



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 5, 2020

MEMORANDUM TO: Ho K. Nieh, Director
Office of Nuclear Reactor Regulation

THRU: John B. Giessner
Deputy Regional Administrator
Region III

FROM: Timothy A. Reed, Senior Project Manager
Plant Licensing Branch IV
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

SUBJECT: LOW SAFETY SIGNIFICANCE ISSUE RESOLUTION WORKING
GROUP RECOMMENDATIONS

Purpose

The purpose of this memorandum is to provide the Low Safety Significance Issue Resolution (LSSIR) working group's recommendations for the resolution of low safety significance (LSS) issues that arise as a result of inspection activities and proposed licensing actions. The LSSIR working group developed these recommendations based on suggestions from both internal and external stakeholders to improve U.S. Nuclear Regulatory Commission (NRC) processes so that LSS issues are promptly resolved without an excessive use of resources, thereby enabling the NRC and licensees to better focus resources on issues of greater safety significance. This memorandum also discusses training that may be necessary to implement the working group's recommendations. These recommendations do not represent official agency policy and their implementation would not alter any regulatory requirement.

Summary

This memorandum outlines the LSSIR working group recommendations on establishing a means of promptly assessing and resolving LSS issues¹ within existing regulatory processes and focusing resources on issues of greater safety significance. These recommendations can

¹ Existing regulatory processes use differing terminology with respect to safety significance, because the processes were developed at different times, by different working groups, serving different purposes, and involving differing numbers of categories that needed descriptions. In this memorandum, LSS is generally intended to mean a level of safety significance where the agency would be least likely to take further regulatory action or require additional assurance. For example, relative to processes that use a binary description of safety significance (e.g., Section 50.69 of Title 10 of the *Code of Federal Regulations*), this would be the lower categorization, i.e., safety-related and nonsafety-related SSCs that perform low safety significant functions. Relative to processes that use a tertiary (or higher) description of safety significance (e.g., Inspection Manual Chapter 0609, "Significance Determination Process," or NRR Office Instruction LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues"), LSS would be the lowest of these categorizations (i.e., findings of very low safety significance and issues of clearly low safety significance).

be implemented without the approval of the Commission, unless noted otherwise. The working group considered three categories of LSS issues: (1) LSS issues that NRC reasonably finds to be within the licensing basis (i.e., issues addressed within existing NRC compliance and enforcement processes); (2) LSS issues that NRC reasonably finds to be outside the licensing basis (i.e., issues not subject to enforcement or compliance, and if pursued are subject to the NRC's backfitting requirements); and (3) LSS issues that require significant further research to determine their licensing basis standing. Most of the recommendations address issues in the third category.

The working group engaged in communications with internal stakeholders, members of the public, and the nuclear industry. Feedback from internal and external stakeholders on the new LSSIR process was generally favorable.

Based on these efforts, the working group developed seven recommendations, which are outlined below. Some of these recommendations will require training to support the new LSSIR process (completed at the regional inspector counterpart meetings in December 2019) and the updated Office of Nuclear Reactor Regulation (NRR) Office Instruction COM-106, "Control of Task Interface Agreements," (projected for June 2020). The implementation of these recommendations will enable more efficient use of agency resources and reduce unnecessary regulatory burden, consistent with the NRC's Principles of Good Regulation.

Background

Risk-informed and performance-based approaches provide for greater focus on items of highest safety significance, enable more efficient use of agency resources, and reduce unnecessary regulatory burden. One of the goals of these approaches is to establish processes and procedures that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety or common defense and security. The Reactor Oversight Process (ROP) is one of the processes the NRC uses to accomplish this goal. The purpose of the ROP is to ensure that issues potentially impacting safety are identified, fully evaluated, and promptly addressed, commensurate with their safety significance. However, there could be more clarity in the ROP about evaluating safety significance prior to the expenditure of significant resources in evaluating an issue.

The LSSIR effort began as a task under the ROP enhancement project. Stakeholder feedback suggested that NRC should establish a process for resolving very LSS issues with a focus on addressing ambiguity in the licensing basis. Because the tasking had broader relevance than the ROP (e.g., licensing and backfitting processes), the NRR Office Director made it a separate initiative and formed the LSSIR working group in November 2018.

The working group worked closely with the Task Interface Agreement (TIA)/Technical Assistance Request (TAR) Program Revitalization working group,² as both groups had common goals regarding addressing LSS issues. The effort to date has focused predominantly on the Operating Reactor Business Line. However, the working group has membership from, or has otherwise interacted with, other NRC business lines, and understands some of these business lines to be considering similar efforts. The working group also benefited from active membership by staff in the Office of the General Counsel and the Office of Enforcement (OE).

² The TIA working group is working on a major overhaul of the TIA/TAR program contained in the Office of Nuclear Reactor Regulation (NRR) guidance, COM-106, "Control of Task Interface Agreements" (Agencywide Document Access and Management System (ADAMS) Accession No. ML15219A174).

The working group found that both the NRC staff and licensees believe that current NRR practices with respect to LSS issues, particularly arising out of circumstances where the plant's licensing basis is unclear, may lead to unnecessary regulatory burden. One such scenario occurs when NRC inspections identify issues and conditions that may be potential violations of governing requirements. However, it may be difficult to determine whether an issue is in the plant licensing basis because of lack of clarity, ambiguity, lack of detail, issue complexity, or subjectivity in interpretation. These issues can give rise to a difference in view between the licensee and the NRC as to whether the licensee is in compliance with its licensing basis. While situations like these are unusual, resolving them through the NRC's current processes can be resource-intensive, inefficient, and untimely. Past assessments also revealed that, for some licensing basis issues, the time and resources expended by both NRC and licensees have not been balanced relative to the underlying issue's importance to public health and safety.

Review Approach

The working group focused on LSS issues arising out of inspection activities and licensing reviews. LSS issues with the potential for resource expenditures incommensurate with their safety benefit can be binned into three broad categories:

- (1) LSS issues that NRC finds to be within the licensing basis with a reasonable amount of research (i.e., issues addressed within existing NRC compliance and enforcement processes);
- (2) LSS issues that NRC finds to be outside the licensing basis with a reasonable amount of research (i.e., issues not subject to enforcement or compliance, and if pursued are subject to the NRC's backfitting requirements); and
- (3) LSS issues that require significant further research to determine their licensing basis standing.

Enclosures 1, "Recommended Revisions to IMC 0612, Appendix B and IMC 0611," through Enclosure 4, "Recommended Actions for Forward Fitting," support staff recommendations described in this memorandum. Enclosure 5, "Potential Organizational Risks," describes potential organizational risks of the new LSSIR process.

LSS Issues Within the Licensing Basis

LSS issues that are clearly within the licensing basis are addressed under existing regulatory processes, as required by the Atomic Energy Act of 1954, as amended. This involves dispositioning potential violations in accordance with the Enforcement Policy. Licensees may also choose to perform corrective actions, request exemptions, or change their licensing basis through Section 50.59 or 50.90 of Title 10 of the *Code of Federal Regulations* (10 CFR). Notwithstanding these constraints, Recommendation 5 of this memorandum proposes an additional effort to determine whether such LSS issues can be dispositioned in a more efficient manner.

LSS Issues that are Outside the Licensing Basis

LSS issues that fall outside the licensing basis can be addressed under the NRC's backfitting requirements, as implemented in accordance with the policy and guidance set forth in

Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” or no action may be appropriate. In this regard, Recommendation #3, “Licensing Basis Standing Guidance” of this memorandum should assist with determining whether an issue of concern is outside the licensing basis, and as such, support determinations for when backfitting is applicable to an issue. Enclosure 2 provides guidance for these determinations.

LSS Issues that Require Significant Further Research to Determine Their Licensing Basis Standing

Most of the working group recommendations for process enhancements are for issues for which the readily-available documentation regarding the licensing basis is not sufficiently clear and that the staff has determined through an appropriate analysis to be of very LSS (as defined by the ROP). For such issues, the staff’s further evaluation of what additional regulatory action should be pursued can be discontinued, and resources can be re-assigned to activities with greater safety significance. The working group concluded that these process enhancements can be implemented in the near-term, enabling both the NRC and licensees to better focus resources on issues of greater safety significance. If an issue is found to have the safety significance to warrant additional resource expenditures, the current regulatory processes will be used.

The NRC has existing regulatory processes to determine safety significance (see Enclosure 3). Each of these processes uses a tailored approach that is founded in common risk-informed decision-making principles. Because of the maturity of existing processes, the working group recommends leveraging these processes to implement the LSSIR approach, which also reduces the training burden for staff compared to creating a new process. This approach also improves consistency between the proposed enhancements and the agency’s well-established practices.

The working group is aware of the Nuclear Energy Institute’s proposal to develop a safety significance evaluation tool specific to the LSSIR process (ADAMS Accession No. ML19218A134). Recommendation # 7, *“Add the safety significance screening process under the ongoing backfit and forward fit guidance development,”* recommends further evaluation of this proposal.

Integrating the above considerations, the LSSIR process enhancements are structured to address LSS issues when the following criteria are met:

1. The licensee has determined the issue is not within the licensing basis;
2. The NRC, after reasonable effort, has not been able to draw a conclusion on the licensee’s characterization of the licensing basis; and
3. The NRC judges that the issue’s safety significance (i.e., its impact on public health and safety) does not warrant additional resource expenditure (i.e., “very low” safety significance as defined in the ROP or the effectively equivalent terminology in other processes).

If the above criteria are met, the inspection effort for this issue would be discontinued and documented in an inspection report³.

Stakeholder Interactions

The working group held three public meetings on March 19, 2019, May 29, 2019, and August 7, 2019, to discuss the LSSIR effort and to obtain stakeholder input on its proposed recommendations. The summaries of these public meetings are provided in ADAMS (ADAMS Accession Nos. ML19074A142, ML19156A428, and ML19226A316). Stakeholders provided feedback that there is no discrete NRC process to address issues where the risk is very low, but resolving the licensing basis standing of the issue requires significant resources. The working group did not receive written comments from members of the public.

External stakeholders provided feedback that was supportive of NRC's effort to promptly assess and resolve LSS issues. There was general alignment in terms of the proposals for addressing LSS issues, however, there was a difference in view on how to best assess safety significance. The industry's view is that the process should be calibrated to demonstrating that an issue is not of high safety significance, as this approach would allow the development of a tool that can be used more rapidly and over a broader spectrum of issues. The NRC staff's view is that the process should be calibrated to showing that the issue or condition is LSS (or very LSS in the ROP terminology). This difference in perspective fundamentally changes how the process would be conducted, and specifically how the safety significance should be determined. The staff's basis for using a more limiting standard to disposition an issue of concern in terms of its safety significance is to avoid prematurely discontinuing evaluation of an issue that could result in regulatory action if it is determined to be within the licensing basis (e.g., an inspection finding under the ROP that could result in an Action Matrix input). It is the staff's view that the industry's approach would undermine the agency's approach to assessing licensee performance.

Recommendations

The working group recommends that the NRR Office Director:

- (1) *Revise Inspection Manual Chapter (IMC) 0612, Appendix B, "Issue Screening," and IMC 0611, "Power Reactor Inspection Reports" to close LSS issues early in the inspection process.*

This recommendation has been implemented via a revision to IMC 0612⁴ to include guidance on which LSS issues can be closed, and a revision to IMC 0611 to include guidance on what needs to be documented in an inspection report when an LSS issue is closed. Enclosure 1 discusses Recommendation 1 in further detail.

³ In the context of a different process (e.g., a license amendment request), the documentation would occur within the relevant process.

⁴ The NRC issued the revisions to IMC 0612 on December 12, 2019, (ADAMS Accession No. ML19247C384), and to IMC 0611 on January 7, 2020 (ADAMS Accession No. ML19317F647). These revisions went into effect on January 1, 2020, and January 7, 2020, respectively.

- (2) *Revise NRR Office Instruction COM-106, “Control of Task Interface Agreements,” to explicitly factor the safety significance into the expenditure of resources.*

The working group recommends a revision to COM-106 by developing a structured assessment of safety significance using the agency’s integrated decision-making principles, as well as supporting licensing basis determination via inclusion of the staff’s licensing basis experts, as part of the broader screening and evaluation that will occur between intake and an in-depth review. Issues of greater safety significance that warrant additional resource expenditures would proceed to the enhanced COM-106 guidance for evaluation. This effort is being undertaken by the TIA Program Revitalization working group and is projected to be completed in Spring 2020.

- (3) *Add licensing basis standing guidance into COM-106 by providing a reference to this memo.*

The working group recommends that the guidance provided in Enclosure 2 to this memo be incorporated into the next revision of COM-106 and the next revision of LIC-100, “Control of Licensing Bases for Operating Reactors.” It is the working group’s view that an underlying challenge to the staff’s implementation of backfitting requirements, the forward fitting policy, and the LSSIR process is the determination of whether a given issue or condition is within the licensing basis. Enclosure 2 provides guidance for these determinations.

- (4) *Assess the effectiveness of the LSSIR process within one year of its implementation.*

The working group recommends that NRR conduct a self-assessment within one year of the LSSIR process’s implementation to review its effectiveness.

- (5) *Establish another working group to evaluate other options for LSS issues within the licensing basis.*

The working group recommends that the NRR Office Director establish another working group to evaluate other options for disposing LSS issues within the licensing basis.

- (6) *Request OE to revise the Enforcement Manual to reduce instances where LSS issues are pursued in the absence of a clear compliance concern, and at the expense of expending resources on issues of greater safety benefit.*

The working group recommends a revision to the Enforcement Manual to clarify that not all potential compliance issues must be documented in inspection reports. A review of the Enforcement Manual revealed guidance consistent with the concept of the program office procedures providing direction for content of inspection reports.⁵ However, only one section included the guidance. OE plans to explicitly include the guidance in each relevant section in the next Enforcement Manual update.

⁵ Enforcement Manual Section 2.2.3, “Assessment of Violations Identified Under the ROP and cROP.”

- (7) *Add the safety significance screening process under the ongoing backfit and forward fit guidance development.*

Coordinate with the Office of Nuclear Material Safety and Safeguards and the Office of Nuclear Reactor Regulation to use a conceptual approach for using an LSSIR-like process to inform decisions regarding forward fits, which would provide working-level direction to the NRC staff, and in doing so, complement the higher-level guidance in Management Directive 8.4 and NUREG-1409, which are also under development. This augmented direction would foster more efficient use of NRC resources, thereby enabling those resources to be focused on issues of greater safety significance. As noted in Enclosure 4, a process that makes use of available information on costs and benefits could support more efficient decision-making when considering a backfit or forward fit.

Training

This memorandum contains several recommendations that are likely to require supporting training. Those are: (1) LSSIR in the revised versions of IMCs (Recommendation 1); (2) LSSIR in the revised version of COM-106 (Recommendation 2); (3) Inclusion of new guidance for determining licensing basis standing in the updated COM-106 and LIC-100 (Recommendation 4); and (4) Development of an LSSIR-like process to support forward fit decisions (Recommendation 7). The working group notes that training has been completed on the revised version of the IMCs which contain the LSSIR guidance and some introductory training has been completed on the updated COM-106. This training was completed at the regional December 2019 inspector counterpart meetings.

If the NRR Office Director agrees with the recommendations to implement LSSIR into backfit and forward fit decisions and include licensing basis standing guidance into COM-106 and LIC-100, then the working group recommends that the backfitting and forward fitting training to support the implementation of NUREG-1409, "Backfitting Guidelines" be updated to include the LSSIR process. In the longer term, backfitting and forward fitting training following issuance of the final NUREG-1409 would reflect the final approved LSSIR processes.

If you have any questions, please contact me at (301) 415-1462 or timothy.reed@nrc.gov.

Enclosures:

1. Recommended Revision to IMC 0612, Appendix B and IMC 0611
2. Criteria for Supporting the Determination for Whether an Issue of Concern is Within the Licensing Basis
3. Determining Safety Significance
4. Recommended Actions for Forward Fitting
5. Potential Organizational Risks

SUBJECT: LOW SAFETY SIGNIFICANCE ISSUE RESOLUTION WORKING GROUP
RECOMMENDATIONS DATED FEBRUARY 5, 2020

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ADAMS Accession No.: Package ML19311B524; Memo ML19260G224 ***via e-mail**

OFFICE	NRR/DORL/LSPB/PM*	NRR/DORL/LSPB/LA	NRR/DRA/APOB*	NRR/DIRS/IRGB/BC*	OE/HQAT/AC*
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DATE	9/26/19	9/24/19	9/24/19	9/24/19	9/24/19
OFFICE	NRR/DORL/LSPB/PM*	NRR/DSS/SCP/BC(A)*	NRR/DSS/SCP/BC*	RI*	RIII*
NAME	BVenkataraman	SJones	SAnderson	EDiPaolo	KStoedter
DATE	9/25/19	10/1/19	9/25/19	9/26/19	9/25/19
OFFICE	RIV*	OE*	OGC (NLO)*	RIII/DRA*	NRR/DORL/LPL4/PM*
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The working group recommends that IMC 0612, Appendix B, "Issue Screening," and IMC 0611, "Power Reactor Inspection Reports," be updated to reflect how issues may be evaluated, documented and closed out using the LSSIR process.¹

The LSSIR process may interface as appropriate with the Office of NRR Office Instruction COM-106, "Control of Task Interface Agreements," which is currently undergoing a revision to, among other things, enhance the screening process for potential Task Interface Agreements (now denominated Technical Assistance Requests).

Screening LSS Issues in Inspection

If the question as to whether an issue is within the licensing basis cannot be resolved without a significant level of effort, then the issue may be closed as part of the very LSSIR process. This process can be used if all of the following are met:

- The licensee has determined, with an explanation, that the issue of concern is not in their current licensing basis;
- The inspector (using the resource estimate in the applicable inspection procedure as a guideline, which may involve NRC Headquarters support) has not been able to determine that the issue of concern is part of the plant's licensing basis;
- The issue (if it were assumed to be an inspection finding) would have insufficient safety significance to warrant additional resource expenditure (very low as defined in the ROP²). The inspector determines that the issue has insufficient safety significance by processing the issue using IMC 0609, "Significance Determination Process," and if the issue does not proceed to a "detailed risk evaluation," or a Phase 2 evaluation when relevant, or Appendix M, then the issue would have insufficient safety significance; and
- The inspector's Branch Chief concurrence that spending more time researching the current licensing basis is not likely to benefit public health and safety relative to other inspection activities.

Documenting LSS Issues

The purpose of documenting the resolution of an LSS issue is to record the agency's decision regarding whether additional resources will be used to determine if an item is part of the licensing basis. This documentation should also mitigate the potential for a future inspector to re-inspect the same LSS issue when no additional information has been identified to change the agency's decision. This documentation is not intended to be a final closure of the issue. If additional information becomes available, then the issue may be re-opened. Inspectors should consult their division leadership before spending inspection resources on issues previously closed through the LSSIR process at that site.

¹ The NRC issued the revisions to IMC 0612 on December 12, 2019, (ADAMS Accession No. ML19247C384), and IMC 0611 on January 7, 2020 (ADAMS Accession No. ML19317F647). These revisions went into effect on January 1, 2020, and January 7, 2020 respectively. These revisions were done in parallel with the development of this memorandum.

² Definition from IMC 0609, "Significance Determination Process," Section 04.02d.

If the above conditions are met, document as:

- "In accordance with IMC 0611-12, "Minor Performance Deficiencies, Minor Violations, Observations, Assessments, and Very Low Safety Significance Issues""; or
- "In accordance with IMC 0611-06, "Unresolved Items," if an Unresolved Item (URI) was previously opened on the issue and now requires to be closed."

The documentation must include:

- A statement that the very LSSIR process is being used to document the issue;
- A brief description of the issue;
- A description of relevant information on the licensing basis developed during the inspection process;
- How the issue was determined to be of very LSS, the recommendations of the updated COM-106 guidance, if applicable; and
- The condition report number if the licensee entered the issue into its corrective action program.

The following guidance is intended to support NRC staff efforts to determine whether an issue of concern is within the existing licensing basis, and therefore subject to compliance, or not within the licensing basis, and therefore possibly subject to backfitting if safety significance warrants such action.

The licensing basis for a nuclear power reactor consists of three categories of information: obligations (also referred to as regulatory requirements), which include regulations, orders, and the license; mandated licensing basis documents (e.g., the updated final safety analysis report, quality assurance program); and regulatory commitments.

The licensing basis changes over time, due both to the changes in the governing requirements, as well as changes to that portion of the licensing basis that provides the means by which the licensee complies with the governing requirements. It is important therefore to ensure that the existing licensing basis is used in these determinations. An issue of concern may involve an aspect of the licensing basis that was originally addressed decades ago. The key is to determine whether that portion of the licensing basis has stayed the same or changed since that time to ensure that a proper determination is made.

Fundamentally, for an issue of concern to be within the licensing basis, it must fall within this set of existing licensing basis information. The criteria that follow are intended to assist in making that determination. Note that this discussion reflects power reactors licensed under Part 50, and the concepts remain the same for Part 52.

Governing Requirements

The first two criteria below focus on the proper understanding of the governing requirements. At a high level, this is about determining which Commission requirements are in effect and applicable. The governing requirements are found in the statutory requirements of the AEA as amended and other applicable laws; NRC regulations in Title 10 of the *Code of Federal Regulations* (CFR); the license, including the technical specifications; applicable Orders; exemptions from the regulations; and approved relief requests from the requirements in 10 CFR 50.55a. The key here is to understand the meaning and intent of the governing requirement as understood at the time of the relevant approval.

- (1) If the governing requirements reside in the CFR, then the meaning and intent of those requirements is established when the regulation was issued as a final rule. It is important to understand to what extent the new requirement applies to the specific licensee, recognizing that new requirements are not always backfitted, in whole or in part, on existing licensees. The meaning for the requirement is established by the Commission. If the plain language of the requirement does not resolve the specific licensing basis question, the requirement can be interpreted by examining its context in the CFR, or the Statements of Consideration associated with the final rule (the Statements of Consideration associated with the proposed rule may also be informative). This interpretation can be further informed by any guidance that was issued at the time as providing an acceptable means for compliance with the new requirement. Guidance provides one acceptable means for compliance with the requirement and can provide insights into the understanding of the meaning of the requirement. OGC should be consulted on questions of regulatory interpretation.

- (2) If the requirement is in the license, including a license condition and the TSs, or a license modification imposed by an order, then it should be possible to determine the meaning and intent from the supporting information. The supporting information could include the license application and supplements, in conjunction with the associated safety evaluation or safety evaluation report as applicable. If the governing requirement concerns a TS, then supporting information may be found in a supporting NUREG (if it involves a standard TS amendment). If the governing requirement is in an order, then the order and its attachments should provide information that enables an understanding of the order requirements.

Supporting Licensing Basis Information

In many cases the issue of concern involves the supporting information in the licensing basis that describes the means by which the licensee meets or complies with the governing requirements. This information is typically provided to the NRC initially during licensing for review and approval, and then can change over time due to either licensee changes in accordance with change control requirements (e.g., 10 CFR 50.59), or due to changes that result from NRC reviews and approvals (e.g., 10 CFR 50.90).

- (1) The issue of concern should fit within the existing known and established standards that are currently applicable to the issue and reflect NRC review and approval. Additionally, the licensee could have, on its own volition, adopted later standards and guidance that are now applicable and constitute the current licensing basis applicable to the issue of concern. The General Design Criteria are high level criteria that are used by applicants to propose principal design criteria (some of which are also high level), which are in many cases translated into much more detailed codes and standards that are then used to design the facility. This design was described in the applicant's preliminary safety analysis report, which the Commission reviewed and approved to issue the construction permit. When the principal design criteria reference or are implemented through more detailed codes and standards, the interpretation of the licensing basis is likely to focus on the wording of a referenced standard from the Institute for Electrical and Electronics Engineers, American Society of Mechanical Engineers, American Nuclear Society, vendor engineering standard, or, if applicable, the regulatory guide (RG). If an issue relates to a technical standard, such as an Institute for Electrical and Electronics Engineers, American Society of Mechanical Engineers, American Nuclear Society, or vendor engineering standard, or an RG, the staff should consider whether the licensee has a regulatory requirement to follow that standard. If so, the staff should consider which version of the standard the licensee committed to use.
- (2) The issue of concern needs to align with the facts, supporting analyses, or inferences from those facts or analyses that were used as the means for compliance, at the time of approval as reflected in the existing licensing basis. To judge whether this is the case, the standards and practices (for implementation or compliance with the governing requirement) that were prevailing at the time of approval in the relevant technical area should be consulted. While RGs and standards provide guidance acceptable to meet regulations, there is typically a more detailed engineering analysis. It is likely that the same, or very similar, analysis or calculational approach was used within the industry at the time that the NRC (or Atomic Energy Commission (AEC)) reviewed and approved the submittals that implemented the RG. This set of information would likely provide the facts, supporting analyses, and inferences from those analyses.

- (3) The understanding of what constitutes proper implementation of the regulations, standards, and practices must be “widely known or understood by professionals in the relevant technical area,” and reflect the practices at the time of approval. For example, the oldest issues will likely be issues that were addressed by one of the four nuclear steam supply system vendors or the major architect/engineering firms in the industry. The “widely accepted practice” would be the AEC’s or NRC’s acceptance of these standard analyses and calculations (i.e., as the accepted practice) as discussed above in Criterion # 2. However, if the issue of concern involves a new and novel approach to addressing an issue, that was not used at the time, or an engineering insight that was not understood at the time, then it would not fit within the widely accepted practices that were used to implement the known and established standards from that time period for that aspect of the licensing basis. This new approach would reflect new understanding and insights that may be important to safety but would not be something that is within the licensing basis (i.e., if significant, it may warrant consideration under backfitting).

Conclusion

In short, the approval of the means by which the licensee complies with, or implements, the governing requirements in the licensing basis is constrained by what was known and understood when the existing licensing basis was established (including the standard practices used at the time). The requirements that govern the applicable portion of the licensing basis are those that are in effect and applicable, based on the meaning of those requirements. While it can be very informative to understand the history of an issue and its evolution, it is key that the licensing basis used to make the determination reflects the existing licensing basis.

If an issue of concern involves information, insights, methods, or a meaning of a governing requirement that is outside of these criteria, then the issue, while it may be important to pursue from a safety perspective, is not within the existing licensing basis.

This enclosure provides an overview of safety significance within the context of the LSSIR process. It provides some contextual information, as well as a brief safety significance discussion for each programmatic area where the LSSIR working group recommends modifications. A greater level of detail is provided in a separate LSSIR product, which can be found at Agencywide Documents Access and Management System (ADAMS) Accession No. ML19311B590.

External Stakeholder Input on Significance Determination in LSSIR

External stakeholders provided feedback on safety significance related to the approach being recommended under the COM-106, “Control of Task Interface Agreements,” process, as follows:

- Allowing multiple approaches for each integrated decision-making (IDM) element could result in differing outcomes depending on the user’s selection;
- Leveraging results from application of Section 50.69 of 10 CFR is complicated by that program’s use of relative risk measures (i.e., measures of how SSCs rank against one another);
- There is confusion about how the process would handle issues like security and emergency preparedness;
- The staff should consider a recently available Electric Power Research Institute report on IDM concepts⁸;
- The feedback step could become a driver for not fully dispositioning issues; and
- The issue should be looked at through the lens of “not high” instead of “clearly low” (or “very low” in ROP assessment).

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 ultimately rejected, as described in the following section. Additional feedback will be sought, as appropriate, within the context of implementing the individual recommendations.

The industry also proposed an approach to addressing issues, via a presentation available at ADAMS Accession No. ML19149A230, and it later augmented this proposal with a draft White Paper available at ADAMS Accession No. ML19218A134. The Nuclear Energy Institute (NEI) proposed 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. Safety 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

⁸ A Framework for Using Risk Insights in Integrated Risk-Informed Decision-Making. EPRI, Palo Alto, CA: 2019. 3002014783.

concern was voiced by NRC staff that the qualitative nature of the tool would lead to subjective rather than objective decision-making, 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 safety 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 direction to assess if there were improvements to be made in the area of dispositioning LSS 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 this approach could not be broadly incorporated because it would be more likely to lead to the NRC prematurely discontinue effort on issues of potential safety significance, or 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 could spend exploring the issue could 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 LSS. This refers to the ability to make more rudimentary assumptions in the analysis, due to the higher acceptance threshold.

One potential means of incorporating this feedback, which the staff is continuing to consider (e.g., in the specifics of how LSSIR concepts are introduced in to the COM-106 update), is to accommodate three possible outcomes: (i) clearly low, (ii) clearly high, or (iii) somewhere in-between. As the licensing basis standing is better understood through additional investigation (e.g., through the updated COM-106 process), it might be possible later in a given 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 licensing basis), especially in light of recent Commission direction with regard to backfitting and forward fitting. At that point, a higher screening threshold (e.g., NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission”) could be applied, akin to the thresholds that would need to be met to pursue a backfit. The main cons associated with using three outcome categories 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).

The Staff’s Guiding Principles

The following guiding principles frame the working group’s pursuit of enhanced consideration of safety significance:

- 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 clearly (or very) LSS 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.;
- 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 safety 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 each programmatic area.

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, 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 the licensing basis is verified, and licensing basis capabilities are being maintained. Nevertheless, the existing inspection approach can sometimes result in NRC staff resource expenditures, as well as licensee resource expenditures, being incommensurate with the actual safety significance of the identified issue.

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 paragraph 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 LSS, 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. These include: (i) taking care to not imply that an SDP is being conducted, but rather that the tools associated with SDP are being utilized, (ii) addressing the fact that an SDP evaluation is performed to assess the safety significance of a specific performance deficiency within a specific cornerstone of the ROP, and (iii) addressing the difference in context when identifying the actual impact on the plant's response to accident sequences. Each of these are discussed in greater detail in the aforementioned separate working group product.

Despite all of the above considerations and challenges, the actual implementation is fairly straightforward. 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 LSS (using the IMC-0609 parlance). Some issues may be too poorly defined and understood at this stage of the lifecycle to be efficiently characterized in this way. If this is the case, the new TIA/TAR process could be used.

Safety Significance in the TIA/TAR (Office of 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 clearly of LSS, so as to inform whether additional staff resource expenditures associated with an in-depth response to the request would be commensurate with the issue's safety significance.

The worksheet is designed to assess an issue that:

- has been considered within the appropriate existing processes;
- has received a due diligence level of effort to date (e.g., tens of hours);
- is likely to need a significant additional resource expenditure to disposition (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., on the order of 10 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.

Safety Significance in Enforcement

There are currently no planned changes regarding how safety significance is assessed in this area.

Safety Significance in Forward-Fitting

The changes in this area require further exploration, as described in the associated enclosure. 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.

Safety Significance in Licensing

There are currently no planned changes regarding how safety significance is assessed in this area.

Recent Commission direction provided in Staff Requirements Memorandum (SRM)-SECY-18-0049, "Management Directive and Handbook 8.4, 'Management of Backfitting, Issue Finality, and Information Collection'" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19149A294), established a new policy governing "forward fitting." Forward fitting is defined as imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. This policy has the potential to increase the number of instances in which a regulatory analysis (RA) (a form of cost benefit analysis) would be required to support licensing actions. For example, under this new policy, a RA would be required for a forward fit that does not involve adequate protection.

While development of the staff guidance to implement the Commission's recent direction on forward fit is ongoing, the purpose of this enclosure is to recommend development of instructions the staff could use in screening the potential safety significance of potential forward fits using LSSIR principles to determine whether the forward fit is warranted before beginning to prepare an RA,⁹ which can be resource-intensive. This is intended to complement NUREG-1409, currently undergoing revision to align it with the revised MD 8.4, and potentially provide a means to support judicious use of resources for forward fit decisions.

The first two steps in evaluating a forward fit are to determine whether the imposed NRC conditions:

- (1) have a direct nexus to the licensee's request; and
- (2) are essential to the staff's determination of the acceptability of the request.

If the above criteria are met, the staff would then need to estimate the costs and benefits associated with the contemplated forward fit, which would be documented in an RA, to demonstrate that the benefits of this change outweigh the costs.

To provide an early indication of whether the proposed staff conditions may be cost beneficial, a preliminary estimate of the costs and benefits is needed. These estimates should be quantitative to the maximum extent possible. However, at this early screening stage sufficient data may not be available such that some elements may need to be evaluated qualitatively or semi-quantitatively based on previous cost benefit analyses for nuclear power plants performed as part of the license renewal process (i.e., the Environmental Report Severe Accident Mitigation Alternative (SAMA) analysis), the staff's NUREG-1437 Environmental Impact Statements, and cost benefit analyses (e.g., backfit analyses and regulatory analyses) used to support rulemakings and other regulatory activities.

⁹ More information on regulatory analyses can be found in NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Draft Report for Comment."

It is envisioned that staff will bin the benefits of a proposed forward fit as follows:

- “Significant” benefits:
 - the change would result in public health and safety benefits that, if monetized, would equate to 1 million dollars;
 - the change would result in benefits (safety or security) that are not quantifiable, but are on par with past safety improvements that were promulgated;
- “Modest” benefits: the change does not meet the above criteria, but does have associated benefit that is clearly discernible; or
- “Insignificant” benefits: the change has no (or little) discernible benefit to public health and safety.

The staff could use several approaches for binning the benefits:

- (1) The first approach would be for the agency to develop and implement a tool to assess safety significance based on answering questions about failure modes, likelihood, consequences, and related factors. For example, the NEI proposed the development of a safety SSET specific to the LSSIR process. The early development of the tool was described in a draft White Paper (ADAMS Accession No. ML19218A134), submitted in conjunction with an August 7, 2019, public meeting. The NRC, potentially working with NEI, would need to further develop this concept and the aforementioned tool.
- (2) The second approach would be to utilize the results of past cost benefit analyses (Severe Accident Mitigation Alternatives (SAMA) analyses, regulatory analyses, and backfit analyses) to develop a perspective on the potential benefits by analogy (i.e., identifying a similar regulatory action for which a cost benefit analysis was performed). In some respects, this would be similar to the way that the NRC evaluated potential safety enhancements under the Near-Term Task Force (NTTF) Recommendation 2.1 seismic reevaluations. In that case, a spreadsheet tool was developed to leverage past SAMA evaluations in determining the potential maximum benefits associated with seismic-related impositions, so as to guide decisions about whether to proceed with regulatory analyses. The tool developed is described in a publicly available August 29, 2017, memorandum (ADAMS Accession No. ML17146A200), and provides a useful template for the development of some aspects of the tool envisioned here.
- (3) The third approach would be to utilize the agency’s risk tools (e.g., Standardized Plant Analysis Risk models) to directly quantify the change in risk (via quantification of risk surrogates such as core damage frequency), along with past analyses to correlate these core damage surrogates to monetized benefits (again, potentially using the recent NTTF 2.1 tool as a template).

Based on their experience and judgment, the staff will bin the proposed forward fit into one of these three categories. In making these judgements, the staff would consult the aforementioned sources of cost benefit information or may discuss their estimates with their supervisor or an NRC regulatory analyst, as necessary.

Separately, the staff would bin costs into one of three categories:

- “High” costs such as: changes requiring a moderate to extensive plant modification (notionally greater than 1 million dollars);
- “Medium” costs such as: changes requiring a narrowly scoped plant modification (notionally between 500,000 and 1 million dollars); or
- “Low” costs such as: procedural changes (notionally less than 500,000 dollars).

Table 1 shows how the above determinations would then be translated into a recommendation to NRC management.

Table 1: Screening Concept for Formulating a Recommendation to Management

Benefits	Costs	Recommendation to NRC Management
Insignificant	N/A	Stop work. Forward fit cannot be justified.
Modest	High	
	Medium	Proceed with RA and forward fit justification. Stop work if the RA shows change is not cost-beneficial or if forward fit cannot be justified.
	Low	Proceed with the RA and forward fit justification
Significant	High	Proceed with the RA and forward fit justification. Stop work if the RA shows change is not cost-beneficial or if forward fit cannot be justified.
	Medium / Low	Proceed with the RA and forward fit justification.

The outcome would be a clear and defensible basis for whether additional resource expenditure is warranted, having factored in the issue’s safety significance.

This enclosure provides an overview of potential organizational risks of the LSSIR process. The organizational risks are as follows:

- (1) *If the determination made in the inspection process about a plant's licensing basis is wrong and the issue is later determined to be in the licensing basis, what would be the impact?*

The significance screening tool that already exists (and is well-known and trained on by inspectors) would be applied as if the issue is a violation. With a "very low" safety significance threshold, it is unlikely higher risk items would have been inadvertently screened through. Therefore, the risk is that some LSS compliance items may have been missed and not corrected. Because these would be very low in safety significance, no strategy is needed to mitigate the organizational risks.

- (2) *The new process could have many items processed through the LSS section of the Reactor Oversight Process.*

The concern could occur if licensees begin defaulting to stating that an issue is not in their licensing basis without doing enough research on their licensing basis. This would place the burden more on the NRC to resolve the licensing basis question. Additionally, this would negate the idea of being more efficient in use of agency resources and negate the goal to reduce unnecessary burdens to licensees. This could also create a concern about the cumulative significance of numerous very LSS issues. In addition, this may occur as NRC inspectors and licensees work through the new LSSIR process.

In discussions with the staff and licensees, there needs to be a good-faith effort on the part of both parties to use the process judiciously. Because this could have a negative effect on resources by all stakeholders, this requires training and information rollout to all staff, as well as roll out to the industry. A self-assessment should take place within one year of the implementation of the LSSIR process to review its effectiveness. NRC management discussions with the licensee will need to occur if a licensee attempts to overuse the LSSIR process.

- (3) *The new process could have very few items processed through the LSS section of the ROP.*

This would defeat the purpose of having the LSS section. This could occur because NRC inspectors and supervisors in the Regions work through the new LSSIR process but may be reluctant to pursue items. A roll-out and training would mitigate this concern. However, similar to item 2 above, there needs to be a good-faith effort on the part of staff and licensees to use the process judiciously. In addition, the screening tool is at a very low threshold, so if questions exist, inspectors may not have enough information to reasonably say the safety significance is "very low," and the items may be passed to the new TAR process. The intent is not to create another process hold point. For this reason, both the TAR process and LSSIR process should be issued together. This also requires a roll-out strategy, which may include real time discussions with inspectors, Senior Reactor Analysts, members of the public, and industry, as needed.