Wright, Darlene

From: Marv Lewis <marvlewis@juno.com>
Sent: Monday, June 09, 2014 10:06 AM
To: kevin@beyondnuclear.org; catalyst@actionPa.org; tomclements329@cs.com; traci@energyjustice.net
Cc: parhangelsky@emord.com; et@prop1.org
Subject: Fw: Cumulative Effects of Regulation for Fuel Cycle Facilities quarter ly meeting
Attachments: ATT00003.txt; ATT00004.htm; 6-9-14 NRC and NEI Slides to Support Quarterly CER Meeting for Fuel Cycle.pdf; Fuel Cycle Integrated Schedule of Regulatory Activities Supporting CER.pdf; 05-29-14 NEI Letter Submittal of DRAFT Regulatory Issue Resolution Protocol for Discussion During June 9 2014 NRC Public Meeting Regarding the Cumulative Impacts on Fuel Cycle Facilities.pdf; May 2014 NEI Enclosure Draft Regulatory Issue Resolution Protocol.pdf

Friends,
This looks important. The public could get deregulated out of everything.
marvu

Please note: forwarded message attached

From: "Bartlett, Matthew" <Matthew.Bartlett@nrc.gov>
To: "marvlewis@juno.com" <marvlewis@juno.com>
Subject: Cumulative Effects of Regulation for Fuel Cycle Facilities quarterly meeting
Date: Mon, 9 Jun 2014 08:37:08 -0400

Marvin,

Attached please find the slide presentation supporting today's 2:30-4:00pm (Eastern) Category 2 public meeting entitled "PUBLIC MEETING TO DISCUSS REGULATORY INITIATIVES RELATED TO THE FUEL<http://meetings.nrc.gov/pmns/mtg?do=details&Code=20140883>
CYCLE INDUSTRY<http://meetings.nrc.gov/pmns/mtg?do=details&Code=20140883>." Also attached is an updated version of the Fuel Cycle Integrated Schedule of regulatory activities (previous version here<http://www.nrc.gov/materials/fuel-cycle-fac/regs-guides-comm.html#cumeffects>).

Note that industry representatives from the Nuclear Energy Institute (NEI) plan to discuss a proposed "Regulatory Issue Resolution Protocol" for fuel cycle facilities, see attached.

Agenda
DISCUSS REGULATORY INITIATIVES RELATED TO THE FUEL CYCLE INDUSTRY
June 09, 2014, 02:30 PM to 04:00 PM
Bridge Line: 888-530-3072
Code: 63953
AGENDA:
2:30-2:40 pm - Introductions
2:40-3:00 pm - NRC updates on the Integrated Schedule and process for new regulatory activities
3:00-3:30pm - NEI presentation on proposals for an issue resolution protocol
3:30-4:30pm - General discussion on cumulative effects of regulation for fuel cycle facilities

Note that today's cumulative effects of regulation meeting will focus on the area of the Nuclear Fuel Cycle. To my knowledge, no reactor representatives will be present either from the NRC or industry.

Let me know if you need any additional information. (I will be away from my office after 12:00pm)

Sincerely,

Matt Bartlett
Project Manager
NMSS/FCSS/CDMB
301-287-9112

Marvin,

Attached please find the slide presentation supporting today's 2:30-4:00pm (Eastern) Category 2 public meeting entitled "PUBLIC MEETING TO DISCUSS REGULATORY INITIATIVES RELATED TO THE FUEL CYCLE INDUSTRY." Also attached is an updated version of the Fuel Cycle Integrated Schedule of regulatory activities (previous version here).

Note that industry representatives from the Nuclear Energy Institute (NEI) plan to discuss a proposed "Regulatory Issue Resolution Protocol" for fuel cycle facilities, see attached.

Agenda

DISCUSS REGULATORY INITIATIVES RELATED TO THE FUEL CYCLE INDUSTRY

June 09, 2014, 02:30 PM to 04:00 PM
Bridge Line: 888-530-3072
Code: 63953

AGENDA:

2:30-2:40 pm - Introductions
2:40-3:00 pm - NRC updates on the Integrated Schedule and process for new regulatory activities
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3:30-4:30pm - General discussion on cumulative effects of regulation for fuel cycle facilities

Note that today's cumulative effects of regulation meeting will focus on the area of the Nuclear Fuel Cycle. To my knowledge, no reactor representatives will be present either from the NRC or industry.

Let me know if you need any additional information. (I will be away from my office after 12:00pm)

Sincerely,

Matt Bartlett
Project Manager
NMSS/FCSS/CDMB
301-287-9112

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Cumulative Effects of Regulation

Presenter: Matt Bartlett
NRC Project Manager NMSS/FCSS
301-287-9112, matthew.bartlett@nrc.gov

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Introduction

- CATEGORY 2 MEETING
  - The primary discussions are expected to be between the NRC, the Nuclear Energy Institute and industry representatives. Members of the public will be invited to participate at designated points during the meeting.
- REMINDER
  - The timelines presented are based on best estimates, but may change based on pressing safety issues or other Commission priorities.

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CER Agenda

- **Updated Integrated Schedule**
- **Points of Interest on Integrated Schedule**
- **Issue Resolution Protocol**
- **Consideration of factors that impact CER**

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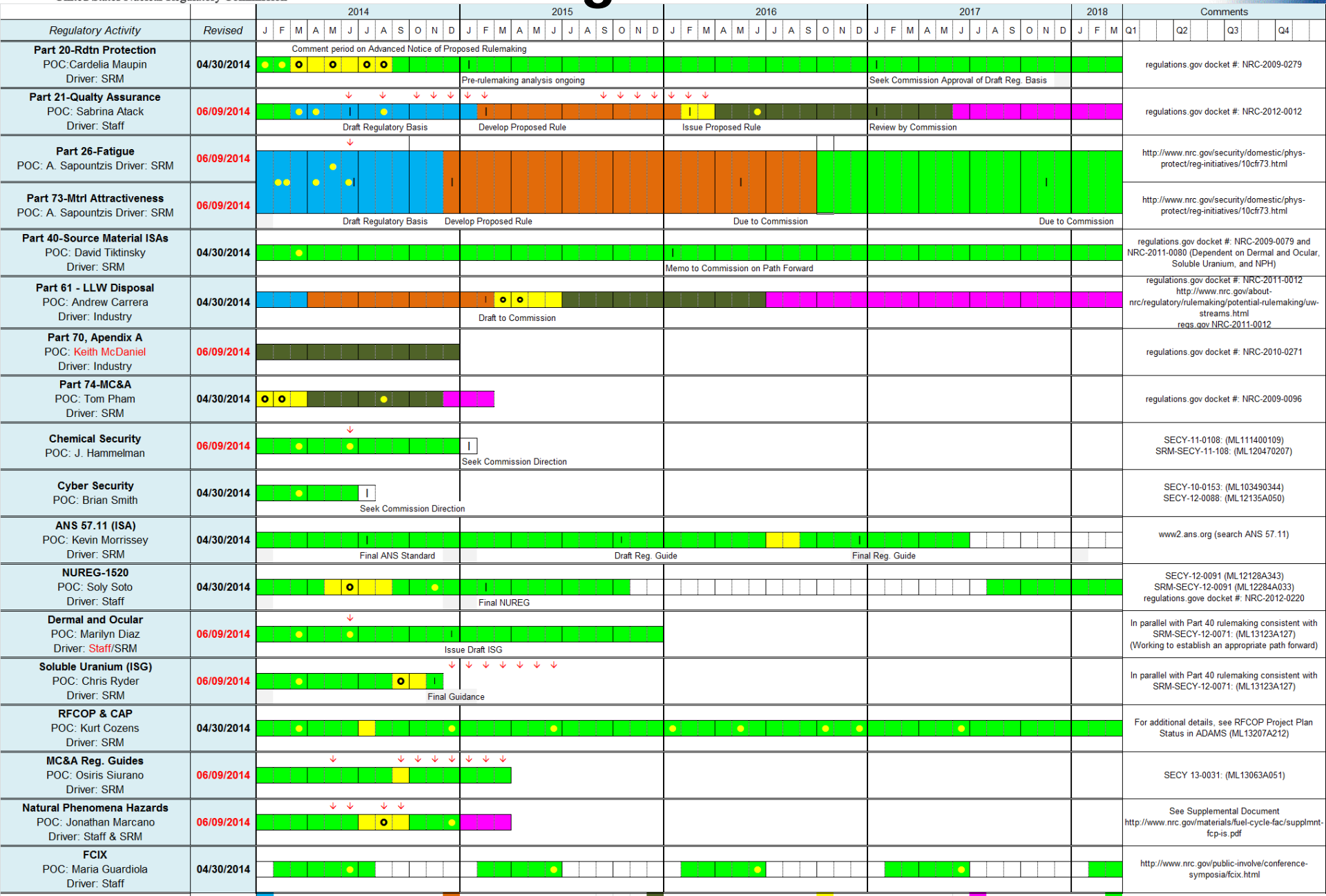
Integrated Schedule



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Points of Interest

- **Rulemakings**
  - Part 21 – Draft regulatory basis will be publically available in June 2014
  - Part 26/73 – Issued regulatory basis, meeting Thursday, June 12, 2014
  - Part 70 – Proceeding to office concurrence.
  - Part 74 – Rebaselining schedule to address comments

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Current Status (continued)

- **Regulatory Initiatives (not-rulemaking)**
  - ANS-57.11 – New draft out for working group comments by July
  - NUREG-1520 – Draft issued for public comment (regs.gov # NRC-2012-0220)
  - Natural Phenomenon Hazards – GL under review by OGC and staff developing ISG

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Issue Resolution Protocol

- **Seeking a Unified Resolution Protocol**

Regulatory Evaluation Summary

Identification	Screening	Planning	Implementation	Closure

- **Regulatory Evaluation Summary**

Document: Issue, Purpose, Challenges, Interactions

- **Improved Communication and Establish Scope**

Leverage CER

Minimize burden

Old Fashioned
Cell Phone

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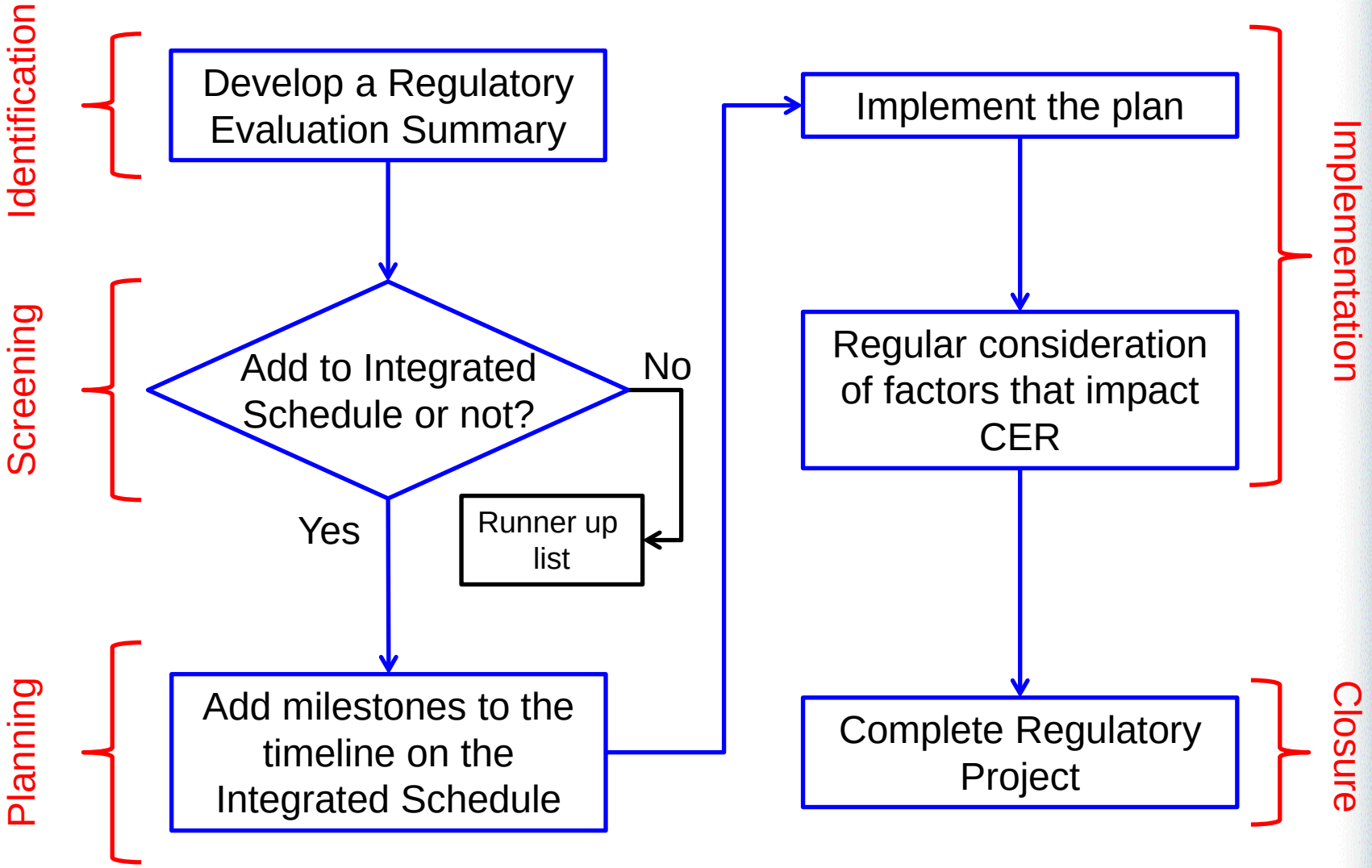
New Initiative Flow Chart



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Consideration of factors impacting CER

- **Develop Items in parallel**

- **Considerations to continue, adjust, or remove activities and milestones on the integrated schedule.**

- **Multiple Questions to Consider**

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Considerations for Schedule

Gap impacting safety/security?
Commission direction on dates?
Resources and skill sets available?
Level of effort/time to completion?
Alternate approaches possible?
Perceived public/industry benefit?

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Summary

- **Maintain Integrated Schedule**
  http://www.nrc.gov/materials/fuel-cycle-fac/regs-guides-comm.html#cumeffects
- **Develop an Issue Resolution Protocol**
- **Considerations to continue, adjust, or remove**
- **Thoughts and feedback**

Cumulative Impact:
DRAFT Issue Resolution Protocol

(See NEI letter to NRC dated May 29, 2014)

Janet Schlueter

Senior Director, Fuel and Materials Safety

June 9, 2014

What is our Goal?

- Establish a transparent and timely process to:
  - Identify and vet new generic issues
  - Clarify and communicate regulatory concern and provide opportunities for stakeholder input;
  - Establish and document applicable regulatory processes or other tools, e.g., rulemaking, guidance development
  - Relative rank issues are reflected in integrated schedule and milestones

What are its Principles?

- Transparent and timely generic issue resolution
- Clear communication, issue documentation and tracking of issues using established forms
- Mutual commitments by NRC and industry to adhere to a process
- Well-documented issue definition, basis to include safety/security nexus and regulatory analysis
- Legal counsel input sought early when indicated
- Risk-informed and performance-based approaches encouraged to resolve issue
- Implementable schedule and milestones

What are its Limitations?

- Issue resolution process not intended to circumvent any formal regulatory process
- Recognize that the result of such a process may need to be further considered through rulemaking, guidance development or other regulatory processes or tools
- Iterative process, e.g., periodic review of protocol for lessons-learned and applied

What are the 5 Issue Phases?

- Identification
- Screening
- Planning
- Implementation
- Closure

Issue forms document phases and help focus NRC and industry efforts.

What is the Path Forward?

- *June 2014* - Public discussion of industry draft protocol and solicit NRC feedback
- *July 2014* - Incorporate NRC feedback and submit final protocol as NEI 14-XX document for NRC endorsement
- *August 2014* – Receive NRC endorsement by letter
- ≥ *September 2014* – Begin its use when new generic issue identified

Current Regulatory Activities Under the Fuel Facilities Business Line

Public Document

Regulatory Activity	Revised	2014 J F M A M J J A S O N D	2015 J F M A M J J A S O N D	2016 J F M A M J J A S O N D	2017 J F M A M J J A S O N D	2018 J F M	Comments
Part 20-Rdtn Protection POC:Cardelia Maupin Driver: SRM	**04/30/2014**	Comment period on Advanced Notice of Proposed Rulemaking	Pre-rulemaking analysis ongoing		Seek Commission Approval of Draft Reg. Basis		regulations.gov docket #: NRC-2009-0279
Part 21-Qualty Assurance POC: Sabrina Atack Driver: Staff	**06/09/2014**	Draft Regulatory Basis	Develop Proposed Rule	Issue Proposed Rule	Review by Commission		regulations.gov docket #: NRC-2012-0012
Part 26-Fatigue POC: A. Sapountzis Driver: SRM	**06/09/2014**	Draft Regulatory Basis	Develop Proposed Rule	Due to Commission	Due to Commission		http://www.nrc.gov/security/domestic/phys-protect/reg-initiatives/10cfr73.html
Part 73-Mtrl Attractiveness POC: A. Sapountzis Driver: SRM	**06/09/2014**						http://www.nrc.gov/security/domestic/phys-protect/reg-initiatives/10cfr73.html
Part 40-Source Material ISAs POC: David Tiktinsky Driver: SRM	**04/30/2014**			Memo to Commission on Path Forward			regulations.gov docket #: NRC-2009-0079 and NRC-2011-0080 (Dependent on Dermal and Ocular, Soluble Uranium, and NPH)
Part 61 - LLW Disposal POC: Andrew Carrera Driver: Industry	**04/30/2014**		Draft to Commission				regulations.gov docket #: NRC-2011-0012 http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/uw-streams.html regs.gov NRC-2011-0012
Part 70, Apendix A POC: Keith McDaniel Driver: Industry	**06/09/2014**						regulations.gov docket #: NRC-2010-0271
Part 74-MC&A POC: Tom Pham Driver: SRM	**04/30/2014**						regulations.gov docket #: NRC-2009-0096
Chemical Security POC: J. Hammelman	**06/09/2014**		Seek Commission Direction				SECY-11-0108: (ML111400109) SRM-SECY-11-108: (ML120470207)
Cyber Security POC: Brian Smith	**04/30/2014**	Seek Commission Direction					SECY-10-0153: (ML103490344) SECY-12-0088: (ML12135A050)
ANS 57.11 (ISA) POC: Kevin Morrissey Driver: SRM	**04/30/2014**	Final ANS Standard	Draft Reg. Guide	Final Reg. Guide			www2.ans.org (search ANS 57.11)
NUREG-1520 POC: Soly Soto Driver: Staff	**04/30/2014**		Final NUREG				SECY-12-0091 (ML12128A343) SRM-SECY-12-0091 (ML12284A033) regulations.gove docket #: NRC-2012-0220
Dermal and Ocular POC: Marilyn Diaz Driver: Staff/SRM	**06/09/2014**	Issue Draft ISG					In parallel with Part 40 rulemaking consistent with SRM-SECY-12-0071: (ML13123A127) (Working to establish an appropriate path forward)
Soluble Uranium (ISG) POC: Chris Ryder Driver: SRM	**06/09/2014**	Final Guidance					In parallel with Part 40 rulemaking consistent with SRM-SECY-12-0071: (ML13123A127)
RFCOP & CAP POC: Kurt Cozens Driver: SRM	**04/30/2014**						For additional details, see RFCOP Project Plan Status in ADAMS (ML13207A212)
MC&A Reg. Guides POC: Osiris Siurano Driver: SRM	**06/09/2014**						SECY 13-0031: (ML13063A051)
Natural Phenomena Hazards POC: Jonathan Marcano Driver: Staff & SRM	**06/09/2014**						See Supplemental Document http://www.nrc.gov/materials/fuel-cycle-fac/supplmnt-fcp-is.pdf
FCIX POC: Maria Guardiola Driver: Staff	**04/30/2014**						http://www.nrc.gov/public-involve/conference-symposia/fcix.html

O/● = Meetings

I = Marks a milestone with text

= Regulatory Basis/Draft Guidance **= Proposed Rule/Draft Guidance** **= Final Rule/Final Guidance** **= Public Interaction** **= Implementation** **= Non-rulemaking/NRC Activities**

↓ = Change occurred in the box below arrow

http://www.nrc.gov/materials/fuel-cycle-fac/cer-integrated-schedule.xlsx

Dates are subject to change.

JANET R. SCHLUETER
Senior Director, Fuel and Materials Safety

1201 F Street, NW, Suite 1100
Washington, DC 20004
P: 202.739.8098
jrs@nei.org
nei.org

NUCLEAR ENERGY INSTITUTE

May 29, 2014

Ms. Marissa G. Bailey
Director, Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: DRAFT Regulatory Issue Resolution Protocol for Discussion During June 9, 2014 NRC Public Meeting Regarding the Cumulative Impacts on Fuel Cycle Facilities

Project Number: 689

Dear Ms. Bailey:

On behalf of the fuel cycle industry, the Nuclear Energy Institute (NEI)[1] appreciates the quarterly public meetings held since June 2013 to discuss our collective progress in managing the cumulative impact of U.S. Nuclear Regulatory Commission (NRC) regulatory actions on fuel cycle facilities. We continue to believe that the dialogue between the NRC and industry has resulted in tangible improvements regarding the planning and execution of certain initiatives. While the improvements have been primarily in the form of communications and certain initiative milestones, future discussions regarding regulatory priorities and a generic regulatory issue resolution protocol also show promise. As such, we look forward to significant progress on these two program areas during 2014.

By way of background, during the March 2014 NRC public meeting in Atlanta on cumulative impacts, we discussed the need to develop a relative ranking or prioritization for new regulatory initiatives as well as the viability of a generic regulatory issue resolution process. We believe that making progress on these two key program elements is critical to ensuring that industry and NRC resources are better focused in the future on issues of the highest safety significance. We appreciate the NRC support demonstrated to date in this regard, and look forward to the June 9, 2014 NRC public meeting on cumulative impacts where these program elements will be discussed.

[1] The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

To that end, attached please find a draft NEI guidance document entitled, "Draft Regulatory Issue Resolution Protocol." We submit this draft document as a strawman to facilitate our June 9, 2014 discussion. It should in no way be considered near final, rather it is provided to focus and facilitate our discussions on a potential issue resolution protocol. It should also be noted that the draft protocol is modeled after an existing NEI guidance (NEI 10-03) document in use today between NEI and NRC's Division of Spent Fuel Storage and Transportation. Any implied or explicit timeliness measures contained in the protocol are placeholders and subject to change based on NRC feedback. Finally, while industry considered using a real or fabricated regulatory issue to walk through the protocol during our upcoming meeting, there was concern that our discussions on the draft protocol would be diluted or distracted by the details of the issue, be it real or fabricated.

Our goal during the June 9, 2014 meeting is three fold: 1) discuss the guiding principles, process phases, documentation tools, timelines, etc., in the draft protocol; 2) solicit NRC feedback on its completeness and clarity, and 3) solicit NRC feedback on whether such a protocol is viable from NRC's perspective and, if not, how it can be improved to increase the likelihood that NRC would endorse its use. We recognize that NRC may not be in a position to make a final decision during the June 9th meeting, but we trust that NRC will provide industry feedback during the meeting and a timely decision afterwards on the viability of this protocol and path forward. Upon receipt of NRC feedback, we would modify the draft protocol as appropriate and forward it to your office by letter that would request NRC's endorsement for its use when new generic regulatory initiatives are identified by either NRC or industry.

It is also our understanding based on the March 2014 meeting and subsequent follow up that NRC plans to provide a draft regulatory initiative prioritization or relative ranking scheme for discussion during the June 9th meeting. We look forward to discussing this key program element as well, and appreciate NRC taking the lead on it. It would be most helpful if NRC could forward background information in advance of the June 9th meeting on this subject to facilitate our discussions and enable industry to provide complete and timely input on it.

If you have any questions, please feel free to contact me or Andrew Mauer at 202-739-8018; anm@nei.org.

Sincerely,

Janet R. Schlueter

c: Ms. Catherine Haney, NMSS, NRC
Mr. Anthony T. Gody, Jr., R-II/DFFI, NRC
Mr. Matthew A. Bartlett, NMSS/FCSS/CDMOB, NRC
NRC Document Control Desk

DRAFT REGULATORY ISSUE RESOLUTION PROTOCOL

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

May 2014

Nuclear Energy Institute, 1201 F. Street N. W., Suite 1100, Washington D.C. (202.739.8000)

ABSTRACT

This guideline describes a Regulatory Issue Resolution 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 not a new regulatory process. It 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 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 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 potential generic issue is promptly brought to the attention of the other organization to determine, collectively, whether the issue should advance 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 using the specific questions outlined in the screening criteria. Issues that do not meet the screening criteria would likely be dispositioned to 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 time line with milestones, responsible organization and communication tools.

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 NRC based on the results of the implementation phase, e.g., issuance of generic guidance or communication, endorsement of industry approach.

DRAFT REGULATORY ISSUE RESOLUTION PROTOCOL

1 OBJECTIVES

The Nuclear Energy Institute (NEI) developed this resolution protocol to govern the identification, screening, evaluation, resolution, and closeout of regulatory issues with generic implications that apply to operating or future fuel cycle facilities. This protocol is essentially identical to others in use today in such NRC regulatory program areas as 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

2 ISSUE RESOLUTION PROTOCOL

The Regulatory Issue Resolution Protocol (RIRP) 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 in situations such as those where licensees are being asked to take actions that are not consistent with accepted industry practice, previous NRC positions or expectations, 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 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 whether NRC or industry identifies or proposes a generic 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 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.

3 ISSUE RESOLUTION PROTOCOL 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 communication is 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 indicated, 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 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, when indicated, to capture feedback for continuous improvement and possible modification of the protocol.

3.2 PHASES

The regulatory issue resolution protocol has five phases: 1) Identification; 2) Screening; 3) Planning; 4) Implementation; and 5) Closure.

3.2.1 Identification Phase

1. An individual or group (hereafter referred to as the Identifier) of either organization identifies a potential generic regulatory issue and raises this issue within its organization, e.g., NRC's Fuel Cycle Safety and Safeguards Division, fuel facility management and NEI's Fuel Operations Committee for initial discussion. It is recognized that there may be issues that do not proceed into the screening phase which involve both organizations.

2. If the identifying organization evaluates the issue as having generic implications, the potential issue is then shared with the other organization for initial discussion and potential screening in accordance with this protocol.

3.2.2 Screening Phase

1. The Identifier presents the issue to NRC and industry members for timely "screening" and discussion to ensure that the full scope of the issue and its potential impact are identified and clearly understood by both organizations at the appropriate management level, e.g., NRC Division Director and NEI Senior Director.

   a) If the screening process determines that any screening criteria (see below) are *not* satisfied, the issue should be documented as "closed" for the purposes of this RIRP, and returned to the Identifier with the basis for the determination within 30 days of the decision to close it.

   b) If all screening criteria are satisfied, the issue is granted preliminary acceptance for consideration under the RIRP and documented accordingly.

2. Within 60 days of a decision to "accept" the issue under this protocol, 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 policies and procedures.

   a) If mutual agreement cannot be reached that the issue satisfies all screening criteria, the issue is rejected for resolution via this protocol method. The reasons for rejection and a proposed alternative path for resolution are summarized on the Issue Closure Form and returned to the Identifier within 30 days of the "rejection" decision.

   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. It is assumed that both organizations will commit necessary resources to resolve the issue in a timely manner commensurate with its potential significance.

   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, when practicable, each comprised of regulatory and technical specialists. An issue team leader, who acts as the primary point of contact and protocol facilitator, and responsible manager is identified for each organization, e.g., NRC Division Director,

NEI Director. The teams interact as necessary in a transparent manner consistent with NRC policies and procedures.

2. Within 60 days from entering the planning phase, the team leaders jointly develop the issue resolution project 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 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 organizations at the management level.

4. As a normal course of action, NRC will articulate a detailed draft regulatory basis that will drive issue resolution. When indicated, industry will provide written comments on NRC's draft regulatory basis for consideration prior to finalizing it. 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 is considered final when both organizations agree on the scope of activities, the gate reviews and milestone schedule. The relative priority of the issue will determine the schedule. This would normally occur prior to the implementation phase although it should be considered a living document that would be modified as needed.

6. The issue resolution project plan can be modified based on the emergence of new information that changes the 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 policies and procedures. The NRC or 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. After all tasks are completed, the implementation phase produces a resolution that is ultimately durable, e.g., rulemaking, guidance. An issue is considered resolved when agreements are reached and commitments made to: 1) resolve the issue through documenting the agreements and commitments 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
g) New or revised guidance drafted by external organizations, e.g., ANS

3.2.5 Closure Phase

1. The NRC or 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 NRC and industry.

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 regulatory issue. If it is determined that a revision to any of the regulatory issue forms is 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.

3.4 LESSONS LEARNED

At the conclusion of the resolution phase, the industry should gather lessons learned from all stakeholders, as appropriate, to improve the NEI Regulatory Issue Resolution Protocol. The lessons learned should be communicated to NRC with the goal of reaching alignment and ultimately being incorporated into this protocol when indicated.

APPENDIX A
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

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 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

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, 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 and, if so, why and when?

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. 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 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. 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 products produced by licensees.

Timeliness needs to be assessed and discussions held to aid in the prioritization of the resolution and assignment of resources. . The need for expedient resolution needs to be documented.

Section IV - Date

After the team leads and respective NRC and NEI management approve the issue proceeding, 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 engage in issue resolution using this NEI protocol.

APPENDIX C
ISSUE RESOLUTION PROJECT PLAN

Title: _____

I. Problem Statement

II. Success Criteria

III. Regulatory Basis

IV. Summary of Resolution Plan

V. Milestones, Responsibility Party, and Due Date

Milestones	RESPONSIBLE PARTY	DUE DATE

APPENDIX D
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. 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
  - 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 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' 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 need to be specific, measurable, realistic, 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' inputs 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, when indicated, 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 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 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. Milestones, Responsible Parties, and Due Dates

Periodically, the NRC management sponsor, e.g., Division Director and NEI should be 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 modification or cancellation. Milestone actions and due dates are outlined with the level of detail commensurate with the complexity of the issue.

Reviews are 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.

Initial reviews are scheduled for feedback and confirmation of the problem statement and success criteria.

APPENDIX E
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

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 70.76 to establish administrative standards for NRC imposition of new regulations or new interpretations of existing regulations. The rule defines the term "backfitting" as 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.

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, 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
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, 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.

OBLIGATION
An "obligation" is any condition or action that is a legally binding requirement imposed on licensee holders through applicable rules, regulations, orders, licenses and certificates of compliance (including technical specifications). 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.

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.

PROBLEM STATEMENT
The "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
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: 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.

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.

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.