Binned Comment ID	NRR Commenter Designation	Original Comment ID	Comment	Similar Comments
2	BG	APHB-1	Qualitative - Section 5.1 – The final bullet frames the statement as if this is a “yes/no” question. I agree that this is an important perspective to include, however, I recommend clarifying that the match of the validation to actual circumstances is important. In other words, the quality of the validation/demonstration is important and should not be minimized. I recommend rephrasing that bullet: “Consideration of the realism of circumstances under which deployment and installation of equipment has been demonstrated and/or validated”	
3	BG	APHB-2	Qualitative - Section 6.1 – What is the basis for the 90 day limit on unavailability of equipment? It seems like this is a long time to leave equipment unavailable with compensatory actions in its place. (This may be explained in NEI 12-06).	
4	BG	APHB-3	Qualitative – Section 6.2 – Commercial grade equipment often uses dubious science in order to make marketing claims. Are manufacturer testing and reliability information sources appropriate for environmental circumstances expected to occur in BDB events? Is there a process to consider the quality of such information to separate actual test information from potentially unsubstantiated marketing claims?	
5	BG	APHB-4	Qualitative – Section 7. – The System Time Window graphic is useful, however it is somewhat oversimplified (focused on actions). For instance, a node could be added between Initiating Event and Begin Deployment called “Make Decision to Deploy FLEX.” Significant delays in making this decision will reduce the time available to prepare for deployment. This consideration may be important to EOPs/SAMGs etc. Similarly, the roll of environmental factors is not considered here but it will likely affect the placement of many nodes on this timeline (environment is considered elsewhere in the document). I recommend putting a pointer in to that section so it does not appear to be left out.	
6	BG	APHB-5	Qualitative – Section 7. – The final paragraph describes performance shaping factors which should be included in site specific documentation. These factors have the potential to significantly affect task success. The NRC will likely have significant interest in the level of detail considered with regards to these factors. Additional information (in this document, or perhaps in another referenced document) may be necessary than what is provided here (i.e. sample analyses or specific criteria).	
7	BG	APHB-6	Qualitative – Section 8.1 – This section is focused on operators. Is there guidance being provided regarding the training of non-operators who may be used for FLEX actions? Some plants have suggested using security forces to supplement operators. Would security forces fall under this training guidance or only the operators? What training is necessary for non-operators?	
8		RES-1	The staff thinks it is appropriate to credit FLEX equipment in PRA because it gives the operators unconventional capabilities to mitigate an accident that they did not previously have, especially considering the mitigation of an extended loss of ac power (ELAP) and a loss of ultimate heat sink (LUHS) event. But there are a number of technical issues requiring more investigation and understanding to credit FLEX in PRA.	
8		RES-2	There are knowledge gaps that need to be addressed before crediting FLEX in PRA	
9		RES-3	The two NEI white papers cover the issues at a high level but do not provide guidance with sufficient detail and coverage for quality implementation.	

10		RES-4a	Reconcile with current PRA assumptions: There is a long list of initial conditions and assumptions, initially considered in WASH-1400 and some were reconsidered in NUREG-1150, applied to PRA models. For example, initial conditions assumed in the model include: a. The components are capable of performing their intended function in the operating conditions associated with the accidents they are intended to mitigate. b. The components are installed nuclear grade components; qualified, tested and maintained at a minimum requirement that ensures operability in the environment (both internal and external) they are intended to function. c. The equipment has been operated and tested sufficiently to ensure it is no longer in the infant mortality region, and is assumed to be in the constant failure rate region. d. Automatic features function as designed. e. Appropriate cues are provided to the operators in the control room. Would crediting the FLEX equipment invalidate the initial conditions and assumptions of the PRA model? FLEX equipment does not meet most of the above PRA assumptions.	
11		RES-4b	In addition, staging the FLEX equipment violates the PRA initial assumption that the equipment is in a protected environment when the beyond design basis accident occurs. This change leads to a technical item of assessing FLEX reliability – including component reliability and human reliability. These two items are discussed later.	
12		RES-5	Satisfy PRA success criteria FLEX was initiated as a means to mitigate beyond design basis (BDD) accidents. From a PRA perspective, we have not studied these beyond design basis accidents to the degree to have good confidence to model the BDD event in PRA. FLEX was initiated as a means to mitigate beyond design basis accidents. Until we do and better understand and define the beyond design basis accidents the staff cannot assure that we know exactly what it is that we are modeling. Using FLEX to obtain credit in the PRA model may be appropriate and advantageous, however, the staff do not believe we have a sufficient understanding at this time to do so	
13		RES-6	FLEX will be used when specified installed equipment will no longer perform their intended function. That indicates that the installed equipment is either no longer operational or is assumed to be non-operational. If that is the case, then the accident scenario (event tree in the PRA) will need to be modified to fail this equipment, since for the purpose of the PRA, the failed components will be assumed to be permanently failed. Using FLEX is not the same as a typical recovery. So how do we model this? If we treat it as a recovery, we may need to change the accident sequence. The following are two examples: - In an ELAP event, the off-site power and the EDGs are no longer functional. In the standard PRA model, failure of off-site power and the EDGs typically leads to core damage. Taking credit for FLEX to prevent core damage in an ELAP requires a change of the PRA event sequence. - Shedding the dc load disables certain components and plant functions. The effects are not modeled in current PRAs. Revisions to the PRA models may be needed.	

14		RES-7	Assess component reliability The component reliability in PRA is under a number of conditions, such as: - The components are installed nuclear grade components; qualified, tested and maintained at a minimum requirement that ensures operability in the environment (both internal and external) they are intended to function. - The components are capable of performing their intended function in the operating conditions associated with the accidents they are intended to mitigate. - The equipment has been operated and tested sufficiently to ensure it is no longer in the infant mortality region, and is assumed to be in the constant failure rate region. The NEI white paper uses the factor Equipment Availability to cover equipment availability and equipment reliability. It uses two unavailability/failure probabilities: · If N set of equipment is available, P = 0.1 · If N+1 set of equipment is available, P = 0.01 The white papers do not provide technical justification for the above simplified equipment availability and reliability model.	
15		RES-8	The FLEX strategies are expected to be the last resort of options to be used to prevent core damage. In PRA, the plant must be brought to a safe and stable state to prevent core damage. The requirements for bringing the plant to a safe and stable state must be considered to assess FLEX equipment reliability.	
16		RES-9	Inadequate feasibility analysis The papers discuss feasibility assessment but do not use formal criteria (or the complete set of criteria) such as the fire HRA guidelines (NUREG-1921), or its originating document NUREG-1852. The feasibility considerations discussed in the two white papers are inadequate compared to the NUREG-1921 and NUREG-1852 guidance.	
17		RES-10	Qualitative analysis is very important in that it provides information for quantitative analysis, i.e., calculation of human error probabilities (HEPs) and uncertainty. A good qualitative analysis should include the following three aspects: • Scenario: e.g., the initial condition, initiating event, and boundary conditions or assumptions, scenario progression, and task flow (what needs to be done and their sequences). With the information presented in an event timeline, it would improve transparency and facilitate understanding and communication. • Staffing: each FLEX strategy typically requires a few people to perform. Staffing may be a limiting factor for task performance. Staffing analysis is required to provide assurance of sufficient manpower and skill-sets to perform the tasks. • Task: information such as “is it a time critical task?”, “Are there system operation related factors that could become limiting factors for performing the task”, etc., and a brief description of how the task is performed help to understand the task. The above information provides a basis to understand the context of performing the tasks to calculate human error probabilities (HEPs). The two papers do not provide guidance on qualitative analysis.	

5		RES-11	Missing Diagnosis element in quantitative analysis There are two sub-items in this item. They are related. The cognitive failure (i.e., failure to understand the condition to decide to implement the FLEX strategy in time) is not discussed in the white papers. HEP = HEP(cognition) + HEP (execution) is a common practice to calculate an HEP. The quantitative white paper only calculates the HEP(execution). The quantitative white paper references NUREG-1921 in the time margin discussion. But the white paper omits the cognition time in the NUREG-1921's time window (Figure 1). The NEI white paper timeline is shown in figure 2. Missing the Tcog has two effects: • Missing HEP(cognition) • The Tcog should be, but was not, included in the Time Margin equation. Equation 1 shows the time margin equation in NUREG-1921. Equation 1 Time Margin (TM)= (T_avail - T_reqd)/T_reqd × 100% =[(T_SW- T_delay)- (T_cog + T_exe)]/((T_cog+ T_exe)) ×100%	
6		RES-12	Coverage of performance influencing factors The white paper's HEP decision tree uses the following three factors to adjust HEPs: time margin command and control environmental factors Other important factors such as workload and task complexity do not seems to be included. A well-documented example is bringing power back using off-site power. In an extended loss of ac power (ELAP) event, operators install a portable diesel generator to power the battery chargers in the situations that the operators have disabled other components (shed the dc load to prolong battery operation). Management of the disabled components and shed loads implies that bringing normal AC power back via off-site power or the EDGs can be challenging. This human performance challenge does not appear to be considered in the white paper. Using a single factor of "Command and Control" to cover all human performance influencing factors (PIFs) except the environmental effects and time constraint does not provide sufficient instruction to evaluate a broad range of factors that may be important to human performance.	
18		RES-13	Assessing performance influencing factors' status The white papers discuss procedures and training but do not make commitments to EOP-like procedure development or realistic training (i.e., NOT just classroom training). Both the NFPA-805 fire HRA/PRAs and Level 2 HRA/PRA have revealed that these are very important with respect to making realistic predictions on what operators will do & how long it will take when procedures are under-specified and training is not realistic.	
6		RES-14	Technical basis of HEP adjusting factors The white papers' decision tree to calculate failure probability discussed the branches and their HEP multipliers but does not provide technical justification for the values of the HEP multipliers.	

1		RES-15	Technical basis for the base failure probability of 0.1 The white paper's HEP decision tree starts with a base failure probability of 0.1. The base failure probability should be associated with a base condition, i.e., the condition and task that a failure probability of 0.1 is expected. The white paper does not discuss the base condition (situation or event, etc.) for the base failure probability.	
19		RES-16	Application scope Reference [1] states that there are the following four types of equipment for mitigation strategies: Permanently Installed Plant Equipment On-site Portable Equipment Permanently Staged Equipment Off-site Portable Equipment In chapter 4 of [1], it states "These mitigating strategies utilize on-site permanent equipment, pre or permanently staged equipment, and portable equipment." The equipment in each bullet has its unique factors affecting deployment reliability. The white paper states that, "This guidance provides a suitable approach in crediting the use of equipment associated with various plant's mitigating strategies in risk informed decision making. The focus of this guidance is around FLEX and provides examples based on those strategies." Please clarify which groups of equipment are within the scope of these two white papers including the HEP decision tree applicability to these four groups of equipment.	
9	MRF	APLA-1	Generally, a new proposed methodology such as the incorporation of FLEX equipment (that must be brought in from staging areas) into the PRA, is best accomplished through the submittal of Topical Reports. Each Topical should provide details of the specific plants, plant configurations and specific methods, including the population of plants for which (each) Topical is applicable. The methodology would include the interaction between the typically external initiating event and the transportation, alignment, and subsequent operation of the FLEX equipment.	

9	MRF	APLA-2	While the semi-quantitative treatment, with appropriate considerations, could potentially be used for limited scope applications, such as SDPs and NOEDs, the staff finds that additional development and explanation is needed before determining whether the semi-quantitative treatment can be developed to provide a foundation for direct implementation of FLEX capabilities in PRA models that are used to support risk-informed applications for changes to a licensing basis. As discussed in the Background section, the existing NRC guidance provides an acceptable approach to determine the technical adequacy of PRA models compatible with safety implications of the application. Consistent with this guidance, following a change to a PRA model such as integration of FLEX capabilities, the model should be evaluated against all relevant supporting requirements (e.g. human reliability analysis, data analysis, system analysis, accident sequence analysis, etc.) and peer-reviewed if the change in the model qualifies as an upgrade (as is expected to be the case here). Subsequently, the impact of those supporting requirements that do not meet the appropriate CC should be evaluated for the specific application and generally be included in the risk-informed application. The proposed framework in the White paper does not seem to provide a level of detail, plant specify or realism to be suitable for evaluation against ASME PRA Standard as clarified by RG 1.200 and, therefore, the technical adequacy of the model cannot be determined using the existing guidance. Furthermore, the white paper does not provide sufficient information to show that the proposed framework will be technically adequate for a wide range of risk-informed applications for changing a licensing basis. It should be noted that some of those applications require a high-level of rigor for reviewing technical adequacy of both internal and external PRA models. Some elements of the proposed approach (e.g. HRA and data analysis) discussed in later comments do not seem to have been adequately justified for even more limited scope applications.	
1	MRF	APLA-3	The base HEP of 0.1 is not supported by any analyses or data. For risk-informed applications to make changes to the licensing basis, the acceptable guidance requires a human reliability analysis (HRA) to be performed and reviewed consistent with ASME PRA Standard and RG 1.200, if FLEX capabilities are included in the PRA and credited in the analysis. For applications with a limited scope, such as SDPs or NOEDs, using a single base HEP value, use of an arguably conservative value may be sufficient if acceptable to APHB. Although the paper presents one value for base HEP, some scenarios may involve multiple operator actions for successful deployment of FLEX systems. For risk‐informed applications to make changes to a licensing basis, the HRA should appropriately consider those actions and their dependencies.	
20	MRF	APLA-4	Under the discussion of base HEP value, the assumption that other adverse environmental conditions (that were not present in the validation exercise) are random with respect to when the demand could occur may be valid only for internal events. There could be a dependency between occurrence of such environmental conditions and the demand for FLEX capabilities for external events and, therefore, the relationship needs additional evaluation. Most of the risk‐informed applications for making changes to a licensing basis require an evaluation of external events and, if FLEX capabilities are credited for those evaluations, the stated assumption is not valid and explicit modeling is warranted for those scenarios. An HRA that meets the appropriate CC of ASME PRA Standard supporting requirements would ensure that the human failure events are adequately modeled and quantified in a PRA.	
6	MRF	APLA-5	Similar to the previous comment, the description of those time windows seems to apply only for internal events. TTrans, TInstall and TExe from validation studies does not take into account the adverse impact of the conditions on those time windows following an external event. Although under Environmental Factors the nominal value is increased by a factor of two for adverse conditions, that factor may not sufficiently capture the impact of adverse conditions as increase in those time windows because of those adverse conditions may make the actions unfeasible.	

6	MRF	APLA-6	Comment is regarding "command and control" node - PRAs typically assign a range of values to some of the elements identified under this node, such as availability of sufficient cues and indications for the direction of the actions and adequacy of associated procedures to support confidence in successful completion of the manual action, instead of using go/no go criteria. The licensee should either use an acceptable approach or justify that the criteria used to implement the proposed approach is conservative.	
21	MRF	APLA-7	In some regulatory activities such as SDPs or NOEDs, it may be practical to look back or predict the environmental conditions for the next few days. In risk-informed applications for making changes to a licensing basis, where external hazards typically need to be analyzed, the environmental condition cannot be anticipated. As noted earlier, for external events, it is likely that adverse environmental conditions exist for those scenarios that take credit for FLEX capabilities and the PRA model should assume a high dependency between adverse conditions and the demand for FLEX capabilities for those conditions.	
4	MRF	APLA-8	1- White paper does not provide enough justification to support the statements that the “equipment reliability should not be a serious concern” and that those presented values are “conservative”. The current practices in PRA provide generic and plant-specific data for systems and trains in plants. Reliability for FLEX equipment should be based on data obtained from surveillance test of that equipment, and the capability of the surveillance to develop reliability estimates evaluated. This analysis should also appropriately consider and estimate the reliability of those FLEX systems for which the reliability data may not be as readily available as other typical plant systems. It is also unclear whether damage from movable FLEX equipment is included in the equipment unavailability or the HEP. The ASME PRA Standard describes supporting requirements for data analysis elements to provide estimates of the parameters used to determine the probabilities of the basic events representing equipment failures and unavailabilities modeled in the PRA. Where FLEX capabilities are credited in risk-informed applications for changes to a licensing basis, in accordance with the acceptable approach the licensees consider the reliability data consistent with the ASME PRA Standard and RG 1.200. If relevant SRs are not met, the licensee should clearly justify that the data used to support the analysis is conservative for that specific application or has no impact on the application.	
22	MRF	APLA-9	2- The unreliability discussion in the streamlined quantitative approach does not seem to consider the common cause failure (CCF). The ASME PRA Standard describes supporting requirements for systems analysis and data analysis elements as they relate to treatment of CCF. For almost all risk-informed applications for changes to a licensing basis, the NRC staff verifies whether those supporting requirements are met at the appropriate CC.	
23	LM	NRO-1	NRO is supportive of the qualitative approach--which is described in one of the white papers—with some modification, as a potential solution for situations in which actual plant conditions are known at the time of the licensee request. However, in general, details about implementing the credit necessarily vary by the risk-informed decision being made. Since the NEI proposed white papers address only a subset of these risk-informed decisions, the white papers may not be sufficient to make any definitive decisions regarding the viability or usability of the proposed approaches. Awaiting NRC review/endorsement of the full draft NEI guidance with PRA considerations would be more appropriate than endorsement of the draft white papers via ISG.	
9	LM	NRO-2	Neither white paper establishes the extent of applications or context for their approach. Without a clear applicability or context, the merits of the approach cannot be determined. The qualitative approach and semi-quantitative approach may be appropriate solutions for situations in which actual plant conditions are known at the time of the licensee request, but are likely not appropriate for other types of applications where the plant conditions are not completely known when the licensee request is submitted. Each type of application needs to be fully considered (operational conditions/considerations and scope, level of detail, or technical adequacy) prior to determining if either of these approaches are acceptable for that type of application. A clear statement, with supporting rationale, is needed in each white paper of what specific types of applications are considered viable using that approach prior to the NRC being able to determine if the approach has any merit. Some applications might be viable, but need to be evaluated fully.	

24	LM	NRO-3	The relationship/interaction between the two white papers, if any, is not presented. It is not clear if the semi-quantitative evaluation is an enhancement of the qualitative considerations of the other paper or if these two white papers are addressing different aspects (e.g., one is to be used in the context of defense-in-depth and/or safety margins, while the other is to be used in the context of risk calculations) or if they are mutually exclusive. An explanation of the intentions, relationships, and interactions between these two white papers needs to be presented.	
25	LM	NRO-4	Many of the discussions in both white papers seem to leverage the basis for acceptance of the FLEX strategies for their defined regulatory role, which is deterministic in nature, to make conclusions to use in the qualitative or semi-quantitative approaches. For example, in the qualitative approach, it is stated that "[t]he FLEX program considered deployment of equipment for the applicable external hazards … which can be used as a reference to justify the use in a given scenario." This is inferred to mean that there is no need to consider the potential that deployment could fail because it was considered when the program was established. Though such a position might be acceptable in addressing defense-in-depth or safety margins in a qualitative fashion, the approach would not be acceptable for consideration in a risk assessment.	
26	LM	NRO-5	The NEI presentation materials final (Proposed Path Forward) slide refers to "NRC endorsement of white papers via ISG" and the NRC final (Next Steps) slide refers to "Discuss options to incorporate Whitepapers to regulatory processes." As discussed below, there are numerous issues associated with these white papers that need to be addressed before a thorough review can be performed; let alone endorsement. It has been suggested that the NRC address these white papers by incorporating them into the regulatory processes, but no explanation is given for why these white papers should not be addressed in a manner similar to how the NRC addressed the white papers that were developed by the industry Risk-Informed Steering Committee (RISC) working groups. This latter process is more appropriate. To complete the process, including a potential pilot of the approaches for various proposed applications, the industry needs to obtain staff review/feedback on a draft guidance document, finalize the guidance addressing any staff comments, and then obtain ultimate endorsement of the guidance.	
23	LM	NRO-6	NOEDs might be an application where the qualitative approach is likely to be viable. For this type of application, the current condition of the plant is known and FLEX strategies could be considered as part of the associated compensatory actions used to support granting the NOED. The ROP initiating event assessments, in the area of defense-in-depth (consistent with RG 1.174 guidelines), might also be an application where the qualitative approach might be viable since the exact condition of the plant is known (e.g., weather conditions, operational conditions, etc.).	
23	LM	NRO-7	Maintenance Rule (a)(4) assessments might be an application where the qualitative approach may be considered. However, since this aspect of the Maintenance Rule does not require a probabilistic-oriented calculation and reliance on FLEX strategies should not be the sole basis for supporting entry into a maintenance activity.	
23	LM	NRO-8	An application like the significance determination process (SDP) might be an application where the qualitative approach may be proposed for situations that are near a threshold to potentially show additional margin. However, since this is an NRC process, any such considerations for this program that involve qualitative or quantitative credit of the FLEX strategies should be reflected in the NRC RASP manual.	
27	LM	NRO-9	The qualitative approach white paper states in the opening sentence (and title) that its purpose is related to "Mitigating Strategies Equipment." A similar sentence is in the purpose of the semi-quantitative white paper; referring to FLEX. However, throughout the qualitative approach white paper there is reference to "[o]ther equipment" or "other functions" (or similar language) that "may need further evaluation to determine if use is appropriate." This could be interpreted as including equipment that is not currently considered in any of the mitigating strategies for the licensee and constitutes an expansion of the scope of the approach beyond its stated purpose. These references "[o]ther equipment" or "other functions" should be explained.	

28	LM	NRO-10	There does not appear to be a step in the qualitative approach or semi-quantitative approach for assessing the potential for adverse effects from implementation of the strategy. For example, there was no discussion in the example for the qualitative approach of evaluating the potential for steam generator waterhammer. In the example scenario, the steam generator feedwater ring would most certainly become uncovered, given the timeline shown, and possibly drained depending on the plant design. With the feedring and piping filled with steam, cold water introduced at an unnecessarily high flow rate can lead to steam generator water hammer. Other potential adverse effects could arise from system interactions. The potential for system interactions under actual plant operating conditions (not considered in the FLEX validation) should be evaluated prior to implementing a strategy.	
16	LM	NRO-11	The Initial Feasibility Assessment section in the qualitative approach states that the considerations "are not intended to be all-inclusive." However, no guidance or criteria is presented to determine what other considerations need to be addressed. To be able to have confidence that the implementation of the approach will be comprehensive and consistent, either the considerations need to be expanded to be all-inclusive or criteria needs to be presented that licensees can apply in identifying all the considerations that need to be addressed.	
29	LM	NRO-12	The "Scenario Assessment" step in the qualitative approach may sometimes require engineering analysis. A similar concept is in the Equipment Capability Evaluation where it is stated that "[i]f conditions are outside of design parameters, is there any evidence to support use for these conditions?" These type statements seem counter to a qualitative approach and represents an expansion of this approach into a more quantitative approach that is not consistent with its purpose. If retained, there should be some guidance on acceptable analytical tools and analysis methods and level of quality assurance expected for those aspects that expand into quantitative arenas. There was no mention of this in the slides or white paper.	
30	LM	NRO-13	It is stated in the example for the qualitative approach that an extension of 36 hours is needed for repair of the AFW pump and that the mitigating strategy would require refilling the condensate storage tank (CST) since it only holds enough water for about 8 hours of cooling. It does not appear from the description of the example that the considerations in the qualitative approach would be applied to the equipment needed to refill the CST. Such an omission should be corrected or explained.	
23	LM	NRO-14	The technical adequacy and rigor of a semi-quantitative approach should be commensurate with the specific application (e.g., use of subjective inputs in the decision tree, use of appropriate base HEP values, modeling choice of recovery actions adjustment factor, mitigating strategies equipment may not have the same pedigree as SSCs in the base PRA).	
37	BS	RGN1-1a	While the NEI proposal has merit and provides a rational framework for providing FLEX credit, we propose the use of a simpler and more realistic crediting approach.	
31	BS	RGN1-1b	We believe that any FLEX crediting approach, short of full integration into the plant's PRA is only a temporary remedy and full integration of the FLEX strategy into the full scope PRA should be expeditiously pursued.	
4	BS	RGN1-2	The absence of a good database of FLEX equipment reliability information and associated human actions performance data results in wide uncertainty estimates for any risk applications and renders FLEX strategies in conflict with current PRA quality standards as endorsed by RG 1.200.	
32	BS	RGN1-3	we are opposed to the broad application of FLEX credit. Our preference would be to initially limit the application of FLEX credit to the Significance Determination Process (SDP). Only after gaining greater experience, understanding and confidence, would we be inclined to extend its use to other regulatory processes.	
33	BS	RGN1-4	we would recommend that FLEX credit be withheld from use by the licensee or NRC staff until after the Region has completed the site Temporary Instruction (TI)-191 inspection that will verify the adequacy of FLEX equipment and implementing strategies. Withholding use of FLEX credit until completion of a site inspection is consistent with other agency review practices.	

32	BS	RGN1-5	The Region is opposed to the broad application of FLEX credit as outlined under the "Purpose" section of the NEI White Paper. Our preference would be to initially limit the application of FLEX credit to the Significance Determination Process (SDP) and then, only after gaining greater experience, understanding and confidence, would we extend its use to other regulatory processes such as NOEDs or license applications.	
57	BS	RGN1-6a	A FLEX strategy failure probability of 0.1 appears to be an appropriate maximum value, assuming all the attributes contributing to successful strategy implementation are satisfied.	
1	BS	RGN1-6b	Region I does not agree with the NEI White Paper use of 0.1 as an initial base value, with adjustments made using a modified Event Tree that potentially reduce this failure probability.	
4	BS	RGN1-7	Modeling FLEX strategy credit via the proposed NEI Event Tree (Figure 2) is inappropriate and is not consistent with standard Event Tree methodology. The proposed failure probabilities and crediting factors assume an initial FLEX credit of 0.1 with adjustments potentially reducing the failure probability by an approximate order of magnitude (0.01). This approach does not reflect the fact that there is an absence of FLEX portable equipment reliability data and no currently acceptable human performance assessment methodology for modeling operator actions conducted outside the control room. Further, assuming 99 successes out of 100 FLEX implementation attempts does not appear realistic. Lastly, the proposed Event Tree (Figure 2) attempts to integrate all four attributes, but does not follow accepted PRA practice.	
34	BS	RGN1-8	As an alternative, Region I proposes use of 0.1 as the maximum risk credit, with adjustments reflecting the adequacy of procedural guidance and equipment availability. Most importantly, the credit for the FLEX strategy implementation should only be applied to those initiating events and associated dominant sequences where sufficient time (time margin) and environmental (weather) conditions permit. The credit would not be applied broadly as a recovery of all sequences. Although this alternative approach is similar to the NEI White Paper proposal, it more narrowly applies FLEX strategy credit to only those events where FLEX has some probability of success, vice a broad, non-specific recovery credit. More specifically, FLEX credit should only be applied on a cutset by cutset basis, because of the time critical nature of any mitigation actions and the amount of time needed to implement FLEX portable equipment strategies. This alternative approach provides a reasonable order of magnitude risk credit. Lastly, this alternative approach provides an incentive for licensees to develop detailed procedures for integration of FLEX equipment and operator actions into emergency and off-normal operating procedures (with eventual integration into the site specific PRA).	
6	BS	RGN1-9	With respect to the attributes outlined in the NEI White Paper (time margin, environment, command & control and equipment availability) the Region considers these four FLEX elements to have appropriately captured the major considerations for successful FLEX strategy implementation. However, the overall success of any FLEX strategy is highly dependent upon each of these attributes. As a result, the modeling of their independent failure probabilities is inappropriate. More importantly, their dependencies would infer, by NUREG 1792, Sections 4.4.3.5 and 4.4.5.6 standards, a higher overall probability of failure than 0.1 (between 0.1 and 0.5 for high dependence). That is, time margin and environmental conditions are essentially "Go – No Go" attributes. If there is insufficient time to line-up FLEX equipment or weather conditions preclude equipment relocation and placement, the FLEX strategy accident mitigation option has failed, regardless of the number of trains or FLEX equipment available or the adequacy of procedures. Command and Control is highly dependent upon the adequacy of the strategy implementing procedures. Equipment availability is currently governed by a potential 90 day allowed outage time (AOT), with currently undefined compensatory measures. Accordingly, a single train N, can always be assured, but N+1 trains may not always be available. The NEI White Paper suggests 0.01 failure probability for N+1 trains, but this is viewed as overly optimistic, given the current guidance.	

18	BS	RGN1-10	Command and Control – is highly dependent upon the adequacy of procedures and training. Currently NEI 12-06 guidance only addresses implementation of FLEX following a beyond design basis loss of all AC power and consequential ELAP declaration. FLEX implementing strategies are initiated only via this one EOP pathway. To credit FLEX for design basis events or conditions, detailed written procedures should provide event specific guidance. Periodic operator training for familiarization is also important to support the relatively high success probabilities proposed for FLEX strategy implementation. It appears that the absence of step-by-step procedural guidance, would more correctly support a FLEX credit of 0.5, or 50-50 probability of success or less	
6	BS	RGN1-11	Equipment reliability N and N+1 – similar to the Command and Control comments provided above, if only N equipment trains for a particular mitigation strategy are available, a reduction by a factor of 2, or doubling of the risk, would appear to be appropriate (less than the full complement of FLEX systems).	
6	BS	RGN1-12	Time Margin – To properly assess available time margin, a sequence-by-sequence approach must be taken with a digital outcome of either granting credit or not. Either there is sufficient time available to align the FLEX equipment or not. There is no practical means to formulate a risk variable for having time to make FLEX equipment available.	
6	BS	RGN1-13	Environmental conditions – another simple Go or No-Go value appears appropriate. There are no simple means available to predict weather conditions for a particular scenario or to judge the ability of an operator to cope with inclement weather conditions	
35	BS	RGN1-14	Without incorporating the flex capabilities in the base model, the licensee gets to reap the risk reduction benefits, post processing, without having to absorb any of the risk consequences for failed or degraded flex equipment.	
36	BS	RGN1-15	1) From the NEI White Paper – “Once the key contributors are identified, the analysts can look at the FLEX validation studies and related procedural direction to determine what scenarios would benefit from credit for the FLEX mitigation strategies.” This will not improve SDP timeliness or predictability, since each event will have to be manually scrubbed to prescribe the appropriate credit. As above, without the placement of the strategies in the base model, only the benefits will be realized.	
37	BS	RGN1-16	An alternative approach to the NEI proposal for FLEX recovery credit (and to the matrix approach discussed above and summarized in the table below), would be a blended quantitative and qualitative assessment. This blended approach would be applied in a stepwise fashion, only if the initial quantitative analysis (detailed risk evaluation) is at or near a risk threshold (Green/White, White/Yellow, Yellow/Red). Any high White (>5E-6), high Yellow (>5E-5), or high Red (>5E-4) detailed risk evaluation delta CDF estimates would not be candidates for FLEX credit. Assuming the initial detailed risk evaluation (using the current SPAR and/or licensee PRA model) yields a risk significance value that is at or near an SDP risk threshold, then FLEX credit is possible. This initial quantitative assessment would be followed by the confirmation of FLEX strategy readiness (i.e., verification of equipment availability, adequacy of procedural guidance, environmental conditions support deployment, and available time for strategy implementation to prevent core damage). Verification of FLEX readiness ensures that the licensee has properly integrated the FLEX strategies into normal operating and design basis accident mitigation guidance. Lastly, a detailed sequence by sequence evaluation of the quantitative assessment, to confirm FLEX recovery credit is appropriate to the circumstance, is performed. If these three steps are successfully completed, it would then be appropriate to qualitatively lower the initial detailed risk evaluation delta CDF value without necessarily assigning a numerical value to the credit from FLEX. For example, assume an initial DRE value of between 1E-6 and 5E-6 (low White). With appropriately evaluated FLEX credit, this low White issue would be reduced to a Green issue. The report Analysis Section would highlight the initial DRE value, but state that the overall risk of this performance deficiency was further qualitatively reduced due to the availability of FLEX.	
37	BS	RGN1-17	Proposed table in tab "RGN1 Table"	

38	LK	RGN3-1	The licensee should determine that the use of a qualitative risk assessment is acceptable for the specific RIDM process being evaluated (e.g. Shutdown Risk Assessment, Online Risk Management, ~~Significance Determination Process (SDP), and Notice of Enforcement Discretion (NOED))~~ Comment: The SDP and NOED processes are not licensee processes, but rather NRC processes. The NRC will determine appropriate credit and in the case of SDP will perform and independent assessment. SDP and NOED should be removed from this list.	
27	LK	RGN3-2	This guidance uses FLEX as an example case, ~~however equipment of other mitigating strategies is applicable.~~ Comment: What other mitigating strategies? Too vague to agree to this.	
39	LK	RGN3-3	~~This qualitative risk assessment can supplement or be used in lieu of quantitative risk assessment if applicable.~~ Comment: Currently SDP and NOED do not have a provision for using qualitative risk assessment in lieu of quantitative risk assessment? Not clear what is meant by qualitative assessment. This paper, in general, describes a process you need to go through to begin to quantitatively credit mitigating strategies, but it alone doesn't provide information for decision-making.	
27	LK	RGN3-4	The focus of this guidance is around FLEX and provides examples based on those strategies; ~~however, the approaches can be applicable to similar equipment procured by the plant independent of the strategies they were originally designed to support.~~	
40	LK	RGN3-5	Off-site Portable Equipment - Equipment almost identical to the on-site portable equipment but housed remotely at locations such as national response centers or other plant sites. This guidance is directly applicable to this type of equipment but it is recognized that crediting this equipment is likely to only be applicable in scenarios with much longer mission times and ~~may not be readily~~ **is not** creditable in most qualitative assessments.	
15	LK	RGN3-6	We need to establish what is "safe and stable" with FLEX. Is using installed portable equipment and manual operator actions a "safe and stable" endstate. Possibly not consistent with some evaluations that have been done that require restoration of normally functioning equipment to be safe and stable (offsite power, RHR, etc.)	
41	LK	RGN3-7	Section 5 Intial Feasibility Assessment Comment: This needs to be done before any potential application (i.e., up front). Performing such and assessment prior to or during an NOED, SDP, emergent diesel maintenance, etc. will not allow for an adequate review to be performed. Additionally, the NRC will have to perform this review for SDP purposes.	
41, 25	LK	RGN3-8	The initial step is to perform an overall feasibility assessment to determine if a detailed evaluation is warranted. This feasibility assessment performs a high level evaluation of the specific scenarios that credit mitigating strategies equipment, whether the equipment can be used to mitigate a loss of function given the conditions of the scenario, and whether the specific equipment has the capability to perform the function. The considerations in this section are not intended to be all-inclusive. Comment: The assessments described here are very good and necessary in order to evaluated FLEX for internal events, fire, which are the likely risk contributors but there are others. These assessments will be time consuming as they were not performed for compliance with the Order..	
42	LK	RGN3-9	Determine which functions are desired to be credited in the qualitative assessment. For example, scenarios with the following functions may be mitigated using FLEX equipment: • Restoration of RCS inventory and reactivity control Comment: Clarify what is meant by reactivity control in this context	

42	LK	RGN3-10	Determine which functions are desired to be credited in the qualitative assessment. For example, scenarios with the following functions may be mitigated using FLEX equipment: • Maintenance of containment function Comment: Clarify which containment functions – isolation, cooling, venting for DHR?	
27	LK	RGN3-11	~~For scenarios associated with mitigation of the above functions, the qualitative assessment can reference details of the FLEX program appropriately to credit the mitigating strategy equipment in RIDM. Other functions may need further evaluation to determine if use is appropriate.~~	
25	LK	RGN3-12	~~Plants developed the FLEX equipment and documented performance capability in accordance with NEI 12-06 Sections 11.2 and 11.3. For this qualitative assessment, the specific capability should be documented or referenced from the site's program documents . Other equipment may need further evaluation to determine if use is appropriate.~~ Comment: FLEX performance capability was evaluated and documented for a specific set of assumptions outlined in NEI-12-06 which will not be applicable to the scenarios for which credit is desired. The whole purpose of the qualitative assessment should be to determine whether FLEX is capable, reliable, will be used, etc. under other conditions different from the NEI 12-06 guidance.	
4, 43	LK	RGN3-13	~~The existing requirements of the FLEX program should be referenced for FLEX equipment being credited . Other equipment and connections may need further evaluation to determine an acceptable level of availability.~~ Comment: What is needed is a value of the unavailability of the equipment similar to all other equipment modeled in the PRA? Will the monitoring program provide that information?	
4	LK	RGN3-14	A discussion of the relevant reliability information of the equipment should be evaluated and discussed in the qualitative assessment. Comment: We need to develop reliability estimates for portable equipment and for installed equipment being used well outside its' design basis (i.e., RCIC reliability at elevated suppression pool temperatures). Existing reliability can't be directly applied.	
27	LK	RGN3-15	NEI 12-06 requires key FLEX equipment to be subject to maintenance and testing guidance provided in INPO AP 913, "Equipment Reliability Process," and EPRI 3002000623, "Nuclear Maintenance Applications Center: Preventive Maintenance Basis for FLEX Equipment - Project Overview Report," to verify proper function. ~~The FLEX program established for each site can be used as a reference for reliability of the equipment. Other equipment may need further evaluation to determine an acceptable level of reliability.~~	
44	LK	RGN3-16	The location and storage of equipment must be considered including the deployment capabilities. Support equipment (e.g. for hauling or debris removal) should be available after the event, if required. Pre-deployment or pre-staging may be credited to ensure equipment is at the proper location to meet the time line established for the scenario. The FLEX program considered deployment of equipment for the applicable evaluated external hazards (seismic, flooding, wind, cold and hot temperatures) which can be used as a reference to justify the use in a given scenario. Other equipment may need further evaluation to determine deployment requirements. Comment: This is unlikely to be an issue for crediting in internal events and fire which will be the main scenarios of interest.	

6	LK	RGN3-17	Time Availability and Margin Comment: Time seems to be the most relevant factor to industry in determining operator reliability. Other PSFs such as complexity, frequency of training for the specific scenario, quality of procedures, context specific experience need to be considered and are arguably more important performance drivers.	
45	LK	RGN3-18	The availability of time margin to complete necessary actions is an important consideration in the qualitative risk assessment of the mitigating strategies equipment. To support this effort, a timeline of the necessary actions should be constructed, and adequate time margin should be demonstrated to provide confidence in meeting the success criteria. Comment: There should be a discussion of what triggers the declaration of ELAP, which is the only entry into FLEX. It is not at all clear that any other procedure or cue will trigger FLEX.	
46	LK	RGN3-19	Time to Deploy – This is the duration of time needed to fully deploy the equipment so it is ready to be installed. This includes the time associated with getting the equipment out of the storage location, clearing any debris from the route, and transporting the equipment to the appropriate location. Actions for pre-deployment may be considered to adjust the timeline. Comment: Pre-deployment may help with maintenance risk assessment or NOED but should be excluded for SDP, as conditions were not previously known and equipment was not pre-deployed.	
2	LK	RGN3-20	The site specific validation documentation should be used as a reference for time considerations if applicable for crediting FLEX equipment. Other mitigating strategies or new scenarios not previously assessed may need further evaluation to determine adequate time margin. Comment: The time validation was a specific study under ideal conditions for the event as defined in NE 12-06. It is not likely directly applicable to other scenarios.	
18	LK	RGN3-21	For portable equipment it is recognized that not all instructions will be contained within plant procedures, however other written instructions may be implemented to deliver the same level of clarity. Though not explicitly called procedures, these instructions should be reviewed, evaluated and credited based on their clarity and effectiveness. Comment: I don't think we should crediting mitigating strategies that don't have procedures.	
18	LK	RGN3-22	FSGs were developed during implementation of the FLEX program. In general, the command and control was retained within the EOPs. The EOPs direct the implementation of the FSGs to complete steps required for the mitigating function associated with the specific conditions that necessitated entry into the FSGs. The site specific development and procedural structure can be referenced and reviewed to ensure the operating staff has sufficient information to implement the strategy being credited. **Written procedure guidance must be available and adequate in the context FLEX is being credited**.~~Additionally, operation placards developed for FLEX equipment and standardized in the industry were installed to ensure adequate instruction is available for operation of the portable equipment and can be referenced in the assessment. Written instructions for other equipment or mitigating strategies may need further evaluation to determine adequacy.~~	
18	LK	RGN3-23	Initial training has been provided and continued training has been established for appropriate site personnel on BDB response strategies and implementing guidelines . Comment: We should establish what the continuing training is and how frequently it is conducted. In most cases, I've see very limited continued training for these types of strategies.	

46	LK	RGN3-24	The availability of the staffing required to implement the mitigating strategies equipment needs to be evaluated given the specific scenario being assessed. Sites with multiple units should consider whether the scenario affects all units. Pre-deployment of equipment or additional staffing (e.g. staffing during an outage) ~~should be considered~~ **can be considered for maintenance risk assessments.**	
6, 39	LK	RGN3-25	The nuclear industry has added additional equipment in support of regulations and orders following events on September 11, 2001 and Fukushima accident in March 2011. Equipment was procured and strategies were developed ~~as an additional layer of defense in depth~~ to add flexibility and diversity to permanent station equipment. Considerations of availability and reliability, adequate time margin to implement, clear/effective command and control, **complexity of operator actions, procedural adequacy, context-specific training** and environmental factors were taken into account when these strategies were developed for specific scenarios. These same considerations can ~~be credited or~~ further established for additional scenarios and applications. ~~A qualitative risk assessment that properly evaluates these considerations can demonstrate that these mitigating strategies and associated equipment can be used to further improve safety margin in a variety of scenarios.~~	
47	LK	RGN3-26	Streamlined Approach for ~~Crediting~~ **Modeling** FLEX in Risk-Informed Decision Making	
13	LK	RGN3-27	As part of the FLEX in Risk-Informed Decision Making (FRIDM) Task Force established by NEI, the objective of this white paper is to develop a streamlined quantitative approach for crediting FLEX in risk-informed decision making activities via use of a decision tree for post quantification techniques to better reflect the actual plant condition or configuration. This is one of several activities that the FRIDM Task Force is developing to establish an effective path forward for considering ~~the benefits of~~ FLEX equipment and strategies in risk-informed regulations, applications, and plant PRA models. ~~without imposing any undue regulatory burden.~~	
38	LK	RGN3-28	The purpose of this white paper is to establish a streamlined approach for crediting FLEX in regulatory activities (e.g., ~~SDPs,~~ NOEDs, Recommendation 2.1 SPRAs, etc.). ~~Currently there is no accepted consensus guidance for getting such credit. Activities are underway to establish acceptable guidance by the industry and NRC, but this guidance is not immediately available, and the timeline for development and acceptance is uncertain. In the meantime,~~ **N**~~n~~early 2/3 of the industry will have completed FLEX implementation by the end of 2015 with the remainder to be completed by the end of 2016. Comment: SDP is the responsibility of the NRC not the licensee. It also is not a consensus process.	
13	LK	RGN3-29	~~As specified in NEI 12-06 [NEI 2015], FLEX capabilities will help reduce the risk from some contributors in plant-specific PRAs (e.g., station blackout and loss of ultimate heat sink scenarios).~~ Comment: Risk reduction is not specified in NEI 12-06. In fact, the NRC has not estimated the change in risk due to FLEX implementation. ~~As such,~~ **T**~~t~~he degree of ~~potential benefit~~ **impact** is highly plant-specific and is dependent on the implementation details. However, the FLEX validation studies that have been performed at most sites indicate that the actions and responses are ~~highly~~ feasible **under the conditions studied** and warrant consideration ~~to reduce the site risk profile~~ **of the risk impact** when the actions are directed. Therefore, the approach described here is intended to provide a means to obtain an initial estimate of the calculated CDF/LERF ~~reduction~~ **change** that may occur in certain applications of PRA models. Comment: What is “highly feasible’?	

13, 47	LK	RGN3-30	The approach taken is to focus the ~~credit for~~ **modeling of** FLEX on the key contributors to a decision. That is, the risk reduction would be applied after initial quantification of the existing PRA models is performed. There are five initial steps associated with this approach: 1) Review the initial PRA model results to determine if FLEX ~~capabilities~~ **implementation** could ~~reduce~~ **change** the calculated CDF/LERF values for the specific application of the PRA model. 2) Identify the applicable contributors (cutsets or sequences) impacted by FLEX capabilities. 3) Determine if a ~~reduction~~ **change** in risk in the applicable scenarios will impact the regulatory decision. 4) If it could impact the decision, perform a feasibility assessment to evaluate the potential to ~~credit~~ **model** the FLEX strategies for the key contributors. 5) If the feasibility assessment indicates that ~~crediting~~ **modeling** FLEX is viable and that doing so may impact the regulatory decision, document the basis ~~for the credit~~ and influence on decision.	
13,47	LK	RGN3-31	Figure 1 –Assessment of Credit for FLEX in Decision Making Comment: The language of the flow chart also needs to be changed consistent with comments above.	
13	LK	RGN3-32	Once the key contributors are identified, the analysts can look at the FLEX validation studies and related procedural direction to determine what scenarios would ~~benefit from credit for the~~ **be impacted by** FLEX mitigation strategies. Comment: The validation studies are of limited value. Most scenarios were the licensee will want FLEX credit will be different from the boundary conditions used in the analysis and from the validation studies.	
48	LK	RGN3-33	This requires ensuring that any installed equipment required in Phase 1 has not failed in the scenarios of interest. Comment: Phase 1, 2, 3 is not terminology used in PRA. Suggest not referencing it here.	
49	LK	RGN3-34	~~Ancillary actions required for implementation of the Phase 2 equipment must be deemed feasible as part of the assessment. Their failure probabilities, however, are implicitly included in the bounding approach provided below.~~ Comment: What does this mean?	
6	LK	RGN3-35	The decision tree accounts for the following factors which are then discussed in turn. Comment: Other factors such as complexity and training/experience and stress are equally if not more important.	
1	LK	RGN3-36	The process assumes a base human error probability (HEP) of 0.1 and a base availability/reliability rate of 0.1 per available train . Each of these base values can be modified, as applicable, based on the process outlined in this paper. An initial failure probability screening value of 0.1 is used for nominal deployment of the applicable FLEX mitigation strategy . Comment: The base HEP of 0.1 is too low. Considering high stress, high complexity, experience/training being low, and ergonomics potentially being poor, an HEP of between 0.3 to 0.5 is more realistic.	
5	LK	RGN3-37	Note that much of the discussion provided here was adapted from a paper presented at PSAM 12 for crediting Emergency Mitigation Equipment Deployment in CANDU plants (PSAM 2014). Comment: The paper states that the method is to estimate the failure probability associated with the retrieval, transportation and installation, referred to as deployment. Determining the need to initiate (diagnosis) and operate once deployed were not part of the methodology. This means that is method represents only one of the necessary HEPs that needs to be developed for considering FLEX modeling.	

18	LK	RGN3-38	Determining the adequacy of training is somewhat subjective, but adequate training could be described as: Comment: Context specific training/experience is necessary for any action to be reliable.	
6	LK	RGN3-39	For the internal events analysis, the environmental conditions in which the deployment will occur are likely similar to those conditions in which the validation exercise was performed . Comment: This is doubtful. Actions likely to be taken under SBO conditions with loss of lighting at least and potentially other negative conditions It is possible that other environmental conditions may exist that were not present in the validation exercise, such as: Extreme cold weather Extreme hot weather Heavy rain Heavy snow High winds Other adverse conditions Comment: The PSAM paper also listed night time deployment	
1	LK	RGN3-40	A failure probability of 1.0E-01 is assigned for this base value , which is consistent with a screening HEP value from NUREG-1792 (NRC 2005). Comment: This is not really consistent with NUREG-1792. The screening HEP is good when you have EOP-type control room actions that are well known, routinely trained on, and sometimes actually implemented in response to events. It is known that a detailed HRA will yield a lower value than 0.1. FLEX deployment and/or implementation is not the same.	
6	LK	RGN3-41	Expansive = Time Margin >= 100% (Reduce nominal value by factor of 2) Comment: I don't think time, if there is enough with some margin, is a significant performance driver. Also, since there is little to no data on time to implement (one validation) it is hard to really conclude that a large margin exists.	
44	LK	RGN3-42	TDebris = debris removal time (if applicable). Comment: This is unlikely to be a factor. Most events where the licensee will want credit will not involve the generation of debris.	
50	LK	RGN3-43	In reference to Texe (i.e. time to intiate water flow after everything is hooked up) [Note that the failure probability of this portion of the FLEX implementation action is inherently included in the base HEP value and is not assessed by this node, but the timing assessment for the deployment portion of the action is required to account for the execution time in the time margin assessment.] Comment: The PSAM paper states this differently. It states that the failure probability of the implementation is not assessed by this methodology.	
45	LK	RGN3-44	The first requirement is that the FLEX mitigation strategy or equipment deployment would be procedurally directed in the scenarios of interest and that sufficient cues and indications are available for the direction of the actions . Comment: This is extremely important and must be part of any guidance we ultimately use.	

45	LK	RGN3-45	As is the practice for incorporation into PRA models, manual actions must be procedurally directed **for the scenario of interest**, trained upon, and able to be successfully performed in order to receive realistic credit for the risk-informed decision.	
6	LK	RGN3-46	Environmental Factors Comment: This section seems to be focused on the impact of external events. While this needs to be considered, more important are the lack of lighting, lack of ventilation, difficulty in hauling/moving equipment, etc.	
6	LK	RGN3-47	In this streamlined approach, there are three possible outcomes: (1) it is deemed that nominal conditions exist, (2) it is deemed that adverse conditions exist that will challenge but not preclude deployment, or (3) it is deemed that the environmental factors will preclude deployment or other conditions exist to make the FLEX equipment unavailable for deployment. Comment: At the very least, adverse conditions are always likely to exist. FLEX will only be deployed in SBO scenarios after deep load shedding as occurred. The consequence of this will be adverse conditions.	
47	LK	RGN3-48	For each hazard in which FLEX is desired to be ~~credited~~ **evaluated**, it	
50	LK	RGN3-49	o No credit should be taken for FLEX deployment in internal or external flooding scenarios where part of the activity must be performed in a location that is flooded unless plant procedures specifically address this condition. Comment: The PSAM paper is different. It suggests that deployment not be credited when flood conditions exist in the zone where the activity is required.	
4, 43	LK	RGN3-50	Equipment Availability Comment: Realistic availability and reliability data should be tracked to provide this information.	
14	LK	RGN3-51	The N+1 capability applies to the portable FLEX equipment that directly supports maintenance of the key safety functions. Other FLEX support equipment only requires an N capability. Comment: This is key. FLEX should be treated as a "single train"	
4	LK	RGN3-52	~~Given this requirement and assuming that the site has fully met the intent of this requirement, equipment reliability should not be a serious concern. Multiple trains of equipment typically lead to unreliability values in the E-3 range or lower in most PRA models, and in the E-2 range for single trains of equipment. Given the uncertainty of deploying the FLEX equipment for potentially longer time periods, it is deemed appropriate, however, to utilize a conservative value of 1E-2 in this node assuming that the N+1 requirement is maintained. If the reliability of one of the trains of equipment is questionable or it is known that one train of the FLEX equipment would not be available for the subject analysis (NOED, SDP, etc.), then a conservative value of 1E-1 would be applied for the single train of equipment that is available to support the FLEX mitigation strategy deployment. Additionally, if the time margin is nominal, conservatively, no credit is taken for the additional train.~~ Comment: We should not compare FLEX reliability to that of installed plant equipment that is routinely used and tested. Since FLEX will never be fully deployed until/unless it is really necessary, it's reliability is questionable. Suggest using 0.3 or 0.5	
1	LK	RGN3-53	The nominal failure value for crediting FLEX mitigation strategy in applicable scenarios starts at 0.1. This is a well-established screening value for feasible actions under nominal conditions. Comment: Well established for post-initiator EOP type actions in PRAs per NUREG 1792. This is not the same and the 0.1 does not apply.	

6	LK	RGN3-54	Expansive = Time Margin >= 100% (Reduce nominal value by factor of 2) Comment: Timing too uncertain to conclude that it is expansive and that the extra time is a performance driver.	
6	LK	RGN3-55	Nominal = Environmental Factors Nominal (Retain nominal value) Comment: Environmental factors will always be adverse.	
14	LK	RGN3-56	~~Finally, the Equipment Availability node of the decision tree applies a 0.01 or 0.1 additional term to the overall credit for deploying the FLEX mitigation strategy depending on whether N or N+1 (or more) FLEX equipment is determined to be available and how much time margin is available for the scenarios of interest. A conservative value of 0.1 is assigned when only N trains are available. When N+1 trains of equipment are available and could both be used based on the time margin analysis, then a value of 0.01 (0.1 * 0.1) is applied. Note that this term is added to the values in the decision tree derived up to this point, since the equipment reliability represents an additional potential mode of failure for deployment. When applicable, in this portion of the decision tree, it has already been determined that sufficient time is available to deploy the equipment (at least once), that procedural direction, cues, and sufficient staffing exist to deploy the equipment, and that environmental factors have not precluded deployment of the equipment. Credit for the N+1 branch is only given when the Time Margin was assessed to be expansive (>100% margin) and therefore the operators have time to deploy the FLEX equipment, determine there is a hardware failure, and replace the affected equipment with a spare.~~ ~~Equipment Availability Branch Descriptions~~ ~~• N = 1 Train of FLEX Equipment Available (Add 0.1)~~ ~~• >=N+1 = More than 1 Train of FLEX Equipment Available (Add 0.01)~~	
6	LK	RGN3-57	FFLEX = 0.1 * TM * CC * EF + EA Comment: This is not 0.1, and This (EA) should be 0.3 or 0.5 Where TM is 1.0 ~~or 0.5 depending on whether the time margin available is nominal or expansive~~, CC is 1.0 when functional, EF is ~~1.0 or~~ 2.0 depending on whether the environmental factors are nominal or adverse, and EA is ~~0.01 or 0.1~~ **0.3 or 0.5** depending on whether N+1 or more of equipment is available and sufficient time exists to deploy the spare equipment.	
1, 6	LK	RGN3-58	An example application of this process is included in Appendix A Comment: I think there are some concepts in this paper to use in developing our own guidance but I don't believe we should adopt this process. It doesn't start with a realistic HEP to modify with PSFs, it doesn't consider other HEPs regarding diagnosis and operations, it doesn't consider all the relevant HEPs, and it doesn't consider the potential negative impacts of declaring ELAP early (effects of deep load shedding).	
41	LK	RGN3-59	Note that it might be about a day or so worth of effort to go through the full process. Therefore, it is probably worthwhile to examine the base model results in advance to determine what sequences or cutsets would be candidates that could benefit from credit for the FLEX mitigation strategies and pre-determine the associated feasibility for each one. Comment: The NRC needs to do this for ourselves.	
38	LK	RGN3-60	~~A Significance Determination Process (SDP) evaluation is performed for a hypothetical Emergency Diesel Generator failure with a representative BWR model.~~ Comment: The NRC does SDP evaluations, not the licensee.	

20	LK	RGN3-61	The impact from seismic and other external events hazards was determined to be negligible and would not impact the characterization of the SDP evaluation. Comment: Interesting. The order is about external hazards but industry concludes the risk impact is internal and fire. I agree this is probably the case.	
51	LK	RGN3-62	Based on a review of the CDF cutsets, the dominant contributors to the increase in risk involve SBO sequences which lead to core damage after initial battery depletion. Comment: Also interesting. I did several SPAR model runs and did not find this to be the dominant sequence. In one BWR example, early RCIC/HPCI failure was dominant – FLEX would not help. In another (Mark III) HPCS worked but ultimately failed due to no containment heat removal (would FLEX be implemented here). In a third PWR case, the dominant scenarios were all fire-induced SBO. How is FLEX integrated with fire procedures? All of my independent investigation shows that it is much more complex than the industry example provided.	
13	LK	RGN3-63	These sequences would clearly benefit from deployment of the FLEX generators (to extend DC availability), and from deployment of a FLEX pump to provide RPV or suppression pool makeup. Comment: It is not that clear. How has the station changed the SBO response procedure – impact of load shedding, early declaration of ELAP, previously were they crediting other methods of extending DC availability that are no longer implemented because of FLEX.	
45	LK	RGN3-64	Deploy and install one FLEX pump to provide RPV injection or suppression pool makeup within 6 hours. Comment: Many models, including SPAR, often already credit exiting fire pump injection. Likely operators would use that method first as opposed to hooking up a portable pump.	
13	LK	RGN3-65	Initiate and complete DC load shed by 1.5 hours . Comment: Must account for impact of successful load shedding on plant equipment. Loss of breaker control power, loss of indication and annunciators, more manual control required, bypassing high level trips, etc.	
14	LK	RGN3-66	For this assessment, credit for N+1 is deemed feasible for the expansive time margin case, but only for N in the nominal time margin case. Comment: This is not very realistic. Using the redundant portable diesel or pump should be viewed in terms of recovery of initial failed attempt, rather than a separate train. Since use of FLEX is a recovery attempt when installed systems have failed, it would be inappropriate to view FLEX as a two train system	
52	LK	RGN3-67	FFPIE = 0.1 * 0.5 * 1.0 * 1.0 + 0.01 = 0.06 Comment: The result here doesn't make sense. HPCI failure probability for 24 hour mission time in Monticello SPAR model is 7.5E-2. So FLEX is more reliable than HPCI? A single EDG has a failure probability for a 24 hour mission time on the order of E-2, so FLEX is on par with EDG reliability?	
6, 13, 51	LK	RGN3-68	SDP CDF (ΔCDF * T) < 1.0E-06 for Green 6.69E-07 (Green) Comment: This conclusion that the result is Green is very much influenced by 1) an assumption that the majority of contributing sequences are long term loss of DC and 2) significant credit for FLEX in the internal event scenarios. Looking at real examples with the SPAR models and SPAR-H leads to different conclusions – significantly lower percentage of scenarios that are impacted and 2) higher failure probability for FLEX.	

53	JD	RGN4-1	It is implied, but never actually stated that the licensee would be following the NEI guidance for maintaining and testing the FLEX equipment. The NEI guidance has a sentence to this effect also but not direct. This does not mean that the licensee is actually following the guidance. In order to even consider using the equipment for risk credit I think that we should have a hard tie that requires maintenance of the equipment in accordance with the NEI guidance at a minimum. Possibly even something more stringent if the equipment is used frequently. For example, STP has a trailer mounted portable pump that they use to assist in draining the waterboxes every outage. They also use the pump for other activities, replace a fire water pump for maintenance. This means that this pumps gets a fair amount of run time. STP does "monitor" the performance of the pump more closely then NEI requires to ensure its availability. If a licensee is going to use a piece of equipment "regularly" it should have a higher maintenance requirement.	
5	BH	RGN4-2	while the "Qualitative Assessment…" paper describes considerations that licensees should assess before deciding to use FLEX equipment in "non-FLEX" situations, it doesn't even suggest how licensees should use the assessment results to make a "go/no-go" decision about using that equipment. (We suspect that for several of the considerations, thresholds exist that should establish a line between deciding "yes" and deciding "no".)	
23	MF	RGN2-1	Rather than endorsing the NEI White papers as submitted, Region II recommends that a more appropriate treatment would be to consider the recommendations made by NEI, vet them through the NRC Analysts and other stakeholders and then subsequently incorporate them into the RASP manual.	
54	MF	RGN2-2	The insights and approaches described in "Qualitative Assessment for Crediting Mitigating Strategies Equipment in Risk Informed Decision Making" are already in use by the NRC risk community and consequently no changes or modification need to be made. Several recent findings treated under the SDP process have used some limited FLEX equipment credit. The SRAs and Risk Analysts already have the tools/techniques necessary and no further action is required. The guidance is a useful framework for the licensees to ensure issues have adequately addressed all aspects.	
13	MF	RGN2-3	The approach described in "Streamline Approach for Crediting FLEX in Risk Informed Decision Making" is flawed in that it assumes that there is only a risk benefit from implementing the FLEX strategies. For example, there may be scenarios where operators implement FLEX for a LOOP and/or LOHS event where they increase risk to the public by performing deep load shedding of 125VDC buses, which might preclude recovery of offsite or onsite power because of a lack of instrumentation and/or control. We would recommend that the quantification process evaluate the net change in risk due to both positive changes (due to extra equipment available) and negative changes (due to LOOP/LOHS) strategies that may not be successful under FLEX implementation.	
13, 34	MF	RGN2-4a	Region II recommends that quantitative credit be considered only on an individual scenario basis and that the quantification must consider both the risk increase and risk benefit from the strategy on the specific scenario. The treatment should follow current RASP guidance similar to any recovery action and meet the associated requirements.	
31	MF	RGN2-4b	If a specific FLEX strategy and equipment had the potential to be implemented in a time period where it can prevent, or delay, core damage or large early release, then the approach can be used on a temporary basis while a properly performed full model update can be performed. This should only be considered on a scenario basis as the equipment and human actions required to support success of the strategies are scenario dependent.	
36	MF	RGN2-4c	It should be recognized up front that the existing SPAR models do not contain the FLEX equipment and considering its risk benefits along with the risk increase will add substantial time to the RIDM process.	
4	MF	RGN2-5	The equipment, procedural guidance and training for the specific FLEX strategies has a much higher uncertainty than the permanently installed equipment. There is little data on the failure probabilities or Human Error Probabilities associated with this equipment which will reduce the risk credit substantially if the full range of uncertainty is considered.	
35	MF	RGN2-6	To properly evaluate the risk of a performance deficiency, the risk analysts determine the increase above the base plant risk associated with the performance deficiency. The impact of the FLEX equipment needs to be addressed in the base case as well as the non-conforming case to get a proper assessment of the increase in risk.	
55	MF	RGN2-7	The White papers do not detail how the impact of the FLEX strategies not being available will be dealt with.	

1	MF	RGN2-8	Regarding the streamlined decision tree in the Quantitative approach, the initial use of 0.1 for nominal development does not appear to have a good basis. A better value would be 1.0 and work from there.	
41	MF	RGN2-9	The licensee should review the FLEX equipment and determine if the FLEX equipment and strategy could be implemented to support specific functions and determine the potential risk benefit ahead of time if possible to prevent delays in the RIDM process which will occur if the crediting is attempted during the timeframe of the specific RIDM issue, i.e. NOED, MD8.3 or SDP issue.	
56	MF	RGN2-10	If the licensee's add this equipment to their full scope models, the NRC will need to budget for an activity to update the SPAR models accordingly.	