

July 14, 2015

MEMORANDUM TO: Tara Inverso, Chief
Rulemaking Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

FROM: Natreon Jordan, Project Manager **/RA/**
Rulemaking Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

SUBJECT: NOTICE OF FORTHCOMING CATEGORY 3 PUBLIC MEETING ON
STAFF RECOMMENDATIONS REGARDING RISK MANAGEMENT
REGULATORY FRAMEWORK OPTION 2 – ALTERNATIVE
RISK-INFORMED LICENSING BASIS

DATE & TIME: Wednesday, July 29, 2015
8:30 p.m. – 1:00 p.m.

LOCATION: U.S. Nuclear Regulatory Commission (NRC)
Two White Flint North Room T 6A01
11545 Rockville Pike
Rockville, MD 20852-2738

PURPOSE: The purpose of this meeting is to discuss possible implementation
details associated with nuclear power reactor Risk Management
Regulatory Framework (RMRF) implementation Option 2: Alternative
Risk-Informed Licensing Basis.

CATEGORY 3: This is a Category 3 Public Meeting: Public participation is actively
sought for this meeting to fully engage the public in a discussion of
regulatory issues. No classified, proprietary, or protected information
will be discussed.

The NRC's Policy Statement, "Enhancing Public Participation in NRC
Meetings," effective May 28, 2002, applies to this meeting. The policy
statement may be found on the NRC Web site, www.nrc.gov, and
contains information regarding visitors and security.

MEETING CONTACT: Glenna Lappert, NRR/DPR
301-415-2552
Glenna.Lappert@nrc.gov

BACKGROUND: Three RMRF implementation options are described in the NRC staff's draft white paper entitled, "NRC Staff White Paper on Options for Responding to the June 14, 2012, Chairman's Tasking Memorandum on 'Evaluating Options Proposed for a More Holistic Risk-Informed, Performance-Based Regulatory Approach.'" This document is publicly available at Agency-wide Documents Access and Management System (ADAMS) Accession No. ML15107A402. During a May 27, 2015, public meeting to discuss the RMRF issues described in the white paper, the NRC staff was not prepared to respond to stakeholder questions regarding further details on how Option 2 would be implemented.

After the meeting, the NRC staff worked to develop additional possible implementation details for Option 2. An expanded description of possible implementation approaches for Option 2 is provided in the Attachment. The purpose of this meeting is to discuss these potential implementation details of Option 2 to ensure a better stakeholder understanding of the staff's proposed initiative. The agenda for the discussion is provided in the Enclosure.

PUBLIC COMMENTS: Public comments were previously requested on the description of Option 2 contained in the May 2015 staff white paper (ADAMS Accession No. ML15107A402). Members of the public who would like to provide supplemental written comments on Option 2 after reviewing the Attachment and/or participating in the July 29, 2015, public meeting, may do so until August 17, 2015. Supplemental comments may be submitted by any of the following methods:

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0254. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov.
- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Pre-registration: Seating may be limited and will be available on a first-come basis. Inform the NRC's meeting contact, Glenna Lappert, of your intention to attend by July 23, 2015. This step will ensure that sufficient copies of meeting materials are available.

If you need a reasonable accommodation to participate in this meeting (e.g., a translator, handicapped accessibility) or need this meeting notice or other information from the meeting in another format (e.g. Braille, large print, a language other than English), please notify the meeting contact, Glenna Lappert, as specified on this meeting notice or call the NRC's toll-free number, 1-800-368-5642, and ask the operator

to be connected to Glenna Lappert. Determinations on requests for reasonable accommodations will be made on a case-by-case basis.

Teleconferencing: Interested members of the public unable to attend the meeting may participate by telephone via a toll-free teleconference. For additional details, please contact Glenna Lappert (301-415-2552; Glenna.Lappert@nrc.gov) or call the NRC's toll-free number, 1-800-368-5642, and ask the operator to be connected to Glenna Lappert. Those interested in participating in this meeting by teleconference should call or e-mail Glenna Lappert as soon as possible, but no later than July 23, 2015.

Web conferencing: Interested members of the public who are unable to attend the meeting may participate remotely on the internet and via a toll-free audio teleconference bridge-line. For additional details, please contact Glenna Lappert (301-415-2552; Glenna.Lappert@nrc.gov) or call the NRC's toll-free number, 1-800-368-5642, and ask the operator to be connected to Glenna Lappert. Individuals interested in participating in this meeting by Web conference should call or e-mail Glenna Lappert as soon as possible, but no later than July 23, 2015.

Because meetings are sometimes canceled or rescheduled as a result of unforeseen circumstances such as severe weather, confirm the meeting schedule with the meeting contact.

PARTICIPANTS: NRC managers, staff, interested stakeholders, and members of the public. Participants from the NRC include members of the NRC's RMRF Staff Working Group. Other participants will likely include the Nuclear Energy Institute (NEI), other industry representatives, and representatives from certain non-governmental organizations.

NRC
Joseph Giitter
RMRF Working Group, et al.

External
NEI
Industry Representatives
Union of Concerned
Scientists
Members of the Public, et al.

Enclosure:
Agenda

Attachment:
Further Thoughts on RMRF Option 2

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***via e-mail**

NRC-001

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DATE	7/14/2015	7/14/2015	7/14/2015	7/14/2015	7/14/2015

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AGENDA FOR PUBLIC MEETING
U.S. NUCLEAR REGULATORY COMMISSION (NRC)

Wednesday, July 29, 2015

8:30 a.m. – 1:00 p.m.

<u>Time</u>	<u>Topic</u>	<u>Led By</u>
8:30 – 8:40 a.m.	Welcome, Safety Briefing, and Introductions	NRC
8:40 - 8:45 a.m.	Background	NRC
8:45 – 8:55 a.m.	Opening Remarks	NRC
8:55 – 9:15 a.m.	Staff Presentation on Overview of Option 2	NRC
9:15 – 9:40 a.m.	Questions/Discussion on Overview	All
9:40 – 10:10 a.m.	Staff Presentation on Possible Details of Option 2	NRC
10:10 – 10:40 a.m.	Questions/Discussion on Details	All
10:40 – 10:55 p.m.	Break	All
10:55 – 11:25 p.m.	Additional Questions/Discussion on Details	All
11:25 – 11:40 p.m.	Industry Remarks (optional)	Industry
11:40 – 11:55 p.m.	UCS Remarks (optional)	UCS
11:55 – 12:15 p.m.	Public Remarks/Questions	Public
12:15 – 12:20 p.m.	Next Steps	NRC
12:20 – 12:30 p.m.	Questions	All
12:30 – 12:35 p.m.	Wrap-up/Adjourn	NRC

Note: Provided times are estimates and are for planning purposes only. Adjustments may be made during the meeting as necessary.

Enclosure

FURTHER THOUGHTS ON RISK MANAGEMENT REGULATORY
FRAMEWORK (RMRF) OPTION 2
“Implement a Risk-Informed Alternative Licensing Basis”
July 13, 2015 DRAFT for Discussion with Interested Stakeholders

PURPOSE

Note: The following revised and more detailed description of Option 2 is intended to facilitate discussion of this option with interested stakeholders in a public meeting scheduled for July 29, 2015.

At a public meeting held on May 27, 2015, and a meeting on June 8, 2015, before the Advisory Committee for Reactor Safety (ACRS) Reliability & Probabilistic Risk Assessment (PRA) Subcommittee, the NRC staff received feedback on “Option 2” of its draft white paper entitled, “NRC Staff White Paper on Options for Responding to the June 14, 2012 Chairman’s Tasking Memorandum on ‘Evaluating Options Proposed for a More Holistic Risk-Informed, Performance Based Regulatory Approach,’” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15107A402).

The staff originally developed Option 2 as a logical step beyond the existing risk-informed regulations, but something less than full implementation of NUREG-2150 (Option 3), with the recognition that certain deterministic requirements in some site-specific instances are causing the staff and industry to devote a disproportionate focus on compliance issues of low safety significance. However, based on feedback at the May 27, 2015, public meeting and at the June 8, 2015, ACRS subcommittee meeting, it was evident that Option 2 needed to be better defined and explained. As a result, the NRC decided to hold an additional public meeting to discuss, in greater detail, some of the potential concepts and revisions being contemplated for Option 2. The results of this meeting will help inform the NRC decision on whether or not to pursue any or all of these concepts.

REVISED HIGH LEVEL DESCRIPTION OF OPTION 2

After evaluating written comments and feedback from the public meetings, the staff is contemplating revising and clarifying the high-level description of Option 2 that was provided in the May, 2015 white paper as follows:

The NRC would retain its existing generic regulatory structure but would promulgate a rule that allows licensees and applicants to comply with a risk-informed alternative licensing basis. The alternative licensing basis would utilize a suitable PRA model to provide plant-specific risk insights, which would be used along with the other elements of risk-informed regulation such as defense-in-depth, safety margins, and performance measurement strategies. Licensees/applicants of plants with a suitable PRA model would be able to risk inform how they address certain regulations and aspects of their licensing basis (e.g., which accidents ~~and transients~~ are to be included in their licensing

basis). They would also be able to use the suitable PRA model to provide additional operational flexibility in responding to generic issues and informing NRC oversight activities. Licensees/applicants that choose to adopt the risk-informed alternative licensing basis would also be required to ~~use their PRAs to search for and mitigate risk-significant events and/or accident sequences on a plant-specific basis in accordance with criteria to be developed and specified in the implementing regulation.~~ address vulnerabilities that might be identified by the plant-specific PRA. Criteria to define vulnerabilities would be developed. This option could result in eliminating or reducing requirements associated with some design-basis accidents included in a plant's licensing basis. In the event that vulnerabilities were identified, a licensee might have to address ~~and adding~~ some currently unregulated events ~~to be mitigated~~.

Stakeholder input would be sought during the rulemaking for developing the actual details of such a rule. The main aspects of Option 2 above are as follows, and each is discussed further in this paper:

1. It would be an alternative risk-informed approach.
2. A "suitable" plant-specific PRA would be required.
3. The applicable regulations and other aspects of the licensing basis amenable to risk-informing would be determined by NRC (in advance or ad hoc – see further discussion below).
4. Operational flexibility should increase.
5. A definition of "vulnerability" would be included in the rule.

Each of these aspects is discussed below. However, the reader should note that many of the actual details would be worked out, with a high level of interaction between NRC and interested stakeholders, if the NRC pursues such an approach. Therefore, the ideas below should be considered "notional" and are intended to stimulate discussion at a public meeting scheduled for July 29, 2015.

DISCUSSION OF KEY ASPECTS OF OPTION 2

1. Alternative Risk-Informed Approach

The rule to implement Option 2 could be adopted by licensees or applicants as an alternative to certain regulations and aspects of a facility's licensing basis. The new rule and associated implementation guidance would identify which existing rules and aspects of the licensing basis could be replaced with a risk-informed alternative, describe the risk-informed approach and process, describe the submittal and review requirements, and describe the acceptance and reporting criteria that would be applied to transition to the new licensing basis.

The NRC staff's vision is that this rule would be written at a high level and be performance-based. Implementation details would be included in guidance documents (e.g., Regulatory Guides) to a large extent. In effect, the Option 2 rule would codify NRC's approach to risk-informed regulations that would allow risk-informed changes to the licensing basis without the

need for an exemption request under 10 CFR 50.12. In addition, the rule would either identify the specific rules and aspects of the licensing basis that could be risk-informed or it would provide criteria for the licensee to identify which rules or aspects of their licensing basis the licensee could propose to risk-inform.

2. Suitable PRA

A licensee that requested to implement a risk-informed licensing basis under an Option 2 rule would need to have a “suitable” PRA model. The suitability of the PRA model would depend upon which regulations or aspects of the plant licensing basis would be included in changes proposed by that licensee (see item 3, below, for some thoughts on the possible scope of an Option 2 rule). As with current risk-informed applications, the PRA model would only need to be sufficient (in terms of scope, level of detail, and technical adequacy) for the intended applications requested by the licensee/applicant.

The current approach to determining the suitability of a PRA (RG 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” ASME/ANS PRA Standard, and associated NEI peer review guidance) may need to be modified to have the necessary robustness to support the risk-informed alternative licensing basis. For discussion purposes, two approaches to improving the current approach are discussed briefly below. Details would have to be worked out in developing the implementing guidance.

a. Enhance the current process, retaining “peer review” as an integral part

- The initial peer review of the PRA model would be expanded to be in-depth, cover the entire model, ensure that accepted methods are employed, and include satisfactory resolution of the findings of the review.
 - The peer review guidance may need to contain criteria for assessing if the PRA is acceptable for use for either all applications or individual applications.
 - The criteria for the scope, level of detail and periodicity of the peer reviews may need to be expanded to ensure that the peer review is sufficient to address the application.
 - The resolution of the findings of the peer review may also need to be peer reviewed for acceptability.
- The rule or implementing guidance would need to specify detailed criteria for what is needed to maintain, update and upgrade the PRA.
- Certain methods have not necessarily been accepted as the state-of-practice¹ and may require review for acceptability which is currently not addressed in either RG 1.200, the ASME/ANS PRA standard or the associated NEI peer review guidance.

¹ State-of-practice are those practices that are generally accepted throughout the industry and have shown to be technically acceptable in documented analyses or engineering assessments.

b. Develop a “Certified PRA” Process

This second approach would not rely on *peer review* per se, but rather on a process leading to a “certified PRA” that would produce the needed confidence in the PRA to support the proposed rule. This approach is based on lessons learned during the NFPA-805 reviews and other recent experience related to the current peer review process:

- The peer review is a framework to characterize the technical adequacy of the base PRA model. Though it provides findings and suggestions related to individual aspects of the technical elements of the PRA, it does not have criteria for accepting or not accepting the technical adequacy of the overall PRA and does not look at the application of the model or the other aspects, such as scope and level of detail.
- Peer reviews are a snapshot of a PRA and look at only a sample of the model.
- Findings of a peer review are not closed out by the peer review team but are left to the licensee to disposition on an application-by-application basis.
- New methods have been handled inconsistently in peer reviews (some accepting the methods without any significant review and others flagging the new method with a finding, essentially indicating it was an un-reviewed area). Often peer review team members don’t have the requisite background or qualifications to perform such a technical review.

The “certified PRA” approach could consist of the following steps. Details would have to be worked out, and challenges resolved (e.g., ensuring that the level of NRC involvement in the certification process is consistent with existing statutory requirements), so these steps should be taken as an example approach to illustrate the concept:

- NRC could specify acceptable PRA methods for each risk-informed application.
- Minimum qualification and experience requirements could be set (by NRC or some independent body) for PRA analysts who maintain, update and upgrade the PRA.
- The initial review of the PRA model, whether done by NRC or some independent body, should be in-depth, cover the entire model, ensure that accepted methods are employed, address all envisioned applications, and include satisfactory resolution of the findings of the review.
- The outcome of such an approach could be a “certified” PRA model that a licensee could use to make licensing decisions without the need for further NRC review and approval unless certain thresholds were reached.
- Additionally (consistent with the phased approach to PRA Policy) this certified model could become the model of record for all regulatory applications, such as the Significance Determination Process.

The above ideas are intended to foster discussion, and other approaches could also provide the necessary confidence in the PRA models to support the Option 2 rule. Either approach (or another proposal to achieve the same end) could be the subject of a pilot project for further

exploration. Also, note that the “Certified PRA” concept could be pursued ahead of or in the absence of a rulemaking

3. Determining the Scope of an Option 2 Rule – Regulations and Licensing Basis

The scope of Option 2 would be determined during the rulemaking process. It could, for example, be a list of regulations and aspects of the licensing basis that are amenable to being risk-informed. Note that a comprehensive assessment of 10 CFR Part 50 regulations that might be risk-informed may be found in NUREG-1860, “Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing” (for example, in Appendices H, J and K). The staff would work with interested stakeholders in an open process to develop the list of items that (1) could be risk-informed and (2) could result in benefits by being risk-informed.

The rule might even be written in an open-ended manner to facilitate increased use of risk-informed regulation. Under this sort of rule, a licensee could propose to risk-inform a regulation or aspect of its licensing basis not on the previously-approved list. The Option 2 regulation would provide stability in the risk-informed process, including suitability of plant-specific PRA models, so as to focus the NRC review and approval of new applications. Once a plant piloted a new risk-informed application, other Option 2 plants could use the approved application approach and adopt the new licensing basis with minimal NRC review of any new license amendment. This new approach would still need to address all aspects of the needed PRA scope, level of detail, and technical adequacy and also address all the other aspects of being risk-informed, such as defense-in-depth, safety margins, and performance measurement strategies.

Some examples of regulations and aspects of the licensing basis that might be amenable to being risk-informed include:

- Set of design bases events included in the licensing basis (current list could be reduced and new events added based on risk information)
- Large LOCA re-definition (proposed 50.46a)
- Selected General Design Requirements (10 CFR 50 Appendix A)
- Acceptance of as-found conditions at variance with original licensing basis; e.g., tornado missile protection; debris effects on sump strainers
- Risk-informed alternative regulations (e.g., 50.69)
- Risk-informed applications with existing guidance (e.g., risk-managed technical specifications)

4. Operational Flexibility

An Option 2 licensee would have a suitable PRA model for some set of regulations and aspects of its licensing basis. This might provide additional operational flexibility in several areas, including:

- Risk-managed Technical Specifications – Limiting Conditions for Operation, Allowable Outage Times, Completion Times, surveillance intervals, and possibly replacing OPERABLE with FUNCTIONAL
- Significance Determination Process – use the suitable PRA in lieu of NRC SPAR models
- Addressing as-found, non-conforming conditions
- Risk-informed augmentation of 10 CFR 50.59 for Option 2 licensees

The above list is notional; any final list would have to be established by rulemaking with participation of interested stakeholders and subsequent Commission approval.

5. Addressing Vulnerabilities

The NRC staff is contemplating modifying its vision for Option 2 in that there would not be a requirement to “search” for potential vulnerabilities using the plant-specific PRA. Such searches have been conducted in the past (e.g., IPE, IPEEE) and the NRC staff does not consider it likely that new vulnerabilities would be uncovered by yet another search. However, experience has shown that, as PRA models are expanded to include updated and enhanced models, methods and data, it is possible that new risk insights could indicate a new vulnerability.

Therefore, the rule should establish criteria for identifying a potential vulnerability. This will require some thought by NRC and its stakeholders during the rulemaking. This is necessary to assure that “risk outliers,” issues involving insufficient defense-in-depth or safety margin, or other vulnerabilities that may not have been covered by the current regulations are appropriately identified and addressed. The threshold for a licensee to address a risk-significant event or accident sequence, for example, might be the same as the current backfit guidance. That is, if a safety-significant improvement were identified by the plant-specific PRA, then the licensee might be required to assess whether the burden of such an improvement is justified.

On the other hand, the threshold could be whether reasonable assurance of adequate protection of public health and safety were provided. Under this approach, the rule might require Option 2 licensees to address and report in a timely manner any event, accident sequences, or overall risk metric (for example) that exceeded some high risk threshold or serious degradation of defense-in-depth or safety margins to enable the NRC to determine whether adequate protection was challenged. The main point is that this aspect of any Option 2 rule would be developed via rulemaking with full participation of interested stakeholders.

THOUGHTS ON ATTRIBUTES OF OPTION 2

There are several attributes that the NRC staff believes must be incorporated into the rule and implementing guidance. These attributes include the following:

1. The rule must be performance based (as defined in SRM-SECY-98-144, “White Paper on Risk-Informed and Performance-Based Regulation”).
2. The rule must allow risk-informed amendments to the license without the need for an exemption under 10 CFR 50.12.

3. The implementing guidance for the rule must have objective acceptance criteria for performance measurement, risk measurement, defense-in-depth, and safety margins.
4. The rule must provide regulatory stability, predictability, and consistency with respect to risk-informed implementation for the in-scope regulations and aspects of the licensing basis.
5. The rule must provide a definition of vulnerability and specify actions that must be taken if a vulnerability is identified in the course of developing or using the “suitable” PRA model. Implementing guidance on what constitutes a vulnerability would be developed as part of the rulemaking.

The content of the rule or implementing guidance would likely include the following:

1. The rule would include a delineation of the current regulations and aspects of the licensing basis to which the risk-informed alternative may be applied; i.e., those that are amenable to being risk-informed and that are judged appropriate for this alternative licensing basis.
2. For each regulation or aspect of the licensing basis in item no. 1, the rule would state (1) that the PRA must be of the appropriate PRA scope, risk metrics, level of detail and technical adequacy, (2) that the risk, defense-in-depth, and safety margins must meet certain goals, (3) that the intent of the regulations that are risk-informed are maintained and the ability to determine compliance and inspection is established, (4) that a performance measurement program is established that provides effective performance monitoring, feedback, and corrective action, and (5) that the PRA would need to be updated, and upgraded as appropriate, at a specified periodicity. The implementation guidance would provide the:
 - a. The criteria for the appropriate PRA scope, level of detail, and technical adequacy
 - b. The acceptance criteria for risk, defense-in-depth, and safety margins
 - c. The basis that the intent of the risk-informed regulation is still achieved, the specific approach to demonstrating compliance with the risk-informed regulation, and the means, scope, and approach for the inspection of those regulations that are risk-informed
 - d. The criteria for the performance measurement program, including monitoring, feedback, and corrective action aspects of the program
 - e. The criteria for PRA correction and updating, including update frequency
3. The implementation guidance would provide a description of how the “suitable” plant-specific PRA could be used in addressing NRC inspection findings, non-conforming conditions, generic issues, and other areas where risk-insights would help determine the appropriate license response.
4. The rule or implementation guidance would contain a definition of “vulnerability” (in terms of risk, defense-in-depth, or safety margin) and the criteria for determining when a potential vulnerability has been discovered and how this continual check for vulnerabilities will be integrated into the licensees change management process throughout the life of the plant.

5. The rule might contain criteria for self-approval of changes to the licensing basis (a risk-informed 50.59-like process).
6. The rule, and further details in the implementation guidance, would contain requirements for reporting.

Items 5 and 6 are to ensure that the risk-informed licensing basis is maintained over time and that NRC is informed whenever certain reporting criteria are met.