC rulemaking, NRC guidance, licensee or CoC holder amendment requests, etc.) or why the issue was closed for other reasons (i.e., a change in circumstances).

1. The issue owner team leader documents the approved resolution in Section V of the Issue Summary Form, referring to the agreements, action(s) taken, or to be taken, and the regulatory process or processes to be used to provide final resolution of the issue, as applicable. The Closeout Summary in Section V of the Issue Summary Form must include a clear description of how the success criteria were satisfied.
2. If future actions are required, an itemized list of actions with owner and due dates should be included along with the method use to track closure of action items, i.e., NEI task force action item list.
3. The issue owner POC signs the last page of the Issue Summary Form. The signed Form is returned to the NEI POC for retention. A copy of the form is sent to the NRC POC and the issue is considered resolved. The NEI log is updated to indicate closure of the issue and the projected date of completion for future actions, if any.

3.2 REVISIONS TO ISSUE SUMMARIES

Issue Summary Forms are intended to contain clear and concise descriptions of the problem statement, responses to the screening criteria questions, and success criteria with appropriate wording to focus the resolution of the issue. The intent is that this information would be used by the team to stay focused on the resolution of the issue. The Issue Resolution Plan may be periodically updated with the details of the resolution process. The issue resolution would ultimately be documented in the “Closeout” section of the Issue Summary Form.

If a change arises to an issue that is so fundamental that it affects the problem statement, responses to the screening criteria questions, or the success criteria, consideration should first be given to closing the issue and creating a new issue. If it is determined that a revision to the Issue Summary Form is the appropriate action, the issue owner POC may coordinate such a revision. The same process should be used for a revised issue summary as for the original issue summary and receive the same level of review and concurrence as the original issue.

3.3 RECORDS

All revisions to the Issue Summary Form and the final version of the Issue Resolution Plan should be kept as retrievable records by NEI.

- Identify applicable regulatory and technical requirements and associated guidance.
- Identify success criteria before problem solving begins.

REGULATORY ISSUE SUMMARY FORM

REGULATORY ISSUE RESOLUTION SUMMARY FORM

Issue Number _____ **Revision** _____

I. Problem Statement (Provide a clear, concise description of the issue. Use continuation sheets as required.)

II. Screening Criteria (Provide an explanation as to how the issue meets each of the screening criteria to be considered for generic issue resolution. Include regulatory significance. Use continuation sheets as required.)

1. Does the proposed issue involve multiple Licensees and/or certificate holders?
2. Why does the proposed issue warrant generic resolution?
3. Why does the issue warrant engagement between the industry and NRC?
4. What regulatory process is being utilized or should be utilized?
5. What tangible benefits will generic resolution of the issue produce?

III. Success Criteria (Describe the criteria to be used to define success for resolving this issue. Use continuation sheets as required.)

POC: Are all screening criteria satisfied? **Yes** _____ **No** _____

IV. Concurrence (Issues accepted for evaluation require concurrence by NEI and NRC)

For Industry: _____
Print/Sign Date

For NRC: _____
Print/Sign Date

REGULATORY ISSUE RESOLUTION SUMMARY FORM

Issue No. _____ **Revision** _____

V. Closeout (Summarize the reason for rejecting the issue or the satisfaction of the success criteria and the regulatory process(es) to be used to resolve the issue)

Closeout Summary

Print/Sign

Date

Page ____ of ____

APPENDIX B
REGULATORY ISSUE RESOLUTION SUMMARY FORM GUIDANCE

REGULATORY ISSUE RESOLUTION SUMMARY FORM GUIDANCE

This appendix provides additional detail to be used as guidance in completing the Issue Summary Form in Appendix A. The over-arching goal in developing the Issue Summary Form is to write with precision and flexibility, without pre-disposing the resolution. The wording used in the problem statement, responses to the screening criteria questions, and the success criteria 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 different solutions without having to revise the Issue Summary Form because the wording is unnecessarily restrictive. 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

The problem statement required for Section I of the Issue Summary 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 Issue Summary Form is to provide only that information required for the screener to understand the basic problem and the generic applicability in order to answer the screening criteria questions in Section II of the form and propose success criteria in Section III of the form.

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 but not repeated in detail. A more detailed problem description will be developed by the issue team included in the Issue Resolution Plan.

Section II - Screening Criteria

The issue identifier may provide proposed responses to the screening criteria questions when the Issue Summary Form is created. The owner organization's POC should perform research and consult with appropriate technical and regulatory experts, as necessary, to confirm or revise the responses to the screening criteria questions. Each question should be answered as proposed below.

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

Provide an explanation of the type and number of regulated entities affected by the issues (i.e., all licensees, all 10 CFR Part 50 or 10 CFR Part 52 licensees, all 10 CFR Part 72 CoC holders, all licensees storing PWR fuel, 10 CFR Part 71 regulated entities limited to used fuel transportation, etc.).

2. Why does the proposed issue warrant generic resolution?

Provide an explanation of why the issue should be resolved generically rather than each affected entity addressing the issue individually.

3. Why does the issue warrant engagement between the industry and NRC?

Provide an explanation of why the issue should be resolved through interaction between industry and the NRC. Include the regulatory significance. Industry may desire NRC action to clarify the Agency's position on an issue. The NRC may desire industry guidance to ensure a consistent approach to an issue.

4. What regulatory process is being utilized or should be utilized?

Provide an explanation why an existing regulatory process cannot sufficiently address the issue without using this resolution protocol. For example, 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 is not providing the desired results in the products produced by licensees or CoC holders.

5. What tangible benefits will generic resolution of the issue produce?

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?

Section III - Success Criteria

Success criteria are required to be proposed by the issue owner organization POC if the issue is deemed to meet all screening criteria and preliminarily accepted for generic resolution. The criteria are finalized as part of the industry-NRC concurrence process. They are intended to be identified early in the process to in order to "think with the end in mind".

The success criteria proposed for any issue need to be specific and tangible. Success criteria must be precise to focus the resolution but not to pre-determine the solution. The success criteria may involve simply forging an agreement and commitments between industry and the NRC to address the issue in a certain manner. The criteria may include specific future actions and the creation of documents requiring additional effort. Success criteria may involve industry agreeing to create generic guidance for all licensees to adopt and the NRC may agree to endorse the guidance.

Achievement of the success criteria forms the objective of the Issue Resolution Plan developed to guide the evaluation phase.

Section IV - Concurrence

If a proposed issue is rejected during the screening phase, the concurrence signature blocks are left blank in the final version of the Issue Summary form, even if initially signed by the owner organization's POC. Closeout of a rejected issue is documented in Section V and signed by the owner organization's POC.

For issues deemed preliminarily to meet all screening criteria, Section IV is first signed only by the POC of the organization owning the issue, indicating preliminary acceptance of the issue for generic resolution. The Issue Summary Form is then reviewed by the non-owner organization. If industry and the NRC agree on final acceptance of the issue for generic resolution, both parties sign in Section IV indicating mutual agreement on the problem statement, the responses to the screening criteria questions, the success criteria and the commitment of resources to resolve the issue. If agreement cannot be reached, the issue is rejected with a brief synopsis to close the issue.

In indicating concurrence, the signatories should confirm that the manner in which the problem statement, responses to the screening criteria questions, and the success criteria are worded is flexible enough to permit the issue resolution team to explore different avenues that achieve the objective. If restrictions on the resolution path are suggested or implied, they should be reviewed for reasonableness and clarified as necessary.

Section V - Closeout

The closeout section is used to document issue closure in one of two ways:

1. Rejection. If an issue is rejected by the owner organization POC or because industry and the NRC are unable to reach agreement on the problem statement and/or the responses to the screening questions, the basis for that rejection is summarized in Section V and signed by the owner organization's POC.
2. Resolution. After the evaluation phase, the issue is considered resolved within this protocol and moves to the implementation phase. The closeout summary should clearly indicate the final resolution, and further any actions required. If further actions are required, the responsible organization(s) should be identified and estimated completion dates provided. Additionally, the verification method of completion should be indicated.

APPENDIX C
KEY TERMS AND DEFINITIONS

[need to delete the definitions that are not used in the text]

KEY TERMS AND DEFINITIONS

ADEQUATE PROTECTION

The Atomic Energy Act delegates to the NRC the responsibility to interpret what is necessary to meet “adequate protection.” The NRC establishes what is meant by adequate protection through rulemaking and the adjudicatory process. In general, adequate protection is presumptively assured by compliance with NRC requirements. The NRC staff evaluates situations of noncompliance to determine the degree of risk and whether immediate action is necessary. If the NRC determines that non-compliance itself is of such safety significance that adequate protection is no longer provided, or that it was caused by a deficiency so significant it questions a licensee’s or CoC holder’s ability to ensure adequate protection, the NRC may demand immediate action, up to and including cessation of licensed activities. [Reference: Atomic Energy Act, Section 182]

APPLICABLE STAFF POSITION

An “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 SRP (Standard Review Plan), 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

The Commission recognized the importance of “backfitting” controls when it approved 10 CFR 72.62 to establish administrative standards for NRC imposition of new regulations or new interpretations of existing regulations. The rule defines the term “backfitting” as the addition, elimination, or modification, after the license has been issued, of 1) structures, systems, or components of an ISFSI; or the procedures or organization required to operate an ISFSI. 10 CFR 72.62 only applies to licensees, not CoC holders, pursuant to 10 CFR 72.13. [Reference: 10 CFR 72.62(a)]

COMMITMENT

See Regulatory Commitment.

COMPLIANCE

The term “compliance” means that a structure, system or component (SSC) satisfies all requirements of applicable rules, regulations, orders and licenses (including Technical Specifications). Compliance is based on the intent of the requirement at the time of its promulgation. The NRC typically documents the intent of a requirement in a *Federal Register* notice, and licensees/CoC holders typically incorporate implementing language into the licensing basis by updating the Final Safety Analysis Report (FSAR) or other document controlled by the licensee or CoC holder. NRC regulations (10 CFR 50.59, 10 CFR 50.109, 10 CFR 72.48 and 10 CFR 72.62), supplemented by NRC and licensee/CoC holder procedures, control the imposition of new or different interpretations.

DESIGN BASIS

“Design basis” means that information that identifies the specific functions to be performed by a structure, system or component of an ISFSI facility or of a used fuel storage cask and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted state-of-the-art practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system or component must meet its functional goals. [Reference: 10 CFR 72.3]

DETERMINISTIC

The term “deterministic” means that specific causes completely and certainly determine effects. As applied in used fuel storage and transportation, it generally deals with evaluating the safety of a dry storage system or transportation package in terms of the consequences of a predetermined bounding subset of accident sequences. Compare with PROBABILISTIC. [Reference: NRC Website Glossary]

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 industry or NRC personnel, absent a nuclear safety issue. It may or may not be subject to a change-control process. Regulations, Regulatory Guides, and the Standard Review Plan are NRC guidance documents with a change-control protocol. The ISFSI license and the final safety analysis report are examples of specific licensee durable guidance documents with a change-control protocol. The dry storage system or transportation package CoC and the related [final] safety analysis report are examples of CoC holder durable guidance documents with a change-control protocol. NRC Regulatory Issue Summaries, NRC staff letters, NUREGs, industry letters to the NRC, and NEI reports, represent durable guidance documents that are not subject to a change-control protocol.

GENERIC SAFETY ISSUE

The NRC has classified five groups of issues as “generic safety issues:” (1) TMI Action Plan items, documented in NUREG-0660 and NUREG-0737; (2) Task Action Plan items, documented in NUREG-0371 and NUREG-0471, as well as all Unresolved Safety Issues (USIs) not originally identified in these two documents; (3) new generic issues identified from various sources; (4) human factors issues, documented in NUREG-0985; and (5) Chernobyl issues, documented in NUREG-1251. [References: NUREGs 0371, 0471, 0660, 0737, 0933, 0985, and 1251]

ISSUE OWNER ORGANIZATION

The organization (either Industry or the NRC) that identifies a potential issue for generic resolution using this protocol. The issue owner organization owns the issue until closeout, although different members of the issue owner organization need to be involved.

ISSUE RESOLUTION PLAN

The ‘issue resolution plan’ describes the issue background, actions, and schedule to be executed to resolve and close an issue. The issue team leader that owns the issue prepares, maintains and ensures implementation of the issue resolution plan.

LICENSING BASIS

The ‘licensing basis’ for an issue is comprised of:

- The set of obligations established by rules, regulations, licenses, certificates of compliance, and orders.
- The site-specific licensing basis documented in the final safety analysis report and other docketed correspondence (for specific licensees).
- The site-specific licensing basis documented in the dry storage system final safety analysis report, 10 CFR 72.212 Report and other docketed correspondence (for general licensees).
- The dry-storage system-specific licensing basis documented in the final safety analysis report and other docketed correspondence (for CoC holders).
- The regulatory guidance that a non-licensee is expected to satisfy in order to conform to NRC staff expectations, for example safety evaluations of storage system, transportation package designs or vendor topical reports.
- Official NRC interpretations by the Office of General Counsel.
- Precedent-setting regulatory decisions.

LICENSING PROCESS

The ‘licensing process’ is the collection of industry and NRC staff activities that are necessary to prepare, submit, review, approve, and maintain a license or CoC granted by the 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 (10 CFR 50.90, 10 CFR 72.56), the CoC amendment process (10 CFR 72.244), various reporting processes (10 CFR 50.72, 10 CFR 50.73, 10 CFR 72.75), various change-management processes (10 CFR 50.59, 10 CFR 72.48), the backfitting process (10 CFR 50.109, 10 CFR 72.62), the inspection process, and others. Some sub-processes are broken down further. For example, the license and CoC amendment processes include the acceptance review process and the request for additional information (RAI) process.

OBLIGATION

An ‘obligation’ is any condition or action that is a legally binding requirement imposed on licensees or CoC holders through applicable rules, regulations, orders, licenses and certificates of compliance (including technical specifications and license/CoC conditions). These conditions (also referred to as regulatory requirements) generally require formal NRC approval as part of the change-control process. Also included in the category of obligations are those regulations and license/CoC conditions that define change-control processes and reporting requirements for licensing basis documents such as the FSAR, quality assurance program, emergency plan, security plan, fire protection program, etc. [References: NEI 99-04 , LIC-105]

PRECEDENT

The term “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.

PROBABILISTIC

The term "probabilistic" is associated with an evaluation that explicitly accounts for the likelihood and consequences of possible accident sequences in an integrated fashion. Compare with DETERMINISTIC. [Reference: NRC Website Glossary]

PROBLEM STATEMENT

A “problem statement” is a detailed statement of the situation or circumstances that give rise to a regulatory issue. It should convey to a knowledgeable reader the nature and extent of a potential deficiency or non-compliance. The person or group from industry or the NRC that identifies the issue prepares a draft problem statement as part of the issue identification portion of the protocol. The problem statement is refined by the POC for the identifying organization as part of the screening portion of the protocol, and finalized by mutual consensus between industry and the NRC for those issues that meet the criteria for resolution as a generic issue.

PROTOCOL

The term “protocol” is defined as an administrative methodology for inter-organizational coordination and communications.

REGULATORY ANALYSIS

The NRC has developed guidance on performing a “regulatory analysis” of any regulatory action that involves backfitting. A structured analysis helps ensure that the agency bases its decisions on adequate information, and that the staff arrives at its decisions by following a systematic process. [Reference: NUREG/BR-0058]

REGULATORY COMMITMENT

A “regulatory commitment” is an explicit statement to take a specific action agreed to, or volunteered by, a licensee or CoC holder and submitted in writing on the docket to the NRC. [Reference: NEI 99-04, RIS 2000-17]

REGULATORY FINDING

A “regulatory finding” is a determination made by the Commission based on the Code of Federal Regulations. Before approving a licensing action, the NRC reviewer or reviewers must make a regulatory "finding." One objective of the issue resolution protocol is to understand the finding and its basis in the rules and regulations.

REQUIREMENT

The term “requirement” as used in this guideline means a legally binding requirement such as a statute, regulation, license/CoC condition, technical specification or order. In this guideline, it is synonymous with the term “obligation.”

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, from the identifying organization (NRC or Industry).

RISK-INFORMED REGULATION

The term “risk-informed regulation” refers to the use of probabilistic risk assessment (PRA) techniques in evaluating regulatory issues. A PRA considers nuclear safety in a comprehensive way by examining a broad spectrum of initiating events (circumstances that put a facility in an off-normal condition, such as a reactor trip or “scram” at a nuclear power plant). PRA analysts explore the frequency and consequences of various scenarios, giving a measure of risk.

[Reference: NRC website]

SCOPE OF APPLICABILITY

The “scope of applicability” for an issue is the set of licensees and other organizations subject to the results of a regulatory evaluation of the issue. The scope of applicability is identified early in the protocol and affected organizations are notified and given the opportunity to comment.

SCREENING CRITERIA

The “screening criteria” are the questions used to determine if an issue warrants evaluation and resolution on a generic basis. The issue screening criteria are defined in Appendix B.

STANDARD PROJECT MANAGEMENT TECHNIQUES

The protocol employs the following “standard project management techniques:”

- Problem statement
- Criteria for establishing the scope of applicability
- Resource planning (licensing and technical resource needs)
- Success criteria
- Milestones
- Stakeholder participation
- Documented summaries of public meetings
- Periodic status reports

SUCCESS CRITERIA

The “success criteria” are the attributes necessary to achieve closure of an issue within this protocol. The industry or NRC issue team that owns the issue develops the success criteria, subject to concurrence by the counterpart team. Success criteria typically include entering the issue into an existing regulatory process for final resolution.

TECHNICAL BASIS

The “technical basis” for an issue is comprised of:

- The standards and guidance documents that are incorporated by reference into the CFR, or cited by another NRC guidance document as an acceptable way to meet NRC expectations.
- Calculations, specifications, drawings, operating and test data, and other empirical information germane to the issue.
- Prudent engineering practice.

- An applicable probability risk assessment.

TOPICAL REPORT

A “topical report” is a technical document typically submitted by a vendor, an Owners Group or EPRI for NRC review and approval. Licensees may reference the NRC safety evaluation (SE) in requests for licensing action, subject to conditions and limitations documented in the SE.

**APPENDIX D
ACRONYMS**

ACRONYMS

CFR	Code of Federal Regulations
CLB	Current Licensing Basis
CoC	Certificate of Compliance (10 CFR 71 (transportation) and 10 CFR 72 (storage))
DSTF	NEI Dry Storage Task Force
EPRI	Electric Power Research Institute
FSAR	Final Safety Analysis Report (Part 72 specific licensees and Part 72 CoC holders)
GSI	Generic Safety Issue
IN	Information Notice
ISG	Interim Staff Guidance
LAR	License Amendment Request (also used for CoC amendment requests)
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
POC	Point-of-Contact
PRA	Probabilistic Risk Assessment
RAI	Request for Additional Information
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RLA	Request for Licensing Action
SAR	Safety Analysis Report (10 CFR 71 CoC holders)
SE	Safety Evaluation (NRC staff)
SER	Safety Evaluation Report (NRC staff)
SRP	Standard Review Plan (NUREG-1536, -1567, -1617, and -1927)
SSCs	Structures, Systems, and Components
STS	Standard Technical Specifications (NUREG-1745)
TI	Temporary Instruction
TIA	Task Interface Agreement
TS	Technical Specifications
UFST	Used Fuel Storage and Transportation

APPENDIX E
ISSUE RESOLUTION PLAN GUIDANCE

ISSUE RESOLUTION PLAN GUIDANCE

The Issue Resolution Plan should contain the following sections at a minimum. Other sections and subsections may be added as necessary to create a resolution plan to guide the issue to successful resolution.

I. Background

Provide a detailed historical summary of the issue and why it is an issue requiring generic resolution and industry-NRC interaction. The following elements should be considered in developing the background:

- Detailed Problem Statement
 - SSCs Affected
 - History
 - Affected Entities
 - Relevant Field Experience
 - Source and Reference Documents
 - Burden Created
- Regulatory Significance
 - Safety
 - Risk
 - Cost
 - Schedule
 - Precedent

II. Team Members

List the team members by organization and/or functional titles. The NEI POC should be included on all teams. Use of specific names is permitted but may want to be avoided to permit flexibility in the team membership without having to revise the plan simply to change the membership list. The issue team leader should create and maintain an email distribution list to facilitate communication and transmittal of documents.

III. Regulatory Baseline

- Licensing Basis (obligations, requirements, guidance, applicable staff positions)
- Technical Basis (design and performance requirements, guidance, codes, standards)
- Plant-specific or CoC-specific considerations

IV. Objectives and Success Criteria

Summarize the desired outcomes, including how the success criteria contained in the approved Issue Summary Form will be met. If different options for resolution are to be investigated, those options should be described with the associated advantages and disadvantages described.

Achievement of the success criteria should be memorialized in the issuance of “durable guidance.” Durable guidance is defined as a written document. If an issue is resolved simply by agreement between Industry and NRC to address the issue in a certain manner, the durable guidance is the final Issue Summary Form itself, where that agreement is explained in Section V, “Closeout.”

For issues requiring further action in another process, two types of durable guidance are available: those for which changes thereafter are controlled under a recognized change-control process, such as rulemaking or 10 CFR 72.48, or those not governed by a change control process, such as an NEI guidance document. If the latter type of durable guidance is used to resolve an issue, the document should not be changed in the future (unless a significant nuclear safety issue is involved) without using this protocol again to ensure mutual agreement between industry and the NRC. Additionally, NRC endorsement of the NEI guidance document is expected.

V. Action Plan and Schedule

Provide specific actions to be taken and who is responsible. Actions may be assigned to any involved entity or person. However, agreement on responsibility for those actions and the schedule for completion must be established with the affected party before the action plan is finalized.

Each action must have a duration, due date, and relationship to other actions (e.g., finish-to-start) shown in a schedule. The schedule may be in whatever format works for the complexity of the particular issue, from a simple table of actions and start/finish dates to a schedule using a more sophisticated tool, such as Microsoft Project. Because the schedule will be maintained for the life of the issue, simplicity is a key. Provide the necessary information to convey a clear assignment of actions and schedule for resolution without unnecessary complexity.

APPENDIX F REFERENCES

REFERENCES

1. Title 10, Code of Federal Regulations, Part 71, "Packaging and Transportation of Radioactive Material."
2. Title 10, Code of Federal Regulations, Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor Related Greater Than Class C Waste."
3. Atomic Energy Act of 1954 (as amended), Section 182, "License Applications."
4. U.S. Nuclear Regulatory Commission, Management Directive, MD 8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," October 28, 2004.
5. U.S. Nuclear Regulatory Commission, Website, "Glossary."
6. U.S. Nuclear Regulatory Commission, NUREG-0371, "Task Action Plans for Generic Activities (Category A)," November 1978.
7. U.S. Nuclear Regulatory Commission, NUREG-0471, "Generic Task Problem Descriptions (Categories B, C, and D)," June 1978.
8. U.S. Nuclear Regulatory Commission, NUREG-0660, Rev. 1, "NRC Action Plan Developed as a Result of the TMI-21 Accident," August 1980.
9. U.S. Nuclear Regulatory Commission, NUREG-0737, "Clarification of TMI Action Plan Requirements," November 1980.
10. U.S. Nuclear Regulatory Commission, NUREG-0933, "Resolution of Generic Safety Issues," Supplement 32, August 2008.
11. U.S. Nuclear Regulatory Commission, NUREG-0985, Rev. 2, "Human Factors Program Plan," April 1986.
12. U.S. Nuclear Regulatory Commission, NUREG-1251, "Implications of the Accident at Chernobyl for Safety Regulation of Commercial Nuclear Power Plants in the United States," April 1989.
13. Nuclear Energy Institute, NEI 99-04, "Guidelines for Managing NRC Commitment Changes," July 1999.
14. U.S. Nuclear Regulatory Commission, NRR Office Instruction LIC-105, Rev. 1, "Managing Regulatory Commitments Made by Licensees to the NRC," September 7, 2004.
15. U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Rev. 4, "Regulatory Analysis Guidelines of the U.S Nuclear Regulatory Commission," September 2004.

16. U.S. Nuclear Regulatory Commission, Regulatory Issue Summary, RIS 2000-17, “Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff,” September 21, 2000.
17. NEI Dry Storage Task Force Charter, Revision 0.
18. U.S. Nuclear Regulatory Commission, Website, “History of NRC’s Risk-Informed Regulatory Programs.”