U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 6.4	GENERIC ISSUES PROGRAM	DT-09-14
Volume 6:	Internal Management	
Approved by:	R. W. Borchardt, Executive Director for Operations	
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Issuing Office:	Office of Nuclear Regulatory Research Division of Risk Analysis	
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EXECUTIVE SUMMARY

Directive and Handbook 6.4, which delineate the prioritization and resolution process for generic issues (GIs), are being revised to incorporate the principles of SECY-07-0022, "Status Report on Proposed Improvements to the Generic Issues Program," intended to ensure timeliness of issue resolution, clarify roles and responsibilities, increase stakeholder participation, and establish clear interfaces between the Generic Issues Program (GIP) and other program office processes and activities used to address GIs outside the GIP. This guidance applies to all GIs related to public health and safety and common defense and security. Enhanced criteria ensure the revised GIP will address only those issues that cannot be more effectively handled by other regulatory programs and processes. Another major change includes the use of a "graded approach" depending on an issue's safety significance.

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I. POLICY

It is the policy of the U. S. Nuclear Regulatory Commission to have an effective agencywide program for the resolution of generic issues (GIs), including unresolved safety issues (USIs), which are a subset of GIs.

II. OBJECTIVES

- To timely and effectively address GIs in support of agency objectives.
- To coordinate the Generic Issues Program (GIP) with other agency programs to avoid duplication, channel issues to appropriate agency programs, and build consensus and cooperation throughout the GIP process.
- To effectively track, document, and report GI status to support GIP process management and communication with stakeholders.
- To provide a process that is open to proposed GIs from public and staff.
- To coordinate with other offices to identify potential GIs from existing information sources.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Commission

Makes decisions on the significant policy issues associated with the resolution of GIs when appropriate.

B. Executive Director for Operations (EDO)

1. Oversees the agency's GIP and directs appropriate office roles and responsibilities.
2. Oversees actions, as necessary, associated with GIs or proposed GIs.
3. Oversees dissemination of selected documents associated with GIs.

C. General Counsel (GC)

1. Provides legal advice and assistance in the processing of GIs.
2. Provides legal interpretation of regulations and statutes relevant to GIs.

D. Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on the Medical Uses of Isotopes (ACMUI)

1. Review staff analyses of GIs related to their respective areas of review.
2. Advise the Commission and the staff on the processes and methodologies for addressing GIs related to their respective areas of review.

E. Director, Office of Nuclear Reactor Regulation (NRR)

1. Refers to the GIP those issues under NRR's area of responsibility that appear to meet the GI definition.
2. Develops and maintains office-level procedures and administrative controls, if appropriate, for GIP implementation.
3. Provides support for the processing of licensed reactor-related GIs in all stages of the GI process.
4. Coordinates with the Director of RES for new GIs in NRR's area of responsibility.
5. Coordinates with the Director of RES for the transfer of reactor-related GIs from the GIP to other regulatory programs.
6. Assigns a representative to serve as the office contact for coordination with the GIP staff and communication with other offices, as required.
7. Appoints Senior Executive Service (SES) managers to serve as chairs of the Generic Issue Review Panels and appoints technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk/Security Assessment and Regulatory Assessment Stages of the GI process, as appropriate.
8. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions. Implements regulatory solutions.
9. Provides input and support to RES for periodic reporting to the Commission and the Congress, GI and Generic Issue Management Control System (GIMCS) updates through all GIP stages, and completion of office-specific actions.

F. Director, Office of Nuclear Material Safety and Safeguards (NMSS)

1. Refers to the GIP those issues under NMSS's area of responsibility that appear to meet the GI definition.
2. Develops and maintains office-level procedures and administrative controls, if appropriate, for GIP implementation.

3. Provides support for the processing of waste-, transportation-, and fuel cycle-related GIs in all stages of the GI process.
4. Coordinates with the Director of RES for new GIs in NMSS's area of responsibility.
5. Approves the transfer of waste-, transportation-, and fuel cycle-related GIs from the GIP to other regulatory programs.
6. Assigns a representative to serve as the office contact for coordination with the GIP staff and communication with other offices, as required.
7. Appoints SES managers to serve as chairs of the Generic Issue Review Panels and appoints technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk/Security Assessment and Regulatory Assessment Stages of the GI process, as appropriate.
8. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions. Implements regulatory solutions.
9. Provides input and support to RES for periodic reporting to the Commission and the Congress, GI and GIMCS updates through all GIP stages, and completion of office-specific actions.

G. Director, Office of Nuclear Regulatory Research (RES)

1. Refers to the GIP those issues under RES's area of responsibility that appear to meet the GI definition.
2. Develops and maintains office-level procedures and administrative controls for GIP implementation.
3. Is responsible for the processing of GIs in all stages of the GI process.
4. Coordinates with other office directors to authorize new GIs.
5. Coordinates and approves the transfer of GIs from the GIP to other regulatory programs.
6. Assigns a branch chief to serve as the GIP Manager responsible for GIP coordination and communication with other offices.
7. Appoints SES managers to serve as chairs of the Generic Issue Review Panels and appoints technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk/Security Assessment and Regulatory Assessment Stages of the GI process, as appropriate. Endorses the preferred regulatory solution resulting from the regulatory assessment stage.
8. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions.
9. Is responsible for periodic reporting to the Commission and the Congress, GI and GIMCS updates through all GIP stages, and completion of office-specific actions.
10. Provides overall management of the GIP.

H. Director, Office of Nuclear Security and Incident Response (NSIR)

1. Refers to the GIP those issues under NSIR's area of responsibility that appear to meet the GI definition.
2. Develops and maintains office-level procedures and administrative controls, if appropriate, for GIP implementation.
3. Provides support for the processing of security-related GIs in all stages of the GI process.
4. Coordinates with the Director of RES for new GIs in NSIR's area of responsibility.
5. Coordinates with the Director of RES for the transfer of security-related GIs from the GIP to other regulatory programs.
6. Assigns a representative to serve as the office contact for coordination with the GIP staff and communication with other offices, as required.
7. Appoints SES managers to serve as chairs of the Generic Issue Review Panels and appoints technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk/Security Assessment and Regulatory Assessment Stages of the GI process, as appropriate.
8. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions. Implements regulatory solutions.

I. Director, Office of New Reactors (NRO)

1. Refers to the GIP those issues under NRO's area of responsibility that appear to meet the GI definition.
2. Develops and maintains office-level procedures and administrative controls, if appropriate, for GIP implementation.
3. Provides support for the processing of GIs related to certified and approved reactor designs, and yet to be licensed reactors, in all stages of the GI process.
4. Coordinates with the Director of RES for new GIs in NRO's area of responsibility.
5. Coordinates with the Director of RES for the transfer of GIs in NRO's area of responsibility.
6. Assigns a representative to serve as the office contact for coordination with the GIP staff and communication with other offices, as required.
7. Appoints SES managers to serve as chairs of the Generic Issue Review Panels and appoints technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk/Security Assessment and Regulatory Assessment Stages of the GI process, as appropriate.

8. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions. Implements regulatory solutions.

9. Provides input and support to RES for periodic reporting to the Commission and the Congress, GI and GIMCS updates through all GIP stages, and completion of office-specific actions.

J. Director, Office of International Programs (OIP)

Serves as the principal contact for the establishment and administration of formal arrangements between NRC and the agencies of foreign countries and international organizations for the exchange and collection of information on GIs.

K. Director, Office of Federal and State Materials and Environmental Management Programs (FSME)

1. Refers to the GIP those issues under FSME's area of responsibility that appear to meet the GI definition.

2. Develops and maintains office-level procedures and administrative controls, if appropriate, for GIP implementation.

3. Provides support for the processing of waste-, materials-, or security-related GIs in all stages of the GI process.

4. Coordinates with the Director of RES for new GIs in FSME's area of responsibility.

5. Coordinates with the Director of RES for the transfer of waste-, materials-, or security-related GIs from the GIP to other regulatory programs.

6. Assigns a representative to serve as the office contact for coordination with the GIP staff and communication with other offices, as required.

7. Appoints SES managers to serve as chairs of the Generic Issue Review Panels and appoints technical experts to serve on the panels, as appropriate. Provides technical support for the Safety/Risk/Security Assessment and Regulatory Assessment Stages of the GI process, as appropriate.

8. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions. Implements regulatory solutions.

9. Provides input and support to RES for periodic reporting to the Commission and the Congress, GI and GIMCS updates through all GIP stages, and completion of office-specific actions.

L. Director, Office of Enforcement (OE)

1. Refers to the GIP those issues under OE's area of responsibility that appear to meet the GI definition.

2. Assigns a representative to coordinate with the GIP to ensure that issues that may involve OE programs (e.g., Enforcement Program, Allegations Program, Differing Professional Opinions Program) are directed to the most appropriate office or program.

M. Regional Administrators (RAs)

Refer to the GIP those issues under the RA's area of responsibility that appear to meet the GI definition.

IV. APPLICABILITY

This directive applies to all NRC employees and activities involved in processing proposed GIs.

V. HANDBOOK

Directive Handbook 6.4 describes activities involved in the processing of proposed GIs, provides guidance to facilitate coordination of the activities of the NRC offices responsible for review of GIs, and describes the elements necessary for their management.

VI. REFERENCES

Code of Federal Regulations

Title 10, "Energy."

Nuclear Regulatory Commission Documents

Charter of the Committee To Review Generic Requirements.

NUREGs

NUREG/BR-0053, "NRC Regulations Handbook."

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

NUREG/BR-0090, Vol. 27, "Report to Congress on Abnormal Occurrences."

NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook."

NUREG-0510, "Report to Congress by NRC Staff on Identifying Unresolved Safety Issues."

NUREG-0660, "Action Plans for Implementing Recommendations of Studies of TMI-2 Accident."

NUREG-0705, "Identification of New Unresolved Safety Issues Relating to Nuclear Power Plants," Special Report to Congress.

NUREG-0933, "Resolution of Generic Safety Issues."

NUREG-1409, "Backfitting Guidelines."

Office of Executive Director for Operations Procedure—0430, "Communication Plans," March 2, 2006.

Policy Statements

"Program for Resolution of Generic Issues Related to Nuclear Power" (43 FR 1565; January 10, 1978).

"Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138; August 8, 1985).

"Regulation of Advanced Nuclear Power Plants" (51 FR 24643; July 8, 1986).

"Safety Goals for the Operation of Nuclear Power Plants" (51 FR 28044; August 4, 1986, as corrected and republished at 51 FR 30028; August 21, 1986).

"Program for Resolution of Generic Issues Related to Nuclear Power Plants" (Notice of Withdrawal, 54 FR 24432; June 7, 1989).

"Regulation of Advanced Nuclear Power Plants" (59 FR 35461; July 12, 1994).

Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."

SECY-07-0022, "Status Report on Proposed Improvements to the Generic Issues Program," January 30, 2007.

Staff Requirements Memoranda

SRM to the EDO, "SECY-89-102—Implementation of the Safety Goals," June 15, 1990.

SRM to the EDO, "SECY-05-0126—Summary of Activities Related to Generic Safety Issues," August 31, 2005.

Office of Management and Budget

OMB Circular No. A-4, "Regulatory Analysis," September 17, 2003, http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.

United States Code

Atomic Energy Act, 1954, as amended (42 U.S.C. 2011 et seq.).

Energy Reorganization Act of 1974, as amended, Sections 208 and 210 (U.S.C. 5801 et seq.).

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EXHIBITS

I. GENERAL

A. Introduction

1. This handbook provides guidance for the NRC staff to process generic issues (GIs) including Unresolved Safety Issues (USIs) and gives an overview of the Generic Issues Program (GIP); describes the five GIP stages; covers GI tracking and communication, roles and responsibilities; and contains a glossary of key terms. For detailed GIP implementation guidance, refer to RES TEC-002, "Procedures for Processing Generic Issues," and other office instructions (OIs), as applicable.
2. On October 8, 1976, the Commission directed the staff to develop a program plan for resolution of generic issues. On December 12, 1977, the Energy Reorganization Act of 1974 was amended by Congress through Public Law 95-209 to include, among other things, a new Section 210, "Unresolved Safety Issues (USIs)." In order to meet both Commission and congressional directives, the staff developed a GIP that provided for the identification of GIs, the assignment of priorities, the development of detailed action plans, projections of dollar and manpower costs, continuous high-level management oversight of progress, and public dissemination of information related to the issues as they progressed.
3. The GIP has continued to evolve over the years as described in NUREG-0933, "A Resolution of Generic Safety Issues."
4. The GIP supports agency objectives through timely and effective treatment of GIs.

B. Overview of GI Identification

1. The NRC staff or members of the public may propose a GI when an issue is identified that satisfies the definition (see Section II, "Glossary," of this handbook).
2. Proposed GIs that pass the Acceptance Review Stage are referred to the responsible program office to determine if prompt actions are necessary to fulfill the agency's mission.

C. Priority Status of Generic Issues

1. In accordance with 10 CFR 52.47(a)(21), applications for design certification must contain "Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design."

2. Similarly, in accordance with 10 CFR 52.79(a)(20), applications for combined licenses must contain "Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design."

3. As indicated in Pilot MD 6.4, dated July 21, 1999, prioritization of GIs was replaced by the screening process, described in this management directive (Section I.E.3 of this handbook), in which a determination is made to either establish the proposed issue as a bona fide GI or reject the issue from the program. For the purposes of 10 CFR 52.47(a)(21) and 10 CFR 52.79(a)(20), any GI established by the MD 6.4 screening process is considered equivalent to a HIGH-Priority GI.

D. Overview of the GIP Process

1. The GIP process in perspective with other agency programs and processes is shown in Exhibit 1. This exhibit reflects the GI criteria which are structured such that issues that should be addressed by other NRC programs and processes or industry initiatives, will be appropriately directed to those programs and processes on a timely basis. The criteria are designed such that the GIP will not be an alternative to other programs that address the concerns of employees and stakeholders such as the Differing Professional Opinion (DPO) Program and the Allegations Program.

2. The GIP includes five stages: Identification, Acceptance Review, Screening, Safety/Risk Assessment, and Regulatory Assessment. During each stage, staff determines if more information is needed, if the issue should proceed to the next stage, or if the issue should exit the GIP. When an issue exits the GIP, the possible outcomes include no action, further research, referral to appropriate regulatory program(s), or a voluntary industry initiative. GIs and pre-GIs (see Section II, "Glossary," of this handbook) are formally closed or transferred by memorandum. A program office director may also initiate, at any time, a transfer memorandum informing the GIP Manager that an issue will be processed using existing regulatory program(s) and that the issue can exit the GIP. In general, whenever a GI exits the program, the GI is closed, and any implementation and verification activities are tracked to completion. A pre-GI is closed whenever it exits the program, and subsequent actions are not tracked.

3. In any case, the GIP provides feedback to the requestor of the GI regarding the outcome at each stage. Issues that proceed through all five stages normally result in regulatory solutions being provided to program offices for implementation and verification. The offices coordinate information flow about issue status through the stages and RES tracks issue status in the Generic Issue Management Control System (GIMCS) database. Additional information about the GIP, and GIP history, is available through the GIP Web page (at the external Web site http://www.nrc.gov/about-nrc/regulatory/gen-issues.html and at the internal Web site http://www.internal.nrc.gov/RES/projects/GIP/index.html).

E. Five-Stage Process

The GIP uses a five-stage process as shown in Exhibit 2. Throughout these five stages, the GIP staff track and communicate GI status, facilitate stakeholder interaction, and coordinate interactions with other offices.

1. Stage 1, Identification

   Anyone (public or NRC staff) can propose a GI (see Exhibit 3). Proposed GIs are not yet formal GIs. The GIP staff provides assistance to persons considering proposing a GI, when requested. The anticipated time needed to complete the GI proposal form is 1 to 2 hours.

   (a) Issues Considered for GIP

   The GI and USI criteria (see Section I.F of this handbook) contain guidance for the types of issues that are suited to the GIP. Issues not suited to the GIP may be appropriate for other agency programs or processes.

   (b) Ways to Propose a GI

   (i) The public can propose a GI by accessing the GI proposal form for the public at the external Web site (http://www.nrc.gov/about-nrc/regulatory/gen-issues.html), filling out the form, and submitting the form to the GIP mailbox at GIP.Resource@nrc.gov.

   (ii) The NRC staff may propose a GI; it is recommended that the originator inform his or her management of his or her issue. The originator and his or her management should contact GIP staff and the associated office contact for assistance in deciding if the issue should be submitted as a proposed GI and in preparing the form. The NRC staff can access the GI proposal form for NRC staff at the GIP Web page (http://www.internal.nrc.gov/RES/projects/GIP/index.html) and submit the form to the GIP mailbox at GIP.Resource@nrc.gov. The GIP does not normally process issues that require confidentiality for the submitter.

   (c) Use of the GI proposal form and GI criteria to consider suitability

   The GI proposal form captures information about the issue to help the NRC staff determine whether the issue should be processed as a GI or whether it might be more suitable to another agency program.

2. Stage 2, Acceptance Review

   The proposed GI has been submitted to the GIP mailbox and the NRC staff assesses the information on the form to determine if more information is needed and whether the issue should proceed to the formal screening stage. The target period for completing the acceptance review is 1 to 2 weeks.

   (a) Receipt in the GIP Mailbox

   The proposed GI is assigned a pre-GI number, and the NRC staff is assigned to perform the acceptance review of the GI. The pre-GI is tracked in the GIMCS, but it is not included in periodic reports.

(b) Initial GIP Review of Proposed Issue Against Criteria

The GIP staff reviews the information provided on the GI proposal form. The GIP staff performs a limited assessment of this information for completeness and reasonableness to decide the outcome. The GIP staff may seek additional information from the submitter or other NRC staff to understand the issue for this limited assessment, as warranted. The GIP staff assesses the issue against the GI criteria using information gathered and a graded approach (see Section II, "Glossary," of this handbook) and makes a recommendation regarding further processing of the proposed GI. In general, GIP staff will recommend that the proposed issue proceed to the Screening stage unless the issue clearly does not meet one or more GIP criteria. The acceptance review for an issue may be deferred by the GIP if the existing state of knowledge, relevant to assessment of the issue, is insufficient but sufficient information is expected to be developed within 3-6 months, for example, by performance of an RES scoping study.

(c) Possible Outcomes

The possible outcomes of the acceptance review include a determination that the proposed GI does not meet the GI criteria and does not warrant further processing as a GI. Another possible outcome is that the issue is transferred to another office program or programs for further action. The other possible outcome is a determination that the issue warrants further processing and will proceed to Stage 3.

(d) Communication and Coordination

The GIP staff informs the originator of the outcome. When the outcome is to transfer the issue to another program office, the GIP staff coordinates the transition to that office. While a proposed GI is in the identification and acceptance review and screening stages, it is tracked in the GIMCS, but discussion of the proposed GI is not included in GIMCS reports to the Commission and Congress.

3. Stage 3, Screening

For proposed GIs that enter the screening stage, the GI Program Manager assigns a Responsible Project Manager (RPM) from RES to assess the issue through the screening stage. The RPM engages the office contacts for GIP activities, as appropriate, applies the screening criteria, and formally documents the screening analysis. The RPM coordinates the conduct of the Generic Issue Review Panel (GIRP) and provides the screening analysis to the GIRP. The GIRP makes the final recommendation for further actions for the proposed GI. The target period for completing the screening is 6 to 7 weeks (i.e., a total of 2 months to complete the acceptance review and screening).

(a) Actions by the RPM

(i) The RPM collects information to assess the proposed GI against the screening criteria, as appropriate. The screening analysis typically includes a literature search and a duplication review against other GIs.

(ii) The RPM applies a graded approach to the entire screening analysis. For complex issues, the RPM may request and utilize resources outside the GIP.

(iii) The RPM prepares and documents a screening analysis, including a recommendation for further actions for the proposed GI, to the GIRP.

(b) Actions by the GIRP

The GIRP reviews the RPM's screening analysis and provides a consensus recommendation to the Director of RES for endorsement after receiving concurrence by the affected regulatory offices.

(c) Possible Outcomes

One possible outcome of the screening is a determination that the proposed GI does not meet the GI screening criteria and does not warrant further processing as a GI. Another possible outcome is that the issue is transferred to another office program or programs for further action or is addressed by a voluntary industry initiative. Another possible outcome is a determination that the issue warrants further assessment as a GI and will proceed to Stage 4.

(d) Communication and Coordination

The GIP staff informs the originator and the responsible program office of the outcome. When the outcome is to transfer the issue to another program office, the GIP staff coordinates the transition to that office. The GIP does not include information on proposed GIs in the screening stage in routine reports. A proposed GI that proceeds to Stage 4 becomes a formal GI, is given a GI number, and continues to be tracked and is now included in routine reports. For proposed GIs that are screened in, the GIP staff prepares a Communication Plan that is issued before the screening memorandum is issued.

4. Stage 4, Safety/Risk Assessment

The GIP Manager assigns a Responsible Project Manager (RPM) to develop an Action Plan for the actions necessary to perform a risk or security assessment of the GI and formally document the assessment that provides a recommendation to a GIRP for future GIP actions. The GIRP makes the final recommendation for further actions for the GI. The target period for completing safety and risk assessment is 4 months. The GIP staff follows RES TEC-002, "Procedures for Processing Generic Issues," which describes additional details on activities performed for the Safety/Risk Assessment. The safety/risk criteria in TEC-002 are based on existing agency guidance documents for performing regulatory analyses. The TEC-002 safety/risk criteria will only be updated when the associated agency guidance is changed.

(a) Actions by the RPM

(i) The RPM develops an Action Plan, which contains the detailed schedule, milestones, and responsibilities necessary to determine the risk or security of the GI in order to determine if the GI merits enhanced regulation. As part of the Action Plan development, the RPM arranges for necessary contractor support and negotiates for support staff from within RES and the program offices.

(ii) The RPM applies a graded approach in the safety/risk assessment.

(iii) The RPM implements the Action Plan as a project with roles and responsibilities as specified.

(iv) The RPM monitors and reports the progress of the Action Plan implementation to the GIP Manager using appropriate metrics.

(v) The RPM prepares and documents a safety/risk assessment, including a recommendation for further actions for the GI, to the GIRP. A limited cost-benefit analysis of proposed regulatory solutions may be included in the safety/risk assessment to inform the ensuing regulatory assessment.

(vi) The RPM interfaces with and provides the safety/risk assessment (after receiving concurrence by the affected regulatory offices) to the review committees, as appropriate, soliciting their involvement.

(b) Actions by the GIRP

The GIRP reviews the RPM's safety/risk assessment and provides a consensus recommendation to the Director of RES for endorsement after receiving concurrence by the involved regulatory offices.

(c) Possible Outcomes

One possible outcome of the safety/risk assessment is a determination that the GI does not warrant further processing as a GI and is either closed with no further action, or is closed with followup actions, such as transfer to another office program or process, research activities, or industry initiatives. Another possible outcome is the determination that the GI warrants further regulatory assessment as a GI and will proceed to Stage 5.

(d) Communication and Coordination

The GIP staff informs the originator and the responsible program office of the outcome. The Communication Plan for the GI is updated by the GIP staff. When the outcome is to transfer the GI to another program office, the GIP staff coordinates the transition to that office. A GI that proceeds to Stage 5 continues to be tracked and included in routine reports.

5. Stage 5, Regulatory Assessment

The GIP Manager assigns an RPM to develop an Action Plan for the actions necessary to perform a regulatory assessment of the GI and to document the results that provide justification for the preferred regulatory solution. The target period for completing regulatory assessment is 1 to 2 years.

(a) Actions by the RPM

(i) The RPM develops the Action Plan, which contains the detailed schedule, milestones, and responsibilities necessary for the regulatory office to identify and develop regulatory solutions for the GI. As part of the Action Plan development, the RPM arranges for necessary contractor support and negotiates for support staff from within RES and the program offices. The

RPM obtains concurrence on the Action Plan from the affected regulatory offices.

(ii) The RPM applies a graded approach in the regulatory assessment.

(iii) The RPM implements the Action Plan as a project with roles and responsibilities as specified.

(iv) The RPM monitors and reports the progress of the Action Plan implementation to the GIP Manager using appropriate metrics.

(v) The RPM obtains possible regulatory solutions and recommendations for further actions for the GI from the affected regulatory offices. The RPM prepares and documents a regulatory assessment. The RPM obtains concurrence on the regulatory assessment and preferred regulatory solution from the affected regulatory offices.

(vi) After receiving concurrence from the affected regulatory offices, the RPM provides the regulatory assessment, including the preferred regulatory solutions to the review committees, as appropriate, requesting their comments and endorsement.

(vii) After incorporating comments from the review committees, the RPM obtains endorsement of the regulatory assessment from the Director, RES. This completes stage 5. The issue exits the GIP and enters Regulatory Office Implementation.

(b) Possible Outcomes

One possible outcome of regulatory assessment is a determination that the GI does not warrant further processing as a GI and is either closed with no further action, or is closed with followup actions, such as regulatory office implementation, research activities, or industry initiatives. Another possible outcome is the regulatory solution for the GI to be provided to the regulatory office for development, implementation, and verification. In any case, the GI ceases to be a formal GI and exits the GIP at the completion of this stage.

(c) Communication and Coordination

The GIP staff informs the originator of the outcome. The Communication Plan for the issue is updated by the GIP staff. When the outcome is to transfer the GI to another program office, the GIP staff coordinates the transition to that office. A GI in Stage 5 continues to be tracked and included in routine reports. The status of issues transferred to the responsible program office will be reported and tracked in the GIMCS until the program office informs the GIP that its actions are complete.

F. Generic Issue and Unresolved Safety Issue Criteria

1. The GIP will address only those issues that meet the following criteria. A proposed GI or a GI that does not meet any of these criteria at any time will not be processed further by the GIP.

(a) The issue affects public health and safety, the common defense and security, or the environment.

(b) The issue applies to two or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals.

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

(d) The issue can be resolved by new or revised regulation, policy, or guidance.

(e) 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).

(f) The issue is well defined, discrete, and involves a radiological safety, security, or environmental matter.

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

2. USIs are a subset of GIs and meet all of the GI screening criteria. In addition, USIs meet the following additional criteria:

(a) The issue is directly related to nuclear power plant safety.

(b) The issue involves an adequate protection issue.

(c) There is no staff position and one is not expected to be developed within 6 months.

G. Generic Issue Status Tracking and Reporting

The GIP maintains a Generic Issue Management Control System to track GIs (including USIs) and report their status to stakeholders.

1. Generic Issue Management Control System (GIMCS)

(a) RES maintains the GIMCS database on the basis of input from the RPM for each GI.

(b) GI status is tracked throughout the GI life cycle from acceptance through issue closure. Once screened in, an issue becomes a formal GI and it is included in periodic reports. In the case of a GI that has been transferred for regulatory office implementation, the GI continues to be tracked and updated in GIMCS through completion of these actions.

(c) The RPM provides quarterly status updates to the GIP Manager for GIs to support routine reports to the Commission and to Congress (as required by 42 USC Sec. 5850).

2. NUREG-0933, “Resolution of Generic Safety Issues”

   The GIP Manager provides an annual supplement to NUREG-0933 that incorporates the updated information on GIs through their closure.

H. Roles and Responsibilities

1. The GIP Manager

   The Chief of the Operating Experience and Generic Issues Branch (RES), or designated alternate, is the GIP Manager and has overall responsibility for GIP administration and centralized leadership for GIP management. Specific responsibilities include the following:

   (a) Administering the GIP using a graded approach to the extent practical.

   (b) Ensuring that the GIP is consistently implemented across offices.

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

   (d) Communicating and coordinating with other offices through all GIP stages for resource allocation, information flow, and decisions on transitions to other programs.

   (e) Assigning GI staff or RPMs for tasks in all stages of the GIP.

   (f) Coordinating with program offices to staff the GIRP and with the GIRP to complete the assigned reviews.

2. The Responsible Project Manager (RPM)

   The RPM is the RES staff member who is assigned the overall lead role for all actions involved in the designated GIP stage. Specific responsibilities include the following:

   (a) Use a graded approach, gather information to perform screening; develop, implement, and maintain the Action Plan for Stages 3, 4, and 5.

   (b) Coordinate with technical staff assigned to the GI and their management in developing, implementing, and maintaining the Action Plan for Stages 4 and 5. (Action Plan is optional for Stage 3.)

   (c) Provide GIMCS updates to the GIMCS Tracking Coordinator.

   (d) Facilitate the conduct of the GIRP in Stages 3 and 4.

   (e) Prepare the recommendation memorandum in GIP Stages 3, 4, and 5.

   (f) Coordinate advisory committee involvement, as needed.

   (g) Coordinate stakeholder interactions, as appropriate.

   Note: For issues that are no longer formal GIs, for example, issues in regulatory office implementation (see Section II, “Glossary,” of this handbook), the assigned

regulatory office task or project manager is responsible for providing GIMCS updates.

3. Generic Issues Review Panel (GIRP) Members

   The GIRP is responsible for providing a review of the GI assessment and for making recommendations for further actions. The GIRP members are assigned by their respective office management in coordination with the GIP Manager. Specific responsibilities include the following:

   (a) Reviewing output for each Action Plan and analysis for GIP Stage 4. (Action Plan is optional for Stage 3.)

   (b) Reaching consensus and making recommendations for GIP Stages 3 and 4.

   (c) Providing input on recommendations to the RPM for inclusion in a memorandum to the Director of RES.

4. Staff With Assignments Under Action Plans or GI Actions in Regulatory Office Implementation

   (a) Coordinate with the RPM through his or her line management in supporting the development, implementation, and maintenance of the plan for Stages 3, 4, and 5.

   (b) Perform Action Plan tasks as assigned.

   (c) Report progress to the RPM and line management.

   (d) Provide input to periodic GIMCS requests to the GIP Manager and GIMCS Tracking Coordinator through line management.

5. Management (Branch Chiefs/Division Directors) With Staff Having Action Plan Assignments or GI Actions in Regulatory Office Implementation

   (a) Coordinate with the RPM and the GIP Manager in supporting the development, implementation, and maintenance of the plan for Stages 3, 4, and 5.

   (b) Manage staff and review staff work output.

   (c) Review and approve GIMCS update information.

6. GIMCS Tracking Coordinator (GTC)

   The GTC is designated by the GIP Manager to lead and coordinate interoffice information flow for GIMCS updates in support of routine reports to the Commission and Congress. The duties of the GTC include the following:

   (a) Preparation and issuance of a memorandum requesting GIMCS update input.

   (b) Contacting the RPM and their branch chief and discussing a request for agreement on the date they will provide information and any assistance from the GIP.

(c) Documenting coordination efforts, updating and verifying information provided, archiving the information as appropriate, and entering updated information into the GIMCS.

(d) Providing the updated GIMCS report information and the compiled GI status update information to the RPM or the task manager and their branch chief for each GI for their review and comment (confirming the input).

(e) Obtaining concurrence on the compiled GI status update information for transmittal to OEDO.

7. Office Contacts for GIP Activities

The office contacts for GIP activities are designated by the office director to lead and coordinate office activities and information flow involving the GIP, as follows:

(a) Facilitation of office review of GIP policy documents.

(b) Coordination of development of office instructions for GIP documents.

(c) Communication and coordination with GIP and other offices through all GIP stages for resource allocation, information flow, and decisions on transitions to other programs.

II. GLOSSARY

Action Plan. A detailed plan, with appropriate managerial approvals, developed for the conduct of the Safety/Risk Assessment or Regulatory Assessment Stage of the GIP.

Active Generic Issue (GI). A GI that involves actions under the Generic Issues Program (also referred to as a "formal GI").

Adequate Protection. A facility that is licensed and complies fully with the applicable rules and regulations is considered to meet the "adequate protection" standard. Whenever a proposed issue passes the Acceptance Review Stage, the program office is notified to determine if prompt actions are necessary to fulfill the agency's mission.

Closed Generic Issue (GI). For the purposes of the GIP, the phrase indicates that GIP actions associated with the GI are complete. Implementation and verification activities by the regulatory office (if any) are tracked to their completion.

Formal Generic Issue (GI). A GI that has passed the screening stage and has not yet exited the Generic Issues Program, as shown in Exhibit 2.

Generic. Affecting two or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals (including design certification rules).

Generic Issue (GI). A well-defined, discrete, radiological safety, security, or environmental matter, the risk significance of which 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.

Generic Issue Management Control System (GIMCS). Electronic database used to store and maintain information on generic issues and to prepare quarterly reports.

Generic Issue Management Control System (GIMCS) Updates. Status input for generic issues (GIs) being tracked in the GIMCS that includes problem description, work scope plan and milestones for addressing the GI, current status description, problems impacting milestones, and reasons for schedule changes and affected documents.

Generic Issues Program (GIP) Safety/Risk Assessment Stage. Stage 4 in the GIP for processing generic issues that includes security assessment, when applicable. Security assessment is considered part of this assessment, when applicable, but not specifically stated in the title in order to keep the title tractable.

Generic Issues Review Panel (GIRP). The GIRP is responsible for providing a review of the generic issue assessment and for making recommendations for further actions. The GIRP members are assigned by their respective office management in coordination with the Generic Issues Program Manager.

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 GIP stage.

Long Term Research. For the purpose of this Management Directive, long term research is considered to be any study related to a GI which is expected to take longer than 6 months.

Open Generic Issue (GI). Those GIs that are not closed (i.e., either inside or outside the Generic Issues Program) for which further agency actions are planned.

Proposed Generic Issue (GI) (pre-GI). An issue submitted to a Generic Issues Program (GIP) mailbox and remains a pre-GI until (and unless) it screens in as a GI (passes the screening stage).

Regulatory Office Implementation. This Generic Issue Management Control System (GIMCS) action level designation indicates that the generic issue (GI) has exited the formal Generic Issues Program (GIP) but includes remaining actions outside the GIP, which are tracked in GIMCS updates until the regulatory actions are complete and communicated to the GIP. Thus, this is a formal GI for which RES actions of safety/risk assessment or regulatory assessment are complete, and remaining actions reside with program offices

(e.g., regulatory compliance, reactor oversight process, rulemaking, further research, coordination with industry initiatives).

Transfer Memorandum. A memorandum from the Director of RES that clearly transfers ownership of the generic issue (GI) from the Generic Issues Program (GIP) to the appropriate regulatory offices for further actions in accordance with their office programs and processes. The transfer memorandum documents the transition of the GI from the RES lead for GIP activities to the responsible regulatory office(s) for regulatory office implementation for a GI, thus exiting the formal GIP.

Transition Process. Any time there is a change or transition in the status of an issue, this change needs to be clearly documented and communicated so that there is no confusion 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, (3) passed/failed screening of a proposed GI, (4) passed/failed safety/risk assessment, (5) passed/failed regulatory assessment, and (6) transfer to a more appropriate program, for example, long-term research, 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 not likely to be acceptable over the lifetime of the plants affected.

EXHIBITS

Exhibit 1 Generic Issue Program (GIP) in Perspective With Other Regulatory Programs and Processes

Generic Issue Program in Perspective With Other Regulatory Programs and Processes

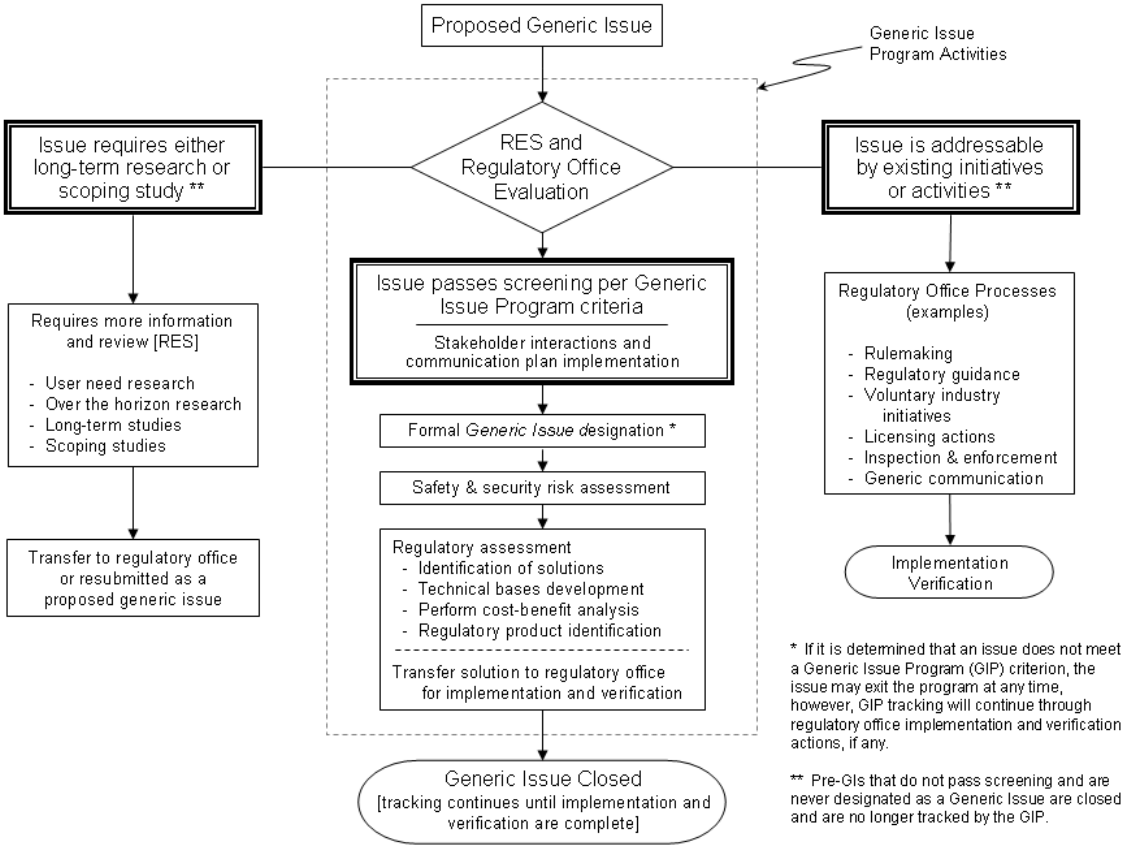

Exhibit 2 Generic Issue (GI) Five-Stage Process

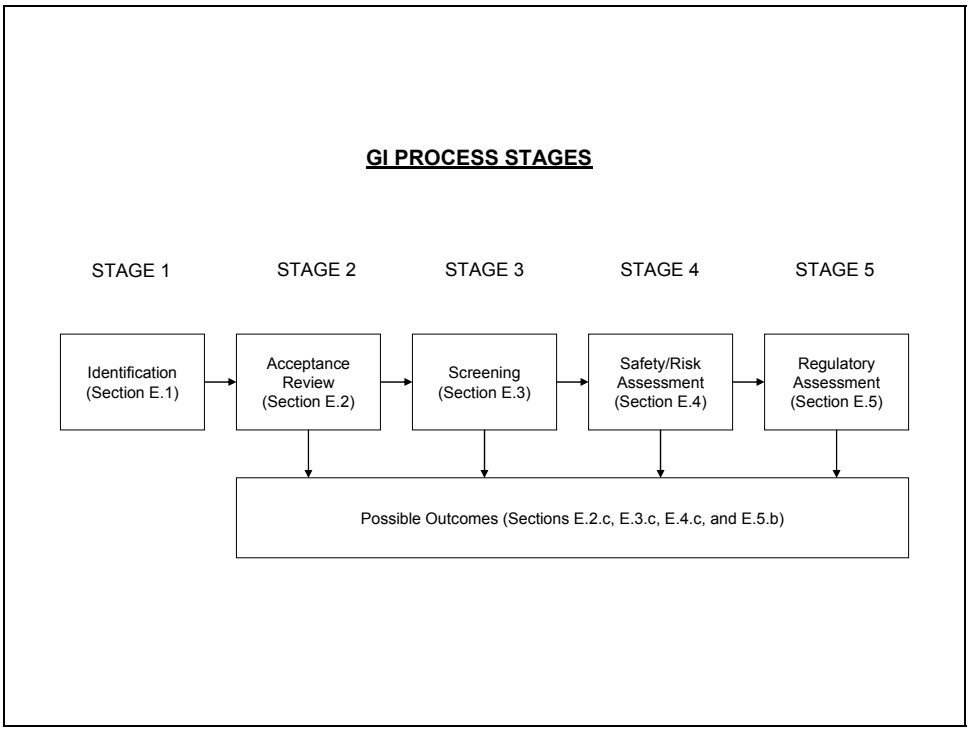

Exhibit 3 Sources of Proposed Generic Issue (GI)