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

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Volume 6:	Internal Management	
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EXECUTIVE SUMMARY

Directive and Handbook 6.4, "Generic Issues Program," delineate the process for handling generic issues (GIs). Major changes in this revision are (1) program simplification by reducing the number of stages from five to three, (2) increased management involvement and accountability, and (3) new guidance to identify and act on immediate safety concerns and to document the justification for ongoing operation so that the issue could be worked on without having to implement any remedial actions during the timeframe the issue is being addressed.

This revision incorporates enhancements identified by a tiger team that was implemented as a business process improvement initiative, as documented in the "Completion of Generic Issues Program Tiger Team Activities" (ADAMS Accession Number ML13296A417).

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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).

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 of 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 SES managers to serve as members on Generic Issues Review Panel (GIRP), and appoints technical experts to serve on the panels, as appropriate, to provide 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 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.J of this directive.

G. Director, Office of New Reactors (NRO)

1. 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.
2. Coordinates with the Director of RES for new GIs in the area of NRO responsibility.
3. Coordinates with the Director of RES on the transfer of GIs in the area of NRO responsibility.
4. Performs the GI Program duties and responsibilities specified in Section III.J of this directive.

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

1. Provides support for the processing of GIs related to operating reactor in all stages of the GI process.
2. Coordinates with the Director of RES for new GIs in the area of NRR responsibility.
3. Coordinates with the Director of RES on the transfer of GIs related to reactor from the GI Program to other regulatory programs.
4. Performs the GI Program duties and responsibilities specified in Section III.J of this directive.

I. 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 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.J of this directive.

J. Directors, Office of Nuclear Material Safety and Safeguards (NMSS), Office of New Reactors (NRO), Office of Nuclear Reactor Regulation (NRR), and Office of Nuclear Security and Incident Response (NSIR) – GI Program Responsibilities

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 Senior Executive Service (SES) managers to chair the GIRP and appoint technical experts to serve on the panels, as appropriate.
5. Appoint SES managers 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 the Office of Nuclear Regulatory Research (RES) for periodic reporting to Congress and the Commission, through all GI Program stages, and completion of office-specific actions.

K. 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 Opinions Program) are directed to the most appropriate office or program.

L. 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.

M. 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 directive and handbook 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."

Executive Orders (EOs)

EO 12866, "Regulatory Planning and Review," September 30, 1993.

EO 13563, "Improving Regulation and Regulatory Review," January 18, 2011.

Nuclear Regulatory Commission

Charter of the Committee to Review Generic Requirements (ML110620618).

Completion of Generic Issues Program Tiger Team Activities (ML13296A417).

GI Program Web page on the NRC internal Web site: http://www.internal.nrc.gov/RES/projects/GIP/.

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

Guidance on Communication Tools & Plans, available on the NRC internal Web site: http://www.internal.nrc.gov/communications/comm_tools/guidance.html.

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

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Office of Management and Budget

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

OMB Circular No. A-4, " Regulatory Impact Analysis: Frequently Asked Questions (FAQs)," February 7, 2011, available at http://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a004/a-4_FAQ.pdf.

United States Code

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

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

Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104-66).

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 staff to process generic issues (GIs). This overview of the GI Program describes the three program stages, GI tracking and communication, and roles and responsibilities. For detailed GI Program implementation guidance, refer to Office of Nuclear Regulatory Research (RES) Office Instruction (OI) TEC-002, "Procedures for Processing Generic Issues," 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 Web site, at http://www.nrc.gov/about-nrc/regulatory/gen-issues.html, and on the NRC internal Web site, at http://www.internal.nrc.gov/RES/projects/GIP/index.html.

B. On October 8, 1976, the Commission directed the staff to develop a program plan for resolution of GIs. 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.

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

2. The GI Program supports agency objectives through timely and effective treatment of GIs.

II. 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 III.D 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. 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) 52.47(a)(21), applications for design certification must contain, “Proposed technical resolutions of those unresolved safety issues (USIs) 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 USIs 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. The process for prioritization of GIs (high, medium, low, drop) was replaced in 1999 by a screening and assessment process. This management directive (MD) requires completion of the screening and assessment process to determine whether the proposed issue is a bona fide GI or should be rejected from the program.

4. For the purposes of 10 CFR 52.47(a)(21) and 10 CFR 52.79(a)(20), 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 (see Exhibit 1 for an overview of the GI process). 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, and the Allegations Program).

3. When an issue exits the GI Program, the possible outcomes include no action, further study, or referral to the appropriate regulatory program. GIs and proposed GIs (Section VIII, “Glossary,” of this handbook) 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 that it is not 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.

4. When a proposed generic concern 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 is performed to determine whether it remains valid.

5. The GI Program provides feedback to the requestor 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.

III. IDENTIFICATION OF A GENERIC ISSUE FOR THE THREE-STAGE PROCESS

A. General

The GI Program uses a three-stage process as shown in Exhibit 2a and Exhibit 2b. 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 (Exhibit 3). Proposed GIs are not yet GIs. The GI Program staff provides assistance to persons considering proposing a GI when requested.

C. Issues Considered for GI Program

The GI 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 can propose a GI by accessing the GI proposal form for the public on the NRC public Web site, at http://www.nrc.gov/about-nrc/regulatory/gen-issues/gi-form.html, filling out the form, and submitting the form to the GI Program mailbox at

GIP.Resource@nrc.gov. The GI Program normally does not process issues that require confidentiality for the submitter.

2. The NRC staff may propose a GI. It is recommended that an originator inform their management of the issue. The originator 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. The GI proposal form for NRC staff is on the GI Program Web page at http://www.internal.nrc.gov/RES/projects/GIP/UserInstructions.html. NRC staff can submit the form to the GI Program mailbox at GIP.Resource@nrc.gov. The GI Program normally does not process issues that require confidentiality for the submitter.

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 to 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.

IV. THE THREE-STAGE PROCESS FOR GENERIC ISSUES

A. Stage 1, Screening (target for completing screening is typically 9 to 18 months)

The purpose of this stage is to evaluate the proposed generic issue against the seven screening criteria 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 to continue through the GI process.

(b) The regulatory offices will follow their specific office instructions, (e.g., Office of Nuclear Material Safety and Safeguards (NMSS) will use LIC-357, “NMSS Generic Issues Program,” and the Office of Nuclear Reactor Regulation (NRR) will follow LIC-504, ”Integrated Risk-Informed Decision-Making Process for Emergent Issues") to evaluate if the issue is an immediate safety concern.

(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 procedures. A 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 memorandum, including information justifying the ongoing operation of the potentially affected nuclear facilities (without having to implement any remedial actions) during the time required to process the GI.

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

(i) If the initial review finds that the proposed GI fails to meet all of the 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. The proposed GI may be transferred to another RES division for further study at management discretion.

(ii) If the initial review finds the proposed GI appears to meet all of the 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 and management discretion.

2. The GIRP performs a detailed evaluation to determine if the proposed GI satisfies all of the seven screening criteria identified in Section V of this handbook. The GIRP can recommend the issue be transferred to another RES division for further study.

(a) If the GIRP concludes that the proposed GI does not satisfy all of the 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. A letter is also sent to the originator of the issue summarizing the actions taken and stating that the issue has exited the GI process. The memorandum should provide a justification for ongoing operation if the issue will be addressed by another process.

(b) If the GIRP concludes that the proposed GI satisfies all of the 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 of the 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. Once the Director of RES concurs on the panel's recommendations, the proposed GI proceeds to Stage 2 for an assessment to be performed.

4. The Office of 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, a limited regulatory analysis, and a proposed regulatory path forward.

1. An assessment team is formed and the team develops an assessment plan.

2. 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 originator 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.

3. Once the Director of RES concurs with the GIRP 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) A limited regulatory analysis.

   (f) Proposed regulatory action to resolve the issue.

4. 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.

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

C. Stage 3, Regulatory Office Implementation (ROI) (target for completing implementation is typically 5 to 10 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 GI, who is responsible for reporting the status of the GI to the GI Program on actions taken to resolve the GI. The GI Program continues to track the status of the GI until resolution and closure of the GI.

2. The responsible regulatory office performs a regulatory analysis to determine the appropriate action 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 a regulatory 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 a regulatory 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 requirement (e.g., rule, order, or generic communication).
6. Licensees implement required actions to comply with the new regulatory requirement.
7. The NRC staff performs inspections to verify all required actions have been completed.
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.

V. GENERIC ISSUE AND UNRESOLVED SAFETY ISSUE CRITERIA

A. Criteria for Generic Issues

The GI Program will address only those issues that meet the following criteria. If at any time a proposed GI or a GI does not meet any of these criteria, 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 affects public health and safety, the common defense and security, or the environment (with respect to radiological health and safety). For issues that are not

amenable to quantification using risk assessment, qualitative factors may be developed and applied as necessary to assess safety/risk significance.

2. The issue applies to two or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals.
3. The issue is not being addressed using other regulatory programs and processes; existing regulations, policies, or guidance.
4. The issue can be resolved by new or revised regulation, policy, or guidance.
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).
6. The issue is well defined, discrete, and technical.
7. Resolution of the issue may involve review, analysis, or action by the affected licensees, certificate holders, or holders of other regulatory approvals.

B. Unresolved Safety Issue

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

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

2. The following definition of an unresolved safety issue (USI) 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. On October 8, 1976, the Commission directed the staff to develop a program plan for resolution of GIs. To meet both Commission and congressional directives, the staff developed the GI Program that provided for the identification and resolution of USIs and GIs. The status of USIs and GIs was reported annually to Congress beginning in

1978 until the requirement for an annual report to Congress was later rescinded by the Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104-66).

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 generic issues.

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 Responsible Project Manager (RPM) for each proposed GI and from the regulatory office project manager for each GI. The status is tracked throughout the GI life cycle after passing initial review by the RPM through issue closure.
3. A proposed issue becomes a GI when responsibility for the issue is transferred to the regulatory office. The proposed issue 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 quarterly status updates to the GI Program Manager through the Tracking Coordinator (TC) for GIs to support routine reports to Congress and the Commission (as required by 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 Guidance and Generic Issues Branch (RGGIB), 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 the

issue by the responsible organizations and people. Specific responsibilities include the following:

1. Administer the GI Program using a graded approach to the extent practical.
2. Ensure that the GI Program is consistently implemented across offices.
3. Coordinate activities for GI status tracking, reporting, and the periodic update to NUREG-0933.
4. Communicate and coordinate with other offices, through all GI Program stages, resource allocation, information flow, and decisions on transition to other programs.
5. Assign GI staff or RPMs 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.
8. Ensure that the justification for ongoing operation remains valid throughout the GI process.
9. Support executive review meetings.
10. Oversee dissemination of selected documents associated with GIs.

B. The Responsible Project Manager (RPM)

The RPM is an RGGIB 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. Specific responsibilities of the RPM include the following:

1. Upon receipt of a proposed GI, promptly determine if the proposed generic issue 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 to 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 clearly does not meet any of the seven screening criteria.

(b) If the issue clearly does not meet any 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 submitter for additional information, as required.

   (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 when the proposed GI is submitted and reviewed by the GI program staff.

   (c) Assign an identification number to the GI 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) 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 originator 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, which typically occurs shortly after the public meeting.

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. Participate on the assessment team.

    (a) Using a graded approach, develop an assessment plan to determine if the proposed GI meets the criteria for further regulatory action based upon an assessment of safety and risk significance, and identifies possible regulatory options.

    (b) Establish schedules.

(c) Determine necessary milestones to determine potential safety significance, the risk, or security significance of the GI to determine if the GI merits enhanced regulation.

(d) Prepare a limited cost-benefit analysis of proposed regulatory solutions in the assessment, if desired.

(e) Prepare and document the results of the assessment to the GIRP.

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

18. Participate on the transition team.

(a) Coordinate with the regulatory office to assign a new project manager to the transition team.

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

C. Staff with Assignments in Regulatory Office Implementation

1. Project Managers

(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) Provide input to periodic status update requests to the GI Program Manager through line management.

(d) Perform GI closeout functions.

2. Technical Reviewers

(a) Coordinate with the project manager in supporting the development and implementation of the regulatory action.

(b) Develop the technical basis for the regulatory action.

D. Management (Branch Chiefs or Division Directors) with Staff Having GI Actions in 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. Tracking Coordinator (TC)

The TC is a RES staff member designated by the GI Program Manager to lead and coordinate interoffice information flow for status updates in support of routine reports to the Commission and Congress. The duties of the TC include the following:

1. Prepare and issue a memorandum requesting status update input.
2. Contact the RPM and their branch chief and decides the date they will provide information, as well as requests any assistance from the GI Program.
3. Document coordination efforts, update and verify the information provided, archives the information as appropriate, and enter updated information into the tracking system.
4. Provide the updated status information and the compiled GI status update information to the RPM and their branch chief.
5. Obtain concurrence on the compiled GI status update information for publication, as appropriate.

F. 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.

G. 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 chairman at the Senior Executive Service (SES) level, selected technical experts, the RPM, and a member of DE, RES 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.

H. Assessment Team

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

1. The Assessment Team

   (a) Develop an assessment plan containing a detailed schedule, milestones, and responsibilities necessary to determine if the proposed GI merits enhanced regulation.

   (b) Develop the technical basis of the issues using risk as a screening threshold.

   (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) Provide an evaluation of the following criteria, as applicable:

      (i) Security significance,

      (ii) Regulatory compliance,

      (iii) Limited regulatory analysis, and

      (iv) Regulatory path forward.

   (e) Provide the GIRP with sufficient information to determine whether the proposed GI should proceed to Stage 3 for Regulatory Office Implementation.

I. Transition Team

The mission of a transition team is to ensure that an issue receives the necessary attention in the appropriate receiving regulatory office to ensure progress is maintained. The transition team is typically composed of a team lead at the SES level, the RPM, and selected individuals with specific knowledgeable of the GI. The transition team reports to the team leader receiving the GI. The transition team provides support until the transition

team leader is satisfied that sufficient knowledge has been transferred to their office staff so that they can successfully continue processing the GI.

1. Transition Team Formation

   (a) Screening Stage

   The GIRP determines that the proposed GI passes all of the 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 process and is transferred to the designated regulatory office for implementation.

   (b) Assessment Stage

   The Director of RES approves the transfer memorandum that the proposed GI proceed to Regulatory Office Implementation.

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

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

   (b) Assist in developing an action plan for Regulatory Office Implementation with associated milestones for GIs. Typical milestones are dependent on the chosen regulatory action and include—

      (i) Regulatory basis/technical development (typically up to 30 months for rules, 6 months for generic letters, less time for orders).

      (ii) Committees (the ACRS and the CRGR) review and public comments as appropriate (typically up to 3 months for rules and generic letters, less time for orders).

      (iii) Finalize and issue rules, orders, and generic letter (typically up to 18 months for rules, 9 months for generic letters, less time for orders).

      (iv) Licensee implementation (typically up to 48 months – may not be applicable for generic letters).

      (v) Inspection or verification (typically up to 12 months – may not be applicable for generic letters).

   (c) Develop a regulatory analysis, through coordination with the responsible regulatory office.

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

(e) Participate in outreach to external stakeholders.

(f) Conduct public meetings, if appropriate.

(g) Interface with the ACRS and incorporates or addresses ACRS comments, as appropriate.

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

VIII. GLOSSARY

Assessment Plan

A detailed plan containing a detailed schedule, milestones, and responsibilities necessary to determine if a proposed generic issue merits enhanced regulation.

Closed Generic Issue (GI)

A generic issue 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 generic issue process. It should be 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 by teleconference, electronic mail, or other methods that do not require the physical presence of all of the panel members in the same room at the same time may suffice. More process rigor and resources are applied as an issue proceeds through each GI Program stage.

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 (see Exhibit 1). Examples of milestone memorandum include—

1. Receipt Memorandum: acknowledgment of receipt of an issue from the GI staff to the originator;

2. Initial Review Memorandum: documentation of the results of the initial review of the issue by the RPM, to include 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 (GI) (pre-GI)

An issue submitted to the GI Program for consideration of a new regulatory requirement. The issue remains a proposed generic issue until transferred to the responsible regulatory office for implementation. 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 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 that different technical experts be used.

Status Updates

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.

EXHIBIT 1 Generic Issues Process Overview

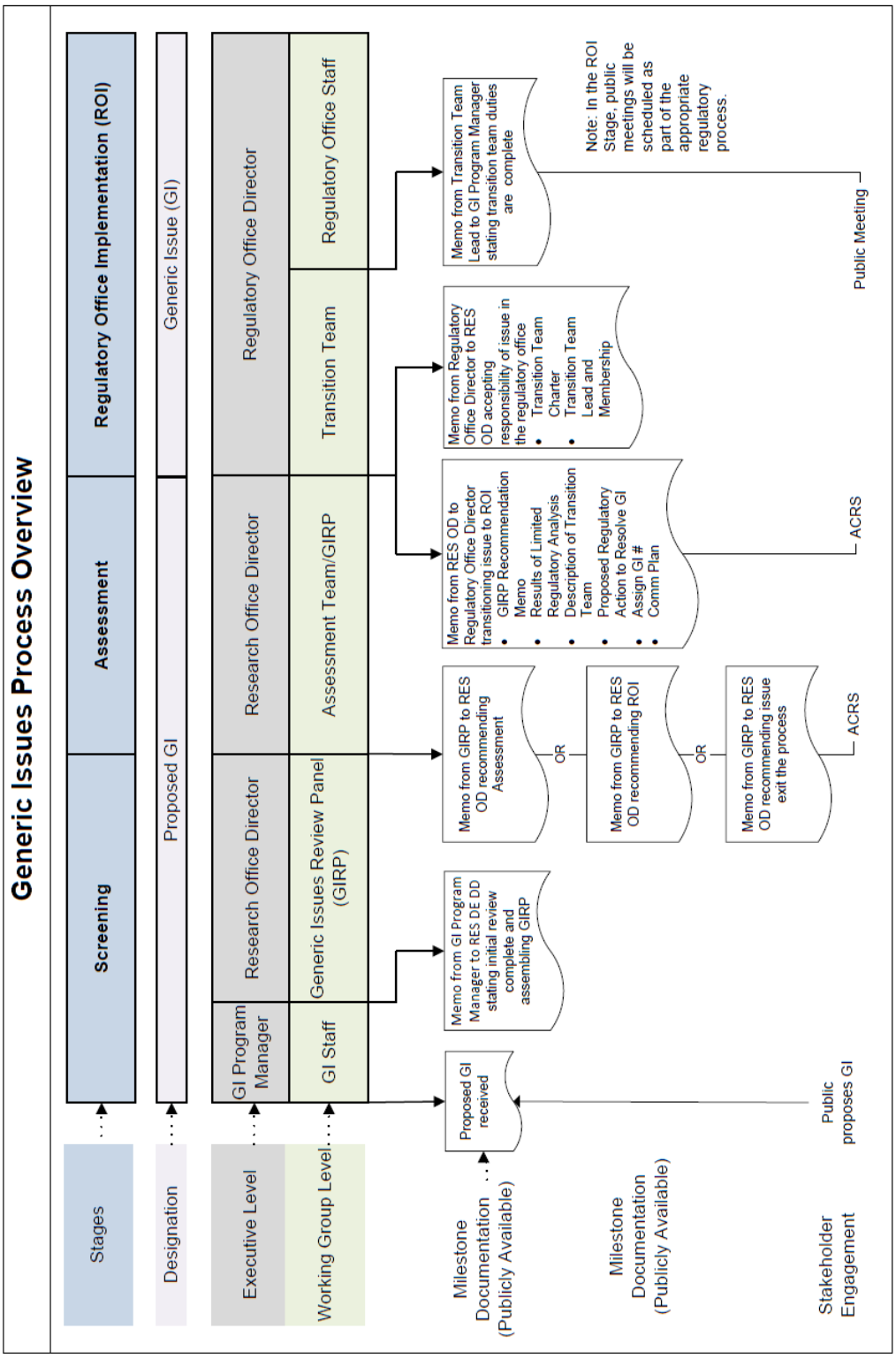

EXHIBIT 2a Generic Issue (GI) Process - Stage 1

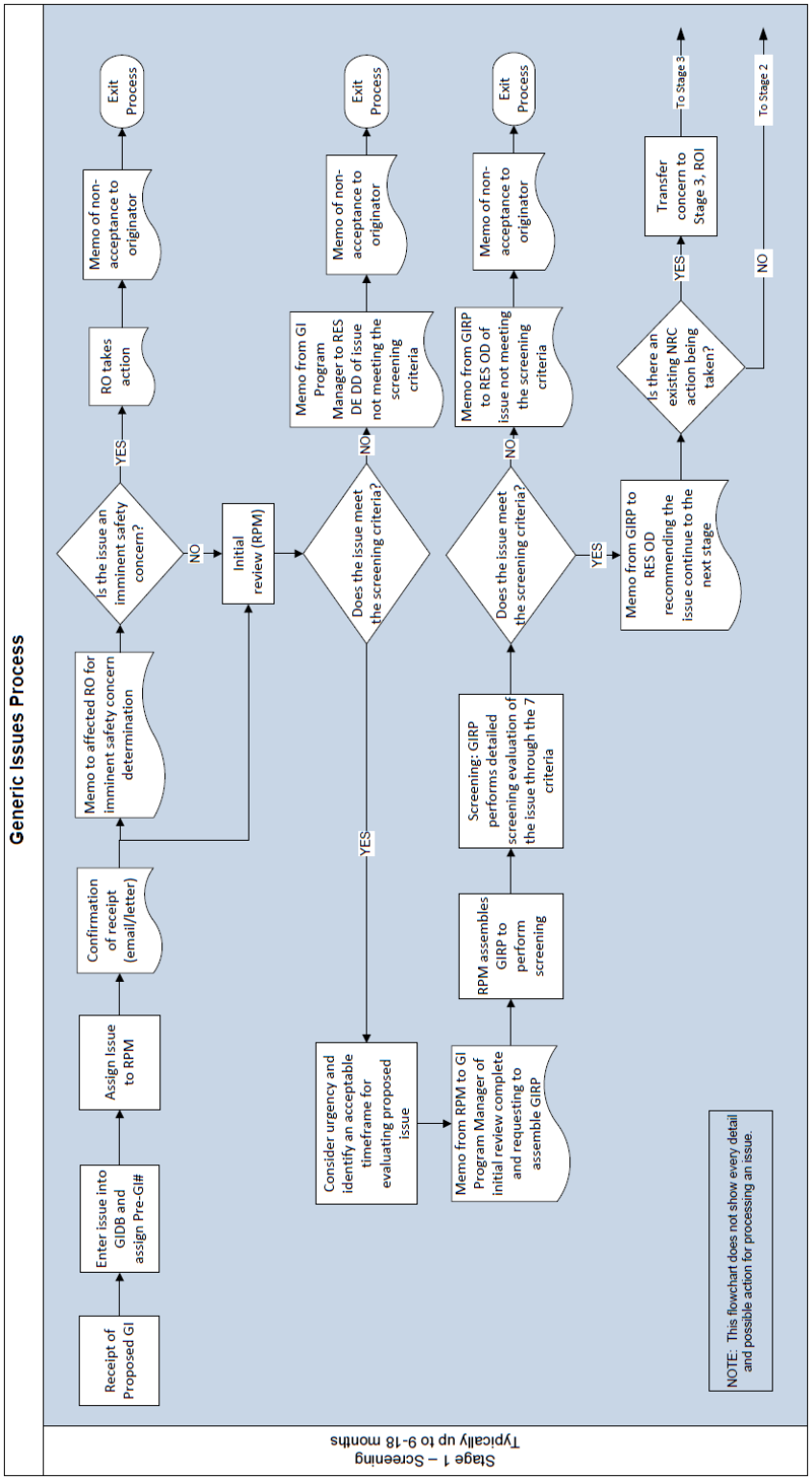

EXHIBIT 2b Generic Issue (GI) Process - Stage 2 and Stage 3

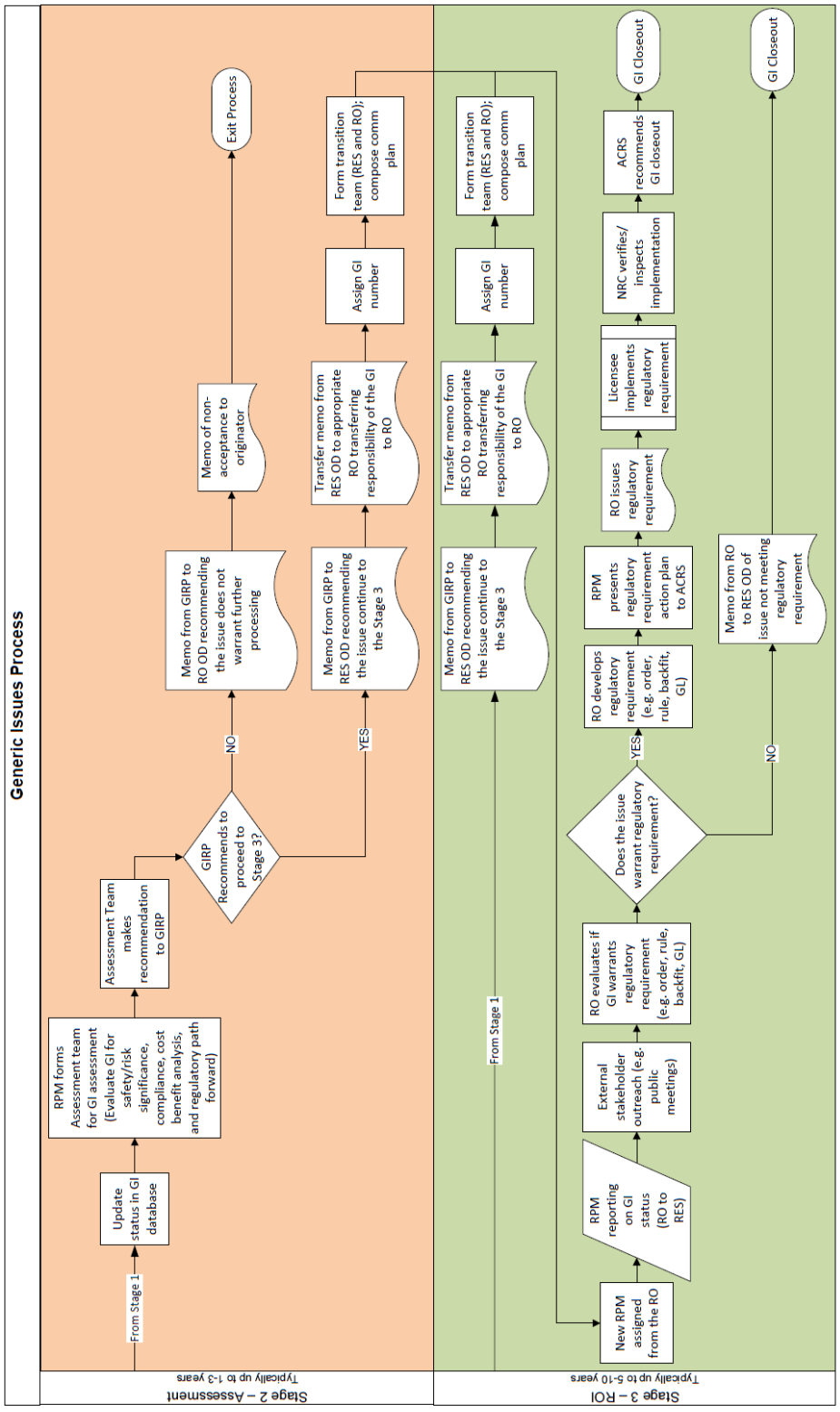

EXHIBIT 3 Sources of Proposed Generic Issues (GIs)