NRC FORM 757
(06-2019)
NRC MD 10.156

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS COVER PAGE

The U.S. Nuclear Regulatory Commission (NRC) strives to establish and maintain an environment that encourages all employees to promptly raise concerns and differing views without fear of reprisal and to promote methods for raising concerns that will enhance a strong safety culture and support the agency's mission.

Employees are expected to discuss their views and concerns with their immediate supervisors on a regular, ongoing basis. If informal discussions do not resolve concerns, employees have various mechanisms for expressing and having their concerns and differing views heard and considered by management.

Management Directive, MD 10.158, “NRC Non-Concurrence Process,” describes the Non-Concurrence Process (NCP).

The NCP allows employees to document their differing views and concerns early in the decisionmaking process, have them responded to (if requested), and include them with proposed documents moving through the management approval chain to support the decisionmaking process.

NRC Form 757, “Non-Concurrence Process," is used to document the process.

Section A of the form includes the personal opinions, views, and concerns of a non-concurring NRC employee.

Section B of the form includes the personal opinions and views of the non-concurring employee's immediate supervisor.

Section C of the form includes the agency's evaluation of the concerns and the agency's final position and outcome.

NOTE: Content in Sections A and B reflects personal opinions and views and does not represent the official agency's position of the issues, nor official rationale for the agency decision. Section C includes the agency's official position on the facts, issues, and rationale for the final decision.

1. If the process was discontinued, please indicate the reason (and skip to #3):

   - ☐ Non-concurring employee(s) requested that the process be discontinued
   - ☐ Subject document was withdrawn

2. At the completion of the process, the non-concurring employee(s):

   - ☐ Concurred
   - ☑ Continued to non-concur
   - ☐ Agreed with some of the changes to the subject document, but continued to non-concur

3. For record keeping purposes:

   - ☐ This record is non-public and for official use only
   - ☑ This record has been reviewed and approved for public dissemination

NRC FORM 757
(06-2019)
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U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS (Continued)

1. NCP Tracking Number
NCP-2020-011

Date
11/30/2020

Section A - To Be Completed By Non-Concurring Employee

2. Title of Subject Document
Recommendation on Nuclear Energy Institute's Proposed Technical Specification on Changes to PRA Methods (Newly Developed Methods)

3. ADAMS Accession Number
ML19226A207

4. Document Signer
Sunil Weerakkody

5. Document Signer's Phone Number (Enter 10 numeric digits)
(301) 415-2870

6. Title of Document Signer
Senior Level Advisor

7. Office (Choose from the drop down list or fill in)
NRR

8. Name of Non-Concurring Employee(s)
Michael T. Markley

9. Employee's Telephone Number (Enter 10 numeric digits)
(301) 415-5723

10. Title of Non-Concurring Employee
Branch Chief

11. Office (Choose from the drop down list or fill in)
NRR

12. ☐ **Document Author** ☑ **Document Contributor** ☐ **Document Reviewer** ☐ **On Concurrence**

13. Name of Non-Concurring Employee's Supervisor
Caroline Carusone

14. Office (Choose from the drop down list or fill in)
NRR

15. Title of Non-Concurring Employee's Supervisor
Deputy Director

16. Supervisor's Telephone Number (Enter 10 numeric digits)
(301) 415-1453

17. ☑ **I would like my non-concurrence considered and would like a written evaluation in Section B and C.**

☐ **I would like my non-concurrence considered, but a written evaluation in Sections B and C is not necessary.**

18. When the process is complete, I would like management to determine whether public release of the NCP Form (with or without redactions) is appropriate (Select "No" if you would like the NCP Form to be non-public):

☑ **Yes** ☐ **No**

19. Reasons for the Non-Concurrence, Potential Impact on Mission, and the Proposed Alternatives
Attachment 1: NCP and supporting information
Attachment 2: Alternate TS mark-up

20. Signature and Date of Non-Concurring Employee
Michael T. Markley
Digitally signed by Michael T. Markley
Date: 2020.11.28 10:35:01 -05'00'

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(06-2019)
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U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS (Continued)

1. NCP Tracking Number
NCP-2020-011

Date
11/30/2020

Section B - To Be Completed By Non-Concurring Employee's Supervisor

2. Title of Subject Document
Recommendation on Nuclear Energy Institute's Proposed Technical Specification on Changes to PRA Methods (Newly Developed Methods)

3. ADAMS Accession Number
ML19226A207

4. Name of Non-Concurring Employee's Supervisor
Caroline Carusone

5. Office (Choose from the drop down list or fill in)
NRR

6. Title of Non-Concurring Employee's Supervisor
Deputy Director

7. Supervisor's Telephone Number (Enter 10 numeric digits)
(301) 415-1453

8. Comments for the NCP Reviewer to Consider

Mr. Markley has been engaged in varying degrees throughout the development of the revision to TSTF-505 which introduces a revised characterization and use of PRA newly developed methods. As a result of those interactions, a comprehensive list of issues/concerns are attached for review, including a suggested revision to the standard TS section for implementation of TSTF-505.

9. Signature and Date of Non-Concurring Employee's Supervisor
Caroline L. Carusone
Digitally signed by Caroline L. Carusone
Date: 2020.12.04 16:39:14 -05'00'

NRC FORM 757
(06-2019)
NRC MD 10.156

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS (Continued)

1. NCP Tracking Number: NCP-2020-011

Date: 11/30/2020

Section C - To Be Completed By NCP Coordinator

2. Title of Subject Document	3. ADAMS Accession Number
Recommendation on Nuclear Energy Institute's Proposed Technical Specification on Changes to PRA Methods (Newly Developed Methods)	ML19226A207

4. Name of NCP Coordinator	5. Office (Choose from the drop down list or fill in)
Shivani Mehta	NRR
6. Title of NCP Coordinator	**7. Coordinator's Telephone Number** (Enter 10 numeric digits)
Technical Assistant	(301) 415-0860

8. Agreed Upon Summary of Issues

1. For licensees using PRA to modify the license and/or TS, the plant-specific PRA is now part of the licensing basis of the facility.

   Context: *Current licensing basis* (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

   Based on the above, licensees that have made voluntary changes to the license and/or TS (e.g., NFPA 805 for fire protection, TSTF-425/Initiative 5b for surveillance frequency control programs, TSTF-505/Initiative 4b for risk-informed completion times (RICT), and 10 CFR 50.69 for the risk-informed categorization of structures, systems and components (SSCs)) have incorporated the PRA and its methods and models in the CLB. See Background Document excerpts for Vogtle Initiative 4b TS (ADAMS ML15127A669) and TSTF-505 TS (ADAMS ML18267A259).

2. The NRC does not license through inspection.

   Context: The NRC issues rules, regulations, and licenses that establish the benchmark of requirements against which NRC conducts inspections. The TS are Appendix A to the license. The inspection program relies on a "trust but verify" process to ensure licensees meet the regulatory requirements and license obligations. The TS proposed as an Enclosure to the White paper inverts this process and places the burden of demonstrating unacceptability of licensee self-initiated changes using newly developed PRA methods on inspectors and the inspection program, rather than NRC authorized changes through licensing. Regional inspectors do not have the licensing or risk analysis experience to determine the acceptability of licensee use of newly developed PRA methods (NDMs) and should not put in the position of providing tacit or *de facto* approval of licensee-initiated NDM affecting the CLB, either through omission or commission.

3. NRC regulations, reactor licenses, and TS rely on the use of NRC-approved codes and methods, analytical methods, and PRA methods.
   Context: The regulations in 10 CFR 50.55a, "Codes and standards," provide for incorporation by reference the

use of various NRC-approved industrial standards. Improved Standard TS (ISTS) 4.2.1 states, in part that, "Fuel assemblies shall be limited to those fuel designs that have been analyzed with applicable NRC staff approved codes and methods and shown by analysis or tests to comply with all fuel safety design bases." ISTS 5.6.3.b., states, in part, that, "The analytical methods used to determine the core operating limits shall be those previously reviewed by the NRC, specifically those described in the following documents: [listed individually in the TS]." NRC-endorsed TSTF-505, Revision 2, states, in part, that, "Methods to assess the risk from extending the Completion Times must be PRA methods approved for use with this program, or other methods approved by the NRC for generic use; and any change in the PRA methods to assess risk that are outside these approval boundaries require prior NRC approval." Departure from the use of NRC-approved methods would undermine confidence in the safe operation of NRC-licensed facilities. As such, this is a policy decision, with broad implications, that should be made by the Commission in a SECY Notation Vote paper and not via an internal DRA memorandum.

4. Many plant PRAs remain incomplete and some are already using unapproved methods.

Context: NRC does not, at present, have a good understanding of circumstances where licensees may have already departed from the use of NRC-approved PRA methods (e.g., fire) or are using newly developed methods (NDMs) without prior NRC approval. Some of these changes could adversely affect the reasonable assurance of safety and undermine the design and licensing basis assumptions.

As an example of the above, DRA approved the topical report for Generation 1 Westinghouse reactor coolant pump (RCP) seals. It was subsequently realized that the Generation I seal cannot perform its intended mitigating safety function for RCP seal loss-of-coolant accident (LOCA) due to deficiencies in the concept and design. It is not apparent that the NRC ever rescinded PRA credit associated with the approval of the Generation I seal and did not evaluate the plant-specific impacts where Generation I seals were being credited improperly in PRAs. PRA credit for Westinghouse Generation III seals were challenged in NCP-2016-004, for Diablo Canyon Power Plant (DCPP) for taking PRA mitigating seal credit in its NFPA 805 application. The NRC did not approve Topical Report PWROG-14001-A for Westinghouse Generation III RCP seals until nearly a year after the DCPP NFPA 805 submittal.

Based on the above and ongoing operating experience, it is apparent that licensees are taking PRA credit for equipment that is yet to be demonstrated to meet its design safety function (e.g., Flowserve mitigating RCP seal failures). This operating experience is generally ignored by the current NRC inspection program with respect to credit in the PRA model.

5. The proposed TS provides an expansion of authority, where licensees can make future changes beyond the current TS authorization without prior NRC approval.
Context: Current TSTF-505 TS requires the use of PRA methods as part of the program in the license amendment approval or other methods approved by the NRC for generic use. The proposed TS in the Enclosure to the DRA White Paper would replace the requirement of "NRC-approved methods" with Regulatory Guide (RG) 1.200, Revision 3, that endorses PWROG-19027, Revision 2, "Newly Developed Method Requirements and Peer Review, and NEI 17-07, Revision 2, "Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard," and a reporting requirement.

RGs do not provide requirements. RGs provide "a method" for meeting regulatory requirements, but licensees can pursue any method of their choosing. PWROG-19027 has tables with "requirements," but mostly refers to NEI 17-07 on the peer review process. Neither PWROG-19027 nor NEI 17-07 provide actual requirements in the context of a TS requirement. The draft TS in the Enclosure to the DRA White Paper provides "requirements" in

NON-CONCURRENCE PROCESS (Continued)

Tables within PWROG-19027, but execution of the peer process relies on NEI 17-07 that has 225 “should” statements and 19 “shall” statements. As such, the proposed TS in the DRA White Paper s not enforceable.

NRC has already had problems with licensee implementation of the Surveillance Frequency Control Program (SFCP) because it refers to NEI guidance that also says “should.” The same problem would exist with PWROG-10927 and NEI 17-07. The proposed TS in the Enclosure to the DRA White Paper is an expansion of authority that cannot be enforced.

To be sufficient, there needs to be a requirement in the proposed TS that states that “all “should” statements in PWROG-10927 and NEI 17-07 are “shall” statements and provide additional TS provisions indicating, “The licensee shall establish, maintain, and adhere to procedures to implement the RICT program.” The TS needs to address loss of function and potential non-conservative changes that would affect the design and licensing basis.

6. The proposed TS for reporting NDMs is flawed.

Context: The TS does not provide a timeline for reporting proposed use of an NDM. It also introduces the likelihood for other licensees to use the NDM without NRC having determined the sufficiency or expressing objection of the first precedent. Because there is no generic approval, each licensee's proposed use of an NDM is inherently plant-specific and dependent on applicability to the design, licensing, and PRA maturity for of that plant. The proposed TS only requires reporting of the first use of an NDN. Even that does not require basic information concerning the completeness or model uncertainty of the NDM. There is also no discussion of Paperwork Reduction Act or requirements for an OMB Clearance.

At a minimum, each licensee using an NDN should have to report of the plant-specifics of the NDM, identify variations from the precedent, and confirm that it reflects the as-built, as operated, and as-maintained plant. Otherwise, the industry is advancing generic approval of a precedent (i.e. a *de facto* method approval). In that regard, the proposed TS would bypass both plant-specific licensing and NRC review and approval of topical reports. This new DRA-direct approach also bypasses other NRC inspection-licensing processes for the use of Technical Assistance Requests (TARs).

NDM Upgrade Reports should be submitted under oath or affirmation confirming that the No Significant Hazards Consideration of the TSTF-505 or Initiative 4b approval remains valid.

7. The NRC inspection program lacks the talent and resources to provide oversight and verification.

Context: The training and qualification of most NRC inspectors in PRA methods is insufficient to assure (1) recognition of a problem in NDMs and associated peer reviews, (2) elevation and follow-through will occur in a timely manner, and (3) closure of the NDM issue has a plant-specific nexus and applicability. The White Paper and TS appear to presume that multiple actions (i.e., fleet submittals and closely sequenced industry submittals) can be handled by DRA with other competing licensing-related work and regional inspection resource challenges. There is no similarity to this process in the review of other NRC reports (e.g., ECCS, effluent, and steam generator reports, etc.).

8. Inspection procedures have been modified but remain insufficient to provide a PRA inspection program to address industry-wide changes concurrently.

Context: The development of an NRR Office Instruction is insufficient, when a PRA Team Inspection procedure and resource allocation appears warranted. It is likely that licensees will make fleet-wide changes using NDMs

with only limited time gaps between the precedent and other NDM adoptions, or multiple power reactor sites implementing NDMs concurrent with the first precedent. The NRC is ill-equipped to handle this scenario, particularly if licensees deviate or take exception to portions of the NDM, as is often done with topical report approvals.

NRC Inspection Procedures are insufficient to address NDMs. IP 71111.13, “Maintenance Risk Assessments and Emergent Work Control,” provides guidance for inspecting RICT approvals but only has one line of guidance stating newly developed PRA methods should receive “priority for sampling.” IP 71111.22, “Surveillance Testing,” provides guidance for inspecting the risk-informed surveillance frequency control program per TSTF-425 but has nothing on NDMs. IP 71111.12, “Maintenance Effectiveness,” has some guidance on PRA but nothing on NDMs. IP 71111.18, “Plant Modifications,” addresses updating the PRA to address plant modifications but has nothing on NDMs. None of the above IPs referenced in the DRA White Paper address NDMs in a manner consistent with the intent of the proposed TS. Only IP 71111.13 provides for sampling NDMs but no assurance that all or any new NDMs will be inspected. The resource estimates are mostly based on routine annual sampling and outages, but certainly would not provide for focused inspection of NDMs in a timely manner as suggested by the DRA White Paper. None of the IPs provide indication of a resource estimate budget for NRR/DRA detailed review of NDMs as part of the inspection module estimate.
It is possible that no NDMs will be selected for inspection samples across the broad fleet of plants. If it had not been directed as a corrective action by the EDO for DPO-2018-002, it is unlikely that any inspection sampling of licensee 10 CFR 50.59 reviews of lead test assemblies for accident tolerant fuel would have been done.

9. No fee billable process has been established for DRA/Headquarters review of NDMs.

Context: In October 2016, NEI requested a fee waiver for review and pilot of NEI 16-04, “New PRA Method Evaluation Process,” using a Vetting Panel process. NEI requested “any present and future activities using the processes outlined in NEI 16-04 also be covered under the fee waiver.” NRC approved the fee waiver for NEI 16-04 to test the Vetting Panel process and three EPRI fire PRA methods but no plant specific applications or future PRA methods. EPRI withdrew the request in June 2018.

By redirecting the effort from licensing to inspection via the DRA White Paper and TS, the industry would essentially gain the requested blanket fee waiver for all NDMs, absent NRC initiating a subsequent review through inspection. Since the DRA White Paper proposes a process and TS that bypasses the OCFO's prior limits on fee waivers for reviewing NDMs, this new process needs to be shared with and authorized by OCFO. It is appropriate and proper for all NDMs to be reviewed as fee billable work.

10. NRC has no budget allocated for the review of NDM PRA Upgrade Reports.

Context: The NRC normally budgets two years forward. At present, review of NDMs via the DRA White Paper and TS would be unbudgeted work. It is also not apparent how the NRC/DRA would proceed if reviews became complex and involved multiple rounds of requests for additional information (RAIs) or audits to determine that a No Significant Hazards Consideration exists and/or an amendment was needed.

11. Proposed changes should preclude NDMs adversely impacting the design and licensing basis.

Context: If it were not for radiation, NRC would not need to exist. Changes described in the DRA White Paper and TS should preclude PRA-based changes that could non-conservatively affect the barriers to the release of radioactivity (e.g., fuel, reactor coolant system, and containment) and mitigating systems (e.g., AFW, ECCS, etc.). The questions surrounding the acceptability of NDMs could undermine the design and licensing basis,

particularly if an unrealized common-cause failure potential is introduced. The peer review is only as good as the panel. Like all populations, there will be a distribution - some being done in an amazingly high quality and thorough manner, some very poorly, but most somewhere in the middle.

There is reasonable assurance in being able to tell the public that licensees use NRC-approved methods. It is good to advance the quality of PRA methods and peer reviews, but an unwinding of the NRC-approved methods is not a good thing in terms of public confidence for public health and safety and protecting the environment. If NDMs contributed to an actual event or accident, it would be a very difficult discussion "how the NRC let this happen" giving testimony before Congress.

12. Public rights for participation are eliminated in bypassing licensing and topical report review processes.

Context: Discussing RG 1.200, PWROG-19027, and NEI 17-07 in public meetings and offering these documents for public comment does not address the need for public engagement by persons living in the vicinity of a plant for which an NDM is being considered. The public has no opportunity to comment on the specific NDM under consideration, because the industry initiative and the DRA White Paper propose to bypass the licensing process and noticing requirements of plant-specific changes. The proposed TS provided in the DRA White Paper on NDMs severely undermines public interest in the safe operation of the plant and rights guaranteed by 10 CFR 50.90, 10 CFR 50.91, and 10 CFR 50.92. Public comment on generic approval of NDMs in topical reports is also lost.

9. Evaluation of Non-Concurrence and Rationale for Decision

As the non-concurrence process approver for NCP-2020-011, I have considered the submission from the non-concurring individual. The non-concurring individual identified a number of important issues associated with proposed changes to the TS for TSTF-505 (also referred to as TS 4b). I appreciate the efforts of this staff member to raise these concerns, along with the efforts of other staff members to actively and collaboratively participate in the resolution of the issues identified. My assessment of each of these issues is provided below. As discussed in my assessment, where appropriate, the staff made enhancements to the proposed TS in response to the issues raised by the non-concurring individual.

Evaluation

Before I address the specific issues raised in in the non-concurrence package, it is important to emphasize that the subject memo of the non-concurrence does not establish an approved NRC process/regulatory framework for reviewing newly developed methods (NDMs). Rather, the memo was written by Sunil Weerakkody, Senior Level Advisor (SLS), in the Division of Risk Assessment (DRA) to communicate his professional opinion on this subject to Mike Franovich, DRA Director; as such, it is an internal memo, conveying Dr. Weerakkody's professional views.

I recognize that Excel Services has plans to formally submit TSTF-591, "Revise Risk Informed Completion Time (RICT) Program," which will refer to RG 1.200, Revision 3, and to make other changes including a new reporting requirement. Consistent with the agency's process, the staff will conduct a formal regulatory review of the appropriate use of NDMs via this TSTF traveler, or any other license amendment requests that may be submitted for NRC staff review on this issue.

Commission views on the peer review process and the PRA Quality, captured in several Staff Requirement Memorandums issued in early 2000s during promulgation of the 10 CFR 50.69 rulemaking and Revision 3 to RG 1.200 issued in 2019 provided the foundational basis in response to a number of the issues raised in the non-concurrence. Revisions to a number of inspection procedures as well as plans to finalize and issue an Office Instruction that we will appropriately coordinate with DRA, DORL, DRO, and regional staff will ensure availability of NRR subject matter assistance to regional staff. The Draft OI and inspection procedures were foundational to the responses to a few other issues raised in the non-concurrence.

NON-CONCURRENCE PROCESS (Continued)

Note that additional context associated with each of the non-concurring individual's concerns is included in Sections A, B and the Summary of Issues of the non-concurrence package and are not repeated below.

Issue 1. For licensees using PRA to modify the license and/or TS, the plant-specific PRA is now part of the licensing basis of the facility.

Response: Approval for licensees to adopt risk-informed initiatives such as TSTF-505 is based, in part, on the technical acceptability of the PRA. Technical acceptability is established using the guidance in RG 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities” (ML20238B871). The guidance in RG 1.200 endorses the peer review process as an acceptable means of demonstrating PRA technical acceptability. Through the licensee's TS or license conditions, it commits to follow RG 1.200, which consequently becomes part of the licensing basis. As such, only a subset of PRA attributes (e.g., PRA model configuration control, any PRA-related information captured into UFSAR), as opposed to the whole PRA model, become part of the licensing basis of the facility.

Unlike plants that are licensed under 10 CFR Part 52, there is no requirement for plants licensed under 10 CFR Part 50 to develop a PRA. Commission deliberations on the acceptable quality for PRAs for those plants licensed under 10 CFR Part 50 led to the development of RG 1.200, ASME/ANS Standards on PRA, and associated license conditions and TSs (see SECY-00-0162, COMNJD-03-02, and SECY-04- 0118). Consistent with Commission direction, when the NRC staff reviews risk- informed licensing applications, such as TSTF-505, the staff focuses its review on the results of licensee peer reviews and does not review the PRA model itself. As such, the actual PRA model is not considered part of the plant's licensing basis. The specific attributes of the PRA that do become part of the licensing basis of the facility are described by language in the administrative TS, license condition, and UFSAR, as applicable, and can vary across risk-informed amendments, such as 10 CFR 50.69 and TSTF-505. Although there may be differences between risk- informed applications that modify TSs using inputs or insights from PRA models, the following generalizations can be made:

- The base PRA model is not part of the licensing basis.
- The configuration control program of the PRA model used for risk-informed applications ensures that the PRA model reflects the as-built, as-operated plant, and is part of the licensing basis.
- Only NFPA 805 and TSTF-505 have specific language, in the regulation, license condition, or TS, on PRA methods being acceptable to the NRC staff. (Footnote 1)

Issue 2. The NRC does not license through inspection.

Response: The proposed TS establishes regulatory control over the PRA configuration and change process by requiring licensees to use NRC staff-endorsed newly developed methods (NDM) review requirements provided in Revision 2 of PWROG-19027 (ML20213C660) using peer review guidance provided in Revision 2 of NEI 17-07 (ML19241A615). These processes are adopted into the TS through NRC review and approval of a license amendment request. The proposed TS and the recently revised inspection procedure (IP 71111.13) provide inspectors with guidance to inspect changes to the licensee's risk-informed completion time programs, including NDMs, on an as-needed basis. The Technical Assistance Request (TAR) process, regional inspector's access to Senior Reactor Analysts (SRAs), the draft Office Instruction (OI), which has been made available to you (non-publicly available, ADAMS Accession Nos. ML 20252A214, ML20252A215, ML20252A216), and the informal requests for subject matter expertise to support the ROP would ensure that inspections pertaining to NDMs are appropriately resourced with the appropriate skill sets needed to ensure licensee adherence to the

requirements that establish, implement, and maintain acceptability of NDMs.

Once the staff has the opportunity to gain some lessons learned/best practices associated with these types of reviews, the staff will then pursue finalizing the OI and will issue it in accordance with our process for implementation and use. The staff will then follow the process outlined in the draft OI to guide its review of the licensees' peer review implementation reports.

Issue 3. NRC regulations, reactor licenses, and TS rely on the use of NRC-approved codes and methods, analytical methods, and PRA methods.

Response: The NRC staff exercise their review and approval authority when a licensee requests to adopt the proposed TS. Moreover, the proposed TS requires the use of the Commission-endorsed peer review process, NRC staff-endorsed review requirements of newly developed methods (PWROG-19027), and NRC staff- endorsed guidance (NEI 17-07) to ensure acceptability of the newly developed methods in the PRA.

The policy matters related to the peer review of PRA methods were deliberated by the Commission prior to the issuance of 10 CFR 50.69, “Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors,” in 2004. The Commission approved the acceptability of the peer review process as an alternative to the staff's review and approval of the plant-specific PRA models (SRM- SECY-04-0118). Both Revision 2 (ML090410014) and the recent Revision 3 (ML19308B636) of RG 1.200 acknowledge that the peer reviewer's purview includes peer review of PRA methods.

Issue 4. Many plant PRAs remain incomplete, and some are already using unapproved methods.

Response: During the licensing process, the NRC staff reviews information about the technical acceptability of the PRA model submitted by the licensee under oath and affirmation (e.g., the peer reviewer team's findings and their disposition) and responses to RAIs, and NRC staff conducts audits to obtain additional technical information. These activities ensure that PRA models used for a given application are technically acceptable, which means that they contain sufficient scope, quality, and level of detail. Since adoption of risk-informed initiatives enables licensees to use inputs from the PRA model to change TS-required completion times, NRC imposes license conditions to require licensees to maintain those models using endorsed processes to reflect the as-built and as-operated plant. (Footnote 2)

Additionally, the NRC-endorsed review requirements for NDMs, as documented in PWROG-19027 include the use of operating experience to justify the technical acceptability for NDMs before they are adopted.

Issue 5. The proposed TS provides an expansion of authority, where licensees can make future changes beyond the current TS authorization without prior NRC approval.

Response: Revision 2 of RG 1.200 (ML090410014), dated March 2009, endorses the Commission-approved peer review process and acknowledges that the process includes peer reviews of PRA methods. The current TS included in Revision 2 of TSTF-505 is inconsistent with the Commission policy because it eliminates the licensee's ability to use the peer review process to approve new methods.

The proposed TS, if approved, would endorse the peer review process described in NEI 17-07. As noted by the non-concurring individual, NEI 17-07 includes many “should” statements when

describing that process. However, the proposed TS itself uses a “shall” statement when referring to the NDM peer review requirements in Tables 1-7.2-2 through 1-7.2-7 of PWROG-19027. Similarly, PWROG-19027, which would become a requirement through the proposed TS, if approved, discusses the necessary attributes of the peer review process. These attributes would also become requirements, if a licensee were to adopt the proposed TS (if approved).

Additionally, DRA and other technical staff carefully review each TSTF-505 license amendment request to ensure that the proposed risk-informed completion times do not include a loss of function. Further, the use of peer reviews for NDMs does not obviate the licensee from complying with 10 CFR 50.59.

Issue 6. The proposed TS for reporting NDMs is flawed.

Response: After considering the non-concurring individual's comments, the proposed TS wase revised as follows. (Footnote 3)

a) Licensees will be required to submit the NDM report no more than 60 days after a focused peer-review has occurred.
b) All licensees who use an NDM will be required to submit an NDM implementation report, regardless of whether the staff has already received an NDM implementation report from the first licensee. This proposed change closes an important gap, because such a report would enable the staff to determine whether deviations from an accepted NDM impacts its acceptability.

Based on endorsed guidance, the use of an NDM in a licensee's plant-specific PRA model would be characterized as a “PRA upgrade” and consequently, would undergo a focused scope peer review. The focused scope peer reviewers review the implementation of the NDM in the plant-specific PRA, with any necessary plant- specific inputs, and its consistency with the peer-reviewed NDM. The focused-scope peer review would also address the consideration of the uncertainties in the NDM.

The burden attributed to the proposed TS for the NRC renewal request to the Office of Management and Budget (OMB) for 10 CFR Part 50 has been approved by OMB.

PRA upgrade inspections will occur based on the normal risk-informed inspection sample process guided by the ROP or be driven using criteria in the OI on NDMs, once finalized and issued. In the event, a regional inspector chooses to inspect an NDM as a part of IP 71111.13, that inspector could use the TAR process to acquire additional NRR expertise to support that activity, if needed.

Submission of the reports required through the proposed TS, if approved, will follow 10 CFR 50.71and 10 CFR 50.4. Consequently, the proposed TS does not need to specifically require the licensee to submit the report under oath or affirmation. As documented in several TSTF-505 approvals, the No Significant Hazards Consideration for those amendments does not rely on either the PRA or the methods in the PRA.

Issue 7. The NRC inspection program lacks the talent and resources to provide oversight and verification.

Response: An important component of the NRC's inspection program is the availability of staff with additional knowledge and skills that can be leveraged on an as-needed basis to support the inspectors. NRR/DRA, with support from regional inspectors and SRAs, is currently proposing the development of a graded, performance-based inspection approach to periodically inspect the implementation of the licensee's PRA configuration control process against the endorsed guidance and the as-built, as-operated plant. The SRAs, who are proficient in PRA techniques, will be members of the inspection

teams.

Finally, DRA has drafted an OI on NDMs to complement the already existing TAR process. The OI, if approved, will create a process in which subject matter experts evaluate the results of the NDM peer review to determine if additional evaluation and/or engagement, via public meetings and/or inspections, is warranted. This process is similar to the process by which NRR engages with licensees on steam generator inspection reports.

Issue 8. Inspection procedures have been modified but remain insufficient to provide a PRA inspection program to address industry-wide changes concurrently.

Response: IP 71111.13, “Maintenance Risk Assessments and Emergent Work Control,” was modified to address inspection of the implementation of TSTF-505 in January 2020. The revised inspection procedure is sufficient to ensure appropriate oversight of NDMs used in PRA models. The IP notes the need to inspect NDMs on an as-needed basis, and further guidance will be provided in an OI for NRR staff to identify and engage with inspectors in cases where NRR/DRA believes that additional oversight may be appropriate. Based on interactions with industry PRA experts, the NRC staff anticipates receiving less than five NDM peer review reports per year, and this is not expected to present a resource challenge on NRR subject matter experts.

Additionally, to further strengthen the inspection program in response to the increased use of risk-informed initiatives by licensees, NRR/DRA, with support from regional inspectors and SRAs, is currently proposing the development of a graded performance-based inspection approach to periodically inspect the implementation of licensee's PRA configuration control process against the endorsed guidance and the as-built, as- operated plant. Use of NDMs will be one (but not the only) focus of such inspections. The inspections will be supported by SRAs, who are proficient in PRA techniques.

Issue 9. No fee billable process has been established for DRA/Headquarters review of NDMs.

Response: Billable processes exist for NRC staff to review NDM peer review reports and NDM implementation reports for acceptability. When the staff receives an NDM peer review report from a vendor, the process used to bill vendors for topical reports can be used. If the NDM peer review report or the NDM implementation report is submitted for review by a licensee, then the process used to bill licensees for license amendment reviews can be used. This approach is analogous to that used for NRR review of steam generator inspection reports.

Issue 10. NRC has no budget allocated for the review of NDM PRA Upgrade Reports.

Response: The resources necessary to review NDM PRA Upgrade Reports are available within the budgeted resources for DRA to support licensing actions (in the event licensees submit NDM implementation reports) and topical reports (in the events vendors provide NDM reports). The NRC requested and received the Office of Manage Budget (OMB)'s approval to use NRC resources to review NDM PRA upgrade Reports to implement the proposed TS, if it is approved using NRC regulatory processes. Based on information received from the Nuclear Energy Institute and Owners Group, DRA estimated that approximately 300 hours per year will be needed to review NDM PRA Upgrade reports. NRC will use the actual review experiences to adjust the resource estimate during the next planned update to OMB Clearance for 10 CFR Part 50.

NON-CONCURRENCE PROCESS (Continued)

Issue 11. Proposed changes should preclude NDMs adversely impacting the design and licensing basis.

Response: The proposed TS, if approved using NRC regulatory processes, should preclude the use of NDMs that adversely impact the design and licensing basis because licensees must ensure that any NDMs that are used have been reviewed against NRC staff-endorsed review requirements. These review requirements ensure, in part, that NDMs are technically adequate and, as such, will not adversely impact safety. Furthermore, the proposed TS does not remove the licensee's responsibility to comply with other regulatory requirements, such as 10 CFR 50.59, for potential adverse impacts on the design and licensing basis.

Issue 12. Public rights for participation are eliminated in bypassing licensing and topical report review processes.

Response: All correspondence between the licensee and NRC that is required by the proposed TS, as well as any report submitted by the NDM developer (vendor), will be publicly available unless a proprietary designation has been made. Furthermore, the proposed TS does not eliminate the public's right to participation in regulatory matters because licensees who choose to adopt the proposed TS are required to do so by submitting a license amendment request. The OI developed by NRR/DRA also includes the provision for public meetings in the event that additional engagement with the licensee and/or industry is warranted for an NDM. These processes provide sufficient opportunities for public participation.

Conclusion

As stated above, I want to reiterate that the subject memo of the non-concurrence does not establish an approved NRC process/regulatory framework for reviewing NDMs. Instead, Dr. Weerakkody is proposing to Mr. Franovich a recommendation to enhance the oversight of risk-informed initiatives using a graded, performance-based approach. As discussed above, I agree with some of the changes proposed by the non-concurring individual on the proposed TS. Those changes have been reflected in the enclosure to the memo. Also, we have modified the NDM reporting requirements in response to suggestions by the non-concurring individual. This non-concurrence has been provided to all those who have previously concurred for their consideration.

I commend the individual for submitting the non-concurrence and for his commitment and dedication to the NRC's mission. His willingness to raise concerns with staff and management is admirable and vital to ensuring a healthy safety culture within the Agency.

Footnotes:

1. NRC staff uses various approaches to determine acceptability of PRA methods (including newly developed methods), including leveraging PRA peer review results, audits, and RAIs.
2. For 10 CFR 50.69 and advanced LWRS, regulations require periodic updates to PRA model.
3. The Office of the General Counsel will need to review these changes for acceptability and the regulated community will be informed.

10. Signature and Date of NCP Coordinator

Shivani N. Mehta

Digitally signed by Shivani N. Mehta
Date: 2022.01.04 22:16:42 -05'00'

11. Signature and Date of NCP Approver

Meena K. Khanna

Digitally signed by Meena K. Khanna
Date: 2022.02.02 15:44:00 -05'00'

RECOMMENDATION ON NUCLEAR ENERGY INSTITUTE'S PROPOSED TECHNICAL SPECIFICATION ON CHANGES TO PROBABILISTIC RISK ASSESSMENT METHODS (NEWLY DEVELOPED METHODS)

Overview of the Non-Concurrence

I agree that peer reviews have been of benefit to the industry in advancing use of risk in licensed activities and NRC confidence in the quality of licensee probabilistic risk assessments (PRAs).

This nonconcurrence (NCP) is concerning the Office of Nuclear Reactor Regulation (NRR) Division of Risk Assessment (DRA) White Paper (ADAMS ML19226A207) entitled, "Recommendation on Nuclear Energy Institute's Proposed Technical Specification on Changes to Probabilistic Risk Assessment Methods (Newly Developed Methods)," that proposes to replace the current technical specification (TS) in Technical Specification Task Force (TSTF) Traveler 505 and Initiative 4b concerning risk-informed completion times (RICT). I have been expressing objection to this proposal since its inception in 2017 and have exercised the open-door policy and held informal discussions with management prior to submitting this NCP.

Background

- On October 2016, NEI requested fee waiver for review and pilot of NEI 16-04, New PRA Method Evaluation Process (ADAMS ML16295A105)
- On April 5, 2017, NRC approved fee waiver for NEI 16-04 for three EPRI fire PRA methods (ADAMS ML17044A071)
- On June 14, 2018, NEI withdrew request for NEI 16-04, and began negotiating a revision to TSTF-505 (ADAMS No. ML18183A059)

  Context: In October 2016, NEI requested "any present or future activities performed using the processes outlined in NEI 16-04 also be covered under the fee waiver." The Vetting Panel process in NEI 16-04 involved approval of new methods by the DRA Director and would have had no licensing involvement. NRC approved the fee waiver for NEI-16-04 to test the Vetting Panel process for three EPRI fire PRA methods but no plant-specific applications or future PRA methods. Industry ceased effort to pilot the Vetting Panel and withdrew NEI 16-04.

Licensing Precedent

- On November 15, 2016, NRC suspended approval of TSTF-505, Revision 1 (ADAMS ML16300A245)
- On August 8, 2017, NRC approved Vogtle Initiative 4b (ADAMS ML15127A669) after 4-year review.
- On November 21, 2018, NRC approved safety evaluation for TSTF-505, Revision 2 (ADAMS ML18267A259)

Context: Revised NRC position maintained most of Vogtle approval in stating, “PRA methods approved for use with this program, or other methods approved by the NRC for generic use…”

Revised Industry Position

- Accepted TSTF-505, Revision 2, to get suspension-induced backlog of plant-specific licensing actions moving
- Returned intensity to pursue approval of industry peer reviews of new PRA methods without NRC-approval
- Developed strategy to leverage RG 1.200, Revision 3 (ADAMS ML20307A046) through:
    - PWROG-19027-NP, Revision 2, “Newly Developed Methods Requirements and Peer Reviews” (ADAMS ML20212C660)
    - NEI 17-07, Revision 2, “Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard” (ADAMS ML19241A615)

Revised NRC Position

- NRC proposes to endorse PWROG-19207-NP, Revision 2, and NEI 17-07, Revision 2, in DG-1362 (RG 1.200, Revision 3) (ADAMS ML20307A046) without exceptions.
- DRA White Paper (ADAMS ML19226A207) proposes new TS that includes RG 1.200, Revision 3, PWROG-19027-NP Revision 2, and NEI 17-07, Revision 2
    - Adopts peer review process in lieu of NRC-approved methods
    - Provides reporting requirement for PRA Upgrades

NCP Summary of Issues

1. For licensees using PRA to modify the license and/or TS, the plant-specific PRA is now part of the licensing basis of the facility.

    Context: *Current licensing basis* (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

Based on the above, licensees that have made voluntary changes to the license and/or TS (e.g., NFPA 805 for fire protection, TSTF-425/Initiative 5b for surveillance frequency control programs, TSTF-505/Initiative 4b for risk-informed completion times (RICT), and 10 CFR 50.69 for the risk-informed categorization of structures, systems and components (SSCs)) have incorporated the PRA and its methods and models in the CLB. See Background Document excerpts for Vogtle Initiative 4b TS (ADAMS ML15127A669) and TSTF-505 TS (ADAMS ML18267A259).

2. The NRC does not license through inspection.

   Context: The NRC issues rules, regulations, and licenses that establish the benchmark of requirements against which NRC conducts inspections. The TS are Appendix A to the license. The inspection program relies on a "trust but verify" process to ensure licensees meet the regulatory requirements and license obligations. The TS proposed as an Enclosure to the White paper inverts this process and places the burden of demonstrating unacceptability of licensee self-initiated changes using newly developed PRA methods on inspectors and the inspection program, rather than NRC authorized changes through licensing. Regional inspectors do not have the licensing or risk analysis experience to determine the acceptability of licensee use of newly developed PRA methods (NDMs) and should not put in the position of providing tacit or *de facto* approval of licensee-initiated NDM affecting the CLB, either through omission or commission.

3. NRC regulations, reactor licenses, and TS rely on the use of NRC-approved codes and methods, analytical methods, and PRA methods.

   Context: The regulations in 10 CFR 50.55a, "Codes and standards," provide for incorporation by reference the use of various NRC-approved industrial standards. Improved Standard TS (ISTS) 4.2.1 states, in part that, "Fuel assemblies shall be limited to those fuel designs that have been analyzed with applicable NRC staff approved codes and methods and shown by analysis or tests to comply with all fuel safety design bases." ISTS 5.6.3.b., states, in part, that, "The analytical methods used to determine the core operating limits shall be those previously reviewed by the NRC, specifically those described in the following documents: [listed individually in the TS]." NRC-endorsed TSTF-505, Revision 2, states, in part, that, "Methods to assess the risk from extending the Completion Times must be PRA methods approved for use with this program, or other methods approved by the NRC for generic use; and any change in the PRA methods to assess risk that are outside these approval boundaries require prior NRC approval." Departure from the use of NRC-approved methods would undermine confidence in the safe operation of NRC-licensed facilities. As such, this is a policy decision, with broad implications, that should be made by the Commission in a SECY Notation Vote paper and not via an internal DRA memorandum.

4. Many plant PRAs remain incomplete and some are already using unapproved methods.

   Context: NRC does not, at present, have a good understanding of circumstances where licensees may have already departed from the use of NRC-approved PRA methods (e.g., fire) or are using newly developed methods (NDMs) without prior NRC approval. Some of these changes could adversely affect the reasonable assurance of safety and undermine the design and licensing basis assumptions.

   As an example of the above, DRA approved the topical report for Generation 1 Westinghouse reactor coolant pump (RCP) seals. It was subsequently realized that the Generation I seal cannot perform its intended mitigating safety function for RCP seal loss-of-coolant accident (LOCA) due to deficiencies in the concept and design. It is not apparent that the NRC ever rescinded PRA credit associated with the approval of the Generation I seal and did not evaluate the plant-specific impacts where Generation I seals were being credited improperly in PRAs. PRA credit for Westinghouse Generation III seals were challenged in NCP-2016-004, for Diablo Canyon Power Plant (DCPP) for taking PRA mitigating seal credit in its NFPA 805 application. The NRC did not approve Topical Report PWROG-14001-A for Westinghouse Generation III RCP seals until nearly a year after the DCPP NFPA 805 submittal.

   Based on the above and ongoing operating experience, it is apparent that licensees are taking PRA credit for equipment that is yet to be demonstrated to meet its design safety function (e.g., Flowserve mitigating RCP seal failures). This operating experience is generally ignored by the current NRC inspection program with respect to credit in the PRA model.

5. The proposed TS provides an expansion of authority, where licensees can make future changes beyond the current TS authorization without prior NRC approval.

   Context: Current TSTF-505 TS requires the use of PRA methods as part of the program in the license amendment approval or other methods approved by the NRC for generic use. The proposed TS in the Enclosure to the DRA White Paper would replace the requirement of “NRC-approved methods” with Regulatory Guide (RG) 1.200, Revision 3, that endorses PWROG-19027, Revision 2, “Newly Developed Method Requirements and Peer Review, and NEI 17-07, Revision 2, “Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard,” and a reporting requirement.

   RGs do not provide requirements. RGs provide “a method” for meeting regulatory requirements, but licensees can pursue any method of their choosing. PWROG-19027 has tables with “requirements,” but mostly refers to NEI 17-07 on the peer review process. Neither PWROG-19027 nor NEI 17-07 provide actual requirements in the context of a TS requirement. The draft TS in the Enclosure to the DRA White Paper provides “requirements” in Tables within PWROG-19027, but execution of the peer

process relies on NEI 17-07 that has 225 “should” statements and 19 “shall” statements. As such, the proposed TS in the DRA White Paper s not enforceable.

NRC has already had problems with licensee implementation of the Surveillance Frequency Control Program (SFCP) because it refers to NEI guidance that also says “should.” The same problem would exist with PWROG-10927 and NEI 17-07. The proposed TS in the Enclosure to the DRA White Paper is an expansion of authority that cannot be enforced.

To be sufficient, there needs to be a requirement in the proposed TS that states that “all “should” statements in PWROG-10927 and NEI 17-07 are “shall” statements and provide additional TS provisions indicating, “The licensee shall establish, maintain, and adhere to procedures to implement the RICT program.” The TS needs to address loss of function and potential non-conservative changes that would affect the design and licensing basis.

6. The proposed TS for reporting NDMs is flawed.

   Context: The TS does not provide a timeline for reporting proposed use of an NDM. It also introduces the likelihood for other licensees to use the NDM without NRC having determined the sufficiency or expressing objection of the first precedent. Because there is no generic approval, each licensee’s proposed use of an NDM is inherently plant-specific and dependent on applicability to the design, licensing, and PRA maturity for of that plant. The proposed TS only requires reporting of the first use of an NDN. Even that does not require basic information concerning the completeness or model uncertainty of the NDM. There is also no discussion of Paperwork Reduction Act or requirements for an OMB Clearance.

   At a minimum, each licensee using an NDN should have to report of the plant-specifics of the NDM, identify variations from the precedent, and confirm that it reflects the as-built, as operated, and as-maintained plant. Otherwise, the industry is advancing generic approval of a precedent (i.e. a *de facto* method approval). In that regard, the proposed TS would bypass both plant-specific licensing and NRC review and approval of topical reports. This new DRA-direct approach also bypasses other NRC inspection-licensing processes for the use of Technical Assistance Requests (TARs).

   NDM Upgrade Reports should be submitted under oath or affirmation confirming that the No Significant Hazards Consideration of the TSTF-505 or Initiative 4b approval remains valid.

7. The NRC inspection program lacks the talent and resources to provide oversight and verification.

Context: The training and qualification of most NRC inspectors in PRA methods is insufficient to assure (1) recognition of a problem in NDMs and associated peer reviews, (2) elevation and follow-through will occur in a timely manner, and (3) closure of the NDM issue has a plant-specific nexus and applicability. The White Paper and TS appear to presume that multiple actions (i.e., fleet submittals and closely sequenced industry submittals) can be handled by DRA with other competing licensing-related work and regional inspection resource challenges. There is no similarity to this process in the review of other NRC reports (e.g., ECCS, effluent, and steam generator reports, etc.).

8. Inspection procedures have been modified but remain insufficient to provide a PRA inspection program to address industry-wide changes concurrently.

   Context: The development of an NRR Office Instruction is insufficient, when a PRA Team Inspection procedure and resource allocation appears warranted. It is likely that licensees will make fleet-wide changes using NDMs with only limited time gaps between the precedent and other NDM adoptions, or multiple power reactor sites implementing NDMs concurrent with the first precedent. The NRC is ill-equipped to handle this scenario, particularly if licensees deviate or take exception to portions of the NDM, as is often done with topical report approvals.

   NRC Inspection Procedures are insufficient to address NDMs. IP 71111.13, "Maintenance Risk Assessments and Emergent Work Control," provides guidance for inspecting RICT approvals but only has one line of guidance stating newly developed PRA methods should receive "priority for sampling." IP 71111.22, "Surveillance Testing," provides guidance for inspecting the risk-informed surveillance frequency control program per TSTF-425 but has nothing on NDMs. IP 71111.12, "Maintenance Effectiveness," has some guidance on PRA but nothing on NDMs. IP 71111.18, "Plant Modifications," addresses updating the PRA to address plant modifications but has nothing on NDMs. None of the above IPs referenced in the DRA White Paper address NDMs in a manner consistent with the intent of the proposed TS. Only IP 71111.13 provides for sampling NDMs but no assurance that all or any new NDMs will be inspected. The resource estimates are mostly based on routine annual sampling and outages, but certainly would not provide for focused inspection of NDMs in a timely manner as suggested by the DRA White Paper. None of the IPs provide indication of a resource estimate budget for NRR/DRA detailed review of NDMs as part of the inspection module estimate.

   It is possible that no NDMs will be selected for inspection samples across the broad fleet of plants. If it had not been directed as a corrective action by the EDO for DPO-2018-002, it is unlikely that any inspection sampling of licensee 10 CFR 50.59 reviews of lead test assemblies for accident tolerant fuel would have been done.

9. No fee billable process has been established for DRA/Headquarters review of NDMs.

Context: In October 2016, NEI requested a fee waiver for review and pilot of NEI 16-04, "New PRA Method Evaluation Process," using a Vetting Panel process. NEI requested "any present and future activities using the processes outlined in NEI 16-04 also be covered under the fee waiver." NRC approved the fee waiver for NEI 16-04 to test the Vetting Panel process and three EPRI fire PRA methods but no plant specific applications or future PRA methods. EPRI withdrew the request in June 2018.

By redirecting the effort from licensing to inspection via the DRA White Paper and TS, the industry would essentially gain the requested blanket fee waiver for all NDMs, absent NRC initiating a subsequent review through inspection. Since the DRA White Paper proposes a process and TS that bypasses the OCFO's prior limits on fee waivers for reviewing NDMs, this new process needs to be shared with and authorized by OCFO. It is appropriate and proper for all NDMs to be reviewed as fee billable work.

10. NRC has no budget allocated for the review of NDM PRA Upgrade Reports.

    Context: The NRC normally budgets two years forward. At present, review of NDMs via the DRA White Paper and TS would be unbudgeted work. It is also not apparent how the NRC/DRA would proceed if reviews became complex and involved multiple rounds of requests for additional information (RAIs) or audits to determine that a No Significant Hazards Consideration exists and/or an amendment was needed.

11. Proposed changes should preclude NDMs adversely impacting the design and licensing basis.

    Context: If it were not for radiation, NRC would not need to exist. Changes described in the DRA White Paper and TS should preclude PRA-based changes that could non-conservatively affect the barriers to the release of radioactivity (e.g., fuel, reactor coolant system, and containment) and mitigating systems (e.g., AFW, ECCS, etc.). The questions surrounding the acceptability of NDMs could undermine the design and licensing basis, particularly if an unrealized common-cause failure potential is introduced. The peer review is only as good as the panel. Like all populations, there will be a distribution – some being done in an amazingly high quality and thorough manner, some very poorly, but most somewhere in the middle.

    There is reasonable assurance in being able to tell the public that licensees use NRC-approved methods. It is good to advance the quality of PRA methods and peer reviews, but an unwinding of the NRC-approved methods is not a good thing in terms of public confidence for public health and safety and protecting the environment. If NDMs contributed to an actual event or accident, it would be a very difficult discussion "how the NRC let this happen" giving testimony before Congress.

12. Public rights for participation are eliminated in bypassing licensing and topical report review processes.

Context: Discussing RG 1.200, PWROG-19027, and NEI 17-07 in public meetings and offering these documents for public comment does not address the need for public engagement by persons living in the vicinity of a plant for which an NDM is being considered. The public has no opportunity to comment on the specific NDM under consideration, because the industry initiative and the DRA White Paper propose to bypass the licensing process and noticing requirements of plant-specific changes. The proposed TS provided in the DRA White Paper on NDMs severely undermines public interest in the safe operation of the plant and rights guaranteed by 10 CFR 50.90, 10 CFR 50.91, and 10 CFR 50.92. Public comment on generic approval of NDMs in topical reports is also lost.

BACKGROUND DOCUMENTS

NEI 16-04, “New PRA Method Evaluation Process Guidelines,” and Vetting Panel Process

View ADAMS Properties ML17089A649
Open ADAMS Package (Letter from Nuclear Energy Institute requesting fee waiver for New PRA Method Evaluation Process Guidelines)

- NEI letter dated October 20, 2016, stated,

  This document details a process to be used by a joint NRC-industry methods vetting panel to make new PRA methods available for use in regulatory applications in a more expeditious manner. It is anticipated that the process used by the vetting panel will substantially reduce NRC resources devoted to reviewing PRA technical adequacy in support of risk-informed licensing applications, and will therefore support more widespread use of these applications throughout the industry.

- NRC letter dated April 5, 2017 states,

  NEI proposes to use these fire PRA methods pilots to assist the NRC in formulating a regulatory position for the use of a vetting panel process for evaluating new PRA methods in RG 1.200, as well as assist NRC in considering NEI 16-04 for possible endorsement in RG 1.200.

  Thus, the NRC staff concludes that NRC review of NEI 16-04, “New PRA Method Evaluation Process Guidelines”, and the assessment of the process using three pilot methods meets the criteria under 10 CFR 170.11(a)(1)(ii). Therefore, the fee waiver request is approved only for the staff review of the three pilot PRA methods and NEI 16-04, as described above, but does not apply to any plant-specific licensing actions. Any future revisions of NEI 16-04 or any further NRC activities with NEI 16-04 beyond those cited in NRC’s acceptance of the fee waiver will require you to submit a new fee waiver request for NRC consideration, pursuant to the new fee exemption provisions under10 CFR 170.11 (a)(1).

NEI withdrawal of request re: NEI 16-04

View ADAMS Properties ML18183A059
Open ADAMS Document (Withdrawal of Request for Review of NEI 16-04, New PRA Method Evaluation Process Guidelines.)

Initiative 4b and TSTF-505

View ADAMS Properties ML16300A245
Open ADAMS Document (Issues with Technical Specification Task Force Traveler TSTF-505, Revision 1, "Provide Risk-Informed Extended Completion Times - RITSTF Initiative 4B.")

Vogtle Initiative 4b plant-specific approval

View ADAMS Properties ML15127A669
Open ADAMS Document (Vogtle Electric Generating Plant, Units 1 and 2 - Issuance of Amendment Nos. 188 and 171, Implementation of NEI 06-09, "Risk Informed Technical Specifications Initiative 4B, Risk Managed Technical Specification Guidelines" (CAC ME9555 and ME9556).)

> The risk assessment approach and methods, shall be acceptable to the NRC, be based on the as-built, as-operated, and maintained plant, and reflect the operating experience of the plant as specified in RG 1.200. Methods to assess the risk from extending the completion times must be PRA methods accepted as part of this license amendment, or other methods approved by the NRC for generic use. If the licensee wishes to change its methods, and the change is outside the bounds of this license condition, the licensee will seek prior NRC approval, via a license amendment.

View ADAMS Properties ML18267A259
Open ADAMS Document (Final Revised Model Safety Evaluation of Traveler TSTF-505, Revision 2, "Provide Risk-Informed Extended Completion Times - RITSTF Initiative 4B")

> The risk assessment approaches and methods shall be acceptable to the NRC. The plant PRA shall be based on the as-built, as-operated, and maintained plant; and reflect the operating experience at the plant, as specified in Regulatory Guide 1.200, Revision **[2]**. Methods to assess the risk from extending the Completion Times must be PRA methods approved for use with this program, or other methods approved by the NRC for generic use; and any change in the PRA methods to assess risk that are outside these approval boundaries require prior NRC approval.

DRA White Paper

View ADAMS Properties ML19226A207
Open ADAMS Document (Review-of NEI-Alternative-to-TSTF-505)

[5.5.15/5.5.18], RISK-INFORMED COMPLETION TIME PROGRAM

e. A RICT must be calculated using [list specific approaches used (e.g., internal events PRA, fire PRA, addition of bounding seismic risk to RICT calculations, etc.)]. Probabilistic risk assessment (PRA) model used to calculate a RICT shall be developed, maintained, and upgraded in accordance with processes described in Regulatory Positions C.1, C.2, C.3, and C.4 in Regulatory Guide (RG) 1.200, Revision 3, “Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities.”

f. Use of any newly developed methods, as defined in RG 1.200, Revision 3, requires satisfying all applicable review requirements in Tables 1-7.2-2 through 1-7.2-7 of Pressurized-Water Reactor Owners Group-19027-NP, Revision 1, “Newly Developed Method Requirements and Peer Review,” Revision 0, in accordance with the process in NEI 17-07, “Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard,” Revision 2.

g. A report, describing the implementation of a newly developed method, shall be submitted in accordance with Section 5.6.8, following a PRA upgrade that uses a newly developed method and prior to using that method in the RICT program.

5.6.8, Newly Developed Method PRA Upgrade Report

A report describing the implementation of a newly developed method shall be submitted following a PRA upgrade that uses a newly developed method and prior to using that method to calculate a RICT in accordance with Specification [5.5.15/5.5.18]. A PRA upgrade report on a newly developed method implementation is not required to be submitted if the implementation of newly developed method has been previously reported to the U.S. Nuclear Regulatory Commission for a RICT program.

The report shall describe the scope of the upgrade and shall include:

a. The PRA models upgraded, and the newly developed method used;

b. A description of the acceptability of the newly developed method consistent with Section 9.1 of NEI 17-07, "Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard," Revision 2;

c. The peer review and finding closure reports for the newly developed method available to the NRC for oversight and inspection activities;

d. All open findings from the peer review of implementation of the newly developed method and how those findings were resolved or demonstrated not to have a significant impact on the PRA; and

e. All changes to key assumptions related to the newly developed method or its implementation.

DG-1362 (RG 1.200, Rev. 3)

View ADAMS Properties ML20307A046
Open ADAMS Document (Draft for ACRS Public Meeting, RG 1.200, R3, Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities)

PWROG-19027-NP, Revision 2

View ADAMS Properties ML20212L660 (not accessible in ADAMS)

Open ADAMS Document (Westinghouse, PWROG-19027-NP, Revision O "Newly Developed Method Requirements and Peer Review" per PA-RMSC-1647)

NEI 17-07 Revision 2

View ADAMS Properties ML19241A615
Open ADAMS Document (NEI 17-07, Rev 2, "Performance of PRA Peer Review Using the ASME/ANS PRA Standard - August 2019.")

[5.5.15/5.5.18], RISK-INFORMED COMPLETION TIME PROGRAM

e. A RICT shall ~~must~~ be calculated using [list specific approaches used (e.g., internal events PRA, fire PRA, addition of bounding seismic risk to RICT calculations, etc.)] based on the as-built, as-operated and maintained plant. Probabilistic risk assessment (PRA) model used to calculate a RICT shall be developed, maintained, and upgraded in accordance with processes described in Regulatory Positions C.1, C.2, C.3, and C.4 in Regulatory Guide (RG) 1.200, Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities."

f. Use of any newly developed methods, as defined in RG 1.200, Revision 3, shall meet ~~requires satisfying~~ all applicable review requirements in Tables 1-7.2-2 through 1-7.2-7 of Pressurized-Water Reactor Owners Group-19027-NP, Revision 1, "Newly Developed Method Requirements and Peer Review," Revision 0, in accordance with the process in NEI 17-07, "Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard," Revision 2. All provisions of PWROG-19027 and NEI 17-07 shall constitute requirements. Written procedures shall be established, implemented, and maintained to manage RICT in accordance with RG 1.200.

g. A report, describing the implementation of a newly developed method, shall be submitted under oath or affirmation in accordance with Section 5.6.8, within six months following a PRA upgrade that uses a newly developed method and prior to using that method in the RICT program.

5.6.8, Newly Developed Method PRA Upgrade Report

~~A report describing the implementation of a newly developed method shall be submitted following a PRA upgrade that uses a newly developed method and prior to using that method to calculate a RICT in accordance with Specification [5.5.15/5.5.18].~~ A PRA upgrade report on a newly developed method implementation shall be submitted indicating the plant-specific applicability of the newly developed method, precedents using the proposed method, and any exceptions, deviations, or clarifications from the precedent(s). In cases where NRC has approved a method for generic use, a report is not required to be submitted. ~~if the implementation of newly developed method has been previously reported to the U.S. Nuclear Regulatory Commission for a RICT program.~~

Commented [MM1]: This is redundant to g. above.

The report shall describe the scope of the upgrade and shall include:

a. The PRA models upgraded, and the newly developed method used;

b. A description of the acceptability of the newly developed method consistent with requirements in Section 9.1 of NEI 17-07, "Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard," Revision 2;

c. A summary of t~~T~~he peer review and finding closure reports for the newly developed method indicating availability ~~le to the~~ for NRC ~~for~~ oversight and inspection activities;

d. All open findings from the peer review of implementation of the newly developed method and how those findings were resolved or demonstrated not to have a significant impact on the PRA or the plant; and

e. All changes to key assumptions related to the newly developed method or its implementation.

f. Confirmation that the no significant hazards consideration approving the RICT program remains valid.