

## Comments on Revision 1 of NEI Draft White Paper: Pandemic Plan

The Nuclear Energy Institute (NEI) submitted a pandemic response plan (Rev. 0), also referred to as a white paper, on January 16, 2007, and a revised plan on December 17, 2007. We reviewed the revised plan for regulatory relief during a pandemic. NEI has not addressed most of our original comments on the first version. The NEI still recommends “NRC enforcement discretion as the most efficient and effective licensing approach to a pandemic” through “a pre-established NRC policy.” The staff finds that this approach presents significant challenges to overall progress for pandemic preparation. The plan does not justify nor support the various components it recommends. The plan also raises significant legal and policy issues.

Our comments are organized as follows. First, we present general comments that concern significant legal and policy issues raised by the plan. Next, we cover continuing concerns from previous comments, and comments that address additional concerns on the new material. We conclude with specific page-by-page comments and questions following the order of the plan itself.

### General comments:

The revised NEI plan raises the following significant legal and/or policy issues:

#### **1. The plan expands the enforcement discretion (NOED) policy beyond relief from license conditions.**

- It addresses enforcement discretion not only regarding license conditions, including technical specifications (TSs), but also explicitly regarding regulations and implicitly regarding orders. The legal and policy issues associated with providing relief from regulations and orders are different from those addressed by the current NOED framework.
- It adapts the NRC NOED policy, including the portions of the NOED policy on severe weather events and the (formerly applicable) Year 2000 transition (Y2K). The current NOED Policy, however, is limited to discretion regarding TSs.

#### **2. The plan permits balancing of potentially increased radiological risk against public health and safety benefits of continued operation.**

- The basic NOED Policy requires that granting the NOED involve no net increase in risk over that associated with compliance with the TS shutdown requirement. The NEI plan, however, would explicitly permit an increase in risk (i.e., a decrease in safety), as does the NOED policy on severe weather. Such balancing under the NOED's severe weather policy is something the Commission has been very concerned about monitoring.
- Moreover, terminology throughout the plan is inconsistent concerning what safety standard may be invoked.

**3. The plan “pre-establishes” discretion and contemplates licensee self-declaration of both the existence of pandemic conditions and the applicability of relief measures.**

- The plan includes "pre-established discretion" for which no plant-specific safety assessment is required and for which the licensee can self-declare a pandemic and qualification for enforcement discretion if certain criteria are met. The plan also would permit licensees to qualify for discretion with no notice to the NRC in certain circumstances, a provision that was specifically rejected by the Commission when it was proposed in the development of the Y2K NOED policy.

**4. The plan continues to refer inappropriately to 10 CFR 50.54(x) emergency relief**

- It continues implicitly to analogize immediate radiological emergencies - the limited focus of § 50.54(x) - to a pandemic event. Whether § 50.54(x) may be invoked is an issue independent of whether a pandemic event is in effect.

**5. The plan defers providing the detailed technical basis for relief requests**

- Many NRC comments on NEI's initial draft requested the basis for advocating relief from specific regulatory provisions; NEI has deferred most of those specific risk analyses or relief templates for future revisions to the plan or joint/public meetings. For example, the plan seeks endorsement of N-1 staffing in several areas but does not explain what the rationale would be in any particular setting.

**6. The plan places implicit constraints on the scope of subsequent NRC enforcement**

- Mirroring the language of the prior Y2K NOED policy, the plan would have the Commission agree to not take enforcement action for licensee's actions under this policy "unless a licensee's action was clearly unreasonable considering all the relevant circumstances." It is not clear that such a constraint is appropriate for the pandemic-relief context.

**7. The plan does not explicitly consider comparable regulatory relief during a pandemic with respect to NRC-licensed activities other than reactors.**

- We think that development of pandemic plans could be appropriate for other NRC-licensed facilities or activities, in particular Category 1 facilities, other major fuel cycle facilities, or the transportation of radioactive materials.

As with Revision 0, the NEI white paper focuses on power operations and does not address other potential scenarios. As stated in our previous comments, the paper does not address start-up from an outage or trip, or maintenance of a safe shutdown condition during pandemic conditions with reduced staffing levels. The paper appears to assume that a nuclear plant could not be in an outage when a pandemic occurs. However, if a

pandemic occurs during the spring or fall outage periods, a number of plants may either be in or approaching a refueling outage. The white paper should consider how adequate staffing can be maintained to assure nuclear safety and security during a pandemic for all modes of operation.

The white paper suggests relaxing various requirements to cope with reduced staffing levels resulting from a pandemic, but does not consider potential licensing basis changes that could be made proactively and does not encourage licensees to pursue such changes. For example, licensees could voluntarily upgrade site-specific PRA models and request license amendments to implement technical specification initiatives 4b and 5b, which allow greater flexibility for completion times and surveillance test intervals, respectively. Such pre-pandemic initiatives could have other practical benefits in addition to improving preparedness for the possibility of a pandemic.

Section 3.2 of the NEI white paper states: "This white paper proposes, and it is reflected in the proposed interim discretion policy, that NRC licensees not be permitted to request enforcement discretion for a noncompliance that occurs during a pandemic unless the noncompliance can be attributed to staffing reductions caused by the pandemic." This phrasing appears to unnecessarily restrict a licensee in the event that a non-pandemic related situation arises during the pandemic. Regulatory relief could still be appropriate to continue to maintain electrical output while the situation was being corrected. This could happen at a plant with adequate or full staff levels. The risk-informed approach currently in use should not be curtailed during a pandemic.

Overall, very little technical basis is provided for the specific types of regulatory relief identified in the white paper. Furthermore, some suggestions do not appear reasonable. Specific comments on staffing levels, technical specification completion times, and technical specification surveillance intervals are provided below.

Although we examined the tables and noted certain issues or ambiguities that could need to be addressed if the plan is further developed, some of us determined that in light of our general concerns it was probably unnecessary to review the tables in detail at this time. Accordingly, our comments on the tables should not be considered complete.

NEI's guidance for security staffing during a pandemic is not acceptable. It makes no provisions for the range of national security levels (Green, Yellow, Orange, Red). It disproportionately reduces the number of security staff compared to other plant staff. The guidance is too generic, does not reflect the complexity of the various sites' protective strategies, and provides no compensatory actions, such as asking local and State law enforcement for increasing their random patrols. There is no mention of using corporate staff or staff from other plants or sites to supplement the shortage.

#### Continuing Concerns From Previous NRC Comments

The following comments are continuing concerns and refer to more than one section of the paper.

The plan still appears to assume that NRC may "pre-authorize" relief such that licensees can begin implementing relief without notifying the NRC in advance and getting plant-

specific approval (pages 6, 9, 12, 16; B-4 thru 6, Comment Responses #43, 50; but see pages 16 and B-5, B-7, which implies at least NRC confirmation or “opt-out”).<sup>1</sup>

The plan is inconsistent as to how noncompliance is to be authorized. Would a licensee seek approval:

- simply by reference to acceptance criteria in a revised Enforcement Policy (i.e., at a high level of generality);
- by more specific reference, as appropriate, to various NRC Safety Evaluations that have analyzed pandemic relief in connection with specific regulations (employing the Enforcement Policy’s acceptance criteria); or
- by almost entirely plant-specific requests that may include both pre-approved SEs and new licensee analyses (compare page 3 to 16 and 16, 17; B-7; NOED template).

The plan does not clearly acknowledge that NRC, pursuant to its own pandemic-response plan, will shed work to give priority to critical functions, including emergency licensing actions. However, the revision does note the NRC’s planning efforts and the intention to follow normal licensing process and relief mechanisms if possible (pages B-3, B-4), so it may not be necessary to repeat this comment. (See also NRC comment #37, which acknowledges that NRC may not have staff to review a lot of very detailed risk-assessment requests.)

It is still unclear from the plan how a pandemic event would be determined and declared. In particular, it is unclear what governmental entity makes such a determination and/or to what extent licensees can “self-declare” a pandemic and begin unilaterally implementing “pre-authorized” relief programs as noted in the comment above (pages 16; B-5; Comment Responses #33, 44).

Ambiguity remains about the plan’s intended NOED standard/criteria for balancing increases in radiological risk against more general “public health and safety” benefits of grid stability and provision of electricity during a pandemic (pages 3, 5, 12; B-3, B-6).

There is inconsistent terminology describing the safety/risk standard for approving NOED relief (though many of these phrasings are also in the NRC Inspection Manual Part 9900 and the Enforcement Policy):

- Safety/security must be “maintained” (page 5)
- Requirements could be relaxed “without affecting the risk profile [and] increasing the likelihood of a radiological accident” (page 3) or without “material” or “adverse” impact (pages 6, 11)

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<sup>1</sup> Page references are generally to the Pandemic Licensing plan, except where noted as being to Appendices or proposed exemption/NOED templates. Other references are to the Comment Response Table attached to the plan or to the pages of the plan’s numbered Recommendations.

- Safety cannot be unacceptably affected (but presumably could be incrementally reduced) (pages 3, 17; B-3)
- Mechanisms are to “minimize the risk from continued operation” (page iii)
- Certain requirements “cannot be compromised”, though paper acknowledges relief in these areas would probably entail an amendment or exemption (page 6)
- Any decrease in safety is “small” (page B-6)
- Action is “consistent with protecting public health and safety” (page B-7)

It appears from these criteria that the plan seeks to extend the NOED risk framework beyond what may have been intended by the Commission in providing for severe weather NOEDs (see Comment Response Table, #3).

Relatedly, the plan has very limited discussion of the likely impact of pandemic on demand for electricity, which may be relevant to the above calculus of risk/benefit of operation under relief-authorized conditions. Although NEI has added an umbrella assumption of 50% demand reduction, the basis for that level is unclear, as is the related assumption that availability of nuclear generation would be essential (the plan references only an assumption of disrupted fuel supplies to other types of generating plants).

The plan continues to advocate (contrary to the NRC Inspection Manual) the use of NOEDs with respect to non-compliance with regulatory requirements, not just license conditions and TSs (Plan Recommendation #5; 15; pages B-4 thru 6). Also, while less emphasized than before (and still described as an atypical approach), the plan still refers to Orders as a possible mechanism for granting relief (pages iii, 8, 15). While it may be appropriate to seek extension of the NOED risk framework, there are some legal and policy implications unique to these related types of relief (the exemption process for regulations, the relaxation process for Orders) that need to be considered.

While now using less problematic comparisons, the plan’s references to § 50.54(x) are still misleading and at least implicitly continue to analogize immediate radiological emergencies - the limited focus of § 50.54(x) - to a pandemic event (pages 8, 9-10, B-4; Comment Response #60).

Additional Concerns/Questions, Including re: New Material

Why does the plan contemplate bi-monthly status reports rather than on a schedule based on the type of relief granted and the timeframe of the specific approvals? (pages 13, 16, B-5) In fact, NEI’s NOED template seems to call instead for daily status reports [See NOED template at pages 3, 5].

The proposed exit criteria for pandemic-related NOEDs differ from the current NOED approach, under which it appears that either the NRC sets an exit time at the time of approval, or the licensee requests NRC approval at the time it seeks to exit the NOED. Why would exit from NOED be a unilateral licensee decision? (pages 13, 16, B-5)

The text concerning limits on subsequent NRC enforcement actions, including text of draft enforcement policy, seems to constrain what actions NRC would evaluate (in terms of root causes) and what enforcement standard would apply, in a manner contradicting existing NRC policy (pages 11, B-4, B-7 thru 8; but see comparable standard in previous Y2K NOED policy).

Saying that a NOED is “authorized” or “concluded on,” may create the misimpression that the NRC has taken a licensing action (thus triggering required Atomic Energy Act processes); the current NOED policy uses the term “issue” or “grant” – perhaps “approve” or “confirm” would be appropriate descriptions.

References to maintaining “safety” may implicitly encompass “security” as well, but it would help to make that aspect explicit (e.g., at iii, “assure...safe *and secure* operation”) when some of the regulatory provisions at issue are related to guard force staffing, etc.

### Additional Page-by-Page Comments and Questions

#### Title

The description of the document as a “Licensing Plan” is problematic, because significant components of the requested relief framework would not involve licensing actions; it would be clearer to refer to a “Response Plan” or “Relief Plan” or “Enforcement Discretion Plan.”

#### Abstract

On page ii, the phrasing could be misunderstood as saying that continued operation of plants during a pandemic is the fundamental guiding principle (not just continued safe operation).

#### Section 1.3

Page 3 declares that adequate, stable power supply is “essential to protect public health and safety.” The NRC does not endorse this as an overarching value judgment.

The last paragraph of page 3 states that “Relief will be withdrawn when stable staffing levels...”. What is the intended definition of “stable”, considering the anticipated wave action of the pandemic described in Section 1.2? This question would also apply to Section 3.2.1 item (3) on page 12 of the white paper.

Page 5. Framing the relief request as an “inability to comply” seems a little inapt – it is a decision, based on a risk analysis and regulatory approval, to not comply in lieu of ceasing operation.

#### Section 1.4

Items 1 and 2. The NRC should not have to endorse NEI-06-09 and NEI 04-10. This plan appears to try to obtain improper endorsement for the TS initiatives. See also Sections 2.3 and 4.3 below.

Item 6. Posting information on the website has security ramifications. Another method should be found. See also section on the Comment Response Table, Comment 24.

Item 7.

Any TS change that is proposed during the pandemic is likely to be requested and approved as only a temporary change. Using a CLIIP is usually a more permanent form of change which might not be appropriate for the sort of TS relief that would be requested during the pandemic emergency. The CLIIP process remains a useful evaluation mechanism where generic TS changes are warranted, including where they relate to actions that could be affected during a pandemic. However, the CLIIP process may not be an appropriate mechanism for providing regulatory relief that is intended to be of very short duration.

There is no mention of low power and shutdown or proposals to interface with FERC and other transmission and generation operators to coordinate activities.

### Section 2.1

The Table 1 column descriptions in Section 2.1 of the paper do not match the column descriptions on the first page of the Table itself. For example, the text says Column 6 recommends the appropriate vehicle for regulatory relief, while page T1-1 says that Column 6 states the basis for relief.

### Section 2.2

It may be construed as inconsistent with the risk-neutral safety standard to say that other actions may be taken to “mitigate the consequences” of noncompliance; or, is that essentially the same as offsetting the risk so that granting relief is a risk-neutral decision?

Category A states that SSCs cannot be compromised, and thus no regulatory relief may be sought during a pandemic. However, emergency preparedness is identified as part of the Commission’s defense-in-depth philosophy and therefore, emergency response equipment (e.g., emergency communications, public alert and notification systems, dose assessment computers, meteorological towers, etc.) that is necessary to provide for the public health and safety during a radiological emergency should be included in this category.

Sections 2.2 and 2.3 seem to indicate NEI’s position is that prior NRC approval via a plant-specific license amendment would be necessary for compliance category A items. As such, there appears to be an inconsistency regarding NEI Recommendation 2 (on page 7 of the white paper), which does not assume prior NRC approval yet is, in part, applicable to category A.

### Section 2.3

#### Section 2.3.1 Risk Basis for Extending LCO Completion Times

In Section 2.3.1 on page 7, NEI recommends that the NRC accept NEI 06-09 for licensees to use to determine which limiting conditions for operation (LCOs) can be

extended during a pandemic (NEI Recommendation 1). It appears that this recommendation does not assume NRC prior approval for licensees to implement the LCO extensions. In a letter dated May 17, 2007 (ADAMS Accession No. ML0712002387), the NRC staff found NEI 06-09 acceptable for referencing by licensees proposing to amend their Technical Specifications (TSs) to the extent specified and under the limitations delineated in NEI 06-09 and in the safety evaluation included as an enclosure to the letter. According to the discussion in Section 4.0 of the safety evaluation, there is a significant amount of plant-specific information each licensee needs to provide to support modification of the TSs in accordance with NEI 06-09. As such, the NRC staff believes that prior NRC approval would be required and, as such, plant-specific license amendment requests would need to be submitted in accordance with 10 CFR 50.90.

Further, NEI states that “[a]ll LCOs are in pandemic compliance category A.” In Section 2.3 on page 6, NEI states that “[r]egulatory relief is highly plant-specific for compliance category A (no relief, or minimal relief).” In Section 2.2 on page 6, NEI states that “Licensees requesting minimal relief from Category A requirements would be required to use the appropriate administrative process defined in existing regulations (typically a license amendment or an exemption) to obtain such relief.” Thus, it would appear that NEI’s position is that prior NRC approval via a plant-specific license amendment would be necessary for each plant to implement the risk-managed TS guidelines discussed in NEI 06-09 (i.e., consistent with NRC position as discussed above). However, in the Comment Response Table, the NEI response to NRC comment 9 (on white paper Revision 0) indicates that it is not feasible to develop full-scope plant-specific license amendment requests as a contingency for a limited-duration pandemic event. This response appears to be inconsistent with the discussion in white paper Sections 2.2, 2.3, and 2.3.1. The NRC staff notes that if an amendment was approved for implementation of the TS changes associated with NEI 06-09, those TS changes would be permanent (i.e., not only applicable during the pandemic event).

Section 2.3.1 does not discuss whether or how the plant specific PRAs will be adjusted for the pandemic conditions (increased likelihood of operator error with reduced or impaired staffing).

As stated in the general comments above, the NEI white paper could serve as a beneficial catalyst for moving licensees toward risk-informed technical specification initiatives that would allow operational flexibility at all times, including during a pandemic. NEI should recommend that licensees develop plans and schedules to implement technical specification initiative 4b at their sites. To the extent this is accomplished before a pandemic hits, this would be a proactive method for effectively anticipating needs for flexibility and regulatory relief during a pandemic.

### Section 2.3.2: Risk Basis for Increasing Surveillance Test Intervals

The white paper recommends (Recommendation 2) that NRC endorse NEI 04-10, “Risk-Informed Method for Control of Surveillance Frequencies” (July 2006), for licensees to use for extending technical specification surveillance test intervals. NEI 04-10 uses both risk assessment results and expert panel consideration of a number of factors to make programmatic changes to the surveillance requirements. This approach – especially the use of an expert panel – would not be viable during a pandemic with high rates of absenteeism.



Page 7 (and 3) of the white paper reference NEI 04-10, dated July 2006, which is Revision 0 of the document (ADAMS Accession No. ML062570416). However, this is not the latest version. Revision 1 of NEI 04-10 was issued in April 2007 (ADAMS Accession No. ML071360456). The NRC staff has found both versions acceptable as discussed in letters dated September 28, 2006, and September 19, 2007, respectively (ADAMS Accession Nos. ML062700012 and ML072570267). The staff notes that the NRC's approval of Revision 0 is applicable to boiling water reactors (BWRs) only. NEI should verify which version it intended to reference.

It appears that Recommendation 2 does not assume NRC prior approval for licensees to implement the longer STIs. As noted above, it is not clear if the white paper intended to cite Revision 0 or Revision 1 of NEI 04-10. Regardless, the NRC's letters of September 28, 2006, and September 19, 2007, stated that NEI 04-10 is acceptable for referencing by licensees who propose to amend their TSs to establish a surveillance frequency control program, to the extent specified and under the limitations delineated in NEI 04-10 and in the safety evaluation included as an enclosure to the letters. Based on the discussion in Section 4.0 of each safety evaluation, the NRC staff expects licensees to submit documentation related to the plant-specific probabilistic risk assessment (PRA) technical adequacy and PRA quality to support modification of the TSs in accordance with NEI 04-10. As such, the NRC staff believes that prior NRC approval would be required and, as such, plant-specific license amendment requests would need to be submitted in accordance with 10 CFR 50.90.

Similarly, as stated above with respect to TS initiative 4b, NEI should recommend that licensees develop plans and schedules to implement TS initiative 5b at their sites.

### Section 3.0

In Section 3.1.1 on page 9, NEI recommends that the NRC develop regulatory guidance to provide flexibility to NRC staff and licensees in implementing the provisions of 10 CFR 50.54(a) for quality assurance plans, 10 CFR 50.54(p) for safeguards and security plans, and 10 CFR 50.54(q) for emergency preparedness plans. Due to the plant-specific nature of these types of plans, it does not seem feasible to develop guidance (for use during a pandemic) that would apply generically for licensee implementation of changes without prior NRC approval. However, it may be possible to streamline the NRC/review approval process for some of these changes during a pandemic event.

### Section 3.2

Page 10. There may be a distinction between declining "to enforce requirements" and declining "to take enforcement actions for noncompliance." The agency's decision not to take enforcement action for noncompliance in specific instances should not be understood to imply that the NRC replaces or circumvents the relevant regulatory standards.

Page 11. It is unclear what section 3.2.1 means: that no safety assessment is necessary because it is "inherent in the interim policy"? Does that imply that no plant-specific analysis is necessary even about the applicability of the specific relief provision? What does it mean to say that Category C relief, "whether individually or collectively employed, would not adversely impact plant safety"?

Section 3.2.1, last paragraph on page 12, states that the NRC will be notified whenever the licensee exercised a provision of the pre-established discretion. When is this notification proposed to occur?

### Section 3.2.3

Page 12. NRC would need to consider whether the “pre-established generic discretion” contemplated here amounts, in practical terms, to a rulemaking or generic exemption.

### Section 3.2.4

Page 13, 17. “request NRC concurrence” – is this the same as “approval” or “authorization”?

Page 13. It is a concern that exit from relief is presented as a unilateral licensee decision that need only involve after-the-fact notification to NRC.

Section 3.2.4 allows licensees discretion to declare the entry criteria met for the pandemic plan. This should be an NRC, not licensee, decision.

Entry criteria need to be revised with some logic. Items 1 and 2 could be logically ANDed together. Item 3 could be logically ORed together with 1 and 2. Items 4 and 5 should be removed from the list - Item 4 is circular logic for an entry condition. Item 5 is not an entry condition.

### Section 3.3.1

Recommendation 7 - We agree that the use of the consolidated line item improvement process (CLIIP) to review generic, pandemic related TS changes could be beneficial. The current use of this process allows licensees to adopt pre-approved changes to NUREG Improved Standard Technical Specifications, also known as “CLIIPed TSTFs” (Technical Specification Task Force), allowing streamlined NRC staff review through the use of a model application and model safety evaluation (SE). Licensee facilities with model plant design similarities who submit license amendment requests conforming to the model application and SE could benefit from reduced application preparation and NRC review time. Therefore, the white paper should propose areas or provide examples where CLIIPs could be developed for pandemic-related TS.

### Section 3.3.2

Section 3.3.2 on page 14 states, in part, that “[i]n response to a plant-specific LAR, the NRC would prepare a safety evaluation and make it available on an expedited basis for public notice and comment in accordance with 10 CFR 50.90(a)(5) and 10 CFR 50.90(a)(6).” It appears that the intended citations should have been 10 CFR 50.91(a)(5) and 10 CFR 50.91(a)(6), which relate to the process for issuance of exigent and emergency amendments. Note, under the current provisions of 10 CFR 50.91(a)(5) and 10 CFR 50.91(a)(6), the NRC staff does not make “safety evaluations” available for public notice and comment (see NRC’s comment on Revision 0 of white paper, Comment Response Table item no. 28) although the staff could presumably could do so voluntarily if it chose.

Section 3.3.2 implies that the conditions for an emergency LAR are not defined in 10 CFR 50.91; however, the conditions for using the emergency provisions are already defined in 10 CFR 50.91(a)(5).

Recommendation 8. We agree that the use of predefined templates for managing proposed pandemic related emergency and exigent technical specification changes could be beneficial. The conditions for using emergency provisions are defined in 10 CFR 50.91(a)(5). Therefore, the criteria for an emergency or exigent license amendment request (LAR) are clearly defined in existing regulation. Therefore, NEI should clarify the need for NRC to “define in advance the criteria for initiating a pandemic-related emergency or exigent LAR.” Since industry has submitted numerous LARs and likely uses templates, NEI should propose templates for use for pandemic related emergency/exigent LAR.

Page 14. The plan suggests that NRC “define” the relief-initiation criteria in advance; however, depending on whether that term implies that the criteria are more binding than “giving guidance,” it could trigger rulemaking processes.

#### Section 3.4

Page 14. NEI should clarify whether and how a pandemic would meet “special circumstances” for an exemption.

#### Section 4.1

The white paper states that the licensee “may declare the onset of a pandemic.” Because NRC would be in direct contact with other federal health/energy agencies and departments and since the onset of pandemic would involve some advanced warning or notification, the NRC should be involved in the decision for a licensee to declare the onset of a pandemic event. Additionally, the need to continue to operate a specific nuclear unit depends on projected generation and demand and could inform an NRC decision to grant relief with respect to continued power operation of a specific nuclear unit through the use of the proposed “Interim Policy.”

The white paper states that “When the pandemic ceases to cause plant-specific staffing impacts for a particular activity at its nuclear station, and the staffing levels with respect to that activity remain stable for a reasonable amount of time, the licensee will determine that the pandemic event for the activity has ended and so notify the NRC.” “Stable for a reasonable amount of time” is not defined and could result in varying licensee interpretation. NEI should clarify this statement.

“Evaluation of Staff Requirements” discusses N-1 staffing as it relates to the positions listed in 10 CFR 50.54(m) and the TS. NEI should clarify whether the N-1 staffing applies to RO and SRO positions individually or as a shift crew.

#### Section 4.2

Section 4.2 should address the impact on the ability of the licensee to carry out emergency plan duties as well as implications for the ability to carry out Appendix R

manual operator actions. Also, it should explain how the ability of the operations staff will be impacted with N-1 staffing regarding the Emergency Operating Procedures.

Page 17 discusses staffing levels for certain job categories and functions but fails to address the new organizational structure (as required by 10 CFR 50.47(b)(1)) that would be in place, for example, during a declared emergency. In an emergency situation, the normal organizational requirements for continued plant operation would be replaced by those required by the licensee's emergency plan. The pandemic plan should consider this emergency response organization when evaluating cross-cutting staffing issues.

As stated by NRC staff regarding the initial issuance of the NEI white paper, the "n minus 1" proposal for staffing appears arbitrary and a sound basis has not been provided. The plan still does not justify, in risk-informed terms, why "n-1 staffing" (or any staffing deviation) would be warranted for various plant functions (also Comment Response #48). The staff notes that many licensees maintain shift staffing above the minimum levels stated in the regulations and have additional qualified staff to support training and routine absenteeism. However, it does not appear that a generic decision to relax staffing requirements during a pandemic can be justified. For example, the white paper does not address the need to consider whether enough non-licensed operators would be available to perform actions required to mitigate certain core damage scenarios. Some plants are highly dependent on operator actions, including actions outside of the control room, in the event of transients and accidents. The white paper does not address use of licensed personnel from training shifts, management ranks, or other sources, or the ability to upgrade inactive licenses to current status, nor does it consider that many licensees currently man shifts that exceed the minimum requirement, which could provide margin to accommodate people out sick without relaxing the underlying requirement. It does not consider the risk impact of reducing shift manning levels. Reduced staffing levels could increase initiating event frequencies, increase latent human errors, and increase human error probabilities following a transient or accident. Reduced staffing may preclude responding to certain events that depend on ex-control room operator actions. None of these factors has been considered in the white paper.

The white paper states that "If staffing continues to fall and the minimum levels cannot be sustained, the licensee must initiate additional communication with the NRC (and possibly other government agencies) to ensure safest operating condition based on a comparative evaluation of local plant conditions and, secondarily, regional grid conditions. The plant would be shut down if staffing falls to a level that can no longer ensure an acceptable level of safety and security." This statement implies that staffing level(s) can fall to a yet-to-be-identified third safe minimum staffing level (the first being the TS minimum staffing level, the second, the Pandemic Plan minimum staffing level) and that the licensee "must initiate additional communications" if this condition occurs. NEI should further explain the basis of the proposed Pandemic Plan minimum staffing and what additional information is expected from the additional communications if the minimum Pandemic Plan staffing cannot be met.

### Section 4.3

The white paper proposes using the risk-informed guidance contained in NEI 04-10 and NEI 06-09 to assign compliance categories for full compliance, extension of the LCO interval, or deferral of surveillances found in Table 3 of the white paper. Those

compliance categories are based on guidance contained in NEI 04-10 and NEI 06-09 and are, therefore, not considered appropriate for use by licensees who have not previously amended their license to include use of risk-informed guidance contained in those documents. Accordingly, use of Table 3 may not be appropriate for use by licensees for the reasons stated below:

Adopting Risk Managed Technical Specifications (RMTS) Initiative 4b (risk informed completion times) changes in accordance with NEI 06-09 requires detailed analysis and a plant-specific PRA that meets the quality standards of Regulatory Guide 1.200. The plant-specific PRA is required to include fire risk and have a capability to calculate Incremental Core Damage Probability and Large Early Release Frequency (LERF) for configurations out-of-service equipment in order to extend CT for a TS limiting condition for operation. Many US plants do not currently meet these criteria. Specific regulatory conditions must be established by the licensee and assessed by the NRC staff prior to approving plant-specific technical specification using these documents. Additionally, initiative 4b only applies to a subset of TS for which the PRA model is determined to be adequate to support (i.e., some systems are not in the PRA model, others are inadequately modeled, like control room HVAC which doesn't cover the dose mitigation function, etc.). Therefore, a change to the plant licensing basis in accordance with 10 CFR 50.90 is required to implement Initiative 4b risk-informed extension of LCO Completion Times.

Adopting RMTS Initiative 5b (risk informed surveillance requirements) changes in accordance with NEI 04-10 requires detailed analysis and a plant-specific PRA that meets the quality standards of Regulatory Guide 1.200. Specific regulatory conditions must be established by the licensee and assessed by the NRC staff prior to approving plant-specific TS changes using these documents. For example, a surveillance frequency control program must be incorporated in technical specifications to meet the requirements for adopting the surveillance test interval relaxations identified in NEI 04-10 and associated NRC staff safety evaluation. Therefore, a change to the plant licensing basis in accordance with 10 CFR 50.90 is required to implement Initiative 5b risk-informed extension of LCO surveillance test intervals for licensed operations and during a pandemic.

#### Table 1

Tables 1-3 are helpful for organizing relevant requirements, staffing guidelines, and surveillance test intervals, and their likely appropriateness for applying some form of pandemic-related relief. The tiered approach consisting of compliance categories A, B, C in Table 1 is a good start for more collaborative work to develop the table for a plant specific application in a pandemic. The staff notes that NEI's revision adopted many of the staff's recommendations for specific additions to Table 1, and the staff agrees that categorizing these regulatory actions remains a useful strategy.

Table 1, page T1-25, authorizes an increase in work hour limits. NEI should consider whether this increase will result in a more fatigued work force that has reduced ability to resist the virus.

Table 1, Page 9-10, identifies 10 CFR 50.47(b)(1) & (2) as being a programmatic requirement but does not recognize the cross-cutting aspects of the emergency response organization when considering overall site staffing requirements. The

regulations (and associated guidance) allow for an individual to be qualified for more than one emergency response position. Many licensees can take credit for this cross-qualification aspect to permit more depth in their organizations. Thus, when individuals become ill, a pool of cross-qualified people may be tapped without the need for the licensee to seek relief. The evaluation of this cross-qualification should be credited in future evaluations.

10 CFR 25.25 and 25.31(c) should be in relief category B instead of C owing to a potential security threat.

Regarding those requirements associated with requests for alternatives to certain parts of 10 CFR 50.55a, NEI indicated that licensees would comply with the requirement but reschedule the inservice inspection (ISI), inservice testing (IST), and integrated leak rate test (ILRT) no later than the next refueling outage. The recommendation listed in Table 1 for 10 CFR 50.55a(a)(1)(3) appears acceptable but the staff does not have detailed comments at this time.

With regard to the requirement associated with the ISI summary report, NEI indicated that licensees would postpone the reporting requirements and that compliance would be restored after the pandemic. The recommendation listed in Table 1 for 10 CFR 50.55a(b)(2)(viii)(D) appears acceptable but the staff does not have detailed comments at this time.

Regarding the requirement associated with the conformance of the IST program with the technical specifications, NEI indicated that licensees would comply with the requirement but reschedule the IST no later than the next refueling outage. The recommendation listed in Table 1 for 10 CFR 50.55a(f)(5)(ii) appears acceptable but the staff does not have detailed comments at this time.

10 CFR 50, Appendix G - Fracture Toughness Requirements. With regard to the requirement associated with fracture toughness testing per American Society of Mechanical Engineers Code, NEI indicated that licensees would postpone the testing requirements and that compliance would be restored after the pandemic. The recommendation listed in Table 1 for 10 CFR 50, Appendix G.III appears acceptable but the staff does not have detailed comments at this time.

10 CFR 50, Appendix H - Reactor Vessel Material Surveillance Program Requirements. With regard to the requirement associated with reporting test results of the reactor vessel material surveillance program, NEI indicated that licensees would postpone the reporting requirements and that compliance would be restored after the pandemic. The recommendation listed in Table 1 for 10 CFR 50, Appendix H.IV appears acceptable but the staff does not have detailed comments at this time.

Shorter, specific comments on Table 1 follow.

- 10 CFR 50.54(k)                      Appears acceptable but no detailed staff comments at this time.
  
- 10 CFR 50.54(m)(1)                      Appears acceptable but no detailed staff comments at this time.

- 10 CFR 50.54(m)(2)(i) Note that a plant-specific licensing action would take significant time to process and may not provide staffing relief in a time frame that would benefit the facility.
- 10 CFR 50.54(m)(2)(ii) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 50.54(m)(2)(iii) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 50.54(m)(2)(iv) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 50.74 Note that facility licensees would, nevertheless, be expected to remove medically unfit operators from duty or implement other appropriate measures to compensate for their operators' medical conditions.
- 10 CFR 50.120(b)(1) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 50.120(b)(2) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 55.21 Appears acceptable but no detailed staff comments at this time.
- 10 CFR 55.25 See comment for 50.74 above.
- 10 CFR 55.53(h) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 55.53(i) Appears acceptable but no detailed staff comments at this time.
- 10 CFR 55.55 Although staff would likely not object to a licensed operator continuing to stand watch with an expired license for a limited period of time during a pandemic emergency, the details of any pre-established enforcement discretion (e.g., length of time, individual versus facility, etc.) would need to be resolved. An alternative might include redefining a timely renewal under 55.55(b) as an application submitted at any time, rather than 30 days, before the expiration

date of the existing license. Facility licensees should also consider renewing their near-end-of-term licenses when a pandemic outbreak appears imminent rather than wait until the 60 – 30 day renewal window currently recommended by NUREG-1021.

- 10 CFR 55.59(a)(1)      Appears acceptable but no detailed staff comments at this time.
- 10 CFR 55.59(a)(2)      Appears acceptable but no detailed staff comments at this time.
- 10 CFR 55.59(c)(1)      Although it may be appropriate for facility licensees to postpone their requalification programs, it would be appropriate to continue communicating safety-significant operating experience to their licensed operators in the form of night orders or required reading.

For many of the listed regulations, the nature of and basis for the requested relief is unclear, particularly where the table references the intended relief only as an “alternative process.” In some instances, it is ambiguous what aspect of the requirement would be subject to relief. For most of the regulations, relief would have policy implications that the staff would need to consider in assessing the adequacy of the technical basis.

### Table 3

Table 3, page T3-2, lists several short term (12/24 hour) surveillances that are relatively easy to verify. Even with a reduced staff, the continuation of these surveillances would not be a large burden and, in fact, might facilitate awareness of plant conditions for the staff on duty.

The use of a standard based on Westinghouse STS while allowing licensees with other NSSS to develop their own is unacceptable. Similar relaxation with respect to other NSSS action statements may cause a different risk profile. TSs should be developed for all reactor types.

TS 3.5.2.3. Relief category should be changed from B to A. Westinghouse plants have experience gas entrainment in their ECCS piping. In addition, for BWRs, this would provide inappropriate relief to RHR keepfull systems.

As in revision 0, the white paper provides no basis for deferring the various surveillance test intervals in table 3. As stated in the previous NRC staff comments, the white paper would be more useful if it developed and presented a process for identifying surveillance test attributes that would allow them to be deferred or skipped.



## Appendix A

The Appendix A summary/excerpts of relevant requirements is helpful.

## Appendix B: Interim Enforcement Policy

The plan retains assumptions about “rare circumstances” when licensees cannot contact NRC (whether pre-implementation to request approval or post-relief to inform NRC of having done so unilaterally) and can thus proceed without NRC approval (pages B-4, B-5, B-7). Similar assumptions have previously been rejected by the Commission.

Page B-3. Some wording changes would be helpful in emphasizing that it is not necessary for NRC to provide this flexibility; rather, NRC believes that such flexibility is possible while still ensuring safety.

Page B-4. Clarify what is meant by “Licensees may decide to continue operations upon making a determination that it is safe and prudent to do so.”

Page B-5. To say the policy applies when licensees “find it necessary to deviate” from requirements further implies a unilateral licensee decision.

Who are the referenced “appropriate health authorities” who would decide that pandemic conditions exist?

To more clearly convey that compliance with the license is not “precluded” by a pandemic (i.e., ceasing operation if necessary remains an appropriate way to comply), we might suggest revising clause (2) under “Initiation and Determination” to read “a power reactor licensee determines that there are plant-specific staffing impacts that have occurred at its nuclear station due to pandemic illness and, absent enforcement relief, these impacts would preclude normal operation in accordance with the license...”

Page B-7. “Unless the initial assessment is unfavorable, the licensee would be permitted to proceed...” It is unclear whether this framework of an “approval unless NRC opts-out” evaluation is intended to be an alternative to the plan’s previous references to situations where NRC would not be notified in advance at all. (It is also unclear to what extent this opt-out approach is more legally defensible than an only “after-the-fact” notification.)

The reference to Part 9900 Section B.3 should probably refer instead to B.2.2. These limitations on the criteria for subsequent NRC enforcement of violations or their underlying causes may be problematic. Existing policy is to always consider enforcement based on the underlying cause of the NOED. (See Inspection Manual Part 9900, at 12.) Likewise, the “clearly unreasonable” standard isn’t really necessary if we understand the NOED policy to preclude implementation of the “pre-established” relief until the NRC has given the plant-specific authorization to implement. [See general comment above.]

## Comment Response Table

General:

As stated above, responses to many specific NRC concerns (in particular, requests for specific criteria or templates) have simply been deferred to later revisions of the white paper or to further public meetings (see Comment Response Table, #3, 6-11, 24, 26-31, 35, 37, 39-43, 47, 49-50, 52, 54, 56, 58, 65, 67-68).

One NRC concern--protecting the licensee emergency staff--must await input from fleet operators, according to NEI. NRC would consider more detailed proposals to streamline its response to incidents during a pandemic, especially communications with licensees.

Comment #7. The NEI response states that contact should be made with other agencies, but does not provide any further details. The plan does not provide for coordination of the readiness of offsite emergency preparedness during a pandemic event. Additionally, NEI consideration for offsite support from groups other than governmental agencies needs to be addressed. Vendor and industry groups (Westinghouse, GE, Areva, INPO, etc) and volunteer, community and emergency response organizations (volunteer fire departments, American Red Cross, hospitals, private ambulance companies, etc) need to be included in an evaluation of the nuclear licensee's continued emergency response capabilities. A licensee's emergency plan relies upon these organizations (the above is not a comprehensive list) to provide reasonable assurance that adequate protection can be afforded to the public in the event of a radiological emergency. Even though NEI cites the GAO report, it has not provided a path forward to establish the coordination activities for resolution of the item.

Comment #24. NRC resources could be challenged with posting site specific NOED packages to a website during a pandemic. Also, site-specific NOED packages may hold little value as a generic tool.

Comments #33, #48 and #80. These comments relate to the proposed n-1 staffing levels and criteria establishing when the grid may be compromised such that entry conditions for the proposed enforcement discretion may be satisfied. NEI was not responsive to NRC's comments on these two issues.

Comment #65 The staff has reserved its comments until after future revision of NEI white paper addresses emergency response staffing functions. Future evaluations of NEI proposed staffing levels will consider expected levels of staffing disruptions (studies show a max disruption of 40%) over a time period and the current depth of the emergency response organization.

Comment #66 No comment. Item closed.

#### Enforcement Discretion Request Template:

The template includes inappropriate references to "exemption" from requirements.

The Conclusion section is improperly modeled on NRC's license amendment template.

The two "request" paragraphs 2.1 and 2.2, (for "generic" and plant-specific requests) have inconsistent wording. It would be preferable here to recharacterize the need to "modify, reschedule, or skip" requirements simply as permitting "noncompliance"; that

phrasing would help emphasize the distinction from the amendment process that generally applies to changes/alternatives.

To the extent NRC agrees that pre-implementation NRC approval/confirmation is still necessary before implementing NOEDs, any “pre-established discretion” should not be described as “authorized” by the policy; “contemplated” by or “considered” by would be clearer terms.

It does not appear that a request following this template would necessarily include either a reference to a more specific “pre-established” evaluation for relief from a particular requirement or to the licensee’s supplemental plant-specific detailed risk assessment. However, without relying on at least one of those two analyses, it’s unclear why listing only the Revised Enforcement Policy’s general acceptance criteria would provide a sufficient basis for the NOED. Elsewhere the plan seems to represent that the “pre-authorized relief” would have already been performed in more detail to analyze particular provisions or regulations, rather than just mentioning very general considerations; under that framework, the requester could reference that particular “generic SE” to support a very streamlined plant-specific approval.

Page. 4-5. Several items on the list of supporting attributes are unclear (8, 9, etc.) and, in some cases, seem duplicative (see 2 vs. 10, 2 vs. 11, 4 vs. 12, 5 vs. 12). For example, several attributes note that additional details are to be provided, but other attributes constitute only an unsupported statement, such as that an unnecessary transient would be avoided (6), or that the testing being avoided might be detrimental to safety (7). If NEI expects that references to these attributes alone will suffice (except where the attribute itself calls for detail, or some pre-established NRC analysis can be referenced), these do not seem like adequate documentation of the basis for a NOED.

#### Exemption Request Template:

The template does not acknowledge the requirement for prior publication of the Environmental Assessment (EA). An "Environmental Assessment" section would be needed for the exemption request template. Our regulations have no emergency exception for issuing exemptions before publication of EAs); see § 51.35 and § 51.13. If an exemption is planned to be used, the NRC as a minimum would need to prepare an EA and publish it in the Federal Register.

The Conclusion section is taken from NRC’s license amendment template, not from the exemptions template, so the language is not entirely apt.

For finding “special circumstances,” the template relies on the standards in § 50.12(a)(2)(iv), (v), and (vi). It may be that invoking (vi) is not appropriate for some regulations; of the long list of regulations under consideration here, at least some might have been promulgated and expressly articulated as safety minimums even under severe conditions. Paragraphs (iv) and (v) seem more applicable to the arguments made in the white paper for pandemic-related relief (and to the associated risk-benefit balancing during the temporary staffing shortage).

Relatedly, the (iv) paragraph should be clarified to limit the benefit to supplying electricity “during the pandemic” to emphasize that supplying electricity is not always a benefit that can be used to balance the safety risk. Likewise, “any small decrease in safety” might

be rephrased as “the small potential decrease in safety” or perhaps could be described in terms of “the small potential increase in risk to public health and safety.”