POLICY ISSUE
(Information)

January 30, 2007 SECY-07-0022

FOR: The Commissioners

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SUBJECT: STATUS REPORT ON PROPOSED IMPROVEMENTS TO THE GENERIC ISSUES PROGRAM

PURPOSE:

To inform the Commission about improvements to the Generic Issues Program (GIP), which the staff of the U.S. Nuclear Regulatory Commission (NRC) will implement to ensure comprehensive and timely resolution of future generic issues (GIs). The staff will implement these conceptual GIP improvements through a revision to Management Directive 6.4, "Generic Issues Program."

BACKGROUND:

In the Staff Requirements Memorandum (SRM), dated August 31, 2005, issued in response to SECY-05-0126, "Summary Of Activities Related To Generic Safety Issues," the Commission directed the staff to develop a plan to focus renewed attention to the GIP that will resolve the older GIs still on the books, and ensure that future GIs are resolved in a timely manner. In response to the SRM, on March 29, 2006, the staff submitted a plan to the Commission (ADAMS Accession #ML053570259), identifying a two-phased approach to improve its timeliness in resolving existing GIs (Phase I), and its intention to perform a more comprehensive and fundamental reevaluation of the GIP (Phase II).

Subsequently, in July 2006, the staff submitted SECY-06-0161, "Summary of Activities Related to Generic Safety Issues." In that summary, the staff reported completion of Phase I with a

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number of accomplishments, and informed the Commission that Phase II had been initiated with a meeting of program office representatives in May 2006. The staff also committed to provide future status updates to the Commission.

DISCUSSION:

As reported in SECY-06-161, the main objective of Phase II is to reevaluate and enhance the current program to significantly reduce the time required to resolve GIs. During Phase II, an inter-office working group representing the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Regulatory Research (RES), the Office of Nuclear Security and Incident Response (NSIR), the Office of Nuclear Materials Safety and Safeguards (NMSS) and the Office of Federal and State Materials and Environmental Management Programs (FSME) examined various aspects of the GIP to identify programmatic and process changes, and develop a consensus approach to make the program more effective. In particular, the working group proposed the following actions to improve the GIP:

(1) Ensure timeliness of issue resolution.

(2) Clarify roles and responsibilities of the participating offices.

(3) Increase participation of the nuclear industry key stakeholders and other stakeholders, as appropriate.

(4) Establish clear interfaces between the GIP and other program office processes and activities used to address GIs outside the GIP.

Objectives

The objective of the proposed improvements is that the new GIP will address only those issues that have significant generic implications related to risk or security that cannot be more effectively handled by other regulatory programs and processes. Toward that end, the staff will also consider whether an issue can be resolved under the existing programs and processes, or by industry initiatives, before beginning assessment under the formal GIP. In addition, for timely and effective GI resolution, a consistent process (i.e., from issue screening to the identification of possible regulatory solution(s)) needs to be uniformly implemented across the offices. Moreover, the roles and responsibilities of the offices, accountability at all stages of GI assessment, and the necessary inter-office interaction need to be clearly defined. The GI assessment process may also involve the participation of key stakeholders, when feasible, to identify the possible regulatory solution(s). Enclosure 1 presents an illustration of the GIP in perspective with other regulatory programs and processes.

Approach

The working group developed the following principles for developing GIP improvements:

(1) Provide centralized leadership for GIP management and strengthen the involvement of regulatory offices (i.e., responsible for implementation of resolutions) in all stages of GIP.

(2) Ensure consistent implementation of the GI assessment process across the offices (i.e., the same process would be applied to address nuclear power reactor issues, nuclear materials and/or radioactive waste issues, and security-related issues).

(3) Enhance the screening process such that the same criteria are consistently applied to identify those issues that are appropriate for the GIP (see Enclosure 2); revise various stages of the GIP; and employ enhanced risk-informed techniques to focus on timely assessment of GIs.

(4) Enhance the staff's ability to resolve issues by using all existing regulatory tools, programs, and processes, with early involvement of key nuclear industry and other stakeholders, as appropriate.

To accomplish these principles of improving the GIP, the following elements will be incorporated in Management Directive 6.4, "Generic Issues Program":

(1) With the appropriate regulatory office involvement, RES will have overall responsibility for GIP management, including routine tracking and documentation of GIP status as well as periodic reporting to Congress and the Commission.

(2) The appropriate regulatory office will have well-defined roles, responsibilities, and accountability in all stages of GI assessment and resolution.

(3) All offices will be involved with applying the screening criteria to identify issues that are suitable for the GIP. Issues for which the risk or safety significance cannot be adequately determined due to phenomena or other uncertainties, and would require long-term studies and/or experimental research to establish the risk or safety significance will be excluded from the GIP, consistent with current processes specified in MD 6.4.

(4) Issues, particularly high-risk issues, that should be addressed by other NRC programs and processes or industry initiatives, will be appropriately directed to those programs and processes. The role of the GIP will be clarified with the roles of other programs that address the concerns of employees and stakeholders such as the Differing Professional Opinion (DPO) Program and the Allegation Program to ensure that GIP does not serve as an alternative to these programs.

(5) To gain efficiency and effectiveness and improve timely assessment of GIs, the staff will employ enhanced risk-informed techniques, which have already been developed as part of other established programs (e.g., the Accident Sequence Precursor [ASP] Program).

(6) RES will ensure necessary inter-office coordination throughout the process. After the issue is screened in as a formal GI, the GIP will consider participation by nuclear industry stakeholders, when feasible, to identify possible solutions (e.g., a regulatory product or industry initiative).

(7) The GI process will be concluded when the regulatory product is identified. The regulatory office will proceed, under other established programs and processes, to develop and implement the identified regulatory solution, and perform appropriate verification.

With the above programmatic improvements, the staff is targeting to complete formal GI assessments within 1-2 years. In some cases, depending upon the technical complexity of the individual issue, the GI assessment process may require additional time. Such cases will be noted in annual reports to the Commission. Enclosure 3 compares the existing GIP and the new GIP, highlighting the potential impact of the proposed improvements.

The staff's routine tracking and documentation of GIP status will be specified in MD 6.4 and other Program Office Instructions, as appropriate.

Management Directive 6.4 is currently being revised to implement these conceptual improvements. The identification, treatment, and processing of new Unresolved Safety Issues (USIs) will also be addressed in the revision of MD 6.4. As a result, the GI and USI assessment processes will be consistently applied across the offices for processing these issues in a comprehensive and timely manner. The staff will keep the Commission apprised of any significant developments in the implementation of its plan to focus renewed attention to the GIP.

RESOURCES:

Total resources required for this activity are $1,600K and 7.0 FTE in FY 2007, and $2,050K and 6.7 FTE in FY 2008. These resources are included in the budgets for FY 2007 and FY 2008 as follows: FY 2007 - RES $1,600K and 6.0 FTE, NRR 0.4 FTE, NMSS 0.2 FTE, FSME 0.2 FTE, and NSIR 0.2 FTE; and FY 2008 - RES $2,050K and 5.7 FTE, NRR 0.4 FTE, NMSS 0.2 FTE, FSME 0.2 FTE, and NSIR 0.2 FTE.

COORDINATION:

The Office of the General Counsel has reviewed this package and has no legal objection. The Office of the Chief Financial Officer has also reviewed this package and has no objection.

/RA/

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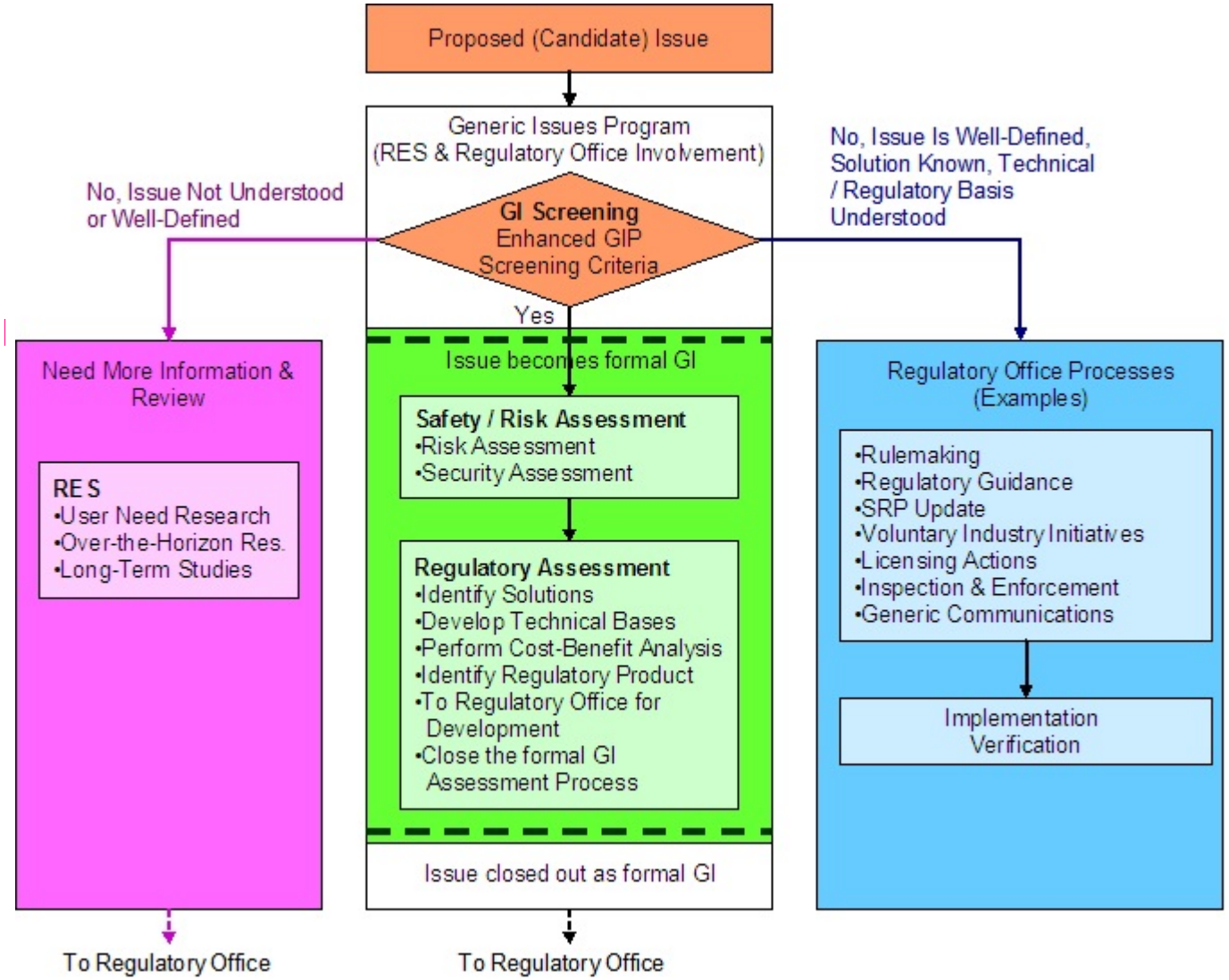
Enclosures:
1. Generic Issues Program in Perspective with Other Regulatory Programs and Processes
2. Guidance on Enhanced Issue Screening Criteria
3. Comparison of the Main Attributes of the Existing and Proposed Generic Issue Program (GIP) and Resulting Program Improvements

Generic Issues Program in Perspective with Other Regulatory Programs and Processes



Enclosure 1

Guidance on Enhanced Issue Screening Criteria

The safety / risk and regulatory assessment stages of a formal GI will address only those issues that meet the following criteria.

- The issue affects public health and safety, the common defense and security, or the environment.
- The issue applies to two or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals.
- The issue cannot be readily addressed through other regulatory programs and processes; existing regulations, policies, or guidance; or voluntary industry initiatives.
- The issue can be resolved by new or revised regulation, policy, or guidance.
- The issue's risk or safety significance can be adequately determined (i.e., it does not involve phenomena or other uncertainties that would require long-term studies and/or experimental research to establish the risk or safety significance).
- The issue is well-defined, discrete, and technical.
- Resolution of the issue may potentially involve review, analysis, or action by the affected licensees, certificate holders, or holders of other regulatory approvals.

Comparison of the Main Attributes

Steps in the Generic Issue (GI) Resolution Process		Resulting GIP Improvements
Existing GIP	**Proposed GIP**	
GI Identification: Designate the proposed (candidate) issue as a GI **Average:** 1 month	**GI Screening:** Apply the Enhanced Screening Criteria to the proposed (candidate) issue. A candidate issue becomes a GI only if it meets the screening criteria **Target Duration:** 2 months	Consistency will be ensured as all offices will use the same screening criteria for GI identification: • Issues involving user need research (long-term studies or over-the-horizon research) will be provided to the appropriate program • Only those issues will be included that are well-defined and discrete; cannot be handled more effectively by other programs; are not covered by the existing regulations, policy or guidance; and have possible solution(s)
Technical Screening: Assess risk or security significance **Average:** 2 years	**Safety / Risk Assessment:** Conduct risk or security assessment using enhanced risk-informed techniques **Target Duration:** 4 months	• Program office will be directly involved. • Cooperation between RES and the program office(s) will be enhanced • Use of tailored risk-informed techniques already developed as a part of other established program [e.g., Accident Sequence Precursor (ASP)] • Issues involving low risk- or security-significance will be excluded • In some cases existing models may need to be supplemented to perform a credible risk assessment (may take more than 4 months).
Technical Assessment: • Identify regulatory solution • Develop technical basis **Average:** 8 years	**Regulatory Assessment:** • Identify regulatory solution(s) • Develop technical basis • Conduct cost-benefit or backfit analysis, as appropriate • Send to the regulatory office for regulatory product development **Target Duration:** 1-2 years	With the program office leading the effort: • Greater interaction between the offices, as necessary • When feasible, an option of inviting participation from key nuclear industry stakeholders, or other stakeholders, early in the process to identify regulatory solution(s) • Flexible process to permit use of all available tools to ensure timely GI resolution • RES to assist, as necessary, in developing technical basis for the regulatory solution(s)
Regulatory Product Development **Duration:** Varies **Issuance of new or revised regulation and/or guidance** **Duration:** Varies **Implementation** **Duration:** Varies **Verification** **Duration:** Varies	N/A	• The GIP will remain separate from, but will complement, other regulatory processes • The formal GI process will end after the technical assessment stage, when the technical assessment establishes the technical basis for the regulatory solution and the program office begins the regulatory product development • The program office will complete development of the regulatory product, and ensure its implementation and verification – outside the GIP • Routine tracking and documentation of GIP status, individual GIs, and candidate GIs will be specified in MD 6.4 and other Program Office Instructions, as appropriate
The GI Resolution Process continues through Implementation and Verification. **Total Duration:** 5 – 10 years	**The GI assessment process ends** with regulatory assessment – when the technical basis for the regulatory solution(s) is identified. **Target Duration:** 1–2 years	• In most cases, shorter technical assessment time; no long-term studies or research • In some instances, technical assessment may take longer because more complex issues may be processed under the GIP • The regulatory office will ensure GI resolution and closure of the issue • Implementation and verification processes will be conducted outside the GIP