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November 13, 2019

MEMORANDUM TO: John B. Giessner, Deputy Regional Administrator
Region III

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SUBJECT: SAFETY SIGNIFICANCE BACKGROUND IN THE CONTEXT OF THE LOW SAFETY SIGNIFICANCE ISSUE RESOLUTION WORKING GROUP

As you are aware, consideration of safety significance is a central theme in the work of the Low Safety Significance Issue Resolution (LSSIR) working group. Integrating safety significance in to the working group's activities in a manner that is consistent with the agency's broader use of integrated and risk-informed decision making is fundamental to the formulation of the working group's recommendations. The working group discusses this at a high level in its products, and the enclosure to this memorandum provides a more complete background. The enclosure describes the working group's perspective on these issues, so as to promote a better understanding of the thought process that resulted in the working group's recommendations. It does not change any existing regulatory positions or guidance, and it does not infer a consensus opinion on any specific topic.

If you have any questions, please contact me at (301) 415-1545 or donald.helton@nrc.gov.

Enclosure:
Safety Significance Background

This enclosure provides a cross-cutting description of safety significance, within the context of the Low Safety Significance Issue Resolution (LSSIR) activity. It provides background and context to how the NRC assesses safety significance in general, and then provides information on safety significance relative to each programmatic area where the LSSIR working group recommends modifications.

General Background

The NRC routinely uses safety significance as a guide for prioritizing resources and making regulatory decisions. While the specifics of how safety significance is assessed varies for each application, the general framework is consistent. That framework uses the NRC's standard approach to integrated decisionmaking. This approach is described in Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (amongst many other places) and is depicted in Figure 1. The approach merges the traditional engineering approaches that are intrinsic to the design and licensing of U.S. operating reactors, with the use of probabilistic analysis (often in the form of a probabilistic risk assessment, or PRA) to provide gradation of safety significance. The approach also acknowledges the strengths and limitations of both deterministic and probabilistic analysis, including the consideration of uncertainty. NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking," discusses treatment of uncertainty in integrated decision-making (also commonly referred to as risk-informed decision-making), and Figure 2 re-produces a figure from that report that shows the concept at the most fundamental level.

Figure 1: NRC Approach to Integrated Decisionmaking

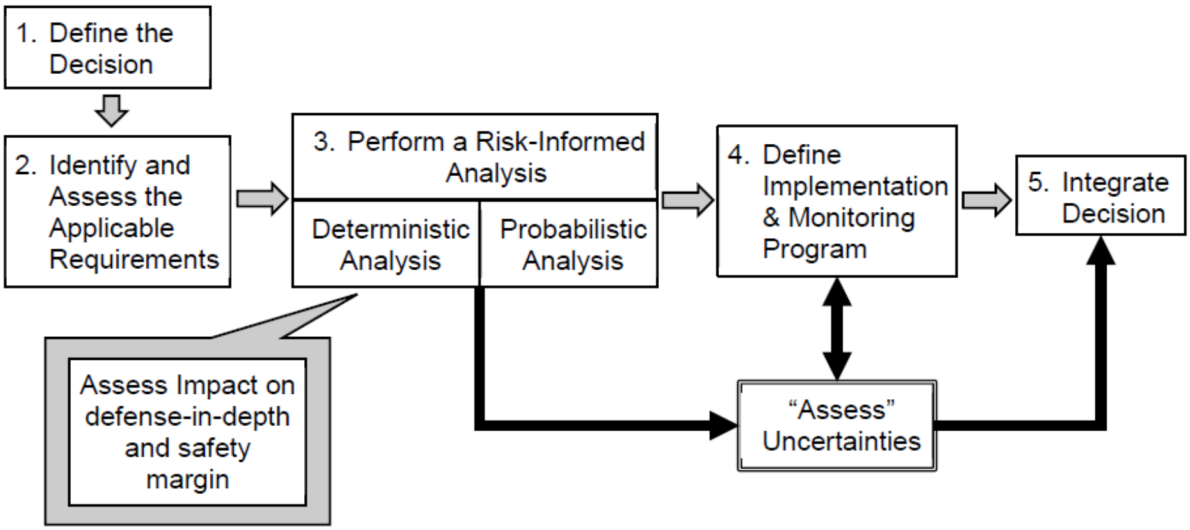

Figure 2: Uncertainty in Integrated Decisionmaking (from NUREG-1855)

These embodiments of NRC's approach to integrated decisionmaking (IDM) reinforce the fundamental tenets in the Commission's 1995 Policy Statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement." These tenets include:

- "The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy;

- PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices…;

- PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review; and

- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees."

Regarding the principle of ensuring that the regulations are met, this enclosure is focused on the situation where the licensing basis (LB) standing of an issue is presently indeterminate. As such, safety significance is being used to determine if it is appropriate to spend significant additional resources to pursue clarity in that dispute, versus using those resources to pursue other issues of potential impact on public health and safety (in light of the fact that overall resources are finite for all involved parties). For this reason, that element of the process is not discussed further here.

In operationalizing the Commission's direction, the concepts of IDM, and the treatment of uncertainty, the staff has developed a number of different means of assessing safety significance. Each variation is tailored to its application, and appropriate differences arise due to factors such as:

- Is the application conducive to the use of a PRA, versus a simpler tool;
- In licensing, acceptable levels of safety margin and defense-in-depth are generally being established or managed, versus oversight, where the focus is on ensuring these traditional elements are not being inappropriately eroded;
- Different measures of risk are appropriate for different situations, such as the use of an incremental and conditional risk measure when looking at a temporary condition (e.g., Technical Specification Limiting Condition for Operation extension) versus a change in core damage frequency (CDF) relative to a baseline CDF when looking at a permanent change (e.g., a permanent plant modification).

Use of PRA Versus Other Tools

A common topic of discussion is whether integrated decisionmaking requires a PRA, particularly since the term risk-informed decisionmaking is commonly used interchangeably with IDM, and since "risk" is often equated to "PRA." To be clear, the NRC uses risk as one step in IDM, and the NRC further equates risk to an evaluation of the risk triplet (what can go wrong; how likely is it; what are the consequences). A PRA is a preferred, but not required, means of systematically assessing the risk triplet in a structured way, for a broad range of postulated accident sequences. A PRA seeks to represent the "as-built" and "as-operated" facility. In other words, it is designed to rely on plant-specific information to the extent practicable.

However, use of a plant-specific PRA is not always practical, or even necessary. For this reason, the NRC often uses insights distilled from PRAs, in lieu of the PRA itself. At times, the NRC also uses qualitative assessments, still anchored to the risk triplet. The key is to avoid the logical extremes of this sliding scale, which arise when either (a) the user attempts to create a PRA-based analysis requiring a resource investment incommensurate with the importance of the issue being informed or (b) the user mistakes "gut feel" or a "value judgment" as being risk-informed. Figure 3 shows one representation of this landscape, for notional purposes. The point of this figure is to show where some existing tools fall in to this spectrum, so as to frame the later discussion on what tools are best-suited for use in the LSSIR recommendations. Meanwhile, Figure 4 shows a notional representation of the pedigree needed for using PRA information in this activity.

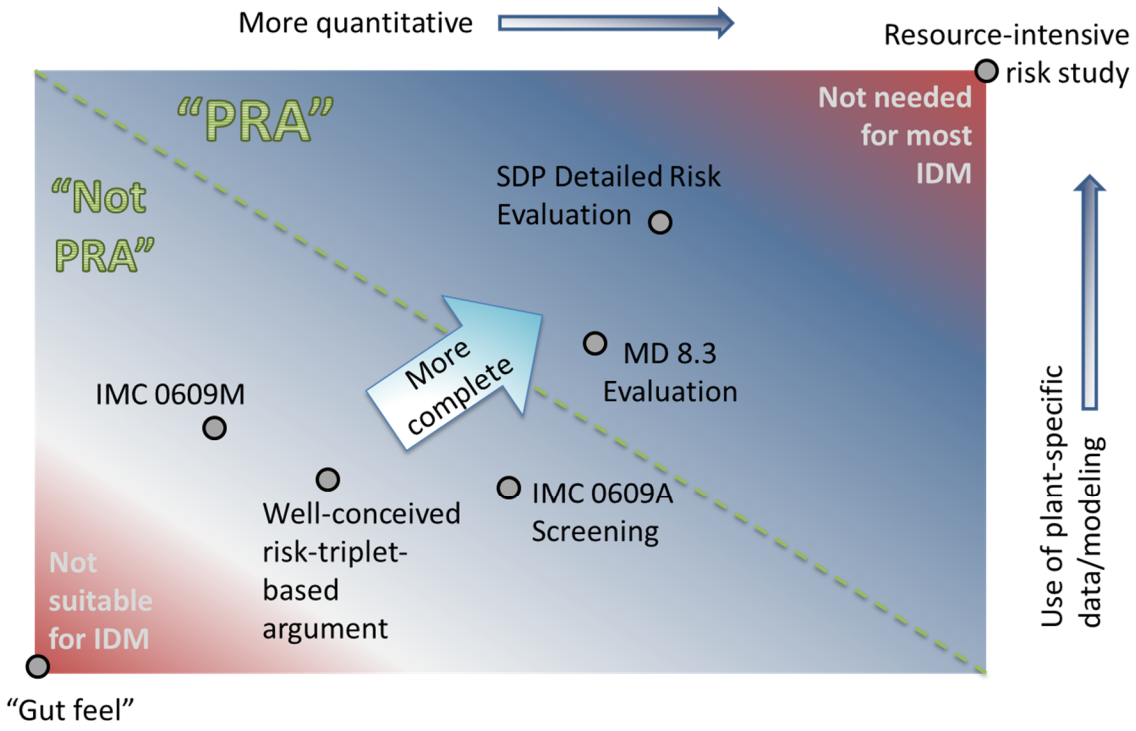

Figure 3: Representation of Alternative Means of Assessing Risk
[MD 8.3 = NRC Management Directive 8.3; IMC 0609 = NRC Inspection Manual Chapter 0609; SDP = Significance Determination Process]

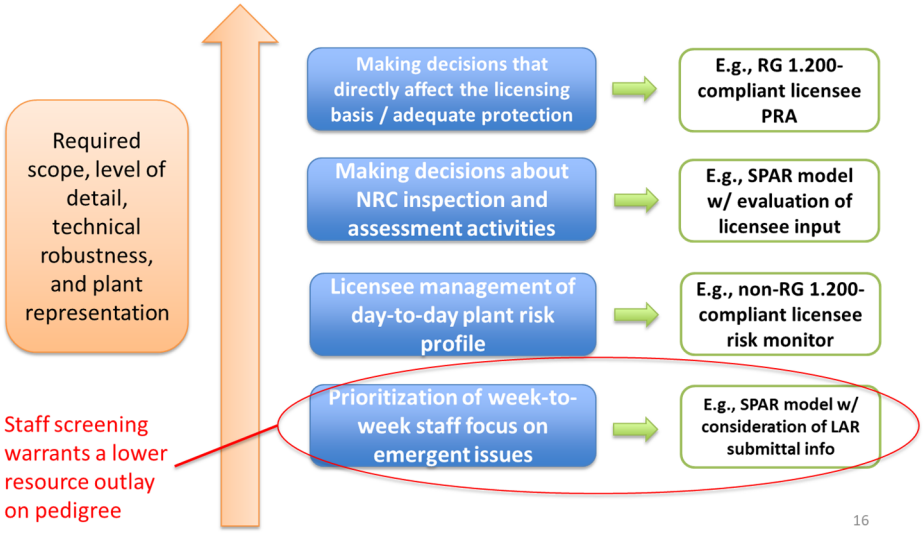

Figure 4: Notional Representation of the Varying Levels or PRA Information

Recent Sunset Efforts

There are several notable examples of efforts within the last 10 years that sought to develop new ways of applying IDM and assessing safety significance, which were terminated after significant development activities. These examples are:

- NUREG-2150, "A Proposed Risk Management Regulatory Framework"
- Near-Term Task Force Recommendation 1
- Risk Prioritization Initiative (RPI) – see SECY-15-0050
- Design Compliance Enforcement Discretion

The first two activities sought to fundamentally change the regulatory structure associated with how NRC licenses and oversees power reactors. The third activity sought to fundamentally change how plants manage their regulatory commitments. The final activity sought to alter how the agency handles the resolution of particular non-compliances. From a safety significance perspective, these efforts included significant effort toward creating new means of assessing significance.

As an example, the RPI effort included the development of industry guidance (Draft Nuclear Energy Institute (NEI)-14-10, "Guidelines for Prioritization and Scheduling Implementation"; Agencywide Documents Access and Management System (ADAMS) Accession No. ML14325A681), and the piloting of that guidance (under NRC observation). The guidance established a Generic Assessment Expert Team (GAET) and an Integrated Decisionmaking Panel (IDP). It included explicit consideration of an item's impact on security, emergency preparedness, and radiation protection, and used judgment-based flow charts for this. The IDP's expertise encompasses plant operations, safety analysis, engineering, PRA, licensing, and other topical subject matter experts as needed. Item significance would have been determined using CDF and large early release frequency (LERF), the change in CDF and LERF, or a percent change in consequences. Significance determination also used an analogy to the NRC's SDP. Finally, overall priority was to be established using a worksheet construct.

However, in all of these cases, the efforts were sunset (either terminated by the Commission or halted by the staff) prior to these developments becoming part of the accepted state-of-practice.

External Stakeholder Input on Significance Determination in LSSIR

At a May 29, 2019, public meeting, the staff presented on its high-level concept for changing how safety significance is considered in NRR's Task Interface Agreement (TIA) process, which is codified in Office Instruction COM-106. The concept presented is similar to that discussed later in this enclosure. The primary feedback related to the following:

- the potential that allowing multiple approaches for each IDM element could result in differing outcomes depending on the user's selection;

- the leveraging of 10 CFR 50.69 results is complicated by that program's use of relative risk measures (i.e., measures of how SSCs rank against one another);

- confusion about how the process would handle issues like security and emergency preparedness;

- availability of a recent Electric Power Research Institute report on IDM concepts;
- the potential that the feedback step could become a driver for not fully dispositioning issues; and
- the notion that the issue should be looked at through the lens of “not high” instead of “clearly low.”

This feedback was considered as the working group proceeded with its efforts, and many of the comments were explicitly factored in to changes to the safety significance worksheet developed under this effort (proposed for use in the updated COM-106). The final item was also considered, but not ultimately incorporated, as described in the following section.

The industry also proposed an approach to addressing issues, via a presentation available at ADAMS Accession No. ML19149A230, and later augmented this proposal with a draft White Paper available at ADAMS Accession No. ML19218A134. NEI proposes a Safety Significance Evaluation Tool (SSET), which it envisions would be applied across various regulatory contexts (e.g., inspection, licensing/forward fitting). It would utilize qualitative criteria, with quantitative insights used when available. Significance could be judged from the standpoint of an item’s absolute or incremental risk. As of an August 7, 2019, public meeting, the tool had gained some level of specification, but was not complete. In addition to finalizing the tool itself, NEI agreed that an underlying basis document would be needed to ensure that the tool is used in a consistent and repeatable manner. In particular, a concern voiced by NRC staff is that the qualitative nature of the tool would lead to subjective rather than objective decisionmaking, particularly given the vision of it being used in differing regulatory contexts. Another outstanding concern is that the tool anticipates a high bar for an issue to screen in (i.e., have sufficient safety significance to warrant continued effort), such as significance commensurate with the potential for the agency to take action under 10 CFR 50.109 (backfit). This concern is discussed further below.

“Not High” versus “Clearly Low”

The staff began its work with the instruction to assess if there were improvements to be made in the area of dispositioning low safety significance issues. During public interactions, representatives from industry suggested that this should be re-framed to look at more efficient dispositioning of issues that are other-than-high safety significance. The staff considered this feedback, but ultimately concluded that the intent of the industry representatives’ comments would lead to the NRC prematurely sun-setting issues of potential safety significance, and as importantly, issues where the agency would potentially have taken regulatory action.

As the staff understands it, the basis for the industry suggestion was two-fold. First, if an issue is not of high safety significance, the amount of resources that the agency would spend exploring the issue could quite easily surpass the benefit associated with any resulting agency action. Second, it would arguably be much easier for the staff to conclude that an issue is not high safety significance, relative to determining that an issue is clearly of low safety significance. This refers to the ability to make more rudimentary assumptions in the analysis, due to the more forgiving acceptance threshold.

One potential means of accepting this feedback, which the staff is continuing to consider, is to go to a tertiary outcome. A tertiary outcome could accommodate the situations where the issue is: (i) clearly low, (ii) clearly high, or (iii) somewhere in-between. As the LB standing is better

understood through additional investigation (e.g., through the updated COM-106 process, it might be possible later in the process to conclude that issues in this third bin are likely to end in backfit space (i.e., are not likely to have the necessary characteristics to be clearly in the LB basis), especially in light of recent Commission direction with regard to "backfit reset." At that point, a higher screening threshold (e.g., like those in NUREG/BR-0058) could be applied, akin to the thresholds that would need to be met to pursue a backfit. The main cons associated with a tertiary construct are the added complexity and the additional resources spent on assessing safety significance (unless the initial assessment was made more efficient by virtue of the additional bin).

While the issue of low versus intermediate versus high safety significance applies to changes in risk, safety margin, and defense-in-depth, it is most easily visualized in terms of changes in risk. This is because this element is typically quantitative, and typically has associated numerical thresholds. Figure 5 shows a notional representation of a range of existing NRC processes, and the various regimes for decisionmaking within these processes. Overlaid on top of this are notional (dashed) lines denoting the threshold for when the agency would typically take action. Note that this figure uses the existing naming scheme for the SDP bins, acknowledging that some of these names are being considered for revision. There is some mixing of differing mathematical metrics in this representation (e.g., ΔCDF versus ΔCore Damage Probability (ΔCDP) versus Conditional Core Damage Probability (CCDP)), and some processes that use different metrics for events versus conditions. This results in an apples-to-oranges comparison here, and for this reason, the graphic is only intended to be illustrative in nature. The purpose for including this figure is to point out that some of the risk levels where the agency takes action in the oversight program are lower than those associated with backfit.

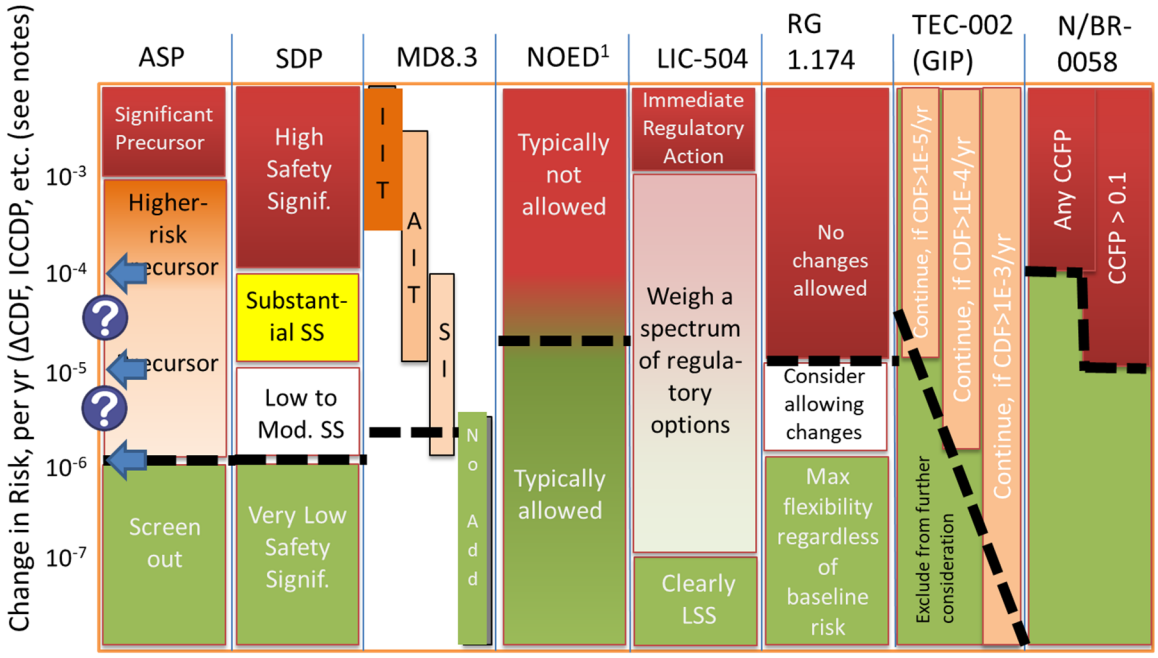

Figure 5: Notional View of Risk Levels Correlating to Agency Response
(NOTE: This does not include ongoing revisions that are still in-progress.)
[1 What is illustrated is an effective ΔCDF based on an ICCDP of 5E-7, a 72-hour exposure time, and an SDP-like annualization process – again, this is not an apples-to-apples comparison.]

Another factor is the degree of uncertainty with respect to early sun-setting of an issue, not in the vein of uncertainty in the general sense (which will always be present), but in the vein that the actual impact of the issue on the plant's response to postulated accidents (and thus its relevance to public health and safety) may be unclear early in the process. The types of assumptions that may be necessary at this point in the process may limit the value of the assessment. In areas of heightened uncertainty, a common engineering practice is to make assumptions that are believed to be inclusive (a.k.a., conservative). If such assumptions still lead to the conclusion of low safety significance then the analyst can proceed confidently, but many times these simplifying assumptions give the item a degree of apparent significance that may not be deserved when the situation is better characterized. Making judgments about the degree of understanding, and the degree of acceptable uncertainty, will remain a key challenge in dispositioning issues efficiently. This is discussed more specifically in the context of the use of SDP tools below.

The Staff's Overarching Mindset

Given the foregoing discussion, the staff concluded that the following guiding principles could best frame the working group's pursuit of enhanced consideration of safety significance, in concert with the overarching context of the LSSIR effort (e.g., that many issues will involve an LB dispute wherein the licensee asserts the issue is not within their LB with an accompanying basis):

- There is insufficient benefit to warrant development of new interpretations of IDM, or to develop new ways of operationalizing the key elements of IDM;

- There are many already-existing tools that can be readily leveraged, with limited or no modification;

- The proposed solutions need not be PRA-based, but they must result in structured and well-reasoned assessments using the IDM principles;

- The tools used should balance the desire to disposition issues of very low safety significance against the need to preserve the intent and value of NRC processes that include specific regulatory responses to issues of intermediate or high safety significance (notwithstanding the disputed LB standing of the issue);

- A range of situations exist, and a one-size-fits-all approach is not appropriate; furthermore, the life cycle of a particular issue may necessarily involve the use of multiple determinations due to the changing level of clarity about the issue's impact on plant response, the issue's standing with regard to the LB, etc.;[1]

[1] For instance, an inspection issue of concern might be assessed for safety significance during the initial issue exploration using a simple tool employed by the inspector. If there is insufficient basis to sunset the issue at that point, it could proceed to a TIA, where, under the enhanced COM-106 process, its significance would be assessed by a risk analyst and topical area subject matter expert, leveraging the earlier significance characterization. If again there is insufficient basis to disposition the issue, it would proceed further, and could ultimately lead to an inspection finding or backfit evaluation where the significance would be assessed using IMC 0609 or NUREG/BR-0058, respectively. Again, the intent would be for these subsequent significance determinations to leverage, as appropriate, the earlier efforts. This situation reflects the reality that, while some issues can be readily dispositioned early in the exploration process, others require more characterization and effort.

- The proposed solutions should work alongside, and not in place of, existing agency processes, both in terms of:
    - The agency's way of doing business (e.g., inspection guidance, licensing guidance, etc.), and
    - The agency's varying levels of rigor in considering significance (e.g., routine judgments on day-to-day decisions, LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues," evaluations on issues of significant potential importance).

These tenets cause the staff to align with the industry viewpoints stated to date in some respects, but to differ in others. In particular, the aforementioned SSET approach described by industry appears to rely on the creation of new infrastructure specific to safety significance determination. At this point, the staff foresees incorporating elements of the external stakeholder feedback, but not pursuing the proposals wholesale.

The following subsections specifically address the candidate approaches for a few specific programmatic areas.

Safety Significance in Early Inspection Issue Handling

Inspectors make judgments about safety significance as part of their daily activities, in terms of what items to inspect and what issues of concern to pursue. Once an issue of concern has been identified, and is being pursued, Inspection Manual Chapter (IMC) 0612, "Issue Screening," drives the issue to resolution. This approach has the positive effect of ensuring that issues are being dispositioned (rather than languishing) and promoting a culture of compliance wherein LB assumptions are being verified and licensing basis capabilities are being maintained. A strong LB is important for effectively managing risk to the public. However, an unintended consequence of the above situation is that NRC inspection and headquarters resources expenditures, as well as licensee resource expenditures, are sometimes incommensurate with their actual safety significance (i.e., their benefit to public health and safety).

To address the above situation, some modifications to IMC 0612 and IMC 0611, "Power Reactor Inspection Reports," are being pursued as described elsewhere. These changes are founded in the leveraging of SDP tools outside of their conventional SDP application, as well as addressing safety significance more rigorously in the enhanced COM-106 process. The former item is discussed more in the paragraphs below, while the latter is discussed in the following sub-section.

The SDP relies on screening tools (sets of questions) that use the distilled results of PRAs, as well as distilled collective judgments when PRA insights are insufficient for the topical area. When screening does not disposition an issue as being of very low safety significance, the PRAs themselves, or additional judgments, are used. There are several aspects of the SDP, as codified in IMC 0308, "Reactor Oversight Process Basis Document," and IMC 0609, "Significance Determination Process," that need to be addressed, if elements of the SDP are to be used outside of their conventional context.

First, per the implementing guidance, care should be taken to not infer that an SDP is being conducted, but rather that the tools associated with SDP are being utilized. This is most easily

accomplished by not invoking the SDP color schemes. IMC 0308, Attachment 3, "Significance Determination Process Technical Basis Document" (issued June 2016) states:

> The color of an SDP result carries with it an assurance that all of the specific applicable process provisions of the overall SDP have been met. Other forms of significance determination may not have the same process attributes, definitions, or assurances, and therefore should not be characterized using the SDP color scheme… Keeping the SDP color scheme independent from other forms of significance determination also aids in ensuring clear and consistent public representations that inspection findings with colors are inputs to the ROP [Reactor Oversight Process] assessment of licensee performance.

Related to this, the wording used to characterize SDP findings can be confusing when compared to the wording used to describe the LSSIR effort. An issue of low safety significance in SDP is an issue that has a change in risk in the range of $1 \cdot 10^{-6}$/yr to $1 \cdot 10^{-5}$/yr, which is not necessarily the range of interest to LSSIR.

Second, and closely related to the above, is the fact that an SDP evaluation is performed to assess the significance of a specific performance deficiency within a specific cornerstone of the ROP. The results are used to determine the regulatory response, and aggregation of multiple instances of deficient licensee performance are aggregated (when applicable) in the Action Matrix, not the SDP. As such, application of the SDP tools within SDP infers deficient licensee performance, and only determines the significance of a particular performance deficiency. Contrast this to the use of SDP tools earlier in the inspection process, when a performance deficiency has not been determined. In this alternate context, the tools are determining the significance of an issue of concern that is less well-framed, and may be considering aspects of degraded plant response that would be ultimately outside the scope of a particular performance deficiency (e.g., degraded operator response capabilities spanning a broader range of contexts). Put differently, prior to the documentation of an inspection finding, the inspector would be characterizing the safety significance of a different and inherently more diffuse (or vague) issue. This situation could lead to a determination that is more or less inclusive than what an actual SDP of the eventual inspection finding would determine, but if implemented carefully, one could expect that the determination would more often be encompassing since the scope of the issue (and thus its potential impact) has not been narrowed to a particular performance deficiency.

Third, a key step in the current SDP process is the translation of the performance deficiency to the actual impact on the plant's response to accident sequences. This step, which involves the expertise of both the inspection staff and the regional Senior Reactor Analyst, often involves a significant degree of exploration and judgment. Performing this step earlier in the process, before an inspection finding has been developed, will be challenging. It will necessarily require a greater degree of judgment, with inherently higher uncertainties. Again, this degree of uncertainty and judgment is appropriate if it is commensurate with screening out issues that are *clearly* of very low safety significance (using the IMC 0609 parlance).

Building upon the above, the focus of early screening in IMC 0612 should be focused on sunsetting issues that are clearly of minimal (or no) impact to public health and safety. Based on this mindset and the above considerations, the LSSIR working group believes that SDP tools can be leveraged for this purpose. That said, the working group acknowledges that doing so may lead to concerns on the part of those that do not see this as a natural evolution of the current ROP. A self-assessment after some run-time could help with this concern.

Despite all of the above considerations and challenges, the actual implementation is fairly straight-forward. The details of where and how this new step would fit in to IMC 0612 will be discussed in the LSSIR working group's separate recommendations. In a nutshell, the inspector would define the issue, use judgment to specify the expected impact on the plant's response to postulated accidents, and process the issue through the checklists and flowcharts of IMC 0609. If multiple cornerstones apply the inspector would use judgment to assess the multiple paths or select the cornerstone that is most controlling. Again, this process will only be conclusive and efficient in cases where the issue is truly of *clear* very low safety significance (using the IMC 0609 parlance). Many issues will be too poorly defined and understood at this stage of the lifecycle to be efficiently characterized in this way.

Safety Significance in the TIA (NRR COM-106) Process

The determination of safety significance in the updated COM-106 process is an area where the staff developed a worksheet to guide an assessment that walks the user through the relevant steps of IDM, and allows the user to select from a menu of existing approaches to assessing change in risk, safety margin, defense-in-depth, and feedback. The worksheet also includes steps for characterizing the issue (at the beginning) and synthesizing the information to make a decision (at the end). The evaluation and worksheet are completed by a designated risk analyst and a topical area subject matter expert, in consultation with the issue owner and the COM-106 integrated team. The safety significance evaluation outcome is a recommendation to the integrated team about whether the issue is of very low safety significance.

The worksheet is designed to assess an issue that:

- does not adversely impact the safety/security interface, nor is expected to be of security-significance;
- has been considered within the appropriate existing processes;
- has received a due-diligence level-of-effort to date;
- is likely to need a significant additional resource expenditure to resolve (e.g., hundreds of hours), that is potentially incommensurate with its safety significance;
- is amenable to a reasonable characterization of its safety significance, using this worksheet, in a modest amount of effort (e.g., 10-20 hours).

The worksheet which has been developed, will be used in the Screening and Evaluation Phase of the updated COM-106 process, which will be implemented via a forthcoming revision to the NRR Office Instruction.

Safety Significance in Forward-Fitting

The changes in this area require further exploration, as will be described in the LSSIR working group's separate recommendations. However, it is expected that the determination of safety significance will be directly tied to the tenets of cost-justification, and that a mix of analyst judgment and previously developed tools will be utilized.

Other

Separate from the LSSIR working group activities, NRR Office Instruction LIC-504 is being revised. The revision may include the introduction of a new, simplified track. While there is significant symbiosis between the LSSIR efforts and the LIC-504 document/revision, the two remain distinct. Specifically, LIC-504 remains an NRR process to assess emergent plant-specific or generic issues, to guide the selection of an agency process (or processes) that are best suited for efficient resolution of an issue. Conversely, LSSIR is focused on the decision of whether to continue pursuing an issue in a given process. For this reason, LIC-504 has significant additional attention on the weighing of different regulatory processes that is not relevant to LSSIR. Even so, to the extent that the two processes should be compatible (e.g., in the operationalization of the IDM principles, use of safety significance terminology), they are.

SUBJECT: SAFETY SIGNIFICANCE BACKGROUND IN THE CONTEXT OF THE LOW SAFETY SIGNIFICANCE ISSUE RESOLUTION WORKING GROUP DATED NOVEMBER 13, 2019

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