OFFICE OF NUCLEAR REGULATORY RESEARCH

RES OFFICE INSTRUCTION

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Summary of Changes: This revision incorporates comments from other offices; clarifies the roles and responsibilities of key personnel, and synchronizes process steps with recent experience.

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RES OFFICE INSTRUCTION
TEC-002, Revision 2
PROCEDURES FOR PROCESSING GENERIC ISSUES

1. PURPOSE

Management Directive (MD) 6.4, "Generic Issues Program," November 11, 2009, delineates the NRC program for addressing generic issues (GIs). Specifically, the program described in MD 6.4 comprises five stages: (1) identification, (2) acceptance review, (3) screening, (4) safety/risk assessment, and (5) regulatory assessment. This Office Instruction (OI) defines the roles and responsibilities of the Office of Nuclear Regulatory Research (RES) staff involved in the processing of GIs and unresolved safety issues (USIs). This OI also provides guidance for each stage of the program as well as guidance for the tracking of issues. This guidance is consistent with MD 6.4.

2. BACKGROUND

MD 6.4 describes the agency policy for the Generic Issues Program and its legal basis. MD 6.4 assigns RES the responsibility for overall management of the program. The agencywide aspects of the Generic Issues Program necessitate some unique RES staff roles, responsibilities, and reporting relationships. This OI provides guidance for RES staff in the implementation and management of the Generic Issues Program to ensure an effective agencywide program for the resolution of GIs and USIs including tracking and reporting status of issues.

3. DEFINITIONS

Action Plan – A detailed plan, with appropriate managerial approvals, developed for the conduct of the Safety/Risk Assessment or Regulatory Assessment stage of the Generic Issues Program. Detailed guidance for action plans is located in Appendix F. Depending on the complexity of the issue, an action plan may be developed for the Screening stage.

Closed GI – For the purposes of the Generic Issues Program, the phrase indicates that Generic Issues Program actions—but not all agency actions associated with the GI—are complete. The Generic Issues Program will continue to track and report the implementation and verification activities to their completion in the Generic Issues Management Control System (GIMCS).

Generic Issue – A well-defined, discrete, radiological safety, security, or environmental matter of which risk significance can be adequately determined and which (1) applies to two or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals (including design certification rules); (2) may affect public health and safety, the common defense and security, or the environment; (3) is not already being processed under an existing program or process; (4) cannot be readily addressed through other regulatory programs and processes, existing regulations, policies, guidance, or voluntary industry initiatives; and (5) can be resolved by new or revised regulation, policy, or guidance or voluntary industry initiatives. A GI may lead to regulatory changes.

Graded Approach – Applies process rigor commensurate with GI importance and reduces the process burden for assessing GIs of lower risk significance. The appropriate amount of process rigor for GI screening and review panels depends on risk significance, importance, or applicability of the GI. GIs of low risk significance or importance may be adequately screened or assessed without using a formal review panel, while unclear GIs or GIs of high risk significance warrant formal and sometimes extensive reviews by expert panel members. Similarly, the value added from formal panel meetings (e.g., group synergy and open debates) varies with GI risk significance or importance and also with information certainty or margins for tolerating error. Formal panel meetings add less value when there is a lower risk significance, importance, uncertainty, or large margins for error tolerance. In cases of moderate risk significance or importance, virtual panel meetings via 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 Generic Issues Program stage.

Immediate Actions – Prompt actions (such as the imposition of compensatory measures or shutdown orders) by the regulatory office in response to an emergent issue. Immediate actions are intended to provide reasonable assurance of adequate protection, which maintains safety while allowing the emergent issue to be processed. The regulatory offices are responsible for determining what constitutes “adequate protection” for their facilities and the need for any immediate actions.

Key Office Contacts – The office contacts for Generic Issues Program activities are staff from other offices designated by the respective office director to lead and coordinate office activities and information flow involving the Generic Issues Program as follows:

- Facilitation of office review of Generic Issues Program policy documents.

- Coordination of development of office instructions for Generic Issues Program documents.

- Communication and coordination with Generic Issues Program and other offices through all Generic Issues Program stages for resource allocation, information flow, and decisions on transitions to other programs.

Transition Process – Any time a change or transition occurs in the status of an issue, this change needs to be clearly documented and communicated to ensure no confusion exists regarding its status and ownership. Normally, these transitions are documented via memorandum. Examples of transitions include (1) receipt of a proposed GI, (2) acceptance/rejection of a proposed GI after the acceptance review stage, (3) acceptance/rejection of a proposed GI after the screening stage, (4) completion of the safety/risk assessment stage, (5) endorsement of a regulatory assessment, and (6) transfer to a more appropriate program (e.g., long-term studies or regulatory office processes such as rulemaking, regulatory guidance, industry initiatives, generic communications, and licensing actions. Transitions that involve ownership of future actions for the issue are coordinated with the recipient.

Unresolved Safety Issue (USI) – A matter affecting a number of nuclear power plants that poses important questions concerning the adequacy of existing safety requirements for which a final resolution has not yet been developed and that involves conditions that

could potentially be unacceptable over the lifetime of the plants affected. USIs are a subset of GIs.

4. RESPONSIBILITIES AND AUTHORITIES

4.1 RES Office Director (RES)

- Provides overall management of the Generic Issues Program including development, maintenance, and implementation of Management Directive 6.4, "Generic Issues Program."
- Ensures that RES staff refers issues under RES's area of responsibility that appear to meet the GI definition to the Generic Issues Program.
- Develops and maintains this office-level procedure and office-level administrative controls for Generic Issues Program implementation.
- Is responsible for the processing of GIs in all stages of the Generic Issues Program process including endorsement of recommendations resulting from screening, safety/risk assessments, and regulatory assessments.
- Coordinates with other office directors to authorize new GIs.
- Coordinates and approves the transfer (handoff) of GIs from the Generic Issues Program to other regulatory programs.
- Assigns a branch chief to serve as the Generic Issues Program Manager (GIPM) responsible for Generic Issues Program coordination and communication with other offices.
- Appoints RES Senior Executive Service (SES) managers when they are selected to serve as chairs of the Generic Issue Review Panels and appoints RES technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk Assessment and Regulatory Assessment stages of the GI process, as appropriate.
- Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions.
- Is responsible for periodic reporting to the Commission and the Congress, GI and GIMCS updates through all Generic Issues Program stages, and completion of office-specific actions.

4.2 RES Division Director

- Oversees the Generic Issues Program, assigns Generic Issues Program staff, and ensures timely and accurate Generic Issues Program status reporting

(applicable only for the division director responsible for the Generic Issues Program program).

- Refers to the Generic Issues Program those issues under the division's area of responsibility that appear to meet the GI definition.

- Coordinates with the Generic Issues Program Manager during all Generic Issues Program stages in applying Generic Issues Program criteria to ensure issues are effectively directed to the most appropriate agency programs.

- Coordinates GI-related assignments with the Generic Issues Program Manager and the Generic Issues Program Responsible Project Manager (RPM), in the development and implementation of Action Plans. Provides appropriate resources, including staff, contractor support, or analytical tools needed for assigned GIs.

- Manages division resources for GI-related assignments to ensure the timeliness, cost-effectiveness, and technical quality of deliverables.

4.3 RES Branch Chief

- Refers to the Generic Issues Program those issues under the branch's area of responsibility that appear to meet the GI definition.

- Coordinates GI-related assignments with the Generic Issues Program RPMs, in the development and implementation of Action Plans. Provides appropriate resources including staff, contractor support, or analytical tools needed for assigned GIs.

- Manages branch resources for GI-related assignments to ensure the timeliness, cost-effectiveness, and technical quality of deliverables.

- Reviews and approves status reporting information to ensure that updated information is timely and accurate for assigned GIs.

4.4 Generic Issues Program Manager

- Has overall responsibility for Generic Issues Program administration and centralized leadership and management of the Generic Issues Program.

- Administers the Generic Issues Program using a graded approach to the extent practical.

- Ensures that the Generic Issues Program is consistently implemented across offices. Communicates and coordinates with other NRC organizations through all Generic Issues Program stages for resource allocation, information flow, and decisions regarding the transition of issues to other programs.

- Coordinates activities for GI status tracking and reporting (e.g., GIMCS and NUREG-0933).

- Maintains internal procedures and controls for routine Generic Issues Program activities, including GIMCS and web updates.

- Assigns and oversees the GIMCS Tracking Coordinator (GTC) and Generic Issues Program RPMs for tasks in all stages of the Generic Issues Program. Generally, the RPM will be assigned from the staff of the GIPM, but circumstances may arise where an RPM is assigned from outside that branch or RES. Such assignments will be made in coordination and consultation with the outside individual's management.

- Coordinates with other program offices to staff the Generic Issue Review Panels and with the selected panels to complete the assigned reviews.

- Meets periodically with the designated Generic Issues Program office contacts to discuss implementation of the program.

4.5 Responsible Project Manager (RPM)

- Has the overall lead role for all Generic Issues Program actions for a specific GI throughout the Generic Issues Program process. The RPM is not expected to be a technical expert on assigned Generic Issues, but is considered the lead coordinator for processing the issue.

- Applies a graded approach; gathers information; and develops, implements, and maintains the Action Plan for Generic Issues Program Stages 3 (Screening - optional), 4 (Safety/Risk Assessment), and 5 (Regulatory Assessment).

- Coordinates with technical staff assigned to the GI and the technical staff's management in developing, implementing, and maintaining the Action Plan for Stages 3 (optional), 4, and 5.

- Provides GIMCS updates to the GIPM and the GIMCS Tracking Coordinator for assigned GIs.

- Facilitates the GI Review Panel meetings and coordinates followup activities in Stages 3 and 4 as described in Section 5.

- Prepares a screening analysis and safety/risk assessment with support from technical staff, as needed.

- Prepares and manages the recommendation memorandum in Generic Issues Program Stages 3, 4, and 5.

- Coordinates advisory committee involvement, as needed.

- Coordinates internal and external stakeholder interactions, as appropriate.

- Prepares and maintains the issue-specific communication plan per OEDO Procedure – 0430, "Communication Plans." The communication plan for GI-199 provides an example of an issue-specific communication plan (ML081850477).

4.6 GIMCS Tracking Coordinator (GTC)

- Leads and coordinates interoffice information flow, as described below, for GIMCS updates in support of routine reports to the Commission and Congress.
    - Prepares and issues a memorandum requesting updated GIMCS information.
    - Contacts the RPM (or program office project manager for issues that have transitioned to regulatory office implementation) and their management to discuss the coordination of specific GI information, offer Generic Issues Program assistance, and followup, as necessary, to obtain the update information.
    - Documents coordination efforts; updates and verifies the information provided; archives the information, as appropriate; and enters information into the GIMCS.
    - Provides the updated GIMCS report information and the compiled GI status update information to the RPM (or program office project manager for issues that have transitioned to regulatory office implementation) and their management for each GI for their review, comment, and approval.
- Provides updated information regarding individual GIs and GIMCS reports for web updates.
- Provides updated information regarding the status of proposed Generic Issueproposed Generic Issues.
- Assigns appropriate proposed Generic Issuenumbers to issues as they enter and proceed through the program.

4.7 Staff with Assignments under Action Plans

- Coordinate with RPM (or program office project manager for issues that have transitioned to regulatory office implementation) through their management in support of the development, implementation, and maintenance of Action Plans for Stages 3 (optional), 4, and 5, as assigned.
- Report progress to RPM (or program office project manager for issues that have transitioned to regulatory office implementation) and management.
- Provide periodic GIMCS updates to the RPM (or program office project manager for issues that have transitioned to regulatory office implementation) and GTC after receiving management endorsement of the input.

5. INSTRUCTIONS

M.D. 6.4, “Generic Issues Program,” describes the objectives and roles and responsibilities for the program. The M.D. 6.4 Handbook provides an introduction to the Generic Issues Program including historical perspective, purpose, GI and USI definitions and criteria, and principles and goals. The MD 6.4 Handbook also provides an overview of the five-stage process and its relationship to other agency programs, including several diagrams. Further program details, including links to important program documents and products are available at the Generic Issues Program internal web page. The instructions in this section are intended to provide guidance for the execution of the five stages, the transition process, and GI status tracking and reporting. The appendices include more detailed guidance on the Generic Issues Program and USI criteria, processing and assessing proposed GIs, and developing and implementing action plans. The steps underlying the screening, safety/risk assessment, and regulatory assessment stages are intended to provide general guidance; however, the relative complexity of the issue may warrant some modification of the order of execution. It is expected that execution of these instructions occurs coincident with an open and collaborative work environment.

5.1 Stage 1 – Identification

A variety of stakeholders, such as the general public and staff, can propose GIs. The general public can submit potential GIs via several methods, including the NRC public web site or United States mail. The NRC staff can propose GIs also using these methods or other internal communication processes. Once the Generic Issues Program receives a proposed GI, the Generic Issues Program Manager will assign Generic Issues Program staff to process the issue.

Step 5.1.1 applies to a NRC staff member that identifies a potential GI and submits it through the Generic Issues Program mailbox. The Generic Issues Program mailbox is configured to notify all Generic Issues Program staff members of proposed GIs submitted to the Generic Issues Program mailbox. This mailbox is the same mailbox used to receive proposed Generic Issues from the public Generic Issues Program web site.

Step 5.1.2 applies to all issues submitted to the Generic Issues Program, including those issues submitted via other methods, e.g. the NRC public web site or United States mail.

5.1.1 The NRC staff member identifying an issue that appears to meet the GI criteria is encouraged to inform management. The NRC staff member and management should contact Generic Issues Program staff for assistance in determining if the issue meets Generic Issues Program criteria (Appendix A) or USI criteria (Appendix B). If the issue appears to meet the criteria, the RES staff member may use the GI proposal form (Appendix C) and follow the instructions for submitting the issue to the Generic Issues Program mailbox (GIP.Resource@nrc.gov). The Generic Issues Program staff shall assist the originator, as needed.

5.1.2 The Generic Issues Program Manager assigns the proposed GI (regardless of whether it was generated internally or externally) to a Generic Issues Program RPM.

5.1.3 The RPM reviews the issue and contacts the originator to acknowledge receipt, request additional information as needed to support an effective acceptance review, and inform the originator about the next step (i.e. the acceptance review) and schedule. The RPM also ensures the proposed GI information and acknowledgement (memorandum or e-mail) to the submitter are entered into the Agencywide Document and Management System (ADAMS). This information shall not be publicly available to maintain the integrity of pre-decisional information and foster the uninhibited generation of potential issues.

5.1.4 The Generic Issues Program Manager contacts the appropriate Generic Issues Program regulatory office contact(s) to inform them of the proposed GI to determine the need for prompt regulatory action and in support of interoffice coordination for subsequent Generic Issues Program activities. Generic Issues Program regulatory office contact(s) are described in MD 6.4 and assigned by the Director of each regulatory office.

In determining the appropriate regulatory office to contact, the Generic Issues Program Manager should consider the broadest applicability of an issue, i.e. have the justification for excluding specific regulatory areas, e.g. materials, reactors, etc. The Generic Issues Program Manager should inform all regulatory offices potentially affected by a proposed GI. Occasionally, a collaborative decision may be reached such that the regulatory office(s) can effectively address the issue outside the Generic Issues Program. In such cases, a transition memorandum is issued, documenting the decision and transfers the issue. The originator is also informed of the decision, typically by being carbon copied on the transfer memorandum. Otherwise, the issue proceeds to the Acceptance Review stage.

5.2 Stage 2 – Acceptance Review

5.2.1 The assigned RPM ensures that the proposed GI is assigned a proposed Generic Issue number by contacting the GTC. The GTC provides a proposed Generic Issue number for the proposed GI and enters the appropriate information into GIMCS.

5.2.2 The assigned RPM contacts the appropriate office contact(s) to support the review of the proposed GI information, including informal identification of technical working groups or teams and expert panels, in the event the issue proceeds to the screening stage. In addition, the RPM reviews the GIMCS database for similar GIs (i.e., performs a duplication review). The RPM performs a limited assessment of the proposed Generic Issue against the Generic Issues Program criteria (Appendix A). During the assessment, as appropriate, the RPM should practice open and

collaborative communication with the submitter to provide status and gain further insight on the issue.

5.2.3 The acceptance review period may be extended if the RPM anticipates the need for additional time to gather the sufficient information to perform the acceptance review. In this case, the RPM should discuss a proposed extension with the Generic Issues Program Manager and consider applying the guidance in Appendix D, “Evaluating the Information and Resources Required to Assess a Proposed or Accepted GI" to identify the potential need for long-term studies. Generally, if study greater than 3 to 6 months is needed, the issue may not meet the generic issue criteria, Criterion 5, as described in Appendix A.

5.2.4 The assigned RPM documents the review and provides a recommendation regarding further Generic Issues Program processing to the Generic Issues Program Manager. The recommendation also identifies other agency programs or processes for further processing the issue, as applicable. The RPM may offer the submitter the opportunity to provide comments on the draft acceptance memorandum. Should the submitter provide formal comments, the RPM will include those comments in the documentation package for the acceptance memorandum.

5.2.5 The Generic Issues Program Manager ensures that the originator and other stakeholders are informed of the final outcome of the acceptance review. The Generic Issues Program Manager also ensures that the final Acceptance Review is documented, and that the GIMCS and internal web page are updated to reflect the outcome of the acceptance review. Appendix E, “Sample Templates for Acceptance Review Memoranda,” provides templates for accepting or rejecting a proposed Generic Issue. This template includes important language that informs the submitter of the circumstances under which a proposed Generic Issue may be reassessed if it is rejected.

For issues that pass the acceptance review stage, the responsible regulatory office director(s) is notified via memorandum to ensure that an *immediate action* determination is or has been made. Generally, 15 days are allowed for a response (which occurs after the Acceptance Review stage) from other office(s). During this time, the RPM should consider applying the guidance in Appendix D, “Evaluating the Information and Resources Required to Assess a Proposed or Accepted GI” to identify challenges to the Generic Issues Program process schedule and the potential need for long-term studies.

Note that if information is identified at any time during the Generic Issues Program process that invalidates or is contrary to the stated basis of a regulatory office *immediate action* determination, then the responsible office director(s) shall be immediately notified via e-mail, to be followed by a memorandum.

The expected time to complete the acceptance review is published in MD 6.4 and represents a base case where sufficient information is available. This completion time presupposes that the Generic Issues Program Manager has communicated any resource needs to the office level and that the appropriate resources are available.

5.2.6 After the submitter has been notified of the outcome of the acceptance review, the submitter may send additional correspondence in response to the outcome. Upon receipt of this correspondence, the RPM will review and respond to it with a memorandum acknowledging receipt and will take further action, if necessary, using the guidelines in Appendix G, "Guidance for Responding to Correspondence Related to Proposed GIs."

5.3 Stage 3 – Screening

5.3.1 If necessary, the RPM develops and maintains a plan with a schedule and milestones for completing the screening. The Generic Issues Program Manager normally approves the plan for the Screening stage but can seek higher level approvals depending on the complexity or safety importance of the issue.

5.3.2 The RPM engages the appropriate office contact(s) to assist in the identification of technical staff that can provide information to support a more thorough assessment of the proposed Generic Issue against the Generic Issues Program criteria.

5.3.3 The Generic Issues Program Manager, in coordination with internal stakeholders and the RES Division Director, applies a graded approach to determine the need for a GI Review Panel, its size, expertise, and degree of formality (e.g., e-mail correspondence, teleconference, or formal in-person panel meetings). The Generic Issues Program Manager coordinates with other offices to identify and request staff members to participate as GI Review Panel members, as needed. The function of the GI Review Panel is to review the screening assessment developed by the RPM with technical staff support (see Section 5.3.4) and to make a recommendation regarding further Generic Issues Program processing to the RES Office Director for endorsement. The recommendation may also identify other agency programs or processes for further processing the issue, as applicable. The GI Review Panel normally consists of three (or more) members, including an SES manager (the Chair), a risk expert, and a subject matter expert. The panel members normally come from two or more NRC offices outside of RES, including the applicable originating or affected regulatory office.

The GI Review Panel members are selected to provide expert, but broadly diverse, perspectives on the issue. In general, the degree of formality of the Generic Issues Program will depend on whether the Generic Issues Program criteria can be applied to reach a screening decision that is clear, without large uncertainties, and with staff consensus.

5.3.4 The RPM, with the appropriate technical staff, performs and documents the screening assessment and provides a recommendation for further Generic Issues Program processing to the GI Review Panel Chair. The recommendation also identifies other agency programs or processes for further processing the issue, as applicable. The RPM will coordinate with other agency offices to determine an agreeable path forward if other agency programs or processes are required. The RPM should also consider engaging the Office of Public Affairs (OPA). An example of a screening assessment is available with ADAMS accession number ML0734004930.

5.3.5 The RPM shall prepare a Communication Plan in accordance with OEDO Procedure 0430, "Communication Plans," for those issues that the GI Review Panel recommends to be screened into the Generic Issues Program. While the GI Review Panel is finalizing the screening recommendation, the RPM should begin preparing the Communication Plan. This early preparation will facilitate the approval and issuance of the communication plan prior to submitting the screening recommendation to the RES Office Director for endorsement. A sample issue-specific Communication Plan is available at ADAMS accession number ML072950292.

5.3.6 The GI Review Panel reaches a consensus screening recommendation that is forwarded to the RES Office Director for endorsement. Note: any dissenting panel member views will be documented in the recommendation memorandum so that the RES Office Director is informed of these dissenting views. If no GI Review Panel is established, the Generic Issues Program Manager provides the screening recommendation. If the RES Office Director does not endorse the screening recommendation, then the GI Review Panel considers the RES Office Director's comments and revisits the screening recommendation.

5.3.7 Once the RES Office Director decides on a course of action, the Generic Issues Program Manager, if appropriate, ensures that the originator and other stakeholders, including appropriate review committees (e.g. the Advisory Committee on Reactor Safeguards) are informed of the screening outcome. The Generic Issues Program Manager ensures the coordination of the transition of the issue to another program office if the screening outcome is to use a program other than the Generic Issues Program to address the issue. The Generic Issues Program Manager ensures that screening is documented, including updates to GIMCS, the Generic Issues Program internal web page, and the Communication Plan. An issue that screens in is given a GI number by the GTC and is considered to be a "formal" GI. At this point, the information on the GI becomes publicly available.

5.3.8 The Generic Issues Program Manager, in coordination with other internal stakeholders, will consider the need for a public meeting to communicate the screening results and the participation of nuclear industry stakeholders. The Generic Issues Program Manager should consider the effect these interactions may have on the action plan schedule. The RPM

should consider applying the guidance in Appendix D, "Evaluating the Information and Resources Required to Assess a Proposed or Accepted GI" to confirm challenges to the Generic Issues Program process schedule and the potential need for long-term studies. The expected total time to complete both the Acceptance Review and Screening stages is published in MD 6.4 and represents a base case where sufficient information is available. This completion time further presupposes that the Generic Issues Program Manager has communicated any resource needs to the office level and that the appropriate resources are available.

5.4 Stage 4 – Safety/Risk Assessment

5.4.1 The RPM develops and maintains an *action plan* (see Appendix F) with a schedule and milestones for completing a Safety/Risk Assessment and subsidiary activities (e.g., Communications Plan update and stakeholder meetings). The Generic Issues Program Manager approves the plan for the Safety/Risk Assessment stage but can seek higher-level approvals depending on the complexity, resource needs, and safety importance of the issue. The Generic Issues Program Manager should assure that needed resources are available to support the action plan.

One part of the outcome of the Safety/Risk Assessment Stage is a determination, based on the figures/tables of Appendix A, whether the risk associated with the issue (and could likely pass the restrictions for) justifies pursuing it further under current backfit provisions (e.g., 10 CFRs 50.109, 52.63, 70.76, 72.62, and 76.76). The second part of the outcome is a recommendation regarding the next step (i.e., continue to the Regulatory Assessment stage of the Generic Issues Program or pursue another process outside the Generic Issues Program).

5.4.2 The RPM engages the appropriate office contact(s) to assist in the identification of technical staff that should be involved in or contribute to tasks of the Safety/Risk Assessment for the GI.

5.4.3 The RPM coordinates with technical staff to perform the Safety/Risk Assessment when resources, existing risk analysis models, and supporting information (e.g., Standardized Plant Analysis Risk [SPAR] Models) are sufficient to perform the Safety/Risk Assessment. Note, to some degree, the Safety/Risk Assessment might have already been performed as part of the Screening Analysis. When more, new, or supplements to existing models or supporting information are needed to perform a credible Safety/Risk Assessment of the issue, then information must first be gathered, which could involve literature searches, experiments, requests for information from licensees or industry stakeholders, operating experience reviews, etc. In these cases, the RPM will reflect these activities in the plan, and the timeframe for completing the Safety/Risk Assessment Stage might exceed the timeline stated in MD 6.4. In cases where the issue is not amenable to performing a quantified Safety/Risk Assessment, the staff will perform the Safety/Risk Assessment on a qualitative basis relying primarily on engineering judgment or an expert elicitation process. For instance, the

staff could develop the qualitative basis by applying the substantial increase standard as stated in the Committee to Review Generic Requirements (CRGR) Charter, Appendix D, “Guidance on Application of the ‘Substantial Increase’ Standard.”

5.4.4 The Generic Issues Program Manager applies an approach similar to 5.3.3 to determine the need for a GI Review panel, its membership size, expertise and degree of formality, e.g. email correspondence, teleconference, or in-person panel meetings. The Generic Issues Program Manager coordinates with other offices to identify and request staff members to participate as Safety/Risk Assessment GI Review Panel members, as needed. The Safety/Risk Assessment GI Review Panel for any issue normally consists of the same members who served on the Screening GI Review Panel. The GI Review Panel for this stage also has an analogous function (i.e., to review the RPM’s Safety/Risk Assessment and recommendations for further Generic Issues Program processing) (see Section 5.4.5).

5.4.5 The RPM performs and documents the Safety/Risk Assessment and provides a recommendation regarding further Generic Issues Program processing to the GI Review Panel. The recommendation also identifies other agency programs or processes for further processing the issue, as applicable. The RPM will coordinate with other agency offices to facilitate acceptance of the path forward if other agency programs or processes are to be used.

5.4.6 The GI Review Panel meets and reaches a consensus Safety/Risk Assessment recommendation that is forwarded to the RES Office Director for endorsement. Note: any dissenting panel member views are encouraged to be documented in the recommendation memorandum to inform the RES Office Director of these dissenting views. If the RES Office Director does not endorse the Safety/Risk Assessment recommendation, then the GI Review Panel considers the RES Office Director’s comments and revisits the recommendation.

5.4.7 Once the RES Office Director endorses the safety/risk recommendation, the Generic Issues Program Manager ensures that the originator and other stakeholders, including appropriate offices, advisory committees, and the Commission, are informed of the Safety/Risk Assessment outcome. This communication may include briefings to the appropriate internal stakeholders. The Generic Issues Program Manager ensures the coordination of the transition of the issue to another program office if the safety/risk assessment outcome is to use a program other than the Generic Issues Program to address the issue. The Generic Issues Program Manager ensures that Safety/Risk Assessment is documented, including updates to GIMCS, the Generic Issues Program internal and external web pages, and the Communication Plan.

5.4.8 The Generic Issues Program Manager, in coordination with other internal stakeholders, will continue to engage nuclear industry stakeholders in a cooperative environment. The Generic Issues Program Manager should

consider the effect these interactions may have on the action plan schedule. The RPM should consider applying the guidance in Appendix D, “Evaluating the Information and Resources Required to Assess a Proposed or Accepted GI” to reassess challenges to the Generic Issues Program process schedule and the potential need for long-term studies. The expected time to complete the safety/risk assessment is published in MD 6.4. This completion time presupposes that the Generic Issues Program Manager has communicated any resource needs to the office level and that the appropriate resources are available.

5.5 Stage 5 – Regulatory Assessment

5.5.1 The Regulatory Assessment will include a regulatory analysis, performed in accordance with the current regulatory analysis guidelines. The RPM develops and maintains an *action plan* (see Appendix F) with a schedule and milestones for completing a Regulatory Assessment and subsidiary activities. The division director overseeing the Generic Issues Program approves the plan for the Regulatory Assessment stage, but can seek higher level approvals depending on the complexity, resource needs, and safety importance of the issue.

The Generic Issues Program Manager, in coordination with other internal stakeholders, will continue to engage nuclear industry stakeholders. The Generic Issues Program Manager should consider the effect these interactions may have on the action plan schedule.

The products of the Regulatory Assessment will include the identification of regulatory approaches, (e.g. rulemaking, enforcement, generic communications), a technical basis to support those approaches, and cost-benefit or backfit analysis, as appropriate. These products are provided to the regulatory office for regulatory product development.

5.5.2 The RPM engages the appropriate office contact(s) to assist in the identification of technical staff that should be involved in or contribute to tasks of the Regulatory Assessment for the GI.

5.5.3 The RPM coordinates with the appropriate regulatory offices to identify and assess the merits of the regulatory alternatives. This includes using the guidelines of NUREG/CR-3971, “A Handbook for Cost Estimating,”, and NUREG/BR-0058, Rev. 4, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission” to prepare a cost-benefit assessment of the alternatives and support a recommendation for approval.

5.5.4 The RPM documents the Regulatory Assessment and provides a recommendation for further action to the Generic Issues Program Manager. The RPM and Generic Issues Program Manager shall ensure that the recommendation has been communicated to and coordinated with the responsible program office(s) and RES Office Director. After receiving approvals from the Generic Issues Program Manager and RES Division Director, the RPM provides the recommendation from the

Regulatory Assessment to the advisory committees for their endorsement.

5.5.5 After receiving advisory committee endorsement, the RPM provides the Regulatory Assessment and recommendation for further actions to the RES Office Director and other Office Directors (as appropriate) for endorsement.

5.5.6 After the RES Office Director endorses (concurs or approves, as appropriate) the regulatory assessment recommendation, the Generic Issues Program Manager ensures that the originator and other stakeholders are informed of the outcome. This communication may include briefings to the appropriate internal stakeholders. The Generic Issues Program Manager coordinates the transition of the issue to another program office if the Regulatory Assessment determines an alternate program office can resolve the issue. The Generic Issues Program Manager ensures that the Regulatory Assessment is documented, including updates to GIMCS, the Generic Issues Program internal and external web pages, and the Communication Plan. The issue is closed out of the Generic Issues Program, but implementation and verification actions by the regulatory office(s) continue to be tracked in GIMCS until their completion by the regulatory office(s). The expected time to complete the regulatory assessment is published in MD 6.4. This completion time presupposes that the Generic Issues Program Manager has communicated any resource needs to the office level and that the appropriate resources are available.

5.6. Generic Issue Tracking and Reporting

5.6.1. The GIMCS Tracking Coordinator (GTC) assigns a number to each proposed GI and will maintain a log of its status and disposition.

5.6.2. The Generic Issues Program Manager will prepare publicly available semiannual memoranda to the RES Office Director of the status of all proposed Generic Issues active within the past year. This status will include those issues that have exited the program for long-term study. Upon completion of those studies, the Generic Issues Program Manager will assist the submitter in determining whether the proposed Generic Issue should proceed through the program.

5.6.3. The Generic Issues Program Manager will prepare semiannual reports to the EDO on significant accomplishments on open GIs for use in the NRC semiannual report to the Congress.

5.6.4. The GTC will provide quarterly updates to GIMCS to incorporate approved action plans for new GIs and to incorporate modifications to schedule information for existing work plans.

5.6.5. The GTC will provide all new GIs in Table II, Table III, and Appendix B of NUREG-0933, “Resolution of Generic Safety Issues,” and provide all

approved screening analyses for publication in annual supplements to NUREG-0933.

5.6.6. The Responsible Project Manager will submit status reports for each approved action plan to the GTC and Generic Issues Program Manager quarterly, or as requested.

5.6.7. The Generic Issues Program Manager will publish annual supplements to NUREG-0933, as needed, if new GIs are identified or GIs are resolved since the previous update of the report. Annual supplements to NUREG-0933 will add information about the identification, acceptance review, and screening stages for all newly identified GIs and will document resolution of those issues with completed actions since publication of the previous supplement.

6. PERFORMANCE MEASURES

No specific performance measure is associated with this Office Instruction.

7. REFERENCES

U.S. Nuclear Regulatory Commission, SECY-07-0022, “Status Report on Proposed Improvements to the Generic Issues Program,” January 30, 2007 (ML063460239).

U.S. Nuclear Regulatory Commission, Management Directive 6.4, “Generic Issues Program,” November 17, 2009 (ML083181192).

U.S. Nuclear Regulatory Commission, NUREG-0933, “A Prioritization of Generic Safety Issues,” July 1991, and Supplements 13 to 33 (ML102440297).

U.S. Nuclear Regulatory Commission, NUREG/CR-3971, "A Handbook for Cost Estimating" (ML072320183).

U.S. Nuclear Regulatory Commission, NUREG/CR-4568, "A Handbook for Quick Cost Estimates" (ML090020304).

U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (ML042820192)."

U.S. Nuclear Regulatory Commission, NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook" (ML050190193).

U.S. Nuclear Regulatory Commission, NUREG/CR-3568, "A Handbook for Value-Impact Assessment" (ML062830096).

U.S. Nuclear Regulatory Commission, NUREG-0705, "Identification of New Unresolved Safety Issues Relating to Nuclear Power Plants" (ML072500161).

U.S. Nuclear Regulatory Commission, Regulatory Guide 1.174, Revision 1, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis” (ML023240437).

APPENDIX A
GENERIC ISSUE CRITERIA

The Generic Issues Program (Generic Issues Program) will address only those issues that meet the following seven criteria. The criteria are continuously applied throughout the Generic Issues Program process such that a proposed GI or a GI that fails to meet any of these criteria at any time will exit the program. The concept of continuously applying the criteria throughout the Generic Issues Program process is critical, especially for determining those proposed or accepted GIs that will require long-term studies to complete the assessment and should therefore exit the program.

1. The issue affects public health and safety, the common defense and security, or the environment.

The purpose of this criterion is to eliminate issues not directly involving or affecting "safety or security" (e.g., purely administrative matters, policy, regulatory process issues, or NRC organization issues) although policy decisions could result in identification of a proposed GI. In addition, Figures A1 through A3 provides guidance based on risk regarding whether a reactor issue should continue in the program or exit it. These figures are derived from the criteria for assessing safety enhancement issues by addressing the safety goal analysis as described in Section 3 of NUREG/BR-0058, Rev. 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." These figures may be applied at anytime during the Generic Issues Program process if the information is known. For issues that are not amenable to quantification using risk assessment, qualitative criteria may be developed and applied as necessary to assess safety/risk significance. For issues related to materials and waste, quantitative health guidelines (QHGs) can be used to determine the applicability of this criterion. A more detailed discussion of the QHGs can be found in "Risk-Informed Decisionmaking for Nuclear Material and Waste Application, Rev 1" (ML080710446).

For some issues, it may not be possible to use probabilistic risk assessment methods and tools either because of their limitations or because they may not have been developed (e.g., some materials applications). In cases where probabilistic tools and methods are not useful, the decision to accept the issue in the Generic Issues Program is generally based on more qualitative elements linked to NRC's strategic plan and expert judgment. In general, only those issues that represent credible threats to NRC's strategic and performance goals and measures, unless current regulatory programs are changed, meet this criterion. Note that such issues might fail Criterion 5.

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

The purpose of this criterion is to eliminate site-specific issues that are handled under other processes such as the Reactor Oversight Process.

3. The issue cannot be readily addressed through other regulatory programs and processes, existing regulations, policies, or guidance; or voluntary industry initiatives.

One way to view the Generic Issues Program is that it facilitates the staff's identification of an efficient mechanism for addressing a regulatory issue. Once another mechanism (regulatory program or process or voluntary industry initiative) to address the issue is

identified and agreed upon by the regulatory office, the issue is transferred to the regulatory office and may exit the Generic Issues Program. Examples of issues to be excluded from the Generic Issues Program using this criterion include those that can be processed more quickly through the Generic Communications Program or the Reactor Oversight (inspection) Process.

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

The Generic Issues Program is intended to provide a way to "fix" identified potential weaknesses and deficiencies in existing safety requirements and guidance. In conjunction with criterion 3, an issue exits the program when a fix is identified and agreed upon that is within the staff's ability to implement (e.g., guidance change). An issue also exits the Generic Issues Program if the staff determines that either no change is needed or that a change cannot be justified under backfit provisions.

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

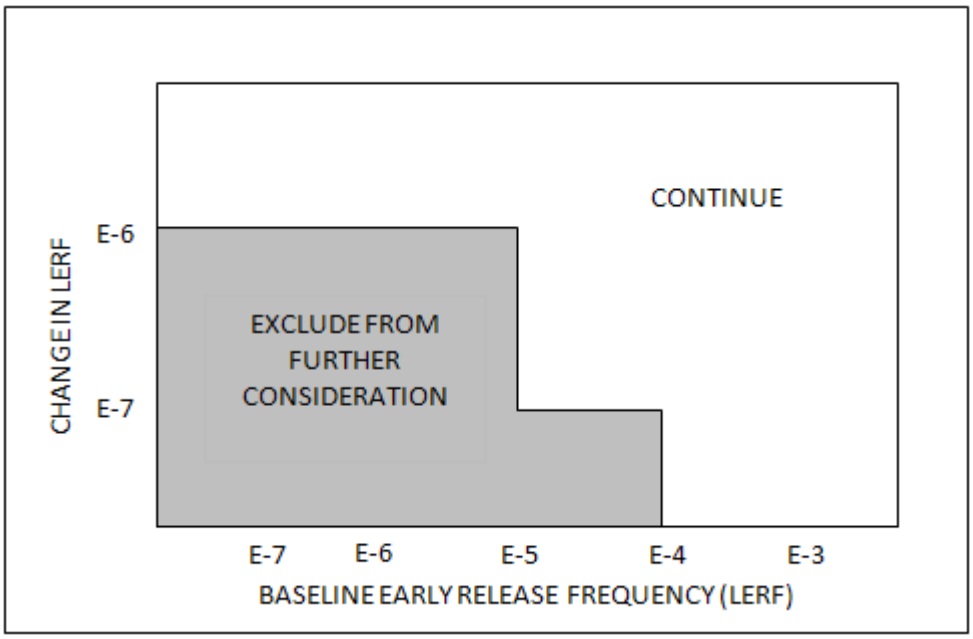
The purpose of this criterion is to eliminate those issues requiring long-term studies. The intent of the Generic Issues Program is to direct or transfer the issue to the most appropriate place and for the issue to be actively worked. Therefore, long-term studies should be conducted and managed by RES rather than under the agencywide Generic Issues Program. Generally, if study greater than 3 to 6 months is needed, then the issue does not meet this criterion. Upon completion of the long-term study, the issue may return to the Generic Issues Program, if appropriate. This criterion also is intended to make clear the ownership and accountability for the conduct of research.

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

The purpose of this criterion is to keep the scope of a GI from growing and to ensure that matters extraneous to the issue are excluded such that the issue remains manageable. In general, related issues or topics may be proposed as a single GI and will likely be separated and undergo individual processing and screening in the Generic Issues Program.

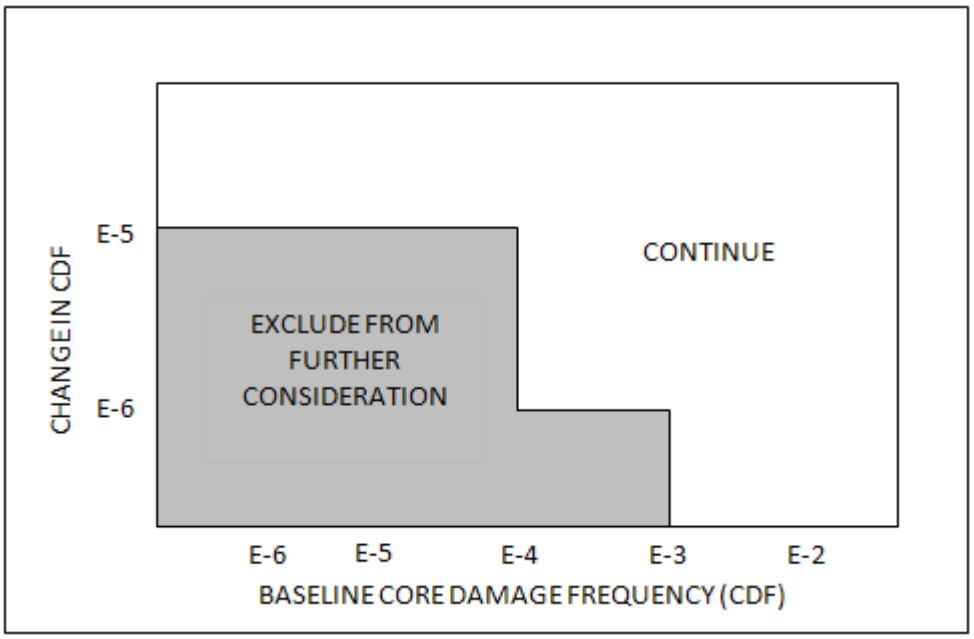
7. Resolution of the issue may potentially involve review, analysis, or action by the affected licensees, certificate holders, or holders of other regulatory approvals.

The criterion is in keeping with the intent of the Generic Issues Program to address potential weaknesses and deficiencies in existing regulations and guidance affecting "safety and security." If it becomes apparent that no licensee action will be needed, then further assessment under the Generic Issues Program is not needed and the issue exits the Generic Issues Program.



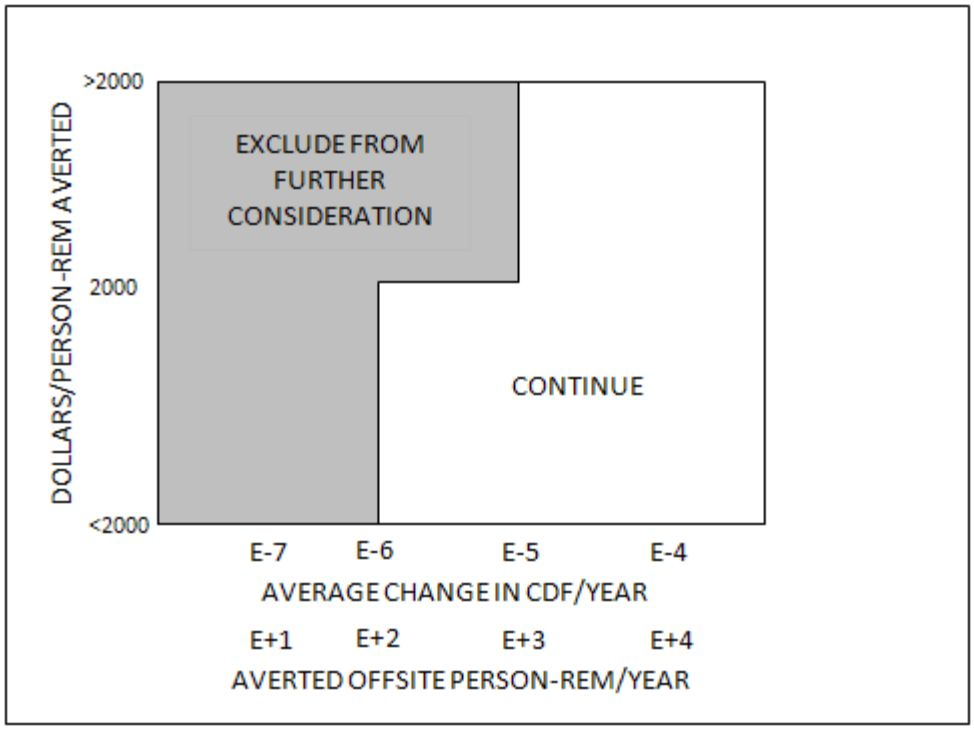
*Change in LERF represents the resulting increase in the LERF from a proposed generic issue

Figure A1. Generic Issues Program Large Early Release Frequency Numerical Criterion for Reactor Issues



*Change in CDF represents the resulting increase in the CDF from a proposed generic issue

Figure A2. Generic Issues Program Numerical Core Damage Frequency Criterion for Reactor Issues



*CDF – Core Damage Frequency

Figure A3. Impact/Value Numerical Threshold for Reactor Generic Issues (Excludes Adequate Protection Issues)

APPENDIX B
UNRESOLVED SAFETY ISSUES (USIs)

USI DEFINITION

The Energy Reorganization Act of 1974, as amended, contains the following requirement:

Unresolved Safety Issues Plan

> Section 210. The Commission shall develop a plan for providing for specification and analysis of unresolved safety issues relating to nuclear reactors and shall take actions as may be necessary to implement corrective measures with respect to such issues. Such plan shall be submitted to the Congress on or before January 1, 1978, and progress reports shall be included in the annual report of the Commission thereafter.

The following definition of an Unresolved Safety Issue (USI) was developed to satisfy the intent of Section 210 and has been used subsequently in identifying USIs:

> An Unresolved Safety Issue is a matter affecting a number of nuclear power plants that poses important questions concerning the adequacy of existing safety requirements for which a final resolution has not yet been developed and that involves conditions not likely to be acceptable over the lifetime of the plants affected.

As the Generic Issues Program has evolved, USI may be considered to be a subset of GIs in that a USI meets the Generic Issues Program criteria and also meets additional criteria. These additional criteria are based on USIs being more focused (nuclear plants only) and more safety and risk significant (involve questions of the adequacy of existing requirements). In addition, USIs are authorized by the Commission rather than the NRC staff. The USI criteria below reflect the historical USI screening criteria of NUREG-0705, “Identification of New Unresolved Safety Issues Relating to Nuclear Power Plants,” (issued in 1981) updated to remove duplication with the new Generic Issues Program criteria of SECY-07-0022 and edited to enhance clarity. If an issue meets the five additional criteria, then Tables B-1 through B-5 are used to evaluate the issue’s general impact on various factors affecting safety. Issues that are determined to meet the USI criteria are handled in accordance with the Generic Issues Program process with the exception that designation as a USI requires Commission approval.

ADDITIONAL USI CRITERIA

1. The issue is directly related to nuclear power plant safety.

USIs only pertain to nuclear power plant safety. For example, issues solely related to transportation of radioactive materials or medical use of radioactive materials could be GIs but not USIs. Issues that are only indirectly related to nuclear power plant safety (e.g., recommended changes to the licensing process, NRC organization, and so forth) will not become USIs.

2. A staff position on the issue has not been developed, and one is not expected to be developed within 6 months.

The purpose of this criterion is to eliminate those issues that are near resolution, and, therefore, are not “unresolved” issues. Such issues do not warrant the attention and resources normally associated with a USI. As background, USIs have been traditionally (but not always) associated with the construction and licensing of new reactors.

3. Definition of the issue does not require long-term research.

The purpose of this criterion is to treat only those issues as USIs for which a clearly identified safety deficiency or improvement exists. An issue requiring long-term research should have that research conducted. Upon completion of sufficient research to define and characterize the issue, the issue may again be considered under the Generic Issues Program, if appropriate.

4. The issue requires a technical solution rather than a policy decision.

The purpose of this criterion is to eliminate those issues that require a management decision only and do not represent potential deficiencies in existing safety requirements for which a resolution must be developed. Similarly, programmatic matters involving implementation of issue resolutions already achieved will not be treated as USIs. In some cases, the results of these policy decisions may require designation of new USIs. The decision whether to combine issues or create separate issues may be subjective.

5. The issue involves a potential question regarding the **adequacy of existing safety requirements**.

The purpose of this criterion is to eliminate consideration of cost-beneficial safety improvements as USIs. However, such issues may be treated as GIs.

Tables are provided to use in assessing the issue against the USI definition.

a) Could the issue result in a “major reduction in the assumed degree of protection?”

-related to equipment concerns (Table B-1),
-related to operator concerns (Table B-2), and
-related to emergency response concerns (Table B-3).

b) Could the resolution of the issue provide a “potentially significant reduction in risk to the public?”

-related to emergency response improvement (Table B-4), and
related to equipment or operator improvement (Table B-5).

Table B1. Possible Major Reduction in Assumed Degree of Protection Related to Equipment Concerns

<table>
<tr><td colspan="9">What is the potential deficiency?</td></tr>
<tr><td colspan="9">What is the likelihood that the potential deficiency exists?</td></tr>
<tr><td colspan="3">Impact on Structural Integrity of Fission Product Boundaries</td><td colspan="3">Impact on Frequency of Transients/Accidents</td><td colspan="3">Impact on Safety Functions</td></tr>
<tr><td colspan="3">What barriers are affected?</td><td colspan="3">What systems are affected?</td><td colspan="3">What systems are affected?</td></tr>
<tr><td colspan="3">What is the likelihood that barriers will fail, given the deficiency?</td><td colspan="3">What is the likelihood that systems will fail due to frequency?</td><td colspan="3">What is the likelihood that systems will fail?</td></tr>
<tr><td colspan="3" rowspan="3">Based on the above, is it likely that fission product boundaries will fail due to this deficiency?</td><td colspan="3">What transients/accidents could result?</td><td colspan="3">What safety functions are affected?</td></tr>
<tr><td colspan="3">What is the likelihood that these transients/accidents will occur?</td><td colspan="3">What is the likelihood of loss of safety functions?</td></tr>
<tr><td colspan="3">Based on the above, would the frequency of transients/accidents be significantly increased by the potential deficiency?</td><td colspan="3">Based on the above, is it likely that the deficiency would cause a loss of safety function when needed?</td></tr>
<tr><td>Yes</td><td>?</td><td>No</td><td>Yes</td><td>?</td><td>No</td><td>Yes</td><td>?</td><td>No</td></tr>
</table>

Yes – USI: Could result in a possible major reduction in the assumed degree of protection.

? – Further Study: Further investigation is required to answer questions necessary to determine if a USI exists.

No – Not a USI: Deficiency does not result in a major reduction in the degree of protection.

Table B2. Possible Major Reduction in Assumed Degree of Protection

Related to Operator Concerns

<table>
<tr><td colspan="6">What is the potential deficiency?</td></tr>
<tr><td colspan="6">What is the likelihood that the potential deficiency exists?</td></tr>
<tr><td colspan="6">What is the likelihood that the deficiency will result in operator errors?</td></tr>
<tr><td colspan="3">Impact on Frequency of Transients/Accidents</td><td colspan="3">Impact on Safety Function</td></tr>
<tr><td colspan="3">What systems are affected?</td><td colspan="3">What systems are affected?</td></tr>
<tr><td colspan="3">What is the likelihood that systems will fail due to the deficiency?</td><td colspan="3">What is the likelihood that the systems will fail?</td></tr>
<tr><td colspan="3">What transients/accidents could result?</td><td colspan="3">What safety functions are affected?</td></tr>
<tr><td colspan="3">What is the likelihood that these transients/accidents will occur?</td><td colspan="3">What is the likelihood of loss of safety functions?</td></tr>
<tr><td colspan="3">Based on the above, would the frequency of transients/accidents be significantly increased by the potential deficiency?</td><td colspan="3">Based on above, is it likely that the deficiency would cause loss of safety function when needed?</td></tr>
<tr><td>Yes</td><td>?</td><td>No</td><td>Yes</td><td>?</td><td>No</td></tr>
</table>

Yes – USI: Could result in a possible major reduction in the assumed degree of protection.

? – Further Study: Further investigation is required to answer questions necessary to determine if a USI exists.

No – Not a USI: Deficiency does not result in a major reduction in the degree of protection.

Table B3. Possible Major Reduction in Assumed Degree of Protection Related to Emergency Response Concerns

What is the potential deficiency?								
What is the likelihood that the potential deficiency exists?								
Impact on Event Assessment Actions			**Impact on Protective Actions**			**Impact on Actions To Aid Affected Persons**		
What actions are affected?			What actions are affected?			What actions are affected?		
What is the likelihood that incorrect actions could result?			What is the likelihood that incorrect actions could result?			What is the likelihood that incorrect actions could result?		
Based on above, is it likely that the dose to plant personnel and/or the public will be significantly increased as a result of the potential deficiency?			Based on above, is it likely that the dose to plant personnel and/or the public would be significantly increased as a result of the potential deficiency?			Based on above, is it likely that the dose to plant personnel and/or the public would be significantly increased as a result of the potential deficiency?		
Yes	?	No	Yes	?	No	Yes	?	No

Yes – USI: Could result in a possible major reduction in the assumed degree of protection.

? – Further Study: Further investigation is required to answer questions necessary to determine if a USI exists.

No – Not a USI: Deficiency does not result in a major reduction in the degree of protection.

Table B4. Potential Significant Reduction in Risk to the Public Related to Emergency Response Improvement

What is the potential improvement?								
Impact on Event Assessment Actions			**Impact on Protective Actions**			**Impact on Actions To Aid Affected Persons**		
What actions are affected?			What actions are affected?			What actions are affected?		
What is the likelihood that the effectiveness of these actions could be significantly improved?			What is the likelihood that the effectiveness of these actions could be significantly improved?			What is the likelihood that the effectiveness of these actions could be significantly improved?		
Based on the above, is it likely that dose to plant personnel and/or the public can be significantly reduced by the improvement?			Based on the above, is it likely that dose to plant personnel and/or the public would be significantly reduced by the improvement?			Based on the above, is it likely that dose to plant personnel and/or the public would be significantly reduced by the improvement?		
Yes	?	No	Yes	?	No	Yes	?	No

Yes – USI: Could result in a possible major reduction in risk.

? – Further Study: Further investigation is required to answer questions necessary to determine if a USI exists.

No – Not a USI: Would not provide significant reduction in risk.

Table B5. Potential Significant Reduction in Risk to the Public Related to Equipment/Operator Improvement

<table>
<tr><th colspan="9">What is the potential improvement?</th></tr>
<tr><th colspan="3">Impact on Design Basis</th><th colspan="3">Impact on Frequency of Transients/Accidents</th><th colspan="3">Impact on Safety Functions</th></tr>
<tr><td colspan="3" rowspan="3">Is it likely that a large reduction in risk will result by implementing this design change?</td><td colspan="3">Frequency of what transients/accidents could be reduced?</td><td colspan="3">Reliability of performing what safety functions could be increased by the potential improvement?</td></tr>
<tr><td colspan="3">What is the likelihood that these transients/accidents would be reduced?</td><td colspan="3" rowspan="2">Based on the above, is it likely that the safety function reliability would be significantly increased?</td></tr>
<tr><td colspan="3">Based on the above, is it likely that a large reduction in the frequency of transients/accidents will result from this improvement?</td></tr>
<tr><td>Yes</td><td>?</td><td>No</td><td>Yes</td><td>?</td><td>No</td><td>Yes</td><td>?</td><td>No</td></tr>
</table>

Yes – USI: Could provide a potentially significant reduction in risk.

? – Further Study: Further investigation is required to answer questions necessary to determine if a USI exists.

No – Not a USI: Would not provide a potentially significant reduction in risk.

APPENDIX C
SAMPLE GENERIC ISSUE PROPOSAL FORM

Form for NRC Staff to Propose a Generic Issue (GI)			
Name or Person Submitting Request	E-Mail Address	Position Title	Date of Request
Office/Division/Branch/Section	Telephone	Mail Stop	Supervisor
GENERAL INSTRUCTIONS FOR COMPLETING AND SUBMITTING THIS FORM: Please contact a Generic Issues Program (Generic Issues Program) representative at Generic Issues Program.Resource@NRC.gov for assistance in completing this form. When the form is complete, including supervisor acknowledgment, please submit completed form to Generic Issues Program.Resource@NRC.gov.			
Identify Source(s) of Information for this Proposed GI (Self, NRC process, Independent Oversight Committee, Other) – Please Describe and Provide Contact Information for Generic Issues Program Representatives to Obtain More Information, as Appropriate.			
INSTRUCTIONS FOR PROVIDING RESPONSES BELOW: Describe situation, condition, Issue, or concern by providing the following information to extent practical (i.e., use readily available information; these requests are not intended to cause an imposition). Describe basis for statements as available or indicate opinion or belief, as applicable. Contact a Generic Issues Program representative at Generic Issues Program.Resource@NRC.gov for assistance completing these responses. If you do not know how to respond to any question, then put "Don't know."			
What Occurs, Occurred, or What Could Occur (Performance Requirement, Standard, or Expectation Not Met, or Potentially Compromised)?			
When It Occurs, Occurred, or Could Occur (Time and Circumstances)?			
Where It Occurs, Occurred, or Could Occur (Physical Location from General to Specific and in a Sequence of Process Steps or Activities)?			

Adverse Consequences of Occurrence (Actual and Potential Damages and Other Negative Impacts)?
Frequency of Occurrence (Relevant Historical Rate, Best Estimate of Rate, and Conditions that Influence the Rate)?
Significance of Occurrence (Reasons It Is Important)?
Ability to Anticipate and Prevent Occurrence (Leading Indicators or Signs)?
Means to Detect or Discover Occurrence (Supporting Evidence)?
Estimated Likelihood of Occurrence (Best Estimate of Chance Under Expected Conditions)?
Causes of Occurrence (Set of Necessary and Sufficient Actions and Conditions)?
Suggestions for Corrective Actions (Remedies to Prevent Adverse Consequences)?
INSTRUCTIONS FOR PROVIDING RESPONSES BELOW: Describe why issue is suitable for assessment under the Generic Issues Program (versus other NRC Programs or Processes) by providing the following information to extent practical (i.e., use readily available information; these requests are not intended to cause an imposition). Describe basis for statements as available or indicate opinion or belief, as applicable. If you do not know how to respond to any question, then put "Don't know." When one or more of the following responses are "No," the issue is generally not suitable for assessment under the Generic Issues Program. In these instances, other NRC programs or processes might be better suited to assessing the issue. Contact a Generic Issues Program representative at Generic Issues Program.Resource@NRC.gov for assistance completing these responses.

Issue impacts (or has potential to impact) public health and safety, common defense and security, or environment.		
Yes (please explain below)	No	Don't Know
Issue indicates susceptibility of, or has applicability to, multiple licensees or entities regulated by NRC.		
Yes (please explain below)	No	Don't Know
Issue indicates there are gaps, voids, conflicts, or excess in existing regulations or industry standards causing inadequate protection, opportunity to substantially improve safety, or undue regulatory burden.		
Yes (please explain below)	No	Don't Know
Issue resolution will likely result in new or revised regulation, policy, or guidance to prevent issue's occurrence (Note: dissenting views should be directed to other NRC programs – DPO, NCP, ROP Feedback, etc.).		
Yes (please explain below)	No	Don't Know
Issue will not require substantial new research to assess risk or safety significance or to gain sufficient understanding to support initial screening assessment (i.e., issue parameters are identified and sufficiently understood to support further assessment of the likelihood that the issue would cause or result in a severe accident).		
Yes (please explain below)	No	Don't Know
Issue is discrete with clear and specific technical scope (bounding physical conditions).		
Yes (please explain below)	No	Don't Know
Issue will likely result in actions by licensees or entities regulated by NRC to address issue.		

Yes (please explain below)	No	Don't Know
Supervisor's Acknowledgment Signature		Date
Supervisor's Comments or Recommendations		
Others Consulted or Contacted		
Provide Comments, Additional Information, Attachments, or References (as desired and appropriate to support comments above).		
Please submit completed form, with supervisor's acknowledgment, to Generic Issues Program.Resource@NRC.gov.		

Note: This form is an example only. Changes can be made to the actual form without revising TEC-02.

APPENDIX D
Evaluating the Information and Resources Required to Assess a Proposed or Accepted GI

This appendix provides guidance on evaluating the information and the potential associated resources required to adequately assess a proposed or accepted GI. This guidance should be applied continuously throughout the Generic Issues Program process to facilitate the early identification of challenges to the Generic Issues Program process schedule and of the potential need for long-term studies. In the event that this evaluation reveals the need for long-term studies, the issue should exit the program based on Criterion 5, “The issue’s risk or safety significance can be adequately determined (i.e., it does not involve phenomena or other uncertainties that would require long-term studies and/or experimental research to establish the risk or safety significance).

The RPM may choose to convene a panel of internal management stakeholders and subject matter experts to consider the responses to the following questions. The responses are expected to be discussed at a high level to gain a broad understanding of the information and resources required to assess the issue.

1. Consider the generic nature of the issue.

    - Will an assessment performed on one facility provide sufficient information to determine the safety or risk significance of the issue or is a facility-specific assessment required?

    - If an assessment performed on one facility is sufficient, will the assessment involve multiple case studies?

2. Consider the current quality and quantity of information supporting the issue.

    - Is the current description of the issue sufficiently detailed and clear to perform an assessment of its safety or risk significance?

    - If not, what resources would be required to collect the appropriate information?

3. Consider the resources to collect the necessary information and perform the assessment.

    - What is the availability of the appropriate resources to collect the required information?

    - What tasks will need to be performed to collect the information?

    - Will collecting the information require the development of new processes or methods?

    - What is the availability of the appropriate resources to perform the assessment after collecting the information?

4. Consider the effects of collecting and assessing the information on the GI process timelines?

   - When will the appropriate resources be available?
   - How long will it take to collect the information?
   - How long will it take to perform the assessment?

APPENDIX E
Sample Templates for Acceptance Review Memoranda

Memorandum Template that Accepts a Proposed Generic Issue

[Date]

MEMORANDUM TO: *[Submitter name and title, if applicable]*
[Submitter address or branch, division, and office, if applicable]

FROM: *[Generic Issues Program Manager name and title]*
[Generic Issues Program branch, division, and office]

SUBJECT: ACCEPTANCE REVIEW OF PROPOSED GENERIC ISSUE (PRE-GI-*XXX*) ON *[PRE-GI TITLE]*

The Generic Issues Program (Generic Issues Program) has received the proposed generic issue (GI) that you submitted via *[submission format, e.g., e-mail]* related to *[brief description of the proposed Generic Issue with submission accession number and brief background on the genesis of the issue.]* The GI staff has performed an acceptance review and has entered this issue, designated as PRE-GI-*XXX*, into the Generic Issues Management Control System for tracking purposes.

The proposed issue will proceed to the screening stage in accordance with the guidelines outlined in Management Directive 6.4, "Generic Issues Program." *[Include the following sentence if the Generic Issues Program is requesting additional information]* Before conducting the screening assessment, the Generic Issues Program requires the following information: *[List of any additional information.]*

It is expected that the initial screening assessment will be completed within 2 months *[Include the following phrase if the Generic Issues Program requests additional information]* of receipt of the information requested above. Please direct questions on the status of proposed Generic Issue-XXX to RPM Contact Name.

Thank you for proposing this issue for Generic Issues Program review.

CONTACT: RPM Contact Name, RES/DRA
301-XXX-XXXX

Memorandum Template that Rejects a Proposed Generic Issue

[Date]

MEMORANDUM TO: *[Submitter name and title, if applicable]*
[Submitter address or branch, division, and office, if applicable]

FROM: *[Generic Issues Program Manager name and title]*
[Generic Issues Program branch, division, and office]

SUBJECT: ACCEPTANCE REVIEW OF PROPOSED GENERIC ISSUE (PRE-GI-XXX) ON *[PRE-GI TITLE]*

The Generic Issues Program (Generic Issues Program) has received the proposed generic issue (GI) that you submitted via *[submission format, e.g., e-mail]* related to *[brief description of the proposed Generic Issue with submission accession number and brief background on the genesis of the issue.]* The GI staff has performed an acceptance review and has entered this issue, designated as PRE-GI-XXX, into the Generic Issues Management Control System for tracking purposes.

DISCUSSION

The proposed GI involves *[detailed description of the issue with supporting excerpts from the submission document and regulatory documents, as appropriate].*

ACCEPTANCE REVIEW RESULTS

The Generic Issues Program staff performed an acceptance review of the proposed GI using the criteria provided in Management Directive 6.4 (MD 6.4), "Generic Issues Program," dated November 17, 2009, (ADAMS Accession No. ML083181192). Seven specific criteria are outlined, none of which can result in a negative response if the proposed issue is to be accepted into the Generic Issues Program.

Specifically, *[citation of the criterion or criteria that result in issue rejection].*

The Generic Issues Program staff's assessment of *[brief description of the issue]* is that *[restatement of the criterion or criteria with detailed discussion of the basis supporting the assessment outcome.]*

[Note any meetings or discussions with the submitter that either demonstrates consensus with the outcome or prior notification of the outcome.]

CONTACT: RPM Contact Name, RES/DRA
301-XXX-XXXX

CONCLUSION

Because the proposed GI *[brief statement characterizing the basis supporting the assessment outcome]*, it does not meet *[Criterion X or Criteria X, Y, etc.]* for acceptance as a generic issue. As such, it will not be accepted into the Generic Issues Program.

The determination of this acceptance review is final unless new information is provided that necessitates a reassessment of the Generic Issues Program criteria. We welcome any correspondence that may provide this information.

[If the proposed Generic Issue was referred for immediate action, include the text below.] Although we did not accept this proposed Generic Issue into the Generic Issues Program, we have referred it to *[responsible office name]* for an immediate action determination. Please contact *[responsible office contact name and phone number]* for further information on the status of this issue.

Thank you for proposing this issue for Generic Issues Program review.

APPENDIX F
Action Plan Guidance and Implementation

The Responsible Project Manager (RPM) develops an *action plan* for the conduct of the Safety/Risk Assessment and Regulatory Assessment Stages (Stages 4 and 5) for the assigned GI. For particularly complex issues, the RPM may use this guidance for developing a plan for the conduct of the Screening Stage (Stage 3). Typically, 6 weeks are allowed for the development of an *action plan.* An *action plan* is approved by the Generic Issues Program Manager for Stage 4 and the division director overseeing the Generic Issues Program for Stage 5.

An *action plan* shall contain the following information:

(a) GI number and title.

(b) Objective of the *action plan.*

(c) RPM and others actively involved.

(d) GI stage.

(e) GI abstract.

(f) Assessment to be conducted (i.e., safety/risk or regulatory assessment and actions/information necessary to conduct the technical portion of the assessment).

(g) Proposed actions to be explored during the assessment, as appropriate, such as an industry initiative, or development of new risk tools or methods for a safety/risk assessment; or new regulations, policy positions, generic communications, Commission paper, or others for a regulatory assessment.

(h) Schedule and milestones: milestones include tests or research, public meetings, industry meetings, and major review/concurrence milestones. As appropriate, the schedule for major milestones contained in the operating plan should include sufficient margin to facilitate timely completion.

(i) Resource estimates for direct technical staff and contractor costs.

(j) Contacts: list technical contacts including affiliations, titles, addresses, phone numbers, and e-mail addresses, etc.

(k) References: list appropriate documents specific to the current Generic Issues Program stage including those documents that provide the basis for the GI.

Provided below are sample tasks and additional information that could be either included in safety/risk assessment and regulatory assessment *action plans* or that is guidance useful for plan implementation. Applicability is designated as “S” for safety/risk assessment, “R” for regulatory assessment, and “B” for both.

Sample tasks and additional information

A task that describes the development of the necessary technical information and understanding that may culminate in a formal staff NUREG or contractor NUREG/CR report to present the technical findings. In most cases, this will begin with a search of the available literature to ensure that existing work will not be duplicated. (B)

A task based on technical findings that develops and evaluates a number of alternative licensing actions that could be used to address the issue. This could include the identification and development of any necessary regulations and supporting regulatory documents. (R)

A task that estimates the incremental net risk reduction that could be achieved for each alternative proposed. Both decreases and increases (e.g., public and/or occupational exposure during plant implementation and thereafter) should be estimated. A task that estimates the net costs to the public, the licensees, and the NRC associated with each alternative. Both increased costs due to design, installation, operation, and maintenance and decreased costs due to improved reliability and plant availability (including averted accidents and precursors) can be estimated using the guidelines of NUREG/CR-3971, "A Handbook for Cost Estimating," and NUREG/CR-4568, "A Handbook for Quick Cost Estimates." (R)

A task that documents a regulatory analysis that discusses the alternatives and the impact/value of each and recommends an alternative that takes into account the requirements of the backfit rule as seen for the issue. The analysis should follow the requirements of 10 CFRs 50.109, 52.63, 70.76, 72.62, and 76.76 and the applicable guidelines such as NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission;" NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook;" and NUREG/CR-3568, "A Handbook for Value-Impact Assessment." (R)

A discussion of the planned coordination with other NRC technical organizations. All requests for regulatory office support and review of draft reports or assignment of a program office technical contact for GI safety/risk or regulatory assessments should be sent from the Division Director to the appropriate managerial level in the program office (e.g., to the Associate Director for Project Licensing and Technical Analysis (ADT) in NRR). The RPM may suggest contacts but cannot assume or decide on an appropriate contact point unless designated by program office management. The program office management should be notified by telephone and a note about 2 to 3 weeks before any formal package is sent. (B)

A discussion of any technical assistance contracting. Specific procedures for RES technical assistance contracting are provided in other RES Office Instructions and on the RES internal web site. (B)

A discussion of the planned interactions with outside organizations. Consideration should also be given to involving appropriate industry groups such as the Nuclear Energy Institute Owners' Groups, Electric Power Research Institute or others. Discussions and agreements can help to ensure industry understanding of the resolution and effective implementation. Procedures that ensure the independence and openness

of NRC need to be followed in pursuing this path. A discussion should be included to address the planned coordination with outside organizations such as licensees, industry groups, nuclear steam supply system vendors, the Advisory Committee on Reactor Safeguards (ACRS), and others, as appropriate. The preferred approach is to conduct meetings open to the public and place the meeting minutes with enclosures in the public document room. Any draft documents that are provided to, or received from, an outside organization should also be placed in ADAMS. (B)

The *action plan* does not have to follow any explicit format or content. The only expectation is that the scope, work plan, needed resources, coordination points, and schedule are clear. (B)

After drafting the *action plan*, the RPM should provide the responsible program office(s) with a copy and request comments to ensure that the proposed assessment approach identifies practical objectives, schedules, and NRR/Region resources. Assignment of a program office lead contact should be confirmed. This contact need not review the detailed technical information developed by RES but should be involved in the key decisions, such as which alternative assessment approaches are to be considered. A copy of the *action plan* should also be sent to ACRS for information. (B)

The RPM and Generic Issues Program manager shall ensure that appropriate *action plan* milestones are incorporated into GIMCS and the RES operating plan. The *action plan* should complement the issue-specific Communication Plan, and the Communication Plan should be maintained to reflect the *action plan*. Any change in the scope of an *action plan* must be approved by the Generic Issues Program Manager or division director overseeing the Generic Issues Program, as appropriate. An updated *action plan* involving significant changes should be sent to the responsible program office(s) and ACRS for information. (B)

Upon completion of any draft NUREG reports (contractor or staff), the RPM provides the responsible program office(s) with a copy for information. Generally, a detailed management review of the draft documents by the responsible Branch Chief and Division Director will suffice. However, on a case-by-case basis, a technical review may be considered. Participation in the technical review process should be formally requested, and arrangements made during the planning stage, if possible. (B)

APPENDIX G
Guidance for Responding to Correspondence Related to Proposed GIs

If the Generic Issues Program rejected the proposed Generic Issue

The RPM will review the correspondence for new information (i.e., information that could change the outcome of the acceptance review because all criteria will be met). If the correspondence reveals new information, the RPM will reassess the proposed Generic Issue as described in 5.2.2 and the subsequent steps.

If the correspondence does not reveal new information, the RPM will respond to the submitter with a memorandum reiterating the rejection and providing guidance on pursuing the issue through other offices, processes, or programs such as the responsible regulatory office, the Differing Professional Opinions Program, etc. The RPM may also include additional information supporting the original rejection decision.

If the Generic Issues Program accepted the proposed Generic Issue

The RPM will review the correspondence for new information (i.e., information that may contribute to an immediate action determination, be significant for the screening assessment, or could change the outcome of the acceptance review because all criteria are no longer met).

If the correspondence reveals new information that may contribute to an immediate action determination, the RPM will immediately notify the responsible regulatory office director(s) via e-mail followed by a memorandum.

If the correspondence reveals new information that may be significant for the screening assessment, the RPM will ensure that the information is included for the screening assessment (see Section 5.3).

If the correspondence reveals new information that could change the outcome of the acceptance review, the RPM will reassess the proposed Generic Issue as described in 5.2.2 and the subsequent steps.

If the correspondence does not reveal new information, the RPM will respond to the submitter with a memorandum acknowledging receipt of the submitter's correspondence.