NEI 10-06, Revision 0

REGULATORY ISSUE RESOLUTION PROTOCOL

A Methodology for Resolving Regulatory Issues with Generic Implications

June 2010

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Nuclear Energy Institute

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ACKNOWLEDGEMENTS

NEI acknowledges the assistance of the Regulatory Issue Resolution Protocol (RIRP) Team, a subset of the Licensing Action Task Force (LATF) in preparing this document. Also, special acknowledgement is extended to the Dry Storage Task Force (DSTF) for their assistance in advancing the protocol. The team's desired outcome is to produce guidance for the industry and the NRC to routinely use to effectively and efficiently resolve regulatory issues.

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NOTICE

ABSTRACT

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

1. **Identification Phase** – Any individual or group identifies a potential regulatory issue for generic resolution. Potential issues are forwarded to the NEI Licensing Action Task Force for screening.
2. **Screening Phase** – The issue is screened for acceptance using the specific questions outlined in the screening criteria. Those issues that do not meet the screening criteria are closed to an alternative course of action. Those issues that satisfy the screening criteria move in to the planning phase.
3. **Planning Phase** – The project plan is developed identifying the actions required to resolve the issue including specific gate reviews, communication plan and milestone schedule.
4. **Implementation Phase** – The tasks identified in the planning phase are executed and a final resolution is agreed upon between the industry and the NRC.
5. **Closure Phase** – The resolution is documented based on the results of the implementation phase. Closure is demonstrated with NRC endorsement or other regulatory action.

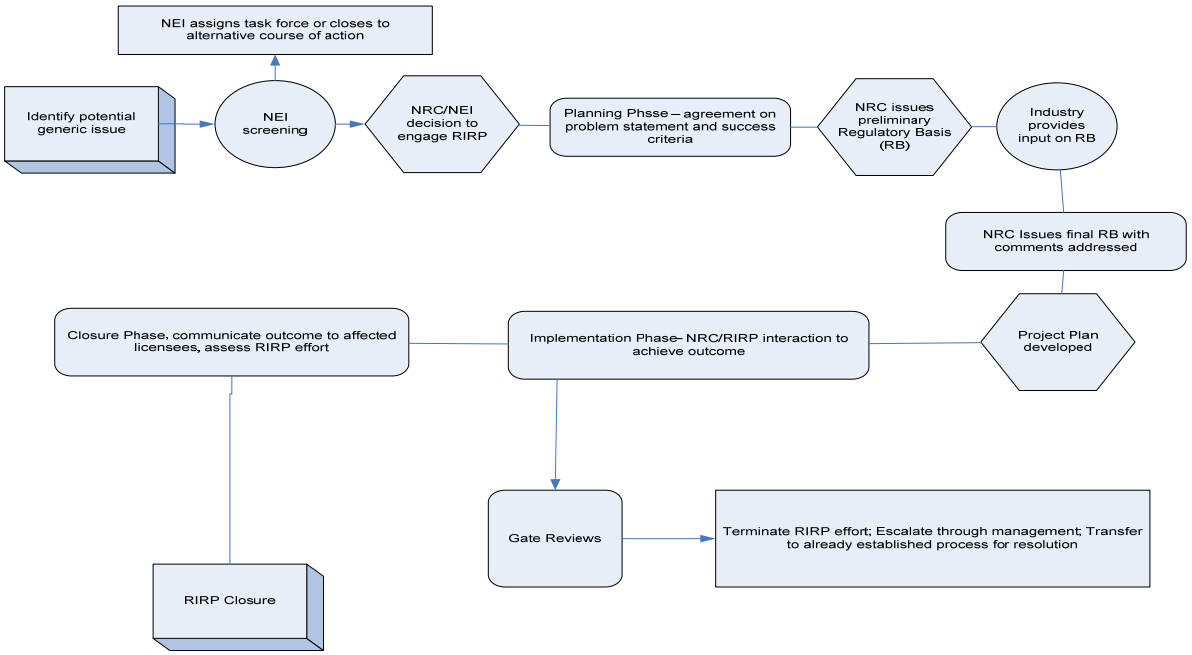

Figure i

Regulatory Issue Resolution Protocol Flow Chart

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REGULATORY ISSUE RESOLUTION PROTOCOL

1 OBJECTIVES

The Nuclear Energy Institute (NEI) has developed this resolution protocol to govern the identification, screening, evaluation, resolution, and closeout of regulatory issues with generic implications that apply to multiple licensees.

The objectives of the protocol are to:

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

2 ISSUE RESOLUTION PROTOCOL

The Regulatory Issue Resolution Protocol (RIRP) provides a framework for promoting timely evaluation and resolution of regulatory issues with generic implications (i.e., regulatory issues that apply to multiple licensees). The protocol provides a structure to consistently identify, screen, and resolve regulatory issues in situations where licensees are being asked to take actions that are inconsistent with accepted industry practice or for an emergent condition that introduces new information for which no current regulatory guidance exist. Issues within the scope of the protocol apply to multiple licensees 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 who identifies or proposes an issue, all resolution paths should point to achieving industry and/or NRC commitment to implementing actions and solutions determined by 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 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 or compliance matters, and does not alleviate the responsibility of licensees to comply with all applicable regulatory requirements.

3 ISSUE RESOLUTION PROTOCOL

3.1 PRINCIPLES

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

1. Clear and concise communication is used throughout the protocol:

   a) Define the problem to be resolved
   b) Develop success criteria including targets for evaluating progress
   c) Identify key terms and definitions needed to resolve differing interpretations
   d) Identify and explain the regulatory baseline to establish a well-understood foundation for the issue resolution
   e) Document NRC staff positions and industry commitments
   f) Track and manage new information or issues that emerge during any phase of the protocol
   g) Develop a communication plan for timely distribution of pertinent information to affected organizations
   h) Keep the management sponsor informed and elevate stalled issues as appropriate

2. Durable guidance is issued to enable longevity of resolution.

3. Lessons learned are documented for each regulatory issue to capture feedback for continuous improvement of the protocol.

3.2 PHASES

The regulatory issue resolution protocol has five phases. W*ho* and *what* are summarized below. The appendices contain recommendations on the *how* to implement.

3.2.1 Identification Phase

1. An individual or group (hereafter referred to as the Identifier) identifies a potential issue and completes the Regulatory Issue Screening Form Section I and II (Appendix A). See Appendix B for guidance.

2. The Issue Screening Form is forwarded to the NEI project manager for distribution to the Licensing Action Task Force for screening.

3.2.2 Screening Phase

1. The Identifier presents the issue to the Licensing Action Task Force to perform the screening by committee. The screening committee reviews the basis provided and

asks clarifying questions.

a) If the screening committee determines that any screening criteria are *not* satisfied, "NA" is entered in Section III of the Regulatory Issue Screening Form, and the reason(s) for closure are summarized in the Issue Closure Form (Appendix E). The Issue Screening Form and Issue Closure Form are returned to the Identifier with the reasons for rejection.

b) If the screening committee determines that all screening criteria are satisfied, the issue is granted preliminary acceptance. The information on the form should be refined based on the screening committees' review and input. The Regulatory Issue Screening Form is forwarded to the NRC in a transparent manner consistent with NRC protocols.

2. The NRC and industry interact as necessary to understand the proposed problem statement, background information, and the answers to the screening criteria questions. Screening discussions are held with the NRC in a transparent manner consistent with NRC protocols.

a) If mutual agreement cannot be reached that the issue satisfies all screening criteria, the issue is rejected and not resolved using this protocol. The reasons for rejection and a proposed alternative path for resolution are summarized on the Issue Closure Form and returned to the Identifier.

b) If industry and NRC agree that all screening criteria are satisfied, the issue is accepted as an issue to be resolved generically using this protocol along with the commitment of resources necessary to resolve the issue.

c) The issue moves to the planning phase.

3.2.3 Planning Phase

1. The planning phase begins when the NRC and industry agree the issue is acceptable to enter the resolution protocol. Industry and NRC form separate issue teams, each comprised of regulatory and technical specialists. An issue team leader and management sponsor are identified. The teams interact as necessary in a transparent manner consistent with NRC protocols.

2. The industry team leader develops the issue resolution project plan with guidance from the management sponsor. 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 C for a sample template and Appendix D for guidance.

3. As a normal course of action, finalization of the problem statement and success criteria should occur prior to problem solving and receive agreement from both management sponsors.

4. As a normal course of action, the NRC issue team will articulate a detailed draft regulatory basis that will drive issue resolution. The industry issue team will provide written comments for the NRC to consider prior to establishing the final regulatory basis. The issue resolution project plan should provide for discussion of both the NRC's draft regulatory basis and industry comments on the draft basis, prior to establishing the final regulatory basis. The regulatory basis will form the foundation upon which the resolution will be based.

5. The issue resolution project plan should consider short term actions to be taken while the long term resolution is in progress.

   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 to comply with all applicable regulatory requirements.

6. Gate reviews should be included along with the milestone schedule to communicate progress to management, industry, stakeholders, etc. The industry issue team will make corrections or adjustments to the resolution plan based on the feedback to keep the resolution on target.

7. When the issue resolution project plan is finalized, the plan should be reviewed with the NRC issue team prior to the implementation phase for agreement on scope of activities, the gate reviews, and the milestone schedule.

8. The issue resolution project plan can be modified based on the emergence of new information that changes the safety significance or urgency of the issues as determined by the NRC and industry.

3.2.4 Implementation Phase

1. Industry and NRC execute the issue resolution plan, interacting as necessary in a transparent manner consistent with NRC protocols. The industry team leader maintains the plan throughout the implementation 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.

2. Communication with the Licensing Action Task Force, the industry, region and other stakeholders should be maintained throughout the implementation phase. In particular, periodic communications should be considered at specific milestones.

3. After all tasks are completed, the implementation phase produces a resolution that ultimately involves durable guidance. An issue is considered resolved when agreements are reached and commitments made to: 1) resolve the issue through documenting the agreements and commitments on the Issue Closure Form (Appendix E), and 2) take specific additional actions, as necessary, to address the issue in the future under an existing regulatory process or processes. Those actions may include, but are not limited to:

   a) NRC 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 endorsed by NRC
   f) New NRC generic communications

3.2.5 Closure Phase

1. The industry team leader documents closure by defining the problem closure statement, identifying the regulatory process capturing the resolution, and describing the satisfaction of the success criteria. The approved resolution is documented on the Issue Closure Form (Appendix E) and includes a clear description of what existing process and durable guidance was utilized to produce a final resolution.

2. If any additional actions are required for final close out, the process used to track the issue to resolution is agreed upon by the industry issue team and NRC issue team.

3. The final gate review is performed by management sponsors to confirm closure.

3.3 REVISIONS TO REGULATORY ISSUE FORMS

Issue Screening Forms are intended to contain clear and concise descriptions of the problem statement and responses to the screening criteria questions 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 project 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 Closure 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 creating a new separate issue. If it is determined that a revision to any of the regulatory issue forms is the appropriate action, the team lead 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 management sponsor concurrence.

3.4 LESSONS LEARNED

At the conclusion of the resolution, the industry team lead should gather lessons learned from the issue teams and other stakeholders, as appropriate, to improve the Regulatory Issue Resolution Protocol. The lessons learned should be incorporated into this guidance document.

APPENDIX A
REGULATORY ISSUE SCREENING FORM

REGULATORY ISSUE SCREENING FORM

Title: _____

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

b. Background Information (Summarize industry events, licensing actions, inspection information, correspondence, and other documents germane to the issue. Attach documents 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** (provide basis)**?**

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

4. **Will generic resolution of the issue produce tangible benefits** (provide basis)**?**

5. **What regulatory process is being utilized or should be utilized** (provide basis)**?**

III. Are all screening criteria satisfied?

Yes _____ No_____

IV. Date: _____

APPENDIX B
REGULATORY ISSUE RESOLUTION SCREENING FORM GUIDANCE

REGULATORY ISSUE RESOLUTION SCREENING FORM GUIDANCE

This appendix provides additional detail to be used as guidance in completing the Regulatory Issue Screening Form in Appendix A. 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 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

The issue identifier provides responses to the screening criteria questions. Each question should be answered as proposed below. In order for the issue to be accepted into the protocol for resolution, Questions 1 through 4 requires a “yes” answer and Question 5 requires a “no” answer.

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, 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. Identify the potential benefits to approaching the resolution from an industry perspective.

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. Industry may desire 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 be clearly stated.

4. Will generic resolution of the issue produce tangible benefits (provide basis)?

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?

5. What regulatory process is being utilized or should be utilized (provide basis)?

Provide an explanation of the existing regulatory process addressing the issue. 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 is not providing the desired results in the products produced by licensees.

In addressing adequacy of the existing process, include timeliness such that if the applicable existing process would not result in timely resolution where time is sensitive, then it is inadequate. To support such an argument, the need for expedient resolution needs to be well documented.

Section IV - Date

After the screening committee reviews and approves the issue, the problem statement and screening criteria should be revised 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 satisfied.

Issues successfully screened are presented to NRC and industry, respectively, for agreement to commit resources to engage in the resolution protocol.

APPENDIX C
ISSUE RESOLUTION PROJECT PLAN

ISSUE RESOLUTION PROJECT PLAN

Title:_____

I. Problem Statement

II. Success Criteria

III. Regulatory Basis

IV. Summary of Resolution Plan

V. Gate Reviews, Milestones and Due Dates

Gate Reviews/Milestones	RESPONSIBLE PARTY	DUE DATE

APPENDIX D
ISSUE RESOLUTION PROJECT PLAN GUIDANCE

ISSUE RESOLUTION 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. Items to consider for inclusion are recommended based on lessons learned from the pilot(s) and practical experience. The detail included in the Issue Resolution Project Plan should be commensurate with the complexity of the issue.

Background – Issue Team Pre-Work

Research the regulatory issue to allow the issue team members to gain an understanding of the issue. 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 significance
  - Risk-insights
  - Cost burden
  - Schedule impact
  - Precedent or current accepted practice

I. Problem Statement

The industry and NRC issue 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 input 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 need to be specific, tangible and directed toward moving the issue to an existing process for final resolution. 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 input are important to ensure the resolution will address the problem being solved.

III. Regulatory Basis

The NRC issue team will articulate a draft regulatory basis for discussion with the industry issue team. The draft regulatory basis 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 NRC and industry teams will discuss the draft regulatory basis and the industry team will provide written comments on the draft. The NRC issue team will provide a written analysis addressing the industry team comments along with the final regulatory basis for the relevant issue. While the iterations should not be extensive, a clear understanding of which regulations apply as well as how those regulations apply will provide the base for the resolution and enable the industry to determine acceptance criteria that will result in compliance.

IV. Summary of Resolution Plan

The summary of the resolution plan should be developed with guidance from the management sponsor and should describe the actions to be taken to resolve the issue and any additional the resources needed. The plan should be detailed commensurate with the complexity of the issue.

V. Gate Reviews, Milestones and Due Dates

Gate reviews are defined points in the issue resolution project plan where the management sponsor is engaged with the issue team to make the decision to proceed on course; to request additional action; or to make a course correction up to and including project cancellation.

Gate reviews are scheduled periodically to communicate progress; to discuss challenges; and to solicit management feedback and concurrence. Consider scheduling gate reviews based on milestone completion as opposed to calendar date.

Initial gate reviews are scheduled for feedback and confirmation of the problem statement and success criteria. Additional gate reviews can be established to confirm the interim compensatory actions required until the longer term final resolution is determined.

Milestone actions and due dates are outlined with the level of detail commensurate with the complexity of the issue. Communications to the Licensing Action Task Force, the industry and other stakeholders should be considered after milestones are completed.

APPENDIX E
ISSUE CLOSURE FORM

REGULATORY ISSUE CLOSURE FORM

Title:_____

I. Problem Statement

II. Closure Statement

For rejected issues: Summarize the reason(s) for issue rejection and forward to the Identifier. 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 responsible party in Section 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.

IV. Durable Guidance

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

IV. Tracking Items and Responsibility

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

Date: _____

APPENDIX F
KEY TERMS AND DEFINITIONS

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 holders typically incorporate implementing language into the licensing basis by updating the Final Safety Analysis Report (FSAR) or other document controlled by the licensee. NRC regulations (10 CFR 50.59, 10 CFR 50.109, 10 CFR 72.48 and 10 CFR 72.62), supplemented by NRC and licensee 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 is subject to a change-control process. Regulations, Regulatory Guides, and the Standard Review Plan are examples of NRC documents with a change-control protocol. NRC Regulatory Issue Summaries, NRC staff letters, NUREGs, industry letters to the NRC, and NEI reports are not subject to a change-control process, and therefore, not considered durable guidance.

ISSUE RESOLUTION PROJECT PLAN
The 'issue resolution project plan" describes the issue background, gate 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 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 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 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
The "problem statement" is a one or two sentence statement that identifies the issue to be resolved. It is not the misunderstanding 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 person or group from industry 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
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 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 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.

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
- Milestone schedule
- Gate reviews
- 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.

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 G
ACRONYMS

ACRONYMS

CFR	Code of Federal Regulations
CLB	Current Licensing Basis
CoC	Certificate of Compliance
DSTF	NEI Dry Storage Task Force
EPRI	Electric Power Research Institute
FSAR	Final Safety Analysis Report
GSI	Generic Safety Issue
IN	Information Notice
ISG	Interim Staff Guidance
LAR	License Amendment Request
LATF	Licensing Action Task Force
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
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