



**OFFICE OF NUCLEAR REGULATORY RESEARCH**  
**RES OFFICE INSTRUCTION**

Office Instruction No.	<b>TEC-002, Revision 3</b>	<b>Approved by: Ray Furstenau</b> <b>Date: July 17, 2019</b>
Office Instruction Title	<b>Generic Issues Program</b>	
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Responsible Division	<b>RES/DE</b>	
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Training	None	
<p><b>SUMMARY OF CHANGES:</b> This revision to TEC-002, "Generic Issues Program," updates the office instruction to conform with Management Directive 6.4, "Generic Issues Program," dated January 2, 2015, and to incorporate lessons learned from reviews of generic issues. Management Directive 6.4 and TEC-002 incorporate enhancements identified in an assessment by an agency interoffice review team, "Completion of Generic Issues Program Tiger Team Activities," dated October 24, 2013 (ADAMS Accession No. ML13296A417). Revisions include (1) program simplification by reducing the number of stages from five to three, (2) increased management involvement and accountability, and (3) new guidance to identify and act on immediate safety concerns and document the justification for ongoing operation.</p>		

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## Generic Issues Program

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### 1. PURPOSE

This office instruction (OI) provides guidance for the project management of the U.S. Nuclear Regulatory Commission's (NRC's) Generic Issues (GI) Program, a function of the Regulatory Guidance and Generic Issues Branch within the Office of Nuclear Regulatory Research (RES). This OI provides guidance for processing GIs through each stage of the GI process, as well as tracking and reporting. This guidance supplements the instructions and requirements in Management Directive (MD) 6.4, "Generic Issues Program," dated January 2, 2015.

### 2. BACKGROUND

MD 6.4 delineates the requirements for the NRC's program for addressing GIs and unresolved safety issues (USIs). MD 6.4 describes the overall agency policy, responsibilities, and legal basis. MD 6.4 also specifies the objectives for the GI Program and the roles and responsibilities of the staff. The MD 6.4 Handbook introduces the GI Program, including an historical perspective, purpose, definitions, criteria, principles, and goals. The MD 6.4 Handbook also provides an overview of the three-stage process for GIs: (1) Screening, (2) Assessment, and (3) Regulatory Office Implementation (ROI). As MD 6.4 specifies, RES is responsible for overall GI Program management.

### 3. DEFINITIONS

MD 6.4 provides a glossary of terms for the GI Program.

### 4. RESPONSIBILITIES AND AUTHORITIES

MD 6.4 identifies the organizational responsibilities of the GI Program.

### 5. INSTRUCTIONS

These instructions are intended to provide specific guidance to the staff for processing a GI through the three stages of the GI process. The instructions explain the process and provide guidance for tracking and managing the GIs as they transition through the stages.

The relative complexity of each GI may warrant some variation or modification in the execution of specific steps. As stated in MD 6.4, the staff should use a graded approach to the rigor applied during the generic issues process. The extent of review effort should be commensurate with the GI's potential risk significance. The RPM can request an initial risk determination from the RES Division of Risk Assessment to help in determining the risk significance. The appropriate amount of process rigor for GI screening and review panels depends on risk significance, importance, or applicability of the GI, thereby reducing the process burden for processing GIs of lower risk significance. The GI program staff can use this risk determination to screen out GIs of low risk significance or importance without using a formal review panel. Complex GIs or those with potentially high risk significance will warrant formal and sometimes extensive reviews, thereby requiring a review by expert panel members. The value added from expert panel meetings (e.g., group synergy and open debates) varies with GI risk significance and

## Generic Issues Program

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uncertainty. Formal panel meetings add less value when there is a lower risk significance, importance, uncertainty, or large safety margins for error tolerance. In cases of moderate risk significance or importance, virtual panel meetings by teleconference, electronic mail, or other methods that do not require the physical presence of all of the panel members in the same room at the same time may suffice. More process rigor and resources are applied as an issue proceeds through each GI Program stage.

The GI Program uses a consistent approach to correspondence and program reports to gain efficiencies and effectiveness in communicating with internal and external stakeholders. Appendix G, "Examples of Generic Issues Documents and Generic Issue-related Web Sites," to this OI lists example correspondence and program reports that are on the GI Program SharePoint site, as well as links to program information on GI-related Web sites.

An important function of the GI Program is to identify the NRC regulatory office most suitable to address the issue. The GI Program staff solicit management support for allocating resources to evaluate and disposition the proposed GI to reach a consensus on the appropriate regulatory office to address the issue. It is expected that GIs will be processed in an open and collaborative work environment.

Anyone can propose a GI. Identification of an issue is primarily accomplished outside the program. Originators, whether a member of the public or NRC staff, can submit a proposed GI into the GI Program using the online GI proposal form on the NRC public Web site, which automatically sends an e-mail to [GIP.Resource@nrc.gov](mailto:GIP.Resource@nrc.gov), notifying all GI Program staff members of the submittal. Originators can also print and mail the GI proposal form through the U.S. mail. In addition, NRC staff can send an interoffice memorandum to submit a GI. The GI Program staff will assist the originator as needed. Before submitting a proposed GI, NRC staff and management are encouraged to contact the GI Program staff for assistance in determining whether the proposed GI is in fact a candidate for the GI Program and thus meets the criteria to continue through the GI Program.

Once an individual submits a proposed GI, the GI Program Manager and GI Program staff inform RES management of the proposed GI and begin Stage 1, "Screening," of the GI process.

### **5.1 Stage 1—Screening (target for completing screening is 9 to 18 months)**

The purpose of the Screening stage is to evaluate whether the proposed GI meets all seven screening criteria, as described in MD 6.4 and provided in Appendix A, "Screening Criteria," to this OI. The proposed GI must meet all seven criteria in order to proceed to Stage 2, "Assessment." If the proposed GI does not meet the criteria, then it should exit the GI process. The GI Program staff can use the following steps to process the proposed GI.

#### **5.1.1 Steps to Process the Receipt of a Proposed GI**

### **Generic Issues Program**

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1. Upon receipt of a proposed GI, whether from the public or NRC staff, the GI Program Manager assigns a responsible project manager (RPM) from the GI Program staff in the Regulatory Guidance and Generic Issues Branch.
2. The RPM can reject proposed GIs back to the submitter which are obviously not candidates for the GI program, (e.g., request for information, worker harassment claims, personnel safety issues, etc.).
3. The RPM initiates a memorandum (letter if from a member of the public) from the GI Program Manager to the originator acknowledging receipt of the issue. At any time, the RPM may contact the originator to request clarification or additional information about the issue.
4. The RPM enters the information from the proposed GI into the Generic Issues Management Control System (GIMCS) and assigns a tracking number (e.g., PRE-GI-0##). The GI Dashboard is used as the database for the GIMCS.

#### **5.1.2 Steps to Review for an Immediate Safety Concern**

1. The RPM forwards the proposed GI to the appropriate regulatory office point of contact to evaluate whether the proposed GI is an immediate safety concern. The RPM requests an immediate safety concern determination through an e-mail and telephone call directly to the regulatory office point of contact, then the RPM follows up with a corresponding memorandum from the GI Program Manager to the regulatory office point of contact to document the activity.

For GIs related to the Office of Nuclear Reactor Regulation (NRR), the RPM coordinates resources through the NRR Division of Licensing Projects. For other offices, the RPM coordinates with the GI Program point of contact for that office. A list of office contacts is maintained on the GI Program SharePoint site.

2. The regulatory offices follow their respective OIs to determine whether the GI is an immediate safety concern (e.g., NRR follows OI LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues").
3. If the regulatory office determines that the proposed GI is an immediate safety concern, the GI Program Manager immediately transfers the proposed GI to that regulatory office so it can be addressed using the appropriate regulatory process.
4. If the proposed GI is transferred to a regulatory office, the GI Program Manager sends a memorandum to the originator stating that the proposed GI has exited the GI process and that the appropriate regulatory office is dispositioning the issue.
5. If the regulatory office determines that the proposed GI is not an immediate safety concern, then the regulatory office responds by memorandum to the GI Program Manager, documenting the basis for this determination and stating why the potentially affected facilities may continue to operate despite the proposed GI. The memorandum should also include the following:

### Generic Issues Program

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- a. Characterization of the safety and risk significance, the basis for determining there is no immediate safety concern, and the justification for ongoing operation (JOO) of the facilities while the staff is assessing the issue (may include circumstances that exist or compensatory measures that are in place)
- b. Timeframe that the justification for ongoing operation is appropriate for the potentially affected facilities, assuming there are no additional compensatory or remedial actions that are implemented (typically the duration of the assessment stage of the GI process)
- c. Potential impact on a nuclear facility if the safety issue identified in the proposed GI occurs (e.g. core damage, containment breach, etc.).

Note: If the RPM identifies information at any time while the proposed GI is in the GI process that invalidates or is contrary to the basis of the immediate safety concern determination, then the RPM shall immediately notify the appropriate managers in the responsible office and follow up with a memorandum from the GI Program Manager addressing the situation.

#### 5.1.3 Steps to Perform an Initial Review

1. Concurrently with sending the proposed GI to the regulatory office for a determination of immediate safety concern, the RPM reviews the proposed GI to determine whether it is an allegation or a physical security issue, thereby requiring immediate action.

If the proposed GI is an allegation or a physical security issue, then the RPM takes immediate action to coordinate with the GI Program Manager to transfer the proposed GI to the NRC Office of Enforcement or Office of Nuclear Security and Incident Response, respectively.

- a. If the issue is referred to the Office of Enforcement or the Office of Nuclear Security and Incident Response, the issue typically exits the GI process. However, the Office of Enforcement or the Office of Nuclear Security and Incident Response may request that the proposed GI continue in the GI process for tracking purposes.
  - b. If the issue exits the GI process, the RPM will draft a closure memorandum for GI Program Manager signature to the originator, explaining why the issue was closed.
2. The RPM performs a literature search of the issue, particularly within NUREG-0933, "Resolution of Generic Safety Issues," to verify that the issue has not already been resolved within the scope of previous GIs.
  3. If the proposed GI is not an allegation or physical security issue, and has not already been resolved, the RPM will draft an acceptance memorandum for GI Program Manager signature to the originator, acknowledging receipt of the issue,

### Generic Issues Program

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assigning a PRE-GI number, and explaining that the first step in the GI process is a quick screening to determine whether the issue meets all seven screening criteria.

#### 5.1.4 Steps to Perform a Quick Screening

1. After the initial review, the RPM performs a quick screening of the proposed GI against the seven screening criteria (see MD 6.4 and Appendix A to this OI) to determine whether any criteria are obviously not met.
2. The RPM also identifies potential challenges in assessing the GI to determine whether the screening and assessment can be completed within the GI process timeliness guidelines in MD 6.4. The timeliness issue is specifically addressed in Criterion 5 of the seven screening criteria, which states that the issue's safety or risk significance can be adequately determined in a timely manner.

Per MD 6.4 the target for completing the screening is 9 to 18 months, and the target for completing the assessment is 1 to 3 years. If the RPM determines that an excessive amount of time is necessary to perform extensive research to resolve the issue, the RPM may propose the GI exit the GI process. At management's discretion, the GI can be closed in order for appropriate RES division can further study the issue. Subsequently a work request will be submitted to evaluate the proposed issue in accordance with PRM-001, "Process for Responding to Work Requests: Informal Assistance, Research Assistance, User Needs, and Research Plans." After the additional research is performed, the safety issue is re-evaluated. If a safety issue still exists, then the issue should be re-submitted into the GI program for screening and assessment as a new GI.

3. If the quick screening finds that the proposed GI appears to meet all seven screening criteria, the RPM initiates the process of forming a Generic Issues Review Panel (GIRP) to perform a more comprehensive, detailed evaluation of the issue against the screening criteria.
4. If the quick screening finds that the proposed GI fails to meet all seven screening criteria, the RPM drafts a memorandum of nonacceptance for GI program manager signature to the originator, describing this determination and explaining why the proposed GI exited the GI process.
5. The immediate safety concern review, the initial review, and the quick screening should be completed within 6 months of initial receipt of the proposed GI.

#### 5.1.5 Steps for Assembling a Generic Issues Review Panel

1. The RPM initiates an informal communications with appropriate regulatory offices to identify possible staff members to serve on a GIRP. Then the RPM formally coordinates with the appropriate regulatory office(s), any internal stakeholders, and the GI Program Manager to determine the number of panel members, needed expertise, and the chairman.

### **Generic Issues Program**

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- a. The GIRP normally consists of at least three staff members, with a Senior Executive Service manager as the chairman.
  - b. The chairman should be from the regulatory office that would likely receive the issue during Stage 3, "ROI." The chairman may, but not necessarily, be from the division that would be responsible for the issue during the ROI stage.
  - c. The GIRP should include staff from the regulatory office that would likely receive the issue during the ROI stage as well as any other affected regulatory offices. The GIRP should also include staff from RES that would be involved in the Assessment stage. The GIRP can also include staff from the originating office.
  - d. A typical GIRP includes a risk expert, a subject matter expert, a systems specialist, the RPM, and the chairman. The GIRP members are selected to provide expert, but broad and diverse, perspectives on the GI.
  - e. The GI Program Manager may elect to augment the composition of the GIRP for more complicated issues.
2. The GI Program Manager sends a memorandum to the appropriate regulatory office(s) requesting staff members to serve on the GIRP.
  3. The appropriate regulatory office(s) should respond within two weeks, through a memorandum, identifying the members of the GIRP, including the chairman.

#### **5.1.6 Steps for GIRP to Perform Screening Evaluation**

1. The GI Program Manager establishes an appropriate timeframe and milestones for evaluating the proposed GI based upon its urgency, complexity, and management discretion.
2. The GIRP chairman decides upon the degree of formality of the GIRP's proceedings. It will depend largely on whether the panel members can reach a decision that is clear, without large uncertainties, and with consensus of all the members. Any member opinions which differ from the panel consensus should be noted in the screening report.
3. The GIRP's first task is to perform a detailed evaluation to determine whether the proposed GI satisfies all seven screening criteria in order to recommend whether the proposed GI should continue to the Assessment stage.
4. The GIRP's screening recommendation should identify if any other agency programs or processes are required to support further assessment of the issue.
5. The GIRP collects information to assess the proposed GI against the screening criteria, as appropriate. If needed, the RPM can contact the originator to obtain additional information.

### Generic Issues Program

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6. The screening evaluation typically includes a literature search and a review of previous related GIs, using the results of the RPM's efforts during the quick screening.
7. The RPM tracks and documents the completion of any screening milestones. The RPM monitors the GIRP's activities to ensure the focus remains on the issue and avoids scope creep.
8. The GIRP prepares a detailed screening analysis, and all members concur (any non-concurrence should be noted in the screening report).
9. The GIRP screening report should include the following, as applicable:
  - a. A detailed definition of the scope of the issue and affected facilities—the scope can include multiple facility types and should consider the implications on different types of reactors and other licensed facilities; the GIRP may create separate issues if deemed more appropriate
  - b. The basis for excluding any NRC-regulated facilities that the issue may or may not affect (e.g., fuel fabrication/enrichment facilities)
  - c. A limited scope evaluation of the potential safety or risk significance of the issue, based upon information and resources available; a best-estimate projective risk may be qualitative or quantitative assessed
  - d. If the GIRP recommends the proposed issue proceed to the Assessment stage, the report should also include:
    - i. Suggested milestones for completing the assessment in a time frame specified in MD 6.4
    - ii. A justification for ongoing facility operations are safe to continue while the GIRP completes the formal assessment.
10. The GIRP applies a “graded approach,” as defined in MD 6.4, to perform the screening analysis. For complex issues, the GIRP may request and use outside agency resources.
11. If the GIRP finds that there is insufficient information available, and determines that extensive additional research is required to properly evaluate the proposed GI, the GIRP can recommend to the RES Office Director that the GI exit the GI process to perform additional research as appropriate.

This proposed GI can be closed out, subsequently a work request will be submitted to evaluate the proposed issue in accordance with PRM-001, "Process for Responding to Work Requests: Informal Assistance, Research Assistance, User Needs, and Research Plans." After the additional research is performed the

### Generic Issues Program

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safety issue is re-evaluated. If a safety issue still exists, then the issue should be re-submitted into the GI program for screening and assessment as a new GI.

12. If the GIRP concludes that the proposed GI does not satisfy all seven screening criteria, the GIRP informs the RES Office Director of its recommendation that the proposed GI should not proceed to the Assessment stage and should exit the GI process.
  - a. The RPM assists the GIRP in preparing a memorandum to the RES Office Director, stating why the proposed GI does not meet the screening criteria.
  - b. The RPM coordinates with the RES Office Director to determine whether the Office Director requires a formal briefing from the GIRP.
  - c. Once the RES Office Director agrees with the GIRP recommendation, the GI Program Manager or the RES Office Director sends a closure memorandum to the originator, summarizing the GIRP's evaluation and stating that the issue has exited the GI process.
13. If the GIRP concludes that the proposed GI meets all seven screening criteria, the GIRP informs the RES Office Director of its recommendation that the proposed GI should continue to the Assessment stage.

If at any point during the screening or assessment stages, new information becomes evident that the proposed issue poses an immediate safety concern to nuclear facility, the RPM will contact the appropriate regulatory office and issue will be immediately transferred bypassing the formal assessment stage.

14. The RPM assists the GIRP in preparing a memorandum to the RES Office Director, stating why the proposed GI satisfies the screening criteria.
  - a. The memorandum should include a justification that adequate protection of safety is assured for ongoing facility operations while the GI is in the Assessment stage.
  - b. The RPM coordinates with the RES Office Director to determine whether the Office Director desires a formal briefing from the GIRP.
  - c. The GIRP memorandum to the RES Office Director documenting the results of the screening analysis should include GI Program management concurrence to ensure consistency in the GI process. The memorandum should also document any additional views or non-concurrences from any GIRP member to inform the RES Office Director.
15. The RES Office Director reviews the GIRP's recommendation.
  - a. The RES Office Director can request a meeting with the GIRP to discuss its findings and conclusion.

### **Generic Issues Program**

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- b. If the RES Office Director does not agree with the screening evaluation or the GIRP's recommendations, the GIRP will reconvene to consider the RES Office Director's comments and revisit the screening evaluation.
  - c. If the RES Office Director agrees with the GIRP's screening evaluation and recommendations, the RPM issues the screening results as final on behalf of the GIRP and makes the screening results and associated documents publicly available. The RPM forwards the GIRP report to the appropriate regulatory offices for regulatory review and potential action.
  - d. The RES Office Director can issue a memorandum acknowledging the results of the GIRP screening report. The RES Office Director may provide modifications or additional recommendations. The memorandum establishes expectations for the staff in RES and affected regulatory offices during the Assessment stage, particularly the members of the GIRP. Depending on the extent of the assessment, the RES Office Director can request additional personnel and funding to accommodate the work required for the assessment.
16. The RPM updates the internal GI Program status and tracking database (GI Dashboard) to reflect the outcome of the screening.
17. The RPM is responsible for informing the originator, the Office of the Advisory Committee on Reactor Safeguards (ACRS), and other stakeholders of the screening results. This is normally accomplished by including these individuals on the distribution list for the screening memorandum. For high-interest issues, the GI Program Manager or the RES Office Director may provide additional communications to various stakeholders.

## **5.2 Stage 2—Assessment Stage**

The purpose of the Assessment stage is to determine whether the proposed GI has enough safety and regulatory significance to merit an NRC staff effort to develop new or revise regulations or guidance. The assessment includes an evaluation of risk significance, safety significance, environmental significance (with respect to radiological health and safety), security significance, and regulatory compliance. The assessment should propose a regulatory path forward, which should include an initial "limited" regulatory analysis (see Appendix E) and "limited" backfit evaluation (see Appendix F). A more in-depth evaluation will be performed by the program office in the Regulatory Office Implementation stage.

### **5.2.1 Actions during the Assessment Stage**

- 1. The objective of the assessment is to provide a more detailed analysis of the risk significance, regulatory significance, and safety significance of the proposed GI to determine whether the GI merits regulatory actions to address the proposed GI.

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**Generic Issues Program**

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2. The RPM is responsible for forming an assessment team. An assessment team can consist of the existing GIRP members, or the RPM can request additional support staff as necessary.
3. The GIRP members from the Screening stage typically continue to the Assessment stage. However, panel members can change to accommodate factors such as individual workloads, organizational changes, and retirements.
4. The RPM arranges for any necessary contractor support, additional support staff from within RES, and staff from other program offices.
5. The GIRP directs the assessment team on the scope of the issue and any scope changes.
6. The first step for the RPM and the assessment team is to develop an assessment plan, identifying the actions necessary to complete the assessment. The objective of the assessment plan is to accumulate enough information to complete a formal assessment report, documenting the results of the team's investigation. The plan should contain include information from the Screening Report, e.g., detailed schedules, milestones, and responsibilities necessary to complete the assessment report. Appendix C, "Assessment Plan Instructions," to this OI provides details of the contents of a typical assessment plan.
7. The assessment team may use a graded approach, as defined in MD 6.4. The key areas to be assessed are the safety and risk significance of the issue.
8. The assessment team is encouraged to use risk as a screening threshold. The team may use the figures and tables located in Appendix B, "Risk Criteria," to this OI to determine whether the risk associated with the issue is significant enough to justify forwarding the GI to the regulatory office to pursue changes to nuclear facilities or other regulatory actions. For issues that are not amenable to quantification of the change in risk, the assessment team may use qualitative criteria to assess the risk significance. NRC guidance on risk is in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."
9. The assessment team develops possible regulatory options to address the issue, which should also include the technical basis and a safety/risk assessment of the options. The options will be used to develop an initial "limited" regulatory analysis.
10. The team will prepare an assessment report to document its analysis. The assessment report should include the following key elements, as applicable:
  - a. environmental significance
  - b. security significance
  - c. safety and risk significance (Appendix B to this OI provides guidance and criteria for performing a risk assessment)

### Generic Issues Program

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- d. regulatory compliance (assess existing applicable regulations and licensees' licensing bases to determine whether the GI may be backfit issue)
  - e. initial limited regulatory analysis (Appendix E, "Limited Regulatory Analysis," to this OI provides guidance on performing a limited regulatory analysis that is applicable to a GI)
  - f. proposed regulatory path forward
11. The assessment report may recommend changes to nuclear facilities. In accordance with NRC guidance, there must be sufficient benefits in order to justify the costs. The assessment team will perform limited scope preliminary backfit and cost-benefit analyses to demonstrate that the suggested changes will result in a substantial increase in the overall protection of public health and safety or the common defense and security. The assessment team can use the criteria in Appendix F, "Consideration of Impact/Value in Backfit Analysis," to this OI to evaluate the issue to determine whether it meets the criteria for backfitting. A formal backfit evaluation will be performed by the appropriate regulatory program office in the Regulatory Office Implementation stage.
- Title 10 of the *Code of Federal Regulations* (10 CFR)—specifically 10 CFR 50.109, 70.76, 72.62, 76.76, all titled "Backfitting," and 10 CFR 52.63, "Finality of Standard Design Certifications"—contains the backfit provisions for various types of nuclear facilities.
12. Once the assessment report is complete, the assessment team submits the report to the GIRP to determine whether the proposed GI warrants additional regulatory action.
13. If the GIRP concludes that no additional actions are required, the GIRP will inform the RES Office Director of its recommendation that the proposed GI should not proceed to the ROI stage and should exit the GI process.
- a. The RPM assists the GIRP in preparing a memorandum to the RES Office Director, stating why the proposed GI should not proceed to ROI stage.
  - b. The RPM coordinates with the RES Office Director to determine whether the Office Director desires a formal briefing from the GIRP.
  - c. Once the RES Office Director acknowledges agreement with the GIRP recommendation, the GI Program Manager or the RES Office Director sends a closure memorandum to the originator, summarizing the GIRP's evaluation and stating that the issue has exited the GI process.
14. If the GIRP concludes that additional actions are required, the GIRP will inform the RES Office Director of its recommendation that the proposed GI should proceed to the ROI stage.

**Generic Issues Program**

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- a. The RPM assists the GIRP in preparing a memorandum to the RES Office Director, stating why the proposed GI should proceed to ROI stage.
  - b. The memorandum should include a justification that adequate protection of safety is assured for ongoing facility operations while the GI is in the ROI stage.
  - c. The RPM coordinates with the RES Office Director to determine whether the Office Director desires a formal briefing from the GIRP.
  - d. The RES Office Director sends a memorandum to the appropriate regulatory offices, notifying them of the GIRP's evaluation together with any modifications or additional recommendations, as described in Section 5.2.2.
15. The GIRP memorandum to the RES Office Director documenting the results of the assessment should include GI Program management concurrence to ensure consistency in the GI process. The memorandum should also document any additional views or non-concurrences from any GIRP member to inform the RES Office Director.
18. The RES Office Director may desire additional information as part of the Office Director's review of the GIRP's assessment report.
- a. The RES Office Director can request a meeting with the GIRP to discuss its findings and conclusion.
  - b. If the RES Office Director agrees with the assessment report and the GIRP's recommendations, the RPM issues the assessment report as final on behalf of the GIRP and makes the assessment report and associated documents publicly available.
  - c. If the RES Office Director does not agree with the assessment report or the GIRP's recommendations, the GIRP will reconvene to consider the RES Office Director's comments and revisit the assessment report.
  - d. The RES Office Director may modify or make additional recommendations in the memorandum forwarding the results of the GIRP's report to the affected regulatory offices or other stakeholders, as described in Section 5.2.2.
18. The RPM updates the internal GI Program status and tracking database (GI Dashboard) to reflect the outcome of the assessment.
19. The RPM is responsible for informing the originator, the ACRS, and other stakeholders of the assessment results. This is normally accomplished by including these individuals on the distribution list for the assessment report. For high-interest issues, the GI Program Manager or the RES Office Director may

### Generic Issues Program

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provide additional communications to various stakeholders.

#### 5.2.2 Actions during Transition from Assessment to Regulatory Office Implementation

1. Once the assessment is complete, the RES Office Director sends a transfer memorandum to the Directors of the affected regulatory offices receiving the GI for regulatory office implementation.
2. The transfer memorandum transfers ownership of the GI from RES to the appropriate regulatory office for implementation. The memorandum also describes the role of a transition team in facilitating the transfer of ownership and knowledge of the issues to the regulatory office.
3. The transfer memorandum should include the following:
  - a. copy of the GIRP recommendation memorandum
  - b. evaluation of the environmental, security, safety, and risk significance
  - c. justification for ongoing safe operation while the GI is being addressed
  - d. assignment of a permanent GI identification number (GI-00#)
  - e. description of the transition team and its purpose
  - f. assessment of regulatory compliance
  - g. initial limited regulatory analysis
  - h. proposed regulatory action to address the issue
  - i. draft communication plan:
    - i. The draft communication plan is intended to help ensure ongoing communications with public stakeholders and other regulatory offices. A final plan may be formal or informal, as determined by the transition team.
    - ii. The communication plan provides information on resource allocation, information flow, limited regulatory analysis, and decisions on transitioning to the regulatory office for regulatory action.
    - iii. The communication plan typically outlines the need for public meetings, as necessary, during the ROI stage.
    - iv. As desired, the RPM prepares a draft communication plan in accordance with "Guidance on Communication Tools & Plans," available on the web site for the Office of the Executive Director for Operations (OEDO). Section 5.4.9 of this OI provides additional guidance.

Note: The RPM should begin preparing the communication plan while the GIRP is completing the assessment recommendation. This early preparation will facilitate the approval and issuance of the communication plan before the recommendation is given to the RES Office Director for endorsement.

### Generic Issues Program

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4. The Director of the receiving regulatory office should issue an acknowledgment memorandum assuming responsibility of the GI for regulatory implementation. The acknowledgment memorandum should include the following to ensure a smooth transition:
  - a. identification of the transition team lead
  - b. membership of the transition team
  - c. a transition team charter that includes knowledge transfer and a draft resolution plan for the ROI stage
5. The RPM submits the final assessment report, transition team documents, and regulatory office acceptance memorandum to the NRC's Agencywide Documents Access and Management System (ADAMS) and updates the GI Dashboard to reflect the transition from the Assessment stage to the ROI stage.
6. The RPM is responsible for informing the originator, the ACRS, regulatory office Directors, and other stakeholders of the assessment results, as described in the communication plan.

### 5.3 Stage 3—Regulatory Office Implementation Stage

The purpose of the ROI stage is to develop appropriate regulatory actions and implement resolution of the issue in a timely manner. The actions listed below describe and outline the intended GI process activities during the ROI stage. These actions are not intended to supersede existing regulatory office procedures.

The transition team assists the regulatory office in implementing the appropriate regulatory actions during the ROI stage. As stated in MD 6.4, the mission of a transition team is to ensure that an issue receives the necessary attention in the appropriate receiving regulatory office to ensure progress is maintained. The transition team supports the regulatory office in its decision as to the appropriate regulatory action to address the GI, and to facilitate the transition to the appropriate regulatory process. For example, the transition team could support actions 1-10 in Section 5.3.1. Regulatory office management may terminate the transition team when the purpose has been accomplished, at its discretion.

#### 5.3.1 Actions during the Regulatory Office Implementation Stage

1. Activities associated with the ROI stage typically occur within the scope of existing regulatory programs (e.g., generic communications and rulemaking).
2. The responsible regulatory office assigns a new project manager to the GI. This project manager is responsible for managing the resolution of the GI and periodically reporting to NRC managers and the RPM on the status of activities necessary to resolve the GI.
3. The RPM continues to track and report on the status of active GIs in the ROI

### Generic Issues Program

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stage until all required actions have been completed, at which time the RPM closes out the GI.

4. The responsible regulatory office performs an appropriate regulatory analysis to determine the proper action within the regulatory process (e.g., rulemaking, backfit, orders, generic communication). This analysis should build on the initial limited regulatory analysis developed during the Assessment stage.
5. If the regulatory analysis determines that no new regulatory requirement is necessary, the responsible regulatory office will issue a memorandum to the RES Office Director or GI Program Manager describing the evaluation and the justification for reaching this determination. The RPM, GI Program Manager, or RES Office Director issues a closeout memorandum to the originator, informing him or her of the decision to close the GI and any actions taken. The GI will then exit the GI process.
6. If the regulatory analysis determines that there is a need for a new regulatory requirement, the responsible regulatory office will initiate the appropriate regulatory process.
7. The assigned project manager establishes milestones to resolve the GI. Typical milestones are dependent on the chosen regulatory process and should include the following:
  - a. regulatory basis and technical development (typically up to 30 months for rules and 6 months for generic letters, less time for orders)
  - b. communications with the ACRS and the Committee to Review Generic Requirements (CRGR), and conduct of public meetings, as appropriate (typically up to 3 months for rules and generic letters, less time for orders)
  - c. completion and issuance of rules, generic letters, and orders (typically up to 18 months for rules, 9 months for generic letters, and less time for orders)
  - d. licensee implementation of facility modifications (typically up to 48 months)
  - e. NRC inspection and verification (typically up to 12 months following implementation)
8. The assigned project manager performs the following functions:
  - a. tracks and documents completion of ROI milestones
  - b. monitors for scope changes
  - c. updates the communication plan
  - d. organizes public meetings to gain stakeholder input, as appropriate; public meetings can be held as part of developing a regulatory analysis to

### Generic Issues Program

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determine the appropriate regulatory action; public meetings may also be held as part of a regulatory process

9. The ACRS may request a meeting to support the development of a regulatory analysis to determine the appropriate regulatory action. The ACRS may hold additional meetings as part of the regulatory process selected for the GI. The ACRS has the option to review actions taken as it deems necessary.
10. The responsible regulatory office implements the new regulatory action (e.g., issues a rule, order, generic communication, etc.).
11. Licensees may be required to implement actions to comply with the new regulatory action. The regulatory offices track the status of implementation and provide status reports to the RPM. The RPM maintains the status of the GI on the GI Dashboard.
12. The NRC staff performs inspections to verify that licensees have completely implemented all required actions, as appropriate, for the regulatory action.
13. After all licensees have implemented the appropriate corrective actions and the NRC staff has verified that all the affected licensees have implemented all required actions, the project manager notifies the RPM that the GI can be closed.
14. The RPM, GI Program Manager, or RES Office Director issues a closeout memorandum to the originator, notifying him or her that the GI has been closed and briefly describing the actions taken.

#### 5.4 Generic Issue Tracking and Reporting

The GI Program maintains a system to track GIs and report the status of issues to stakeholders. The GI Program uses the NRC public Web pages, online GI Dashboard, NUREG-0933, and several periodic reports to communicate activities about GIs.

1. The GI Program is intended to be transparent and open to the public. The GI Program maintains a Web page on the NRC public Web site under the tab, "About NRC," and under the heading, "How We Regulate," under the topic, "Operational Experiences." The "Generic Issues Program" Web page contains the following links:
  - a. Policy and Procedure Documents (links to program documents, such as TEC-002 and MD 6.4)
  - b. Frequently Asked Questions (answers to commonly asked questions about the GI Program)
  - c. How to Propose a New Generic Issue (contains NRC Form 833, "Form to Propose a Generic Issue (GI)," to submit a new GI via mail and a link to an online form to send directly to the NRC mailbox, [GIP.Resource@NRC.gov](mailto:GIP.Resource@NRC.gov))

### Generic Issues Program

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- d. Generic Issues Program Status (GIMCS semi annual reports (formerly issued quarterly))
- e. NUREG-0933, "Resolution of Generic Safety Issues" (link to historical data of all issues accepted into the GI Program)
- f. Generic Issue Dashboard (database containing the status of active GIs within the three-stage GI process and proposed GIs that were screened out of the process before acceptance as GIs)

#### 5.4.1 GI Tracking

1. When a GI is initially proposed, the RPM assigns a PRE-GI number and enters the information into the tracking database (GI Dashboard). The RPM has the option to enter the information into the GI Dashboard even if the proposed GI is not accepted. Such issues may be a source of knowledge for similar issues submitted in the future.
2. Once the GIRP completes its assessment and recommends that the GI proceed to the ROI stage, the RPM assigns the proposed GI a new, permanent GI number.
3. The RPM tracks the GI as it proceeds through the three stages of the GI process, updating the status on the GI Dashboard.

#### 5.4.2 GI Dashboard

1. The RPM uses the GI Dashboard as an issue management database to record proposed GIs, track their progress through the GI process, and document results of evaluations as required by the program guidelines.
2. The RPM updates the GI Dashboard to reflect important milestones, activities, documents, and notifications associated with GIs.
3. The RPM coordinates with the assigned regulatory office project managers for active GIs in the ROI stage to update the status on the GI Dashboard as progress is made toward resolution.

#### 5.4.3 Generic Issues Management Control System (GIMCS) Report

1. The purpose of the GIMCS report is to periodically inform NRC Office Directors, stakeholders, and members of the public of activities associated with active GIs in the ROI stage that are being processed for regulatory actions.
2. The RPM issues a GIMCS report on a semiannual basis to NRC managers and makes it publicly available on the GI Program Web site to inform external stakeholders of progress in addressing active GIs.
3. The GIMCS report typically consists of the following elements:

### Generic Issues Program

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- a. identification of the open GIs currently in the ROI stage
- b. description of significant activities that occurred during the previous reporting period
- c. brief description and a summary of activities (similar, if not identical, to the semiannual report to Congress)

#### 5.4.4 Semiannual Report to Congress

1. The purpose of the semiannual report to Congress is to inform members of Congress of activities associated with active GIs that are in the regulatory offices for implementation. A dedicated 2- to 3-page section of the report discusses the status of GIs. The discussion may include significant PRE-GIs that have passed the screening criteria and are in the Assessment stage.
2. The input is ticketed correspondence in the Office of the Executive Director of Operations (EDO) tracking system. The RPM prepares input for the RES Office Director to send to the EDO to report on activities associated with active GIs. The regulatory office project managers provide information to the RPM for this report.
3. The input to the report should include the following items:
  - a. the number of active GIs in the ROI stage
  - b. a brief description of each active GI
  - c. recent significant activities and near-term future significant activities
  - d. actions required to close out the GIs
  - e. approximate date the GIs are expected to close

#### 5.4.5 NUREG-0933

1. The RPM periodically updates information in NUREG-0933 through supplements.
2. The RPM adds a new GI to NUREG-0933 when a proposed GI is assigned a permanent GI number.
3. The NRC uses supplements to NUREG-0933 to add information about the description, screening, and assessment of all newly identified permanent GIs. The supplements also document resolution of the GIs closed out since publication of the previous supplement.
4. NUREG-0933 is available on the NRC public Web site at <http://nureg.nrc.gov/sr0933/>.

#### 5.4.6 NUREG-1925

1. The RPM provides revisions to NUREG-1925, "Research Activities," describing the GI process.

### Generic Issues Program

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2. The latest version of NUREG-1925 is available on the NRC public Web site at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1925/>.

#### 5.4.7 Convention on Nuclear Safety (CNS) Report

1. In support of U.S. participation in the Convention on Nuclear Safety (CNS), the RPM provides updates for the CNS report to the point of contact in NRR, as required.
2. The U.S. national reports are issued as NUREG-1650, "The United States of America National Report for the Convention on Nuclear Safety." The NRC issues revisions to NUREG-1650 every 3 years.

#### 5.4.8 Advisory Committee on Reactor Safeguards

1. The RPM provides information to the ACRS on GI activities. The NRC staff notifies the ACRS when the following reports are issued:
  - a. GIRP final screening report
  - b. GIRP final assessment report
  - c. GI closeout memorandum
2. The staff normally notifies the ACRS by including the ACRS on distribution for the reports listed above. The staff may also notify the ACRS through a separate memorandum for issues of significant interest, such as GIs that are anticipated to transition to the ROI stage.

#### 5.4.9 Communication Plans

1. A communication plan lays out **how** the NRC is going to communicate with stakeholders about a particular issue. It is not intended to communicate information about the issue. The communication plan can contain details about the GI, such as background, key message, audience, timeline, communication tools, and questions and answers.
2. Instructions and templates on preparing a communication plan and example of communication plans are at the following internal NRC Web pages:
  - [http://www.internal.nrc.gov/communications/comm\\_tools/guidance.html](http://www.internal.nrc.gov/communications/comm_tools/guidance.html)
  - <http://www.internal.nrc.gov/communications/plans/guidance.html>
3. The RPM or project manager prepares a communication plan for those issues the GIRP recommends for screening into the GI Program.
4. The RPM or project manager issues the initial communication plan along with the GIRP's screening recommendation and periodically updates the communication

### Generic Issues Program

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plan as major milestones (e.g., assessment plan, assessment report) are met to inform stakeholders of the progress of the GI.

#### 5.4.10 External Stakeholder Involvement in the Generic Issues Program

1. The GI Program Manager and the regulatory office consider the need for a public meeting with nuclear industry stakeholders. A public meeting can be conducted for the following reasons:
  - a. to communicate the results of the Screening and Assessment stages
  - b. to gain stakeholder input, as necessary
  - c. as part of developing a regulatory analysis to determine the appropriate regulatory action
  - d. as the transition team transfers responsibility of the GI to the appropriate regulatory office, as necessary
  - e. during the regulatory process in the ROI stage, as often as necessary
2. The GI Program Manager communicates any needs for external resources to the office level as necessary to resolve complex proposed GIs. This could include contracts, grants, and international collaboration.

#### 5.4.11 Accounting for NRC Staff Resources

1. NRC staff working on issues in the GI process should record the time expended working on GIs to the appropriate cost activity codes (CACs) in the agency timekeeping system. This includes time spent on attendance at meetings, meeting preparation, and assessing the proposed GIs. CACs for GIs in the ROI stage should be established by the regulatory offices based on the regulatory process selected to resolve the GIs.
2. The RPM will notify the staff of the appropriate CACs for proposed GIs, and will perform periodic reviews of the time charged to the GI program CACs to facilitate accurate accounting for NRC staff efforts on generic issues.

## 6. PERFORMANCE MEASURES

None.

## 7. REFERENCES<sup>1</sup>

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<sup>1</sup> Publicly available NRC-published documents are available online through the NRC Library on the NRC's public Web site at <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax: (301) 415-3548; and e-mail: pdr.resource@nrc.gov.

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## Generic Issues Program

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### Appendix A

#### Screening Criteria

The Generic Issues (GI) Program addresses only those issues that meet all of the following seven criteria:

- 1. The issue affects public health and safety, the common defense and security, or the environment (with respect to radiological health and safety). For issues that are not amenable to quantification using risk assessment, qualitative factors may be developed and applied as necessary to assess safety/risk significance.**

This criterion eliminates issues not directly involving or affecting “safety or security” (e.g., purely administrative matters, policy, regulatory process issues, or U.S. Nuclear Regulatory Commission (NRC) organizational issues).

- The staff may use quantification methods for assessing the associated risk. Figures in Appendix B to this office instruction provide guidance on a threshold risk to determine whether a GI should continue to be evaluated in the GI process or exit the process. The staff may use the figures at any time during the GI process. These figures are derived from Figures 4 and 5 in Regulatory Guide 1.174, Revision 3, “An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” issued January 2018. These figures define the levels of acceptable risk associated with a change in a nuclear facility.
- Draft revision 5 of NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” Table 2-1, “PRA-Related Information for Use in Preliminary Screening Analyses,” describes similar criteria that may be helpful to NRC staff to use in preliminary screening of the merit of proposed new regulatory requirements.
- For GIs that are not amenable to risk assessment using quantification methods, reviewers may develop and apply qualitative criteria as necessary to assess the safety and risk significance.
- For issues related to materials and waste, reviewers can use quantitative health guidelines (QHG) to determine the applicability of this criterion. The Office of Nuclear Regulatory Research (RES) technical report, “Risk-Informed Decisionmaking for Nuclear Material and Waste Applications,” Revision 1, dated February 28, 2008, provides a more detailed discussion of QHGs.

- 2. The issue applies to two or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals.**

This criterion ensures that plant-specific issues are handled under other, more appropriate processes, such as the Reactor Oversight Process.

### Generic Issues Program

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- 3. The issue is not being addressed using other regulatory programs and processes, existing regulations, policies, or guidance.**

The intent of the GI Program is to direct or transfer the issue to the most suitable NRC regulatory office and for the staff to actively work through the issue. This criterion ensures that the GI Program staff is not addressing an issue that other NRC staff are already handling. It also facilitates the staff's identification of an efficient mechanism for addressing a regulatory issue. If an NRC regulatory office is using another mechanism (regulatory program or process) to address the issue, the issue exits the GI process. Examples of issues to be excluded from the GI process using this criterion include issues that are being processed through the Generic Communications process or the Reactor Oversight Process.

- 4. The issue can be resolved by new or revised regulation, policy, or guidance.**

This criterion ensures that the staff has the ability to address the issue. It also assists in identifying and recommending a regulatory product to resolve the issue.

- 5. The issue's risk or safety significance can be adequately determined in a timely manner (i.e., it does not involve phenomena or other uncertainties that would require long-term study and/or experimental research to establish the risk or safety significance).**

This criterion eliminates those issues requiring a long-term research study before entry into the GI process, rather than using a prolonged evaluation under the GI process. The appropriate regulatory office should evaluate issues requiring long-term studies under a User Need Request or other request for RES support. Alternatively, RES may initiate and manage the issue. Upon completion of the long-term study, the issue may enter the GI process for evaluation.

- 6. The issue is well defined, discrete, and technical.**

This criterion is intended to ensure that the initial scope of the proposed GI is manageable. This will help prevent scope creep and exclude matters extraneous to the issue from evaluation. Reviewers may propose to address closely related issues or topics as a single GI. Likewise, reviewers may separate GIs for individual processing if necessary to expedite important issues through the GI process.

- 7. Resolution of the issue may involve review, analysis, or action by the affected licensees, certificate holders, or holders of other regulatory approvals.**

This criterion identifies potential weaknesses and deficiencies in existing regulations and guidance that affect safety and security. If it becomes apparent that no licensee action is needed, then further assessment under the GI process is not needed, and the issue exits the GI process.

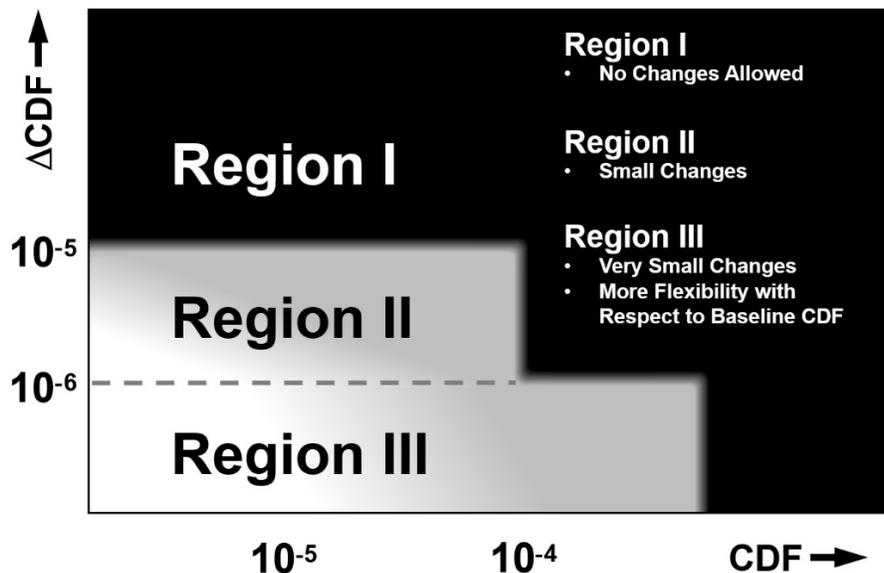
**Generic Issues Program**

**Appendix B**

**Risk Criteria**

The Generic Issues (GI) Program is designed to address only those issues that raise a question about the safety of a nuclear facility. In order to determine whether the proposed GI could potentially impact facility safety, the U.S. Nuclear Regulatory Commission (NRC) staff can perform a quantitative risk analysis using event probabilities. Issue reviewers can use the criteria in this appendix as guidance for determining whether a proposed GI poses a significant enough risk to warrant continuation in the GI process. If a proposed GI fails to meet the criteria, the staff can recommend that the issue exit the GI process.

The criteria are based on the same technical bases used for determining whether the risk associated with a specific facility design change is acceptable. The criteria are illustrated in Figure 4 of Regulatory Guide 1.174, Revision 3, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis,” issued January 2018, and reproduced below in Figure B-1. If a proposed facility change has a high risk, then the change should not be allowed, which is shown as “Region I” in Figure B-1.



**Figure B-1 Acceptance guidelines for core damage frequency  
(Source: Regulatory Guide 1.174, Figure 4)**

Figure B-2 shows the criteria for core damage frequency (CDF) for the GI Program. The change in core damage frequency ( $\Delta CDF$ )/reactor-year represents the increase to the facility’s baseline CDF because of potential negative effects from the proposed GI. Analogous to RG 1.174, if a proposed GI has a high-risk impact, then it should continue in the GI process. Thus, “Region I” in Figure B-1 corresponds to “continue in process.” The numerical values associated with defining the regions are to be interpreted as indicative values only. In the context of integrated decisionmaking, the boundaries between regions shown in gray, are not definitive.

**Generic Issues Program**

Figure B-3 shows the criteria for large early release frequency (LERF) for the GI Program. The discussion for Figure B-2 applies similarly to Figure B-3.

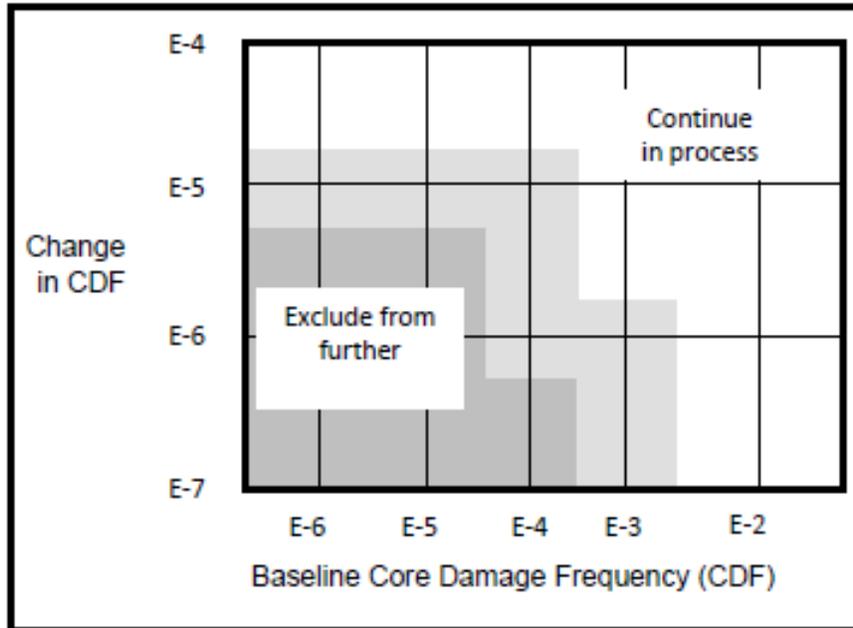


Figure B-2 Core damage frequency (CDF) criteria for the GI Program

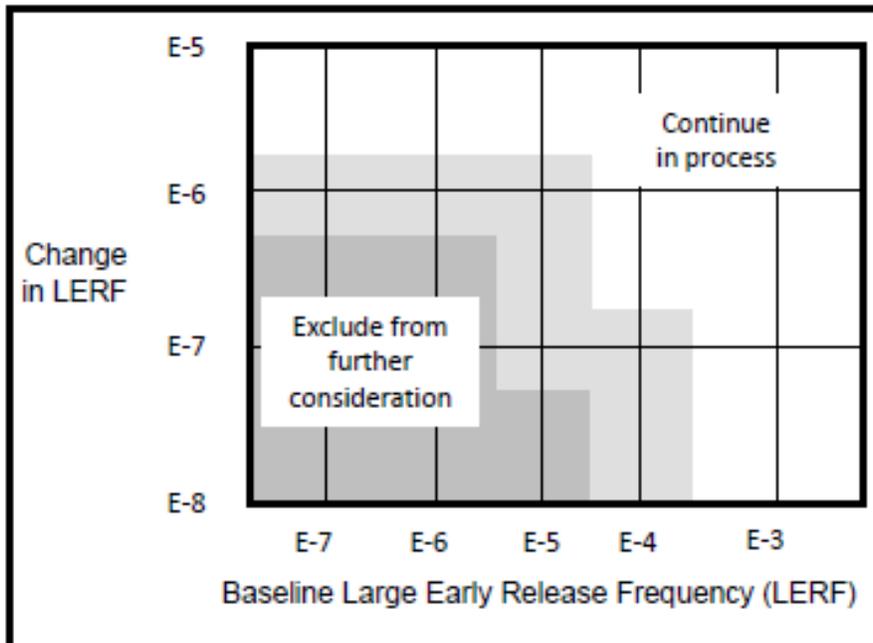


Figure B-3 Large early release frequency (LERF) criteria for the GI Program

### Generic Issues Program

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NUREG/BR-0058, "Regulatory Analysis Guidelines of the United States Regulatory Commission," Revision 4, issued September 2004, contains additional guidance on the use of risk to make regulatory decisions. This guidance is illustrated in Figure 3.2, "Safety Goal Screening Criteria." Consistent with the discussion in NUREG/BR-0058, the staff has created thresholds for determining whether the GI should continue in the GI process based on risk.

- If regulatory initiatives to address the proposed GI result in a substantial change, that is, if the  $\Delta$ CDF is equal to or greater than  $1 \times 10^{-4}$ /reactor-year, then the staff should consider the proposed GI substantial and recommend that the proposed GI continue in the GI process.
- If the proposed GI results in a small change, that is,  $\Delta$ CDF less than  $1 \times 10^{-5}$ /reactor-year, then, generally, the proposed GI should not continue in the GI process unless management decides otherwise (based on strong engineering or qualitative justification, as well as consideration of uncertainties). One such circumstance may involve a class of accident sequences involving the potential for early containment failure or containment bypass, such as an estimated conditional containment failure probability of greater than  $1 \times 10^{-1}$ /reactor-year.
- If the  $\Delta$ CDF is between  $1 \times 10^{-4}$  and  $1 \times 10^{-5}$ /reactor-year (i.e., 10 percent of the subsidiary safety goal of  $10^{-4}$ ), then the staff should consider other factors, such as the probability of containment failure, before reaching a conclusion on whether the proposed GI should continue in the GI process. Management should make the final determination on whether to proceed.

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**Generic Issues Program**

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**Appendix C**

**Assessment Plan Instructions**

1. The assessment is to provide a formal evaluation of the proposed generic issue (GI) in order to determine whether the issue should proceed to the appropriate U.S. Nuclear Regulatory Commission (NRC) regulatory office for implementation. An assessment typically consists of the following elements:

- a. safety assessment

A safety assessment should evaluate whether the fundamental safety principles on which the facility design was based are not compromised. It should include a discussion on how the facility maintains defense-in-depth principles and safety margins. Appendix D, "Safety Assessment," to this office instruction contains information a safety assessment.

- b. risk assessment

With respect to a change in the facility, a risk assessment should follow the guidance in Regulatory Guide 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant- Specific Changes to the Licensing Basis," issued January 2018, to determine whether there is a significant change in the core damage frequency. Appendix B to this office instruction contains more information on completing a risk assessment.

- c. technical assessment

A technical assessment should provide an in-depth analysis of the problem, including an explanation of the phenomenon and the potential effects on the nuclear facility.

- d. regulatory assessment

A regulatory assessment should evaluate whether the NRC bases its decision on adequate information. This will ensure that agency decisions that impose regulatory burdens on licensees are based on adequate information about the values and impacts associated with a reasonable set of alternatives. Appendix E to this office instruction contains information on developing a regulatory analysis.

2. Steps to Develop an Assessment Plan

- a. The Responsible Project Manager (RPM) develops and issues an assessment plan.
- b. If the assessment plan requires support from other divisions in the Office of Nuclear Regulatory Research (RES), then it may be appropriate for the RPM to send a memorandum to the appropriate RES division directors and the RES Office Director requesting additional assistance.

**Generic Issues Program**

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- c. The assessment plan should include guidance, milestones, and a schedule for the evaluation of the proposed GI.
- d. The assessment plan does not have to follow any explicit format or content. The only expectation is that the scope, work plan, resources, coordination points, and schedule are clear.
- e. The assessment plan should include the following as appropriate:
  - i. description of the proposed GI
  - ii. objective of the assessment plan
  - iii. members of the assessment team
  - iv. specific tasks required (which may include tests)
  - v. schedule for implementation (including sufficient margin to facilitate timely completion of the schedule for major milestones)
- f. The assessment plan should include the actions proposed for exploration during the assessment, as appropriate, e.g., industry initiatives, new risk tools or methods, etc.
- g. The assessment plan should discuss the formulation of new regulations, policy positions, generic communications, Commission papers, or others regulatory actions.
- h. The assessment plan should discuss milestones that include tests or research, public meetings, industry meetings, and major review and concurrence.
- i. The assessment plan should include estimates of resources required for direct technical staff and contractors as well as requests for assignment of a technical staff for preparing or reviewing safety/risk/regulatory assessments to the appropriate managerial level in the program office.
- j. The assessment plan should include a list of technical contacts, including their affiliations, titles, addresses, phone numbers, and e-mail addresses.
- k. The assessment plan should include a list of appropriate documents specific to the current GI process stage, including those documents that provide the basis for the GI.
- l. The assessment plan should complement the issue-specific communication plan, if developed.
- m. If the assessment plan proposes interactions with outside organizations (such as licensees), industry groups (such as the Nuclear Energy Institute Owners'

### Generic Issues Program

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Groups, the Electric Power Research Institute, nuclear steam supply system vendors, the Advisory Committee on Reactor Safeguards), and others, as appropriate, then the plan should address the planned coordination with such organizations.

- n. The preferred approach is to conduct meetings that are open to the public and to place the meeting minutes, with enclosures, in the NRC Public Document Room.
- o. The RPM places documents provided to, or received from, an outside organization into the Agencywide Documents Access and Management System.
- p. The NRC staff documents the results of tests outside agencies conduct in a NUREG report, as applicable. The RPM provides the responsible regulatory offices with a copy of the test report for information. The RPM considers whether a technical review is required and should formally request staff's participation in the technical review process.
- q. Once an assessment plan has been drafted, the RPM provides a copy to the involved program offices, requesting comments to ensure that the proposed assessment approach identifies practical objectives, schedules, and staff resources.
- r. The RPM should confirm assignment of a regulatory office lead contact. This contact does not need to review the detailed technical information RES develops but should be involved in the key decisions, such as which alternative assessment approaches are to be considered.
- s. The RPM tracks appropriate assessment plan milestones. In the event of significant changes to milestones or timeliness, the RPM consults with the GIRP chairman. If deemed necessary, the RPM updates the assessment plan and distributes to the responsible regulatory office or offices.

## Generic Issues Program

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### Appendix D

#### Safety Assessment

##### Evaluation of Defense-in-Depth Attributes and Safety Margins

One aspect of the engineering evaluations is to show that the fundamental safety principles on which the facility design was based are not compromised. Design-basis accidents (DBAs) play a central role in nuclear facility design. DBAs are a combination of postulated challenges and failure events against which facilities are designed to ensure adequate and safe facility response. During the review, design engineers evaluate facility response and associated safety margins using conservative assumptions. National standards and other considerations, such as defense-in-depth attributes and the single-failure criterion, constitute additional engineering considerations that also influence facility design and operation. The proposed generic issue (GI) may also affect safety margins. Therefore, as part of the evaluation to determine the issue's safety significance, the NRC staff should evaluate the impact of the issue on the functionality, reliability, and availability of affected equipment.

#### 1. Defense in Depth

The engineering evaluation should evaluate whether the impact of the proposed GI (individually and cumulatively) is consistent with the defense-in-depth philosophy. In this regard, the intent of this principle is to ensure that the licensee maintains the philosophy of defense in depth, not to prevent changes in the way defense in depth is achieved. The defense-in-depth philosophy has traditionally been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance and, in particular, to account for the potential for unknown and unforeseen failure mechanisms or phenomena, which neither the probabilistic risk analyses nor traditional engineering analyses reflect (whether because they are unknown or unforeseen). If a comprehensive risk analysis is done, it can provide insights into whether the extent of defense in depth (e.g., balance among core damage prevention, containment failure, and consequence mitigation) is appropriate to assure protection of public health and safety. However, to address the unknown and unforeseen failure mechanisms or phenomena, the licensee should use and maintain traditional defense-in-depth considerations. The engineering evaluation should consider the intent of the general design criteria in Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix A, "General Design Criteria for Nuclear Power Plants"; national standards; and engineering principles, such as the single-failure criterion. Further, the evaluation should consider the impact of the proposed GI on barriers (both preventive and mitigative) to core damage, containment failure or bypass, and the balance among defense-in-depth attributes.

The NRC staff should assess whether the proposed GI meets the defense-in-depth principle. Defense in depth consists of a number of elements, and consistency with the defense-in-depth philosophy is maintained if the following occurs:

- A reasonable balance among prevention of core damage, prevention of containment failure, and consequence mitigation is preserved.

### Generic Issues Program

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- Overreliance on programmatic activities as compensatory measures is avoided.
- System redundancy, independence, and diversity are preserved, commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers).
- Defenses against potential common-cause failures are preserved, and the potential for the introduction of new common-cause failure mechanisms is assessed.
- The independence of barriers is not degraded.
- Defenses against human errors are preserved.
- The intent of the facility's design criteria is maintained.

#### 2. Safety Margin

The engineering evaluation should assess whether the impact of the proposed GI is consistent with the principle that sufficient safety margins are maintained. The bullets below summarize an acceptable set of guidelines for making that assessment. Other equivalent acceptance guidelines may also be used. With sufficient safety margins, the following are true:

- Codes and standards or their alternatives approved for use by the NRC are met.
- Safety analysis acceptance criteria in the licensing basis (e.g., final safety analysis report, supporting analyses) are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty.

The NRC has developed application-specific guidelines reflecting this general guidance. The staff can refer to guidance provided in the latest revision of the following regulatory guides:

- Regulatory Guide 1.174, "An Approach For Using Probabilistic Risk Assessment In Risk-Informed Decisions On Plant-Specific Changes To The Licensing Basis"
- Regulatory Guide 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing"
- Regulatory Guide 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications"
- Regulatory Guide 1.178, "An Approach for Plant-Specific, Risk-Informed Decisionmaking for Inservice Inspection of Piping"
- Regulatory Guide 1.201 (for trial use), "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance"

## Generic Issues Program

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### Appendix E

#### Limited Regulatory Analysis

Executive Order 12866, "Regulatory Planning and Review," dated September 30, 1993, requires preparation of a regulatory analysis for all significant regulatory actions. The U.S. Nuclear Regulatory Commission (NRC) requires regulatory analyses for a broader range of regulatory actions than just "significant rulemakings" as defined in Executive Order 12866. In general, each NRC office should ensure that all mechanisms the NRC staff uses to establish or communicate generic requirements, guidance, requests, or staff positions that would cause a licensee to change the use of resources include an accompanying regulatory analysis.

The NRC staff performs regulatory analyses to ensure that the agency bases its decisions on adequate information, the agency considers alternative approaches to meet the regulatory objectives, and to determine the preferred alternative for the proposed action. Regulatory analyses typically accompany new or revised regulations and guidance, such as rules, orders, bulletins, generic letters, regulatory guides, standard review plans, and standard technical specifications. For some of these regulatory actions, a more limited regulatory analysis can be justified. In particular, a detailed cost-benefit analysis can introduce additional costs that are disproportionate relative to the action being undertaken.

For generic issues (GIs), as part of the Assessment report, the staff should develop a limited regulatory analysis. As stated in NUREG/BR-0058, a limited regulatory analysis should be limited only in terms of depth of discussion and analysis, not in the scope of the regulatory analysis or in the need to justify the proposed action. The limited regulatory analysis must conform to NRC guidance and policies, including scope and need to justify the proposed action. The staff develops an initial limited regulatory analysis during the assessment stage, and the transition team in the appropriate regulatory office should develop a final limited regulatory analysis, depending on the intended regulatory action.

The following documents provide guidance in preparing a regulatory analysis and a detailed description of the regulatory analysis requirements:

- NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, issued September 2004
- Draft Revision 5 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," issued April 30, 2017
- NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," dated January 31, 1997
- the Commission's "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," (Volume 51 of the *Federal Register*, page 28044, dated August 21, 1986), which presents a risk-based philosophy for the NRC staff to use as part of its regulatory analysis process for proposed actions that may impact commercial nuclear power reactors

### Generic Issues Program

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The regulatory analysis also ensures that proposed actions subject to the backfit rule, and not within the exceptions in the backfit rule, provide a substantial increase in the overall protection of public health and safety or the common defense and security and that the direct and indirect costs of implementation are justified in view of this substantial increase in protection.

Accordingly, all proposed facility-specific and generic backfits to facilities regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," require a regulatory analysis, including an evaluation of values and impacts, except when one of the following conditions identified within 10 CFR 50.109(a)(4) applies:

- A modification is necessary to bring a facility into compliance with a license, a Commission requirement, or a written commitment by the licensee.
- Regulatory action is necessary to ensure that the facility provides adequate protection to public health and safety and is in accord with the common defense and security.
- Regulatory action involves defining or redefining what level of protection to public health and safety or the common defense and security is considered necessary for adequate protection.

The regulatory analysis also may not be required for the following:

- generic actions, such as notices, policy statements, and generic letters, that only transmit information and do not present new or revised staff positions, impose requirements, or recommend actions
- generic information requests issued under 10 CFR 50.54(f) that require a specific justification statement and are reviewed by the Committee to Review Generic Requirements when directed to one or more classes of nuclear power reactors
- new requirements affecting certified nuclear power facility designs that are justified through the notice and comment rulemaking process specified at 10 CFR 52.63, "Finality of Standard Design Certifications"
- requirements arising out of litigation, such as discovery, in a licensing proceeding
- given actions whose regulatory analysis requirements are eliminated or modified at the discretion of the Commission, the Executive Director for Operations, a Deputy Executive Director, or the responsible NRC Office Director (as determined, for example, based on the degree of urgency associated with the regulatory action, such as urgent NRC bulletins and orders that may need to be issued without regulatory analyses)

In preparing the limited regulatory analyses, the NRC intends to ensure that its decision to impose regulatory burdens on licensees is based on adequate information on the values and impacts associated with a reasonable set of alternatives. The staff arrives at these decisions using a systematic and disciplined process that is open and transparent. The staff can use the following steps:

1. Identify the problem and associated objectives.

### Generic Issues Program

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2. Determine whether a proposed action is needed.
3. Identify courses of action to meet the stated objectives.
4. Based upon the limited available preliminary information, perform an elementary analysis of the costs and benefits of each identified course of action.
5. Select a preferred course of action and provide adequate justification for that action.
6. Present a clear and well-documented explanation of why the NRC staff recommended that particular action.

As with all activities related to the protection of public health and safety, when preparing a regulatory analysis, the staff adheres to the Commission's "Principles of Good Regulation," of independence, openness, efficiency, clarity, and reliability (NRC 1991).

When writing a regulatory analysis, the staff should consider the following:

- identification of basic assumptions
- appropriateness of assumptions
- selection and elimination of alternatives
- estimation techniques
- uncertainties associated with estimates
- evaluation methods
- limitations on data used
- decision rationale
- transparency
- reproducible results
- data underlying the analysis
- document analysis, using best reasonably attainable scientific, technical, and economic information available
- source documents for all original information

Section 2.3 of Draft Revision 5 of NUREG/BR-0058, provides a suggested list of the elements of a regulatory analysis. The staff should use the below suggested outline, although addressing all elements is not required or needed.

### Generic Issues Program

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1. Statement of the Problem and Objective

A. Problem Statement

- a. State the problem; focus on the nature, extent, and magnitude of the problem.
- b. Provide a concise summary of the problems or concerns.
- c. Identify the specific class of licensees, reactors, or other facilities affected.
- d. Explain why the problem exists.
- e. Identify where the problem exists.
- f. Explain why the problem requires action.
- g. Provide a measure of its safety importance (qualitative or quantitatively).
- h. Demonstrate that the issue requires actions to be taken.
- i. Explain the implications of taking no action.

B. Background

- a. Provide a brief history of the problem and the outcome of past efforts to alleviate it.
- b. Identify any legislation or litigation that directly or indirectly addresses the problem.
- c. State whether existing requirements have created or contributed to the problem or can be modified to achieve the regulatory objective more effectively.
- d. Describe the extent to which the immediate problem is part of a larger problem.
- e. Describe the relationship of the problem to other ongoing studies or actions.
- f. Provide the objectives of the proposed new requirement and the relationship of the objectives to the NRC's legislative mandates and authority, safety goals for the operation of nuclear facilities, and policy and planning guidance (e.g., the NRC's Strategic Plan).
- g. Describe the relationship of the problem to formal positions adopted by national and international standards organizations.
- h. Identify any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness.

### Generic Issues Program

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- i. Identify any constraints or other cumulative impacts that work against solutions to the problem.
  - j. Provide draft papers or other underlying staff documents supporting the requirements or staff positions.
- C. Objective
  - a. Provide a concise statement of the improvement sought by the proposed action.
  - b. The objective should also be as specific as possible.
2. Identification and Preliminary Analysis of Alternative Approaches to the Problem (e.g., the most promising courses of action)
  - a. List all significant alternatives considered by the staff. The list of alternatives should be reasonably comprehensive to ensure that the staff considered the range of all potentially reasonable and practical approaches to the problem.
  - b. Provide the base case for analysis, normally it is the no-action alternative. Its primary value is to establish the baseline condition from which all incremental values and impacts can be calculated.
  - c. Identify the action to be taken. It may be appropriate to identify alternative ways to resolve the problem. Viable alternatives could be based on variability in the physical and technical requirements needed to address the problem at hand. Alternatives could also include varying the scope of requirements and the number of licensees affected.
  - d. Identify the group responsible for taking action. Different entities may be capable and, therefore, could assume responsibility for resolving the problem. For example, licensee and industry support group initiatives may constitute a viable alternative to some NRC initiatives.
  - e. Identify how the NRC should accomplish the change, considering the various mechanisms (e.g., generic letter, rule, policy statement) available to the agency.
  - f. Identify when the change should become effective. Alternative implementation schedules and compliance dates may be appropriate.
  - g. Briefly explain the reason for eliminating alternatives that were not selected for further study.
  - h. After the initial list of alternatives is identified, conduct a preliminary analysis of the feasibility, values, and impacts of each alternative to potentially eliminate some alternative approaches, based on factors such as the following:
    - i. excessive impacts in relation to values
    - ii. technological impracticality

**Generic Issues Program**

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- iii. severe implementation difficulties
3. Estimation and Evaluation of the Costs and Benefits (Values and Impacts for Selected Alternatives, including Consideration of the Uncertainties Affecting the Estimates)
- a. Include values (i.e., the beneficial aspects anticipated from a proposed regulatory action) such as the following:
    - i. enhancement of health and safety
    - ii. protection of the natural environment
    - iii. promotion of the efficient functioning of the economy and private market
    - iv. elimination or reduction of discrimination or bias
  - b. Include impacts (i.e., the costs anticipated from a proposed regulatory action) such as the following:
    - i. direct costs to the NRC and Agreement States in administering the proposed action and to licensees and others in complying with the proposed action
    - ii. adverse effects on health, safety, and the natural environment
    - iii. adverse effects on the efficient functioning of the economy or private markets
    - iv. assessment of the following four items (to the extent applicable):
      - (1) costs to licensees
      - (2) costs to the NRC
      - (3) costs to State, local, or Tribal governments
      - (4) adverse effects on regulatory efficiency or scientific knowledge needed for regulatory purposes
  - c. Evaluate quantified estimates of the values and impacts associated with a proposed regulatory action involving NRC licensees by expressing values and impacts on a common basis, such as a present-worth basis, to allow meaningful summations and comparisons.
  - d. Comparison of Courses of Action
- Compare the alternatives with respect to the following factors:
- i. safety
  - ii. NRC resources
  - iii. licensee and applicant resources
  - iv. regulatory stability and predictability
  - v. public transparency and confidence

### Generic Issues Program

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4. Presentation and Summary of Results (optional: for a limited regulatory analysis all the associated cost estimates may not be known)
  - a. presentation of the estimated net monetized benefit
  - b. estimates of costs and benefits for each attribute for each alternative
  - c. presentation of any attributes quantified in nonmonetary terms in a manner to facilitate comparisons among alternatives
  - d. distribution of estimated costs and benefits on affected entities
  - e. discussion of key assumptions and results of sensitivity analyses or uncertainty analyses
5. Decision Rationale
  - a. Identify the proposed NRC instrument for implementing the proposed action (e.g., rule, regulatory guide) and discuss the reasons for selecting the proposed instrument.
  - b. Include the rationale for selecting the proposed action over the other alternatives considered.
  - c. Consider taking no action as an alternative, except when the action has been mandated by legislation or a court decision.
  - d. Identify the decision criteria for the selection of the proposed action, which should include, but not be limited to, the following:
    - i. net value and value-impact computations
    - ii. the relative importance of attributes that are quantified in nonmonetary terms
    - iii. the relative importance of nonquantifiable attributes
    - iv. the relationship and consistency of the proposed alternatives with the NRC's legislative mandates, safety goals, and policy and planning guidance that are in effect at the time the proposed alternative is recommended
    - v. the impact of the proposed action on existing or planned NRC programs and requirements
6. Implementation -Once a course of action is decided, include the following:

**Generic Issues Program**

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- a. when appropriate, the safety goal evaluation, a tentative implementation schedule, and implementation instrument for the proposed regulatory action
- b. how and when the proposed action is to be implemented
- c. a specific date for implementation, including a schedule showing the steps needed to implement the proposed action
- d. a realistic proposed implementation schedule that allows sufficient time for analyses, approvals, procurement, installation and testing, training, and resources needed by licensees to implement NRC and Agreement State requirements

Generic Issues Program

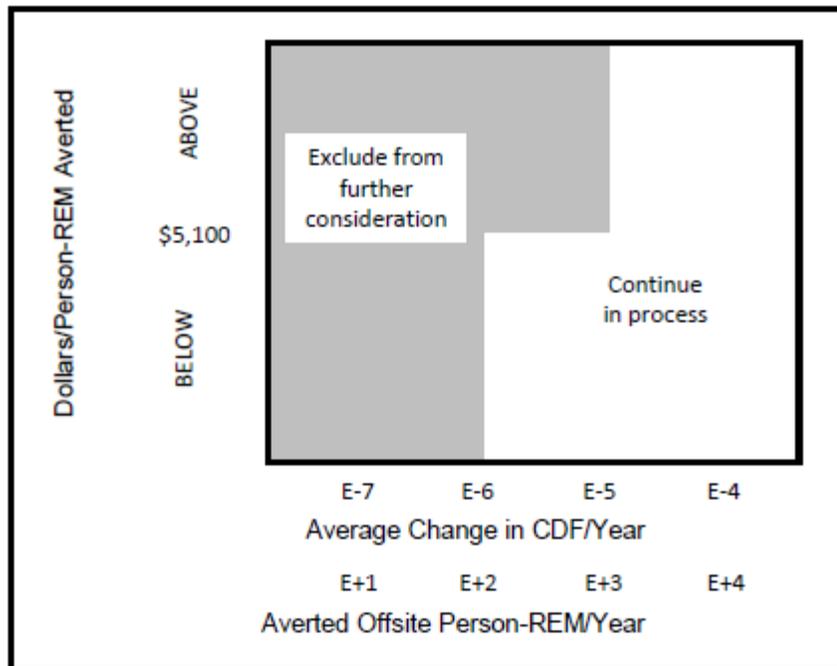
Appendix F

**Consideration of Impact/Value in Backfit Analysis**

The backfit rule establishes a more difficult standard than the cost beneficial standard used in regulatory analysis. For backfitting, the U.S. Nuclear Regulatory Commission (NRC) staff should first show that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the backfit. If that step is met, the staff should then show that “the direct and indirect costs of implementation for that facility are *justified* in view of this increased protection” (emphasis added). If a proposed GI does not appear to meet the backfit criteria, then the staff should consider whether the proposed GI should exit the GI process.

Management Directive (MD) 8.4, “Management of Facility-Specific Backfitting and Information Collection,” dated October 9, 2013, provides guidance for backfits. For generic backfits, the Committee to Review Generic Requirements (CRGR) Charter provides guidance on what cost and benefit information is needed in the backfit analyses for CRGR review. One way of meeting these requirements is for the NRC staff to address each backfit analysis factor (which is specifically listed in the CRGR Charter) in the regulatory analyses. An example of this approach is provided in NUREG-1409.

Figure F-1 provides a threshold for the staff to determine whether a proposed generic issue (GI) would have sufficient cost benefit.



**Figure F-1 Impact/value numerical threshold**

One method to justify cost is to quantify the benefit of averted dose. The staff may use the dollar-per-person-rem conversion factor. NUREG-1530, “Reassessment of NRC’s Dollar per

### Generic Issues Program

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Person-Rem Conversion Factor Policy,” Revision 0, issued December 1995, provided the dollar-per-person-rem conversion factor for health effects to calculate the product of the value of a statistical life and the risk coefficient. Revision 1 to NUREG-1530, issued as a draft report for comment in August 2015, updated the dollar-per-person-rem conversion factor estimates from \$2,000 to \$5,000. Based on the recommendations concerning the value of a statistical life (\$9 million) and the risk coefficient for stochastic health effects ( $5.7 \times 10^{-4}$ ), the dollar conversion factor for health effects would equal \$5,100 per person-rem averted.

For example, based upon the graph, if the costs for implementing the required modifications were high, that is, the dollars per person-rem averted exceeded \$5,100, the issue would continue in the review if the risk was significant (i.e., criteria for the change in core damage frequency ( $\Delta$ CDF)/year was greater than  $1 \times 10^{-5}$ ). If the costs for implementation were low, that is, less than \$5,100 per person-rem averted, the GI could continue in the review if the risk was marginally significant (i.e., CDF/year was greater than  $1 \times 10^{-6}$ ). The basis for making this decision can be correlated to the acceptance guidelines in Regulatory Guide 1.174, figures 4 and 5, for allowing changes in nuclear facilities.

The NRC recognizes, however, that not all regulatory actions are amenable to a quantitative risk assessment and that certain evaluations may be based directly on engineering, regulatory judgment, or qualitative analysis.

Regulatory actions requiring facilities to make modifications are subject to the following requirements and guidance:

- Title 10 of the *Code of Federal Regulations* (10 CFR)—specifically, 10 CFR 50.109, 70.76, 72.62, and 76.76, all titled “Backfitting”—which contains backfit provisions for the nuclear power reactors and certain materials facilities, including fuel facilities, spent fuel and radioactive waste storage facilities, and the gaseous diffusion facilities
- 10 CFR 52.63, “Finality of Standard Design Certifications,” which contains backfit provisions for new power reactor licensees that wish to use one-step licensing
- NUREG-1409, “Backfitting Guidelines,” issued July 1990
- Committee to Review Generic Requirements (CRGR) Charter, Section IV(B)(ix) for generic backfits
- Office of Nuclear Material Safety and Safeguards (NMSS), “NMSS Draft Policy and Procedure Letter 1-82, ‘10 CFR Part 70 Backfit Guidance,’” dated June 20, 2003.
- Office of Nuclear Material Safety and Safeguards, (NMSS) Policy and Procedures Letter 1-53, “Policy and Procedures Letter 1-53, Revision 0, Gaseous Diffusion Plant Specific and Generic Backfit Management,” Revision 0, September 1999.
- NRC MD 8.4, “Management of Facility-Specific Backfitting and Information Collection,” dated October 9, 2013.

### Generic Issues Program

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- NRC Inspection Manual, Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," issued August 1988, which contains plant-specific regulatory requirements when preparing a plant-specific analysis

If the staff performs the analysis in accordance with these guidelines, then the analysis will satisfy the documentation requirements of the backfit rule and the provisions of the CRGR Charter without a need to prepare separate submissions.

#### Key Terms:

- Executive Order 12866, "Regulatory Planning and Review," dated September 30, 1993, defines "significant regulatory actions" to include actions that are likely to result in a rule that may do one of the following:
  - (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities.
  - (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.
  - (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.
  - (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.
- Safety Goals:
  - (1) The safety goals for the operation of nuclear facilities, which are in the Commission's "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants" (Volume 51 of the *Federal Register*, page 28044, dated August 21, 1986), establish a guide for regulatory decisionmaking.
  - (2) A safety goal evaluation is applicable only for regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard of 10 CFR 50.109(a)(3).
  - (3) A safety goal evaluation is used when a regulatory requirement should not be imposed because the residual risk is acceptably low. The staff can also use a safety goal evaluation for determining whether the substantial added protection standard of 10 CFR 50.109(a)(3) is met. The risk associated with adequate protection is the level at which continued operation would not be allowed if exceeded.

## Procedure for Processing Generic Issues

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### Appendix G

#### Examples of Generic Issues Documents and Generic Issue-Related Web Sites

The generic issue (GI) Program documents the status of GIs in correspondence that are issued when a GI reaches a designated point in the process. The GI staff has issued the following documents, which are available on the GI Program SharePoint site. These documents provide examples that the staff should use when drafting new program documents:

- Examples of correspondence:
  - GI submittal
  - acceptance or nonacceptance into the GI process
  - request for a regulatory office to perform an immediate safety determination
  - response to an immediate safety concern determination
  - GI staff initial review recommending screening issue out and exiting the GI process
  - GI staff initial review recommending forming a Generic Issues Review Panel (GIRP)
  - request to a regulatory office for members to form a GIRP
  - identification of GIRP members or additional members to augment a GIRP
  - results of a GIRP screening evaluation
  - Office of Nuclear Regulatory Research (RES) Office Director acceptance of GIRP screening recommendation and continuance to Assessment stage
  - results of assessment
  - formulation of a transition team
  - recommendation from RES Office Director to transfer issue to regulatory office
  - closeout documentation
  - notification to the Office of the Advisory Committee on Reactor Safeguards of GIs that screen out or transition to regulatory office or close out
- Examples of programmatic reports and input into other agency periodic reports:
  - Generic Issues Management Control System (GIMCS) report

### Procedure for Processing Generic Issues

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- input into the semiannual report to Congress
- input into “The United States of America National Report for the Convention on Nuclear Safety” report
- input into NUREG-1925, “Research Activities”
- GI-related Web pages:
  - GI home page (public): <https://www.nrc.gov/about-nrc/regulatory/gen-issues.html>
  - GI submittal form page (public): <https://www.nrc.gov/about-nrc/regulatory/gen-issues/prop-new-gen-issue.html>
  - NUREG-0933, “Resolution of Generic Safety Issues,” page (public): <https://www.nrc.gov/sr0933/>
  - GIMCS report page (public): <https://www.nrc.gov/reading-rm/doc-collections/generic-issues/quarterly/>
  - GI Dashboard page (public): <https://www.nrc.gov/about-nrc/regulatory/gen-issues/dashboard.html>
  - GI Dashboard page (internal NRC): <http://gid.nrc.gov/Planning>