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Mr. David L. Skeen
Director, Japan Lessons Learned Project Directorate
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: NEI Comments on Fukushima Near-Term Task Force Recommendation 1 – Regulatory Framework

Project Number: 689

Dear Mr. Skeen:

NRC's Fukushima Near Term Task Force (NTTF) Recommendation 1 states that NRC should establish a "logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations." The Commission has tasked the NRC staff to provide options and a staff recommendation in this regard in February 2013. This has been appropriately recognized by NRC staff as a long term activity. NRC conducted a public meeting on November 8, and provided "Draft Staff Response to Fukushima Near Term Task Force Recommendation 1" for stakeholder comment. We appreciate the staff's efforts to provide for stakeholder input. The Nuclear Energy Institute (NEI)[1] provides the following comments on behalf of the U.S. Nuclear Power Industry.

As stated in NEI's July 16 letter to NRC, we believe NRC's schedule for this effort could be tempered to provide for more informed consideration by stakeholders, given the substantive issues at hand and the long term nature of the effort. Also, as we noted, the problem statement needs better definition and justification, as this activity contributes to cumulative impact in the near term while considerable post Fukushima actions are underway. Finally we noted that lessons learned from previous risk-informed applications are instrumental to determining any new regulatory framework.

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

While we believe there is no clear problem statement compelling a new regulatory framework, we also believe improvements could conceivably be made to provide for more safety focused and predictable regulation; however, we do not agree with the specific staff options as provided. There are elements of certain options that merit further consideration. This letter discusses our proposal for a framework.

Should the Commission direct the staff to proceed with this activity, the NRC should develop a process that would test any changes in a pilot program. As Options 3 and 4 could lead to a new framework for promulgating and evaluating regulations, a pilot prior to industry-wide implementation is a necessary tool to ensure that the revised process implementation will result in the desired and anticipated impact on the both the licensees and the regulator. Even if Option 2 is adopted, a pilot program for that implementation is also warranted.

We would note that NRC has two parallel activities in this regard. We believe NRC should consider better integrating these efforts and their schedules.

1. NTTF Recommendation 1 – initial staff options paper due to the Commission in February 2013
2. NUREG 2150, "Proposed Risk Management Framework" under review by NRC staff with a paper due to the Commission six months after the above paper

Further, based on the on-going evaluation of containment filtering options for BWR Mark I and II plants, we believe that additional refinements to the regulatory framework would support better predictability and regulatory stability. This staff activity on Recommendation 1 represents an opportunity for the Commission to establish such a process.

NRC staff outlined the following options to address Recommendation 1 in their November 2 paper:

Option 1 – Maintain the existing regulatory framework (status quo)

Option 2 – Clarify the role of voluntary industry initiatives in the NRC's regulatory process

Option 3 – Establish process and considerations for balancing risk, defense-in-depth and safety margins in NRC decision-making

Option 4 – Develop and implement a design-basis enhancement category for regulatory requirements related to beyond design-basis events and severe accidents (this category could be established in two different ways)

Option 4a – Establish a design-basis extension category on a generic basis (similar to Alternative 1 of Appendix H to NUREG-2150)

Option 4b – Require licensees to perform a plant-specific PRA to establish and maintain a plant-specific design-basis enhancement category (similar to Alternative 2 of Appendix H to NUREG-2150)

Options 3 and 4b would rely on increased use of probabilistic risk analysis (PRA). As industry representatives noted during the November 8 public meeting, we believe information provided by NRC significantly underestimated the cost of developing, reviewing, and maintaining PRA models. A proper dialogue on potential regulatory framework improvements should use the most realistic information available based on industry's considerable experience with internal events and fire PRAs. The attachment to this letter provides a table of typical costs for PRA model development, peer review, and maintenance. These costs are based on experience and are not hypothetical.

The question of what new or existing regulatory requirements should be considered necessary for adequate protection of the public health and safety is central to the regulatory framework discussion. We believe the new framework should retain the current NRC approach to adequate protection, for the following reasons:

1. Congress has provided the Commission with the authority and discretion to decide on a case-by-case basis whether new information (operating experience, changes to external hazards) warrants new requirements for inclusion under adequate protection. Past examples include the NRC's decisive action to issue orders and regulations post 9-11 and for some – but not all – of the Tier 1 Fukushima actions. Absent a change in the Atomic Energy Act, this Commission prerogative will remain despite any future regulatory framework changes the Commission may pursue. However, predictability of the Commission's use of its adequate protection authority could be improved through a more consistent platform for consideration of new information.

2. It has long been part of the NRC's regulatory framework that its obligation under the Atomic Energy Act to ensure adequate protection of the public health and safety does not mean that it must achieve zero risk. This is not only the NRC's view, as it has been endorsed by the courts in a number of challenges to the NRC's requirements. Adequate protection does not mean absolute protection, a conclusion which necessarily requires the agency to accept some degree of uncertainty and risk in making decisions about whether or not to impose new requirements.

3. NRC staff's Options 3 and 4a seem to suggest an abandonment of this fundamental position on the NRC's statutory mandate. Specifically, the staff's discussion of "defense-in-depth" is inconsistent with the notion of "no risk" in that it would implement an agency policy that risk information should be disregarded in determining whether defense-in-depth has been achieved. For example, the staff states that "accident prevention alone could not be relied on to reach an acceptable level of safety." In other words, no matter how infinitesimally small the risk may be as a result of implementation of a prevention measure, this would still not prevent the agency from pursuing additional regulatory requirements.

4. For purposes of being legally-binding and enforceable, it is irrelevant whether a new regulatory initiative is ultimately determined to be necessary for adequate protection or a cost-justified substantial safety enhancement under the backfit rule. When codified in regulations or NRC orders, both types of requirements have the force and effect of law. The difference is in the quality of the analytical process through which those requirements were achieved. "Adequate protection" requirements are not

> generally subject to a rigorous analysis and cannot, as a matter of law, consider economic costs. Cost-justified, substantial safety enhancements, on the other hand, do undergo an extensive analysis that considers all factors. More importantly, that process is transparent and enables stakeholders to assess and comment on the agency's bases for the new requirement. Prematurely designating new matters as necessary for adequate protection is not transparent, and will deprive the agency of valuable information and insights into new initiatives.

With regard to other options discussed in the NRC staff paper, we offer the following:

Option 1: Status quo

Given the lack of substantial safety nexus and the potential for diversion for post-Fukushima and other ongoing regulatory activities, we continue to believe stakeholders would benefit from a better problem statement justifying this activity. The NRC Near-Term Task Force suggested that the NRC needed a strong program for dealing with the unexpected, including severe accidents. For over 50 years, the NRC and its predecessor, the Atomic Energy Commission, have demonstrated a strong program for dealing with the unexpected. The 30-plus recommendations that have been approved by the NRC show that the current regulatory framework is robust and capable of responding to the unexpected. The Near-Term Task Force noted:

> "Although complex, the current regulatory approach has served the Commission and the public well and allows the task force to conclude that a sequence of events like those occurring in the Fukushima accident is unlikely to occur in the United States and could be mitigated, reducing the likelihood of core damage and radiological release."

As technology advances and lessons are learned from operating experiences, regulatory processes and national consensus standards evolve. All effective regulatory systems will, by definition, require changes and additions to address unanticipated events. NRC staff acknowledged that any of the proposed regulatory reform options could still be subject to additions or changes following such significant events or significant new information.

Given the above, and the potential resource and potential operational impacts of a large scale regulatory framework changes, a clear problem statement should be defined with public input to justify the level of effort involved, and taking into account the regulatory enhancements already under development.

As noted by the staff, this is not a "do nothing" option. Specific post-Fukushima regulatory actions are already underway that will address many of the identified needs for beyond design-basis safety improvement. The Commission has already determined that certain of these requirements are justified under adequate protection, whereas others will be effected through normal regulatory processes. Thus far, the existing regulatory approach has been appropriate and effective.

We do acknowledge that a framework for identification and treatment of beyond current design-basis events could provide for better regulatory consistency, stability and safety effectiveness, and that the current framework does not focus resources efficiently towards risk due to its emphasis on the stylized design-basis accidents.

Option 2: Regulatory Framework for Industry Initiatives

This option would clarify the role of voluntary industry initiatives in NRC's regulatory processes by defining when or under what circumstances the NRC would incorporate such initiatives into regulatory requirements (e.g., rules, orders, or license conditions). The need for this option is not clear. As noted below, regulatory footprints have generally been established for industry initiatives within the current framework.

The NRC staff paper noted that "The results of the Severe Accident Management Guidelines (SAMG) inspection do not indicate, nor does the Task Force conclude that, the SAMGs would not have been effective if needed. However, indications of programmatic weaknesses in the maintenance of the SAMGs are sufficient to recommend strengthening this important activity." We would note that NRC is now pursuing rulemaking with regard to severe accident management guidance. Regulation was established for Extensive Damage Mitigation Guidelines (EDMGs) prior to the accident at Fukushima. Even industry's initiative on shutdown safety management is now covered by the Maintenance Rule. Given these rulemakings, and others that will be associated with post Fukushima activities, it is not clear that there still exists a compelling need for further regulatory treatment.

From Page 6 of the staff paper: "As discussed below, both the NTTF and the Risk Management Task Force expressed concerns that in some cases use of licensee voluntary initiatives has led to inefficiencies and potentially less robust resolutions of issues. The lack of inspection and enforcement for such initiatives, which has been NRC's practice, may have contributed to some measures implemented as part of voluntary initiatives to degrade over time." This is not a completely accurate characterization. Several programs, such as maintenance rule, pull plant changes into inspection space.

From Page 10 of the staff paper: "In addition to incorporation of selected industry initiatives into regulatory requirements that are then subject to the NRC's routine inspection and oversight programs, the NRC should make greater use of the oversight processes (inspections, audits, significance determination process, etc.) to monitor the implementation and long-term effectiveness of voluntary industry initiatives (i.e., that have not been incorporated into a legally binding requirement) that are used for either a means to comply with a regulatory requirement or in lieu of the NRC imposing additional requirements." As noted above, changes related to industry initiatives are evaluated in NRC inspection space.

In a number of cases, the industry initiatives (e.g. groundwater protection) concern areas that the NRC has already determined to not have public health and safety consequences, but industry has nonetheless voluntarily undertaken to address them as a matter of public confidence. To reconsider whether these initiatives should be subject to a more rigorous framework suggests that the NRC is reconsidering whether these issues have health and safety consequences; something there is no evidence for.

Option 3: Establish a Decision Process for Balancing Risk, Defense-in-Depth and Safety Margins

We believe there could be value from efforts to achieve a more consistent and clearer definition of defense-in-depth (DID). This concept, although important, has been inconsistently applied by industry and NRC. As previously noted, under some definitions, defense-in-depth can be used to override systematic and exhaustive approaches to address risk, or to require actions which are not safety focused. (An example is Branch Technical Position 8.8, requiring alternate AC sources as a condition of any diesel generator allowed outage time extension regardless of risk significance. Another timely example is the staff's reliance on DID as the basis to justify filtered vents in SECY-12-0157 despite the fact that the agency's previous analyses of filtered vents have resulted in a conclusion that they could not be justified.) This is problematic and leads to regulatory uncertainty if invoked without clear definition. The basic elements of the Regulatory Guide 1.174 integrated decision process are sound and could provide a model for more complete guidance. NRC staff should continue their activity to address DID in Regulatory Guide 1.174, and consider expansion to other areas, but a complete DID definition will remain elusive and is not in itself likely to significantly change the regulatory framework. An NRC policy statement could provide value, although any backfitting implications deserve further discussion for reasons mentioned previously in this letter.

As noted by NRC staff, a DID definition has historically proven difficult – hence the large number of definitions and sources cited by NRC in their paper. It is impossible to define all situations and applications of defense-in-depth, and by nature some subjectivity would remain regardless of efforts to achieve better structure. In particular, addressing "unknown unknowns" rationally is problematic. Certain considerations noted in the staff paper, such as the need for DID to address errors of commission or not relying on prevention alone, appear problematic. Creating a comprehensive regulatory framework relying on decision criteria based on "adequate" defense-in-depth and "sufficient" safety margin to complement a specified "acceptable" risk level would likely prove to be unworkably vague and would not lead to the objectives of consistency, predictability, and repeatability expected in good regulatory practice.

The NRC should bear in mind that the difficulty it will encounter in clearly defining DID is not dissimilar from the difficulty the NRC has had in defining "adequate protection." In the 1988 Backfit Rule, for instance, the Commission rejected demands to define or develop criteria for adequate protection. It explained that "such a definition is not possible in the near future," and that "[t]here does not exist, and cannot exist, at least not yet, a generally applicable definition of what constitutes 'adequate protection' which would guard against every possible misuse of the phrase." Rather, the Commission explained that the adequate protection standard "may be given content through case-by-case applications of its technical judgment

rather than by a mechanical verbal formula or set of objective criteria...." Though some regularity in the agency's use of DID is needed, the NRC should be mindful of the difficulty of developing a formulaic solution.

Option 4A – Establish a Design-basis Extension Category on a Generic Basis

From the industry viewpoint the only advantages of this option are increased clarity, at considerable and possibly unjustified cost. This option would attempt to clearly identify a set of beyond current design-basis events and regulatory treatments, and could conceivably provide an opportunity to distinguish treatment from that for safety related SSCs, using an approach similar to 10 CFR 50.69. However, we would note this regulation has not yet been successfully implemented and the treatment provisions remain controversial.

This option has significant disadvantages. In short, this option would introduce large regulatory uncertainties and remove current regulatory analysis requirements for an unspecified body of existing and new regulations under the name of adequate protection.

Because the staff has yet to clearly identify what events might constitute "design extension events," its statement that protection against such events would be necessary for adequate protection seems premature and lacks a regulatory basis. If the staff intends to do a legitimate and rationale analysis as part of Option 4a, it cannot state what its conclusions will be before it has conducted any rigorous analytical process or received any stakeholder feedback.

Finally, it has long been understood that plant external event and other beyond design-basis risks are plant-specific – and a generic regulatory approach would be ineffective for many plants.

Option 4B – Establish Design Enhancement Category –Licensee Performs PRA to Designate Applicable Enhancements

As a conceptual approach, we believe NRC staff Option 4b: "Establish a Design-Basis Enhancement Category for Power Reactor Regulations Using a Plant-Specific PRA" provides a more rational basis for regulation than Option 4a, and the industry proposal that follows reflects similar thinking with regard to using PRA to define the regulatory treatment and to determine any "substantial additional protection" requirements. However, it should be recognized there are limitations to state of knowledge; that not all hazards and events are amenable to PRA, and that uncertainty must be considered in decision making. State of knowledge issues and uncertainty remain (shutdown, seismic, etc.) that are hard to deal with in practice and often lead to bounding solutions. To some degree we have experienced these issues with current regulatory use of PRA, with varying degrees of success. For an approach using risk methods to be workable, the existing regulatory foundation for PRA adequacy and use could be reconsidered and targeted more towards a practical and timely approach for deriving insights rather than supporting precise quantitative decision making. In addition to cost benefit analysis, we believe PRA could serve as a useful tool for prioritizing regulatory actions as part of the

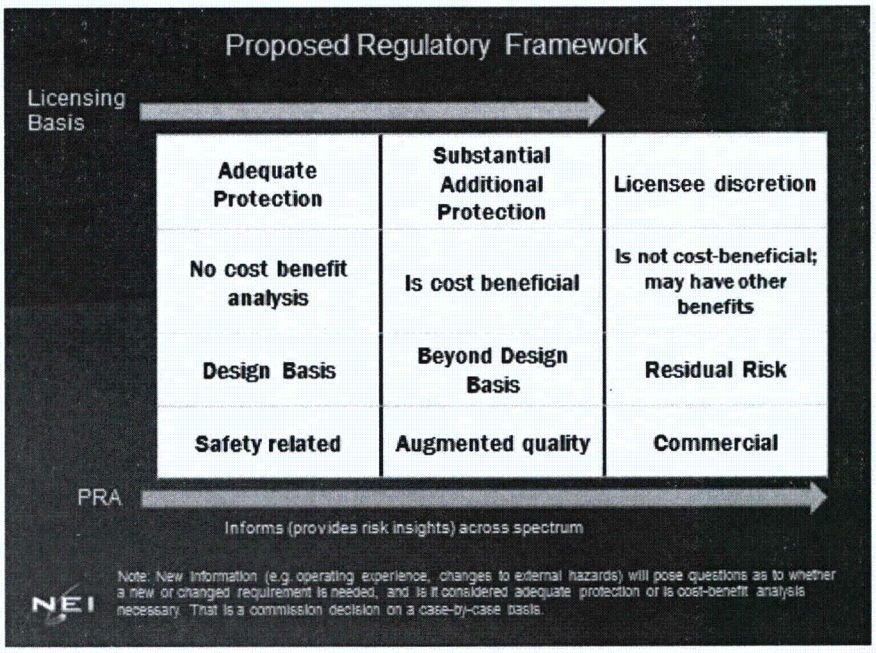
cumulative regulatory effects activity. This potential use could incentivize development of broader scope PRAs by licensees.

In Option 4b (page 39), the staff states that "the burden for demonstrating whether measures to implement an 'additional protection' feature would be on licensees. Current policy is that NRC staff demonstrates that a substantial safety improvement is justified in terms of cost." This statement seems to fundamentally confuse the role of the government versus regulated entities with respect to regulatory responsibility in which the government as a matter of law has the burden of justifying the imposition of new legally-binding requirements on regulated entities. By flipping this paradigm, and placing the burden on licensees, the agency seems to be abdicating its basic legal obligations to provide a regulatory basis for each new requirement. It is also fundamentally inconsistent with the requirements of the backfit rule, which the staff seems to recognize, and which would require a significant rulemaking change.

The staff's concept for Option 4b does not specifically acknowledge or account for the intense regulatory effort that would be required for implementation. Even if it were possible to complete a single, plant-specific PRA, the ensuing licensing, adjudication, and rulemaking activities would constitute an enormous undertaking by both the NRC and licensees. Assuming that no changes were made to the regulations, to effectively implement the results of a PRA, licensees would likely have to submit numerous license amendments (along with the required environmental analyses) and exemption requests to adjust their specific licensing basis in light of the existing regulatory framework. Considering the regulatory, political, and public relations challenges the agency has experienced as a result of one narrow area – fire protection – the staff cannot reasonably ignore these same implications when it comes to Option 4b.

Industry proposal:

Provided below is a conceptual depiction of a proposed framework that utilizes three categories to define the regulatory basis, treatment, and risk implications.



The first category (column) includes features that are required under adequate protection to meet the plant design-basis. By definition, deeming a feature as required for adequate protection does not permit a cost-benefit justification. These features would be subject to regulatory oversight against clear acceptance criteria, as we do today. PRA can serve to inform the relative risk significance of these features with respect to beyond design conditions. Examples of features in this category might include plant features required as part of a plant licensing basis to prevent or mitigate a design-basis event or accident.

The second category includes features that are implemented in order to provide substantial additional protection. These, too, would consist of legally-binding requirements and therefore subject to regulatory oversight; however, a decision to implement such features requires a rigorous regulatory analysis and cost-benefit justification. PRA can serve to inform the appropriate treatment for these features based on the role the feature plays in maintaining acceptable risk. An example of features in this category might include those required to mitigate beyond design-basis scenarios such as station blackout or beyond design-basis external hazards. Special treatment requirements would be tailored to the functions required of the feature and the significance of the feature in maintaining plant risk.

The third category includes all other plant features that are outside the regulatory footprint. These features may play some minor role in plant risk, but, by definition, they are contributors only to residual risk. An example of features in this category might include those required for power production. Where these features are relevant to plant risk, they would be subject to monitoring under the Maintenance Rule, as they are today. Otherwise, these features are subject to licensee defined treatments.

This approach represents an evolutionary shift in the regulatory framework that builds upon the existing processes in a manner that could rationalize and improve the regulatory process, rather than extensively overhaul a process that is fundamentally sound. This process could be applied prospectively as well as retrospectively to more coherently and consistently categorize the regulatory framework.

There are parallels between this industry proposal and the framework described in NUREG-2150. Industry believes that substantial effort would be required to define the process for distinguishing these categories and the associated treatments. Further, since risk contributors are plant-specific, additional work would need to be done to characterize risks, although not necessarily via a Regulatory Guide 1.200 PRA. Nevertheless, for the reasons outlined above, industry believes that such a framework would be more appropriate than the options proposed to date by the NRC staff.

In summary, we believe there is value in a long term effort to provide better definition to the regulatory framework reflecting the considerations discussed in this letter. Industry will support this effort going forward to the extent a more predictable, pragmatic, and safety focused approach is envisioned. We look forward to a productive engagement with NRC.

If you have any questions in this regard, please do not hesitate to contact me.

Sincerely,

Biff Bradley

Attachment

c: Mr. Richard F. Dudley, Jr., NRR/DPR/PRB, NRC

PRA Cost Summary

	Development Cost Range	Peer Review Cost Range	Peer Review Finding Resolution Cost Range	Annual Maintenance Cost Range
Internal Events	600,000-4,000,000 (Note 1)	90,000-150,000	75,000-250,000	125,000-150,000
Fire	1,500,000-4,000,000 (Note 2)	350,000-625,000 (Note 3)	130,000-500,000	50,000-250,000
Seismic	1,500,000-3,500,000	150,000-250,000	200,000-250,000 (Note 4)	100,000-150,000

Notes:

(1) The majority of the fleet upgraded existing internal events PRAs to meet the ASME/ANS PRA Standard; the lower end of this range reflects plants that used this approach while the upper end represents those plants that undertook a substantial model reconstruction.

(2) The lower end of this range reflects the fact that not all plants include fire modeling and circuit analysis in their Fire PRA development costs.

(3) The upper end of this range reflects the fact that some plants had to do substantial documentation work to support their Fire PRA peer reviews.

(4) As no final Seismic PRA Peer Review report has been issued, these are estimates.