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

MD 6.4	GENERIC ISSUES PROGRAM	DT-24-10
Volume 6:	Internal Management	
Approved By:	Marissa G. Bailey, Acting Deputy Director Office of Nuclear Regulatory Research	
Date Approved:	July 2, 2024	
Cert. Date:	N/A, for the latest version of any NRC directive or handbook, see the online MD Catalog.	
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EXECUTIVE SUMMARY

Management Directive (MD) 6.4, "Generic Issues Program," which delineates the process for handling generic issues (GIs), is revised to—

- Reflect a change in the frequency of staff status reports to the Commission on Generic Issues from quarterly to semi-annually.
- Reflect the changes in organizational responsibilities (e.g., consolidation of the Office of New Reactors and the Office of Nuclear Reactor Regulation).
- Incorporate recommendations from an internal review of the GI program by NRC's EMBARK Ventures Studio that include an annual review of issues that are in the Assessment Stage to determine if they should continue in the GI program, a provision for a team of technical experts in the Screening Stage, and editorial recommendations for consistency with the Office of Nuclear Regulatory Research Office Instructions TEC-002, "Generic Issues Program."
- Eliminate the need for performing a limited regulatory analysis during the Assessment Stage.

TABLE OF CONTENTS

I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to have an effective agencywide program for the resolution of generic issues (GIs).

II. OBJECTIVES

- Effectively address GIs in support of agency objectives in a timely manner.
- Coordinate the GI Program with other agency programs to avoid duplication, channel issues to appropriate agency programs, and build consensus and cooperation.
- Effectively track, document, and report GI status to support GI Program process management and communication with stakeholders.
- Provide a process that allows the public and NRC staff to propose GIs.
- 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 GIs when appropriate.

B. Executive Director for Operations (EDO)

1. Oversees the agency's GI Program and directs appropriate office roles and responsibilities.
2. Oversees actions, as necessary, associated with GIs or proposed GIs.

C. General Counsel (GC)

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

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

1. Provides overall management of the GI Program including conducting periodic executive review meetings on GI progress with other office directors who have GIs in Stage 3 of the GI process, "Regulatory Office Implementation."
2. Assigns a branch chief to serve as the GI Program Manager responsible for GI Program coordination and communication with other offices.
3. Develops and maintains office-level procedures and administrative controls for GI Program implementation.
4. Coordinates with other office directors to authorize new GIs.
5. Refers to the GI Program those issues that appear to meet the GI definition within the office's area of responsibility.
6. Responsible for the processing of GIs in all stages of the GI Program.
7. Appoints Senior Executive Service (SES) managers to serve as members on the Generic Issues Review Panel (GIRP) and appoints technical experts, as appropriate, to serve on the GIRPs by providing technical support during the Screening and Assessment Stages.
8. Appoints technical experts to serve on the transition team, as appropriate.
9. Facilitates industry stakeholder participation in the GI resolution process, when appropriate, to identify and implement regulatory solutions.
10. Endorses the preferred regulatory solution resulting from the Assessment Stage.

11. Coordinates and approves the transfer of GIs from the GI Program to other regulatory programs.
12. Responsible for periodic reporting to Congress and the Commission, through all GI Program stages, and completion of office-specific actions.

E. 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.

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

1. Provides support for the processing of GIs related to waste, transportation, materials, security, and fuel cycle in all stages of the GI process.
2. Coordinates with the Director of RES for new GIs in the area of NMSS's responsibility.
3. Coordinates with the Director of RES on the transfer of GIs related to waste, transportation, materials, security, and fuel cycle from the GI Program to other regulatory programs.
4. Performs the GI Program duties and responsibilities specified in Section III.I of this directive.

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

1. Supports the processing of GIs related to operating reactors in all stages of the GI process.
2. Supports the processing of GIs related to certified and approved reactor designs and yet to be licensed reactors in all stages of the GI process.
3. Coordinates with the Director of RES for new GIs in the area of NRR's responsibility.
4. Coordinates with the Director of RES on the transfer of GIs related to reactors from the GI Program to other regulatory programs.
5. Performs the GI Program duties and responsibilities specified in Section III.I of this directive.

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

1. Provides support for the processing of GIs related to security and emergency preparedness in all stages of the GI process.

2. Coordinates with the Director of RES for new GIs in the area of NSIR's responsibility.
3. Coordinates with the Director of RES on the transfer of GIs related to security and emergency preparedness from the GI Program to other regulatory programs.
4. Performs the GI Program duties and responsibilities specified in Section III.I of this directive.

I. Directors, Office of Nuclear Material Safety and Safeguards (NMSS), Office of Nuclear Reactor Regulation (NRR), and Office of Nuclear Security and Incident Response (NSIR)

1. Refer to the GI Program those issues that appear to meet the GI definition within the office's area of responsibility.
2. Develop and maintain office-level procedures and administrative controls, if appropriate, for GI Program implementation.
3. Assign a representative to serve as the office contact for coordination with the GI Program staff and communication with other offices, as required.
4. Appoint an SES manager to chair the GIRP and appoint technical experts to serve on the GIRPs, as appropriate.
5. Appoint an SES manager to serve as team lead for the transition team and appoint technical experts to serve on the team, as appropriate.
6. Provide technical support during the Screening and Assessment Stages, as appropriate.
7. Provide oversight for assigned issues that are in the Regulatory Office Implementation stage.
8. Facilitate industry stakeholder participation in the GI resolution process, when appropriate to identify and implement regulatory solutions.
9. Provide input and support to RES for periodic reporting to Congress and the Commission through all GI Program stages and completion of office-specific actions.

J. Director, Office of Enforcement (OE)

1. Refers to the GI Program those issues that appear to meet the GI definition within the office's area of responsibility.
2. Assigns a representative to coordinate with the GI Program to ensure that issues that may involve Office of Enforcement programs (e.g., Enforcement Program, Allegations Program, and Differing Professional Opinion Program) are directed to the most appropriate office or program.

K. Director, Office of International Programs (OIP)

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

L. Regional Administrators (RAs)

1. Refer to the GI Program those issues that appear to meet the GI definition within the regional administrators' (RAs) area of responsibility.
2. Coordinate with the Director of RES for new GIs in the RAs' area of responsibility.
3. Assign a representative to serve as the office contact for coordination with the GI Program staff and communication with other offices, as required.

IV. APPLICABILITY

The policy and guidance in this MD apply to all NRC employees and activities involved in processing proposed GIs.

V. DIRECTIVE HANDBOOK

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

Charter of the Committee to Review Generic Requirements, Revision 9, June 2018 (ML17355A532).

EMBARK Ventures Studio, "Generic Issues Program: Report of Recommendations," December 2023 (ML23317A310).

GI Program web page on the NRC internal website: https://usnrc.sharepoint.com/teams/RES-Generic-Issues.

GI Program web page on the NRC public website: http://www.nrc.gov/about-nrc/regulatory/gen-issues.html.

Management Directives

MD 8.8, “Management of Allegations.”

MD 10.159, “NRC Differing Professional Opinion Program.”

NRC Form 833, “Form to Propose a Generic Issue (GI)”: https://www.nrc.gov/about-nrc/regulatory/gen-issues/prop-new-gen-issue.html.

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

RES Office Instruction TEC-002, Revision 4, “Generic Issues Program” (ML23219A073).

United States Code

Energy Reorganization Act of 1974, as amended, Sections 208 and 210 (42 U.S.C. 5801 et seq.).

Unresolved Safety Issues Plan (42 U.S.C. 5850).

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I. INTRODUCTION

A. This handbook provides guidance for the U.S. Nuclear Regulatory Commission (NRC) staff to process generic issues (GIs). This overview of the GI Program describes (1) the three program stages, (2) GI tracking and communication, and (3) roles and responsibilities. For detailed GI Program implementation guidance, refer to Office of Nuclear Regulatory Research (RES) Office Instruction (OI) TEC-002, "Generic Issues Program," and other OIs, as applicable. Additional information about the GI Program and its history is available through the GI Program web page on the NRC public website, at https://www.nrc.gov/about-nrc/regulatory/gen-issues.html.

B. On October 8, 1976, the Commission directed the staff to develop a program plan for resolution of GIs (NUREG-0410). 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)." To meet both Commission and congressional directives, the staff developed a GI Program 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.

C. The GI Program has continued to evolve over the years as described in NUREG-0933, "Resolution of Generic Safety Issues."

II. GENERIC ISSUE AND UNRESOLVED SAFETY ISSUE CRITERIA

A. Criteria for Generic Issues

The GI Program will address only those issues that meet all the criteria listed below. If at any time a proposed GI or a GI does not meet all these criteria, then it will not be processed further by the GI Program. Resolution of the issue may potentially involve review, analysis, or action by the affected licensees, certificate holders, or holders of other regulatory approvals.

1. The issue has the potential to significantly impact public health and safety, the common defense and security, or the environment (with respect to radiological health and safety). For issues that are not amenable to quantification using risk assessment, qualitative factors may be developed and applied as necessary to assess safety/risk significance. This criterion eliminates issues that do not have the potential to be significant (minor findings, Reactor Oversight Process (ROP) Green findings, Severity Level IV traditional enforcement inspection findings, or below applicable Regulatory Guide (RG) 1.174 thresholds) or that do not directly involve or affect "safety or security" (e.g., purely administrative, policy, regulatory process, or NRC organizational issues).

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

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

4. The issue can be resolved by new or revised regulation, policy, or guidance. This criterion ensures that the staff can address the issue. It also assists in identifying and recommending a regulatory product to resolve the issue.

5. The issue's risk or safety significance can be adequately determined in a timely manner (i.e., it does not involve phenomena or other uncertainties that would require long-term study and/or experimental research to establish the risk or safety significance). This criterion eliminates those issues requiring a long-term research study before entry into the GI process, rather than using a prolonged evaluation through the GI process. If the appropriate regulatory office (in coordination with RES) determines that the issue appears to potentially be sufficiently safety significant to warrant expending the resources needed for a long-term study and/or research to verify the significance, they may pursue it under a User Need Request or other request for RES support. Upon completion of the long-term study, the issue may enter the GI process for evaluation.

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

7. Resolution of the issue may involve review, analysis, or action by the affected licensees, certificate holders, or holders of other regulatory approvals. This criterion identifies potential weaknesses and deficiencies in existing regulations and guidance that affect safety and security. If it becomes apparent that no action is needed by holders of licenses or other NRC approvals, then further assessment under the GI process is not needed, and the issue exits the GI process.

B. Unresolved Safety Issue

1. Section 210 of the Energy Reorganization Act of 1974, as amended, contains the following requirement:

   > The Commission shall develop a plan providing for the specification and analysis of unresolved safety issues relating to nuclear reactors and shall take such action as may be necessary to implement corrective measures with respect to such issues. Such plans 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.

2. The following definition of an unresolved safety issue (USI) (found in the Energy Reorganization Act of 1974) was developed to satisfy the intent of Section 210 and has been used subsequently to identify 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.

3. In its January 1, 1978, Report to Congress (NUREG-0410), the NRC issued a program plan for the identification and resolution of USIs and GIs.

4. There has been no new USI designated by the Commission since December 1981. Instead, the agency addresses the issues that are identified to the program as GIs.

III. GENERIC ISSUES PROGRAM: PROPOSAL, PRIORITY, AND PROCESS

A. Sources of Generic Issues

1. The NRC staff or members of the public may propose a GI when an issue is identified that satisfies the definition of GI (see Section VIII, “Glossary,” of this handbook for the definition of GI and Section IV of this handbook for details on how to propose a GI).

2. Proposed GIs that are received from outside the agency are processed by the GI Program Manager, evaluated for any immediate safety concerns, and may be referred to the responsible regulatory office to determine if prompt action is necessary to fulfill the agency’s mission, unless the regulatory office already performed that evaluation. Similarly, proposed GIs from within the agency will be referred to the responsible regulatory office unless the proposal indicates that the responsible regulatory office has already determined that prompt action is not necessary.

B. Applicability to New Reactor Applications

1. In accordance with Title 10 of the *Code of Federal Regulations* (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.” Similar requirements apply to applications for design certifications, standard design approvals, and manufacturing licenses in 10 CFR 52.47(a)(21), 52.137(a)(21), and 52.157(f)(28), respectively.
2. The process for prioritization of GIs (high, medium, low, drop) was replaced in 1999 by a screening and assessment process. Completion of the screening and assessment process is necessary to determine whether the proposed issue is a *bona fide* GI or should be rejected from the program.
3. For the purposes of 10 CFR 52.47(a)(21), 52.79(a)(20), 52.137(a)(21), and 52.157(f)(28), any GI established by the screening and assessment process is considered equivalent to a high-priority GI.

C. Generic Issues Program Process

1. The GI Program includes three stages: Screening, Assessment, and Regulatory Office Implementation. During the first two stages, the staff determines if more information is needed, if the issue should proceed to the next stage, or if the issue should exit the GI Program.
2. The GI Program is structured so that issues that are being addressed or should be addressed by other existing NRC programs and processes will be appropriately directed to those programs and processes in a timely manner. In particular, the GI selection criteria are designed so that the GI Program will not accept issues that are more appropriately addressed by other existing NRC programs and processes (e.g., rulemaking, orders, generic communications, the Differing Professional Opinion Program (see MD 10.159, “Differing Professional Opinion Program”) and the Allegations Program (see MD 8.8, “Management of Allegations”)). When a proposed GI is received, the regulatory office provides an initial justification for ongoing operation to determine whether a safety concern would arise during the time the issue is being processed. Whenever an issue moves forward in the GI process, a review of the justification for ongoing operation may be performed to determine whether the justification remains valid.
3. The GI Program provides feedback to the submitter of the GI regarding the outcome at each stage. Issues that proceed through the first two stages normally result in the implementation and verification of a regulatory solution by the regulatory offices in the third stage. The offices coordinate information flow about issue status through the stages, and RES tracks issue status.

4. When an issue exits the GI Program, the possible outcomes include no action, further study, or referral to the appropriate regulatory program with concurrences from the involved offices. GIs and proposed GIs are formally closed or transferred by memorandum. A regulatory office director may also initiate, at any time, a transfer memorandum informing the GI Program Manager that an issue will be processed using existing regulatory programs and that the issue can exit the program. GIs are tracked to completion, including all implementation and verification activities.
A proposed GI is closed whenever it exits the program. Subsequent actions may be tracked, if appropriate (e.g., issue is transferred for additional research to assess whether it is part of an ongoing, major research project). If a proposed GI exits the program because further study is needed, the GI staff will assist the regulatory office as needed to transfer the issue to another RES division for further study.

IV. IDENTIFICATION OF WAYS TO PROPOSE A GENERIC ISSUE IN THE THREE-STAGE PROCESS

A. General

The GI Program uses a three-stage process. Throughout these three stages, the GI Program staff track and communicate GI status, facilitate stakeholder interaction, and coordinate interactions with other offices.

B. Identification

Identification of an issue is primarily accomplished outside the program. Anyone (the public or NRC staff) can propose a GI. Proposed GIs are not yet GIs. The GI Program staff answers questions from persons considering proposing a GI when requested.

C. Issues Considered for GI Program

The GI criteria (see Section II.A of this handbook for the criteria) contain guidance for the types of issues that are suited to the GI Program. Issues not suited to the GI Program may be appropriate for other agency programs or processes.

D. Ways to Propose a GI

1. The public and NRC staff can propose a GI by submitting the GI proposal form (NRC Form 833, “Form to Propose a Generic Issue (GI)”) on the NRC public website, at http://www.nrc.gov/about-nrc/regulatory/gen-issues/gi-form.html, or by emailing a completed NRC Form 833 to the GI Program mailbox at GIP.Resource@nrc.gov. The GI Program normally does not process issues that require confidentiality for the submitter. Those issues normally are addressed by NRC’s Allegations Program. NRC Form 833 is available in the NRC Forms Library on SharePoint, at https://usnrc.sharepoint.com/teams/NRC-Forms-Library.

2. When NRC staff propose a GI, they should inform their management of the issue. The submitter and their management should contact GI Program staff and the associated office contact when deciding if an issue should be submitted as a proposed GI and for assistance in preparing the form. Once it has been decided that the issue should proceed to the GI Program, then the submitter should follow the steps above to propose an issue.

E. 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 for another agency program. The important functions of the program are to identify the best place within the agency to work the issue, gain consensus to transfer the issue to that place, and build management support for resources to work the issue.

V. THE THREE-STAGE PROCESS FOR GENERIC ISSUES

A. Stage 1, Screening (target for completing screening is typically 6 to 12 months)

The purpose of this stage is to evaluate the proposed GI against the seven screening criteria in Section II of this handbook to determine if the issue should proceed to the Assessment Stage or if the issue should exit the GI Program.

1. Upon receipt of a proposed GI from the public or NRC staff, the Responsible Project Manager (RPM) promptly performs an initial review and concurrently forwards the issue to the appropriate regulatory office to evaluate whether the proposed GI is an immediate safety concern.

   (a) The RPM performs an initial review to determine if the issue requires immediate action, particularly if it concerns an allegation or physical security.

      (i) If immediate action is required, the RPM refers the proposed GI to the appropriate regulatory office (i.e., the Office of Enforcement (OE) or the Office of Nuclear Security and Incident Response (NSIR)).

      (ii) If the proposed GI is related to an allegation or physical security, the issue typically exits the GI process; however, NSIR may elect to have the proposed GI continue through the GI process.

   (b) The regulatory offices will follow their specific office instructions to evaluate if the issue is an immediate safety concern, unless the issue originated from the regulatory offices and has previously been evaluated, thereby rendering this evaluation unnecessary.

      (i) If the regulatory office determines the proposed GI is an immediate safety concern, the proposed GI is transferred to the regulatory office and processed in accordance with their office instructions. An email or memorandum is

issued to the submitter stating that the proposed GI has exited the GI process.

(ii) If the regulatory office determines the proposed GI is not an immediate safety concern, the regulatory office notifies RES of the findings by email or memorandum.

(c) The RPM performs an initial review of the proposed GI against the seven screening criteria identified in Section II of this handbook.

(i) If the initial review finds that the proposed GI fails to meet all seven screening criteria, then a memorandum of non-acceptance is issued, and a copy is sent to the submitter stating that the proposed GI has exited the GI process.

(ii) If the initial review finds the proposed GI appears to meet all seven screening criteria, a screening analysis plan is formulated, and a Generic Issues Review Panel (GIRP) is assembled. An appropriate timeframe for evaluating the proposed GI is established based upon its urgency as agreed to by the regulatory office in coordination with RES.

2. The GIRP performs a detailed evaluation to determine if the proposed GI satisfies all seven screening criteria identified in Section II of this handbook.

(a) If the GIRP concludes that the proposed GI does not satisfy all seven screening criteria, the proposed GI exits the GI process. A memorandum stating why the proposed GI failed the screening criteria is sent to the Director of RES and regional administrators. A letter is also sent to the submitter of the issue summarizing the actions taken and stating that the issue has exited the GI process.

(b) If the GIRP concludes that the proposed GI satisfies all seven screening criteria, a memorandum is sent to the Director of RES summarizing the panel's conclusion and recommendation for the proposed GI to continue to the Assessment Stage. The memorandum should provide a justification for ongoing operation while the GI is being addressed.

(c) If the GIRP concludes that the proposed GI satisfies all seven screening criteria and finds that there is an existing appropriate regulatory process that should address the issue without the need for further assessment, the proposed GI completes the screening process, a transition team is formed, and the issue is transferred by memorandum to the designated regulatory office for implementation. The memorandum should provide a justification for ongoing operation while the GI is being addressed.

3. After the GIRP panel addresses comments from the Director of RES and the Director of RES concurs on the GIRP's recommendations, the proposed GI proceeds to Stage 2 for an assessment to be performed.

4. The Advisory Committee on Reactor Safeguards (ACRS) is informed of the issue's progress.

B. Stage 2, Assessment (target for completing assessment is typically 1 to 3 years)

The purpose of this stage is to develop an assessment of the proposed GI to determine if it merits further regulatory action. The assessment of the issue in the Assessment Stage includes an evaluation of risk significance, safety significance, security significance, regulatory compliance, and a proposed regulatory path forward.

1. An assessment team is formed, and the team develops an assessment plan.
2. Once every calendar year after the proposed GI enters the Assessment Stage, the GIRP will conduct an annual evaluation of the proposed GI to determine if the issue continues to meet all seven screening criteria and if it warrants additional expenditure of agency resources and should remain in the program. This assessment should consider any updated information on the risk significance of the issue and feedback from stakeholders on the current state of knowledge and significance of the issue.
3. The assessment team develops recommendations for the proposed GI and presents their recommendations to the GIRP.
   (a) If the GIRP concurs with the recommendation that the proposed GI does not warrant further processing, then the proposed GI exits the GI process. The GIRP sends a memorandum to the Director of RES stating why the proposed GI did not meet the assessment criteria. A memorandum is also sent to the submitter of the issue summarizing the actions taken and stating that the issue has exited the GI process.
   (b) If the GIRP concurs with the recommendation that the proposed GI does warrant further regulatory action, the GIRP sends a memorandum to the Director of RES recommending that the proposed GI proceed to Stage 3, “Regulatory Office Implementation.” The memorandum should provide a justification for ongoing operation while the GI is being addressed.
4. After the GIRP panel addresses comments from the Director of RES and the Director of RES concurs with the GIRP’s recommendation, the Director of RES issues a transfer memorandum to the office director receiving the GI for implementation. The transfer memorandum transfers ownership of the GI from RES to the appropriate regulatory office for implementation, and includes the following:
   (a) GIRP recommendation memorandum.
   (b) Communication plan to ensure that communication is maintained with the GI Program and other regulatory offices. The communication plan provides information on resource allocation, information flow, and decisions on transitions to other programs.

(c) Assignment of a GI Identification Number (GI-00#).

(d) Description of the transition team.

(e) Proposed regulatory action to resolve the issue.

5. Concurrently, or within a short period of time, the receiving office director will issue an acknowledgment memorandum assuming responsibility of the GI for regulatory implementation. The acknowledgment memorandum will include—

   (a) A Transition Team Charter with a mission to provide knowledge transfer, draft a plan for Regulatory Office Implementation, and ensure a smooth transition so that progress on resolving the GI is maintained.

   (b) Identification of the Transition Team Lead, and

   (c) Membership of the Transition Team.

6. The ACRS is informed of the issue's progress.

C. Stage 3, Regulatory Office Implementation (target for completing implementation is typically 3 to 5 years)

The purpose of this stage is to develop and perform the appropriate regulatory action to implement resolution of a GI in a timely manner.

1. Management in the responsible regulatory office assigns a new project manager to the GIs who is responsible for reporting the status of the action taken to resolve the GI to the RES GI RPM because the GI Program continues to track the status of the GI until resolution and closure of the GI.

2. The responsible regulatory office performs an analysis to determine the appropriate action(s) and decides the regulatory process for addressing the GI (e.g., rule, order, or generic communication, as appropriate).

   (a) If there is no new regulatory requirement, the responsible regulatory office will issue a memorandum to the Director of RES describing the evaluation and the justification for the conclusion.

   (b) If there is a need for a new regulatory requirement, the responsible regulatory office will develop the appropriate regulatory action (e.g., rule, order, or generic communication).

3. A public meeting is conducted to gain stakeholder input, as appropriate. A public meeting can be conducted as part of developing an analysis to determine the appropriate regulatory action, or a public meeting may be held as part of a regulatory process, or both.

4. The ACRS may request a meeting as part of supporting the development of an analysis to determine the appropriate regulatory action, or an ACRS meeting may be held as part of a regulatory process, or both.
5. The responsible regulatory office issues the new regulatory action (e.g., rule, order, or generic communication).
6. Licensees implement actions needed to comply with the new regulatory requirement.
7. The NRC staff performs inspections to verify all required actions have been completed, as appropriate.
8. The ACRS reviews actions taken as appropriate for the regulatory process.
9. The regulatory office tracks the status of implementation and provides a report to the GI Program Manager.
10. Upon final closeout of the GI, notifications are sent by the regulatory office to the GI Program Manager of the GI closeout status.

VI. GENERIC ISSUE STATUS TRACKING AND REPORTING

The GI Program maintains a system to track GIs and report the status of issues to stakeholders.

A. Generic Issue Tracking

1. When an issue is proposed as a possible GI, the proposed GI (pre-GI) is assigned a tracking number (PRE-GI-00#) by the RPM.
2. RES maintains a GI database using input from the program offices. The status is tracked throughout the GI life cycle after passing initial review by the RPM through issue closure.
3. The “pre-GI” becomes a GI when responsibility for the issue is transferred to the regulatory office. The GI is then assigned a GI Identification Number (GI-00#) to facilitate tracking, periodic GI reporting until completion of all agency actions, and recording in NUREG-0933.
4. The RPM provides semi-annual status updates to the GI Program Manager for GIs to support routine reports to Congress and the Commission, which addresses compliance with 42 U.S.C. 5850.

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

The GI Program Manager provides a periodic (generally, every 2 years) supplement to NUREG-0933 that incorporates the updated information on GIs through the time of their closure.

VII. ROLES AND RESPONSIBILITIES

A. The GI Program Manager

The Chief of the Regulatory Guide and Programs Management Branch (RGPMB), Division of Engineering (DE), RES, or designated alternate, is the GI Program Manager and has overall responsibility for program administration and centralized leadership for program management. The GI Program Manager facilitates timely actions for an issue by the responsible organizations and people. The specific responsibilities include the following:

1. Administer the GI Program using a graded approach as defined in the Glossary in Section VIII to the extent practical.
2. Ensure that the GI Program is consistently implemented across offices.
3. Coordinate activities for GI status tracking, reporting, and periodic updates to NUREG-0933.
4. Communicate and coordinate resource allocation, information flow, and decisions on transitioning to other programs with all offices and throughout all stages of the GI Program.
5. Assign GI staff or project managers for tasks in all stages of the GI Program.
6. Coordinate with the RPM and regulatory offices to staff the GIRP.
7. Communicate with the RPM and the GIRP to complete screening and assessment stages described in Section V.
8. Ensure that the justification for ongoing operation remains valid throughout the GI process.
9. Support office director review meetings.
10. Oversee dissemination of selected documents associated with GIs.

B. The Responsible Project Manager (RPM)

The RPM is an RGPMB staff member who is assigned the overall lead role for managing actions in the GI Program Stages 1 and 2. In Stage 3, the assigned regulatory office will assign their own staff member as a project manager. The specific responsibilities of the RPM include the following:

1. Upon receipt of a proposed GI, promptly determine if the proposed GI involves an allegation or physical security issue.
   (a) If so, immediately refer the proposed GI to OE or NSIR, respectively.

(b) A proposed GI related to an allegation or physical security typically exits the GI process; however, NSIR may elect to have the proposed GI continue through the GI process.

2. Refer the proposed GI, by memorandum, to the responsible regulatory office, requesting a determination whether there is an immediate need for prompt regulatory action.
3. Perform an initial review of the proposed GI.
   (a) Determine if the issue does not meet all of the seven screening criteria.
   (b) If the issue does not meet all of the seven screening criteria, recommend to the GI Program Manager that the issue exit the GI process.
   (c) Propose a detailed definition of the issue scope.
4. Collect information related to the GI.
   (a) Engage the submitter and stakeholders for additional information, as necessary.
   (b) Identify new information that might affect the scope of the issue.
   (c) Coordinate with appropriate organizations to support the GIRP in assessing whether the new information should be considered within the scope of the existing proposed GI or whether the new information should be a new, separate GI.
5. Coordinate with technical staff assigned to the GI and their management.
6. Coordinate with stakeholders on assigned issues, as appropriate.
7. Arrange for necessary contractor support and negotiate for support staff within RES and other regulatory offices.
8. Provide status updates.
   (a) Track the issue from submittal to closeout.
   (b) Assign an internal identification number to the proposed GI (i.e., PRE-GI-00#) when the proposed GI is submitted and reviewed by the GI program staff.
   (c) Assign an identification number to the GI (i.e., GI-00#) after the proposed GI is designated to proceed to Stage 3 for Regulatory Office Implementation.
   (d) Initiate office level tracking and documentation of completed milestones in the assessment plan.
9. Provide periodic reports.
   (a) Update information in NUREG-0933.
   (b) Issue routine reports on the progress of the GI until the regulatory office notifies the GI Program that all actions are complete.

(c) Complete annual assessment.

(d) Monitor and report on the progress of the assessment plan implementation to the GI Program Manager using appropriate metrics.

10. Prepare memoranda to document the results of the GI process.

(a) Document the findings of the regulatory offices on whether a proposed GI is an immediate concern.

(b) Document the results of the GI staff's initial review of the seven screening criteria, in support of the GIRP.

(c) Draft the results of the analysis performed by the GIRP of the seven screening criteria.

(d) Document the transfer of ownership of the GI from RES to the appropriate regulatory office for implementation.

(e) Draft the acknowledgment memorandum, accepting the transfer of ownership of the GI from RES to the appropriate regulatory office for implementation.

(f) Document other transition memoranda. For example, whenever a proposed GI exits the GI process, the RPM will issue a memorandum informing the Director of RES, RES division directors, and the submitter of the outcome.

(g) Based upon the results of the assessment, prepare formal documentation of the GIRP recommendations to the Director of RES.

(h) Draft the memorandum to close out the transition team after the regulatory office is satisfied with the knowledge transfer.

11. Coordinate with the ACRS and the Committee to Review Generic Requirements (CRGR), as needed.

(a) Inform the ACRS by memorandum of the outcome of the proposed GI during each stage of the process (i.e., screening, assessment, and regulatory office implementation).

(b) Interface with the ACRS, soliciting its involvement, as appropriate.

12. Manage the proposed GI throughout the screening and assessment stages.

13. Engage appropriate office contacts for GI Program activities.

14. Participate as a member of the GIRP.

15. Document the basis for excluding any NRC-regulated facilities that may be affected by the issue but are not included in the scope of the proposed GI.

16. Establish schedules for the three stages.

(a) The goal for completion of Stage 1 is typically 6 to 12 months,

(b) Stage 2 is typically 1 to 3 years, and

(c) Stage 3 is typically 3 to 5 years.

17. Participate on the assessment team.

(a) Develop an assessment plan.

(b) Prepare an assessment report that documents the results of the assessment. The assessment report should include the following key elements, as applicable:

(i) Environmental significance,

(ii) Security significance, and

(iii) Safety and risk significance.

18. Create, update, and implement a communication plan in accordance with the NRC guidance for creating basic communication tools. The communication plan is drafted as part of the transfer memorandum.

19. Participate on the transition team.

(a) Coordinate with the regulatory office to assign a Regulatory Project Manager to the transition team.

(b) Coordinate with the regulatory office to assign technical staff to the transition team.

C. Staff with Assignments in Regulatory Office Implementation

1. Regulatory Project Manager

(a) Develop and perform appropriate regulatory actions to implement resolution of GIs in a timely manner.

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

(c) When requested by the GI Program Manager, provide input into the periodic status update through line management.

(d) Perform GI closeout functions.

2. Technical Reviewer

(a) Coordinate with the Regulatory Project Manager in supporting the development and implementation of the regulatory action.

(b) Develop the basis for the regulatory action.

D. Management (Branch Chiefs or Division Directors) with Staff Having GI Actions in the Regulatory Office Implementation

1. Manage staff and review staff work output in developing appropriate regulatory actions to implement resolution of GIs in a timely manner.
2. Review and approve status update information.

E. Office Contacts for GI Program Activities

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

1. Facilitate office review of GI Program policy documents.
2. Coordinate development of OIs for GI Program documents.
3. Communicate and coordinate with the GI Program and other offices through all GI Program stages for resource allocation, information flow, and decisions on transitions to other programs.

F. Generic Issues Review Panel (GIRP)

The GIRP is responsible for guiding and reviewing the GI evaluations and assessments performed for the screening and assessment stages and for making decisions for further actions. The GIRP members are assigned by their respective office management in coordination with the GI Program Manager. The GIRP is typically composed of a Chair, at the Senior Executive Service (SES) level, selected technical experts, the RPM, and a member of RES/DE line management. Specific responsibilities include the following:

1. Guide and develop a screening analysis in Stage 1, and review and recommend the regulatory assessment in Stage 2.
2. Reach consensus and make a decision for the GI Program in Stages 1 and 2.
3. Identify and make a decision regarding issue scope, scope expansion, and handling of new subsidiary issues. The GIRP will determine whether the subsidiary issue should be handled as a separate issue or included in the original issue. If there is no GIRP, the responsible division director will make the scope determination.
4. Assist in developing the communication plan.
5. Conduct an annual evaluation during the assessment stage to determine whether the GI will remain in the GI Program.
6. Issue a memorandum on the results of the annual evaluation to the Director of RES.
7. Determine appropriate interactions with stakeholders to ensure updated information on GIs is obtained.

G. Assessment Team

1. The RPM and selected individuals with specific knowledge of the issue comprise the Assessment Team. The assessment team reports to the Chair of the GIRP. The Assessment Team provides support until the GIRP reaches a conclusion on whether the proposed GI should continue to Stage 3.

2. The Assessment Team's responsibilities include the following:

   (a) Develop an assessment plan containing a detailed schedule, milestones, and responsibilities to determine whether the issue should proceed to Stage 3, Regulatory Office Implementation.

   (b) Develop the technical basis of the issues.

   (c) Develop a safety/risk assessment through coordination with RES staff. 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.

   (d) Develop an assessment report addressing the following criteria, as applicable:

      (i) Security significance;

      (ii) Regulatory compliance;

      (iii) Regulatory path forward;

      (iv) Determination of whether the proposed GI meets the criteria to proceed to Stage 3, Regulatory Office Implementation, using a graded approach based upon an assessment of safety and risk significance;

      (v) Recommendation to the GIRP whether the proposed GI should proceed to Stage 3 for Regulatory Office Implementation.

H. Transition Team

The mission of the transition team is to ensure that an issue receives the necessary attention in the appropriate receiving regulatory office to ensure progress is maintained. The transition team is typically composed of a team lead at the SES level, the RPM, and selected individuals with specific knowledge of the GI. The transition team reports to the team lead receiving the GI. The transition team provides support until the transition team leader is satisfied that sufficient knowledge has been transferred to the receiving regulatory office staff so that they can successfully continue processing the GI.

1. Transition Team Formation

   (a) Screening Stage

   A transition team may be formed in the Screening Stage if the GIRP determines that the proposed GI passes all seven screening criteria and finds that there is an existing appropriate regulatory process that should accept ownership of the issue. In this case, the proposed GI completes the Screening Stage and is transferred to the designated regulatory office for implementation.

   (b) A transition team may be formed if the Director of RES approves the transfer memorandum that the proposed GI can proceed to the Regulatory Office Implementation Stage.

2. Specific responsibilities of the transition team for issues that proceed to Regulatory Office Implementation are as follows:

   (a) Provide sufficient knowledge transfer to the regulatory office to ensure a smooth transition so that progress on resolving the issue is maintained.

   (b) Verify that the justification for ongoing operation remains valid.

   (c) Assist the regulatory office with outreach to external stakeholders, e.g., public meetings, if appropriate.

   (d) Assist the regulatory office with interface with the ACRS, as appropriate, and address ACRS comments, as appropriate.

   (e) Provide a closeout memorandum from the transition team leader to the GI Program Manager stating that the duties of the transition team are complete.

VIII. GLOSSARY

Assessment Plan

A detailed plan containing a schedule, milestones, and responsibilities necessary to determine if a proposed generic issue should proceed to Stage 3, Regulatory Office Implementation.

Closed Generic Issue (Closed GI)

A GI for which all agency actions associated with the GI are complete, including implementation and verification activities by the regulatory office.

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 (with respect to radiological health and safety) matter of which safety/risk significance has been adequately determined and has been transferred to the appropriate regulatory office for implementation.

Graded Approach

The level of rigor applied during the GI process. It should be commensurate with GI importance and reduce the process burden for assessing GIs of lower safety, risk, or security significance. The appropriate amount of process rigor for GI screening and review panels depends on significance, importance, or applicability of the GI. GIs of low significance or importance may be adequately screened or assessed without using a formal review panel, while complex GIs or those with potentially high 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 significance or importance and with information certainty or margins for tolerating error. Formal panel meetings add less value when there is a lower significance, importance, uncertainty, or large margins for error tolerance. In cases of moderate significance or importance, virtual panel meetings by teleconference, electronic mail, or other methods that do not require the physical presence of all the panel members in the same room at the same time may suffice. More process rigor and resources are applied as an issue proceeds through each GI Program stage.

Justification for Ongoing Operation

Assessment that the risk and consequence to a nuclear facility for a proposed GI or GI is acceptable without having to implement any remedial actions during the timeframe the issue is being addressed by the GI development process or the appropriate regulatory process.

Milestone Memorandum

Documents the progression of an issue through the stages in the GI process. Examples of milestone memoranda include:

1. Receipt Memorandum: acknowledgment of receipt of an issue from the GI staff to the submitter;
2. Initial Review Memorandum: documentation of the results of the initial review of the issue by the RPM and includes any immediate safety concerns;
3. GIRP Screening Memorandum: recommendation of detailed screening results by the GIRP;

4. Transfer Memorandum: transfer of ownership of the GI from the office of RES to the responsible regulatory office for implementation in accordance with their office programs and processes;
5. Acknowledgment Memorandum: acknowledgment from the responsible regulatory office assuming responsibility of the GI for regulatory implementation;
6. Transition Team Closeout Memorandum: documentation of the satisfactory completion of the transition team duties; and
7. Closeout Memorandum: documentation of the resolution and closeout of the GI.

Proposed Generic Issue (pre-GI)

An issue submitted to the GI Program for consideration of a new regulatory action. The issue remains a proposed generic issue until transferred to the responsible regulatory office for implementation or closure. A proposed issue must meet the seven screening criteria to be considered for processing in the GI Program.

Scope Change

Introduction of a new aspect into a proposed GI or when a GI is determined to require additional study. Examples of these aspects include, but are not limited to issues:

1. Causing an effect on a different type of facility,
2. Causing a different effect on the same facility or causing a different plant response,
3. Resulting from a different source of the effect, or
4. Requiring additional studies that would—
   (a) Substantially extend the time required to resolve the initial issue,
   (b) Require lengthy research or additional information from licensees,
   (c) Make the use of a second generic communication tool necessary, or
   (d) Necessitate different technical experts be used.

Status Update

Status input for GIs being tracked 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.