Enhancing Regulatory Effectiveness by Improving the Process for Identifying and Resolving Generic Issues

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Abstract

The Generic Issues Program first began formally in response to a Commission directive in October of 1976. In 1983, it became one of the first programs to make successful use of probabilistic risk information to aid in regulatory decision making. In the 16 years since the program became quantitative, 836 issues have been processed. Of these, 106 reactor safety issues were prioritized as requiring further evaluation to determine the final resolution. Approximately a dozen generic issues remain unresolved. Although there is far less reactor licensing activity than in the 1970s, new issues continue to be identified from research and operational experience. These issues often involve complex and controversial questions of safety and regulation, and an efficient and effective means of addressing these issues is essential for regulatory effectiveness. Issues which involve a significant safety question require swift, effective, enforceable, and cost-effective regulatory actions. Issues that are of little safety significance must be quickly shown to be so and dismissed in an expeditious manner so as to avoid unnecessary expenditure of limited resources and to reduce regulatory uncertainty. Additionally, in the time since the generic issue program began, probabilistic risk assessment techniques have advanced significantly while agency resources have continued to diminish. Accordingly, the paper

discusses the steps that have been taken to enhance the effectiveness and efficiency of the generic issue resolution process. Additionally, two recently-resolved issues are discussed, along with key elements of a proposed new procedure for resolving potential generic issues.

Introduction

A generic issue is defined as a concern that is applicable to all, several, or a class of nuclear reactors or reactor-related facilities. Generic issues have been classified into several distinct categories:

– A Generic Safety Issue (GSI) is defined specifically as a safety concern that may affect the design, construction, operation, or decommissioning of all, several, or a class of reactors or facilities and may have the potential to require licensees to make safety improvements and/or require the promulgation of new or revised requirements or guidance.

– A Regulatory Impact Issue (RI) is not related to improving safety but to modifying current NRC requirements or guidance with the primary purpose of reducing the regulatory impact, usually cost, of requirements on licensees or applicants.

- An Environmental Issue (EI) involves impacts on those items protected by the National Environmental Policy Act (NEPA).

- A Licensing Issue (LI) addresses actions the NRC staff should take to (a) increase its knowledge, certainty, and/or understanding of safety issues in order to gain confidence in assessing levels of safety; (b) improve or maintain the NRC capability to make independent assessments of safety; (c) establish, revise, and carry out programs to identify and resolve safety issues; (d) document, clarify, or correct current requirements and guidance; or (e) improve the effectiveness or efficiency of the review of applications.

- An Unresolved Safety Issue (USI) is related to generic issues and is defined as a matter affecting a number of nuclear power plants that poses important questions concerning the adequacy of existing safety requirements for which a final resolution has not yet been developed and that involves conditions not likely to be acceptable over the lifetime of the plants affected. USIs can be thought of as exceptionally important GSIs. The two types are treated identically, except that the progress on any issue defined as a USI must be regularly reported to Congress.

There are two major documents which govern the NRC staff's procedure for dealing with generic issues: NUREG-0933, "A Prioritization of Generic Issues," which is updated semiannually and is publicly available on the NRC web page, and NRC/RES Office Letter 7, "Procedures for Identification, Prioritization, Resolution, and Tracking of Generic Issues."

History of Program

The generic issues program began in the 1970s, well before the TMI-2 accident. Reactor licensing was extremely active because of the number of applications and because of the large number of individual plant designs under review. Moreover, the regulations (e.g., Appendix K to 10 CFR 50) were being revised and updated. The Standard Review Plan was just being issued, with the purpose of bringing both uniformity and efficiency to the review process.

As this activity progressed, a number of issues arose which were applicable to more than one docket. Rather than resolve these issues on individual dockets, the generic issue program was begun, with the purpose of providing uniform resolutions, and also saving the administrative effort required for consideration of each issue as an “open item” on each docket. (Most of the licensing activity was on construction permits, and it was assumed that the various issues would be resolved before issuance of an operating license.)

The number of issues became quite large, and it was necessary to set some priorities to make the best use of the agency’s limited staff resources. Three schemes were used:

– In 1977, all existing issues were classified into four categories according to importance, from “significant” to “little or no importance.” This classification was done by a review committee, using a point scale. It is this classification which resulted in the letter designations found in the older generic issues, e.g., A-45, “Decay Heat Removal,” and B-17, “Criteria for Safety-Related Operator Actions.” Some of the “A” category issues were designated as Unresolved Safety Issues.

- In early 1978, the issues were reclassified into Groups 1 through 8, this time by type of issue rather than by order of importance.

- Late in 1978, the staff began using risk assessment to place the issues into four categories ranging from Group I (potential high risk) to Group IV (items not directly related to risk). This classification was not quantitative in nature. Instead, a group of people who had been involved in the WASH-1400 project was convened. This group used its extensive experience and knowledge of which systems and event sequences were important to risk to place each generic issue into an appropriate category.

At this point, there were 142 generic issues in the system, which made for rather extensive discussions in the committee meetings associated with the classifications listed above. The TMI-2 accident added approximately 400 more generic issues. It was at this point that a new, more quantitative prioritization approach was tried. This was done in two stages:

- In 1981-82, a PRA-based quantitative methodology was developed. Issues were evaluated, usually using rudimentary event tree calculations, and a risk figure was developed for each issue. The objective was to develop an ordered list.

- In 1983, this methodology was redefined to conform to the Safety Goal Policy Statement, which was under development at the same time.

The quantitative methodology had several major advantages:

- Even though the calculations were quite basic, the quantitative approach forced the analyst to thoroughly research the safety significance of the issue in a disciplined manner.

- When quantifying an issue, it became very easy to separate out regulatory impact, environmental, and licensing issues.

- The calculations and the associated writeups provided a thorough, reasonably comprehensible explanation of how the priority figure was generated. This written record could then be reviewed by all interested parties. If omissions or errors were found, the calculation could be corrected.

- The prioritizations could be done by a large number of analysts working independently in parallel, as opposed to panels or committees which evaluated issues sequentially.

- Once the method was renormalized to incorporate the Safety Goal Policy Statement, a low score became a legitimate, defensible reason to drop an issue entirely, rather than to just assign a low priority. Issues of little or no safety significance could be dropped from any further consideration at the prioritization stage.

Management responsibility for the generic issues program was moved from the Office of Nuclear Reactor Regulation to the Office of Nuclear Regulatory Research in 1987. In April

1993, after approximately ten years of experience with the methodology, adjustments were made in the numerical thresholds for categorizing generic issues, while retaining the basic features of the method. These adjustments involved raising risk thresholds and simplifying the way in which costs entered the priority rankings. What motivated the raising of risk thresholds was the observation that, of the issues resolved, only 3 of the 27 medium-priority issues and about half of the high-priority issues resulted in decisions to take regulatory action, i.e., in retrospect, it appeared that resources had been devoted to resolving a large number of issues with no resultant safety improvement. (This outcome must be interpreted with the qualification that generic issue resolution efforts that have not led to regulatory action have, nevertheless, in many instances, produced safety benefits through licensee actions taken voluntarily, in consideration of the issues raised, or in response to interim guidance.) However, the extent of these benefits, when they occurred, was generally in proportion to the priority rank, and medium-priority issues usually resulted in marginal improvements. The proposed revisions were submitted to the Commission in SECY-93-108, "Revised Guidelines for Prioritization of Generic Safety Issues" (1993); in July 1993, Commission approval was obtained.

The threshold adjustments were intended to cause the prioritization process to model the resolution process without the earlier, apparently excessive margin for initial uncertainties, in order to reduce resources expended on analysis, evaluation and review efforts that do not produce safety improvements, while still ensuring attention to issues that require it. The raising of the numerical safety thresholds was accompanied by strengthened attention to uncertainties and special considerations, to help recognize instances when a priority rank higher than the indication from the new numerical formula was warranted, the objective being to improve the efficiency of the prioritizations without impairing their validity.

Generic Issue Process

Generic issues have been addressed using six separate and distinct steps: identification, prioritization, resolution, imposition, implementation, and verification. An explanation of each of these six steps is given below (see Figure 1).

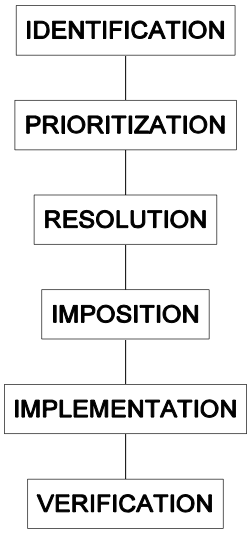

Figure 1. Current Generic Issue Process (from NUREG-0933)

Identification. Generic concerns may be identified by individuals or organizations within the NRC staff or by the Advisory Committee on Reactor Safeguards (ACRS), the

nuclear power industry, or the public. RES Office Letter No. 1, “Procedures for Identification, Prioritization, Resolution, and Tracking of Generic Issues,” (Morrison, 1996) provides a procedure and suggested content for individuals or organizational units within the NRC to request consideration of a concern as a new generic issue. This procedure may also be used by parties outside the NRC to express their concerns to the staff for consideration as potential generic issues. Sources of potential generic issues are many and varied and include, but are not limited to, the following: evaluation of safety-related research, operating experience reviews, risk assessment analyses, and public and industry concerns.

Prioritization. The prioritization step is described in detail in the introductory chapter of NUREG-0933, "A Prioritization of Generic Safety Issues" (1983). Estimates are made of the change in core damage frequency, public risk (as measured by the potential change in total whole-body person-rem out to a radius of 50 miles), total cost of resolution, and remaining plant lifetime. The resulting parameters (ΔCDF, public risk, and value/impact ratio) are compared with the priority decision criteria in NUREG-0933 to determine a priority rating. Generally, the prioritization write-up is circulated to the person or organization that raised the issue, the organizational unit that would eventually have responsibility for resolving the issue, and some persons with expertise in PRA and in the technical area involved in the issue. Comments from all of these entities, which often have very different viewpoints, are incorporated before the prioritization is issued in final form.

Many issues are dropped at the end of the prioritization stage, because of little or no safety significance. Because this is the end of the process for such issues, some conservatism is built into the process to ensure that marginal issues are not dropped inappropriately. It is a truism among analysts that one must be much more careful and thorough when dropping an issue, and the write-ups are often more detailed for such issues.

Prioritization calculations are fairly limited and are performed using what information is readily available. Once an issue receives a high or medium priority, a task action plan is written, and it competes for resources just as would any other agency project. The obtaining of more or better information, by means of calculations, experiments, or requests of the industry, is done at the resolution stage.

Resolution. After an issue has been prioritized and approved for resolution (i.e., not dropped following prioritization), the first task is the development of a plan to delineate the work to be done, assignment of major responsibilities, identification of project resource needs, and scheduling of milestone dates. These activities vary in scope and depth in accordance with issue priority and the depth of information on a given issue. The second task involves development of a technical solution. Typically, the information used to resolve an issue comes from experience data, experiments, tests, analyses, and probabilistic risk assessments.

In the final stage of resolution, the technical findings are used as a basis to develop a proposed resolution for the issue involving a change to NRC requirements or guidance.

Several alternatives may be considered. A regulatory analysis, including a detailed cost/benefit analysis of each practical alternative, and consideration of the best methods of imposition, implementation, and verification are used in selecting a proposed resolution. One alternative may be the imposition of a “backfit,” as defined in Part 50.109 of Title 10 of the Code of Federal Regulations. If a backfit is proposed, first, a determination is made as to whether the backfit is in fact required to provide adequate protection to the health and safety of the public or simply provides for enhancement of public health and safety. If it is determined that the backfit is necessary to provide an adequate level of protection, the backfit will be imposed regardless of the costs to achieve it. If it is determined that the backfit provides for enhancement of public health and safety, a generic analysis is required that assesses the nine factors specified in 10 CFR 50.109(c). Once the cognizant NRC Office Directors have agreed to a proposed resolution, it is then forwarded to the Committee for the Review of Generic Requirements (CRGR), the ACRS, the Executive Director for Operations (EDO), and the Commission for review and approval as appropriate. Changes to regulations, Policies, the Standard Review Plan (SRP), and Regulatory Guides are published in the Federal Register for public comment. Comments received are then incorporated, as appropriate,

with the final product published in the Federal Register. Resolution of a generic issue can take from several months to a few years depending on the length of time required by the deliberations involved at each of the above steps.

Imposition. Imposition is the step in the generic issues program where each affected licensee and/or applicant is required or guided to prepare a schedule for implementing

the generic issue resolution consistent with a Rule, Policy, Regulatory Guide, generic letter, bulletin, and/or licensing guidance developed during the resolution stage

For backfits, imposition is considered complete when each affected licensee has committed to compliance actions and schedules for implementing these actions. For forward-fits, i.e., changes in NRC requirements or guidance that are put in place before an applicant submits an application, the imposition of a generic issue resolution is complete when the new requirement or guidance becomes effective as an integral part of NRC regulations, policies, and/or guidance.

Implementation. Implementation is the step in the generic issues process where the affected licensees perform the actions on existing plants to satisfy the commitments made during the imposition stage. These may include modifications/additions to equipment, structures, procedures, technical specifications, operating instructions, etc. No later than 30 days after each affected licensee has completed all of the actions required for a particular generic issue resolution, and the modified/additional system is fully operational, the licensee is required to certify in writing to the NRC that plant modifications/additions have been completed in accordance with NRC requirements, policies, and/or guidance. When all affected licensees have officially notified the NRC of completion of all required/committed actions, the implementation stage is complete, unless it is determined by the staff from subsequent verification inspection that additional licensee actions are needed for compliance.

Verification. The verification step consists of three parts. First, the portions of a licensee's actions, if any, that warrant NRC inspection must be determined. This decision is made during the resolution stage based on the judgment of the safety significance of the issue relative to other matters in the inspection program, licensee performance, and the resources needed to accomplish a meaningful inspection. Next, as necessary, inspection instructions are prepared to ensure that the NRC inspection is performed in a consistent and appropriate manner at all affected plants; the inspection, by its very nature, is an audit. Therefore, carefully thought-out instructions must be developed and provided to the NRC inspectors so that the maximum safety benefit is achieved for the limited resources devoted to this effort. The third part of the verification process is the actual verification and documentation of the results in an inspection report. Physical inspections are performed on an audit basis in a manner consistent with general inspection procedures which involve a sampling of changes made by licensees or applicants, as opposed to a 100% inspection of all actions.

Recent Generic Issues

Four recently-resolved generic issues are illustrative of the current process. These issues were not dropped following the prioritization step, and task action plans were developed and carried out for these issues.

Generic Issue 158, "Performance of Safety-Related Power-Operated Valves Under Design Basis Conditions," was first identified in 1991. The issue was initiated because reactor operating experience and research results on solenoid-operated, air-operated, and hydraulically-operated valves indicated that testing under static conditions did not always reveal

how these valves would perform under design basis conditions. A number of failures had occurred because of inadequate design, installation, or maintenance. (A similar concern on motor-operated valves was investigated under GI-II.E.6, and eventually resulted in the issuance of Generic Letter 89-10.)

A prioritization calculation was performed by changing the failure probabilities for these valves in several PRAs, and observing the change in core damage frequency. Based on these calculations, a priority of “medium” was assigned to the issue, and a task action plan was generated to resolve it.

After considerable investigation in the resolution step, it was discovered that, although there is safety significance for this issue, there is no cost-effective generic solution - the use of these valves, and consequently the nature of any program to increase their reliability, varies greatly from plant to plant. However, the lack of a generic solution did not imply that nothing should be done, and several programs have been voluntarily undertaken by industry groups to increase the reliability of these valves. The issue was judged to be a “compliance” issue as defined in 10 CFR 50.109 paragraph (a)(4)(i), and removed from the Generic Issues program. Instead, the NRC staff is monitoring industry voluntary efforts to develop an acceptable guidance document. If licensees do not take adequate action to address questions related to power-operated valve function under dynamic design basis conditions, appropriate regulatory action will be taken.

Generic Issue 165, “Spring-Actuated Safety and Relief Valve Reliability,” was first identified in 1992. This issue was identified by NRR when it was found that, on a number of occasions, licensees reported that spring-actuated safety valves and relief valves failed to meet setpoint

criteria within the desired tolerance. Other reported incidents included more seriously degraded performance of safety and relief valves. These results suggested that other systems with safety and relief valves could be adversely affected by setpoint drift. More importantly, at Shearon Harris, the failure (open) of a high head safety injection system relief valve at a very low setpoint resulted in the undetected degradation of the entire system and would have resulted in inadequate emergency core coolant injection if a small-break or intermediate-break LOCA had occurred.

Spring-actuated safety valves and relief valves provide overpressure protection for a number of fluid systems in both PWRs and BWRs. However, the spurious opening failure of these valves in safety-related support systems could cause a significant diversion of flow from these systems and thus prevent the systems from performing their designed function. A prioritization calculation using this assumption resulted in this issue being given a “high” priority designation

A task action plan was generated and approved, and a full investigation of the issue was performed. In the course of this investigation, it was discovered that, although many systems are equipped with small safety or relief valves, these valves are virtually always too small to divert sufficient flow to fail the system. Only in a few, very rare instances was there any possibility of causing a safety system failure even if one of these valves failed in the full open position. Those few instances where an “oversized” valve could have caused system failure by diverting flow were investigated and either dismissed on probabilistic grounds or resolved by voluntary action on the part of the licensee. The issue was declared “resolved” and closed.

Generic Issue 145, "Actions to Reduce Common Cause Failures," originated as part of another generic issue that arose from the agency's response to the loss of all feedwater event which occurred at the Davis-Besse plant in 1985. GI-145 was a longer-term program to address the general subject of common cause failures, including their discovery, methods of analysis, and means of avoidance.

Because plant systems are designed to meet the single failure criterion, any common cause failure mechanisms are generally significant contributors to system unavailability. Based on the potential public risk reduction, the requirement to consider CCFs in the IPE program, and the extent of existing work on common cause failures, this issue was given a "high" priority designation.

The staff's proposed resolution to GI-145 was to: (1) provide licensees with information about CCFs for use in performing IPEs, and (2) encourage licensees to conduct engineering analyses and to provide training to plant personnel so that they would be made aware of the importance of CCFs and the types of actions that can increase or decrease the frequency of occurrence of CCFs. It was believed that licensees could then voluntarily make changes in maintenance programs, testing, procedures, etc., to reduce the potential for CCFs.

The staff had earlier conducted research on procedures for identifying CCFs, the results of which were documented in NUREG/CR-4780, "Procedures for Treating Common Cause Failures in Safety and Reliability Studies," (Mosley, 1988) and NUREG/CR-5460, "A Cause-Defense Approach to the Understanding and Analysis of Common Cause Failures," (Paula, 1990). Although NUREG/CR-4780 documented an approach for performing plant-specific CCF analyses, it provided little guidance on the analysis of data. Furthermore, the data required for

application of the approach were not generally available in a readily accessible form. Each application involved significant pre-screening of a large amount of data by each analyst using the approach. In the past, the majority of CCF analyses performed in support of PRAs used generic estimates for CCF parameters. Some used the methods of NUREG/CR-4780 but produced widely varying results because of differences in the individual analysts' screening of industry data derived primarily from licensee event reports.

In response to the deficiencies related to CCF data, the staff developed a CCF database and analysis software package to aid in this aspect of system reliability analyses and related risk-informed applications. In July 1998, licensees were informed of the availability of the CCF database in Administrative Letter 98-04, "Availability of Common-Cause Failure Database." With the establishment, dissemination, and ongoing use of this common-cause failure database, the proposed resolution was considered complete.

At the request of the ACRS, Administrative Letter 98-04 was followed up with Regulatory Issue Summary 99-03, "Resolution of Generic Issue 145, Actions to Reduce Common-Cause Failures." With this second communication, Generic Issue 145 was declared "resolved" and closed.

Generic Issue B-17,"Criteria for Safety-Related Operator Actions," was identified in 1978. The issue was based on the fact that plant designs are such that reliance on the operator to take action in response to certain transients is necessary. The generic issue stated that the NRC should develop a time criterion to determine whether certain time-critical safety-related actions should be automated, rather than relying on manual actions by the plant operators. The

required time, during which the actions must be completed, is determined by the characteristics of the transient or accident scenario (e.g., rate of coolant loss) and by plant design parameters (e.g., inventory of coolant in the refueling water storage tank). If the required time for the action were less than the time criterion, the action would be considered to be too quick to place high confidence in operator performance, and automation of the action would be required.

Much has happened in the 22 years since this issue was identified, particularly in the area of emergency procedures and the analysis of operator performance. It is now well established that the required time interval is not the only parameter of interest; the complexity of the action and the stress associated with the accident or transient, to name just two, also greatly affect the reliability of operator performance. The staff reviewed the regulatory actions which have taken place since Generic Issue B-17 was identified, especially those actions that followed the accident at Three Mile Island, and concluded that implementation of these actions meets the intent of Generic Issue B-17.

These actions include the requirement for operator training to be based on the Systems Approach to Training (SAT). The SAT-required task analyses and operational experience reviews identify those safety-related operator actions which are time-critical. These same operator actions are then used in operator license examinations. Operators are not licensed unless they can demonstrate on a plant-specific simulator that they can perform the required actions in the required time. This requirement by itself largely addresses the concerns raised in B-17.

In addition, there are training requirements for actions performed outside the control room, requirements for demonstration of actions which would be performed by non-licensed personnel, and requirements for minimum staffing levels. Moreover, all emergency operating procedures are now required to be symptom-based, and these symptom-based procedures were required to be validated by plant walk-downs. All of these together provide convincing assurance that operating crews can perform safety-related actions successfully in the required time interval.

Finally, the Individual Plant Examination program required licensees to identify those safety-related operator actions which are of greatest risk significance. In their IPE programs, licensees quantitatively evaluated time-critical safety-related operator actions as part of their searches for vulnerabilities. Actions identified in this way are also included in operator training and examinations.

Based on all of the above, Generic Issue B-17 was declared “resolved” and closed.

Still other generic issues have gone through the process. These four examples are not a comprehensive list. Other recently-resolved generic issues include GI-23, “Reactor Coolant Pump Seal Failures,” B-55, “Improvement of Reliability of Target Rock Safety Relief Valves,” GI-190, “Fatigue Evaluation of Metal Components for 60-Year Plant Life,” and GI-148, “Smoke Control and Manual Fire-Fighting Effectiveness.” The generic issue process remains very active.

Planned improvements with the New Generic Issue Resolution process

Although the current generic issue process has been used successfully for many years, a number of changes have been suggested and included in Draft Management Directive 6.4, "Generic Issue Program." The new process is currently in a trial period. Its effectiveness and practicality will be evaluated after the trial period ends in August, 2000.

- Generic Safety Issues will be classified as "adequate protection," "substantial safety enhancement," or "burden reduction" issues, for consistency with 10 CFR 50.109, the "backfit rule." (These terms did not appear in 50.109 until approximately 1988.)

- Administrative and licensing issues will be addressed in other programs, and will no longer be addressed by the Generic Issue Program.

The workflow steps will be modified as follows (see Table 1):

Table 1: Steps in Current and New Generic Issue Processes

Current Generic Issue Process Step	New Draft Management Directive 6.4, "Generic Issues Program" Process Step
Identification	Identification
Prioritization	Initial Screening
	Technical Screening
Resolution	Technical Assessment
	Regulation and Guidance Development
Imposition	Regulation and Guidance Issuance
Implementation	Implementation
Verification	Verification

As can be seen from Table 1, several steps will be modified:

– The prioritization step will be dropped and replaced with two steps involving an initial screening step (performed by review panels), to remove compliance issues and the like, and a technical screening step, similar to the quantitative prioritization in the current

process. In view of the fact that the large backlog of issues of the 1970s and early 1980s has been worked off, and only a small number of new issues are now expected each year, it is no longer necessary to give a priority. Instead, the technical screening will only result in a conclusion of “continue” or “drop.”

– The “Resolution” step will be divided into a “Technical Assessment” step (which will provide the regulatory analysis necessary to proceed) and “Regulation and Guidance Development” step. In the current process a generic issue is considered “resolved” once the agency decides upon a course of action. The terms “resolution” and “resolved” were often confused with another term, “closure.” To clarify terminology, the new process defines an issue as “resolved” once all steps have been completed, including “Implementation” and “Verification.”

– The “Imposition” step will become the “Regulation and Guidance Issuance” step. In addition to the name change, process guidance is now provided.

– “Implementation” and “Verification” steps will have the same titles. However, process guidance is now provided.

Technical improvements

In addition to the procedural changes described above, several technical changes are planned. When quantitative techniques were first introduced into the generic issue program in the early

1980s, most of the calculations were done using WASH-1400 techniques and data. When personal computers became available, many calculations were based on the Reactor Safety Study Methods Application Program (RSSMAP) studies for the Oconee and Grand Gulf plants. Some of these techniques are still in use today. Several improvements are planned:

First, newer PRA models will be used for those calculations where ΔCDF and change in public risk are estimated by varying the parameters in an existing PRA. The RSSMAP PRAs are obsolete both in calculational techniques and in modeling (e.g., reactor coolant pump seal leaks are not modeled). In addition, the two plants that were used, Grand Gulf and Oconee, are not very representative of the spectrum of plants currently operating.

The staff is beginning to use the Rev. 2QA SPAR models (Long, et.al., 1998) developed for the Accident Sequence Precursor program. This is a set of models which cover virtually every domestic operating plant. Moreover, these models are already loaded into the SAPHIRE code package. (NUREG/CR-6116, 1974.)

There are limitations to the SPAR models - not all support systems are modeled, and, because they were intended for the analysis of precursor events, large break LOCA sequences are not included. When the Rev. 3 SPAR models are issued, both of these limitations will be addressed. Moreover, the Rev. 3 models will include uncertainties, which will allow the use of uncertainty analyses in generic issue calculations for the first time.

When a more detailed model is needed, or when external events must be considered, the PRA models in NUREG-1150, “Severe Accident Risks: An Assessment for Five U. S. Nuclear Power

Plants," (1990) can be used. However, there will always be cases where a new model must be constructed - no existing PRA can include all possible phenomena, systems interactions, etc., which may be present in a generic issue.

Second, the consequence analysis will be updated. These calculations are still based on calculations of WASH-1400 release categories. As resources become available, new consequence analysis tables will be generated.

Conclusion

The current generic issue process has worked well for many years. To assess the program's regulatory effectiveness (both the current process and the new process), the following should be considered:

– *The process is directly related to public health and safety*. From its inception, risk has been the yardstick by which the most important (i.e., safety-significant) issues were worked on first. The risk yardstick has also been used to eliminate issues with little or no risk significance, and, in accordance with the backfit rule (10 CFR 50.109), risk and cost effectiveness are the final measures which determine what regulatory action is taken.

– *The process makes maximum use of risk information*. This program (along with the Accident Sequence Precursor program) was one of the first to make use of probabilistic risk assessment techniques in regulatory decision making.

– *The methods and criteria are objective, clear, and public*. The criteria are those of the Safety Goal Policy Statement. The methods have long been published in NUREG-0933, which is now available on the agency's World Wide Web site as well as being available in printed form. Updates are published every six months.

– *The treatment of each individual issue is open, defensible, and public*. The individual write-ups on each issue are also published, in both printed and electronic form, in NUREG-0933. The treatment of each issue is reviewed by both the originator of the issue, and by the entity which will have responsibility for any regulatory action. These two may be the same entity, but more often have somewhat of an adversarial relationship where the specific generic issue is concerned. The treatment of the issue is defended at both the prioritization and resolution stages.

It is therefore concluded that this program does contribute significantly to regulatory effectiveness.

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