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Effects of Generic Issues Program on Improving Safety

Mehdi Reisi Fard and John V. Kauffman
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Tel: 301-251-7490, Fax: 301-415-5389, Email: mehdi.reisifard@nrc.gov

Abstract – *The U.S. Nuclear Regulatory Commission (NRC) identifies (by its assessment of plant operation) certain issues involving public health and safety, the common defense and security, or the environment that could affect multiple entities under NRC jurisdiction. The Generic Issues Program (GIP) addresses the resolution of these Generic Issues (GIs). The resolution of these issues may involve new or revised rules, new or revised guidance, or revised interpretation of rules or guidance that affect nuclear power plant licensees, nuclear material certificate holders, or holders of other regulatory approvals.*

U.S. NRC provides information related to the past and ongoing GIP activities to the general public by the use of three main resources, namely NUREG-0933, "Resolution of Generic Safety Issues," Generic Issues Management Control System (GIMCS), and GIP public web page. GIP information resources provide information such as historical information on resolved GIs, current status of the open GIs, policy documents, program procedures, GIP annual and quarterly reports and the process to contact GIP and propose a GI.

This paper provides an overview of the GIP and several examples of safety improvements resulting from the resolution of GIs. In addition, the paper provides a brief discussion of a few recent GIs to illustrate how the program functions to improve safety.

I. INTRODUCTION

The Generic Issues Program (GIP) is one of many programs within the NRC's regulatory framework for handling emergent issues. Certain issues involving public health and safety, the common defense and security, or the environment that could affect multiple facilities or holders of regulatory approvals have been identified by this program. Resolution of these Generic Issues (GIs) has been pursued, tracked and documented under GIP.

A GI is formally defined as "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." NRC staff developed the GIP in response to Commission and Congressional directives in 1976 and 1977, respectively. By these directives, NRC staff was asked to develop a program plan for resolution of GIs and completion of technical projects. The developed program provided for the identification of GIs, the assignment of priorities, the development of detailed action plans, projections of costs, continuous high level management oversight of progress and public dissemination of information related to the issues as they progressed. The process of handling GIs has been modified several times since the inception of the program in the late 1970s. More than 850 generic issues have been identified by the program to date, which have resulted in a variety of regulatory products.

This paper provides an overview of the historical and current GIP processes used to resolve GIs along with a discussion of regulatory products, which have been resulted from resolution of issues. In Section II, an overview of the both historical and current GIP processes are presented. This section also includes a discussion of the recent changes and improvements in the program. In Section III a discussion of the various GIP products and program's historical performance are provided. In Section IV, sources of publicly available information that are utilized to track, document and disseminate information related to GIP activities are presented.

II. GIP PROCESS OVERVIEW

After issuance of a Policy Statement in 1978 that introduced and outlined the GIP, this NRC program underwent many reviews and changes. The process used to resolve the issues has been described in reports, Office Letters, Commission Papers and recently in Management Directive (MD) 6.4.[1] Since 1999, the guidance in MD 6.4 provides a useful, consistent framework for handling, tracking, and defining the minimum documentation associated with the processing of GIs. Different stages of the program are defined by procedures. However, because of the varying technical disciplines and levels of difficulty, the flexibility is built in the program to address various issues.

II.A. Historical GIP Processes

During the early years of the program, a few different methods were used to implement the generic issues program and to classify generic issues. The first attempts by the NRC staff to classify generic issues were qualitative and based largely on engineering judgments. Later in 1978, the NRC staff began to take a quantitative approach by using risk assessment to place the issues into various risk categories. With increased confidence in this risk assessment approach, the NRC staff introduced a more comprehensive quantitative system in early 1979. In the aftermath of the Three Mile Island Unit 2 (TMI-2) accident, a quantitative "prioritization" methodology was developed, which would assign a numerical priority score to each generic safety issue. With this approach, priorities were based on an evaluation of the estimated risk reduction associated with the potential change in requirements that could result from resolution of an issue, and the estimated costs to the NRC and the industry in implementing such a change. This method of prioritization was used from 1983 to 1999. In this period, the program was prioritizing the identified issues into four priority rankings of HIGH, MEDIUM, LOW, and DROP. Only those issues that were prioritized as HIGH and MEDUIM proceeded to the resolution stage. Following the identification, prioritization and resolution stages, issues proceeded through three distinct stages of imposition, implementation, and verification. More than 300 issues were prioritized in this period.

II.B. Current GIP Process

Beginning in June 1999, the method of prioritizing GIs was replaced with the screening process of MD 6.4,[1] and the NRC staff discontinued using priority rankings. In the new process, as explained in the current version of MD 6.4,[1] the GIP process consists of five stages, 1) identification, 2) acceptance review, 3) screening, 4) safety/risk assessment, and 5) regulatory assessment. The GIP staff members apply a "graded approach" throughout the process, i.e. as an issue proceeds through the program, more resources are devoted to it. Similarly, more safety significant issues receive more resources and priority than less significant issues. Essentially, stages 2-5 are each a progressively more rigorous application of the GIP criteria. In this section, a brief description of each stage is explained. MD 6.4[1] contains a detailed description of these stages.

1) Identification: Generic issues may be proposed by the general public or NRC staff. GIs may also result from NRC programs and processes, such as the Operating Experience Program. A member of the public who has an issue that they believe should be treated as GI should go to the NRC public website (http://www.nrc.gov/about-nrc/regulatory/gen-issues.html) and follow the instructions for completing and submitting the form. The form guides the submitter through the GIP criteria and also provides information for GIP staff to understand the issue. The Identification Stage occurs essentially outside the GIP, so it has no target duration. Once the GIP staff is satisfied that the form is complete, the Identification Stage is completed. The issue is assigned a "Pre-GI" tracking number, and it proceeds to the Acceptance Review Stage. GIP and regulatory office staff members review the information provided on the submittal form and perform a limited assessment of the information. Based on this assessment, the NRC staff makes a recommendation regarding further processing.

2) Acceptance Review: The Acceptance Review Stage has three possible outcomes: 1) the issue does not meet the GI criteria and does not warrant further GIP processing, 2) the issue is transferred to another office program for action, or 3) the issue proceeds to the GIP Screening Stage. GIP staff informs the originator and the responsible program office of the outcome. The GIP staff does not include information on proposed GIs in routine reports.

3) Screening: A GIP staff member is assigned as a responsible project manager (RPM) to assess the issue. The RPM collects information, typically including a literature search and duplication review against other GIs. The RPM may also request and utilize resources outside the GIP for complex issues. The RPM prepares and documents a screening analysis, including a recommendation for further actions to a review panel. The panel reviews the screening analysis and provides a consensus recommendation to the Director of the Office of Nuclear Regulatory Research (RES) for endorsement. The Screening Stage has three possible outcomes: 1) the issue does not meet the GI criteria and does not warrant further GIP processing, 2) the issue is transferred to another office program for actions, such as rulemaking or licensing actions or is addressed by a voluntary industry initiative, or

3) the issue proceeds to the GIP Safety/Risk Assessment Stage. GIP staff informs the originator and the responsible program office of the outcome. The GIP staff does not include information on proposed GIs in routine reports. A proposed GI that proceeds to the Safety/Risk Assessment Stage becomes a formal GI, is given a GI number, and continues to be tracked and is now included in routine reports. For pre-GIs that are screened in, GIP staff prepares a Communication Plan to manage agency communication of the issue.

4) Safety/Risk Assessment: The RPM develops a plan, including detailed schedule, milestones and responsibilities necessary to determine the risk to safety or security of the GI in order to determine if the GI merits enhanced regulation. The plan may contain matrix or contractor support, as necessary. The RPM prepares and documents a safety/risk assessment, including a recommendation for further actions to a review panel. The RPM interfaces with the agency's review committees and solicits their involvement, as appropriate. The panel reviews the safety/risk assessment and provides a consensus recommendation to the RES Director for endorsement. The Safety/Risk Assessment Stage has two possible outcomes: 1) the issue does not warrant further GIP processing, and is either closed with no further action, or is closed with follow up actions such as regulatory office implementation, research activities, or industry initiatives, or 2) the issue proceeds to the GIP Regulatory Assessment Stage. GIP staff informs the originator and the responsible program office of the outcome. The GIP staff updates the Communication Plan for the issue. A GI that proceeds to the Regulatory Assessment Stage, or that is transferred to another program office continues to be tracked and included in routine reports.

5) Regulatory Assessment: The RPM develops a plan, including detailed schedule, milestones and responsibilities necessary to identify and develop regulatory solutions for the GI. One of the key activities of the regulatory assessment is performance of a backfit analysis to develop the justification necessary for imposition of a regulatory solution. The plan may contain matrix or contractor support, as necessary. The RPM prepares and documents a regulatory assessment, including a recommendation for further action to the RES Director. The RPM interfaces with the agency's review committees and regulatory offices and solicits their involvement, as appropriate. The Regulatory Assessment Stage has two possible outcomes: 1) the issue does not warrant further GIP processing, and is either closed with no further action, or is closed with follow up actions such as regulatory office implementation, research activities, or industry initiatives, or 2) the regulatory solution is provided to the regulatory office for development, implementation, and verification. In any case, the GI ceases to be a formal GI and exits the GIP at completion of this stage. GIP staff informs the originator and the responsible program office of the outcome. The GIP staff updates the Communication Plan for the issue. A GI in the Regulatory Assessment Stage is tracked and continues to be included in routine reports. The status of issues transferred to program offices is reported and tracked until the program office completes the associated actions.

II.C. GIP Improvement

Historically, actions to resolve some GIs were not completed for many years. The lengthy resolution process for these issues resulted from a variety of reasons, including issues entering the program that did not belong, such as research projects; scope growth; overly broad topics; complex issues, a prioritization scheme that kept low priority issues in the program but did not actively work them; and a program that included additional stages (implementation and verification) that can be lengthy. To address this problem, the NRC staff informed the Commission of proposed improvements to the GIP in SECY-07-0022.[2] The improvements were developed by an inter-office working group. The working group proposed actions to: 1) ensure timeliness of issue resolution, 2) clarify roles and responsibilities of the participating offices, 3) increase stakeholder participation, and 4) establish clear interfaces between the GIP and other program office processes and activities used to address GIs outside the GIP. These changes have been incorporated in the latest revision of MD 6.4.[1] In this section, results of the improvements in the program are discussed.

GIs tend to involve complex questions of safety and regulation. The efficient and effective means of addressing these issues is very important for regulatory effectiveness. If an issue proves to pose a genuine, significant safety question, then swift, effective, enforceable, and cost-effective action needs to be taken. Conversely, if an issue is of little safety significance, the issue should be dismissed in an expeditious manner, avoiding unnecessary expenditure of resources and regulatory burden or uncertainty. GIP staff improved the effectiveness of the program in 2007 by implementing a number of improvements such as using the GIP screening criteria. The GIP screening criteria and process are intended to control GIP entry and assist in identifying the appropriate agency program for those issues that do not belong in the GIP. The criteria apply throughout the GIP. When an issue clearly does not satisfy at least one criterion, the issue exits the program. By implementing these criteria, NRC staff determines effectively which issues belong to the program. To become a formal GI, an issue must meet the following seven criteria: 1) a well-defined, discrete, technical or security issue, 2) the risk/or safety significance of which can be adequately determined, and which 3) applies to two

or more facilities and/or licensees/certificate holders, or holders of other regulatory approvals (including design certification rules); 4) affects public health and safety, the common defense and security, or the environment; 5) is not already being processed under an existing program or process; 6) cannot be readily addressed through other regulatory programs and processes, existing regulations, policies, guidance, or voluntary industry initiatives; and 7) can be resolved by new or revised regulation, policy, or guidance or voluntary industry initiatives.

As a result of the changes to the program, timeliness and effectiveness of the program have significantly improved. As an example of these improvements, Fig. 1 shows the time needed to complete the screening process for issues that were identified at three different periods. As explained earlier, before 1999, GIP staff was using the prioritization method to rank the issues. Between 1999 and 2007, the prioritization method was replaced with the screening stage. After 2007, GIP staff started implementing the seven screening criteria and the other

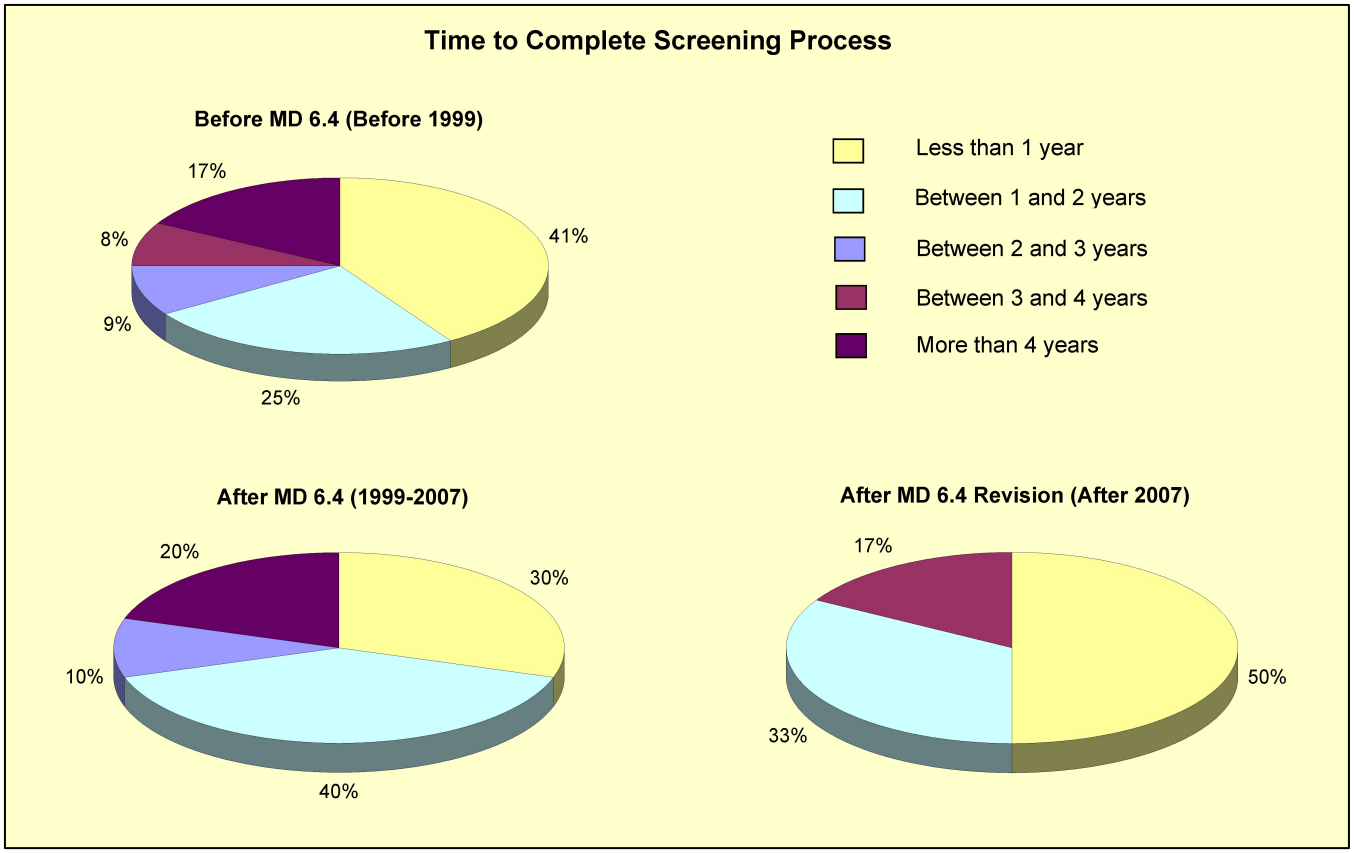

Fig 1. Time to complete the screening process

In addition to establishing the screening criteria, a number of other actions were taken to improve the timeliness and effectiveness of the program. Some of these actions include centralizing GIP management within the NRC Office of Nuclear Regulatory Research, defining roles, responsibilities, and accountability for all GIP stages, increasing stakeholder involvement by the explicit consideration of participation by nuclear industry stakeholders, and shortening the GIP process by ending the process when the regulatory product is identified.

improvements introduced in SECY-07-022.[2] As shown in Fig. 1, the screening stage was completed faster as a result of changes in the program. Recent performance (since January 2007) indicates the success of these changes.

A number of other improvement actions were also taken, which were described in other publications by the GIP staff. [3]

III. GIP PRODUCTS

Through the resolution of generic issues, GIP has contributed significantly to the NRC's mission, which is to "regulate the nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, to promote the common defense and security, and to protect the environment." GIP contributes to NRC's mission by creating a wide range of regulatory products. Because of the diverse nature of topics that have become GIs, a variety of products have been developed to resolve generic issues. Regulatory products resulting from the resolution of generic issues include establishing new rules and policies, publishing generic communications such as generic letters and information notices, and publishing regulatory guides and NUREGs. In this section, GIP products and their impact on improving the safety and security are discussed.

Many of Generic Issues that proceeded to the screening stage have resulted in regulatory products. As explained in Section II, historically, generic issues were prioritized according to a numerical priority score. Only issues that were prioritized as USI, HIGH, MEDIUM, or Nearly Resolved proceeded to the resolution stage. Therefore, only issues in these four categories could potentially result in a regulatory product. In the new process, all the issues with the status of CONTINUE, which indicates that they have not failed any of the screening criteria, could potentially lead to a regulatory product. About 300 issues proceeded to the resolution stage and could have resulted in a regulatory product. These products are divided into four broad categories: 1) new policies and rules, 2) generic communications, 3) regulatory guidance and 4) no direct requirement but associated actions that allowed the resolution. In addition, a portion of issues were resolved with no requirements.

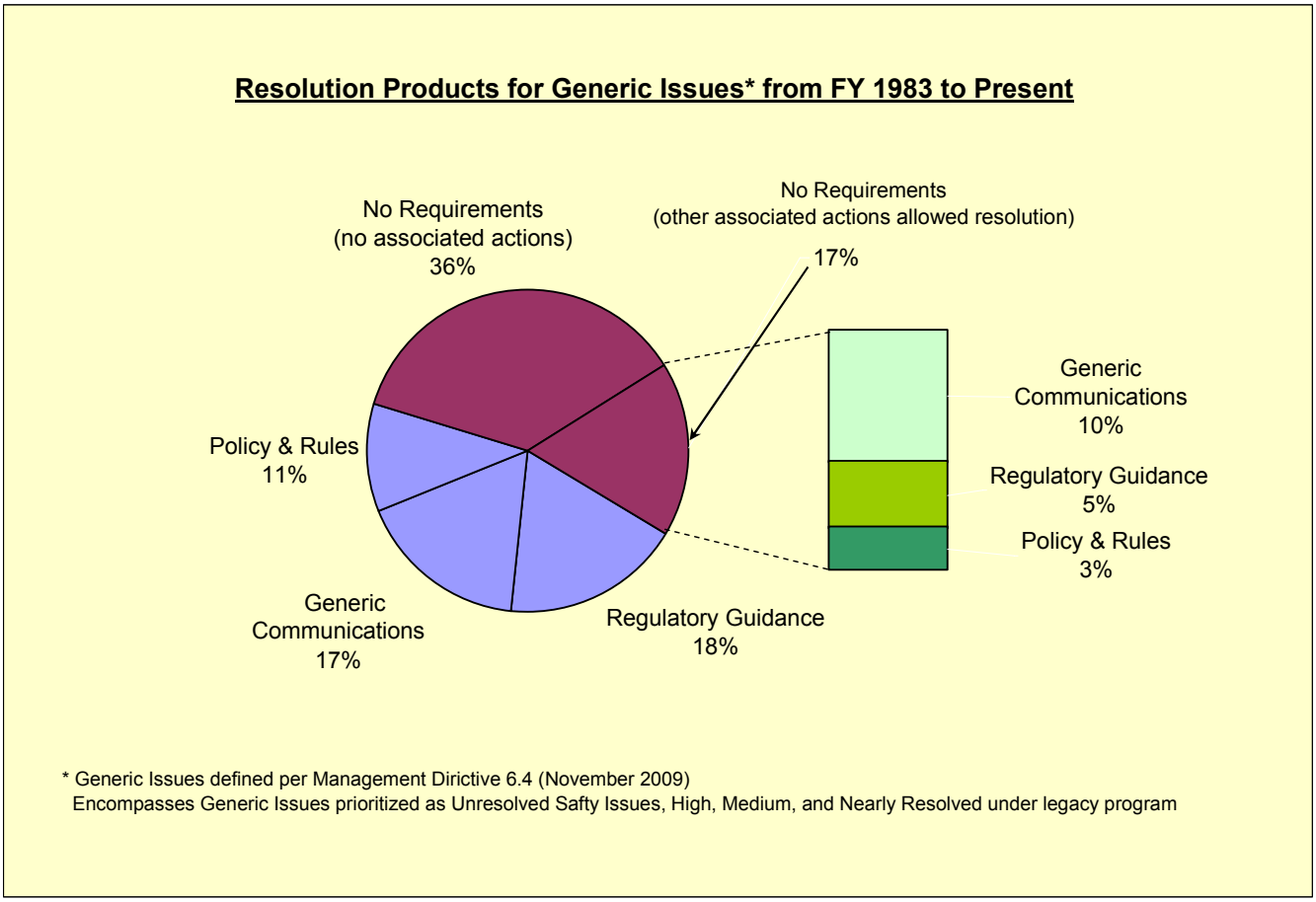

Fig. 2. Breakdown of resolution products for Generic Issues

Fig. 2 shows a breakdown of resolution products for generic issues processed under the GIP from 1983 to 2009.

By establishing a number of new policies and rules, GIP has directly contributed to NRC's mission to regulate the nation's civilian use of byproduct, source, and special nuclear materials. For instance, Issues A-9, "ATWS," [4] and A-44, "Station Blackout," [5] are two examples of issues that resulted in establishment of important rules along with a number of other regulatory products. Technical findings for resolution of Item A-9 were published in Volume 4 of NUREG-0460[6] and the issue was resolved with the publication of a new rule (10 CFR Part 50.62, "Reduction of Risk from Anticipated Transients Without Scram (ATWS) Events for Light-Water-Cooled Nuclear Power Plants") in June 26, 1984. For Item A-44, the final evaluation of station blackout accidents at nuclear power plants was performed by the NRC staff and published in NUREG-1032.[7] In resolving Item A-44, "Station Blackout," a regulatory analysis was performed and documented in NUREG-1109.[8] In June 1988, this issue was resolved with publication of a new rule (10 CFR 50.63) and Regulatory Guide 1.155.[9] Both ATWS and Station Blackout rules have significantly improved the safety of nuclear power plants.

In addition to establishing new policies and rules, resolution of issues has resulted in issuance of numerous generic communications. These generic communications include bulletins, generic letters, regulatory issue summaries, information notices, and staff reports. Information Notices are issued to addressees to provide significant recently identified information about safety, safeguards, or environmental issues. Addressees are expected to review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. By issuance of generic letters, NRC staff requests that addressees perform analyses or submit descriptions of proposed corrective actions regarding matters of safety, safeguards, or the environment. Addressees of a generic letter may also be required to submit technical information that NRC needs to perform its functions or submit proposed changes to technical specifications. By a generic letter, the NRC may also provide the addressees the technical or policy positions not previously communicated or broadly understood or solicit participation in voluntary pilot programs. As shown in Fig. 2, the resolution of a number of GIs has resulted in issuance of generic letters and information notices, which has improved the safety and security by identifying and communicating the potential safety concerns and, in some cases, imposing actions to address them.

Issuance of regulatory guides is the third category of GIP regulatory products. This category includes two main regulatory products namely regulatory guides and NUREGs. Regulatory guides provide guidance to licensees and applicants on implementing specific parts of the NRC's regulations, techniques used by the NRC staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits or licenses. NUREGs are reports or brochures on regulatory decisions, results of research, results of incident investigations, and other technical and administrative information. More than 30 GIs were resolved by issuance of a regulatory guide or a NUREG. In addition, resolution of a number of issues has resulted in issuance of both products.

Finally, as shown in Fig. 2, approximately 17% of issues resulted in no requirements, however other associated actions allowed their resolution. Although generic issue resolution efforts have not led to regulatory action for issues in this category, the resolution of these issues has produced safety benefits through licensee actions taken voluntarily, in consideration of the issues raised, or in response to interim guidance. A recent example is GI-163, "Multiple Steam Generator Tube Leakage." The GI-163 resolution effort was related to substantial industry changes, voluntarily adopted during the conduct of GI-163. While those changes facilitated the resolution of GI-163, those changes were not requirements of GI-163.[10]

Approximately two third of the issues prioritized from 1983 to 1999 or screened after 1999 were not pursued further for resolution. These issues were either integrated with other issues, their safety concerns had been addressed by other issues or their prospect of safety improvements was not substantial and worthwhile. Although a large number of issues were not pursued to the resolution stage and consequently their disposition did not formally result in a regulatory product, completing the prioritization or screening stages provided an in-depth insight on risk and safety significance of these issues. Fig. 2 does not include these issues because these issues were not pursued to the resolution stage.

IV. GIP RESOURCES

As explained in the previous section, GIP has processed and resolved numerous issues. The NRC provides information regarding the GIP and the resolution of generic issues to the public in the form of various reports and publications. These reports include 1) NUREG-0933, "Resolution of Generic Safety Issues," [11] 2) Generic Issues Management Control System (GIMCS) quarterly reports, 3) Generic Issues Program Public Web page,[12] and 4) Annual Generic Issues Status Reports.

NUREG-0933, "Resolution of Generic Safety Issues,"[11] contains a description of the process and results of the resolution of each GI prioritized, screened and resolved under the GIP. This report, which was first published in 1983, has been regularly updated to include a description of newly identified GIs and the major updates on the status of active GIs. NUREG-0933[11] contains a wealth of information about each issue such as the identification of the issue, safety significance of the issue, analyses performed for prioritizing or screening the issue, and the resolution product. In addition to information about each issue, this report includes a detailed discussion of the current and historical GIP processes. Furthermore, valuable information regarding the program's historical performance is summarized in a number of tables in NUREG-0933.[11]

The GIMCS Quarterly Reports provide information relevant to the management and resolution of generic issues that are either active in the program or in the regulatory office. Status input for GIs being tracked in GIMCS includes: problem description, work scope plan and milestones for addressing the GI, current status description, problems impacting milestones, reasons for schedule changes and affected documents.

The GIP public web page[12] contains a program description and links to related information about the program, including: 1) policy and procedure documents, 2) records for issues that are active in the program, open in regulatory office, or recently closed, 3) frequently asked questions, 4) the GI submittal form, and 5) program status reports. Routine reports, including the GIP annual SECY paper, and quarterly Generic Issue Management Control System reports can be accessed at the GIP public web page, Public Document Room, or through the agency's ADAMS document control system.

Finally, Annual Generic Issues Status Reports provide the annual summary of the GIP activities including status of GIs and improvements to the program.

V. CONCLUSION

NRC's Generic Issues Program has identified and processed more than 850 generic issues. A variety of regulatory products have been produced by resolution of these issues. These regulatory products have significantly contributed to NRC's mission to regulate the nation's civilian use of byproduct, source, and special nuclear materials. GIP staff continues to identify and receive new proposed generic issues. In addition, GIP staff continues to make improvements in the program to enhance the effectiveness of the resolution process and dissemination of information regarding the GIP products and current status of issues to the public.

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