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MEMORANDUM TO: Joseph G. Giitter, Director ***/RA/***
Division of Risk Assessment
Office of Nuclear Reactor Regulation

From: Mehdi Reisi-Fard
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SUBJECT: ASSESSMENT OF THE NUCLEAR ENERGY INSTITUTE 16-06, "CREDITING MITIGATING STRATEGIES IN RISK-INFORMED DECISION MAKING," GUIDANCE FOR RISK-INFORMED CHANGES TO PLANTS LICENSING BASIS

This memorandum assesses the guidance in Nuclear Energy Institute (NEI) 16-06, "Crediting Mitigating Strategies in Risk-Informed Decision Making," in relation to guidance that the U.S. Nuclear Regulatory Commission (NRC) staff uses to determine the acceptability of the probabilistic risk assessments (PRA) used to support risk-informed applications (i.e., Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities"). The NRC staff found that certain elements of NEI 16-06 guidance lack sufficient technical justification. For those elements, this memorandum clarifies the NRC staff's position and provides staff conclusions. This memorandum also identifies areas where improved industry guidance will strengthen the technical basis for NEI 16-06 and, consequently, enhance the predictability and efficiency of review of risk-informed applications that credit mitigating strategies.

In order to meet certain NRC regulations and orders (such as NRC Order EA-12-049, "Issuance of Order to Modify Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," issued after the Fukushima Dai-ichi accident), the nuclear industry has developed mitigating strategies which include procuring portable equipment to restore or maintain various safety functions during beyond-design-basis conditions and the loss of permanently installed plant equipment. In August 2016, the Nuclear Energy Institute issued NEI 16-06 to provide guidance to licensees on the treatment of plant mitigating strategies in risk-informed decisionmaking. NEI believes that licensees can apply the guidance of NEI 16-06 to portable equipment independent of the strategies that portable equipment were originally designed to support.

Enclosure:
Assessment of NEI 16-06, "Crediting Mitigating Strategies in Risk-Informed Decision Making" Tier 3 Approach

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NEI 16-06 outlines a three-tiered approach for evaluating the potential safety benefits of plant mitigation strategies: (Tier 1) qualitative assessment, (Tier 2) semi-quantitative streamlined assessment, and (Tier 3) full probabilistic risk assessment. The Tier 3 approach of NEI 16-06 provides guidance for fully quantifying the impact of mitigating strategies in PRA models that should meet the guidance of Regulatory Guide (RG) 1.200.

The NRC staff recognizes the safety improvements that could be achieved by implementing mitigating strategies and notes the importance of updating PRA models to reflect as-built, as-operated conditions. For applications where PRA is used to change a plant's licensing basis, incorporation of mitigating strategies in PRA models should be performed in a manner consistent with the American Society of Mechanical Engineers (ASME)/ the American Nuclear Society (ANS) PRA Standard RA-Sa-2009, as endorsed by RG 1.200. The NRC staff believes that the information provided in the enclosure to this memo, when used in conjunction with NEI 16-06, could enhance the predictability and efficiency of reviewing risk-informed applications that use PRA models to credit mitigating strategies.

NEI 16-06 identifies unique aspects of modeling mitigating strategies and portable equipment, which are to be considered in a PRA model that meets the guidance of RG 1.200, for most of the PRA elements discussed in the guidance. In the enclosure to this memo, staff has identified issues related to four areas in NEI 16-06. These four areas are: scope of the applicability of the guidance, PRA upgrade, human reliability analysis, and data analysis. The enclosure will discuss NRC staff conclusions on how those issues could be appropriately addressed in risk-informed applications that take quantitative credit for mitigating strategies using PRA models that meet the guidance of RG 1.200. When reviewing risk-informed applications that follow the guidance in NEI 16-06 and are within the scope of the enclosed assessment, the staff will consider the identified issues and may request additional information related to them, as necessary.

Staff based its conclusions on information available at this time. Over time, industry will gain more experience in implementing mitigating strategies and incorporating those strategies in PRA models. The NRC staff will also gain more experience in reviewing risk-informed applications that incorporate mitigating strategies. With this gained experience, NRC staff conclusions on NEI 16-06 may evolve and change. NRC staff will communicate any such changes.

SUBJECT: ASSESSMENT OF THE NEI 16-06, “CREDITING MITIGATING STRATEGIES IN RISK-INFORMED DECISION MAKING,” GUIDANCE FOR RISK-INFORMED CHANGES TO PLANTS LICENSING BASIS DATE May 30, 2017

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Assessment of the NEI 16-06, "Crediting Mitigating Strategies in Risk-Informed Decision Making" Tier 3 Approach

1. PUROPOSE AND SCOPE

Nuclear Energy Institute (NEI) 16-06, "Crediting Mitigating Strategies in Risk-Informed Decision Making," outlines a three-tiered approach for evaluating the safety benefits of plant mitigating strategies in risk-informed decisionmaking;

- Tier 1. Qualitative assessment evaluates the key considerations that need to be addressed. In this tier, the licensee should collect the necessary information to produce the foundation of the overall approach to credit mitigating strategies.
- Tier 2. Semi-quantitative assessment applies a decision tree process to the qualitative considerations identified in the previous tier to estimate the risk benefit of a mitigating strategy. The NEI document states that it is not the intent of the assessment in Tier 2 to meet the Probabilistic Risk Assessment (PRA) requirements of Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities" and therefore is not intended to be implemented in areas where a PRA that meets RG 1.200 is required.
- Tier 3. Full probabilistic risk assessment, seeks to fully quantify the risk impact of mitigating strategies using a PRA that meets the guidance of RG 1.200.

The scope of the U.S. Nuclear Regulatory Commission (NRC) staff's assessment in this document is limited to the application of NEI 16-06 guidance to those risk-informed applications that should meet the guidance of RG 1.200. As noted above, Tier 1 and Tier 2 do not directly support the risk-informed applications that meet the guidance of RG 1.200. Therefore, this document only provides the NRC staff's evaluation of the Tier 3 approach. This document also discusses potential issues related to incorporation of mitigating strategies and portable equipment in PRAs when the NEI 16-06 guidance is followed.

The NRC evaluated Tiers 1 and 2 under a separate effort. The Director of the Office of Nuclear Reactor Regulation (NRR) issued a letter to NEI (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16167A034) that highlights several areas in which the NRC staff may focus their attention during reviews when licensees use the content of Tiers 1 and 2 for providing credit in risk-informed decisionmaking areas.

The NRC staff recognizes safety improvements that could be achieved by implementing plant mitigating strategies and the importance of updating PRA models to reflect the as-built, as-operated conditions. The incorporation of those mitigating strategies in PRA models should be performed in a technically sound manner by using acceptable methods and data. This assessment clarifies the staff positions pertaining to elements of NEI 16-06 guidance that were found to lack sufficient technical justification. By clarifying these positions, the staff attempts to improve the consistency of reviewing risk-informed applications that take quantitative credit for mitigating strategies and portable equipment using PRA models that should meet the guidance of RG 1.200. The NRC staff based its conclusions on information available at this time. Over time, industry will gain more experience in implementing mitigating strategies and incorporating those strategies in PRA models. The NRC staff will also gain more experience in reviewing risk-informed applications that incorporate mitigating strategies. With this gained experience, NRC staff conclusions on NEI 16-06 may evolve and change. NRC staff will communicate any such changes.

2. ASSESSMENT OF NEI 16-06 TIER 3 APPROACH

The approach in NEI 16-06, Section 7, "Modeling Mitigating Strategies Equipment in a PRA" evaluates modeling of mitigating strategies and portable equipment in accordance with the American Society of Mechanical Engineers (ASME)/ the American Nuclear Society (ANS) PRA Standard. The staff agrees that, for most of the technical elements in the ASME/ANS PRA Standard, the discussion provided in NEI 16-06 identifies unique aspects of modeling mitigating strategies. However, the staff concludes that issues should be considered and addressed in the following four areas: scope, PRA upgrade, data analysis, and human reliability analysis.

2.1 SCOPE

NEI 16-06, Section 3, "Applicability of Guidance," identifies types of equipment (onsite portable, offsite portable, etc.) that may be used to support mitigating strategies. Section 3 states that the guidance in NEI 16-06 is applicable to those identified types of equipment to be credited in various plant mitigating strategies. Discussions in Section 7 and examples in the appendices do not provide enough detail regarding some aspects of crediting offsite portable equipment (e.g., equipment stored at SAFER response centers). For instance, considering the existing gaps in human reliability analysis (HRA) methodology for evaluating the onsite portable equipment, it is not clear to the staff how human error probabilities (HEPs) related to offsite portable equipment will be evaluated. Because of significant uncertainties in human error probabilities and lack of operating experience associated with deployment and operation of offsite portable equipment and in the absence of comprehensive human reliability analysis methodologies and guidance, the NRC staff makes the following conclusion:

> CONCLUSION 1: NEI 16-06 has not provided accepted human reliability analysis methods for inclusion of offsite portable equipment to take quantitative risk credits in risk-informed applications that should meet the guidance of RG 1.200; therefore, claiming quantitative credits for offsite equipment is not appropriate until evaluations consistent with the guidance of RG 1.200 or improvements in the NEI guidance or state-of-art methods address the technical gaps.

2.2 PRA UPGRADE

The NEI 16-06 guidance states in Section 7:

> *It is anticipated that incorporating plant procedure changes and modifications associated with the use of additional portable equipment, when performed in a manner consistent with the base PRA model, represents PRA maintenance activities, and will not generally fall into the PRA upgrade category as defined in the ASME/ANS PRA Standard. Since representation of the portable equipment and associated actions can often be handled through the direct use or extension of existing methods, a focused scope peer review should not be warranted unless the incorporation of these changes results in significant changes "that impact the significant accident sequences or the significant accident progression sequences" per the ASME/ANS PRA Standard.*

The ASME/ANS PRA Standard defines PRA upgrade as, "the incorporation into a PRA model of a new methodology or significant changes in scope or capability that impact the significant accident sequences or the significant accident progression sequences." Although including mitigating strategies and portable equipment in base PRA models may not generally result in

incorporation of new methodologies at this time, some changes, such as incorporating DC load shedding, may affect significant accident sequences. Therefore, depending on the strategies incorporated and the how the PRA scope is affected, the changes in PRA could include extensive model structure/logic changes. These changes fall into the spirit of changes in capabilities that impact significant accident sequences or the significant accident progression sequences. In addition, a number of existing gaps, especially items related to human reliability analysis, may be addressed through complex changes or new methodologies in the future and merit suitable scrutiny. Therefore, the staff does not agree with the NEI 16-06 assertion that the use of additional portable equipment in base PRA models will not generally fall into the PRA upgrade category.

> CONCLUSION 2: For any new risk-informed application that has incorporated mitigating strategies and should meet the guidance of RG 1.200, the licensee should either perform a focused-scope peer review of the PRA model or demonstrate that none of the following criteria is satisfied: (1) use of new methodology, (2) change in scope that impacts the significant accident sequences or the significant accident progression sequences, (3) change in capability that impacts the significant accident sequences or the significant accident progression sequences.

> CONCLUSION 3: Licensees may incorporate mitigating strategies in PRA models after the issuance of amendments for applications that use PRA models to exercise self-approval for a plant change. For such applications, the licensee should, in addition to conforming with specific license condition(s) associated with those applications, either perform a focused scope peer review and resolve the focused scope peer-review findings before using the new models to support any risk-informed decision-making or document an evaluation demonstrating that none of the upgrade criteria is satisfied. NRC will monitor those evaluations and their documentation, along with evaluations and documents related to other items identified in this assessment, through appropriate regulatory processes (e.g., inspections).

The NRC staff can review risk-informed submittals more efficiently if NEI 16-06 provides more detailed guidance, to the extent generically applicable, to help in making a distinction between PRA upgrade and PRA maintenance when mitigating strategies are incorporated in PRA models.

2.3 DATA ANALYSIS

The NEI 16-06 guidance in Section 7.6, “Data Analysis,” states:

> *Until sufficient industry data is compiled to estimate generic industry failure rates for the portable equipment in use at nuclear power plants, each site including portable equipment in their PRA models will have to use engineering judgements regarding the failure rates. [EPRI 3002003151] report compared failure rates of portable military equipment to that of permanently-installed nuclear equipment. This report found that portable military failure rates were higher than corresponding permanently-installed equipment failure rates assessed, but in all cases, they were less than 10 times the permanently-installed equipment failure rates.*

The document further identified the following techniques for providing initial failure rates for portable equipment until enough industry- and plant-specific experience is available to calculate failure rates:

1. Assume a bounding failure rate based on a multiple (e.g., 2 to 10 times) of the failure rate of similar permanently installed equipment based on engineering judgement.

    a. Instead of using a multiple on the permanently installed equipment failure rates, address potential increases in the failure rates by crediting spare portable equipment not modeled in the PRA, when sufficient time is available for deployment.

2. Assume an equivalent failure rate as that of similar permanently installed plant equipment and perform sensitivity studies to determine the impact of that assumption on the PRA results.

In Section C.6 and for the presented example, the NEI 16-06 guidance states:

> *Without sufficient plant-specific or generic industry failure rates for the portable equipment, in this example, the failure rates for permanently-installed equipment were used, and a sensitivity study performed to increase those failure rates by a factor of 10 to determine if the PRA results are sensitive to that assumption. Once the generic industry failure rates are available, the probabilities of failure will be updated as part of the normal PRA update process.*

Industry initiatives to collect and share operating experience of mitigating strategies equipment expeditiously using approaches that are already in place for other components in PRA models provide licensees an option to use failure rates that are acceptable to the staff. The following summary describes the staff conclusions regarding the proposed techniques in NEI 16-06 related to data analysis.

ASME/ANS PRA Standard Capability Category II (CC-II) for supporting requirement (SR) DA-D1 states that realistic parameter estimates for significant basic events should be calculated "based on relevant generic and plant-specific evidence unless it is justified that there are adequate plant-specific data to characterize the parameter value and its uncertainty". Parameter estimates for the remaining events should be calculated by using generic industry data. Supporting Requirement DA-D2 states that "if neither plant-specific data nor generic parameter estimates are available for the parameter associated with a specific basic event, USE data or estimates for the most similar equipment available, adjusting if necessary to account for differences. Alternatively, USE expert judgment and document the rationale behind the choice of parameter values." The example provided in Appendix C does not provide a rationale for the choice of parameter values. Therefore, to ensure the parameter values are justified, the NRC staff makes the following conclusion:

> CONCLUSION 4: The use of expert judgment consistent with the ASME/ANS PRA Standard as endorsed by RG 1.200 is acceptable for estimating parameter values under certain conditions and the rationale for estimated values should be documented. In reviewing future risk-informed applications, the staff may request additional information to understand the rationale for parameter values. Using the appropriate regulatory processes, the NRC will review the rationale for parameter values added to PRA models after issuance of applications that use PRA models to exercise self-approval for a plant change.

CONLCUSION 5: The NRC staff does not agree with crediting spare portable equipment not modeled in the PRA in lieu of using appropriate failure rates because this approach is not consistent with the ASME/ANS PRA Standard and RG 1.200. Furthermore, the potential impact of underestimating failure rates could be larger than the unquantified risk benefits of spare equipment not modeled in PRAs.

Sensitivity analyses are typically performed for those structures, systems, and components (SSCs) that are directly affected by proposed changes in a submittal. Once reliability data are included in base PRA models, the licensees generally do not provide sensitivity analyses nor does the staff require them when a requested change is not related to those SSCs. Furthermore, inclusion of that reliability data in the base PRA models would imply to some degree that the proposed reliability data is technically justified. However, not only is the similarity between the failure rates of the permanently installed and portable equipment not justified in NEI 16-06, the limited information available indicate a potential significant difference.

CONLCUSION 6: The failure rates of permanently installed equipment cannot be used for portable equipment even if sensitivity analyses are performed. Licensees should use plant-specific of generic data collected and analyzed using acceptable approaches to estimate the failure rates for portable equipment.

Supporting Requirement DA-D8 states that "if modifications to plant design of operating practice lead to a condition where past data are no longer representative of current performance, LIMIT the use of old data". The supporting requirement further states that "If the modification is unique to the extent that generic parameter estimates are not available and only limited experience is available following the change, then ANALYZE the impact of the change and assess the hypothetical effect on the historical data to determine to what extent the data can be used". As some reliability data seem to fall in the category described by the supporting requirement, the staff concludes that:

CONLCUSION 7: NEI 16-06 and risk-informed applications should address whether and how the analysis described in Supporting Requirement DA-D8 is performed.

Supporting Requirement DA-D3 requires providing "a mean value of and a statistical representation of the uncertainty intervals for, the parameter estimates of significant basic events. Acceptable systematic methods include Bayesian updating, frequentist method, or expert judgment." NEI 16-06 does not discuss how this uncertainty is considered.

CONCLUSION 8: The uncertainty associated with failure rates of portable equipment should be considered in the PRA models consistent with the ASME/ANS PRA Standard as endorsed by RG 1.200. Risk-informed applications should address whether and how these uncertainties are evaluated.

3. The NEI 16-06 guidance states that Section 2.5 in PWROG-14003, "Implementation of FLEX Equipment in Plant-Specific PRA Models," presents an approach for assessing the probability of failure of portable equipment.

CONCLUSION 9: The NRC staff does not have access to and has not reviewed PWROG-14003. At this time, the NRC staff treats approaches proposed by that PWROG document as unreviewed methods.

4. The NEI 16-06 guidance states that common cause data may not be available initially, and the generic common cause factors in NUREG/CR-5496, “Evaluation of Loss of Offsite Power Events at Nuclear Power Plants, 1980 – 1996”, or WCAP-16672, “Common Cause Failure Parameter Estimates for the PWROG,” can be used until such data becomes available.

   CONLCUSION 10: Without any additional data or evaluations, the currently available common cause failure (CCF) parameter values should be used which should appropriately reflect the higher CCF failure rates of the portable equipment when applied to the higher independent failure rates.

The staff recommends that organizations such as the Institute of Nuclear Power Operations (INPO), the Electric Power Research Institute (EPRI), and NRC’s Office of Nuclear Regulatory Research (RES) collect and share operating experience data of portable equipment to improve the technical basis for relevant reliability data.

2.4 HUMAN RELIABILITY ANALYSIS

NEI 16-06, Section 7.5 describes that the current human reliability analysis methods are largely based on observed behavior that does not necessarily translate directly to some human actions required for implementing mitigating strategies. The document states that in some cases, “engineering judgement will be required to estimate human error probabilities until new guidance on these issues is developed. In these cases, a sensitivity study should be performed to evaluate the impact of these estimates on the PRA results.” Furthermore, the document states that “until gaps in the current HRA methodology are addressed in future guidance, the best approach is to determine either equivalent failure probabilities that are currently addressed by the HRA methodology that can be used as surrogates for specific actions or use engineering judgement to estimate the failure probability.” Some examples of the actions that are not explicitly addressed include: making decisions to enter a procedure using judgement based on a belief in a future event (e.g., the expectation that offsite power will not be restored in a certain time frame) and actions to transport and install portable equipment.

NEI 16-06 has implied that current human reliability analysis methods may not be directly applicable to assessment of some human actions required when implementing mitigating strategies. The staff notes that the issues identified in Section 7.5 will be generally resolved by improved guidance that provides a demonstrably conservative assessment of HEPs where gaps exist in human reliability analysis methodologies, along with an adequate variety of examples to show the implementation of that conservative assessment.

Supporting Requirement HR-G1 of the ASME/ANS PRA Standard requires performing detailed analyses for the estimation of HEPs for significant human failure events (HFEs). Further, Supporting Requirement HR-G3 requires evaluation of the impact of the following plant-specific and scenario-specific performance-shaping factors when estimating HEPs:

(a) quality of the operator training or experience (e.g., classroom vs. simulator and frequency)
(b) quality of the written procedures and administrative controls
(c) availability of instrumentation needed to take corrective actions
(d) degree of clarity of cues/indications
(e) human-machine interface

(f) time available and time required to complete the response
(g) complexity of the required response
(h) environment under which the operator is working (e.g., lighting, heat, radiation)
(i) accessibility of the equipment requiring manipulation
(j) necessity, adequacy, and availability of special tools, parts, clothing, etc.

Finally, when assessing the degree of dependence for multiple human actions in the same accident sequence or cut set, Supporting Requirement HR-G7 requires accounting for the influence of success or failure in preceding human actions and system performance on the human event under consideration. Influencing factors include time required to complete all actions in relation to the time available to perform the actions, factors that could lead to dependence (e.g., common instrumentation, common procedures, and increased stress) and availability of resources (e.g., personnel).

The following summary describes the staff conclusions regarding the discussions in NEI 16-06 related to human reliability analysis. The staff notes that the issues identified in Section 7.5 will be generally resolved by an improved guidance that provides a demonstrably conservative assessment of HEPs where gaps exist in human reliability analysis methodologies, along with an adequate variety of examples to show the implementation of that conservative assessment.

The NEI guidance in Section 7 and examples provided in Appendices C and D do not provide enough details on how using engineering judgment or surrogates considers the plant-specific and scenario-specific performance-shaping factors identified in Supporting Requirements HR-G3 and HR-G7, considering the existing gaps in human reliability analysis methodologies. In Section 7.5, the document states, "if there is no appropriate table or item available in the HRA Calculator tool, the analyst can choose a particular table and item that gives the probability of failure determined to be appropriate for the action based on engineering judgement." For Action 5 (deploy and install FLEX generator), Section C.5 states that in the absence of an external event that could require additional steps such as debris removal, for this example, the probability of failure to transport and stage the portable generator is judged to be about 10^{-3}. Therefore, in the EPRI HRA Calculator, Table 20-13, "Locally Operated Valves," is chosen and Item 1 is picked to give a probability of failure of 1.3×10^{-3}. No basis is provided to justify the estimated value of 10^{-3} or to show that the HEP of deploying and installing a generator is similar to the HEP of operating a valve locally.

Examples provided in Appendices C and D focus on adding the FLEX mitigating strategies to the Internal Events PRA. They take significant credit for recovery actions and in many cases assume zero or low dependencies without enough justifications. The NRC staff notes that the human reliability analysis would be significantly impacted by environmental conditions (for example, station blackout conditions following seismic events, hurricanes, etc.). Section 7 and the appendices do not describe approaches or provide examples for addressing those environmental conditions.

<u>CONCLUSION 11:</u> The staff finds that using surrogates for specific actions or engineering judgement to estimate the failure probability do not adequately address the elements needed for a technically acceptable human reliability analysis described in the ASME/ANS PRA Standard (e.g., the impact of the environment under which the operators work). Until gaps in the human reliability analysis methodologies are addressed by improved industry guidance, HEPs associated with actions for which the existing approaches are not explicitly applicable, such as actions described in Sections 7.5.4 and 7.5.5 of NEI 16-06, along with assumptions and assessments, should be submitted to NRC for review.

Section 7.5.3, “Options for Addressing the Use of Judgement,” states that when a procedure is ambiguous, engineering judgement must be used to provide a basis for the probability of failure to initiate mitigating strategies given the subjective nature of the decision point. This Section states that sensitivity studies can be performed during quantification to assess the impact of assumptions on probability of failure to initiate mitigating strategies. Examples provided in Appendix D do not include such sensitivity analyses.

> CONCLUSION 12: If procedures for initiating mitigating strategies are not explicit and the associated failure probabilities are not directly analyzed by accepted approaches, technical bases for probability of failure to initiate mitigating strategies should be submitted to NRC for review.

Section 7.5 states that the maintenance procedures for the portable equipment should be reviewed for possible pre-initiator human failures that renders the equipment unavailable during an event. HLR-HR-D in the ASME/ANS PRA Standard describes the requirement assessing probabilities of the pre-initiator human failure events using a systematic process that addresses the plant-specific and activity-specific influences on human performance. The examples provided in NEI 16-06 do not include any discussion related to consideration of pre-initiator human failure events.

> CONCLUSION 13: Until acceptable guidance is provided for identifying and assessing unique aspects of pre-initiator human failure events for mitigating strategies, the staff may request additional information regarding assessment of those human failure events.

Improved industry guidance that adequately addresses elements of a technically acceptable HRA using conservative assessments will strengthen technical bases for human error probabilities associated with some actions considered in mitigating strategies and will improve the efficiency of reviewing risk-informed submittal.