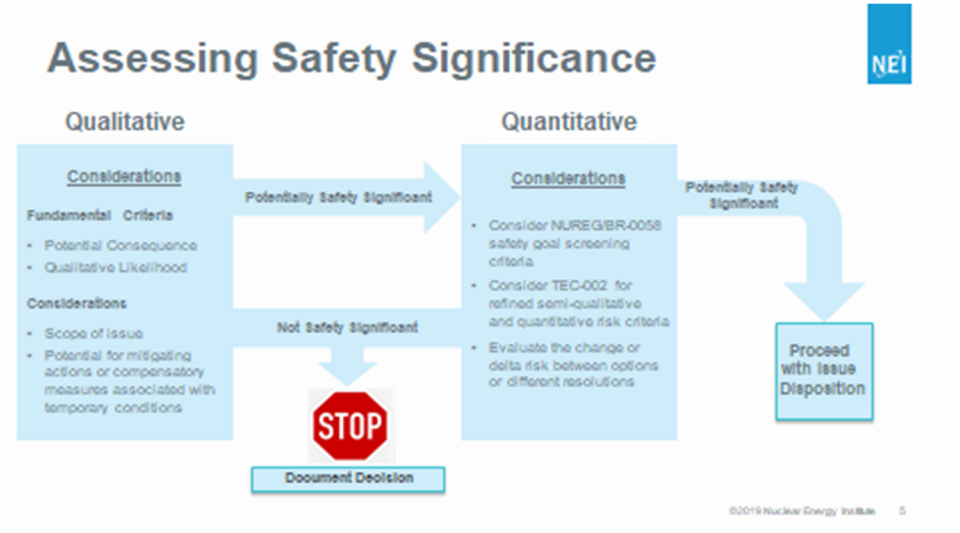
Qualitative Framework to Initially Assess
Safety Significance (NEI Draft August 5, 2019)

As discussed at the May 29, 2019 public meeting on Low Safety Significance Issue Resolution, the assessment of safety significance is essential to the success of the initiative. A simple method is needed to assess safety significance and the first step should involve a qualitative assessment to determine whether an issue is significant enough to require additional resources or analysis to be applied to reach a conclusion. This tool is not intended to drive a detailed risk evaluation when documenting the basis for the response to each question.



The framework associated with the qualitative considerations is to broadly determine the safety significance of a regulatory issue using the fundamental risk concepts of potential consequence and qualitative likelihood in an effort to allocate or prioritize regulatory resources. This framework is intended to be applicable to a broad set of existing regulatory processes and is designed to be used to determine if an issue is of high safety significance prior to the expenditure of significant NRC staff or industry resources.

The construct of the qualitative process is such that an initial qualitative determination of safety significance is designed to rapidly determine if the issue is considered of High Safety Significance rather than expend resources trying to determine, or measure, or prove that an issue is of Low Safety Significance. The qualitative process is also designed to capture a broad spectrum of issues or decisions that may arise because some issues may not be directly evaluated using quantitative tools or processes.

Effective application of this qualitative approach considers the principles of Risk Informed Decision Making (RIDM), namely, compliance with current regulations,

consistency with the defense-in-depth (DID) philosophy, maintaining adequate safety margins, demonstrating acceptable levels of risk, along with a feedback or oversight function to assure consistency across the breadth of regulatory issues and organizations. A qualitative approach considering the above principles provides a more integrated, holistic, and transparent assessment of safety significance than currently exists.

As noted above, the premise of the qualitative assessment of safety significance is to perform a determination by those involved in an issue using existing regulatory safety criteria.

The qualitative framework of the potential likelihood associated with safety significance is conceptually aligned with the regulatory framework used to define Licensing and Design Basis events for existing and new plants. The qualitative questions below are best aligned to those issues that impact initiating event, mitigating sytems, or barrier cornerstones. Although, specific questions associated with barrier issues are not provided. Corresponding questions could be similarly developed to assess issues associated with other cornerstones, but the fundamental premise of using a qualitative assessment can be similarly employed using a slightly modified set of consequence questions.

The qualitative framework of a potential consequence associated with safety significance is based on known significant contributors that influence changes in consequence. Both the likelihood and consequence would need to be characterized as "Safety Significant" to move an issue toward a more refined quantitative assessment during the next step of the process. A determination of minimal safety significance does not imply the issue will not be addressed by the industry, rather it highlights that significant resources, are not, or should not, be applied to resolve an issue. Documentation of the resolution of an issue can be accomplished with minimal resource consistent with the agency direction to apply increased resource to those issues considered safety significant.

The development of the qualitative screening questions also reflect the fact that significant margin to regulatory safety goals and surrogate measures exists, and therefore use of such a value for characterizing an issue as safety significant does not challenge the regulatory objectives of the NRC.

The likelihood determination associated with an issue may be thought of as an aggregate qualitative value or a series of individual values. Similarly, the consequence of an issue may be different for different likelihoods. It is envisioned that the likelihood and associated consequence be paired when performing the qualitative evaluation to limit inadvertent pairing of the most significant consequence with the highest likelihood. This practice would also help refine the basis for the significance determination because it will focus the specific issues' initial qualitative impact on the facility to only those that would be significant.

Lastly, the existing issue process framework and the roles and responsibilities of regulator and utility are not expected to be demonstrably changed through implementation of this qualitative framework. The extent of condition assessment typically employed using existing processes will facilitate the determination of significance. The use of this tool will provide a more holistic characterization and understanding of the significance a particular issue, and subsequent resource application, at a specific facility.

Likelihood

The following proposed questions are designed to determine if the likelihood or change in likelihood associated with an issue can be characterized qualitatively as significant.

Individual Issue or Focused Considerations:

L1. Does the impact of an issue have the potential to create a new initiating event or change the frequency of an initiating event (Licensing Basis Event) that is similar to that of an Anticipated Operational Occurrence (AOO)? If yes, the issue should be considered significant from a likelihood perspective.

SIG ◯
Not SIG ◯
N/A ◯

L2. Does the issue or proposed change significantly increase the likelihood of a cause or event that could create simultaneous mitigation challenges with respect to equipment or operator response? If yes, the issue should be considered significant from a likelihood perspective.

SIG ◯
Not SIG ◯
N/A ◯

Issue Extent of Condition Consideration:

L3. Does the scope of the potential issue significantly impact or increase the likelihood of an event across SSCs, functions, or units at a site? If yes, the issue may be considered significant from a likelihood perspective.

SIG ◯
Not SIG ◯
N/A ◯

A determination of "SIG" in either of the above questions associated with an issue would be characterized as Significant. In addition, the consideration of issue's extent of condition potential to multiple SSCs or plant functions, or multiple units at a site could be initially considered "Significant" given the potential broad implications of an issue.

Consequence

The following proposed questions are designed to determine if the consequence or change in consequence associated with an issue can be characterized qualitatively as "Significant Consequence".

Individual Issue or Focused Considerations:

C1. Does the issue have the potential to significantly impact or change the potential consequences associated with an event? If yes, the issue <u>should</u> be considered significant from a consequence perspective.

SIG ◯
Not SIG ◯
N/A ◯

C2. Does the issue impact multiple aspects of mitigation capability or a defined fission product barrier? If yes, the issue <u>should</u> be considered significant from a consequence perspective.

SIG ◯
Not SIG ◯
N/A ◯

C3. Could the issue significantly diminish evaluated safety margins? If yes, the issue <u>should</u> be considered significant from a consequence perspective.

SIG ◯
Not SIG ◯
N/A ◯

C4. Does the issue create a significant shift from mitigation systems to operator response or significantly increase operator response burden? If yes, the issue <u>should</u> be considered significant from a consequence perspective.

SIG ◯
Not SIG ◯
N/A ◯

Issue Extent of Condition Consideration:

C5. Does the scope of the potential issue significantly impact or increase the mitigation capability or potential consequences across SSCs, functions, or units at a site? Qualitative consideration of the protection in aggregate at the site should be accounted for when assessing the extent of condition of an issue. If yes, the issue may be considered significant from a consequence perspective.

SIG	◯
Not SIG	◯
N/A	◯

A determination of "SIG" in any of the above consequence questions associated with an issue should be characterized as "Significant Consequence".

Temporary or remediated conditions

Can mitigation actions or processes be employed to limit or eliminate the potential consequence of an issue? If yes, the issue may require further confirmatory consideration or assessment beyond this initial screening tool.

NOTE : One unique aspect considered in the consequence questions is associated with the ability to mitigate the identified potential consequence using process, plant changes, or configuration controls. Clearly the consequence would not be considered significant if mitigation or elimination of the consequence can be employed after the issue is identified. Further consideration of such controls and the length of time mitigation of the issue may be warranted.

It is envisioned that both the likelihood of the issue and the potential consequence of an issue would need to be qualitatively characterized as "Significant" for the issue to move forward toward a more quantitative evaluation. Employing additional and diverse personnel resources would ultimately be applied to a particular issue if the initial qualitative determination was safety significant.