MEMORANDUM TO: Ashok C. Thadani, Director, RES
Samuel J. Collins, Director, NRR
Carl J. Paperiello, Director, NMSS
Karen D. Cyr, General Counsel, OGC
Janice Dunn Lee, Director, OIP
Paul H. Lohaus, Director, OSP
James Lieberman, Director, OE
Hubert J. Miller, Regional Administrator, RI
Luis A. Reyes, Regional Administrator, RII
James E. Dyer, Regional Administrator, RIII
Ellis W. Merschoff, Regional Administrator, RIV

July 21, 1999

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PILOT STUDY FOR DRAFT MANAGEMENT DIRECTIVE 6.4, "GENERIC ISSUE PROGRAM"

In May, 1998, an assessment of the NRC's Generic Issue Program began. The assessment used the consultation services of Arthur Andersen LLP to take advantage of expertise that has been developed from assessment experience outside the NRC. The process included document reviews, database reviews and interviews with NRC staff who the team felt would provide specific insights into the program. Following the Generic Issue Program Assessment findings in September 1998, draft Management Directive (MD) 6.4, "Generic Issue Program" was produced and distributed for comment in April 1999, and again in June 1999.

In my letter to Dr. Dana Powers, Chairman, ACRS, dated May 24, 1999, I indicated that the staff would conduct a pilot study to evaluate the effectiveness of using the draft MD. The attached draft MD which you have reviewed and commented on will be used to determine whether a candidate generic issue represents an adequate protection, substantial safety enhancement, or a burden reduction issue. It will also be used to identify a cost-effective solution to generic issues that need to be addressed, and then to implement and verify the solution or set of solutions for that generic issue, as appropriate. The draft MD allows members of the public, industry or the NRC to propose candidate reactor, materials, or waste generic issues for consideration.

The year-long pilot study using the draft MD will begin in August 1999, after which lessons learned will be assessed, implemented, and a final MD will be forwarded to you for your review and concurrence prior to issuance.

Attachment: As stated

cc w/atts.:
Chairman Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
SECY

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 21, 1999

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SECY

Generic Issue Program

Draft Management Directive 6.4

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Policy

- It is the policy of the U.S. Nuclear Regulatory Commission to have an effective program for the resolution of generic issues that may involve new or revised rules, new or revised guidance, or revised interpretation of rules or guidance that affect licensees or certificate holders. A generic issue is 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.

Introduction

- The processes described in the Generic Issue Program (GIP) will be used to determine whether a candidate generic issue represents an adequate protection, substantial safety enhancement, or a burden reduction issue; to identify a cost-effective solution to generic issues that need to be addressed, and then to implement and verify the solution or set of solutions for that generic issue, as appropriate. Administration of the GIP will be accomplished using an eight stage process:

  - Identification,
  - Initial Screening,
  - Technical Screening,
  - Technical Assessment,
  - Regulations and Guidance Development,
  - Regulation and Guidance Issuance,
  - Implementation, and
  - Verification.

Objectives

- To identify a cost-effective solution to a generic issue and to implement the solution or set of solutions for that generic issue, as appropriate.

- To ensure that the immediate and long-term safety, safeguards, and regulatory burden concerns identified as generic issues are documented, tracked, analyzed, implemented, verified, and resolved.

- To ensure that program and regional offices maintain a coordinated and efficient capability to effectively:

  - identify generic issues,
  - document generic issues,

- track generic issues,
- screen generic issues,
- assess generic issues,
- impose new or revised requirements,
- relax requirements, and
- verify licensee implementation and effectiveness of the new or revised requirements.

- To ensure that the public, Congress, Agreement States, licensees, certificate holders and appropriate agencies of foreign countries and international organizations are provided with current information regarding generic issues, including the actual or potential hazards to health and safety.

Organizational Responsibilities and Delegations of Authority

The Commission

- Makes decisions on the resolution of the most serious generic issues that are brought to its attention after analyses determine that the significance to public health and safety requires the attention of the Commission.

Executive Director for Operations (EDO)

- Oversees the GIP and directs the required action to the appropriate offices.

- Oversees the agency's automated document management system for the collection, storage, retrieval, indexing, and distribution of documents involving generic issues.

- Disseminates selected documents associated with generic issues in accordance with distribution directions from the responsible NRC program office.

Director, Office of the General Counsel (OGC)

- Provides legal advice, and assistance during the processing of generic issues. Assist with the interpretation of regulations and statutes relevant to generic issues.

Advisory Committee on Reactor Safeguards (ACRS)

- Identifies candidate reactor generic issues and reviews the analyses of reactor generic issues.

- Advises the Commission and staff on the processes and methodologies for addressing reactor generic issues.

Advisory Committee on Nuclear Waste (ACNW)

- Identifies candidate generic issues and reviews the analyses of generic issues related to waste management and decommissioning.
- Advises the Commission and staff on the technical aspects and methodologies for addressing generic issues related to waste management and decommissioning.

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

- Identifies candidate generic issues and reviews the analyses of generic issues related to medical uses.
- Advises the Commission and staff on the technical aspects and methodologies for addressing generic issues related to medical uses.

Director, Office of Nuclear Reactor Regulation (NRR)

- Ensures that operational safety data is reviewed to identify candidate reactor generic issues in accordance with the requirements of Management Directive 8.5, "Operational Safety Data Review" and this directive.
- Monitors operational safety data to verify the effectiveness of actions taken by licensees to resolve generic issues.
- Assigns a representative, at branch chief level or higher, to serve on the Reactor or Materials Generic Issue Review Panel, as appropriate. Assigns additional personnel to attend the panel meeting as needed.
- Makes recommendations regarding the screening and classification of candidate reactor generic issues.
- Develops new requirements, or revises requirements and guidance, as appropriate, based upon the technical assessment of reactor generic issues and industry initiatives to reduce regulatory burden.
- Imposes requirements on licensees, as appropriate, based on the technical assessment of reactor generic issues.
- Provides appropriate technical support to regional offices, as requested, during licensee implementation and verification of the resolution of reactor generic issues.
- Provides input and support for databases such as the Safety Issue Management System (SIMS) and the Generic Issue Management Control System (GIMCS).
- Conducts public meetings and documents review actions.

Director, Office of Nuclear Materials Safety and Safeguards (NMSS)

- Ensures that operational safety data is reviewed to identify candidate materials and waste generic issues in accordance with the requirements of Management Directive 8.5, "Operational Safety Data Review" and this directive.

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

- Designates the Materials Generic Issue Review Panel Chairperson. This shall normally be the Director, Division of Industrial and Medical Nuclear Safety (IMNS).

- Makes decisions regarding the initial screening and classification of candidate materials generic issues.

- Conducts the technical screening of materials generic issues to determine whether development of a solution warrants expenditure of NRC resources.

- Conducts technical assessments of materials generic issues to determine whether requirements or guidance are needed and to establish the technical bases for requirements or guidance.

- Develops new requirements, or revised requirements and guidance, as appropriate, based upon the technical assessment of materials generic issues.

- Imposes requirements on licensees, as appropriate, based on the technical assessment of materials generic issues.

- Provides appropriate technical support to regional offices, as requested, during licensee implementation and verification of the resolution of materials generic issues.

- Provides input and support for databases such as SIMS and GIMCS.

- Conducts public meetings and documents review actions.

Director, Office of Nuclear Regulatory Research (RES)

- Identifies reactor, materials, and waste generic issues from research programs, including national and international cooperative research programs as well as review of operational experience.

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

- Designates the chairperson of the Reactor Generic Issue Review Panel.
- Assigns a GIP Manager.
- Makes recommendations regarding the initial screening and classification of candidate reactor and materials generic issues.
- Conducts the technical screening of reactor generic issues to determine whether development of a solution warrants expenditure of NRC resources.
- If appropriate, conducts the technical screening of materials generic issues to determine whether development of a solution warrants expenditure of NRC resources.
- Conducts technical assessments of reactor generic issues to determine whether new or revised requirements or guidance is needed and to establish the technical basis for new or revised requirements or guidance.
- If appropriate, conducts technical assessments of materials generic issues to determine whether requirements or guidance is needed and to establish the technical bases for requirements or guidance.
- Develops methodologies to perform technical screenings and technical assessments of generic issues.
- Coordinates data entry into databases (e.g., SIMS, GIMCS) on the status and documentation concerning issues processed in accordance with the GIP.
- Compiles and issues quarterly reports on the status of issues processed in accordance with the GIP.
- Assesses the effectiveness and efficiency of the GIP activities and takes action, as appropriate, to improve the program.

Regional Administrators

- Identify candidate generic issues through inspection and investigation activities.
- Verify licensee implementation of requirements that may result from the resolution of generic issues.
- Coordinate regional efforts with other NRC offices that share responsibility for generic issues.

Director, Office of International Programs (OIP)

- Serves as the principal contact for the establishment and administration of formal arrangements between NRC and the agencies of foreign countries and

international organizations for the exchange and collection of information on generic issues.

- Assists in the establishment and administration of systems for the effective review, tabulation, storage, and retrieval of information related to foreign generic issues.

- 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 generic issues to the appropriate offices for further consideration.

Director, Office of State Programs (OSP)

- Advises, coordinates and reviews Agreement State participation in the review of operational safety data to identify candidate materials and waste generic issues in accordance with the requirements of Management Directive 8.5, "Operational Safety Data Review" and this directive.

Director, Office of Enforcement (OE)

- Identifies candidate generic issues from review of reactor and materials enforcement issues.

- Provides enforcement related support to program and regional offices for resolution of any enforcement issues involved with generic issues.

Applicability

- The policy and guidance in this directive and Handbook apply to NRC employees.

Handbook

- Handbook 6.4 describes activities involved in the processing of generic issues, provides guidelines to facilitate coordination of the activities of the NRC offices responsible for review of generic issues, and describes the elements necessary for a program for the management of the resolution of generic issues.

References

Code of Federal Regulations, Title 10, "Energy."

Energy Reorganization Act of 1974, as amended, Sections 208 and 210.

NRC Management Directive -

2.2, "Planning and Budgeting for Federal Information Processing Resources."

3.50, "Document Management."

3.7, "Unclassified Staff Publications in the NUREG Series."

6.3, "The Rulemaking Process."

8.1, "Abnormal Occurrence Reporting Procedure."

8.2, "NRC Incident Response Plan."

8.4, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants."

8.5, "Operational Safety Data Review."

12, "Security."

NUREG/BR-0053, "Regulations Handbook."

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

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

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

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

NUREG 1409, "Backfitting Guidelines."

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

OMB Circular No. A-94, "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs."

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

"A Plain English Handbook," Office of Investor Education and Assistance, U.S. Securities and Exchange Commission, August 1998.

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B - Unresolved Safety Issue Screening Criteria
C - Criteria and Guidance for Technical Screening of Reactor Generic Issues
D - Generic Issue Task Action Plan (TAP)
E - Quarterly Generic Issue Status Report

Part I

General

Introduction

The Generic Issue Program (GIP) is intended to determine whether a candidate generic issue represents an adequate protection issue, a substantial safety enhancement issue, or a burden reduction issue; to identify cost-effective solutions to generic issues, and then to implement and verify the adequacy of solutions for generic issues, as appropriate.

The following 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 independent assessments of safety, administrative matters, or ensuring compliance with existing rules or written commitments.

In some instances, it may be necessary to obtain additional information from licensees or certificate holders to determine (1) whether adequate protection has been or would be maintained through license compliance, or (2) whether it would be appropriate to reduce the regulatory burden through relaxation or elimination of compliance with some regulatory requirement.

Because of the varying technical disciplines and level of difficulty encompassed by generic issues, the processing of generic issues, 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 generic issues.

- Only potential adequate protection, substantial safety enhancement, and burden reduction issues are subjected to the processes of the GIP.
- Resolution of a generic issue 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.
- Resolution of a generic issue may affect licensees or certificate holders.
- The process stages in the GIP are Identification, Initial Screening, Technical Screening, Technical Assessment, Regulation and Guidance Development, Regulation and Guidance Issuance, Implementation, and Verification.

Responsibilities

Division Level Management

- Ensures that policy guidance on processing generic issues is followed.
- Provides the human and financial resources to process generic issues in accordance with the planning, budgeting, and management process.
- Provides timely review of associated documents and records.
- Ensures that responsible project managers assigned to a particular generic issue have knowledge in the relevant technical area, and are knowledgeable with the GIP and its guidelines.
- Ensures that potential reactor and materials generic issues that fall within the scope of the GIP are included in the process.
- Provides timely review and approval of Quarterly Generic Issue Status Reports prior to submittal to the GIP Manager.

Branch Level Management and Supervisors

- Ensures cost effective performance of work.
- Ensures that qualified staff are performing the work.
- Reviews work for accuracy and completeness.
- Provides timely review of associated documents and records.
- Ensures that work is performed in accordance with the description and schedule as specified in the approved generic issue Task Action Plan (TAP) in accordance with Appendix D.
- Coordinates peer reviews of products produced during the processing of generic issues.
- Ensures that status reports on generic issues are documented and submitted in accordance with requirements.

Reactor Generic Issue Review Panel

- Receives and reviews candidate reactor generic issues,
- Conducts initial screening of candidate reactor generic issues,

- Determines whether a candidate generic issue should be classified as either an adequate protection, a substantial safety enhancement, or a burden reduction issue,
- Defines the scope of reactor generic issues, and
- Reviews any changes in scope of reactor generic issues.

Materials Generic Issue Review Panel

- Receives and reviews candidate materials generic issues,
- Conducts initial screening of candidate materials generic issues,
- Determines whether a candidate generic issue should be classified as either an adequate protection, a substantial safety enhancement, or a burden reduction issue,
- Defines the scope of materials generic issues, and
- Reviews any changes in the scope of materials generic issues.

Generic Issue Program Manager

- Assigns alpha-numeric designations and titles to candidate generic issues received from submitters,
- Transmits to the Reactor or Materials Generic Issue Review Panels, as appropriate, candidate generic issues that are provided by the submitter.
- Supports the activities of the Reactor and Materials Generic Issue Review Panels,
- Coordinates the issuance of Quarterly Generic Issue Status Reports on open generic issues and candidate generic issues,
- Coordinates the issuance of an annual report on open generic issues,
- If necessary, coordinates the issuance of an annual report on unresolved safety issues (USIs), and
- Coordinates data entry into databases (e.g., SIMS, GIMCS) on the status and documentation concerning candidate generic issues and open generic issues.

Project Manager

- Prepares generic issue TAPs in accordance with Appendix D for each GIP stage following the Initial Screening Stage,
- Understands the generic issue scope, associated milestones, deliverables, and status of assigned generic issues
- Documents ongoing analyses, and the basis for decision-making,
- Prepares Quarterly Generic Issue Status Reports for assigned issues in accordance with Appendix E,
- Prepares memoranda to the EDO for dropped or resolved generic issues,
- Coordinates public meetings, as needed, concerning assigned candidate generic issues, or open generic issues.
- Performs or coordinates work in accordance with NRC policies and this directive, and
- Performs work in a timely manner.

Communication and Coordination

Internal

- Effective communication and coordination between cognizant technical and licensing staff is essential for planning and timely completion of each of the stages of the GIP. This is also true for the project managers assigned for each generic issue, and the GIP Manager. Discussions of the plans for completing each stage of the GIP shall be held among appropriate staff and documented by the responsible project manager.
- Cognizant technical and licensing staff should communicate frequently regarding the scope, progress, intermediate findings, expectations, and routine activities (e.g., inspections, safety evaluations) that may affect issue closure to ensure efficient use of resources.

External

- For significant generic issues, a public meeting should be held early in the Technical Assessment and Regulation and Guidance Development Stages of the GIP to inform the public and the industry about the scope of the issue, significance of the issue, and plans for closing the issue. The public and the industry should be given the opportunity to comment on the significance of the issue and plans for closing the issue.

- Consideration should be given to coordinating closure of an issue with appropriate industry groups such as the Nuclear Energy Institute, owners groups, Electric Power Research Institute, the public, or others.

- Meetings with external stakeholders will be held in accordance with NRC policy. Guidance on conducting public meetings is in NUREG/BR-0224, "Guidelines for Conducting Public Meetings."

Documentation

General Provisions

- Adequately documenting the work and decision-making associated with a generic issue or candidate generic issue is important. The documentation should be thorough enough that the work and decision-making can be understood by those who were not directly involved in the generic issue or candidate generic issue.

- Tables 1 and 2 illustrate the documentation typically produced during the processing of a generic issue.

NUREG-xxxx (to be developed)

- Contains summaries of generic issues and candidate issues processed in accordance with this directive.

- Generic issues identified prior to the effective date of this directive are documented in NUREG-0933, "A Prioritization of Generic Safety Issues."

Closure Memorandum

- The responsible office for a generic issue (i.e., RES for reactor generic issues or NMSS for materials generic issues) shall inform the EDO by memorandum when a generic issue has been closed. The responsible project manager shall originate the closure memorandum for signature by the appropriate office director. Copies of the closure memorandum should be sent to the GIP Manager, the appropriate advisory committees (i.e., ACRS, ACNW or ACMUI) and the submitter of the issue. A generic issue is "closed" after it has been determined that the issue should be either dropped from any further analyses, or has been resolved. The memorandum should include the following:

    - description of the candidate generic issue or generic issue,
    - description of the potential or actual impact of the issue on safety or regulatory burden,
    - technical basis for classifying the issue as dropped or resolved, and

- how the implementation of corrective actions was verified, if applicable.

Tracking

General Provisions

- Each candidate generic issue or generic issue shall have an assigned alpha-numeric designation.

- Quarterly Generic Issue Status Reports and summaries should be written in accordance with "A Plain English Handbook" (see References).

Task Action Plan

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

- During each stage after the Identification Stage, a TAP will be prepared and periodically updated, as appropriate, by the responsible project manager. Depending on the complexity of the generic issue, different project managers may be assigned the responsibility to cover different stages of the GIP.

- The TAP describes the actions needed to complete a specific GIP stage. For example, a TAP prepared in the Technical Assessment Stage should only include 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.

Office Level Tracking

- 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.

- Generic issues should be assigned a Technical Assignment Control (TAC) number by the responsible office to facilitate tracking the expenditure of resources.

Quarterly Generic Issue Status Report

Quarterly Generic Issue Status Reports (guidance provided in Appendix E) are living documents that summarize the work and decision-making associated with a generic issue as it passes from one stage to another, and from one project manager to another, if needed.

- Each responsible project manager will prepare a Quarterly Generic Issue Status Report for assigned candidate generic issues and generic issues.

- The GIP Manager will solicit and use the Quarterly Generic Issue Status Reports to prepare an integrated report summarizing the status and activities related to open generic issues and candidate generic issues. The integrated report will include only non-predecisional and non-proprietary information. Copies of the report will be sent to the EDO, ACRS, ACNW, ACMUI, and the Public Document Room (PDR).

Annual Report

The GIP Manager will prepare an annual report that will be provided to the program offices for concurrence. This report will provide a summary of activities related to open generic issues that will be sent to the Commission.

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Part II

Overview of Generic Issue Program Stages

General

Only generic issues that potentially involve adequate protection, substantial safety enhancement, or burden reduction are included in the Generic Issue Program (GIP).

The GIP consists of the following stages:

- Identification,
- Initial Screening
- Technical Screening,
- Technical Assessment,
- Regulations and Guidance Development,
- Regulation and Guidance Issuance,
- Implementation, and
- Verification.

Descriptions of each of the stages including products are given below and in Tables 1 and 2 of this Handbook.

Identification Stage

Candidate generic issues (e.g., adequate protection issue, substantial safety enhancement issue, burden reduction issue) may be identified by organizations or individuals internal or external to the NRC, including the NRC staff, ACRS, ACNW, ACMUI, licensees, certificate holders, industry groups, or the general public.

Candidate generic issues may be identified by the NRC during routine activities. Sources of candidate generic issues 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 generic issues from operational safety data reviews is contained in Management Directive 8.5, "Operational Safety Data Review."

Individuals and organizational units within the NRC who wish to nominate a generic issue must complete the Candidate Generic Issue Submittal Form contained in Appendix A. This form may also be used by parties outside the NRC to express their concerns to the staff for consideration as a candidate generic issue.

- Candidate generic issues are submitted to the GIP Manager, who will forward them to either the Reactor or Materials Generic Issue Review Panel, as appropriate. For candidate generic issues that involve both program areas, the GIP Manager will consult with the program offices to establish a combined review panel including representatives of NRR, NMSS, and RES.

- Candidate generic issues may be previous generic issues that have either been dropped or resolved. This could occur if significant or new information becomes available that may affect their closure.

Initial Screening Stage

During the Initial Screening Stage, the appropriate Generic Issue Review Panel determines whether the candidate generic issue (e.g., adequate protection issue, substantial safety enhancement issue, burden reduction issue) is a generic issue, whether the issue should be processed in the GIP, should be dropped, or sent to another NRC program for review. Also, the scope of the candidate generic issue (and thus the generic issue) is defined at this stage.

The Initial Screening Stage is complete after the appropriate Generic Issue Review Panel reviews the information contained on the Candidate Generic Issue Submittal Form (See Appendix A), and submits its findings and recommendations to the Director of RES for reactor issues, or the Director of NMSS for materials issues.

This stage must be completed within 30 days upon receipt of a candidate generic issue.

- The appropriate office director (or designee) assigns a responsible project manager to coordinate the initial screening of the generic issue. The responsible project manager should be chosen based on the nature of the generic issue (i.e., adequate protection, substantial safety enhancement, or burden reduction), or whether the proposed resolution involves a backfit, rulemaking, or burden reduction.

- The Reactor or 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 the NRC, this review should be in a public meeting.

- The Reactor or Materials Generic Issue Review Panel will perform initial screenings of candidate generic issues with assistance from the submitter, if appropriate. If the submitter is an individual or organization outside the NRC, this screening should be in a public meeting.

- The Reactor or Materials Generic Issue Review Panel recommends whether the candidate generic issue is a generic issue, and if so,

classifies it as either an adequate protection, a substantial safety enhancement, or a burden reduction issue.

- For a candidate generic issue, an initial screening memorandum shall be originated by either the Reactor or Materials Generic Issue Review Panel, as appropriate, and shall consist of a forwarding note with attached findings and recommended actions. Burden reduction issues may not lend themselves to the Technical Screening and Technical Assessment Stages. In some instances, the appropriate Generic Issue Review Panel may recommend that the screening and assessment stages for burden reduction issues be waived, or performed at a lower level of effort. The basis for this recommendation shall be documented in the Panel's Initial Screening memorandum. As a minimum, the initial screening memorandum is to include a clear, concise description of the generic issue, its classification, safety significance, proposed action, and the Candidate Generic Issue Submittal Form (Appendix A) prepared by the submitter. The generic issue memoranda shall be sent to the Director, RES for reactor issues, or to the Director, NMSS for materials issues, as appropriate, through the GIP Manager for concurrence.

- The responsible office director (RES for reactor generic issues or NMSS for materials generic issues) will inform the submitter of the candidate generic issue 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 information memorandum or letter. Copies of the memorandum or letter should be sent to the GIP Manager, ACRS, ACNW, or ACMUI, as appropriate.

- The responsible project manager produces the Quarterly Generic Issue Status Report in accordance with Appendix E for the assigned generic issue.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to the appropriate office director (or designee) for review and approval.

Technical Screening Stage

The Technical Screening Stage is a "quick" look at the generic issue, using information that is readily available and with limited resources.

The main purposes of Technical Screening Stage is to (1) perform additional review of those generic issues that may represent an adequate protection issue, a substantial safety enhancement issue, or a burden reduction issue, (2) determine if these should be designated as USIs and reported to Congress, and (3) identify a cost-effective solution to the generic issue.

Technical screening also provides technical justification for dropping a generic issue that has little safety significance, would not result in a substantial safety enhancement, is not cost justifiable, or is an unwarranted regulatory burden.

Guidance for performing a technical screening of a reactor generic issue is provided in Appendices B and C. Guidance for performing a technical screening of a materials generic issue would use more qualitative methods, expert elicitation, and judgement. Additional guidance for performing a technical screening can be found in the References section of this directive.

The Technical Screening Stage must be completed within 6 months of the receipt of the candidate generic issue from the submitter.

- The appropriate office director (or designee) assigns a responsible project manager to coordinate the technical screening of the generic issue. The responsible project manager should be chosen based on the nature of the generic issue (i.e., adequate protection, substantial safety enhancement, or burden reduction), or whether the proposed resolution involves a backfit, rulemaking, or burden reduction.

- The appropriate office director (or designee) assigns staff to perform the Technical Screening Stage. If the proposed staff come from different offices, arrangements between offices will have to be made to obtain needed expertise. The technical screening staff should be chosen and approved based on the scope of the generic issue.

- RES evaluates adequate protection and substantial safety enhancement issues against the USI screening criteria (see Appendix B).

- RES conducts the technical screening of each reactor generic issue to determine whether it is likely to result in the benefits being sought (e.g., cost effective, increased safety, reduced burden) and thus merits additional expenditure of NRC resources.

- NMSS conducts the technical screening of each materials generic issue to determine whether it is likely to result in the benefits being sought (e.g., cost effective, increased safety, reduced burden) and thus merits additional expenditure of NRC resources.

- The responsible project manager prepares and maintains a Task Action Plan (TAP) in accordance with Appendix D, which includes the activities to complete the Technical Screening Stage.

- The supervisor of the responsible project manager submits the TAP and any substantive revisions to the TAP to the appropriate office director (or designee) for review and approval. A copy of the approved TAP is submitted to the GIP Manager.

- The supervisor of the responsible project manager contacts the supervisors of the appropriate staff members assigned to perform the technical screening to request their assistance, directs the responsible project manager to initiate contractual action to procure the technical assistance (if technical expertise is not available internally) needed to perform the technical screening, or both.

- Completed technical screening analyses shall be documented and sent for peer review to the NRC organizational unit or units whose area of responsibility or specialized knowledge is substantially involved in the generic issue.

- After the generic issue draft technical screening results have been peer reviewed, the appropriate Generic Issue Review Panel will reconvene to address the comments and make changes to the findings and recommended actions, as appropriate.

- The supervisor of the responsible project manager informs the Director of RES (for reactor issues), or the Director of NMSS (for materials issues), as appropriate, by a memorandum of the findings and recommended actions. As a minimum, the memorandum shall include a clear, concise summation of the technical screening analysis, description of the recommended actions (e.g., drop or continue), and a copy of the technical screening analysis.

- After the technical screening analysis has been reviewed and a final decision has been made by the appropriate office director, the supervisor of the responsible project manager informs the ACRS, ACNW, or ACMUI, as appropriate, by memorandum of the office director's final decision.

- The Technical Screening Stage is complete when the Director of RES (for reactor generic issues) or the Director of NMSS (for materials generic issues) determines whether the generic issue should be dropped or continued to the Technical Assessment Stage.

- If the generic issue is dropped, the responsible project manager shall originate a memorandum for signature by the responsible office director to the EDO, providing the basis for the decision, with copies to the GIP Manager, ACRS, ACNW, ACMUI and the submitter of the issue.

- The responsible project manager produces the Quarterly Generic Issue Status Report for the assigned generic issue.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to the appropriate office director (or designee) for review and approval.

- Copies of approved correspondence between the supervisor of the responsible project manager and the appropriate office director shall be sent to the GIP Manager and the submitter.

- Technical screening analyses will be published in NUREG-xxxx (to be developed) or its supplements.

Technical Assessment Stage

The Technical Assessment Stage is an "in-depth" study of a generic issue (e.g., adequate protection issue, substantial safety enhancement issue, burden reduction issue), and may involve contractor support. To form a technical basis for taking or not taking regulatory action, the Technical Assessment Stage may include:

- a review of operational data and events,
- a review of related generic issues,
- experiments and tests,
- system analyses,
- computational analyses,
- field studies,
- inspections,
- model development,
- probabilistic risk assessments,
- integrated safety assessments, and
- expert elicitation.

The extent of these activities vary in accordance with the scope, complexity, or significance of the generic issue, and the depth of information available on a given generic issue.

Typically, the activities performed during this stage will be documented in technical letter reports, NUREG reports, or NUREG/CR reports.

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

- The appropriate office director (or designee) assigns a responsible project manager to coordinate the technical assessment of the generic issue.

- The appropriate office director (or designee) assigns staff to perform the Technical Assessment Stage. 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 based on the scope of the generic issue.

- The supervisor of the responsible project manager contacts the supervisors of staff members assigned to perform the technical assessment, and as required, directs the responsible project manager to initiate contractual action (if technical expertise is not available internally) to procure the technical assistance needed to perform the technical assessment.

- The responsible project manager for the technical assessment shall prepare and maintain a TAP for the activities needed to complete the Technical Assessment Stage.

- A copy of the approved generic issue TAP (including any revisions) and status reports shall be provided to the submitter of the issue. If these documents contain pre-decisional or proprietary information, OGC will determine what information can be released to a non-NRC employee submitter.

- Either RES (for reactor issues) or NMSS (for materials issues), as appropriate, shall conduct or oversee the technical evaluation of the generic issue, verify the legitimacy of the concern expressed, verify that the benefits sought will be obtained, establish the technical basis for new or revised regulations or guidance, and identify solutions for the issue that are likely to result in substantial net plant safety improvements or reduction in regulatory burden without significant decrease in safety margin.

- The supervisor of the responsible project manager for the technical assessment of the generic issue shall submit the TAP and any substantive revisions to the appropriate office director (or designee) for review and approval.

- The responsible project manager produces the Quarterly Generic Issue Status Report for the assigned generic issue.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to the appropriate office director (or designee) for review and approval.

- After the generic issue technical assessment has been completed, the supervisor of the responsible project manager informs the Director of RES (for reactor issues) or the Director of NMSS (for materials issues) by a memorandum of the findings, and requests appropriate actions.

- The Technical Assessment Stage is complete when the Director of RES (for reactor issues) sends a recommendation to the Director of NRR, or when the Director of NMSS (for materials issues) determines whether the issue should be dropped, new or revised rules or guidance are needed, or new or revised NRC programs are needed.

- After the technical assessment of the generic issue has been completed, the supervisor of the responsible project manager informs the ACRS, ACNW, or ACMUI, as appropriate, by memorandum, of their findings.

Regulation and Guidance Development Stage

The Regulation and Guidance Development Stage involves an in-depth review of potential facility or program changes to address the generic issue (e.g., adequate protection issue, substantial safety enhancement issue, burden reduction issue), and selection of needed regulatory actions. Technical findings obtained during the Technical Assessment Stage are, as necessary, used as a basis to develop or revise 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 CRGR briefing packages.

Typically, NRC rules and guidance are contained in Title 10 of the Code of Federal Regulations, standard review plans, safety evaluation reports, bulletins, generic letters, information notices, and regulatory guides.

During the Regulation and Guidance Development Stage, coordination with outside organizations such as licensees, certificate holders, industry groups, and the public to elicit potential industry initiatives that could eliminate or supplement needed regulatory actions by the NRC is performed.

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 generic issue, coordination between this MD and MD 6.3, "The Rulemaking Process" will be required. The generic issue TAP in accordance with this MD and the rulemaking plan in accordance with MD 6.3 will need to be coordinated to reduce duplication of effort.

- The appropriate office director (or designee) assigns a responsible project manager for the Regulation and Guidance Development Stage to coordinate activities (both inside and outside NRC) to develop new or revised rules, guidance, or programs to address the generic issue.

- 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 will have to be made to obtain needed expertise. The regulation and guidance development staff should be chosen and approved based on the scope of the generic issue.

- The supervisor of the responsible project manager contacts the supervisors of staff members assigned to perform the regulation and guidance development review to request their assistance.

- The responsible project manager shall prepare and maintain a TAP for activities needed to complete the Regulation and Guidance Development Stage for the generic issue.

- The supervisor of the responsible project manager submits the TAP for the Regulation and Guidance Development Stage, including any substantive revisions, to either the office director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- If needed, NRR develops or revises regulations, guidance, or programs, and with support from RES as appropriate, performs regulatory and backfit analysis for the reactor generic issue based on the technical basis established during the Technical Assessment Stage.

- If needed, NMSS develops or revises regulations, guidance, or programs, and develops regulatory analysis for the materials generic issue based on the technical basis established during the Technical Assessment Stage.

- After draft rules or guidance have been prepared or revised, the CRGR will be briefed if appropriate, and appropriate advisory committees (i.e., ACRS, ACNW, or ACMUI) will be informed by memorandum from the supervisor of the responsible project manager, of corrective actions to address the generic issue.

- Draft regulation, guidance, or program changes shall be peer reviewed, comments addressed, and final corrective actions developed for implementation by licensees and certificate holders, as appropriate. In addition, if a new rule, rule change, addition or change to the standard review plan or regulatory guide is specified as part of the corrective action, it must be issued for public comment with an appropriate Federal Register notice.

- The responsible project manager for the Regulation and Guidance Development Stage prepares the Quarterly Generic Issue Status Report.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to either the office director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- Copies of approved correspondence between the supervisor of the responsible project manager and the appropriate office director shall be sent to the GIP Manager, members of the appropriate Generic Issue Review Panel, and the submitter.

- The Regulation and Guidance Development Stage is complete when:

  - Either the Director of RES (for reactor issues) informs the Director of NRR that the issue should be dropped; new or revised regulations, guidance, or programs have been developed; and/or industry initiatives are accepted, at least in part, to address the generic issue, or

  - NMSS determines whether the issue should be dropped; new or revised regulations, guidance, or programs have been developed; and/or industry initiatives are accepted, at least in part, to address the generic issue.

Regulation and Guidance Issuance Stage

Documents clearly describing the facility or program changes developed during the Regulation and Guidance Development Stage to address the generic issue shall be issued in a timely and effective manner. New or revised regulations require the review and approval of the Commission. Basic guidance documents necessary for regulation and guidance issuance are contained in the References section of this management directive.

- The appropriate office director or designee (NRR for reactor generic issues, and NMSS for materials generic issues) assigns a responsible project manager 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 generic issue.

- The responsible project manager prepares and maintains a TAP for activities needed to complete the Regulation and Guidance Issuance Stage for the generic issue.

- The supervisor of the responsible project manager submits the TAP for the Regulation and Guidance Issuance Stage, including any substantive revisions, to either the office director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- The responsible project manager for the Regulation and Guidance Issuance Stage prepares the Quarterly Generic Issue Status Report.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to either the office director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- Copies of approved correspondence between the supervisor of the responsible project manager and the appropriate office director shall be

sent to the GIP Manager, members of the appropriate Generic Issue Review Panel, and the submitter.

- The Regulation and Guidance Issuance Stage is complete when the Director of RES (for reactor issues) informs the Director of NRR that new or revised regulations, guidance, or programs to address the generic issue have been issued, or when the Director of NMSS (for materials issues) issues new or revised regulations, guidance, or programs to address the generic issue.

Implementation Stage

The objective of the Implementation Stage is to determine whether the licensee or certificate holder has established and is implementing a program to ensure that facility or program changes taken to address a generic issue (e.g., adequate protection issue, substantial safety enhancement issue, burden reduction issue) are effective and in accordance with committments.

The Implementation Stage occurs when the affected licensee or certificate holder perform the actions necessary to implement the regulatory action to resolve the generic issue. These may include modifications or additions to:

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

- The appropriate office director (or designee) assigns a responsible project manager for the Implementation Stage to coordinate the activities (both inside and outside NRC) needed to address generic issue facility or program changes.

- The responsible project manager prepares and maintains a TAP for activities needed to complete the Implementation Stage for the generic issue.

- The supervisor of the responsible project manager submits the TAP for the Implementation Stage, including any substantive revisions, to either the Director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- The supervisor of the responsible project manager 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 the NRC.

- As required by the NRC, each licensee or certificate holder will establish a program, or ensure the effectiveness of its current program, to assess specific vulnerabilities to the generic issue. From this review, a facility or program change plan will be developed. For burden reduction issues, licensees or certificate holders opting to implement the relaxation of requirements, shall notify the NRC with its plans for implementation. The NRC will be notified by letter of the facility or program change plan in accordance with 10 CFR 50.54(f).

- As required by the NRC, each licensee or certificate holder will inform the appropriate NRC program office by letter regarding proposed changes to programs, processes, or equipment, including schedules for implementation. Any substantive changes in the proposed or actual facility or program changes, or the implementation schedule will be reported to the NRC in accordance with 10 CFR 50.54(f). Copies of this correspondence shall be provided to the responsible project manager and the GIP Manager.

- The responsible project manager for the Implementation Stage prepares the Quarterly Generic Issue Status Report.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to either the office director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- Copies of approved correspondence between the supervisor of the responsible project manager and the appropriate office director shall be sent to the GIP Manager, members of the appropriate Generic Issue Review Panel, and the submitter.

- The Implementation Stage is complete for an affected licensee or certificate holder once it has formally informed the appropriate NRC program office that facility or program changes have been implemented.

Verification Stage

The objective of the Verification Stage is to determine whether licensees or certificate holders have adequately demonstrated the efficacy of facility or program changes in addressing the generic issue (e.g., adequate protection issue, substantial safety enhancement issue, burden reduction issue).

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 or certificate holders, and the risk significance of the generic issue, and the complexity of the corrective actions, it may not be necessary to perform a 100 percent inspection of facility or program changes taken to declare a generic issue resolved.

- The appropriate office director (or designee) assigns a responsible project manager for the Verification Stage to coordinate the activities (both inside and outside NRC) needed to address generic issue facility or program changes.

- The responsible project manager prepares and maintains a TAP for activities needed to complete the Verification Stage for the generic issue.

- The supervisor of the responsible project manager submits the TAP for the Verification Stage, including any substantive revisions, to either the Director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- As required by the NRC, each licensee or certificate holder will inform the NRC by letter upon completion of facility or program changes in accordance with 10 CFR 50.54(f). Forwarded information will include the results of analysis, studies, and tests.

- As required by the NRC, changes made to structures, systems, components, processes, and programs to address the generic issue will be documented and provided to the NRC by letter in accordance with 10 CFR 50.54(f), for review, audit, and inspection to verify that appropriate facility or program changes have been completed.

- Verification inspections at licensee or certificate holder facilities will generally be performed by the regions, with assistance from headquarters staff, as appropriate. Due to the technical nature of some generic issues, it may be appropriate to also use expert contractors or staff members.

- Verification inspections will be performed, as appropriate, through Temporary Instructions to assess generic issue facility or program changes.

- If appropriate, and commensurate with the generic issue, the inspector shall verify and document in an inspection report that the licensee or certificate holder has established plans for periodic verification of the continued effectiveness of the facility or program changes in resolving the generic issue.

- If appropriate, and commensurate with the generic issue, NRC region or headquarters staff shall make recommendations for any continuing or routine inspections to be added to the NRC baseline inspection program.

- A copy of each verification inspection report shall be provided to the appropriate NRC program office for review and concurrence prior to issuance.

- If the inspection report's findings indicated that adequate facility or program changes had not been implemented, the NRC shall develop an order and issue it to the affected licensee. The order will require that the affected licensee or certificate holder repeat the Implementation Stage activities. In addition, the NRC shall reinspect the affected licencee or certificate holder for compliance.

- The verification inspection reports shall be provided to the appropriate Generic Issue Review Panel , the responsible project manager, the GIP Manager, and the submitter.

- The responsible project manager for the Verification Stage prepares the Quarterly Generic Issue Status Report.

- The supervisor of the responsible project manager submits the Quarterly Generic Issue Status Report to either the office director of RES (for reactor generic issues) or NMSS (for materials generic issues) for review and approval.

- Copies of approved correspondence between the supervisor of the responsible project manager and the appropriate office director shall be sent to the GIP Manager, members of the appropriate Generic Issue Review Panel, and the submitter.

- 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. Documentation providing the basis for declaring the Verification Stage complete for a specific licensee or certificate holder shall be provided to the GIP Manager for review.

- The Verification Stage is complete for all affected licensees or certificate holders, once:

  - all final verification inspection reports have been issued,

  - the appropriate NRC program office has determined that facility or program changes are adequate to classify the generic issue as resolved, and

  - the responsible project manager prepares a memorandum to the EDO through the GIP Manager and RES, indicating the basis for declaring the generic issue as resolved.

Table 1: Overview of Generic Issue Program for Stages 1-4; Identification and Assessment

GENERIC ISSUE PROGRAM STAGE	INPUT	OUTPUT/OPTIONS	TRACKING DOCUMENTATION	TECHNICAL AND REGULATORY DOCUMENTATION
(1) Identification	-Advisory committees -Inspection reports -Event reports -Investigation reports -Industry concerns -Public concerns -Staff concerns	-Forward to Stage 2 -Candidate Generic Issue Submittal Form (Appendix A)	-Quarterly Generic Issue Status Report	
(2) Initial Screening	-Stage 1 information	-Generic issue classification -Screening results -Unresolved safety issue -Forward to Stage 3 -Forward to another NRC program for review -Dropped **(30 day completion period)**	-Quarterly Generic Issue Status Report	-Reactor or Materials Generic Issue Panel initial screening memoranda providing results and recommendations
(3) Technical Screening	-Stage 2 information	-Screening results -Unresolved safety issue -Dropped **(6 months completion period)**	-Quarterly Generic Issue Status Report -Task Action Plan	-Reactor or Materials Generic Issue Panel memoranda providing results and recommendations -Technical Screening calculation
(4) Technical Assessment	-Stage 3 information	-Technical basis for regulatory actions -Corrective action recommendations	-Quarterly Generic Issue Status Report -Task Action Plan -Temporary Instruction	-Technical Letter Reports, -NUREGs, -NUREG/CRs, -Research Information Letters

Table 2: Overview of Generic Issue Program for Stages 5-8; Facility or Program Change and Verification

GENERIC ISSUE PROGRAM STAGE	INPUT	OUTPUT/OPTIONS	TRACKING DOCUMENTATION	TECHNICAL AND REGULATORY DOCUMENTATION
(5) Regulation and Guidance Development	-Stage 4 information	-Regulation, guidance, and program changes or additions -Forward to Stage 6 -Dropped	-Quarterly Generic Issue Status Report -Task Action Plan	-New/revised ▸ Rules, ▸ Standard Review Plans, ▸ Regulatory Guides, ▸ Bulletins, ▸ Generic Letters, ▸ Inspection programs, ▸ Temporary Instructions -Regulatory analysis -Closure Memoranda
(6) Regulation and Guidance Issuance	-Stage 5 information	-Issuance of new/revised regulation, guidance, and program changes or additions -Forward to Stage 7	-Quarterly Generic Issue Status Report -Task Action Plan	-Rules, -Standard Review Plans, -Bulletins, -Generic Letters, -Inspection Programs, -Temporary Instructions
(7) Implementation	-Stage 6 information	-Monitor licensee/certificate holders for compliance -Forward to Stage 8	-Quarterly Generic Issue Status Report -Task Action Plan	-Licensee/Certificate Holder Response to 10 CFR 50.54(f) letters -Licensee/Certificate Holder Voluntary Responses
(8) Verification	-Stage 7 information	-Review licensee/certificate holder closure documentation -Verification inspections	-Quarterly Generic Issue Status Report -Task Action Plan	-Inspection Reports, -Audit Reports, -Closure Memoranda

Glossary

Adequate Protection Issue. A generic issue which primarily raises questions and concerns on the adequacy of existing NRC requirements and guidance for ensuring adequate protection of public health and safety.

Burden Reduction Issue. A generic issue which 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.

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

Closed. Refers to candidate generic issues or generic issues that have either been dropped from further review, or generic issues that have been resolved.

Dropped. Status assigned to generic issues that are closed because the issue (1) does not warrant expenditure of NRC resources, (2) does not warrant regulatory actions, or (3) is not cost beneficial.

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 appropriately addressed by existing rules, guidance, or programs. A generic issue may be an adequate protection issue, a substantial safety enhancement issue, or a burden reduction issue.

Generic Issue Program Manager. Person responsible for the overall management of the Generic Issue Program.

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

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

Open. Status assigned to generic issues that have not been dropped or resolved.

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

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

Resolved. Status assigned to generic issues that have completed all the process stages of the Generic Issue Program.

Responsible Project Manager. The person assigned to oversee one or more Generic Issue Program Stages for a specific generic issue.

Submitter. An individual or organization that submits a candidate reactor or materials generic issue to the Generic Issue Program Manager, and for review by either the Reactor Generic Issue Review Panel, or the Materials Generic Issue Review Panel.

Substantial Safety Enhancement Issue. A generic issue which primarily results in cost beneficial safety improvements.

Unresolved Safety Issue. 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 the 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.

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Appendix A

Candidate Generic Issue Submittal Form

The content for each section shall be provided by the submitter.

Information	Explanation/Comment (provided by submitter)[1]
(1) Proposed Title	Provide a descriptive title.
(2) Generic Issue Type	[Adequate protection issue, substantial safety enhancement issue, or burden reduction issue]
(3) Description	Provide a description of the proposed generic issue. Briefly discuss the background (bases) of the issue.
(4) Operational Events	List pertinent operational events.
(5) Affected Licensees, certificate holders, or facilities	List the licensees or facilities that are affected and/or include an estimate of the number of licensees or facilities that are affected.
(6) Safety Issue	Discuss the risk potential (i.e., potential contribution to risk, core melt frequency, or public dose). Be as specific as possible in terms of an objectively observable characteristic, such as the presence or absence of a particular design feature.
(7) Possible solutions	Sufficient attention should be devoted to the proposed issue to suggest a possible or alternative solution (e.g., design and hardware changes or additions, procedural changes, changes in plant staffing and/or management, accident management changes).
(8) Affected regulations	List pertinent regulations and regulatory guidance.
(9) Applicable standards	List pertinent consensus standards.
(10) Industry initiatives	List pertinent industry initiatives.
(11) Applicable references	List appropriate references (memoranda, NUREGs, etc.).
(12) Contact	Submitter's name, organization/company, mailing address, e-mail address, and telephone number.

[1]Indicate if information requested is either unknown or does not apply.

Appendix B

Unresolved Safety Issue Screening Criteria

General

An unresolved safety issue is a matter affecting a number of nuclear power plants that poses important questions concerning the adequacy of existing safety requirements for which a final resolution has not yet been developed; an unresolved safety issue 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:

> "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 of 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."

In order to evaluate safety concerns, recommendations, or general safety issues and determine if these should be designated unresolved safety issues 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 judging their impact on risk to the public health and safety.

Initial Screening Criteria

If the response is "true" to any of the criteria listed in Table B1, the generic issue is not an unresolved safety issue.

Table B1. USI Initial Screening Criteria			
	Criteria	T/F	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 six 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.

Candidate Unresolved Safety Issues

If all the responses are "false," the following tables should be used to evaluate the issue's general impact on various factors affecting safety. In order to use the following tables, the issue should be identified as either a deficiency or an improvement, and the issue should be identified as related to operations, equipment, or emergency response.

The questions in the following tables are intended to evaluate the impact of each candidate unresolved safety issue 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 B2:
Possible Major Reduction in Assumed Degree of Protection Related to Equipment Concerns

What is the potential deficiency?

What is the likelihood that the potential deficiency exists?

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

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 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

What is the potential deficiency?					
What is the likelihood that the potential deficiency exists?					
What is the likelihood that the deficiency will result in operator errors?					
Impact on Frequency of Transients/Accidents			**Impact on Safety Function**		
What systems are affected?			What systems are affected?		
What is likelihood that systems will fail due to the deficiency?			What is the likelihood that the systems will fail?		
What transients/accidents could result?			What safety functions are affected?		
What is likelihood these transients/accidents will occur?			What is the likelihood of loss of safety functions?		
Based on the above, would the frequency of transients/accidents be significantly increased by the potential deficiency?			Based on above, is it likely that the deficiency would cause loss of safety function when needed?		
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 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 incorrect actions could result?			What is the likelihood incorrect actions could result?		
Based on above, is it likely that the dose to plant personnel and/or public will be significantly increased due to the potential deficiency?			Based on above, is it likely that the dose to plant personnel and/or public will be significantly increased due to the potential deficiency?			Based on above, is it likely that the dose to plant personnel and/or public can be significantly increased due to 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 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 would be significantly improved?		
Based on the above is it likely that dose to plant personnel and/or public can be significantly reduced by the improvement?			Based on the above is it likely that dose to plant personnel and/or public can be significantly reduced by the improvement?			Based on the above, is it likely that dose to plant personnel and/or public can 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 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

What is the potential improvement?

Impact on Design Basis			Impact on Frequency of Transient/Accidents			Impact on Safety Functions		
			Frequency of what transients/accidents could be reduced?			Reliability of performing what safety functions could be increased by the potential deficiency?		
			What is likelihood these transients/accidents would be reduced?					
Is it likely that a large reduction in risk will result by implementing this design change?			Based on above, is it likely that a large reduction in the frequency of transients/accidents will result from this improvement?			Based on above, is it likely that the safety function reliability will be significantly increased?		
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 USI: Would not provide a potentially significant reduction in risk.

Appendix C

Criteria and Guidance for Technical Screening of Reactor Generic Issues

General

Technical screening evaluates the possible safety implication of the generic issue in a disciplined, quantitative manner. Moreover, the approach is scrutable and more easily defended 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 Screening Stage.

- The intent of the adequate protection issue technical screening 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 necessary for adequate protection.

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

- The intent of the burden reduction issue technical screening calculation is to determine if public health and safety would continue to be adequately protected if the proposed relaxation or reduction in 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.

Approach

- Technical screening 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 generic issue is represented by the reduction in risk that the facility or program changes could achieve. Safety benefit 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 are 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 pre-judge the final facility or program changes.

- For adequate protection and substantial safety enhancement issues, a quantitative estimate is made of the safety benefit (i.e., accident probabilities and radiological consequences) attributable to the issue and the decrease in that risk (i.e., core damage frequency or exposure) that may be attainable by resolving the issue.

- 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.

- For burden reduction issues, the proposed facility or program changes are used to estimate costs and change in risk. For industry proposed burden reduction 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 generic issue should be:

  - **Dropped** - because the safety benefits being sought are not cost beneficial and thus do not warrant expenditure of NRC resources, or

  - **Continued** - to the Technical Assessment Stage because the safety benefits sought may be cost beneficial and thus warrant expenditure of NRC resources.

- The flow chart in Figures C1- C3 illustrates the basic approach for conducting a technical screening for adequate protection issues, substantive safety enhancement issues, and burden reduction issues.

Probabilistic Risk Assessment Guidance for Technical Screening

- Select a surrogate probability risk assessment (PRA). The PRA must be relevant to the reactor generic issue 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.

- Some generic issues may involve situations or phenomena that were not known when the surrogate PRA was performed, so the existing model must be modified. This 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), core damage frequency-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 this is 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 generic issue should be dropped from consideration or realism is not possible because data are not readily available.

- The analysis should explicitly ensure that the truncation level of the base PRA is sufficiently low for calculations of differences (e.g., change in core damage frequency) 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. It should be noted, however, 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 with sufficient detail to enable the analysis 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:

  - a description of the event or issue,
  - its relationship to safety,
  - the calculational approach,
  - a narrative description of the principal accident sequences,
  - the basis for using engineering judgment in lieu of actual data, and
  - 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 Appendices of NUREG-1489, "A Review of NRC Staff Uses of Probabilistic Risk Assessment."

Cost Estimation Guidance for Technical Screening

- 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 discount rate in OMB Circular A-94 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.

- 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 (SERs) 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), transfer payments should be ignored.

- The estimates should be documented with sufficient detail to enable the estimates 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:

  - a description of the issue,
  - the calculational approach,
  - the basis for using professional judgement in lieu of actual data, and
  - a list of assumptions should be listed and justified, including the source of basic data and any mathematical approximations used.

Impact/Value Guidance for Technical Screening

The technical screening 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 generic issue.

To the extent reasonably possible, quantitative estimates are made of the possible solutions to a substantial safety enhancement issue 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 C-6 for thresholds for "drop" and "continue."

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

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

where the safety benefit is the estimated 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 safety benefit is:

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

where N = number of reactors affected by the safety enhancement
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
F = accident frequency reduction (events/reactor- year)
D = averted public dose (person-rem)

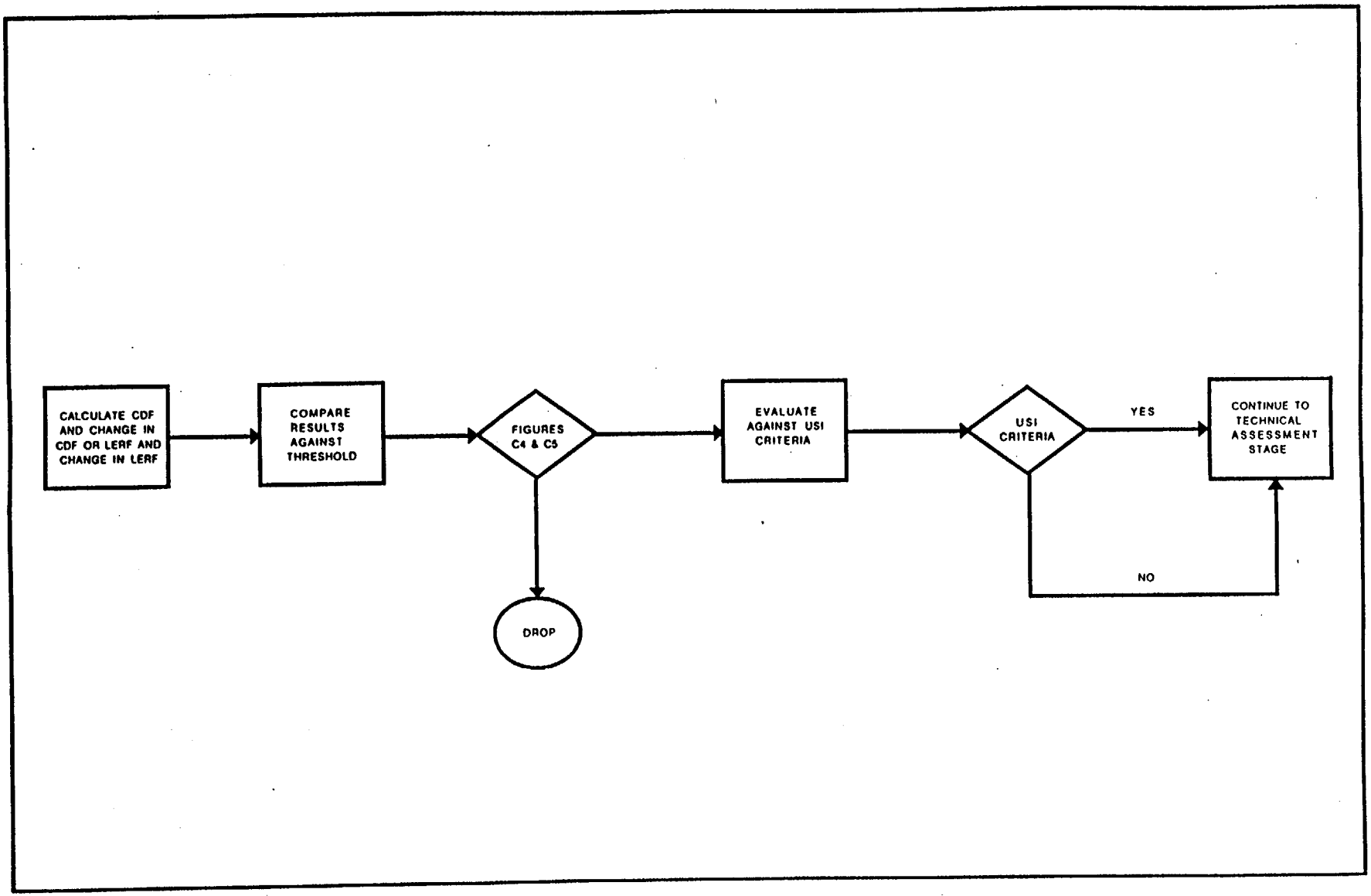

Figure C1: Overview of reactor adequate protection issue; Technical Screening Stage

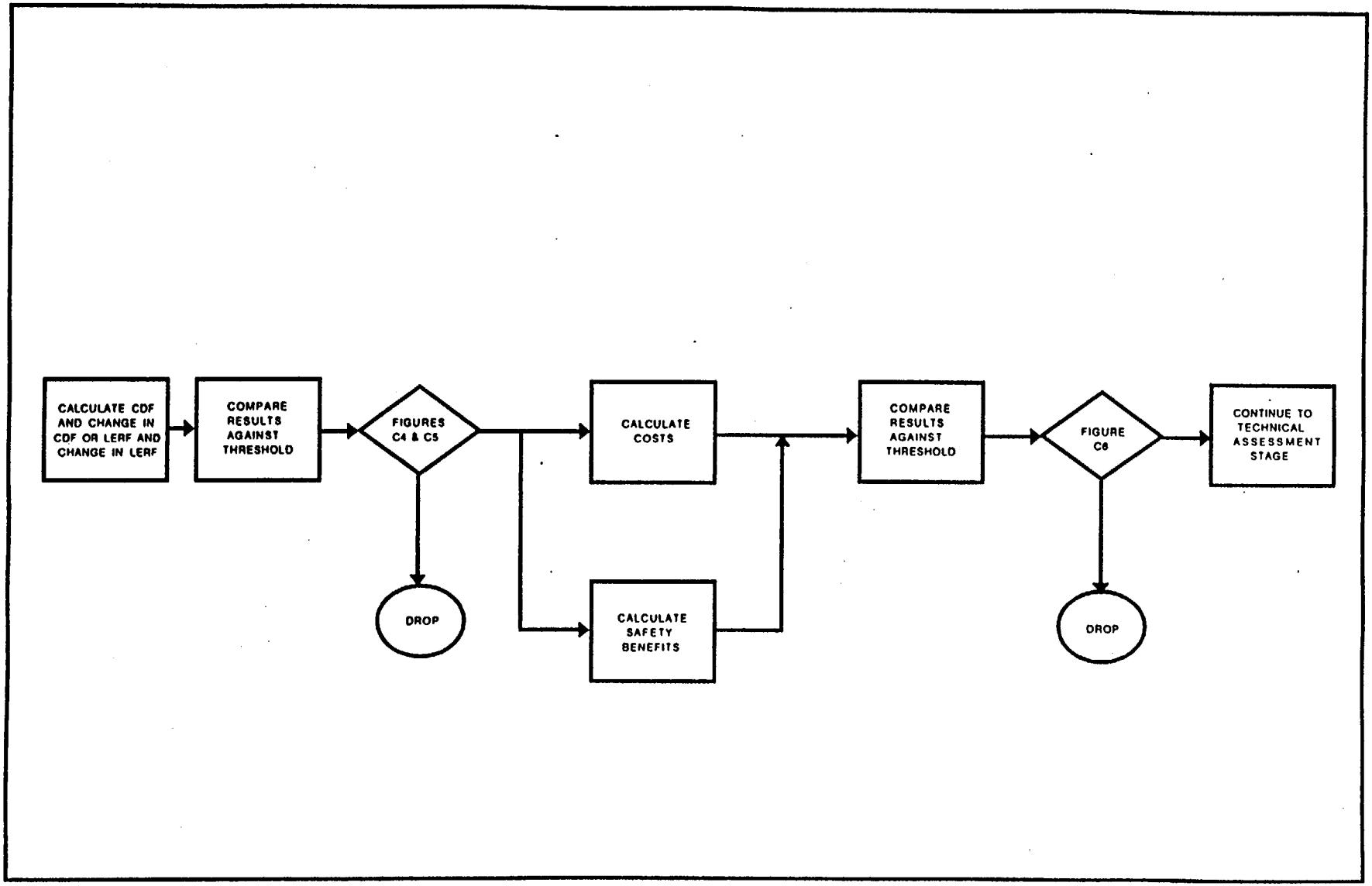

Figure C2: Overview of reactor substantial safety enhancement issue; Technical Screening Stage

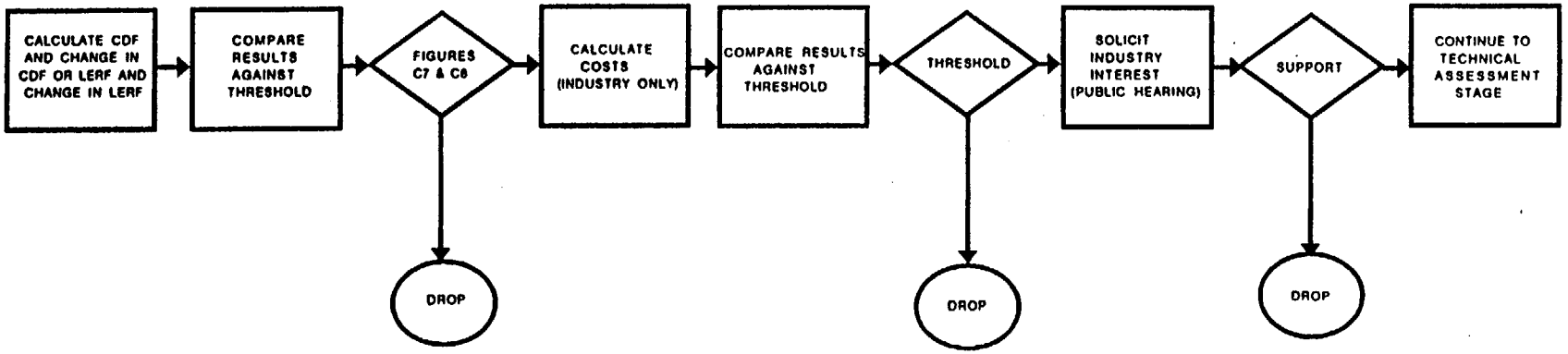

Figure C3: Overview of reactor burden reduction issue; Technical Screening Stage

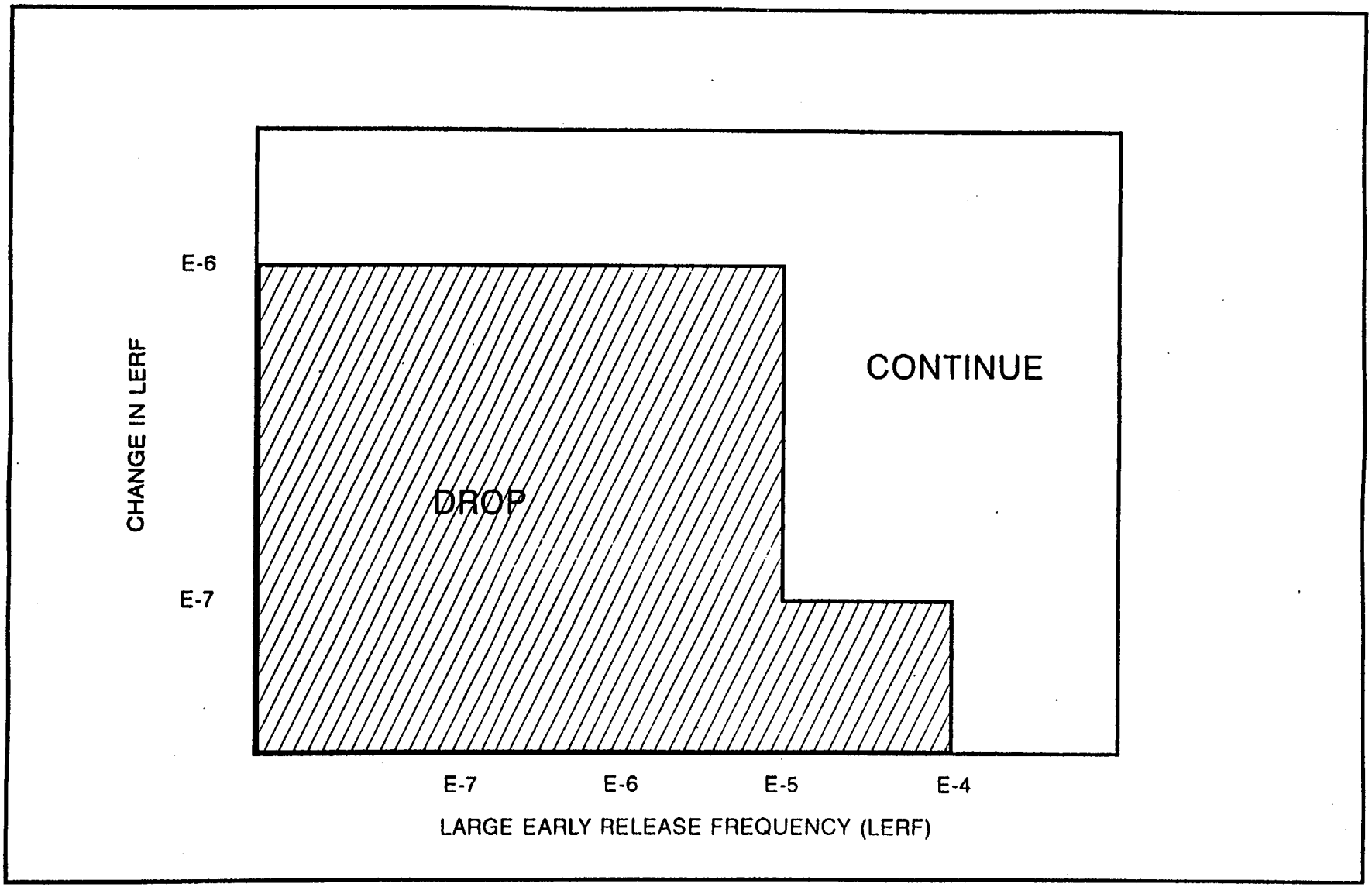

Figure C4: Large Early Release Frequency for reactor adequate protection and substantial safety enhancement issues; Technical Screening Stage

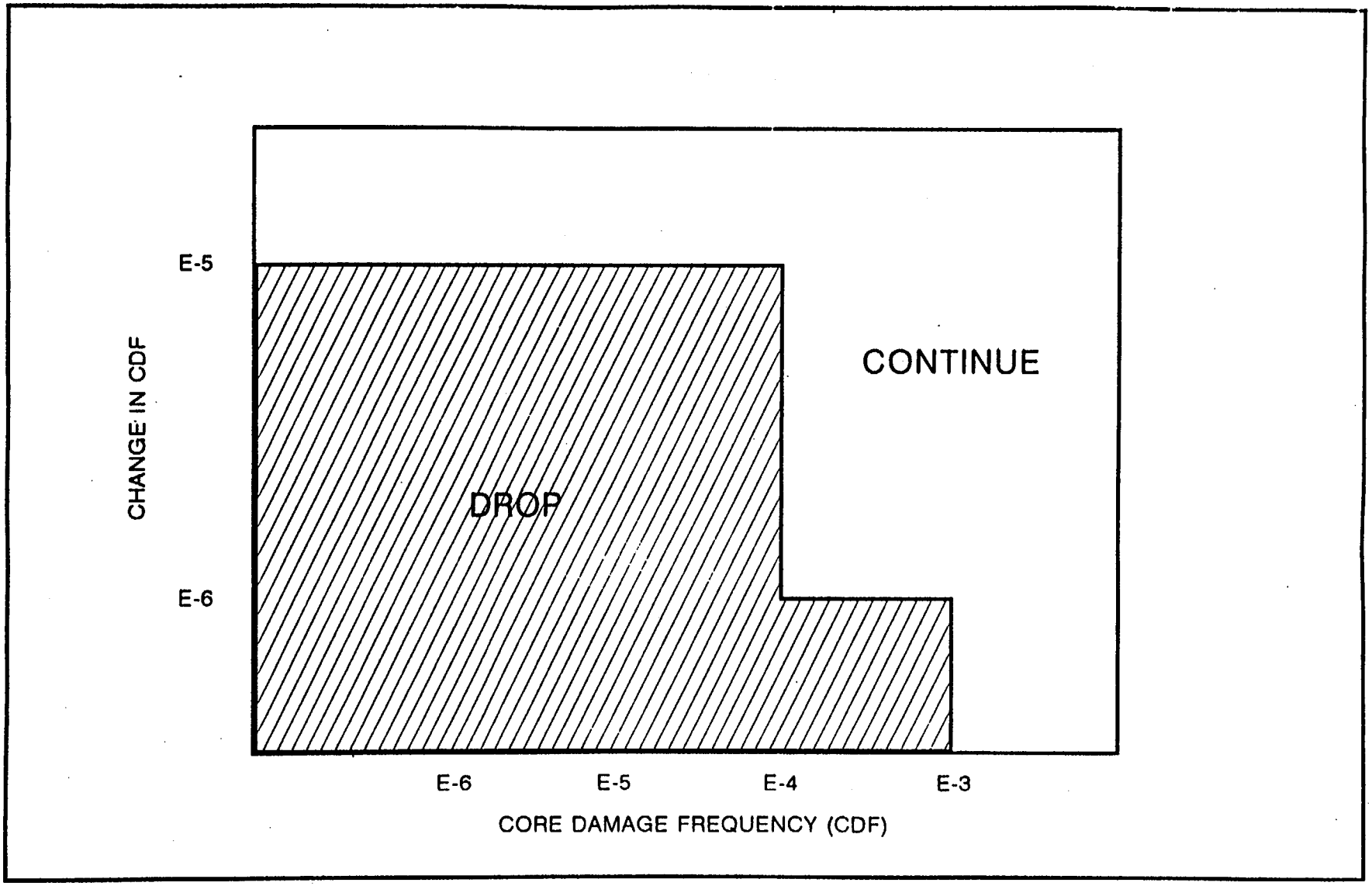

Figure C5: Core Damage Frequency for reactor adequate protection and substantial safety enhancement issues; Technical Screening Stage

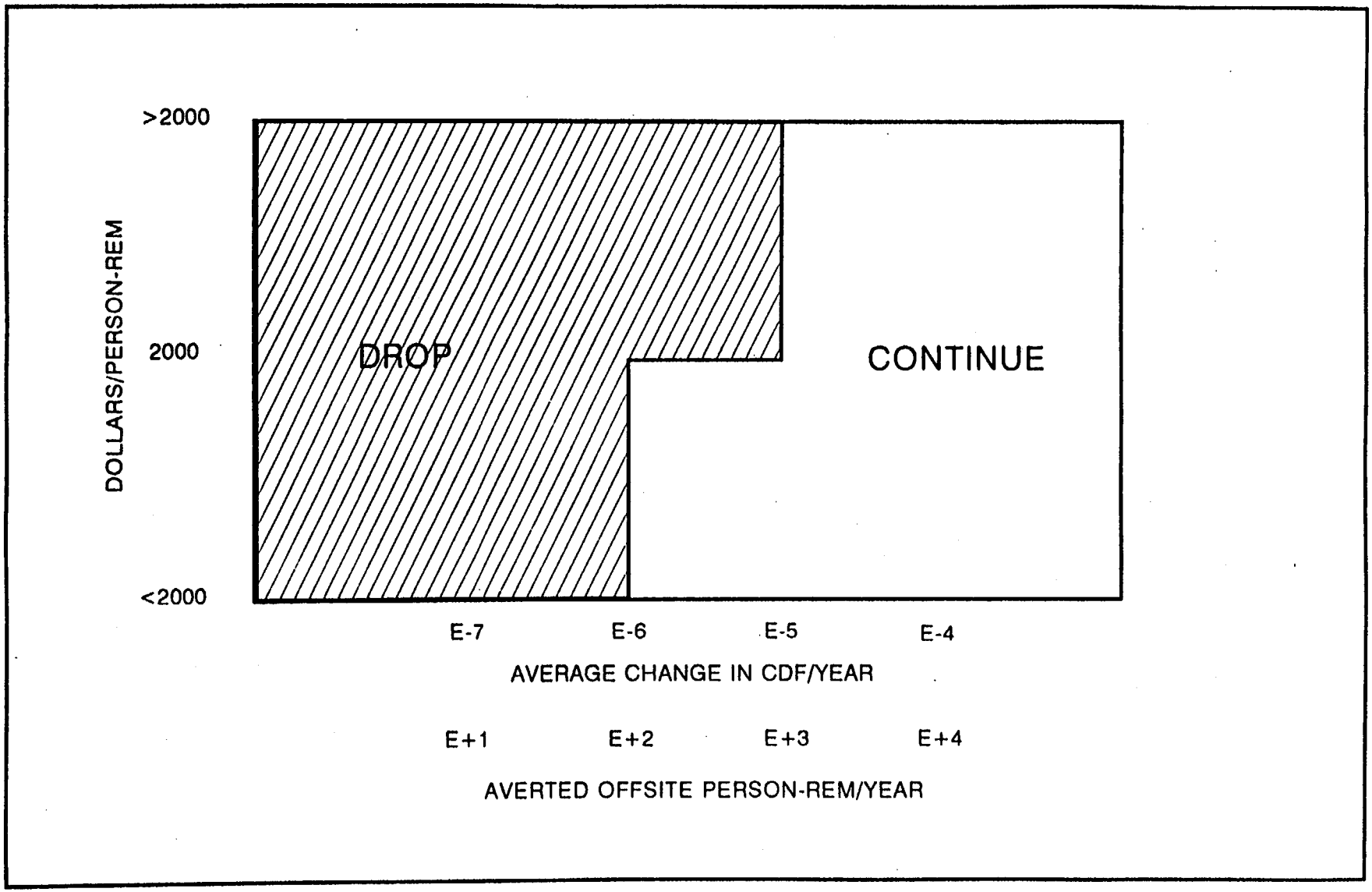

Figure C6: Impact/Value threshold for reactor substantial safety enhancement issue; Technical Screening Stage

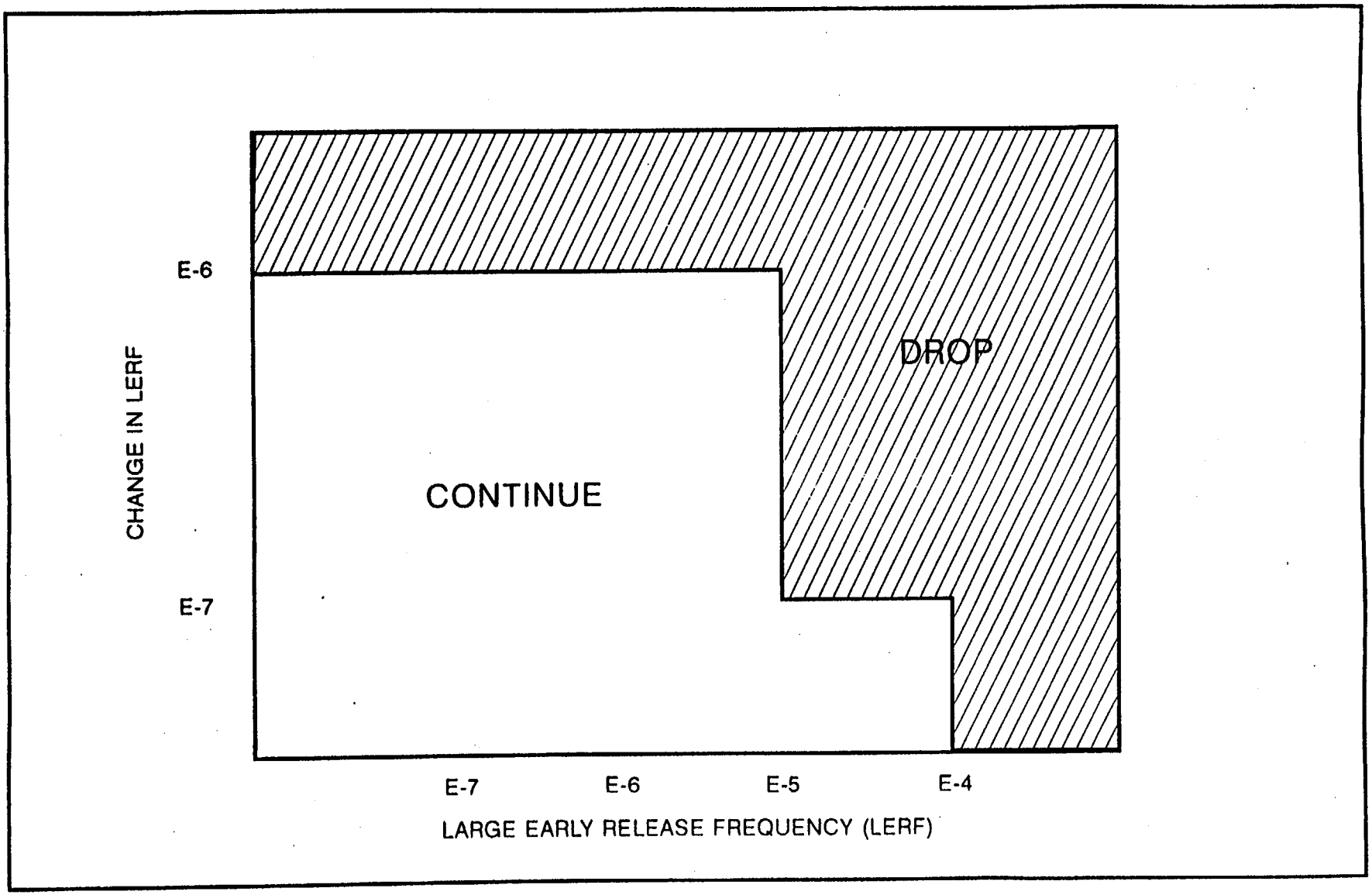

Figure C7: Large Early Release Frequency threshold for reactor burden reduction issue; Technical Screening Stage

Appendix E

Quarterly Generic Issue Status Report

The report content for each section shall be provided by the responsible project manager.

Information	Explanation/Comment[1]
(1) Generic Issue Title	[Provided by Generic Issue Program Manager]
(2) Generic Issue Type	[Adequate protection, substantial safety enhancement, or burden reduction issue]
(3) Generic Issue Stage	List the current Generic Issue Program stage.
(4) Submittal Date	List the submittal date of the generic issue.
(5) Initial Screening Date	List the Initial Screening Stage completion date, or projected date. Include basis for date change from previous report.
(6) Technical Screening Date	List the Technical Screening Stage completion date, or projected date. Include basis for date change from previous report.
(7) Technical Assessment Date	List the Technical Assessment Stage completion date, or projected date. Include basis for date change from previous report.
(8) Regulation and Guidance Development Date	List the Regulation & Guidance Development Stage completion date, or projected date. Include basis for date change from previous report.
(9) Regulation and Guidance Issuance Date	List the Regulation & Guidance Issuance Stage completion date, or projected date. Include basis for date change from previous report.
(10) Implementation Stage Date	List the Implementation Stage completion date, or projected date. Include basis for date change from previous report.
(11) Verification Stage Date	List the Verification Stage completion date, or projected date. Include basis for date change from previous report.
(12) EDO closure memorandum Date	List the EDO closure memo completion date indicating either drop or Verification Stage complete.
(13) Responsible Project Managers	Names of individuals assigned to coordinate processing various stages in the Generic Issue Program.
(14) Technical Assignment Control (TAC) Numbers	List all TAC numbers assigned to the generic issue.
(15) Financial identification number(s)	List all financial identification numbers (FINs) assigned to contracts, if any, for technical assistance.
(16) Affected Regulations	Identify the regulatory documents (e.g., rules, regulatory guides, standard review plans, etc.) that may be affected by the resolution of the generic issue.
(17) Significant Correspondence	Identify significant internal and external correspondence that affected decision-making or that documents decision-making.
(18) Technical Deliverables	Identify reports that have been produced by the NRC staff, NRC contractors, or industry during the processing of the generic issue.
(19) Milestones	List completed milestones from the open Task Action Plan.
(20) Status Summary	Summarize the status of the generic issue. If appropriate for the GIP stage, include individual licensee or certificate holder closure of the generic issue.

[1]Indicate if information requested is either unknown or does not apply.