U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-05-13

To: NRC Management Directives Custodians

Subject: Transmittal of Management Directive 6.4, "Generic Issues Program."

Purpose: Directive and Handbook 6.4, which delineate the prioritization and resolution process for generic safety issues, are being revised to address Recommendation 3.1.3(1) of the Davis-Besse Lessons-Learned Task Force, namely, to revise and simplify the process for submitting candidate generic issues. This guidance applies to all generic issues related to public health and safety and common defense and security. The role and responsibilities of the Committee To Review Generic Requirements have also been included. Additionally, the role of the Advisory Committee on Reactor Safeguards, the Advisory Committee on Nuclear Waste, and the Advisory Committee on the Medical Uses of Isotopes is being clarified.

Office and Division of Origin: Office of Nuclear Regulatory Research
Division of Systems Analysis and Regulatory Effectiveness

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Generic Issues Program

Directive 6.4

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Generic Issues Program
Directive 6.4

Policy
(6.4-01)

It is the policy of the U. S. Nuclear Regulatory Commission to have an effective program for the resolution of generic issues (GIs) that affect licensees, certificate holders, or other entities regulated by or subject to the regulatory jurisdiction of NRC, as well as regulatory approval processes, for example, the design certification rule, standard design approvals, and early site approvals. A GI is a regulatory matter involving design, construction, operation, or decommissioning applicable to several, or a class of, NRC licensees, certificate holders, or other entities regulated by or subject to the regulatory jurisdiction of NRC that may need further examination of and possibly new initiatives, including but not limited to existing NRC rules, guidance, or programs.

Objectives
(6.4-02)

- To improve the internal management and review of issues coming before NRC from both internal and external sources. The program does not create procedures or rights enforceable by law, nor does it replace existing formal processes for obtaining or otherwise participating with respect to agency determinations regarding licensing actions (10 CFR 2.105), rulemaking (10 CFR 2.802), or requesting enforcement action (10 CFR 2.206). (021)

Objectives
(6.4-02) (continued)

- To identify a cost-effective solution for a GI and to implement the solution or a set of solutions for that GI, as appropriate. (022)

- To ensure that the immediate and long-term safety, safeguards, and regulatory burden concerns identified as GIs are clearly identified, documented, tracked, and analyzed and that corrective actions are effectively implemented, and verified. (023)

- To ensure that program and regional offices maintain a coordinated and efficient capability to effectively— (024)

  – identify GIs
  – document GIs
  – track GIs
  – screen GIs
  – assess GIs
  – impose new or revised requirements
  – relax requirements
  – verify licensee implementation and effectiveness of the new or revised requirements

- To ensure that the public, Congress, Agreement States, licensees, certificate holders, other entities regulated by or subject to the regulatory jurisdiction of NRC, and appropriate agencies of foreign countries and international organizations are provided with current information regarding GIs, including the actual or potential hazards to public health and safety or the common defense and security. (025)

Organizational Responsibilities and Delegations of Authority
(6.4-03)

Commission
(031)

Makes decisions on the resolution of the most serious GIs after analyses determine that their significance to public health and safety or the common defense and security requires the attention of the Commission.

Executive Director for Operations (EDO)
(032)

- Oversees the Generic Issues Program (GIP) and assigns actions to be taken by the responsible program offices. (a)

- Ensures that followup actions associated with a candidate GI or a GI are taken. (b)

- Disseminates selected documents associated with GIs in accordance with distribution directions from the responsible NRC program office. (c)

General Counsel (GC)
(033)

- Provides legal advice and assistance during the processing of GIs. (a)

- Assists with the interpretation of regulations and statutes relevant to GIs. (b)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Advisory Committee on Reactor Safeguards (ACRS)
(034)

- Identifies candidate reactor GIs and reviews their analyses. (a)
- Advises the Commission and the staff on the processes and methodologies for addressing reactor GIs. (b)

Advisory Committee on Nuclear Waste (ACNW)
(035)

- Identifies candidate GIs and reviews the analyses of GIs related to waste management and decommissioning. (a)
- Advises the Commission and the staff on the technical aspects and methodologies for addressing GIs related to waste management and decommissioning. (b)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)
(036)

- Identifies candidate GIs and reviews the analyses of GIs related to medical uses. (a)
- Advises the staff on the technical aspects and methodologies for addressing GIs related to medical uses. (b)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Committee To Review Generic Requirements (CRGR)
(037)

- Reviews new or revised draft rules, bulletins, generic letters, information notices, inspection procedures, or regulatory guidance developed to address a GI. (a)

- Where appropriate, advises the EDO regarding these regulatory responses to a GI.* (b)

Director, Office of Nuclear Reactor Regulation (NRR)
(038)

- Ensures that operational safety data are reviewed to identify candidate reactor GIs in accordance with the requirements of Management Directive (MD) 8.5, "Operational Safety Data Review," and this directive.** (a)

- Takes prompt compensatory actions, as warranted by the risk significance of a GI, and monitors operational safety data to verify the effectiveness of actions taken by licensees to implement effective corrective actions in addressing GIs. (b)

*As directed by the Commission (SRM "SECY-97-0052 - Committee To Review Generic Requirements (CRGR) - Scope of Review and Periodic Review Activities," dated April 18, 1998), and incorporated in the CRGR Charter, the committee may review selected topics at the request of the EDO or the Director of the Office of Nuclear Material Safety and Safeguards. Such topics may include potential GIs affecting the nuclear materials facility licensees.

**For the nuclear power reactor operating experience, the existing guidance in MD 8.5 will be replaced by a draft guidance, which is currently being used on a trial basis by both the Office of Nuclear Regulatory Research (RES) and NRR (ML043440295). However, the guidance that is applicable to the operating experience at nuclear materials facilities remains unchanged.

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of Nuclear Reactor Regulation (NRR)
(038) (continued)

- Communicates with the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) and the Director of Nuclear Security and Incident Response (NSIR) the initial screening, the review panel's recommendations, and the planned resolution of a GI related to nuclear power reactors that may also be pertinent to nuclear materials licensees and may potentially affect security considerations. (c)

- Assigns a representative at the level of branch chief or higher to serve on the Reactor Generic Issue Review Panel or the Materials Generic Issue Review Panel, as appropriate. Assigns additional personnel as panel members as needed. (d)

- Makes recommendations regarding the screening and classification of candidate reactor GIs. (e)

- Develops new requirements or revises requirements and guidance, as appropriate, based upon the assessment of reactor GIs to reduce unwarranted regulatory burden. (f)

- Imposes requirements on licensees, as appropriate, based on the assessment of reactor GIs. (g)

- Provides appropriate technical support to regional offices, as requested, during licensee implementation and verification of the resolution of reactor GIs. (h)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of Nuclear Reactor Regulation (NRR)
(038) (continued)

- Provides input and support for databases such as the Generic Issue Management Control System (GIMCS). (i)

- Ensures that public meetings are conducted and that review actions are documented. (j)

Director, Office of Nuclear Material Safety and Safeguards (NMSS)
(039)

- Ensures that operational safety data are reviewed to identify candidate materials and waste GIs in accordance with the requirements of MD 8.5, "Operational Safety Data Review," and this directive. (a)

- Takes prompt compensatory actions, as warranted by the risk significance of a GI, and monitors operational safety data to verify the effectiveness of actions taken by licensees to implement effective corrective actions in addressing GIs. (b)

- Communicates with the Director of NRR and the Director of NSIR the initial screening, the review panel's recommendations, and the planned resolution of a GI related to nuclear materials that may also be pertinent to the nuclear power reactors and may potentially affect security considerations. (c)

- Assigns a representative at branch chief level or higher to serve on the Materials Generic Issue Review Panel or the

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of Nuclear Material Safety and Safeguards (NMSS)
(039) (continued)

Reactor Generic Issue Review Panel, as appropriate. Assigns additional personnel as panel members as needed. (d)

- Designates the Materials Generic Issue Review Panel Chairperson, who shall generally be the Director of the Division of Industrial and Medical Nuclear Safety. (e)

- Coordinates the assignment of additional staff members to support Materials Generic Issue Review Panels. (f)

- Makes recommendations regarding the screening and classification of candidate materials and waste GIs. (g)

- Ensures the screening of materials and waste GIs to determine whether development of a solution warrants expenditure of NRC resources. (h)

- Oversees the assessments of materials and waste GIs to determine whether requirements or guidance is needed and to establish the technical bases for requirements or guidance. (i)

- Develops new requirements or revised requirements and guidance, as appropriate, based upon the assessment of materials and waste GIs. (j)

- Imposes requirements on licensees, as appropriate, based on the assessment of materials and waste GIs. (k)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of Nuclear Material Safety and Safeguards (NMSS)
(039) (continued)

- Provides appropriate technical support to regional offices, as requested, during licensee implementation and verification of the resolution of materials and waste GIs. (l)

- Provides input and support for databases such as GIMCS. (m)

- Ensures that public meetings are conducted and that review actions are documented. (n)

- Coordinates with the Office of State and Tribal Programs to notify Agreement States of the results of GI assessments. (o)

Director, Office of Nuclear Regulatory Research (RES)
(0310)

- Maintains the GIP and assesses the effectiveness and efficiency of GIP activities and takes action, as appropriate, to improve the program. (a)

- Identifies reactor, materials, and waste GIs from research programs, including national and international cooperative research programs as well as review of operational experience. (b)

- Assigns a representative at branch chief level or higher to serve on the Materials Generic Issue Review Panel or the Reactor Generic Issue Review Panel, as appropriate. Assigns additional personnel as panel members, as appropriate. (c)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of Nuclear Regulatory Research (RES)
(0310) (continued)

- Designates the Chairperson of the Reactor Generic Issue Review Panel. (d)

- Coordinates the assignment of additional staff members to support Reactor Generic Issue Review Panels. (e)

- Assigns a GIP Manager to oversee the processing of both reactor and materials candidate GIs. (f)

- Makes recommendations regarding the screening and classification of candidate reactor and materials GIs. (g)

- Oversees the screening of reactor GIs to determine whether development of a solution warrants expenditure of NRC resources. (h)

- If appropriate, oversees the screening of materials GIs to determine whether development of a solution warrants expenditure of NRC resources. (i)

- Oversees the assessments of reactor GIs to determine whether new or revised requirements or guidance is needed and to establish the technical basis for new or revised requirements or guidance. (j)

- If appropriate, oversees the assessments of materials GIs to determine whether requirements or guidance is needed and to establish the technical bases for requirements or guidance. (k)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of Nuclear Regulatory Research (RES)
(0310) (continued)

- Develops methodologies to perform screenings and assessments of GIs. (l)

- Coordinates data entry into databases (e.g., GIMCS) on the status and documentation concerning issues processed in accordance with the GIP. (m)

- Receives Quarterly Generic Issue Status Reports from the Responsible Project Manager for each GI and compiles and issues Combined Quarterly Generic Issue Status Reports on the status of issues processed in accordance with the GIP. The Combined Quarterly Generic Issue Status Reports will be documented in the GIMCS. (n)

Director, Office of Nuclear Security and Incident Response (NSIR)
(0311)

To be developed later.

Director, Office of International Programs (OIP)
(0312)

- 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. (a)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Director, Office of International Programs (OIP)
(0312) (continued)

- Assists in the establishment and administration of systems for the effective review, tabulation, storage, and retrieval of information related to foreign GIs. (b)

- Coordinates U.S. participation in the Nuclear Energy Agency and the International Atomic Energy Agency reporting systems and transmits reports and information received on foreign GIs to the appropriate offices for further consideration. (c)

Director, Office of State and Tribal Programs (STP)
(0313)

- Advises, coordinates, and reviews Agreement State participation in the review of operational safety data to identify candidate materials and waste GIs in accordance with the requirements of MD 8.5, "Operational Safety Data Review," and this directive. (a)

- Provides the results of relevant GI assessments to the Agreement States. (b)

Director, Office of Enforcement (OE)
(0314)

- Identifies candidate GIs from review of reactor and materials enforcement issues. (a)

- Provides enforcement-related support to program and regional offices for resolution of any enforcement issues associated with GIs. (b)

Organizational Responsibilities and Delegations of Authority
(6.4-03) (continued)

Regional Administrators (RAs)
(0315)

- Identify candidate GIs through inspection and investigation activities. (a)
- Verify licensee implementation of requirements that may result from the resolution of GIs. (b)
- Coordinate regional efforts with other NRC offices. (c)

Applicability
(6.4-04)

The policy and guidance in this directive and handbook apply to NRC employees and cover candidate GIs submitted by non-NRC employees for NRC review.

Handbook
(6.4-05)

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

References
(6.4-06)

Code of Federal Regulations

Title 10, "Energy."

References
(6.4-06) (continued)

Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material.”

Part 31, “General Domestic Licenses for Byproduct Material.”

Part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.”

Part 33, “Specific Domestic Licenses of Broad Scope for Byproduct Material.”

Part 34, “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.”

Part 35, “Medical Use of Byproduct Material.”

Part 39, “Licenses and Radiation Safety Requirements for Well Logging.”

Part 40, “Domestic Licensing of Source Material.”

Part 50, "Domestic Licensing of Production and Utilization Facilities."

Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants."

Part 70, "Domestic Licensing of Special Nuclear Material."

Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

(6.4-06) (continued)

Part 76, "Certification of Gaseous Diffusion Plants."

Office of Management and Budget

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

United States Code

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

National Technology Transfer and Advancement Act, Pub. L. 104-113, 110 Stat. 775, 1995, http://ts.nist.gov/ts/htdocs/210/nttaa/113.htm.

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U.S. Nuclear Regulatory Commission Documents

Charter of the Committee To Review Generic Requirements

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2.2, "Capital Planning and Investment Control."

3.7, "NUREG-Series Publications."

3.50, "Document Management."

References

(6.4-06) (continued)

3.52, "Availability, Retention, and Indexing of Codes and Standards."

6.3, "The Rulemaking Process."

8.1, "Abnormal Occurrence Reporting Procedure."

8.2, "NRC Incident Response Program."

8.4, "Management of Facility-specific Backfitting and Information Collection."

8.5, "Operational Safety Data Review."

10.159, "The NRC Differing Professional Opinions Program."

"NRC Information Quality Guidelines," *Federal Register*, Vol. 67, No. 190, pp. 61695-61699, October 1, 2002, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-24944.

NUREGs—

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

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

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

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

NUREG/BR-0224, "Guidelines for Conducting Public Meetings."

References
(6.4-06) (continued)

NUREG/BR-0240, “Reporting Safety Concerns to the NRC.”

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

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

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

NUREG-0933, "A Prioritization of Generic Safety Issues."

NUREG-1409, "Backfitting Guidelines."

NUREG-1489, "A Review of NRC Staff Uses of Probabilistic Risk Assessment."

Policy Statements

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

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

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

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

References
(6.4-06) (continued)

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

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

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

Staff Requirements Memoranda

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

SRM to the EDO, "SECY-97-0052 — Committee To Review Generic Requirements (CRGR) — Scope of Review and Periodic Review Activities," dated April 18, 1998.

U.S. Securities and Exchange Commission

A Plain English Handbook, Office of Investor Education and Assistance, August 1998.

Generic Issues Program

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Part I
General

Introduction (A)

The Generic Issues Program (GIP) provides internal guidance for determining whether a candidate generic issue (GI) represents an adequate protection issue, a substantial safety enhancement issue, or a reduction in unnecessary regulatory burden issue. In addition, the GIP identifies cost-effective solutions to GIs, implements, and then verifies the adequacy of solutions for GIs, as appropriate. Thus, the GIP provides an opportunity for the NRC and Agreement State staff and other parties to recommend safety- or security-related (or reduction in unnecessary regulatory burden) improvements to the agency's regulations and/or implementation of these regulations. Candidate generic issues may arise from many sources, including safety evaluations, operational events, or even suggestions on the part of individual staff members, outside organizations, or members of the general public. Additionally, new issues identified as Unresolved Safety Issues (USIs)[1] or any staff concerns that are raised as part of the NRC's Differing Professional Opinion (DPO)[2] program may also be addressed under the GIP. The staff periodically conducts reviews of the open GIs to identify USIs. Appendix B, "Unresolved Safety Issue Assessment Criteria," of this management directive provides detailed staff guidance on USI identification. (1)

The following items are generally not subject to the provisions of the GIP: obtaining information from licensees or certificate holders, increasing the staff's knowledge in a particular technical area, improving or maintaining the NRC's capability to make

[1]A USI is defined as 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.

[2]A DPO is a formal concern raised by the staff on a technical, legal, or policy issue.

Introduction (A) (continued)

independent assessments of safety and administrative matters, or ensuring compliance with existing rules or written commitments. (2)

In some instances, it may be necessary to obtain additional information from licensees or certificate holders to determine (a) whether adequate protection has been or would be maintained through license compliance or (b) whether it would be appropriate to reduce the regulatory burden through relaxation or elimination of compliance with some regulatory requirements. (3)

Because of the varying technical disciplines and levels of difficulty encompassed by GIs, the processing of GIs does not lend itself to a strict, proceduralized process. The guidance in this handbook is intended to provide a useful, consistent framework for handling, tracking, and defining the minimum documentation associated with the processing of GIs. (4)

- Only potential adequate protection, substantial safety enhancement, and reduction in unnecessary regulatory burden issues are subject to the GIP process. (See Glossary and Appendix G, "Candidate Generic Issue Screening Checklist.") (a)

- Resolution of a GI may involve developing and imposing new or revised rules, developing new or revised guidance, revising the interpretation of rules or guidance, or providing information for voluntary actions. (b)

- Resolution of a GI may affect licensees, certificate holders, or other entities regulated by or subject to NRC's regulatory jurisdiction. (c)

- The process stages in the GIP are identification, initial screening, technical assessment, regulation and guidance development, regulation and guidance issuance, implementation, and verification. (d)

Introduction (A) (continued)

In addition, attached to this management directive are Appendices A through G, which give detailed information on the submittal and assessment of GIs. (5)

Responsibilities (B)

The following responsibilities have been assigned to implement the GIP.

Division-Level Management (1)

- Ensures that policy guidance on processing GIs is followed to the maximum extent practicable. (a)
- Provides the human and financial resources to process GIs in accordance with the planning, budgeting, and management process. (b)
- Provides timely review of associated documents and records. (c)
- Ensures that Responsible Project Managers (RPMs) assigned to a particular GI have knowledge in the relevant technical area and are knowledgeable of the GIP and its guidelines. (d)
- Ensures that potential reactor and materials GIs that are within the scope of the GIP are included in the process. (e)
- Provides timely review and approval of Quarterly Generic Issue Status Reports before they are submitted to the GIP Manager in RES. (f)

Branch-Level Management and Supervisors (2)

- Ensure cost-effective performance of work. (a)

Responsibilities (B) (continued)

Branch-Level Management and Supervisors (2) (continued)

- Ensure that qualified staff are performing the work. (b)
- Review work for accuracy and completeness. (c)
- Provide timely review of associated documents and records. (d)
- Ensure that work is performed in accordance with the description and schedule as specified in the approved GI Task Action Plan (TAP) in accordance with Appendix D, “Generic Issue Task Action Plan.” (e)
- Coordinate peer reviews of products produced during the processing of GIs. (f)
- Ensure that status reports on GIs are documented and submitted in accordance with requirements. (g)

Reactor Generic Issue Review Panel (3)

The Reactor Generic Issue Review Panel is established by the Director of RES, with assistance from other program offices. Reactor Generic Issue Review Panel meetings should be held only if a “quorum” of experts is available to address the candidate GI. The panel Chairman shall make this decision. To the extent possible, the panel should maintain its independence vis-à-vis the candidate GIs. The panel performs the following activities:

- Receives and reviews candidate reactor GIs. (a)
- Defines the scope of candidate reactor GIs. (b)
- Conducts initial screening of candidate reactor GIs. (c)

Responsibilities (B) (continued)

Reactor Generic Issue Review Panel (3) (continued)

- Assesses whether a candidate GI may or may not meet specified thresholds and be classified as an adequate protection, a substantial safety enhancement, or a reduction in unnecessary regulatory burden issue during the initial screening stage. (d)

- Determines and achieves consensus to the extent practical on whether a candidate GI should be classified as an adequate protection, a substantial safety enhancement, or a reduction in unnecessary regulatory burden issue during the technical assessment stage. (e)

- Reviews any changes in the scope of candidate reactor GIs. (f)

Materials Generic Issue Review Panel (4)

The Materials Generic Issue Review Panel is established by the Director of the Office of Nuclear Material Safety and Safeguards (NMSS), with assistance from other program offices. Materials Generic Issue Review Panel meetings should be held only if a "quorum" of experts is available to address the candidate GI. The panel Chairman shall make this decision. To the extent possible, the panel should maintain its independence vis-à-vis the candidate GIs. The panel performs the following activities:

- Receives and reviews candidate materials GIs. (a)

- Defines the scope of candidate materials GIs. (b)

- Conducts initial screening of candidate materials GIs. (c)

- Assesses whether a candidate GI may or may not meet specified thresholds and be classified as an adequate protection, a substantial safety enhancement, or a reduction in unnecessary regulatory burden issue during the initial screening stage. (d)

Responsibilities (B) (continued)

Materials Generic Issue Review Panel (4) (continued)

- Determines and achieves consensus to the extent practical on whether a candidate GI should be classified as an adequate protection, a substantial safety enhancement, or a reduction in unnecessary regulatory burden issue during the technical assessment stage. (e)

- Reviews any changes in the scope of candidate materials GIs. (f)

Generic Issues Program Manager (5)

- Is a RES employee who is designated as the Generic Issues Program (GIP) Manager by the Director of RES (contact GIP@NRC.gov). (a)

- Assigns alphanumeric designations and titles to candidate GIs received from submitters (contact CANDIDATE-GIS @NRC.gov). (b)

- Transmits to the Reactor Generic Issue Review Panel or the Materials Generic Issue Review Panel, as appropriate, candidate GIs that are received from the submitters. (c)

- Supports the activities of the Reactor and the Materials Generic Issue Review Panels. (d)

- Assembles and coordinates the issuance of Quarterly Generic Issue Status Reports from each RPM on open GIs and candidate GIs. (e)

- Coordinates the issuance of an annual report to the Commission on open GIs. (f)

- Coordinates data entry into databases (e.g., the Generic Issue Management Control System [GIMCS]) on the status and documentation of candidate GIs and open GIs. (g)

Responsibilities (B) (continued)

Responsible Project Manager (6)

- Prepares a GI TAP in accordance with Appendix D for each GIP stage following initial screening. (a)
- Understands the GI scope, associated milestones, deliverables, and the status of assigned GIs. (b)
- Documents ongoing analyses and the basis for decisionmaking. (c)
- Prepares Quarterly Generic Issue Status Reports and forwards them to the GIP Manager in RES for assigned issues in accordance with Appendix E, “Quarterly Generic Issue Status Report.” (d)
- Prepares draft memoranda to the Executive Director for Operations (EDO) and forwards them to the GIP Manager in RES for review and concurrence for GIs that are excluded from further consideration, or closed GIs. (e)
- Coordinates public meetings, as needed, concerning assigned candidate GIs, or open GIs. (f)
- Performs or coordinates work in accordance with NRC policies and this directive. (g)

Communication and Coordination (C)

For an effective implementation of the NRC's Generic Issues Program, the office directors and the regional administrators shall ensure effective communication and coordination between their counterparts, with the GIP Manager and the RPM, and among the cognizant technical staffs within the headquarters and the regional offices, as appropriate. (a)

Communication and Coordination (C) (continued)

The GIP-related office and regional procedures and staff guidance shall be written in plain language and include the necessary programmatic and administrative controls for the necessary inter- and intra-office coordination and communication to ensure an effective GIP. (b)

The appropriate staff shall discuss plans for completing each GIP stage, and the RPM shall document them. (c)

The RPM and his or her counterparts in the appropriate offices and regions shall communicate at least quarterly, or more frequently if directed by management, regarding the scope, progress, intermediate findings, expectations, and routine activities (e.g., inspections, safety evaluations) that may affect the issue closure to ensure efficient use of resources. (d)

The cognizant staff shall consult with OGC, as appropriate, to ensure that technical bases are legally defensible and meet all legal requirements. OGC shall also be consulted to ensure that any necessary notifications to the Atomic Safety and Licensing Board are made. (e)

For significant GIs, a public meeting should be held early in both the technical assessment stage and the regulation and guidance development stage of the GIP to inform all interested stakeholders about the scope and significance of the issue and plans for resolving it. The stakeholders should be given the opportunity to comment on the significance of the issue and plans for resolving it. (f)

The RPM should consider coordinating resolution of an issue with appropriate stakeholders, such as the Nuclear Energy Institute, owners groups, the Electric Power Research Institute, the public, and others. (g)

Communication and Coordination (C) (continued)

The RPM shall hold meetings with external stakeholders in accordance with NRC policy. See NUREG/BR-0224, "Guidelines for Conducting Public Meetings." (h)

Documentation (D)

General Provisions (1)

Documentation of the work and decisionmaking associated with a GI or a candidate GI should be thorough enough so that it can be understood by those who were not directly involved in the GI or the candidate GI. (a)

Tables 1 and 2 illustrate the documentation typically produced during the processing of a GI. (b)

NUREG-0933, “A Prioritization of Generic Safety Issues”

NUREG-0933 contains summaries of GIs and candidate GIs processed in accordance with this directive, including reactor issues dating back to the inception of the Generic Safety Issues Program in the late 1970s. This report also presents generic safety issues related to materials issues processed using this directive. NUREG-0933 is primarily a historical document and lists (1) TMI (Three Mile Island) Action Plan items, documented in NUREG-0660, "Action Plans for Implementing Recommendations of Studies of the TMI-2 Accident," and NUREG-0737, "Clarification of TMI Action Plan Requirements"; (2) Task Action Plan (TAP) items, documented in NUREG-0371, "Approved Category A Task Action Plans for Generic Activities," and NUREG-0471, "Generic Task Problem Descriptions—Category B, C, and D Tasks," as well as all USIs not originally identified in these two documents; (3) new GIs identified from various sources; (4) human factors issues, documented in NUREG-0985, "U.S. Nuclear Regulatory Commission Human Factors Program Plan"; and (5) Chernobyl issues, documented in NUREG-1251, "Implications of the Accident at Chernobyl for Safety Regulation of Commercial

Documentation (D) (continued)

General Provisions (1) (continued)

Nuclear Power Plants in the United States." Future supplements to this report will include additional issues as well as updated information on previously reviewed issues.

Closure Memorandum (2)

The office responsible for a GI (i.e., RES or the Office of Nuclear Reactor Regulation for reactor GIs, or NMSS for materials GIs) shall inform the EDO by memorandum when a GI has been closed. The RPM shall originate the closure memorandum for the signature of the appropriate office director. An endorsement letter from the appropriate advisory committee will normally be attached to the closure memorandum. Copies of the closure memorandum should be sent to the GIP Manager in RES, the appropriate advisory committees (i.e., the Advisory Committee on Reactor Safeguards [ACRS], the Advisory Committee on Nuclear Waste [ACNW], the Committee To Review Generic Requirements [CRGR] or the Advisory Committee on the Medical Uses of Isotopes [ACMUI]), and the submitter of the issue. A GI is “closed” after it has been determined that the issue should be either excluded from any further analyses or that corrective actions have been implemented and verified. The memorandum should include the following items:

- Description of the candidate GI or the GI. (a)
- Description of the potential or actual impact of the issue on safety or regulatory burden. (b)
- Endorsement letter from the appropriate committee(s). (c)
- Description of the GI resolution approach and associated corrective actions, including any backfit implications (10 CFR 50.109, 70.76, 72.62, or 76.76). (d)

Documentation (D) (continued)

Closure Memorandum (2) (continued)

- Description of NRC staff-related interactions with industry and the public. (e)

- Technical basis for classifying the issue as excluded or closed. (f)

- How the implementation of corrective actions was verified, if applicable. (g)

Tracking (E)

General Provisions (1)

Each GI or candidate GI must have an assigned alphanumeric designation and must be tracked by the RPM. Various status reports must be provided to the GIP Manager in RES, with input to the GIMCS. (a)

Quarterly Generic Issue Status Reports and Combined Generic Issue Status Summary Reports should be written in accordance with *A Plain English Handbook* (see "References," Section (6.4-06) of the directive). (b)

Task Action Plan (TAP) (2)

The TAP documents the plans, schedules, and assigned responsibilities for managing each candidate GI through the specific stages of the GIP. See Appendix D for assignment of tasks contained within the TAP.

- During each stage after the initial screening stage, the RPM shall prepare and periodically update, as appropriate, a TAP. Depending on the complexity of the GI, different RPMs may be assigned the responsibility of overseeing different stages of the GIP. (a)

Tracking (E) (continued)

Task Action Plan (TAP) (2) (continued)

- The TAP describes the actions needed to complete a specific GIP stage. For example, a TAP prepared in the technical assessment stage should include only the activities needed to complete that stage. The TAP should delineate the work to be done, assignment of major responsibilities, identification of project resource needs, and scheduling of milestone dates. (b)

Office-Level Tracking (3)

The scheduled completion date for each GIP stage and any significant milestones will be included in the tracking system and operating plan of the responsible office and/or division, as appropriate. (a)

At least monthly, the RPM shall update the status of completion of each GI stage, as identified by the current TAP and its milestones. In addition, the RPM shall make the status report available to the GIP Manager in RES and to the appropriate stakeholders, for example, industry, the public, Congress, and others, as needed. (b)

The responsible office should assign each GI a technical assignment control (TAC) number to facilitate tracking the expenditure of resources. (c)

Quarterly Generic Issue Status Report (4)

The RPM should write the Quarterly Generic Issue Status Reports (see Appendix E for guidance) and maintain them as living documents that summarize the work and decisionmaking associated with a GI as it passes from one stage to another, and from one RPM to another, if necessary. (a)

Tracking (E) (continued)

Quarterly Generic Issue Status Report (4) (continued)

Each RPM shall prepare a Quarterly Generic Issue Status Report for assigned candidate GIs and GIs and forward it to the GIP Manager in RES. (b)

Combined Quarterly Generic Issue Status Summary Report (5)

The GIP Manager in RES shall solicit and use the Quarterly Generic Issue Status Reports to prepare an integrated report summarizing the status and activities related to open GIs and candidate GIs. The integrated report will include only nonpredecisional and nonproprietary information. Copies of the report will be sent to the EDO, the ACRS, the ACNW, the CRGR, the ACMUI, and the Public Document Room. The report will also be placed in ADAMS (the Agencywide Documents Access and Management System).

Annual Report (6)

The GIP Manager in RES shall prepare an annual report and provide it to the program offices for concurrence. This report will include a summary of activities related to open GIs and will be sent to the Commission. This report will also be placed in ADAMS.

Part II
Overview of Generic Issues Program Stages

General

Only generic issues (GIs) that potentially involve adequate protection, substantial safety enhancement, or reduction in unnecessary regulatory burden are included in the Generic Issues Program (GIP). (See Glossary and Appendix G, "Candidate Generic Issue Screening Checklist.") (1)

The GIP consists of the following stages: (2)

- Identification: Stage 1
- Initial Screening: Stage 2
- Technical Assessment: Stage 3
- Regulation and Guidance Development: Stage 4
- Regulation and Guidance Issuance: Stage 5
- Implementation: Stage 6
- Verification: Stage 7
- Closure: Stage 8

Descriptions of each of the stages, including products, are given below. Tables 1 and 2 provide, for each stage, input, output options, tracking documentation, and technical and regulatory documentation. (3)

Identification: Stage 1 (A)

Candidate GIs (e.g., an adequate protection issue, a substantial safety enhancement issue, a reduction in unnecessary regulatory burden issue) may be identified by organizations or individuals internal or external to NRC, including the NRC staff, the Agreement State staff, the Advisory Committee on Reactor Safeguards (ACRS), the Advisory Committee on Nuclear Waste (ACNW), the Advisory Committee on the Medical Uses of Isotopes (ACMUI), licensees, certificate holders, industry groups, or the general public. (1)

Identification: Stage 1 (A) (continued)

If any identified candidate GI has the potential for involving an adequate protection issue, prompt actions shall be taken to evaluate the issue and to initiate any necessary compensatory measures. (2)

Candidate GIs may be identified by NRC or Agreement State staff during routine activities. Sources of candidate GIs include, but are not limited to, NRC staff concerns; public concerns; licensee event reports; morning reports; inspection reports; investigation reports; accident sequence precursor program reports; major studies; allegation reports; component failure reports; 10 CFR Part 21, "Reporting of Defects and Noncompliance," reports; industry reports; and reports of operational events at foreign facilities. (3)

Guidance for identifying GIs from operational safety data reviews is contained in Management Directive (MD) 8.5, "Operational Safety Data Review." (4)

Individuals and organizational units within NRC, industry groups, or the public who wish to nominate a GI for review should submit an e-mail (GIP@nrc.gov or Candidate-GIs@nrc.gov), a memorandum, or a letter to the GIP Manager in RES, as described in Appendix A, "Candidate Generic Issue Submittal Process." Any significant, plausible candidate issue should be submitted for screening. (5)

- Candidate GIs are submitted using the guidance provided in Appendix A to the GIP Manager in RES, who shall forward them to either the Reactor Generic Issue Review Panel or the Materials Generic Issue Review Panel, as appropriate. For candidate GIs that involve both program areas, the GIP Manager shall consult with the program offices to establish a combined review panel including representatives of the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), and RES. For security-related candidate GIs, NSIR participation is required. (a)

Identification: Stage 1 (A) (continued)

- Candidate GIs may be related to previous GIs that have either been excluded or closed. This situation could occur if significant new information that may affect their status becomes available. (b)

- The issues identified as Unresolved Safety Issues (USIs) or any staff concerns identified as part of the Differing Professional Opinion program may also be addressed under the GIP. (c)

Initial Screening: Stage 2 (B)

During initial screening, the appropriate Generic Issue Review Panel assesses whether the candidate GI should be processed in the GIP, should be excluded from further analyses, or should be sent to another NRC program for review. Also, the scope of the candidate GI (and thus the GI) is defined at this stage. (1)

Initial screening is complete after the appropriate Generic Issue Review Panel reviews the information submitted in accordance with Appendix A, including any other supporting documentation, as well as any staff-generated screening analysis of the candidate issue, and submits its findings and recommendations to the Director of RES for reactor issues or to the Director of NMSS for materials issues. (2)

This stage should be completed within 90 days, if practicable, upon receipt by the GIP Manager in RES of information describing the candidate GI (Appendix A). The staff shall provide the panel with a risk-informed preliminary evaluation of the issue, if practicable, using the methods described in NUREG-0933 and NUREG-1489. (Not all issues may lend themselves to such an evaluation.) Additional information (e.g., nonduplication review, overlap with the scope of other GIs, historical background) should also be provided, if applicable and not already submitted in accordance with Appendix A.

Initial Screening: Stage 2 (B) (continued)

This completion period may be extended if it is determined by the GIP Manager in RES or during a preview meeting by the applicable Generic Issue Review Panel and approved by the applicable office director that additional data-gathering is necessary before beginning or completing Stage 2. (3)

- The appropriate office director (or designee) assigns a Responsible Project Manager (RPM) to coordinate the initial screening of the GI. The RPM should be chosen on the basis of the technical attributes of the GI (i.e., adequate protection, substantial safety enhancement, or reduction in unnecessary regulatory burden). (a)

- Generic Issue Review Panel meetings should be held only if a "quorum" of experts is available to address the candidate GI. The panel chairman shall make this decision, using guidance provided by office management. (b)

- The Reactor or the Materials Generic Issue Review Panel reviews and, if necessary, revises the scope proposed by the submitter with assistance from the submitter. If the submitter is outside NRC, this review should take place in a public meeting. The Reactor or the Materials Generic Issue Review Panel should make its assessment based on information readily available or easily obtained with minimal resources. (c)

  – For reactor candidate GIs, risk and cost benefit thresholds are provided in Appendix C, "Criteria and Guidance for Technical Assessment of Candidate Reactor Generic Issues." During initial screening (Stage 2), the Reactor Generic Issue Review Panel should, to the extent practicable, use Appendix C in a comparative manner to determine whether the issue should be excluded from further analyses, or continue on to Stage 3, technical assessment, in which a quantitative analysis would be performed. (i)

Initial Screening: Stage 2 (B) (continued)

– For materials candidate GIs, the initial screening stage may be folded into the technical assessment stage. Appendix F, "Criteria and Guidance for Technical Assessment of Candidate Materials Generic Issues," provides guidance on the conduct of panel meetings. (ii)

– Figure 1, "Candidate Generic Issue Screening Process," and Appendix G provide the questions that must be addressed during the GI classification process, primarily in Stages 2 and 3 of the GIP. (iii)

- The Reactor or the Materials Generic Issue Review Panel shall perform initial screenings of candidate GIs with assistance from the submitter, if appropriate. If the submitter is an individual or organization outside NRC, this screening should take place in a public meeting. (d)

- On the basis of established risk thresholds or engineering judgment, the Reactor or the Materials Generic Issue Review Panel assesses whether the candidate GI has the potential to be classified as either an adequate protection, a substantial safety enhancement, or a reduction in unnecessary regulatory burden issue. (The actual classification into one of these categories will be made at the technical assessment stage.) The Reactor or the Materials Generic Issue Review Panel should make its assessment on the basis of information readily available or easily obtained with reasonable resources. (e)

- For a candidate GI, either the Reactor or the Materials Generic Issue Review Panel, as appropriate, should issue an initial screening memorandum consisting of a forwarding note with attached findings and recommended actions. In some instances, the appropriate Generic Issue Review Panel may recommend that the screening and assessment stages for reduction in unnecessary regulatory burden issues be modified, or performed at a lower level of effort.

Initial Screening: Stage 2 (B) (continued)

The panel shall document its recommendation in its initial screening memorandum. As a minimum, the initial screening memorandum is to include a clear, concise description of the GI, its safety significance, and Appendix A information prepared by the submitter. The panel shall send the GI memoranda to the Director of RES (for reactor issues) or to the Director of NMSS (for materials issues), as appropriate, through the GIP Manager in RES for concurrence. A copy will be sent to the Director of NSIR. (f)

- The responsible office director (RES for reactor GIs or NMSS for materials GIs) shall inform the submitter of the candidate GI of the Generic Issue Review Panel findings and recommendations by separate memorandum for internal submitters, and by letter for external submitters. The appropriate Generic Issue Review Panel originates this memorandum or letter. Copies of the memorandum or letter should be sent to the GIP Manager in RES, the ACRS, the ACNW, the Committee To Review Generic Requirements (CRGR), or the ACMUI, as appropriate. (g)

- The RPM produces the Quarterly Generic Issue Status Report in accordance with Appendix E, “Quarterly Generic Issue Status Report,” for the assigned GI. (h)

- The RPM submits the Quarterly Generic Issue Status Report to the appropriate office director (or designee) through the GIP Manager in RES for review and approval. (i)

- The GIP Manager in RES shall use the Quarterly Generic Issue Status Reports to prepare Combined Quarterly Generic Issue Status Reports summarizing the status and activities related to open GIs and candidate GIs and update the GIMCS. (j)

Technical Assessment: Stage 3 (C)

In the technical assessment stage, the appointed staff (a) perform additional review of those GIs that may represent an adequate protection issue, a substantial safety enhancement issue, or a reduction in unnecessary regulatory burden issue; (b) determine if these should be designated as unresolved safety issues (USIs); and (c) identify a cost-effective solution to the GI. (1)

Technical assessment also provides technical justification for excluding from further analyses a GI that has little safety significance, would not result in a substantial safety enhancement, is not cost justifiable, or is a necessary regulatory burden. (2)

Guidance for performing a technical assessment of a reactor GI is provided in Appendix B, “Unresolved Safety Issue Assessment Criteria,” and Appendix C. Guidance for performing a technical assessment of a materials GI would use more qualitative methods, expert elicitation, and judgment as outlined in Appendix F. Additional guidance for performing a technical assessment can be found in "References," Section (6.4-06), of the directive. (3)

Figure 1 and Appendix G provide the questions that must be addressed during the GI classification process, primarily in Stages 2 and 3 of the GIP. (4)

Technical assessment is an “indepth” study of a GI (e.g., an adequate protection issue, a substantial safety enhancement issue, a reduction in unnecessary regulatory burden issue) and may involve contractor support. To form a technical basis for taking or not taking regulatory action, the technical assessment stage may include the following: (5)

- expert elicitation
- a review of operational data and events
- a review of related generic communications and GIs
- model development, experiments, and tests
- system and computational analyses
- field studies and inspections

Technical Assessment: Stage 3 (C) (continued)

- probabilistic risk assessments
- integrated safety assessments
- a detailed regulatory analysis
- corrective action development, including recommendations

The extent of these activities varies in accordance with the scope, complexity, or significance of the GI and the depth of information available on a given GI. (6)

The activities performed during this stage should be documented in technical letter reports, NUREG reports, or NUREG/CR reports. (7)

With input from other offices and regions, completion schedules for technical assessments for specific GIs should be established by RES (for reactor GIs) or NMSS (for materials GIs) on the basis of work prioritization schemes of the assigned office. (8)

The target completion date for the technical assessment stage will be determined by office management in the course of approving the Task Action Plan (TAP) for this stage (see Appendix D, “Generic Issue Task Action Plan”). The implementation of this plan will be given a priority consistent with the generic issue’s safety significance, other work efforts, and budget constraints of the implementing office. This priority assignment should be the prerogative of the NRC office responsible for the technical assessment. (9)

- The appropriate office director (or designee) assigns an RPM to coordinate the technical assessment. (a)

- The appropriate office director (or designee) assigns staff to perform the technical assessment. If the proposed staff come from different offices, arrangements between offices will have to be made to obtain needed expertise. The technical assessment staff should be chosen and approved on the basis of the scope of the GI. (b)

Technical Assessment: Stage 3 (C) (continued)

- The RPM contacts the supervisors of staff members assigned to perform the technical assessment and, as required, initiates contractual action (if technical expertise is not available internally) to procure the technical assistance needed to perform the technical assessment. (c)

- The RPM for the technical assessment prepares and maintains a TAP in accordance with Appendix D for the activities needed to complete the technical assessment. (d)

- The RPM provides a copy of the approved GI TAP (including any revisions) and status reports to the submitter of the issue. If these documents contain predecisional or proprietary information, the Office of the General Counsel shall determine what information can be released to a non-NRC submitter. Any safeguards or classified information should be appropriately handled in accordance with the guidance provided in MD 12.2, "NRC Classified Information Security Program," and MD 12.6, "NRC Sensitive Unclassified Information Security Program." (e)

- Either RES (for reactor issues) or NMSS (for materials issues), as appropriate, conducts or oversees the technical evaluation of the GI, verifies the legitimacy of the concern expressed, verifies that the benefits sought will be obtained, establishes the technical basis for new or revised regulations or guidance, and identifies solutions that are likely to result in substantial net facility safety improvements or reduction in regulatory burden without significant decrease in safety. (f)

- The RPM for the technical assessment of the GI submits the TAP and any substantive revisions to the appropriate office director (or designee) through the GIP Manager in RES for review and approval. (g)

Technical Assessment: Stage 3 (C) (continued)

- The RPM produces the Quarterly Generic Issue Status Report for the assigned GI in accordance with Appendix E. (h)

- The RPM submits the Quarterly Generic Issue Status Report to the appropriate office director (or designee) through the GIP Manager in RES for review and approval. (i)

- The GIP Manager in RES shall use the Quarterly Generic Issue Status Reports to prepare Combined Quarterly Generic Issue Status Reports summarizing the status and activities related to open GIs and candidate GIs and shall update the GIMCS. (j)

- After the GI technical assessment has been completed, the RPM informs the Director of RES (for reactor issues) or the Director of NMSS (for materials issues) through the GIP Manager in RES by memorandum of the findings and requests appropriate actions. (k)

- Technical assessment is complete when the RPM informs— (l)

  – either the Director of NRR (for reactor issues), through the GIP Manager in RES and the Director of RES, indicating whether (1) the issue should be excluded from further consideration, (2) new or revised rules or guidance are needed, and/or (3) new or revised NRC programs are needed, or (i)

  – the Director of NMSS (for materials issues), through the GIP Manager in RES and the Director of RES, indicating whether (1) the issue should be excluded from further analyses, (2) new or revised rules or guidance are needed, and/or (3) new or revised NRC programs are needed. (ii)

- After the technical assessment of the GI has been completed, the RPM informs the ACRS, the ACNW, or the ACMUI, as

Technical Assessment: Stage 3 (C) (continued)

appropriate, through the GIP Manager in RES by memorandum of the findings and requests the committee's comments on the assessment. (m)

Regulation and Guidance Development: Stage 4 (D)

Regulation and guidance development involves an indepth review of potential facility or program changes to address the GI (e.g., an adequate protection issue, a substantial safety enhancement issue, a reduction in unnecessary regulatory burden issue) and selection of needed regulatory actions. Technical findings obtained during the technical assessment stage are used, as necessary, as a basis for developing or revising rules, guidance, and programs. Products to be produced during the regulation and guidance development stage could include draft rules, regulatory guides, bulletins, generic letters, information notices, new or revised inspection procedures, and the CRGR briefing packages. (1)

Typically, NRC rules and guidance are contained in Title 10 of the *Code of Federal Regulations*, standard review plans, regulatory guides, and, to some extent, bulletins, generic letters, information notices, and regulatory issue summaries, as well as pertinent office staff guidance. (2)

The development of rules, guidance, or programs can take from several months to a few years, depending on the length of time required by the deliberations involved. If rulemaking is a potential option to address the GI, coordination between this directive and MD 6.3, "The Rulemaking Process," is required. The GI TAP, in accordance with this directive, and the rulemaking plan, in accordance with MD 6.3, should be coordinated to reduce duplication of effort. (3)

- The appropriate office director (or designee) assigns an RPM for the regulation and guidance development stage to coordinate activities (both inside and outside NRC) to develop

Regulation and Guidance Development: Stage 4 (D) (continued)

new or revised rules, guidance, or programs to address the GI. (a)

- The appropriate office director (or designee) assigns staff to perform the regulation and guidance development stage. If the proposed staff come from different offices, arrangements between offices should be made to obtain needed expertise. The regulation and guidance development staff should be chosen and approved on the basis of the scope of the GI. (b)

- The RPM contacts the supervisors of staff members assigned to perform the regulation and guidance development review to request their assistance. (c)

- The RPM prepares and maintains a TAP in accordance with Appendix D for activities needed to complete regulation and guidance development. (d)

- The RPM submits the TAP for regulation and guidance development, including any substantive revisions, to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (e)

- As needed, NRR develops or revises regulations, guidance, or programs and, with support from RES as appropriate, performs regulatory and backfit analysis for the reactor GI based on the technical basis established during the technical assessment stage. (f)

- As needed, NMSS develops or revises regulations, guidance, or programs and develops regulatory analysis for the materials GI based on the technical basis established during the technical assessment stage. (g)

- If there is a standards-setting issue (e.g., when a rulemaking or guidance document is being considered), the staff shall

Regulation and Guidance Development: Stage 4 (D) (continued)

coordinate with the designated NRC Standards Executive in RES. (h)

- After draft rules or guidance has been prepared or revised, the RPM briefs the CRGR, if appropriate, and informs the appropriate advisory committee(s) (i.e., the ACRS, the ACNW, or the ACMUI) by memorandum of corrective actions to address the GI. (i)

- Draft regulation, guidance, or program changes shall be sent for office and regional review. Comments will be addressed, and final corrective actions will be developed for implementation by licensees and certificate holders, as appropriate. In addition, if a new rule or a rule change is specified as part of the corrective action, it must be issued for public comment with an appropriate *Federal Register* notice. (j)

- The RPM for the regulation and guidance development stage prepares the Quarterly Generic Issue Status Report in accordance with Appendix E. (k)

- The RPM submits the Quarterly Generic Issue Status Report to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (l)

- The GIP Manager in RES shall use the Quarterly Generic Issue Status Reports to prepare Combined Quarterly Generic Issue Status Reports summarizing the status and activities related to open GIs and candidate GIs and update the GIMCS. (m)

- The RPM shall send copies of approved correspondence between the RPM and the appropriate office director to the GIP Manager in RES, members of the appropriate Generic Issue Review Panel, and the submitter. (n)

Regulation and Guidance Development: Stage 4 (D) (continued)

- Regulation and guidance development is complete when the RPM informs either— (o)

  – the Director of NRR (for reactor issues), through the GIP Manager in RES, with a copy to the Director of NMSS and the Director of NSIR, indicating whether (1) the GI should be excluded from further consideration or (2) new or revised regulations, guidance, or programs have been developed to address the GI, or (i)

  – the Director of NMSS (for materials issues), through the GIP Manager in RES, with a copy to the Director of NRR and the Director of NSIR, indicating whether (1) the GI should be excluded from further consideration or (2) new or revised regulations, guidance, or programs have been developed to address the GI. (ii)

Regulation and Guidance Issuance: Stage 5 (E)

The appointed staff shall issue documents clearly describing the facility or program changes developed during the regulation and guidance development stage to address the GI in a timely and effective manner. New or revised regulations may require the review and approval of the Commission except in limited circumstances when the EDO is authorized to conduct rulemaking in accordance with MD 6.3, "The Rulemaking Process." Basic guidance documents necessary for regulation and guidance issuance are contained in "References," Section (6.4-06), of the directive.

- The appropriate office director or designee (NRR for reactor GIs and NMSS for materials GIs) assigns an RPM for the regulation and guidance issuance stage to coordinate the activities (both inside and outside NRC) needed to issue new or revised rules, guidance, or programs to address the GI. (1)

Regulation and Guidance Issuance: Stage 5 (E) (continued)

- The RPM prepares and maintains a TAP in accordance with Appendix D for activities needed to complete the regulation and guidance issuance stage. (2)

- The RPM submits the TAP for the regulation and guidance issuance stage, including any substantive revisions, to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval, with a copy to the Director of NSIR. (3)

- The RPM for the regulation and guidance issuance stage prepares the Quarterly Generic Issue Status Report in accordance with Appendix E. (4)

- The RPM submits the Quarterly Generic Issue Status Report to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (5)

- The GIP Manager in RES shall use the Quarterly Generic Issue Status Reports to prepare Combined Quarterly Generic Issue Status Reports summarizing the status and activities related to open GIs and candidate GIs and to update the GIMCS. (6)

- The RPM shall send copies of his or her correspondence with the appropriate office director to the GIP Manager in RES, members of the appropriate Generic Issue Review Panel, and the submitter. (7)

- Regulation and guidance issuance is complete when the RPM informs either— (8)

  – the Director of NRR (for reactor issues), with a copy to the Director of NMSS and the Director of NSIR, through the GIP Manager in RES, whether (1) the issue should be excluded from further consideration or (2) new or revised

Regulation and Guidance Issuance: Stage 5 (E) (continued)

regulations, guidance, or programs have been issued to address the GI, or (a)

– the Director of NMSS (for materials issues), with a copy to the Director of NRR and the Director of NSIR, through the GIP Manager in RES, whether (1) the issue should be excluded from further consideration or (2) new or revised regulations, guidance, or programs have been issued to address the GI. (b)

Implementation: Stage 6 (F)

The objective of the implementation stage is to determine whether the licensee, the certificate holder, or other entity regulated by or subject to the regulatory jurisdiction of NRC has established and is implementing a program to ensure that facility or program changes made to address a GI (e.g., an adequate protection issue, a substantial safety enhancement issue, a reduction in unnecessary regulatory burden issue) are effective and in accordance with commitments. (1)

The implementation stage occurs when the affected licensee, certificate holder, or other entity performs the actions necessary to implement the regulatory action to close the GI. These may include modifications or additions to— (2)

- the systems, structures, components, or design of a facility; (a)
- the design approval or manufacturing license for a facility; or (b)
- the technical specifications, procedures, programs, or organization required to design, construct, or operate a facility. (c)

Implementation: Stage 6 (F) (continued)

Facility backfitting pursuant to 10 CFR 50.109, 70.76, 72.62 or 76.76 is covered by MD 8.4, "Management of Facility-specific Backfitting and Information Collection." (3)

In the implementation stage, the following activities take place: (4)

- The appropriate office director (or designee) assigns an RPM for the implementation stage to coordinate the activities (both inside and outside NRC) needed to address GI changes, including but not limited to the facility or program changes. (a)

- The RPM prepares and maintains a TAP in accordance with Appendix D for activities needed to complete the implementation stage. (b)

- The RPM submits the TAP for the implementation stage, including any substantive revisions, to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (c)

- The RPM should contact the supervisors of the staff members assigned to review implementation of facility or program changes. Facility or program changes may involve interactions with industry groups, licensees, certificate holders, and/or NRC. (d)

- As required by NRC, each licensee, certificate holder, or other entity shall establish a program, or ensure the effectiveness of its current program, to assess specific vulnerabilities to the GI. From this review, a facility or program change plan will be developed. For issues regarding reduction in unnecessary regulatory burden, licensees, certificate holders, or other entities implementing the relaxation of requirements shall notify NRC of their plans for implementation. The licensee, certificate holder, or other entity shall notify NRC by letter of changes in the plan for implementation of actions responding to the GI

Implementation: Stage 6 (F) (continued)

(e.g., in accordance with 10 CFR 50.54(f) for production and utilization facilities; appropriate mechanisms may be used for the materials licensees). (e)

- As required by NRC, each licensee, certificate holder, or other entity shall inform the appropriate NRC program office by letter regarding proposed changes to programs, processes, or equipment, including schedules for implementation. The licensee, certificate holder, or other entity shall notify NRC of any substantive changes in the proposed or actual implementation schedule (e.g., in accordance with 10 CFR 50.54(f) for reactor issues; appropriate mechanisms may be used for the materials licensees). (f)

- The RPM for the implementation stage prepares the Quarterly Generic Issue Status Report in accordance with Appendix E. (g)

- The RPM submits the Quarterly Generic Issue Status Report to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (h)

- The GIP Manager in RES shall use the Quarterly Generic Issue Status Reports to prepare Combined Quarterly Generic Issue Status Reports summarizing the status and activities related to open GIs and candidate GIs and update the GIMCS. (i)

- The RPM shall send copies of his or her correspondence with the appropriate office director to the GIP Manager in RES, members of the appropriate Generic Issue Review Panel, and the submitter. (j)

- The implementation stage is complete for an affected licensee, certificate holder, or other entity once it has formally informed

Implementation: Stage 6 (F) (continued)

the appropriate NRC program office that facility or program changes have been implemented. (k)

- The GIP Manager in RES shall monitor the implementation of GI facility or program changes by the licensee, the certificate holder, or other entity as reported by the RPM and shall include this information in updates to the GIMCS. (l)

Verification: Stage 7 (G)

In the verification stage, the appointed staff determines whether licensees, certificate holders, or other entities have adequately demonstrated the efficacy of facility or program changes in addressing the GI (e.g., an adequate protection issue, a substantial safety enhancement issue, a reduction in unnecessary regulatory burden issue). (1)

The verification stage involves auditing and inspection of individual licensees and certificate holders to verify that effective actions have been implemented. Depending on the number of affected licensees, certificate holders, or other entities, the risk significance of the GI, and the complexity of the corrective actions, it may not be necessary to perform a 100-percent inspection of facility or program changes made in order to declare a GI closed. (2)

- The appropriate office director (or designee) assigns an RPM for the verification stage to coordinate the activities (both inside and outside NRC) needed to verify implementation actions responding to the GI. (a)

- The RPM prepares and maintains a TAP in accordance with Appendix D for activities needed to complete the verification stage for the GI. (b)

- The RPM submits the TAP for the verification stage, including any substantive revisions, to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (c)

Verification: Stage 7 (G) (continued)

- As required by NRC, each licensee, certificate holder, or other entity shall inform NRC by letter upon completion of facility or program changes (e.g., in accordance with 10 CFR 50.54(f) for production and utilization facilities; appropriate mechanisms may be used for the materials licensees). Forwarded information shall include the results of analysis, studies, and tests. (d)

- As required by NRC, a licensee, certificate holder, or other entity shall document changes made to structures, systems, components, processes, and programs to address the GI and provide them to NRC by letter (e.g., in accordance with 10 CFR 50.54(f) for reactor issues; appropriate mechanisms may be used for the materials licensees). This information shall be made available to NRC for review, audit, and inspection to verify that appropriate actions have been completed. (e)

- Verification inspections at facilities or offices of the licensee, certificate holder, or other entity should generally be performed by the regions, with assistance from headquarters staff, as appropriate. Because of the technical nature of some GIs, it may be appropriate to also use expert contractors or staff members. (f)

- Verification inspections should be performed, as appropriate, through temporary instructions to verify implementation of GI actions. (g)

- If appropriate, and commensurate with the GI, the inspector will verify and document, in an inspection report, that the licensee, certificate holder, or other entity has established plans for periodic verification of the continued effectiveness of the actions in resolving the GI. (h)

- If appropriate, and commensurate with the GI, NRC region or headquarters staff will make recommendations for any

Verification: Stage 7 (G) (continued)

continuing or routine inspections to be added to the NRC inspection program. (i)

- If inspection report findings indicate that adequate actions related to the GI have not been implemented, NRC will use its enforcement tools. For example, NRC may issue an order to the affected licensee, certificate holder, or other entity. Such an order will require that the affected licensee, certificate holder, or other entity repeat the implementation stage activities. In addition, NRC will reinspect the affected facility for compliance. (j)

- The RPM shall provide the verification inspection reports to the appropriate Generic Issue Review Panel, the GIP Manager in RES, and the submitter. (k)

- The RPM for the verification stage prepares the Quarterly Generic Issue Status Report in accordance with Appendix E. (l)

- The RPM submits the Quarterly Generic Issue Status Report to either the Director of NRR (for reactor GIs) or the Director of NMSS (for materials GIs) through the GIP Manager in RES for review and approval. (m)

- The GIP Manager in RES shall use the Quarterly Generic Issue Status Reports to prepare Combined Quarterly Generic Issue Status Reports summarizing the status and activities related to open GIs and candidate GIs and update the GIMCS. (n)

- The RPM shall send copies of his or her correspondence with the appropriate office director to the GIP Manager in RES, members of the appropriate Generic Issue Review Panel, and the submitter. (o)

Verification: Stage 7 (G) (continued)

- The verification stage is complete for an affected licensee or certificate holder once the final inspection report has been issued, and the appropriate NRC program office determines that facility or program changes are adequate. The RPM shall provide documentation giving the basis for declaring the verification stage complete for a specific licensee, certificate holder, or other entity to the GIP Manager in RES for review. (p)

Closure: Stage 8 (H)

Closure can begin when the verification stage is complete for all affected licensees, certificate holders, or other entities once—

- All final verification inspection reports have been issued. (a)

- The appropriate NRC program office has determined that actions have been implemented and are adequate to classify the GI as closed. (b)

- The RPM has prepared a memorandum to the Executive Director for Operations, through the GIP Manager in RES and the Director of RES, indicating the basis for declaring the GI closed. (c)

Table 1
Overview of Generic Issues Program for Stages 1–3; Identification and Assessment

GIP STAGE	INPUT	OUTPUT OPTIONS	TRACKING DOCUMENTATION	TECHNICAL AND REGULATORY DOCUMENTATION
(1) Identification	- Appendix A information - Advisory committees - Inspection reports - Event reports - Investigation reports - Industry concerns - Public concerns - Staff concerns - Background information	- Submit candidate issue to GIP Manager in RES - RPM to develop the initial screening analysis - Form a Generic Issue Review Panel - Forward to Stage 2	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Combined Quarterly Generic Issue Status Summary Report (RES) - GIMCS update (RES)	None required
(2) Initial Screening	- Stage 1 information	- Screening results (panel) - Exclude from further analyses (panel) - Forward to Stage 3 (panel) - Forward to another NRC program for review (panel) (90-day completion period)	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Combined Quarterly Generic Issue Status Summary Report (RES) - GIMCS update (RES)	- Reactor or Materials Generic Issue Panel initial screening memoranda providing results and recommendations (panel)
(3) Technical Assessment	- Stage 2 information	- GI classification (RES/NMSS) - Obtain consensus on the date the assessment is to be completed - Exclude from further analyses (RES/NMSS) - Technical basis for regulatory actions (RES/NMSS) - Corrective action recommendations (RES/NMSS) - Unresolved safety issue determination (RES/NMSS)	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Combined Quarterly Generic Issue Status Summary Report (RES) - Task Action Plan (RPM) - GIMCS update (RES)	- Technical assessment memoranda providing result and recommendations to either NRR or NMSS (RPM) - Technical letter reports (RES/NMSS) - NUREGs (RES/NMSS) - NUREG/CRs (RES/NMSS) - Research information letters (RES)

Abbreviations

GI	-	Generic Issue
GIMCS	-	Generic Issue Management Control System
GIP	-	Generic Issues Program
NMSS	-	Office of Nuclear Material Safety and Safeguards
RES	-	Office of Nuclear Regulatory Research
RPM	-	Responsible Project Manager

Table 2
Overview of Generic Issues Program for Stages 4–7; Facility or Program Change and Verification

GIP STAGE	INPUT	OUTPUT OPTIONS	TRACKING DOCUMENTATION	TECHNICAL AND REGULATORY DOCUMENTATION
(4) Regulation and Guidance Development	- Stage 3 information - CRGR review - ACRS, ACNW, ACMUI feedback - Peer review of draft rules or guidance	- Regulation, guidance, and program changes or additions (NRR/NMSS) - Forward to Stage 5 - Exclude from further analyses (NRR/NMSS) - Regulatory analysis (NRR/NMSS)	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Combined Quarterly Generic Issue Status Summary Report (RES) - Task Action Plan (RPM) - GIMCS update (RES)	- Regulation and guidance development memoranda providing results and recommendations to either NRR or NMSS for review and approval (RPM) - Draft new/revised rules, standard review plans, regulatory guides, bulletins, generic letters, inspection programs, temporary instructions (NRR/NMSS)
(5) Regulation and Guidance Issuance	- Stage 4 information	- Issuance of new/revised regulation, guidance, and program changes or additions (NRR/NMSS) - Forward to Stage 6 - Exclude from further analyses (NRR/NMSS)	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Combined Quarterly Generic Issue Status Summary Report (RES) - Task Action Plan (RPM) - GIMCS update (RES)	- Regulation and guidance issuance memoranda providing results and recommendations to either NRR or NMSS (RPM) - New/revised rules, standard review plans, bulletins, generic letters, inspection programs, temporary instructions (NRR/NMSS)

Table 2 (continued)

GIP STAGE	INPUT	OUTPUT OPTIONS	TRACKING DOCUMENTATION	TECHNICAL AND REGULATORY DOCUMENTATION
(6) Implementation	- Stage 5 information - Licensee/ certificate holder response to NRC correspon-dence - Licensee/ certificate holder voluntary responses	- Monitor licensee/ certificate holders for compliance (NRR/NMSS/ region) - Forward to Stage 7	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Quarterly Generic Issue Status Summary Report (RES) - Task Action Plan (RPM) - GIMCS update (RES)	- Implementation memoranda providing results and recommenda-tions to either NRR or NMSS (RPM)
(7) Verification	- Stage 6 information - Inspection reports (licensees/ region) - Audit reports (licensees/ region) - Licensee/ certificate holder closure documentation (NRR/NMSS/ region) - Licensee plans for verification of effectiveness of GI resolution (licensee)	- Verification inspections (region) - Assess need for routine inspections (NRR/NMSS)	- Quarterly Generic Issue Status Report to GIP Manager in RES (RPM) - Combined Quarterly Generic Issue Status Summary Report (RES) - Verification inspection reports provided to either NRR or NMSS for review and approval before issuance (region) - Task Action Plan (RPM) - GIMCS update (RES)	- Verification memoranda providing results and recommenda-tions to either NRR or NMSS for specific licensees or certificate holders (RPM) - Verification memoranda to EDO through the GIP Manager and RES declaring the GI as closed for all affected licensees or certificate holders (RPM)

Abbreviations

ACMUI - Advisory Committee on the Medical Uses of Isotopes
ACNW - Advisory Committee on Nuclear Waste
ACRS - Advisory Committee on Reactor Safeguards
CRGR - Committee To Review Generic Requirements
EDO - Executive Director for Operations
GI - Generic Issue
GIMCS - Generic Issue Management Control System
GIP - Generic Issues Program
NMSS - Office of Nuclear Material Safety and Safeguards
NRR - Office of Nuclear Reactor Regulation
RES - Office of Nuclear Regulatory Research
RPM - Responsible Project Manager

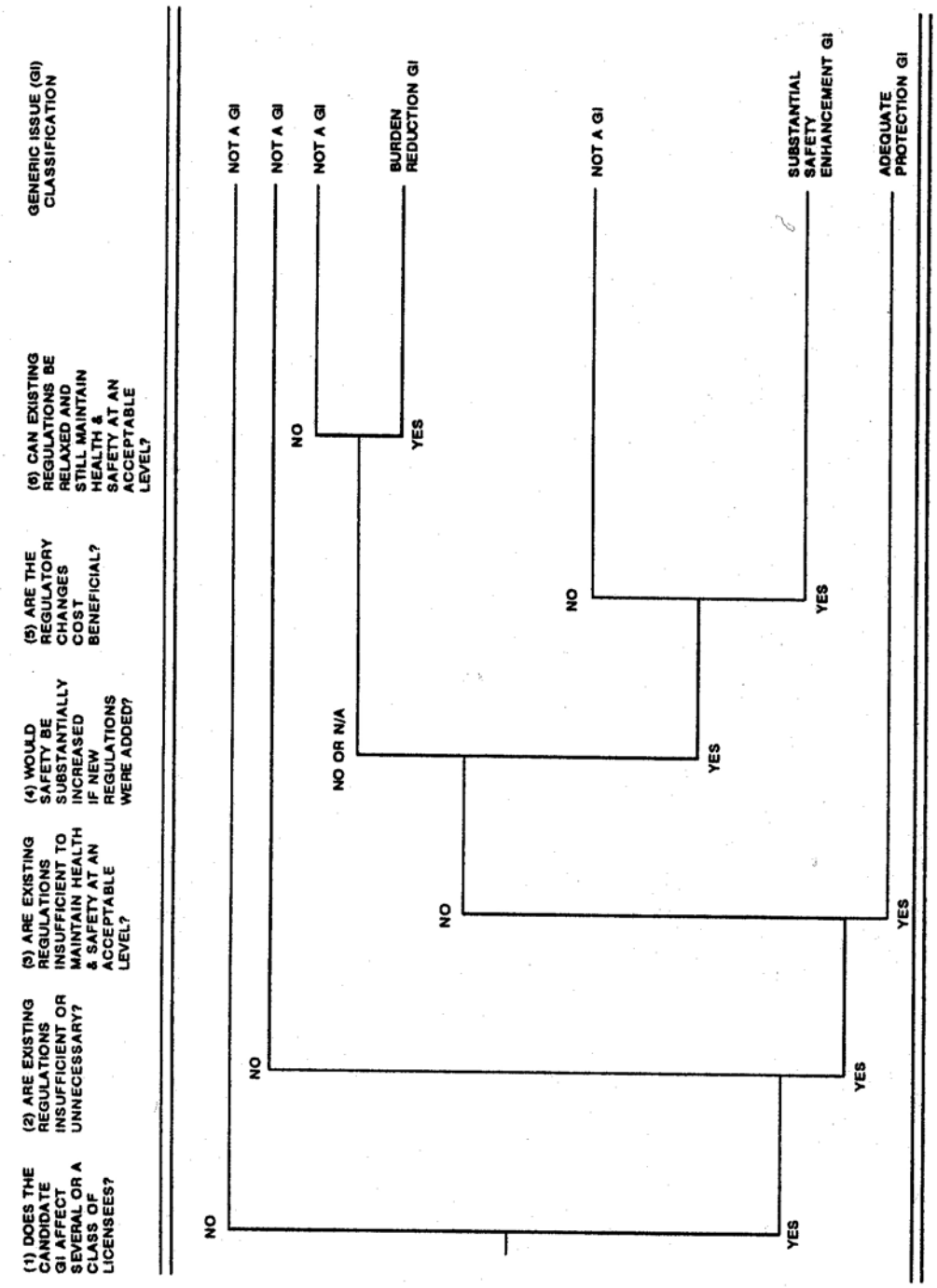


Figure 1

Candidate Generic Issue Screening Process

Glossary

Adequate Protection Issues. Questions and concerns about the adequacy of existing NRC requirements and guidance for providing reasonable assurance of adequate protection to public health and safety.

Candidate generic issue. A proposed generic issue that has not had its initial screening and classification by the Reactor Generic Issue Review Panel or the Materials Generic Issue Review Panel.

Closed. Refers to candidate generic issues or generic issues that have either been excluded (see definition) from further consideration, or where corrective actions have been effectively implemented and verified.

Differing Professional Opinion (DPO). A differing professional opinion (DPO) is raised by the NRC staff. A difference of opinion, developed in the free and open discussion of technical, legal, or policy issues, becomes a DPO when the employee submits a formal concern in accordance with the guidance and procedures presented in Management Directive 10.159.

Excluded. Status assigned to generic issues that are closed because they (1) do not warrant expenditure of NRC resources, (2) do not warrant regulatory actions, or (3) are not cost beneficial.

Generic. When a regulatory matter is applicable to two or more nuclear power reactors or materials facilities.

Generic Issue (GI). A regulatory matter involving the design, construction, operation, or decommissioning of several, or a class of, NRC licensees, certificate holders, or holders of other regulatory approvals (e.g., design certification rules) that is not sufficiently addressed by existing rules, guidance, or programs. A generic issue may be an adequate protection issue, a substantial safety enhancement issue, or a reduction in unnecessary regulatory burden issue.

Glossary (continued)

Generic Issues Program Manager (GIP Manager). Person responsible for the overall management of the Generic Issues Program. The Generic Issues Program Manager is a member of the Office of Nuclear Regulatory Research.

Materials Generic Issue. A regulatory matter that is applicable to several, or a class of, materials licensees or certificate holders.

Materials Generic Issue Review Panel. An interoffice board that reviews candidate materials generic issues.

Open. Status assigned to candidate generic issues or generic issues that have not been excluded from further consideration or closed.

Reactor Generic Issue. A regulatory matter that is applicable to several, or a class of, nuclear reactors or reactor-related facilities.

Reactor Generic Issue Review Panel. An interoffice board that reviews candidate reactor generic issues.

Reduction in Unnecessary Regulatory Burden Issue. A generic issue that has the effect of reducing regulatory burden of unnecessary requirements on licensees, certificate holders, or entities regulated by or subject to the regulatory jurisdiction of NRC. Its purpose is to remove unnecessary regulatory requirements while maintaining existing levels of protection of public health and safety and common defense and security.

Responsible project manager (RPM). The person assigned to oversee one or more Generic Issues Program stages for a specific generic issue.

Submitter. An individual or organization that submits a candidate reactor or materials generic issue to the Generic Issues Program Manager for review and assessment by NRC.

Glossary (continued)

Substantial Safety Enhancement Issue. A generic issue that primarily results in cost-beneficial safety improvements in excess of those necessary to provide reasonable assurance of adequate protection to public health and safety and common defense and security.

Unresolved Safety Issue (USI). A reactor generic issue that affects a number of nuclear power plants and poses important questions concerning the adequacy of existing safety requirements for which a final resolution has not yet been developed. An unresolved safety issue generally involves conditions that are not likely to be acceptable over the lifetime of the plants affected. Section 210 of the Energy Reorganization Act of 1974 requires NRC to develop a plan for analysis of unresolved safety issues relating to nuclear reactors, to implement corrective measures with respect to such issues, and to include such plans in the annual report to Congress. However, the requirement for an annual report to Congress was later rescinded by the Federal Reports Elimination and Sunset Act, Public Law 104-66, 1995.

Appendix A
Candidate Generic Issue Submittal Process

Candidate generic issues (GIs) (e.g., an adequate protection issue, a substantial safety enhancement issue, a reduction in unnecessary regulatory burden issue) may be identified by organizations or individuals internal or external to NRC, including the NRC staff, the Advisory Committee on Reactor Safeguards (ACRS), the Advisory Committee on Nuclear Waste (ACNW), the Committee To Review Generic Requirements (CRGR), the Advisory Committee on the Medical Uses of Isotopes (ACMUI), licensees, certificate holders, industry groups, or the general public. Candidate GIs may be identified by NRC during routine activities. Sources of candidate GIs include, but are not limited to, NRC staff concerns, public concerns, licensee event reports, morning reports, inspection reports, investigation reports, allegation reports, component failure reports, 10 CFR Part 21 reports, industry reports, and reports of operational events at foreign facilities. Guidance for identifying GIs from operational safety data reviews is contained in Management Directive 8.5, “Operational Safety Data Review.”

A candidate GI is an issue that involves a *possible* safety question (or reduction of unnecessary burden). By submitting a candidate GI, the issue submitter is not necessarily asserting that current regulations, guidance, or agency practices are inadequate; instead, the submitter is asking the Office of Nuclear Regulatory Research (for reactor issues) or the Office of Nuclear Material Safety and Safeguards (for materials issues) to investigate the matter. It is recognized that the submitters of these candidate issues may not have complete supporting information. Indeed, the intent of the initial screening and technical assessment stages is to perform research to fill in the missing information. For example, this research could involve gathering data from licensees, vendors, or the international community; investigating the course of an accident scenario using simulation calculations; or even sponsoring experimental work. Thus, an issue submitter should not feel discouraged if the supporting information for the candidate GI contains gaps. Any serious, plausible candidate issue should be submitted for screening.

Individuals and organizational units within NRC or external stakeholders who wish to nominate a GI for review should submit an e-mail (GIP@nrc.gov or Candidate-GI@nrc.gov), a memorandum, or a letter to the GIP Manager in RES. Submitters are welcome to consult with the GIP staff for advice, examples, and so on, before formal submittal of the candidate issue.

Every candidate GI submitted will go through the screening stage. Only those issues that pass screening will go on to the technical assessment stage, which is where significant agency resources may be expended. Because submitting a candidate GI does not directly request significant agency resources, high-level concurrences are not required. Branch-level memoranda, or even memoranda signed by individual staff members, are acceptable.

The memorandum or letter must include, as a minimum, the following information:

– A proposed descriptive title for the issue.

– A technical description of the proposed issue, including the background and basis for the issue.

– A specific description of how the issue affects safety.

– The submitter's name, organization/company, mailing address, e-mail address, telephone number, and other information sufficient for the GIP staff to contact the submitter.

In support, the submitter may wish to include supplementary information or references to such information. Supplementary information depends on the origin and technical nature of the candidate GI. Although inclusion of such information can significantly speed up the processing of the candidate issue, it is recognized that such information is not always readily available to the issue submitter. Such information could include—

– Operational events or statistical studies of such events.

– The licensees to which the candidate issue applies. This could be an actual list, a product line class, or a definition in terms of a particular design feature.

– Possible solutions or possible agency actions.

– The pertinent regulations and regulatory guidance documents affected by the candidate GI.

– References to any pertinent consensus standards.

– References to any pertinent industry initiatives.

– References to any pertinent research reports, databases, publications, and so on.

In most cases, the GIP staff will remain in contact with the submitting individual or organization to ensure that the submitter's intent is being addressed and for clarification and explanation as the screening process takes place.

Appendix B
Unresolved Safety Issue Assessment Criteria

General

An unresolved safety issue (USI) 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; a USI generally involves conditions that are not likely to be acceptable over the lifetime of the plants affected. In 1977, Congress amended the Energy Reorganization Action of 1974 to include the following:

> "Section 210. The Commission shall develop a plan providing for the specification and analysis of unresolved safety issues relating to nuclear reactors and shall take such actions 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."

The Joint Explanatory Statement of the House-Senate Conference Committee for Bill S.1131 provided the following additional information regarding its deliberations on this portion of the bill:

> "Section 3. The House amendment required development of a plan to resolve generic safety issues. The conferees agreed to a requirement that the plan be submitted to the Congress on .... The conferees also expressed the intent that this plan should identify and describe those safety issues, relating to nuclear power reactors, which are unresolved on the date of enactment. It should set forth: (1) Commission actions taken directly or indirectly to develop and implement corrective measures; (2) future actions planned concerning such measures; and (3) timetables and cost estimates of such actions. The Commission should indicate the priority it has assigned to each issue, and the basis on which priorities have been assigned."

Appendix B (continued)

In order to evaluate safety concerns, recommendations, or general safety issues and determine if these should be designated USIs and reported to Congress as such, the process described below was developed. This process is intended to provide a systematic and consistent approach to evaluating these issues and determining their impact on risk to the public health and safety.

Section 210 of the Energy Reorganization Act of 1974 required NRC to include progress reports regarding unresolved safety issues relating to nuclear reactors in NRC's annual report to Congress. However, the requirement for an annual report to Congress was later rescinded by the Federal Reports Elimination and Sunset Act, Public Law 104-66, 1995.

Technical Assessment Criteria

If the response to any of the criteria listed in Table B1 is "true," the GI is not a USI.

Candidate Unresolved Safety Issues

If all the responses are "false," Tables B-2 through B-6 should be used to evaluate the issue's general impact on various factors affecting safety. To use these tables, the issue should be identified as either a deficiency or an improvement, and it should be identified as related to operations, equipment, or emergency response.

The questions in these tables are intended to evaluate the impact of each candidate USI on the probability of an accident or transient; the probability of losing mitigating functions, given the event; and consequences, given the event and loss of mitigating functions. The overall conclusion is based on the answers to the questions in the following tables regarding the potential to significantly affect the fission product barrier integrity, or the frequency of transients or accidents, safety functions, or emergency response capability. Where possible, quantitative information should be used to answer the questions and arrive at conclusions on potential impact. However, qualitative likelihood estimates can be developed and used to draw conclusions.

Table B1
USI Technical Assessment Criteria

Criteria		True/False	Explanatory Note
1	The issue is not related to nuclear power plant safety.		For example, the transportation of radioactive materials.
2	A staff position on the issue has been developed or is expected to be developed within 6 months.		The purpose of this criterion is to eliminate those issues that are near resolution and, therefore, are not "unresolved" issues. Such issues do not warrant the attention and resources normally associated with a USI.
3	The issue is not generic.		
4	The issue is only indirectly related to nuclear power plant safety.		For example, recommended changes in the licensing process, NRC organization, and so forth.
5	Definition of the issue requires long-term confirmatory or exploratory research.		The basis for this criterion is to eliminate investigative studies of matters for which no clearly defined safety deficiency or improvement has been identified.
6	The issue is related to one already being addressed as a USI and can reasonably be or already is included in the current program.		
7	The issue requires a policy decision rather than a technical solution.		The purpose of this criterion is to eliminate those issues that require a management decision only and do not represent potential deficiencies in existing safety requirements for which a resolution must be developed. In some cases, the results of these policy decisions may require designation of new USIs.
8	The issue is related to safety improvements where existing protection is adequate.		
9	The issue includes programmatic matters involving implementation of issue resolutions already achieved.		
10	The issue includes collections of related issues in lieu of focused critical issues.		In this regard, an attempt should be made to define the issue so that matters extraneous to the issue are eliminated.

Table B2
Possible Major Reduction in Assumed Degree of Protection Related to Equipment Concerns

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

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

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

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

Table B3
Possible Major Reduction in Assumed Degree of Protection Related to Operator Concerns

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

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

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

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

Table B4
Possible Major Reduction in Assumed Degree of Protection Related to Emergency Response Concerns

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

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

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

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

Table B5
Potential Significant Reduction in Risk to the Public Related to Emergency Response Improvement

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

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

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

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

Table B6
Potential Significant Reduction in Risk to the Public Related to Equipment/Operator Improvement

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

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

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

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

Appendix C
Criteria and Guidance for Technical Assessment of Candidate Reactor Generic Issues

General

Technical assessment evaluates the possible safety implication of the generic issue (GI) in a disciplined, quantitative manner, if practicable. This approach is scrutable and provides a better decisionmaking base than a qualitative approach.

Calculations should be kept relatively simple for the process to be cost-effective and timely. To the maximum extent possible, existing analysis and calculations should be used to minimize the resources used during the technical assessment stage.

- The intent of the adequate protection issue calculation is to determine whether modifications to regulatory framework are necessary to ensure adequate protection of public health and safety, or that it is necessary to redefine the level of protection that is needed for adequate protection.

- The intent of the substantial safety enhancement issue calculation is to determine if modifications will result in substantial safety improvements within justifiable costs to the industry and NRC.

- The intent of the reduction in unnecessary regulatory burden issue calculation is to determine if public health and safety and common defense and security would continue to be maintained at the existing level if the proposed relaxation or reduction in unnecessary regulatory requirements or positions were implemented; if the cost savings attributed to the action would be substantial enough to justify taking the action; and whether any increase in risk is acceptable.

Appendix C (continued)

Approach

- Technical assessment may involve estimating both the safety benefit of implementing facility or program changes and the cost of developing and implementing facility or program changes.

- The safety benefit of a reactor GI may be represented by the reduction in risk that the facility or program changes could achieve. Reduction in risk is ordinarily expressed in terms of the change in core damage frequency (CDF), change in large early release frequency (LERF), or the product of the frequency of an accident occurrence and the averted public dose (in person-rem) that would result in the event of the accident.

- The issue is identified and defined. Since issues are often complex and interrelated with other issues, careful definition of an issue's scope and bounds is essential in arriving at a sound and applicable assessment.

- A solution is assumed. This assumed solution is used to estimate costs and changes in risk. The assumed solution is not intended to prejudge the final facility or program changes.

- For adequate protection and substantial safety enhancement issues, a quantitative estimate of both the safety benefit attributable to the issue and the corresponding decrease in risk is made to the extent feasible and technically supportable.

- A quantitative estimate is made of the cost of resolution.

- A numerical impact/value ratio is calculated by dividing the estimated cost entailed by the estimated potential risk reduction. The ratio measures the safety benefit received in return for the cost impact incurred.

Appendix C (continued)

- For reduction in unnecessary regulatory burden issues, the proposed facility or program changes are used to estimate costs and change in risk. For industry-proposed reduction in unnecessary regulatory burden issues, industry estimates of cost savings should be considered. Potential risk increases or decreases with the reduction in regulatory requirements should be estimated.

- Using the appropriate thresholds, a determination is made regarding whether the reactor GI should be —

  – **Excluded from further consideration** – because the issue (1) does not warrant expenditure of NRC resources, (2) does not warrant regulatory actions, or (3) is not cost beneficial, or

  – **Continued** – to the regulation and guidance development stage because of (1) potential risk reduction, (2) associated risk and cost benefits, or (3) acceptable reduction in unnecessary regulatory burden, thus warranting expenditure of NRC resources.

- The flow charts in Figures C1–C3 illustrate the basic approach for conducting a technical assessment for adequate protection issues, substantive safety enhancement issues, and reduction in unnecessary regulatory burden issues.

Probabilistic Risk Assessment Guidance for Technical Assessment

- Select a surrogate probability risk assessment (PRA). The PRA must be relevant to the reactor GI being addressed, reflect the current state of PRA technology, include both internal and external events unless it can be shown that some initiators can be excluded, and include low-power and shutdown conditions unless the issue does not involve these conditions.

Appendix C (continued)

- Some GIs may involve situations or phenomena that were not known when the surrogate PRA was performed, requiring the existing model to be modified. This modification may be as simple as changing a component failure probability, or it may be a significant modification involving the addition of new fault trees and event trees to the model.

- The analyst should be familiar with the surrogate PRA. That is, the analyst should be familiar with the system and component nomenclature used in the PRA, the modeling assumptions and limitations, the calculational tools used, and the truncation level.

- The analyst should make use of up-to-date PRA information, including logic diagrams (such as event sequence diagrams, fault trees, and event trees), CDF-to-risk transformations, data (such as component failure rates), and other risk performance displays, such as dependency matrices, current design, and operational information.

- The analysis should define the class of affected plants as specifically as possible and should make use of surrogate PRAs most closely resembling the class of affected plants.

- Uncertainty analyses and mean values should be calculated whenever practical. Even when formal uncertainty analyses are not possible, sensitivity studies should be performed to determine the impact of key assumptions, uncertainties in the inputs, and other factors. When no data are readily available and the analyst must use engineering judgment, the documentation of the analysis should always explicitly so state and give the rationale for substituting for unavailable information.

- The analysis should be as realistic as is practical. However, some conservatism may be used when bounding calculations can demonstrate that a GI should be excluded from further consideration, or realism is not possible because data are not readily available.

Appendix C (continued)

- The analysis should explicitly ensure that the truncation level of the base PRA is sufficiently low for calculations of differences (e.g., change in CDF) to be meaningful. The issue being evaluated may well call the dropped sequences into consideration. That is, these sequences may no longer be negligible when the effect of the issue being evaluated is included. However, the analyst must recognize that as accident sequences with very low frequencies are considered, concerns as to the completeness and adequacy of the models become much more serious.

- The analysis should receive an independent review by staff knowledgeable in PRA and in the design of the affected systems or components, plus reviews by the individual or group that identified the issue and the group that would be responsible for the regulation and guidance development stage.

- The documentation should not present calculational results with more significant figures than are appropriate. More than one significant figure in the mantissa is not appropriate in most cases. However, it should be noted that if intermediate results are presented, a reader attempting to use these intermediate results in duplicating the calculation may not get exactly the same final results because of the round-off error.

- The analysis should be documented in sufficient detail to enable it to be repeated. In addition, sufficient explanatory materials should be provided to enable the reader to understand the significance of the calculations and to reconcile the various calculations with engineering judgment. The documentation should include the following:

  – a description of the event or issue
  – its relationship to safety
  – the calculational approach
  – a narrative description of the principal accident sequences

Appendix C (continued)

  - the basis for using engineering judgment in lieu of actual data
  - a list of assumptions, including the choice of surrogate PRA, choice of parameters, source of basic data, and any mathematical approximations used

- Additional guidance is provided in the appendices of NUREG-1489, “A Review of NRC Staff Uses of Probabilistic Risk Assessment,” and NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

Cost Estimation Guidance for Technical Assessment

- The values and impacts associated with a solution (i.e., action) should be identified. The values include, but are not limited to, enhancement of health and safety and protection of the environment. The impacts include, but are not limited to, direct costs to the NRC and Agreement States; direct costs to the licensee; and adverse effects on health, safety, and the environment.

- Values and impacts are assigned a monetary value (i.e., dollars) and expressed on a present-worth basis. The latest guidance from the Office of Management and Budget (regarding the discount rate) should be used for discounting future benefits and costs.

- Decisions should be based on the net present value associated with a solution (i.e., action). The net present value is obtained by subtracting the total discounted impacts from the total of discounted values.

- The cost includes both the cost of developing the generic solution (typically NRC cost) and the cost of implementing the possible solution at affected plants (typically industry cost). These costs may include design, equipment, installation, test, operation, and maintenance.

Appendix C (continued)

- NRC costs include issue identification, analysis, resolution, and report issuance; research to establish proposed specific changes to licensing requirements (or to determine that no change is required); technical assistance contracts (including associated NRC effort); discussions and correspondence with industry owners groups; plant reviews; and preparation and review of safety evaluation reports and requirement documents.

- The estimated cost of NRC professional time.

- The costs to industry generally consist of some combination of licensing; design; equipment procurement; installation; testing, inspection, monitoring, and periodic maintenance; and plant downtime to effect a change.

- Industry labor costs.

- Calculations of industry cost savings should assume that affected plants will take advantage of the change. However, the option of whether to take advantage of relaxed or reduced regulatory requirements is not mandatory.

- Sunk costs, realized benefits (i.e., values), and transfer payments should be ignored.

- The estimates should be documented in sufficient detail to enable them to be repeated. In addition, sufficient explanatory materials should be provided to enable the reader to understand the significance of the calculations and to reconcile the various calculations with professional judgment. The documentation should include the following:

  – a description of the issue
  – the calculational approach
  – the basis for using professional judgment in lieu of actual data
  – a list of justified assumptions, including the source of basic data and any mathematical approximations used

Appendix C (continued)

Impact/Value Guidance for Technical Assessment

The technical assessment impact/value calculations are not intended to be applied as impact/value determinations for any regulatory proposal that may ultimately result from efforts to resolve the GI.

To the extent reasonably possible, quantitative estimates of the possible solutions to a substantial safety enhancement issue are made by calculating an impact/value ratio that reflects the relation between the risk reduction value expected to be achieved and the associated cost impact. See Figure C6 for the thresholds for the outcomes "exclude from further consideration" and "continue."

- The formula for the impact/value ratio (R) is:

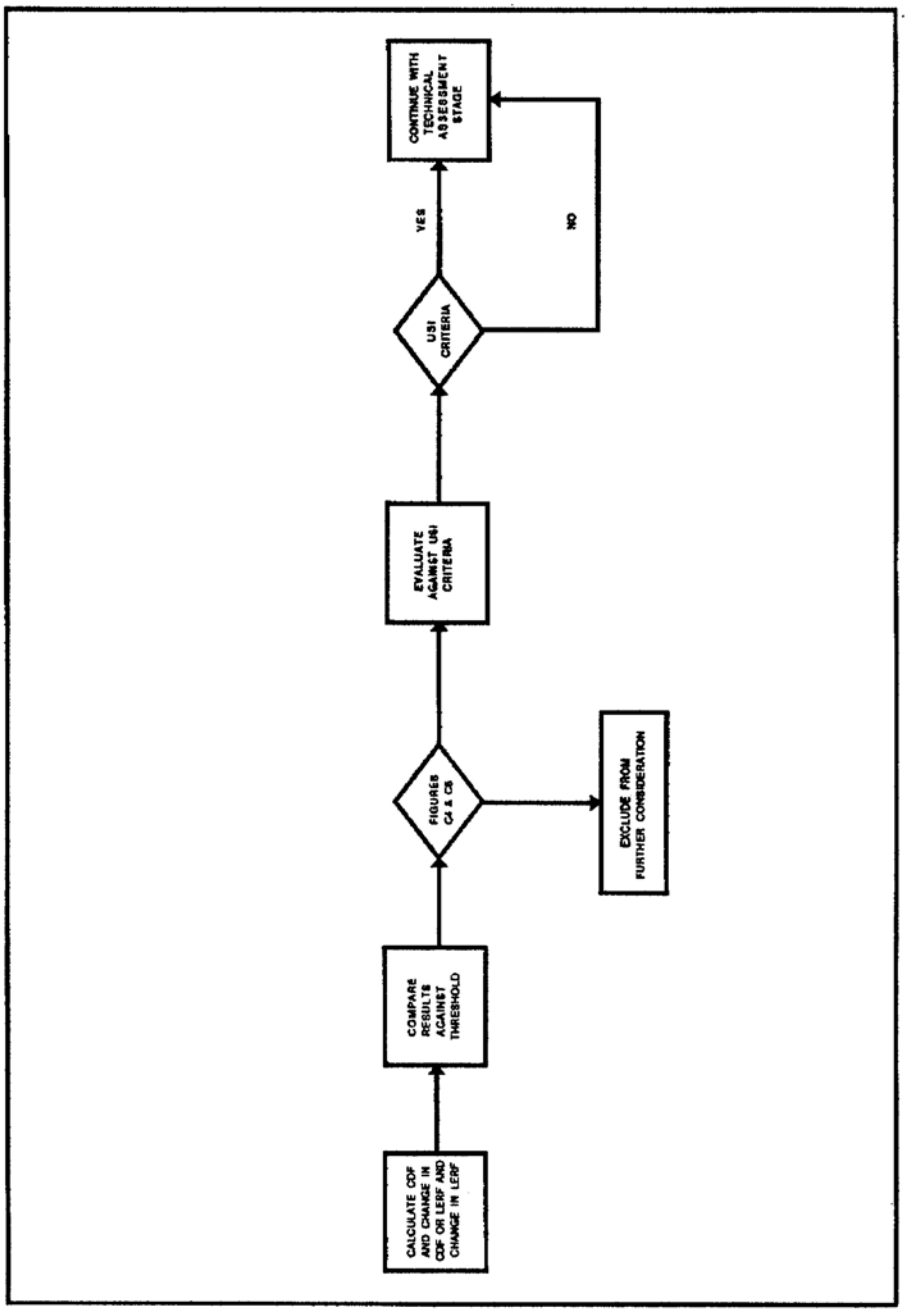
$$R = \frac{Cost}{Safety\ Benefit}$$

  where the safety benefit is the estimated potential risk reduction (event frequency x public dose averted) that may be achieved and the cost (in dollars) is the expense necessary to develop and implement a resolution in the number of plants involved.

- The formula for the safety benefit is:

$$Safety\ Benefit = (N)(F)(T)(D)$$

  where N = number of reactors affected by the safety enhancement
  F = accident frequency reduction (events/reactor-year)
  T = average remaining life (years) of the affected plants, based on an original license period of 40 years, or plant shutdown date, whichever is smaller
  D = averted public dose (person-rem)



CDF - core damage frequency
LERF - large early release frequency
USI - unresolved safety issue

Figure C1
Overview of Reactor Adequate Protection Issue;
Technical Assessment Stage

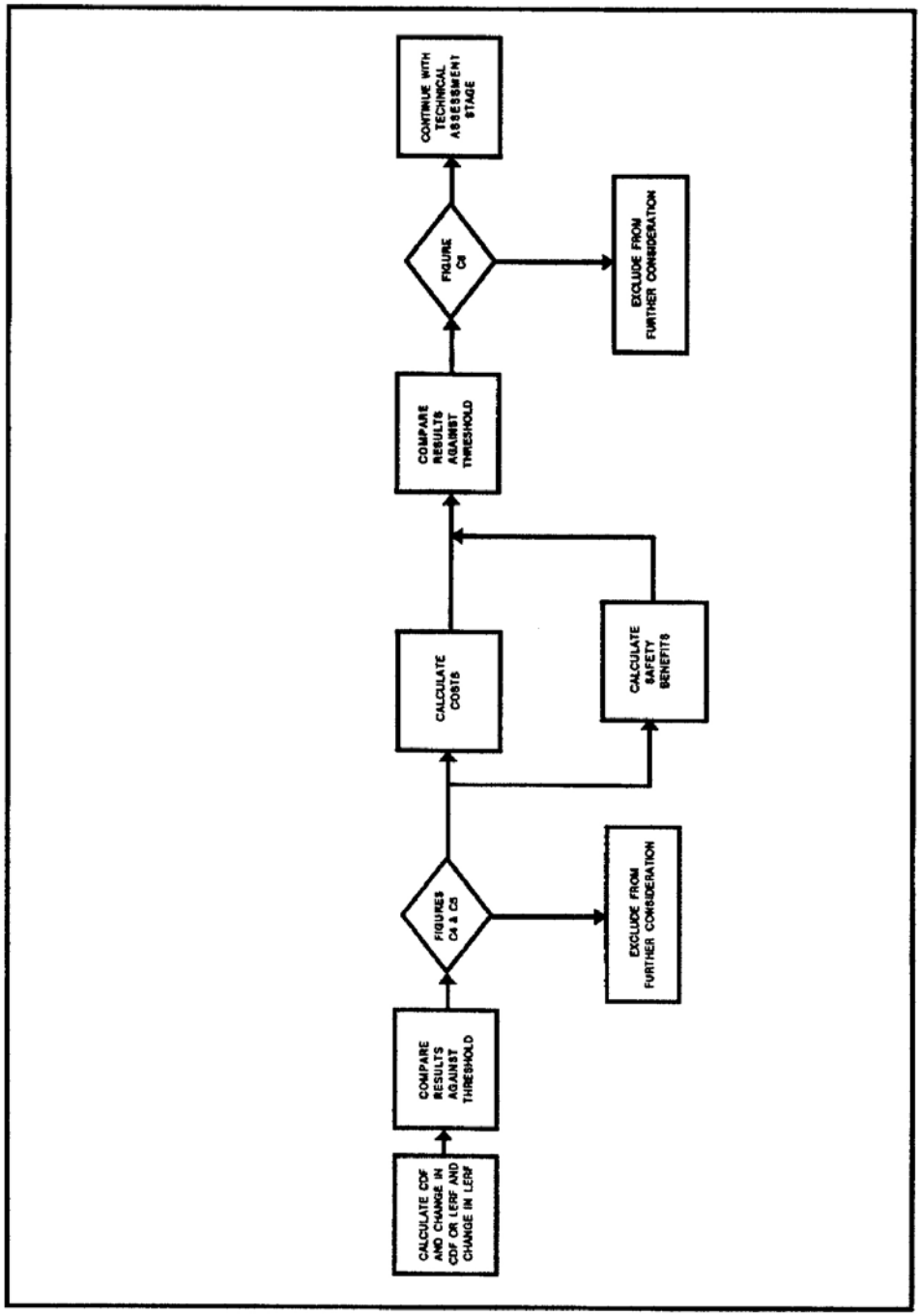


Figure C2

Overview of Reactor Substantial Safety Enhancement Issue; Technical Assessment Stage

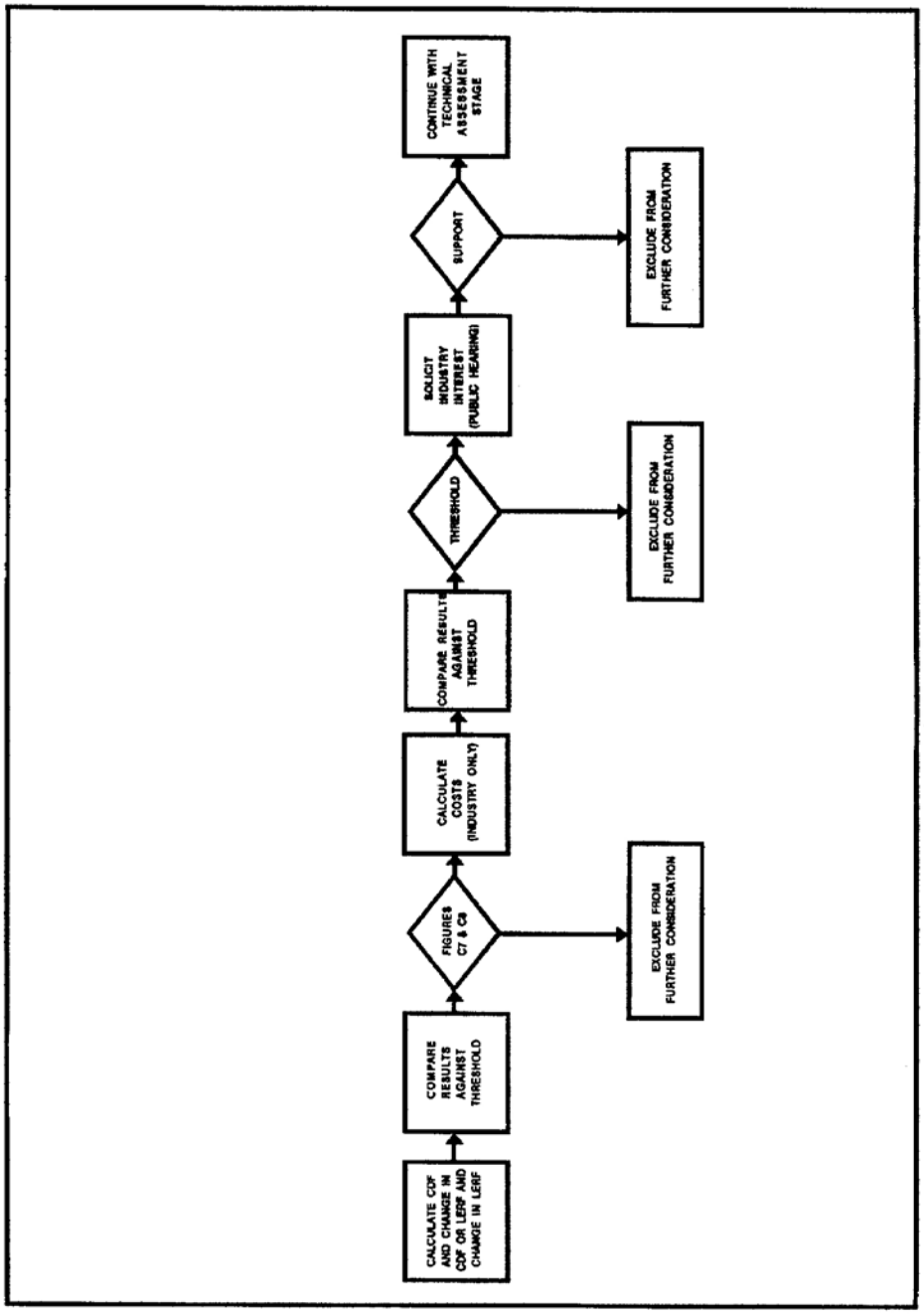


Figure C3

Overview of Reduction in Unnecessary Regulatory Burden Reactor Issue; Technical Assessment Stage

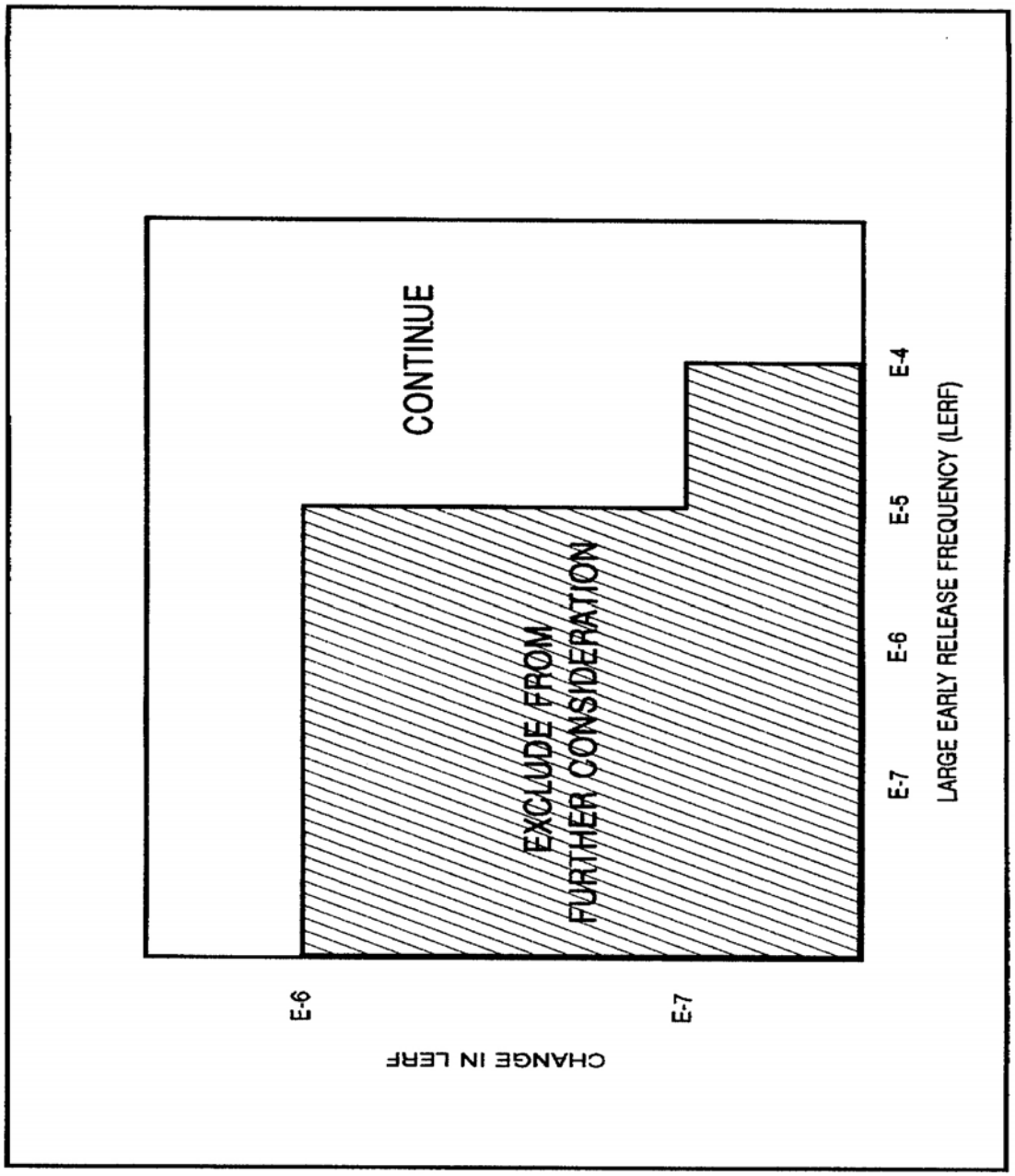


Figure C4
Large Early Release Frequency for Reactor Adequate Protection and Substantial Safety Enhancement Issues; Technical Assessment Stage

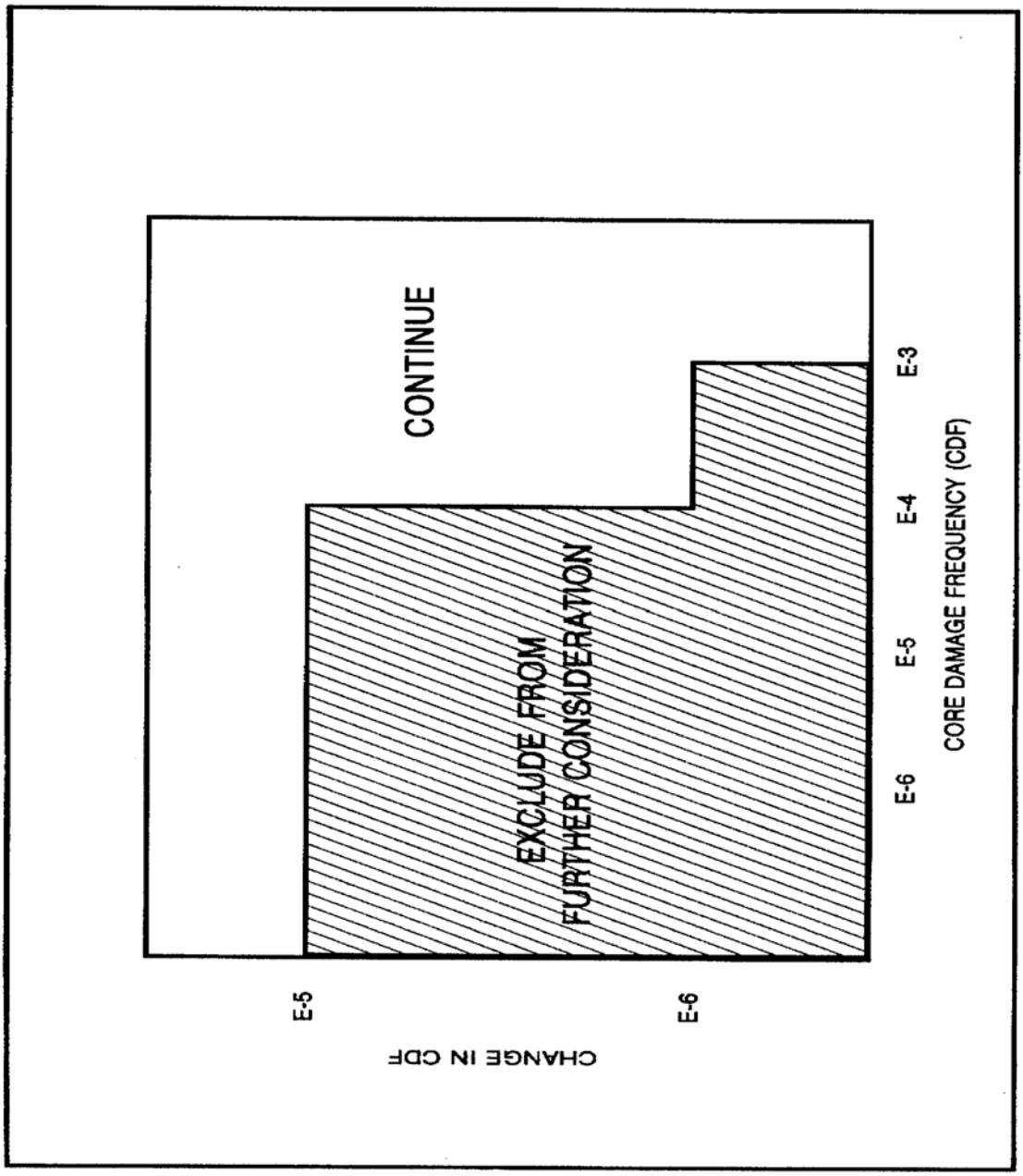


Figure C5
Core Damage Frequency for Reactor Adequate Protection and Substantial Safety Enhancement Issues; Technical Assessment Stage

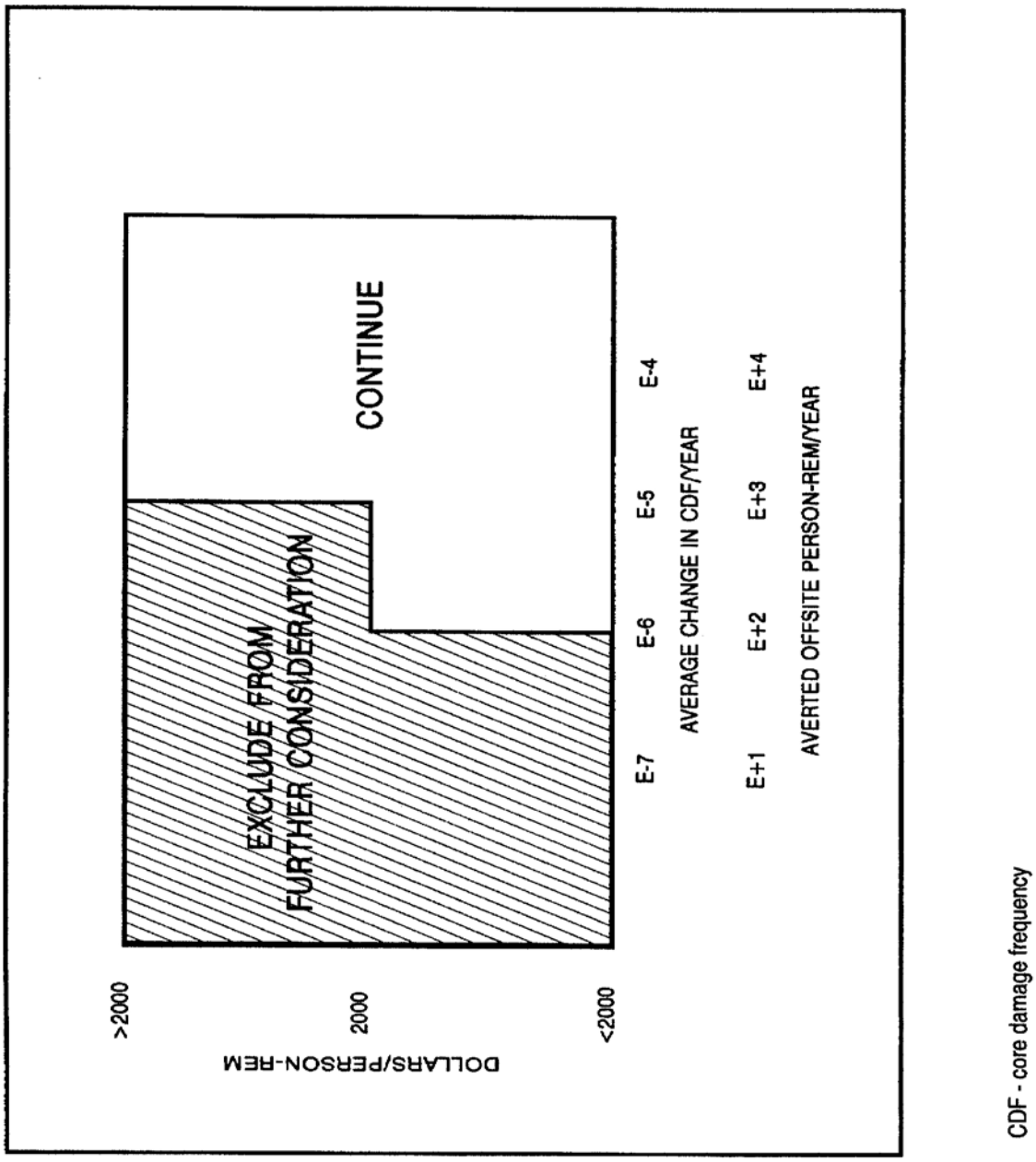


Figure C6

Impact/Value Threshold for Reactor Substantial Safety Enhancement Issue; Technical Assessment Stage

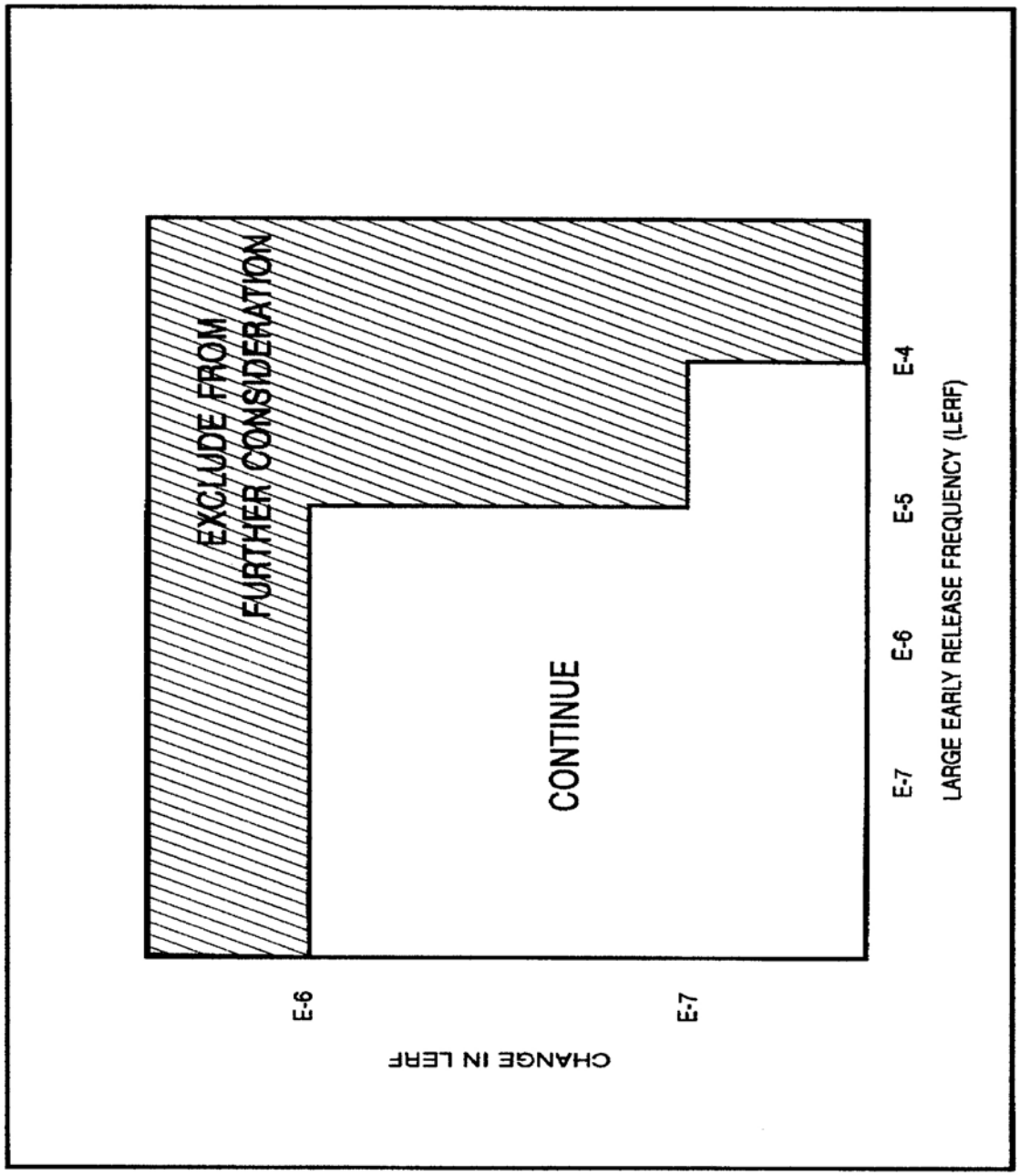


Figure C7
Large Early Release Frequency Threshold for Reduction in Unnecessary Regulatory Burden Reactor Issue; Technical Assessment Stage

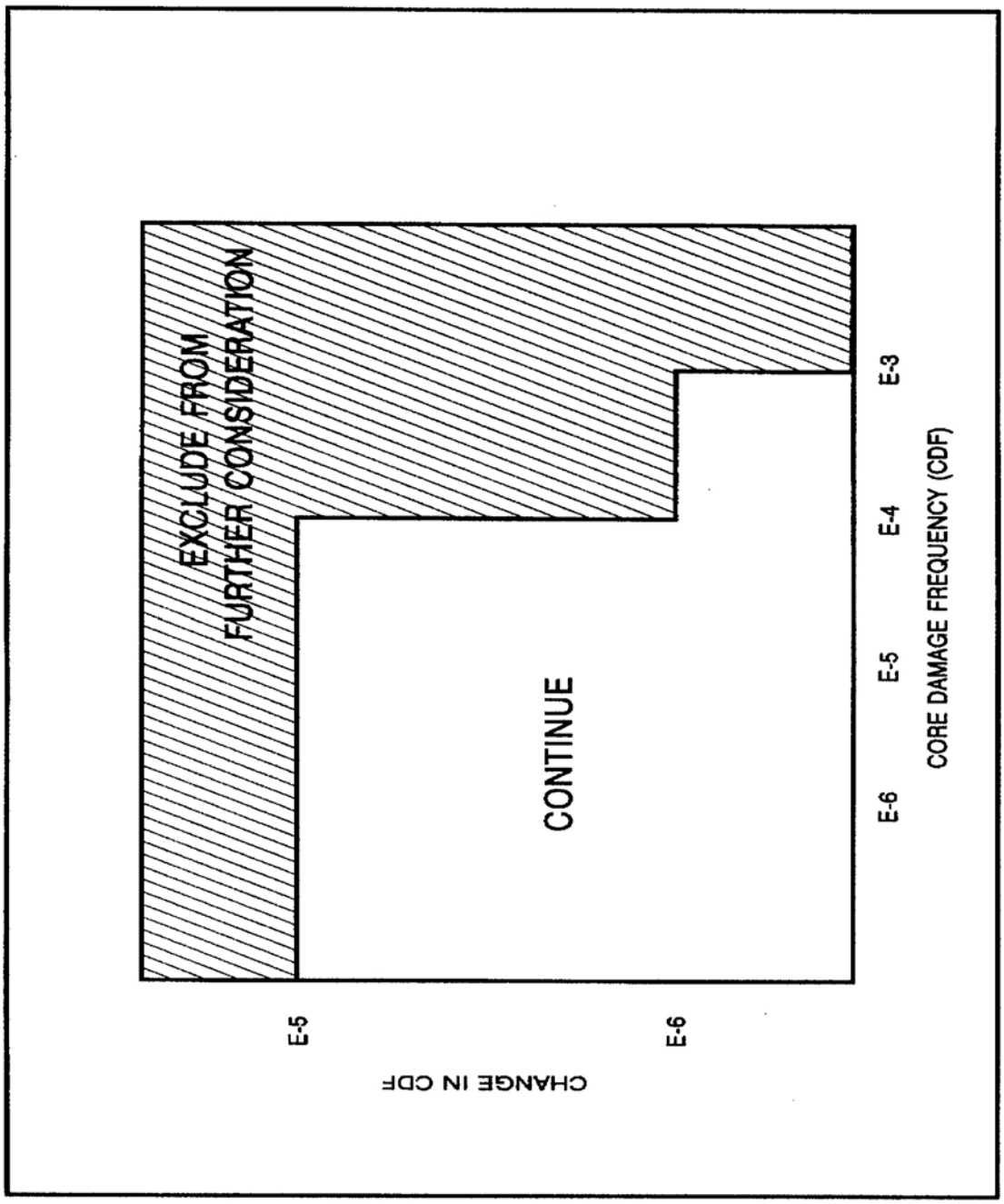


Figure C8
Core Damage Frequency for Reduction in
Unnecessary Regulatory Burden Reactor Issue;
Technical Assessment Stage

Appendix D
Generic Issue Task Action Plan

Task Action Plans (TAPs) are required for Generic Issues Program (GIP) Stages 3 through 7. TAPs are stage-specific and document the plans, schedules, and assigned responsibilities for managing each candidate generic issue (GI). Each TAP will be prepared and periodically updated, as appropriate, by the responsible project manager (RPM). The RPM shall submit the TAP and any substantive revisions to the appropriate office director (or designee) through the GIP Manager in the Office of Nuclear Regulatory Research for review and approval. Table D1, "Task Action Plan Format," provides the minimum amount of information that should be contained within a TAP. For broad-scope candidate GIs, the TAP may have to be significantly expanded, particularly for Stages 5 through 7, to provide adequate assessment and tracking of licensee or certificate holder program or facility changes. If possible, efforts should be made to follow the basic TAP structure guidance shown in Table D1.

Table D1
Task Action Plan Format

TAP Section	Explanation/Comment[1]
(1) GI number and title	[Initially provided by the GIP Manager; may be modified by the applicable GI review panel.]
(2) TAP objective	Provide the TAP objective.
(3) RPM	Name/office of individual assigned to coordinate processing of the current GI stage.
(4) GI classification	Determined by the applicable GI review panel.
(5) GI stage	List the specific GIP stage for the TAP.
(6) GI abstract	Indicate the significance and generic applicability of the issue.
(7) Regulatory assessment	Qualitative or quantitative assessment of the safety significance of the issue, with an adequate technical justification for the time frame to complete the TAP. This justification should address why current regulatory actions are sufficient and additional regulatory action is unnecessary at this time. The technical justification should include the NRR staff rationale for continued facility operation while the issue is being addressed. Note: This "regulatory assessment" may change depending on the GIP stage.
(8) Proposed actions	Proposed TAP actions, such as new regulations, policy positions, generic communications, Commission paper, or others.

Table D1 (continued)

TAP Section	Explanation/Comment[1]
(9) Schedule milestones	Major milestones in support of proposed actions and a proposed schedule for their completion. Examples of milestones are completion of tests or research, inspections, public meetings, industry meetings, NRC inspections, major review/concurrence milestones (NRC offices, ACRS, ACNW, ACMUI, CRGR, EDO), issuance of draft and final disposition documents, implementation status, and verification status.
(10) Resource requirements	State the estimated direct technical staff hours and contractor costs needed for completion of the TAP.
(11) Other contacts	List technical contacts. Include company/agency affiliation, position title, addresses, phone numbers, e-mail addresses, etc.
(12) References	List appropriate document references specific to the current GIP stage, including those documents that provide the basis for the GI.

[1]Indicate if information requested is either unknown, indeterminate, speculative, or does not apply to the current GIP stage.

Abbreviations
ACMUI - Advisory Committee on the Medical Uses of Isotopes
ACNW - Advisory Committee on Nuclear Waste
ACRS - Advisory Committee on Reactor Safeguards
CRGR - Committee To Review Generic Requirements
EDO - Executive Director for Operations
GI - Generic Issue
GIP - Generic Issues Program
NRR - Office of Nuclear Reactor Regulation
RPM - Responsible Project Manager
TAP - Task Action Plan

Appendix E
Quarterly Generic Issue Status Report

Each responsible project manager shall submit a Quarterly Generic Issue Status Report (QGISR) for assigned candidate generic issues (GIs) to the Generic Issues Program (GIP) Manager in the Office of Nuclear Regulatory Research (RES). For consistency, the report format should follow the report outline guidance shown in Table E1, "Quarterly Generic Issue Status Report Format." The level of detail of the report should be commensurate with the amount of analysis performed and the applicable GIP stage. Sections that do not apply to the particular GIP stage should be marked "N/A."

The QGISR should provide factual information that is adequate for someone unacquainted with the candidate GI to understand the issue, including actions taken to analyze any generic implications, impose new or modified program or facility changes, and the basis for closure of the issue, as applicable.

The QGISR is used as a tracking mechanism to assist in timely identification, screening, assessment, corrective action development, implementation and verification, and closeout of candidate GIs. The GIP Manager in RES uses the QGISR to develop a Combined Quarterly Generic Issue Status Summary Report. The combined report will include a summary status of all open generic safety issues and will be widely distributed.

Table E1
Quarterly Generic Issue Status Report Format

Report Section	Explanation/Comment[1]
(1) GI number and title	[Initially provided by GIP Manager; may be modified by the applicable GI review panel.]
(2) Reporting period	List the quarter period.
(3) Report submittal date	List the date that the report was submitted for management approval.
(4) Responsible project manager	List the name/office of the RPM who is submitting the report.
(5) GI classification	[Adequate protection, substantial safety enhancement, or reduction in unnecessary regulatory burden issue.]
(6) GI stage	List the current GIP stage.
(7) Submittal date	List the candidate GI submittal date (see Appendix A).
(8) Initial screening date	List the initial screening stage completion date or projected date. Include basis for date change from previous report.
(9) Technical assessment date	List the technical assessment stage completion date or projected date. Include basis for date change from previous report.
(10) Regulation and guidance development date	List the regulation and guidance development stage completion date or projected date. Include basis for date change from previous report.
(11) Regulation and guidance issuance date	List the regulation and guidance issuance stage completion date or projected date. Include basis for date change from previous report.

Table E1 (continued)

Report Section	Explanation/Comment[1]
(12) Implementation stage date	List the implementation stage completion date or projected date. Include basis for date change from previous report.
(13) Verification stage date	List the verification stage completion date or projected date. Include basis for date change from previous report.
(14) EDO closure memorandum date	List the EDO closure memorandum completion date, indicating either “excluded from further consideration” or “verification stage complete.”
(15) RPMs	Names of individuals assigned to coordinate processing previous stages in the GIP.
(16) Technical assignment control (TAC) numbers	List all TAC numbers assigned to the GI.
(17) Financial identification number(s) (FINs)	List all FINs assigned to contracts, if any, for technical assistance.
(18) Affected regulations	Identify the regulatory documents (e.g., rules, regulatory guides, standard review plans, etc.) that may be affected by the resolution of the GI.
(19) Significant correspondence	Identify significant internal and external correspondence (by title and accession number) that affected decisionmaking or that documents decisionmaking.
(20) Technical deliverables	Identify reports (by title and accession number) that have been produced by the NRC staff, NRC contractors, or industry during the processing of the GI.

Table E1 (continued)

Report Section	Explanation/Comment[1]
(21) Milestones	List completed milestones from the open Task Action Plan(s).
(22) Status summary	Summarize the status of the GI. If appropriate for the GIP stage, include individual licensee or certificate holder status of the GI.

[1]Indicate if information requested is either unknown, indeterminate, speculative, or does not apply given the current GIP stage.

Abbreviations
EDO - Executive Director for Operations
FIN - Financial Identification Number
GI - Generic Issue
GIP - Generic Issues Program
RPM - Responsible Project Manager
TAC - Technical Assignment Control

Appendix F
Criteria and Guidance for Technical Assessment of Candidate Materials Generic Issues

General

The probabilistic risk assessments utilized for reactor generic issues (GIs) do not exist for materials issues. The breadth in the scope and relative risks of activities conducted by materials licensees precludes developing a generalized quantitative approach to establish thresholds for GIs. As a result, the threshold for materials issues is based on more qualitative elements linked to NRC's strategic plan. Those materials issues that represent credible threats to NRC's strategic and performance goals and measures, unless current regulatory programs are changed, are tracked within the Generic Issues Program (GIP) process.

Approach

To assess the potential of an issue to exceed applicable strategic plan goals, the following assessments and estimates should be conducted:

- Estimate the potential consequences of the activity/event, including who or what will be affected (e.g., licensee, equipment, public, environment) and how (dose consequences, releases, etc.).

- Estimate the probability of occurrence of events that may result if the issue is not corrected. This estimate may include an assessment of how often an activity is performed.

- Determine the level of safety significance (risk). This is a judgment based on the consequences combined with the frequency/probability of occurrence.

- Evaluate the likelihood that strategic goal measures or performance goal measures will be exceeded, given the information and estimates obtained above.

Appendix F (continued)

- Incorporate the information gathered above into the Materials Generic Issue Review Panel (panel) briefing package and decision check sheet.

Contents of Materials Generic Issue Review Panel Briefing Package

Meeting Agenda

A clear and logical agenda of the items that need to be addressed during the meeting should be developed. The items that need to be addressed are outlined herein in the section "Items To Be Decided at the Panel Meeting."

Candidate Generic Issue Background Information

Assemble background information according to Appendix A, "Candidate Generic Issue Submittal Process." Particular attention should be given to developing the following information, when available and appropriate:

- Operational events – A listing of operational events related to the issue is to be included. A search of the Nuclear Material Events Database (NMED) will be needed to ensure that applicable events are captured.

- Affected licensees, certificate holders, or facilities – List the affected licensees or identify the categories of licensees affected, including an estimate of how many. The Licensing Tracking System (LTS) may be used to assist in determining how many licensees are affected.

- Existing regulations, programs, and guidance – Provide and be able to discuss the pertinent and affected regulations and/or guidance that may relate to the candidate GI.

- Safety issue – Provide and be able to discuss the risk potential. To adequately evaluate the risk potential of the issue, the following information should be included:

Appendix F (continued)

- Potential consequences of the activity/event, including who or what will be affected (e.g., licensee, equipment, public, environment) and how (dose consequences, releases, etc.).

- An estimate of the probability of occurrence of events that may result if the issue is not corrected. This estimate may include an assessment of how often an activity is performed.

- A determination of the level of safety significance. This is a judgment based on the consequences combined with the frequency/probability of occurrence.

- An evaluation of the likelihood that strategic goal measures or performance goal measures will be exceeded.

• Possible solutions – Provide potential enhancements to NRC requirements, programs, and/or guidance.

- Provide recommendations as to how to most cost-effectively and efficiently resolve the issue, including changes to regulations, programs, and guidance that may be necessary to address the concern.

- Assess the benefit of the changes versus their cost. An array of possible solutions may be suggested, with a discussion of the impact on licensees, public confidence, and NRC included for each solution.

- Provide a very rough estimate of milestones for proposed solutions.

• Burden reduction – If the candidate GI was submitted as a reduction in unnecessary regulatory burden issue, include a discussion of the potential burden relief and the costs to implement the solution. In addition, estimate the additional costs associated with tracking the item as a GI.

Appendix F (continued)

Items To Be Decided at the Panel Meeting

The purpose of the panel meeting is to determine whether the candidate GI satisfies, or may satisfy, applicable threshold criteria and should be processed through the GIP, whether the issue should be excluded from further consideration, tracked within other planning, budgeting, and performance management mechanisms, or referred to another program office for review. In addition, the scope of the issue is defined along with a cost-effective solution, if applicable. To accurately assess these issues, sufficient preliminary operating data and risk analyses should be presented, if available. Appendix G, “Candidate Generic Issue Screening Checklist,” contains a checklist for determining the potential GI classification.

Appendix G
Candidate Generic Issue Screening Checklist

The purpose of the Reactor Generic Issue Review Panel or the Materials Generic Issue Review Panel is to assess whether a candidate generic issue (GI) may satisfy applicable threshold criteria and should be processed through the Generic Issues Program, whether the issue should be excluded from further consideration, tracked within other planning, budgeting, and performance management mechanisms, or referred to another program office for review. In addition, the scope of the issue is defined along with a cost-effective solution, if applicable. To accurately assess these issues, sufficient preliminary operating data and risk analyses should be presented, if available.

The "Candidate Generic Issue Screening Checklist (Form G1)" consists of six questions contained in two sections, as shown on the form.

Guidance for Completion of Section 1 of Form G1

- The Reactor or the Materials Generic Issue Review Panel (the panel) shall be prepared to discuss and decide whether the candidate generic issue shall be classified as "generic."

- For issues that are determined to be generic by the checking of "YES" in both boxes (1) and (2), the appropriate Generic Issue Review Panel should address the type of generic issue by proceeding to Section 2 of Form G1.

- If the panel determines that the candidate generic issue is not generic, the panel shall exclude it from further consideration and issue a closure memorandum. Sufficient basis shall be provided for excluding the issue and not proceeding. Although the candidate issue may not meet the thresholds to be classified as a GI, it may meet other criteria for requiring regulatory action as a compliance issue, or there may be a safety benefit in issuing lower level NRC generic communications such as information notices, bulletins, generic letters, and regulatory issue summaries. In these instances, the applicable program office shall be informed in accordance with this MD.

Appendix G (continued)

Guidance for Completion of Section 2 of Form G1

- This section of Form G1 shall be completed only if the Section 1 review determined the candidate generic issue to be generic. The Reactor or the Materials Generic Issue Review Panel shall be prepared to discuss and decide whether the generic issue will be classified further as an adequate protection issue, a substantial safety enhancement issue, or a reduction in unnecessary regulatory burden issue by answering questions (3) through (6).

- Prioritization of the candidate GI, relative to current office/division work, shall be discussed. Issues that have been classified as GIs need to be bounded by clearly defining the scope of the issue and preparing a resolution plan with milestones in accordance with Appendix D, "Generic Issue Task Action Plan," of this management directive. The panel should also discuss the need to coordinate the processing of the issue with other NRC program offices, advisory committees (e.g., the Advisory Committee on Reactor Safeguards, the Advisory Committee on the Medical Uses of Isotopes, and the Advisory Committee on Nuclear Waste), and/or industry groups. Panel decisions and recommendations shall be documented in accordance with this directive.

Appendix G (continued)

Candidate Generic Issue Screening Checklist (Form G1)

Section 1: Is the Candidate Issue Generic?

YES NO

(1) Does the candidate generic issue (GI) affect several or a class of licensees?

YES NO

(2) Are existing regulations insufficient or unnecessary? (That is, it is not a situation in which the licensee did not comply with existing regulations.)

Generic Issue: *A regulatory matter involving the design, construction, operation, or decommissioning of several, or a class of, NRC licensees or certificate holders that is not sufficiently addressed by existing rules, guidance, or programs. A generic issue may be an adequate protection issue, a substantial safety enhancement issue, or a reduction in unnecessary regulatory burden issue.*

If both boxes (1) and (2) are checked YES, complete Section 2; otherwise, the issue shall be excluded from further consideration.

Section 2: Potential Generic Issue Classification

YES NO

(3) Potential Adequate Protection Issue: Are existing regulations insufficient to maintain health and safety at an acceptable level? (That is, this is not a situation in which the licensee failed to comply with existing regulations. Are modifications to the regulatory framework necessary to ensure adequate protection of public health and safety? Does the issue have a reasonable potential to cause a *strategic goal measure* to be exceeded?)

Adequate Protection Issue – *A GI that primarily raises questions and concerns about the adequacy of existing NRC requirements and guidance for ensuring adequate protection of public health and safety.*

YES NO

(4) Potential Substantial Safety Enhancement Issue (Part I): Would safety be substantially increased if new regulations were added?

If NO, go to Question #6; otherwise, continue.

Appendix G (continued)

Candidate Generic Issue Screening Checklist (Form G1) (continued)

YES NO

(5) Potential Substantial Safety Enhancement Issue (Part 2): Are the regulatory changes cost beneficial? (That is, will enhancements of existing NRC regulatory structure result in substantial safety improvements within justifiable costs to the industry and/or NRC? Does the issue have a reasonable potential to cause a *performance goal measure* to be exceeded?)

Substantial Safety Enhancement Issue – *A GI that primarily results in cost-beneficial safety improvements.*

YES NO

(6) Potential Reduction in Unnecessary Regulatory Burden Issue: Can existing regulations be relaxed and still maintain health and safety at an acceptable level? (That is, will addressing the issue result in significant burden reduction with minimal or acceptable reduction in safety, which the panel, including the office director's representative, does not believe is being adequately tracked within the planning, budgeting, and performance management systems?)

Reduction in Unnecessary Regulatory Burden Issue – *A GI that has the effect of reducing unwarranted burden of unnecessary requirements on licensees or certificate holders. Its purpose is to ease regulatory requirements while maintaining public health and safety*.
