

March 15, 2007

Jack W. Roe  
Director, Operations Support  
Nuclear Generation Division  
Nuclear Energy Institute  
1776 I Street, NW, Suite 400  
Washington, DC 20006-3708

Dear Mr. Roe:

I am responding to your January 16, 2007, letter requesting U.S. Nuclear Regulatory Commission (NRC) feedback on the Nuclear Energy Institute (NEI) draft document entitled "Pandemic Licensing Plan." The NRC staff performed a limited scope review of the document and identified several aspects of the document that should be clarified, modified, or enhanced. A listing of the NRC's comments based on this review is enclosed.

The NRC recognizes the importance of influenza pandemic preparations. As such, the NRC staff looks forward to its March 23, 2007, public meeting with NEI to discuss the enclosed comments. For further review and meeting coordination, please contact Sean E. Peters of my staff at 301-415-1842 or [sep@nrc.gov](mailto:sep@nrc.gov). Thank you for the opportunity to review and comment on the document.

Sincerely,

**/RA by BBoger for/**

J. E. Dyer, Director  
Office of Nuclear Reactor Regulation

Project No. 689

Enclosure: As stated

cc w/encl: See next page

## **Nuclear Regulatory Commission (NRC) Comments on the**

### **Nuclear Energy Institute's (NEI) draft document entitled "Pandemic Licensing Plan"**

#### **General Comments**

The NRC appreciates and fully supports NEI's efforts in pandemic planning. The NRC staff recognizes that this draft submittal is a starting point for continued discussions on the issues associated with plant licensing and operation in a pandemic situation. Given the complexity of the policy and technical issues that must be resolved, the NRC staff envisions significant revision to this plan may be necessary. As such, the NRC staff has developed both high level and detailed comments on this initial plan to aid you in your effort.

Electrical generation and grid reliability to meet the public needs during a pandemic appear to be the primary considerations in this plan. However, this plan does not specifically consider the impact of a pandemic on demand for electric power in a given region, nor consider alternative methods of maintaining sufficient generating capacity. Furthermore, the plan does not provide information on the public health and safety consequences of a loss of the grid or power supply. From a regulatory perspective, the NRC's mission (and its legal authority) is to regulate for the protection of public health and safety, not specifically to ensure power supply.

Given this lack of information, weighing the effects on public health and safety based upon a temporary loss of power supply versus the effects of a possible radiological accident during a time of degraded emergency response capabilities is a significant policy and technical issue that will not be able to be resolved in this forum. Therefore, without direction from the Commission, the NRC staff will not lower its adequate protection standard for nuclear plant operation during a pandemic.

Furthermore, this plan appears to be specifically designed to support plant operation during a pandemic by analyzing and reducing the staffing related regulatory requirements at nuclear power plants. Planning to reduce the number of staff and workload requirements in non-critical operations should be helpful in efforts to mitigate the effects of a pandemic. In fact, the NRC followed a similar strategy in its pandemic planning (see the NRC's Interim Pandemic Response Plan, ADAMS Accession No. ML061710246).

However, decisions on staffing reductions should not be made without identifying the level of staffing required to maintain safe operation. Otherwise, the reductions may pose an unnecessary risk to public health and safety. In the NRC's plan, it identified its primary goal as protection of the public health and safety, identified the duties that would be required to support this goal, and identified the number of staff members required to implement the goal. If this type of planning assumption is not included in NEI's final Pandemic Licensing Plan, a similar guidance document may be needed.

The white paper focuses almost entirely on power operations. Other potential scenarios should be address, for example, start-up from an outage or trip, or maintenance of a safe shutdown condition during pandemic conditions with reduced staffing levels.

Finally, interactions with other agencies should be explored. For example, to provide an accurate assessment of electrical requirements and grid, power plants will need to coordinate with the Federal Energy Regulatory Commission. During a time of a pandemic, the offsite response capability may be severely degraded. Therefore, this white paper should explore the coordination and alternatives related to interactions with state and local authorities and the Federal Emergency Management Association.

### Requested NRC Actions

The NEI white paper recommends that NRC take nine actions to prepare for a pandemic. Some of the recommendations would require a large expenditure of resources to implement. The white paper does not consider the resources required nor weigh the relative benefits or merits of each suggestion.

With regard to Recommendations #1 and #2 on page 3, a significant pre-assessment must be performed by the NRC staff in order to allow non-approved plants permission to implement both NEI-06-09, "Risk-Managed Technical Specifications (RMTS) Guidelines," on risk-informed completion times, and NEI-04-10, "Risk-Informed Method for Control of Surveillance Frequencies," on surveillance frequency control program. Specific criteria must be established by the plant and assessed by the NRC staff prior to approving the site-specific use of these documents. The NRC staff review would include:

- a. Probabilistic Risk Assessment (PRA) capabilities,
- b. Configuration Risk Monitoring capabilities,
- c. Training/knowledge requirements,
- d. Ability to adhere to process requirements,
- e. Ability to adhere to metrics/limits, and
- f. Program constraints and limitations for the non-approved plant.

#### *Recommendation for NRC #1: Endorse NEI 06-09*

The white paper recommends that NRC endorse NEI 06-09 for licensees to use for extending Technical Specification (TS) completion times during a pandemic. NEI 06-09 requires a PRA of sufficient scope for the TS conditions under consideration. Such PRAs would include fire risk and be capable of calculating Large Early Release Frequency (LERF) for various configurations of equipment out of service. Many US nuclear plants do not meet these requirements at present. Paragraph 2.3.1 of the white paper would allow a nuclear plant to use NEI 06-09 and to use "... its current plant-specific PRA ...." This would not be appropriate for a plant without a fire PRA and the ability to calculate LERF, for example.

#### *Recommendation for NRC #2: Endorse NEI 04-10*

The white paper recommends that NRC endorse NEI 04-10 for licensees to use for extending TS surveillance test intervals. The white paper also provides examples of surveillances that could be extended. However, it does not provide adequate justification for those surveillance intervals recommended for extension, and does not use the NEI 04-10 approach. Additional

information regarding how a licensee would use NEI 04-10 during a pandemic and some examples in the white paper would be useful.

*Recommendation for NRC #3: Supplement Regulations*

The white paper recommends that NRC supplement regulations to expand operational flexibility available to licensees during temporary pandemic situations. The NRC staff would welcome specific proposals with criteria explaining the types of regulatory flexibility permitted. However, the NRC staff notes that rulemaking is a time-consuming and resource-intensive effort that may not be completed and implemented in time for a pandemic.

*Recommendation for NRC #4: Interim Enforcement Policy*

The NRC staff is looking into the possibility of publishing an interim enforcement policy for use during a pandemic. Specific comments on the proposed enforcement policy are captured in the comments to Recommendation 5.

*Recommendation for NRC #5: Advance Authorized NOED*

Appendix B of the white paper in the section entitled "Safety Assessments for Licensee-Specific Discretion," discusses NRC Inspection Manual Part 9900, "Operations - Notices of Enforcement Discretion." The third paragraph begins: "Contrary to Part 9900 Section B.3 guidance, it is not necessary for an emergency to be declared ..." The referenced Inspection Manual part does not say a government entity must declare an emergency before NRC can exercise enforcement discretion, as implied.

When a pandemic is determined exist, and it affects the operations of a nuclear plant, the NRC Inspection Manual guidance should be followed to invoke TS relief.

Pre-established generic relief through NOEDs or other mechanisms are problematic for several other reasons:

1. The paper attempts to apply Interim Enforcement Policy discretion to regulatory requirements, not just license conditions and TSs. NOEDs do not allow for exemptions from the regulations.
2. The criteria for determining when a licensee can invoke the pre-established generic relief option is unclear.
3. The paper allows each licensee to declare itself in a pandemic - it does not require the NRC (or other government entity) to make this determination. It then prescribes that when the licensee notifies the NRC, the agency will confirm that the Interim Enforcement Policy may be used. This situation creates a potential for the licensee to declare a pandemic and for the NRC to deny the use of the Interim Enforcement Policy.
4. For the proposed pre-established enforcement discretion, the licensee does not need to give prior notice to the NRC that it is taking advantage of the relief. The

licensee is only required to give written notice to the NRC within 30 days of applying the discretion. This step in effect eliminates the regulatory and oversight role of the NRC.

5. Individual site safety assessments are not required for the proposed pre-established enforcement discretion. Individual site safety assessments are critical to ensuring adequate protection during a pandemic.
6. It may be difficult to use risk-informed techniques to establish advanced enforcement discretion since the plant configurations may not be known in advance.
7. Having pre-established generic relief presupposes that the normal relief mechanisms (amendments, exemptions, etc.) will not be feasible in a pandemic (partly due to the NRC's reduction in staff). This assumption does not credit the fact that the NRC will be shedding its work and only carrying out priority functions, including reviews of relief requests. It is also possible, as noted in the paper, that the licensee site will feel the effects of the pandemic that has not yet hit other parts of the country, in which case the NRC may have a full staff to review relief requests.

Therefore, the white paper should propose areas or provide examples where authorizing enforcement discretion in advance would be appropriate. The basis for such "anticipatory" action should also be provided.

*Recommendation for NRC #6: Post Approved NOED on NRC Website*

The white paper indicates that the data from the proposed website could serve to establish a record and basis for determining that additional pre-established generic discretion items may be adopted. The NRC staff may be able to post the approved NOEDs to a website. However, it would be rare that plant specific safety assessments approving a NOED would be applicable on a generic basis. Further, dedicating resources to a website may take the NRC staff away from more critical pandemic duties, i.e., responding to NOEDs and emergency TS changes.

Furthermore Recommendation 6, should not include posting on the NRC website any correspondence and evaluations associated with approved plant-specific enforcement discretion actions that relate to plant security.

*Recommendation for NRC #7: Use Consolidated Line Item Improvement Process (CLIIP)*

The white paper proposes adopting CLIIPs for pandemic-related modifications to the operating licenses. The NRC encourages the use of the CLIIP process for these changes prior to pandemic outbreaks and looks forward to seeing specific proposals by the industry.

*Recommendation for NRC #8: Define Pandemic Regulatory Framework*

The white paper states, "The NRC could define in advance the criteria for initiating a pandemic related emergency or exigent LAR. [License Amendment Request]" This statement should be

clarified, as the criteria for initiating emergency or exigent LARs are already established in the regulations.

The white paper also states, “In response to a plant-specific pandemic LAR, the NRC would prepare a safety evaluation [SE] and make it available on an expedited basis for public notice and comment in accordance with 10 CFR 50.90(a)(5) or (a)(6).” This statement is inaccurate in that the NRC publishes a proposed “No Significant Hazards Determination” and publishes it for public comment, followed by a “Notice of Issuance” for public notice. Furthermore, for emergency and exigent TS amendments, the NRC has processes in place to make these products available to the public on an expedited basis. NEI should elaborate on this idea if it believes that the NRC should augment the existing processes.

Finally, the white paper states, “LAR and SE templates could be prepared in advance to facilitate the plant-specific amendment process during a pandemic.” The NRC staff welcomes specific proposed changes to the NRR Office Instruction LIC-101, “License Amendment Review Procedures” (ADAMS Accession No. ML040060258) SE template for pandemic purposes. Also, as licensees most likely already use a template in LAR production, significant resources may be saved by having NEI propose the use of one of these already existing templates, modified for pandemic purposes.

#### *Recommendation for NRC #9: Develop Pandemic Exemption Request Template*

The NRC staff supports processing exemptions for pandemic related requests and currently follows the well-defined process in 10 CFR 50.12 that includes provisions for addressing “temporary” circumstances. A template for pandemic related exemption requests may also be useful for non-pandemic purposes. The industry is in the best position to understand the staffing and workload requirements for authoring an exemption request. Therefore, the NRC staff suggests that the industry put forth a proposed template that promotes efficiency in the exemption request process.

#### Regulatory Relief Options

In section 1.3, the white paper indicates that a nuclear plant licensee would “... assure safe plant operation by performing assessments of specific relief ...” However, the white paper does not discuss or recommend any details regarding this assessment, i.e., a process for requesting the regulatory relief. The paper should discuss whether or not a risk-informed assessment is intended. Also, the paper should clarify what is being assessed and how the assessment would demonstrate adequate protection of public health and safety.

#### Orders

Issuance of orders is presented as an option for regulatory relief, and the paper correctly notes that using orders to relieve a licensee from regulatory requirements is atypical. Orders should only be considered as a last resort.

## NOEDs

The white paper provides no basis to justify that maintaining nuclear plant operations to sustain grid stability offsets the risk of continued operations with N-1 staffing levels. No criteria were provided to establish when the electric grid may be compromised such that the implied entry conditions for the proposed enforcement discretion may be satisfied. The paper noted that NRC Inspection Manual Part 9900 should be followed to the extent practicable. Whether there is 'pre-established' or 'plant-specific' enforcement discretion, it should be noted that the risk criteria under Part 9900 were structured under the premise that quantitative risk results for continued plant power operations would be sufficiently small that continued operations would represent essentially normal risk levels and would offset the risk of a plant shutdown and subsequent restart of that specific facility.

The white paper provides a different paradigm that the risks for continued operations are offset by the risks to the regional or national grid if the nuclear plant in question were shutdown. This is a different basis than that which was articulated in the NRC Enforcement Policy.

## Risk Ceilings

The stringent NOED quantitative risk criterion of  $5E-7$  for an Incremental Conditional Core Damage Probability may be difficult to achieve for prolonged plant operations (weeks to months). The risk criteria were developed to handle typical NOED cases of relatively short periods of time (days) with the plant in a safe but degraded state. The stringent criteria were also created bearing in mind that the emergency or exigent LAR process is the preferred approach for approving continued operations beyond the existing allowed outage times (AOTs). The NOED risk criteria are appropriate for routine NRC operations for handling infrequent and plant-specific NOEDs.

However, a pandemic flu with risk of high mortality rates and the potentially large number of plants affected by unavailable personnel raises questions whether the stringent risk ceilings in place for risk-informed license amendment approval or NOED request approval should be adjusted given other risks that the general population will be (or are now) exposed to.

Perhaps NEI and the NRC need to revisit the risk ceilings as a specific policy issue for pandemic flu by taking into consideration the Commission's safety goals and quantitative health objectives given the relatively short duration of the pandemic versus the long-term risks of nuclear plant operations. A higher, but acceptable temporary risk ceiling, endorsed by the Commission, may streamline the approval process via an emergency LAR or NOED request when combined with other PRA related suggestions noted above. Therefore, the NRC staff will review any suggested changes proposed by NEI and will forward the NRC staff recommendations on the proposals to the Commission.

## Endorsements of Risk Guidance Documents and Use of Existing Regulatory Framework

The NEI paper attempts to maximize use of a number of available risk-informed guidance documents to justify approval of an enforcement discretion request or use of the emergency

LAR process within the current regulatory structure. However many of these guidance documents have not been approved for industry-wide application or are predicated on a certain level of model quality has been achieved through the American Society of Mechanical Engineers PRA quality/Regulatory Guide 1.200 effort or other specific guidance documents related to the risk-informed initiative. It is unclear that the entire industry (103 units) will commit to upgrade each PRA model to adequately implement advanced initiatives such as the "Risk Informed Technical Specification (RITS) Initiative 4.b on risk-informed completion times. Currently, the industry efforts to achieve industry-wide commitment appears to be limited by the number of available, qualified PRA practitioners and available industry investment. It is also not clear that licensee's PRA personnel would be available to practicably implement the initiatives during a pandemic.

The NEI recommendations are largely based on sufficient agency resources being available to either provide elaborate and detailed anticipatory guidance or have the capability to handle a potentially large number of emergency or exigent license amendments within the same time-frame during the pandemic. The NRC may be equally affected by the pandemic and not in a realistic position to simultaneously evaluate voluminous risk-informed emergency LARs or NOED requests related to the pandemic. In order to streamline any pandemic related emergency LARs or NOEDs, the industry should consider accelerating PRA model enhancements to conform with Regulatory Guide 1.200 and/or other related industry or regulatory guidance to satisfy the RITS 4.b initiative (for example). Additionally, other PRA model changes may be necessary to appropriately reflect operation with reduced staffing levels (see risk section below).

#### Risk of Continued Operations, Affects on PRA Model Assumptions, and Impact to Maintenance Rule (a)(4) Configuration Risk Management Programs

The paper fails to provide adequate guidance on how licensee PRA models should be changed to realistically reflect that less than minimum staffing levels that would be available. Less than minimum staff levels would clearly and adversely affect human reliability. Human and organizational actions are typically modeled or are assumptions in the PRAs including critical operator actions, maintenance repair recoveries for failed equipment during an event, or recovery measures and actions taken by the technical support center.

Additionally, the maintenance rule 10 CFR 50.65(a)(4) assessments may need to be changed to consider reduced human reliability for mitigating an event. Although many maintenance activities would be postponed until sufficient personnel are available, emergent conditions such as failed equipment could occur which requires that a configuration specific risk assessment be performed and that the risks are adequately managed.

Furthermore, the Tables in the paper do not seem to make adjustment or weigh the importance of equipment to mitigate a loss-of-offsite power (LOOP) or station blackout. If grid conditions may be less reliable during the pandemic period, it would seem appropriate to provide increased attention to emergency power equipment (including station batteries). Also, the average LOOP grid frequencies in the licensee's PRA model for (a)(4) purposes may not be appropriate and should be accounted for in the (a)(4) risk assessments.

### Entry Conditions

The white paper would allow licensees to declare a “pandemic event” based on absenteeism resulting from the virus. This action does not appear appropriate. Other information should be factored into the decision, and the decision should not be made unilaterally by licensees.

The white paper appears to assume that low staffing levels due to pandemic equates to “must produce electric power,” which may not be correct for a given site or situation. During an actual pandemic, governmental emergency response organizations will be directing various mitigation and recovery actions. This could include, for example, efforts to reduce electrical demand to a vital core level such that demand can be met even with reduced generation.

### Staffing Requirements

The NEI white paper proposes reduced staffing requirements during a pandemic. In Table 1, “Evaluation of Staffing Requirements,” the white paper considers explicit and implicit staffing requirements. The majority of Table 1 is based on the requirements. Five entries in Table 1 are based on the “Administrative Controls” chapter of Standard TSs; six “miscellaneous” entries are provided. Table 2 provides guidelines for staffing levels for major departments that support a nuclear plant. Table 3 evaluates surveillance test intervals that could be extended in order to reduce impact on staff.

The following comments are relevant to Tables 1 and 2 of the white paper; comments on Table 3 are provided in the section headed “Surveillance Test Intervals.”

Frequently in Table 1, the “Type of Relief” has been specified to be “Alternative - temporary streamlined program.” Characterizing relief in this manner is insufficient for the NRC to pass any judgment on its use as a relief mechanism. The white paper should provide more details as to the considerations that would need to be addressed in providing relief in each of the regulatory areas.

The “n minus 1” proposal for staffing appears arbitrary and a sound basis is not provided. 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 consider risk implications of reduced staffing 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.

The white paper does not address use of licensed personnel from training shifts, management ranks, or other sources. The white paper does not address 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.

The basis for other relaxations is not provided. For example, postponing reporting requirements or rescheduling In-Service Inspection (ISI), In-Service Testing (IST), or Integrated Leak Rate Testing (ILRT). On the other hand, the white paper should evaluate the recommendations to “postpone” requirements. If an acceptable argument could be made, it may be better to “skip” or “excuse” rather than postpone, to avoid unmanageable backlogs when normal operations resume after the pandemic.

### Surveillance Test Intervals

As stated above, Table 3 of the NEI white paper evaluates surveillance test intervals that could be extended in order to reduce impact on staff. The white paper only considers Westinghouse standard TSs; actual deferrals would have to be based on each licensee’s plant-specific TSs.

The rationale for the entries in Table 3 needs to be further explored and more technical justification needs to be provided for the proposed extensions. For instance, doubling the test interval for frequent surveillance tests may be counter-intuitive. Surveillances performed each shift, daily, or even weekly are not usually resource intensive. These surveillances involve monitoring of important operational parameters. Skipping every other occurrence is an error-likely situation, especially since logs and other processes are already in place to accomplish these surveillances. Additionally, the operators on staff should not be too busy, because the goal during the pandemic will be smooth operation and any work that can be deferred will be. Routine shift items, including the short-periodicity surveillances, may help keep operators alert and aware of plant conditions should an event occur.

On the other hand, Table 3 does not appear to consider that long interval surveillance tests might be candidates for deferral for the duration of the pandemic, provided suitable justification could be provided. Since the interval is long to begin with, deferral of a month or two would not be a large percentage increase in the interval. One may be able to argue, on a case-by-case basis, that some long interval surveillances could be deferred until normal operations resumed after the pandemic.

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. For example, the white paper might recommend skipping a surveillance test during a pandemic, with appropriate regulatory approval, if: (1) the surveillance test can increase the chance of a trip or plant perturbation; (2) there is reasonable expectation that reliability will not be significantly impacted; (3) the function being tested is low risk; and (4) the test requires significant resources to perform.

Furthermore, in some cases, the Table 3 recommendations do not seem prudent. The proposal to allow doubling the emergency diesel generator surveillance test interval needs more thought, since presumably the pandemic may result in poor grid conditions. A similar comment applies to extending battery surveillance tests.

### Limiting Conditions for Operation (LCOs)

Page 7 states that all LCOs are in pandemic category A (no relief or minimal relief). This categorization ignores any risk insights, as not all LCOs have the same risk. Similarly, paragraph 2.2 A says licensees should seek no or “minimal” relief for safety-related Structures Systems and Components. Risk insights should be considered, since safety-related and risk importance are not equivalent.

### Unilateral Changes

The NEI white paper discusses existing mechanisms that allow licensees to make changes without prior NRC review and approval.

In section 3.1.1, the white paper recommends that NRC provide additional guidance to expand portions of 10 CFR 50.54 that allow changes in the quality assurance, safeguards and security, and emergency preparedness programs. This additional guidance would be to increase the operational flexibility available to licensees during temporary pandemic situations. A specific proposal with criteria and the nature of the regulatory flexibility should be developed and shared with the NRC.

In paragraph 2.3.3 (1), the white paper refers to 10 CFR 50.54(dd), but leaves out that §50.54(dd) would apply if the need was immediate to meet national security objectives as designated by the national command authority through the Commission. Later in the white paper, it is noted that it would be unlikely that §50.54(dd) would apply during a pandemic.

The white paper mentions 10 CFR 50.54(x) in a number of locations, and the paper incorrectly suggests that 10 CFR 50.54(x) is automatically available to licensees upon the onset of the pandemic. 10 CFR 50.54(x) is only available in limited circumstances involving immediate radiological consequences. For example, the white paper misinterprets an NRC memorandum in paragraph 3.1.2, as allowing licensees to pre-plan entry into 10 CFR 50.54(x) (ADAMS Accession No. ML060590273). The NRC memorandum states that it is incumbent on a licensee to follow 10 CFR 50.59 and the provisions of the 10 CFR 50.54(x) final rule (48 FR 13968), and further noted that, had the referenced licensee followed the procedure and invoked 10 CFR 50.54(x), it might have been a violation. The paragraph in the NEI white paper needs to be removed or re-worded.

### 10 CFR 50.55a - Codes and Standards

Regarding those requirement 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 ISI, IST, and ILRT. The recommendations listed in Table 1 for 10 CFR 50.55a(a)(1)(3) and 10 CFR 50.55a(f)(5)(ii) of the white paper appear promising, with the exception that there was no mention of when the ISI, IST, and ILRT would be rescheduled. A possible remedy would be for licensees to reschedule the testing to the next refueling outage or indicate that compliance would be restored after the pandemic.

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 NRC staff finds the recommendation listed in Table 1 for 10 CFR 50.55a(f)(5)(ii) of the white paper promising and agrees that the delayed compliance should not adversely affect operation or safety during the pandemic time period.

#### 10 CFR Part 50, Appendix G - Fracture Toughness Requirements

With regard to the requirement associated with fracture toughness testing per ASME Code, NEI indicated that licensees would postpone the testing requirements and that compliance would be restored after the pandemic. The NRC staff finds the recommendation listed in Table 1 for 10 CFR 50.55a(f)(5)(ii) of the white paper promising and agrees that the delayed compliance should not adversely affect operation or safety during the pandemic time period.

#### 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 NRC staff finds the recommendation listed in Table 1 for 10 CFR Part 50, Appendix H.IV of the white paper promising and agrees that the delayed compliance should not adversely affect operation or safety during the pandemic time period.

#### Emergency Response

1. Paragraph A (page 6), recognizes that “regulatory requirements associated with the functionality of safety-related structures, systems, and components cannot be compromised,” but related emergency staff functions are not addressed
2. The NRC staff agrees with NEI (page 11) that an influenza pandemic alone is unlikely to be classified as a national security emergency subject to the provisions of 10 CFR 50.54(dd).
3. The format of Section 4.0 needs an overview of plans for staffing emergency operations and related major department functions as practiced in exercises or identified, for example, in NUREG-0654. Only those positions specified in the requirements appear to be identified. If a plant emergency should occur, there may not be enough time to modify staffing and, if necessary, consult the NRC. The reduced pandemic staffing for response to a plant emergency needs to be addressed.
4. There is no discussion of how licensees plan to maintain a healthy staff once it's in place. Shiftwork and sequestering carry different risks, which will also vary with the virulence of the virus affecting the plant. The NRC needs enough information to gauge the risks to the plant staff, the Resident Inspectors, and any NRC Regional personnel who must travel to the site.

## Security

The requirements of 10 CFR 73.55(d)(7)(i) and 10 CFR 73.55(h)(3) listed in Table 1 of the White Paper should specify that the licensee needs to "Comply" with these requirements until an acceptable "Alternative - temporary streamlined program" is approved by the NRC is developed.

## Radiation Protection

The relief recommended in this white paper that impacts radiation protection (both occupational and public) focuses on delaying compliance with certain administrative requirements in 10 CFR Parts 19 and 20. These "implicit staffing" issues include several training, record keeping, reporting, and notification requirements.

1. The recommendations listed in Table T1 (regarding radiation protection) of the white paper may be acceptable, with the exception of the reporting/notification requirements in Subpart M to Part 20 (last entry on page T1-5). The telephone reporting of theft or loss of licensed material (in 10 CFR 20.2201(a)), and the notification of incidents involving the release of radioactive materials from the site, or excessive exposures to individuals, (in 10 CFR 20.2202) should be listed separately in Table T1 as a "Comply." These requirements deal with very infrequent, safety significant, events for which the NRC needs prompt notification. Complying with these requirements should not constitute a staffing burden on the licensee. In addition, the requirement to report an overexposure to the individual involved (in 20.2206) should also be retained. Therefore, 10 CFR 20.2205 should be listed in the table as "Comply, as it refers to 20.2202 notifications, Postpone others." Again, a very infrequent, but safety significant, issue.
2. The critical requirements in 20.2104(a)(1) and (b) needs to be retained. If the licensee delays the review of records then the possibility exists that the licensee may have an individual who could exceed 5 rem by the time all records are actually verified. The NRC staff recommends retaining licensee compliance with 10 CFR 20.2104(e) at the minimum. This action would allow the licensee to administratively control the individuals' dose for the year.
3. Table 2 (major staffing guidelines) lists a total of 10 total radiation protection personnel (2 management and 3 technicians per shift). This would appear to be in excess of the minimum TS requirement of 1 ANSI-qualified technician on-site. However, this table indicates staffing for only 2 shift versus 3 shift plant coverage.

## Operator Licensing

1. The NRC staff has reviewed the industry's recommendations on page T1-13 (10 CFR 50.74), page T1-14 (10 CFR 50.120), and T1-16 (10 CFR Part 55) and believes that they would be a feasible method of addressing the applicable regulatory requirements. However, the NRC staff believes that the regulatory references to 10 CFR Part 55 on Page T1-16 are incomplete and inaccurate; specifically:

- To be complete, they should also reference 10 CFR 55.25 which complements 10 CFR 50.74 by requiring the facility licensee to notify the Commission within 30 days after learning that a licensed operator or senior operator has been diagnosed with a permanent physical or mental condition that causes the operator to fail to meet the requirements of 10 CFR 55.21. The relief category, type, and basis would be the same as 10 CFR 50.74.
  - The table references 10 CFR 55.59(a)(1), which requires licensed operators to complete the requalification program, but it should also reference 10 CFR 55.59(a)(2), which requires the operators to pass a comprehensive written exam and annual operating test. If the pandemic occurs at or near the end of the facility's 24 month requalification cycle, the facility may not be able to give the examinations and tests, so every operator would require enforcement discretion. The relief category, type, and basis would be the same as for 55.59 10 CFR (a)(1).
  - The table incorrectly references 10 CFR 55.59(b)(1), which does not exist. The correct reference should be 10 CFR 55.59(c)(1).
2. Given that the requirement for operators to complete the requalification program and have a biennial medical exam are repeated as license conditions in 10 CFR 55.53(h) and (i), respectively, it would be appropriate for that regulation to be listed in the table as well; the current proposal only includes 10 CFR 55.25 and 10 CFR 55.59(a).
  3. Another administrative regulatory requirement that should be included in the table is 10 CFR 55.55, which specifies that the operator licenses will expire 6 years after their date of issue unless the operator files for timely renewal at least 30 days before the designated expiration date. This requirement could be handled under Category C, with postponement, and a Note 1 basis.
  4. On page 18, NEI is proposing that licensee's may initiate "N-1" staffing levels for Operations personnel as listed in 10 CFR 50.54(m). Further justification would be needed to expand this staffing reduction for all plants.

### Inspection and Assessment

1. The staff recommends the following changes to the miscellaneous section on page T1-24:

Commitments: comply but inform NRC of commitments that the license cannot meet

Corrective Action Program (CAP): implement normal CAP program; corrective action due dates can be extended for those deficiencies determined to be not safety significant by the licensee's CAP program

NRC inspections: as required by IMC 2515 and IMC 2515 Appendix E

NRC meetings: as needed

NRC plant visits: postpone

Performance indicators: postpone

March 15, 2007

Jack W. Roe  
Director, Operations Support  
Nuclear Generation Division  
Nuclear Energy Institute  
1776 I Street, NW, Suite 400  
Washington, DC 20006-3708

Dear Mr. Roe:

I am responding to your January 16, 2007, letter requesting U.S. Nuclear Regulatory Commission (NRC) feedback on the Nuclear Energy Institute (NEI) draft document entitled "Pandemic Licensing Plan." The NRC staff performed a limited scope review of the document and identified several aspects of the document that should be clarified, modified, or enhanced. A listing of the NRC's comments based on this review is enclosed.

The NRC recognizes the importance of influenza pandemic preparations. As such, the NRC staff looks forward to its March 23, 2007, public meeting with NEI to discuss the enclosed comments. For further review and meeting coordination, please contact Sean E. Peters of my staff at 301-415-1842 or [sep@nrc.gov](mailto:sep@nrc.gov). Thank you for the opportunity to review and comment on the document.

Sincerely,

**/RA/**

J. E. Dyer, Director  
Office of Nuclear Reactor Regulation

Project No. 689  
Enclosure: As stated  
cc w/encl: See next page

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