UNITED STATES NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

DRAFT FOR COMMENT

Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance

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INTRODUCTION

The purposes of this standard review plan (SRP) are to identify the roles and responsibilities of organizations in the NRC that participate in risk-informed reviews of licensee proposals for changes to a plant's current licensing basis (CLB)[1]. The SRP identifies the types of information that may be used in each activity and provides general guidance on how the information from a probabilistic risk assessment (PRA) can be combined with other pertinent information in the process of making a regulatory decision.

The guidance in this document is a logical extension of current NRC policy on the use of PRA in regulatory activities which is documented in the commission's PRA policy statement and PRA implementation plan (references 1, 2 and 3). In developing this document, the staff has considered the NRC regulatory guide on the use of PRA in risk-informed regulatory applications, draft Regulatory Guide DG-1061 (Reference 5) and the relevant industry guidance documented in Reference 4. In addition, reference will be made to other SRP chapters which provide additional guidance for the review of specific applications of PRA in regulated activities.

Risk-informed decisionmaking will be based on the following approach. The design, construction, and operational practices of the plant being analyzed are expected to be consistent with its CLB. The risk evaluations performed to justify regulatory changes are expected to realistically reflect the plant-specific design, construction, and operational practices. The PRA analyses should be as realistic as practicable, and should address significant uncertainties. Results of these risk analyses will be part of the input to the decision process that evaluates margin in plant capability (both in performance and in redundancy/diversity). The decision process will use the

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[1] This SRP adopts the 10 CFR Part 54 definition of current licensing basis, i.e., "CLB is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 51, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports."

risk results in a manner which complements traditional engineering approaches and supports the defense-in-depth philosophy and preserves safety margins. Risk analysis will inform, but will not determine regulatory decisions.

ROLES AND RESPONSIBILITIES

Depending on the technical nature of a licensee's request, an appropriate technical review branch in the Office of Nuclear Reactor Regulation (NRR) will serve as the primary review branch and, as such, has overall responsibility for leading the technical review, drafting the staff safety evaluation report (SER) or other appropriate regulatory document, and coordinating any input from other technical review organizations. The responsibilities of specific review organizations that will normally play a role in reviewing risk-informed proposals are listed below.

The Probabilistic Safety Assessment Branch (SPSB), at the request of the primary review branch, is responsible for review of the PRA information and findings submitted by the licensee. Review support includes the assessment of the adequacy of the scope, level of detail and quality of the PRA used by the licensee to support the regulatory change and the application of risk related acceptance guidelines to support decisionmaking.

The Reactor Systems Branch (SRXB), at the request of the primary review branch or SPSB, provides support in accident sequence modeling, including treatment of reactivity and thermal-hydraulic phenomena, system response, and the implementation of emergency operating procedures and abnormal operating procedures.

The Containment and Severe Accident Branch (SCSB), has primary responsibility for review of any containment response and containment integrity information submitted by the licensee in support of a request for regulatory action.

The Emergency Preparedness and Radiation Protection Branch (PERB) has primary responsibility for review of any evaluations of radionuclide contamination or public health effects submitted by a licensee in support of a request for regulatory action.

The Office of Nuclear Regulatory Research (RES), at the request of the primary review branch, provides technical support in areas involving all aspects of PRA, severe accident phenomenology and engineering studies.

The Office for Analysis and Evaluation of Operational Data (AEOD), at the request of the primary review branch, provides generic and plant-specific data on the frequency of initiating events, common cause failures and human errors from operating experience.

The Regional Offices, at the request of the primary review branch, provides information on licensee operational experience in areas of system performance, operator performance, risk management practices and management controls.

I. AREAS OF REVIEW

The NRC's PRA Implementation Plan (reference 1) identifies a wide scope of regulatory activities for which PRA can play a role. This scope includes activities which require NRC review and approval and other activities which are considered internal to NRC and affect licensees and applicants in a less direct manner, e.g., generic issue prioritization. This Standard Review Plan chapter deals only with licensing amendment requests submitted for NRC review and approval for which PRA can play an effective role in the decisionmaking process. General review guidance for applicable activities is presented in this SRP. In addition, application-specific SRP chapters are available to provide additional guidance for several activities. Examples include:

- Changes to allowed outage times (AOT) and surveillance test intervals (STI) in plant-specific technical specifications;
- Changes in scope and frequency of tests on pumps and valves in a licensee's inservice test (IST) program;
- Changes in scope and frequency of inspections in a licensee's inservice inspection (ISI) program; and
- Grading of activities in the licensee's quality assurance (QA) program.

Draft regulatory guide DG-1061 defines an acceptable approach to analyzing and evaluating proposed CLB changes. This approach supports the staff's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived from the use of PRA methods) on the risk significance of the proposed changes. The decision process leading to the proposed change is expected to be done in an integrated fashion (considering traditional engineering and risk information) and may be based upon qualitative factors as well as quantitative analyses and information.

As discussed later in this section, the scope of the staff review of a risk-informed application will depend on the specifics of the application. However, this scope should include a review of the four-element approach as suggested in chapter 2 of draft Reg Guide DG-1061. The areas of review for each of these elements are summarized below.

Element 1: Define the Proposed Change

The objective of this element is to provide the groundwork for the evaluation of safety impacts of the proposed change. Areas of review in this element therefore includes an evaluation of: the proposed change in light of the CLB; the structures, systems and components (SSCs), procedures and activities that are covered by the proposed change; the method of analysis; and the available engineering studies and risk evaluation findings that are relevant to the proposed change.

Element 2: Conduct Engineering Evaluations

In this element, the reviewer should evaluate the proposed change to ensure that defense-in-depth and safety margins are maintained, and that the calculated change in plant risk is within the guidelines specified in DG-1061. The proposed changes are to be evaluated in light of the licensee's risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions and not just to eliminate requirements the licensee sees as undesirable, and that cumulative risk impacts are appropriately factored into the decision process.

Element 3: Develop Implementation and Monitoring Strategies

Implementation and monitoring strategies can provide early indication of plant performance under the proposed changes and these strategies are therefore important in applications where there is some uncertainty in evaluation models and/or data. As such, the review scope should include provisions to ensure that the licensee proposed process for implementation and monitoring is adequate to in part account for uncertainties with regard to plant performance under the proposed change.

Element 4: Document Evaluations and Submit Request

The reviewer should assure that the submittal includes sufficient information to support conclusions regarding the acceptability of the proposed change and that archival documentation of the evaluation process and findings is maintained and available for staff audit and review. The reviewer should also assure that the appropriate regulatory action is requested, for example, a license amendment, an exemption, or a change to technical specifications. Where appropriate, these actions should include enhancements in regulatory requirements to preserve the assumptions in the supporting risk analysis, and to assure that high risk significant SSCs not currently subject to regulatory control will be subject to requirements commensurate with their risk significance. Finally, the reviewer should assure that CLB changes are appropriately included in a Safety Analysis Report update as necessary.

Application-Specific Reviews

This SRP chapter is written to provide guidance for a full scope review of applications in risk-informed regulation where evaluation findings are dependent on the numerical values of risk indices and where a broad set of scenarios and plant operating modes may be affected. Where it is determined that an application could justify a review that is less than full scope, the reviewer should choose the relevant and applicable parts of this SRP for guidance. In addition, some applications may be supportable without resort to the level of integration and quantitative perspective afforded by PRA, and correspondingly, little or no staff review of the PRA may be necessary. Application-specific SRP chapters (where available) will provide additional guidance in this area.

II. REVIEW GUIDANCE AND PROCEDURES

II.1 General

For each risk-informed application, reviewers should ensure that the following principles for risk-informed decisionmaking are met (SRP sections dealing with each principle are provided in parenthesis):

- The proposed change meets the current regulations. This principle applies unless the proposed change is explicitly related to a requested exemption or rule change (i.e., a 50.12 "specific exemption" or a 2.802 "petition for rulemaking") (section II.3.1);
- Defense-in-depth is maintained (section II.3.1);
- Sufficient safety margins are maintained (section II.3.1);
- Proposed increases in risk and their cumulative effect are small, and these changes do not cause the NRC Safety Goals to be exceeded (sections II.3.2 and II.3.3); and
- Performance-based implementation and monitoring strategies are proposed that address uncertainties in analysis models and data, and provide for timely feedback and corrective action (section II.4).

In demonstrating the above, reviewers should ensure that the following have been addressed as part of the submittal:

- All safety impacts of the proposed change are evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly and not just to eliminate requirements the licensee sees as desirable. The approach used to identify changes in requirements was used to identify areas where requirements should be increased as well as where they could be reduced (section II.3.3);
- The acceptability of the proposed changes is evaluated in an integrated fashion that ensures that all principles are met (section II.3.3);
- Increases in estimated CDF and LERF resulting from proposed CLB changes are limited to small increments (section II.3.2);
- The scope and quality of the engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed CLB change are appropriate for the nature and scope of the change and are based on the as-built and as-operated and maintained plant (section II.3.2);
- Appropriate consideration of uncertainty is given in analyses and

interpretation of findings (section II.3.2);

- The plant-specific PRA that is used to support licensee proposals has been subjected to quality controls such as an independent peer review (section II.3.2); and

- Data, methods, and assessment criteria used to support regulatory decisionmaking are available for public review (section II.5).

II.2 Element 1: Define the Proposed Change

In this element, the reviewer should verify that enough information is provided to meet the staff's expectation that all potential safety impacts have been identified and evaluated. In addition, the reviewer should be satisfied that, where appropriate, the licensee has identified design and operational aspects of the plant related to the change request that should be enhanced consistent with an improved understanding of their safety significance based on the methodology use to support the proposed relaxation in regulation. These enhancements should be appropriately-reflected in licensing basis changes (e.g., technical specification, license conditions, and FSAR)

The proposed changes should be reviewed with regard to the current licensing basis. The licensing basis of the plant documents how the licensee satisfies certain basic regulatory requirements such as diversity, redundancy, defense-in-depth, and the General Design Criteria.

Engineering (or other pertinent) analysis and data that identify the safety margins or plant activities conducted to preserve those margins should be reviewed. If exemptions from regulations or relief requests are needed to implement the licensee's proposed change, the reviewer should ensure that the appropriate requests accompany the licensee's submittal.

The reviewer should verify that available documents reflecting traditional engineering concepts and principles have been identified and appropriately used. Among the non-PRA sources of information that should be examined to support the evaluation of safety significance are the safety insights developed in licensing documents including the Final Safety Analysis Report, and the bases for Technical Specifications such as Limiting Conditions for Operation (LCOs), Allowed Outage Times (AOTs), and Surveillance Requirements (SRs).

Where available, plant specific data and operational information should be factored into the evaluation process. Reviewers should consider the way in which the issues at hand are reflected in operational data. Useful insights from plant specific operating experience can also be obtained from inspections that follow incidents at the facility, including NRC incident investigation and augmented team inspections, INPO incident assessments documented in

significant operating event reports, licensee follow-up investigations and routine inspections by NRC resident inspectors. Inspection results can provide valuable qualitative insights in areas such as human performance, management controls, adequacy of procedures and root causes of events which are often difficult to treat with precision in a PRA.

Finally, as part of the initial review of the licensing amendment, the reviewer should determine if the scope of the impact of the proposed change has been adequately characterized (specifically, if all SSCs affected by the proposed change have been identified) and if the analysis performed and submitted have the scope and depth needed to adequately characterize the impact of this change.

II.3 Element 2: Conduct Engineering Evaluations

In order for the staff to make findings of acceptability regarding a proposed license amendment, the staff position should be based on an integrated assessment of traditional engineering evaluations and probabilistic information. Specific evaluations expected to be performed by the licensee are described in section 2.4 of draft reg guide DG-1061. The scope and quality of the engineering analyses conducted to justify the proposed change should be appropriate for the nature and scope of the change. Types of traditional engineering and probabilistic information which should be included in submittals are described in section 3 of the draft guide.

The results of this element should be reviewed to determine if the following principles for risk-informed decisionmaking are satisfied: the proposed change meets current regulations unless the change is explicitly related to a requested exemption or rule change; defense-in-depth is maintained; sufficient safety margins are maintained; and proposed increases in risk and their cumulative effect are small, and these changes do not cause the NRC Safety Goals to be exceeded.

II.3.1 Evaluation of Defense-in-Depth Attributes and Safety Margins

A review of the engineering evaluations should be performed to demonstrate that the principles identified in Section II.1 are not compromised. These evaluations should include not only the traditional design basis accident (DBA) analyses, but also evaluations of the defense-in-depth attributes of the plant, safety margins, and risk assessments performed to obtain risk insights and quantification of the impact of the proposed change.

II.3.1.1 Defense-in-Depth

Defense-in-depth is defined as a philosophy which ensures that successive measures are incorporated into the design and operating practices for nuclear plants to compensate for potential failures in protection and safety measures.

In risk informed regulation, the intent is to assure that the philosophy of defense-in-depth is maintained, not to prevent changes in the way defense-in-depth is achieved. The defense-in-depth philosophy has been and continues to be an effective way to account for uncertainties in equipment and human performance. In some cases, risk analysis can help quantify the range of uncertainty; however, there will likely remain areas of large uncertainty or areas not covered by the risk analysis. Where a comprehensive risk analysis can be performed, it can be used to help determine the approximate extent of defense-in-depth (e.g., balance among core damage prevention, containment failure and consequence mitigation) to ensure protection of public health and safety. However, because all aspects of defense-in-depth are not reflected in PRAs, appropriate traditional defense-in-depth considerations should also be used to account for uncertainties.

Preservation of Multiple Barriers for Radioactivity Release

Defense-in-depth can be argued based on considerations of the barriers that prevent or mitigate radioactivity release. Release of radioactive materials from the reactor to the environment is prevented by a succession of passive barriers: fuel cladding, reactor coolant pressure boundary, and containment structure. These barriers, together with an imposed exclusion area and emergency preparedness, are the essential elements for accident consequence mitigation. Given these multiple barriers, assurance of safety is provided by application of deterministic safety criteria for the performance of each barrier, and design and operation of systems to support the functional performance of each barrier.

In maintaining the defense-in-depth philosophy, the proposed license amendment should not result in any substantial change in the effectiveness of barriers. The following are review objectives to ensure that the proposed change maintains appropriate safety within the defense-in-depth philosophy:

- the change does not result in a significant increase in the existing challenges to the integrity of the barriers;
- probability of failure of each barrier is not significantly changed by the proposal;
- new or additional failure dependencies are not introduced among barriers that result in a significant increase in the likelihood of failure compared to the existing conditions; and
- the overall redundancy and diversity in the barriers is sufficient to be compatible with the risk acceptance guidelines.

In demonstrating the above, it is a staff expectation that, for the proposed change:

- a reasonable balance among prevention of core damage, prevention of

containment failure, and consequence mitigation is preserved;

- over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided;
- system redundancy, independence, and diversity are preserved, commensurate with the expected frequency and consequences of challenges to the system;
- defenses against potential common cause failures are preserved and the introduction of new common cause failure mechanisms is assessed;
- independence of barriers is not degraded; and
- defenses against human errors are preserved.

The above elements can be addressed by using qualitative or traditional engineering arguments or by using PRA results contained in the model sequences and cutsets.

Role of PRA in Review of Defense-in-Depth

In addition to the usual quantitative risk indices, PRAs provide important qualitative results, namely, the accident sequence minimal cutsets. Each accident sequence minimal cutset is a combination of passive and active SSC failures and human errors that would cause core damage or a radioactivity release. The cutsets therefore directly show one particular aspect of defense-in-depth, in that they reveal how many failures must occur in order for core damage or a radiological release to occur. The minimal cutsets therefore show the effective redundancy and diversity of the plant design.

Events appearing in each minimal cutset are, in most cases, targeted by programmatic activities to assure the reliability of the associated SSC. Specific activities that are important in maintaining reliability of a component include: inservice testing, inservice inspection, periodic surveillance required by Technical Specifications, quality assurance, and maintenance. Therefore, when a review of the minimal cutsets shows areas where redundancy or diversity are already marginal, it would arguably be inappropriate to reduce the level of activities aimed at ensuring SSC performance, unless the activities can be shown to have little or no effect on SSC performance or if it can be shown that uncertainties in the performance of the elements in this cutset are well understood and quantified. It is also possible that compensating or alternative activities could be proposed to provide assurance of SSC performance. The objective of this review is to avoid completely relaxing the defense-in-depth posture at points at which the plant design has the least overall functional independence, redundancy, and/or diversity. On the other hand, in areas where a plant has substantial redundancy and diversity, defense-in-depth arguments used to justify relaxations should be given appropriate weight.

As part of the review of defense-in-depth, the effects of multiple component failures that could potentially result from the proposed change should be evaluated. For example, if all events in a cutset have been proposed for a reduction in requirements, the reviewer should ensure that the effect of the change is modeled properly and that the change does not have an adverse effect on defense-in-depth.

Finally, in the review of sequence cutsets, attention should be given to potential over-reliance on programmatic activities or operator actions that compensate for weaknesses in the plant design. For example, proposed maintenance and surveillance activities should complement and not replace proper plant design.

II.3.1.2 Safety Margins

In the determination of the design performance characteristics of a system, safety margin represents an allowance for uncertainty in SSC performance. Current safety analysis practices incorporate consideration of margin in most areas. As examples, many engineering standards, licensing-analyses, and technical specifications take margin into account.

Incorporating margin can result in over-designing of components, incorporation of extra system trains or extra systems, or in conservative operating requirements for systems and components. Therefore, some licensee applications will seek to reduce this margin in some areas. Reduction of margin should appropriately reflect the current understanding of existing uncertainties and the potential impact of the proposed change.

Therefore, as part of the review of the impacts of a proposed change, its effects on safety margins should be evaluated. For example, the reviewer should establish that:

- engineering codes and standards or alternatives approved for use by the NRC are met, or deviations are justified; and

- safety analysis acceptance criteria in the current licensing basis are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty.

Clearly, these items are closely related to guidance provided in section II.3.1.3 regarding the need to maintain the current CLB. The thrust of the guidance in the present section is to sensitize reviewers to the implications of relaxing margin when evaluating the acceptability of changes to the CLB.

The level of justification required for changes in margin should depend on how much uncertainty is associated with the performance parameter in question, the availability of mechanisms to compensate for adverse performance, and the consequences of functional failure of the affected elements. Therefore, the

results from risk evaluations and the associated analysis of uncertainties, especially in the analysis areas and models affected by the application, will provide useful information to help in the reviewer's decision-making.

In the evaluation of available safety margins, reviewers should also look at the risk profile of the plant. If a proposed CLB change creates or exacerbates a situation where risk is dominated by a few elements (SSCs or human actions) or a few accident sequences, the impact should be carefully evaluated by the reviewer. If one or a few elements clearly dominate risk, then the modeling of these items (including uncertainty) and the effect on risk if they degraded should be reviewed more in detail, and the acceptability of this contribution assessed.

In demonstrating available safety margins, licensees will in some cases cite new data from plant tests or research projects, or analysis with models based on new data to support their proposal. The following examples illustrate situations in which data and analysis can be used effectively to support the CLB change request:

- to show that a phenomenon of concern cannot occur or is less likely to occur than originally thought;

- to show that the amount of safety margin in the design is significantly greater than that which was assumed when the requirement or position was imposed;

- to show that time available for operator actions is greater than originally assumed.

The reviewer's primary objective is to verify the relevance and acceptability of this new information with respect to the CLB change request. Data that apply directly to the original technical concern should be applied in the decision process. Depending on the circumstances, additional specific guidance in the cognizant review branch may be available for reviewing the quality and acceptability of the data. However, the data or analysis must be clearly applicable to the plant and specific circumstances to which it is being applied.

II.3.1.3 Current Regulations

Staff reviewers should be aware that the proposed change satisfies current regulations (including the general design criteria) unless the licensee explicitly includes a proposed exemption or rule change (i.e. a 50.12 "specific exemption" or a 2.802 "petition for rulemaking").

The current licensing basis also applies until modifications to it are accepted by the staff. It is expected that many applications will seek to modify the CLB in risk-informed submittals. Applications that seek to make

qualitative changes to the CLB (such as moving components out of the scope of a required program) should be reviewed in more detail with respect to defense-in-depth and safety margins when compared to applications that seek to make parametric changes (such as incremental changes to surveillance interval).

II.3.2 Risk Assessment

For an effective implementation of risk-informed regulatory approaches, the reviewer should ensure that the licensee has demonstrated that the plant's CLB and actual operating conditions and practices are properly reflected in the risk insights using the plant PRA model. Otherwise, the risk assessment may provide inaccurate or misleading information that will require careful scrutiny before use in any regulatory decisionmaking process.

The development of a plant-specific, risk-informed program will also require that information be available to identify the application-specific SSCs and human actions that contribute most significantly to the plant's estimated risk. For each PRA basic event directly affected by the proposed application, it is desirable for the licensee's process to quantify the event using models that capture the functional relationships between the application and the event. The effects of proposed changes on parameters such as common cause failure probabilities and potential increases in human error probabilities should be addressed within the review process.

The characterization of the proposed change in terms of PRA model elements is discussed in sub-section II.3.2.1. The results of this determination of the cause-effect relationships between the proposed application and the PRA models will help define the scope and the level of detail required of the PRA to support the application. Sub-sections II.3.2.2 and II.3.2.3 discuss these topics.

Many applications, such as those involving changes in component test intervals, allow explicit modeling of the impact of the proposed change in the PRA and quantification of the expected change in risk using plausible models of the impact of the change on SSC unavailability to the extent that the affected components are included in the plant PRA. There are other possible risk-informed applications where it may not be feasible to explicitly model the cause and effect relationship because the actual impact on component unavailability resulting from the proposed change is not clearly understood. For applications such as these, the use of risk categorization techniques provide a useful method to identify groups of less risk important SSCs that are possible candidates for a graded approach to regulatory requirements. Using such a categorization approach, it is still necessary to understand the potential or bounding impact of the proposed change, and to assess the risk impact through such bounding evaluations. In either the detailed quantification approach or the risk categorization approach, risk results should be derived from analyses of appropriate quality. The guidelines to help in the review of PRA quality are discussed in sub section II.3.2.4 and

also in Appendix A of this SRP. Finally, the issues related to the determination of risk contribution/component categorization are discussed in Appendix C of this SRP.

II.3.2.1 Characterization of Change in Terms of PRA Model Elements

Where quantitative PRA results are used as part of a risk-informed evaluation of a proposed change, the licensee should define the change in terms which are compatible with the risk analysis, i.e., the risk analysis should be able to effectively evaluate the effects of the change.

The characterization of the problem should include the establishment of a cause-effect relationship to identify portions of the PRA affected by the issue being evaluated. This includes (i) identification of the specific PRA contributors for the particular application, (ii) an assessment of the portions of the model which should be modified for the application, and (iii) identification of supplemental tools and methods which could be used to support the application. This will help define the scope and level of detail of analysis required for the remaining steps of the change process.

General guidance for the identification of PRA model elements that may be affected by an application is tabulated in Table II-1 of this SRP. This guidance, provided as a list of questions, will assist the reviewer in establishing a cause-effect relationship between the application and the PRA model. The answers to these questions should be used to identify the extent to which the proposed change affects the design, operation and maintenance of plant SSCs.

The reviewer should also verify that the effects of the proposed changes on SSCs are adequately characterized in the PRA elements. For full scale applications of the PRA, this should be reflected in a quantification of the impact on the PRA elements. For applications like component categorization, sensitivity studies on the effects of the change may be sufficient. For other applications it may be adequate to define the qualitative relationship of the impact on the PRA elements or may only require an identification of which elements are impacted.

The review procedure in this element is therefore to verify that the effects of the changes on SSC reliability and unavailability or on operator actions are appropriately accounted for. Where applicable, the modeling and quantification of the effects of the change should also be reviewed to ensure that the models are appropriate and that the results can be supported by plant and/or industry data.

II.3.2.2 Scope of Analysis

The necessary scope of a PRA supporting risk-informed requests will depend on

the specific application. It is not required for risk-informed regulation that licensees submit Level III PRAs that treat all plant operational modes and all initiators. Instead, when full-scope PRAs are not available, licensees should demonstrate that the needed findings are supportable based on traditional engineering analyses, or other plant operational information that address modes and initiators not analyzed in the base PRA.

For plant modes and initiators not analyzed in the PRA such as shutdown, seismic, fire, floods and severe weather, the licensee should consider the effects of the change and provide rationale why additional PRA analyses are not necessary. This rationale could be addressed by assessing the level of redundancy and diversity provided by the plant systems, system trains, human actions, etc. for responding to these unanalyzed configurations. The licensee should also show that the proposed change does not introduce unanalyzed vulnerabilities and that redundancy and diversity will still exist in the plant response capability after the changes are implemented.

This issue is addressed acceptably if:

- The licensee addresses all modes and all initiator types using PRA.

OR

- The licensee demonstrates that the application does not unacceptably degrade plant capability, and does not introduce risk vulnerabilities or remove elements of the plant response capability from programmatic activities aimed at ensuring satisfactory safety performance for plant modes and initiator types not included in the PRA.

OR

- If the proposed change impacts unanalyzed plant modes or initiator types, the licensee demonstrates that a bounding analysis of the change in plant risk from the application (e.g., by qualitative arguments, or by use of sensitivity studies) meets guidelines that are equivalent to the acceptance guidelines specified in Section 2.4.2.1 of draft guide DG-1061.

II.3.2.3 Level of Detail

Generally, the PRA should be detailed enough to account for important system and operator dependencies (functional, operational, and procedural dependencies). SSCs that are being depended upon for more than one function should be modeled explicitly so that potential dependencies will not be obscured in the evaluation process. Initiating events caused by the loss of support systems should be modeled in detail if the failure of the SSCs that could lead to the initiating events could also result in failure of functions that mitigate that event. For components affected by the application, the

reviewer should verify that the models are detailed enough to account for important system and operator dependencies. A check of the licensee failure modes and effects analysis and a review of plant operating and emergency procedures will be useful for this purpose.

The usefulness of PRA results in risk-informed regulation is dependent on the level of resolution of the modeled SSCs. A component level of resolution provides insights at the component level. However, if a PRA is performed at a system or train level, the insights of the PRA will be limited to the system or train level unless it can be demonstrated that component level insights can be bounded by system or train level effects. The direct application of PRA results will be limited to those SSCs that are explicitly modeled as part of PRA basic events. Insights for SSCs that are implicitly modeled (i.e., screened out, assumed not important, etc.) shall only be used after additional consideration of the effects of the proposed change on PRA assumptions, screening analyses and boundary conditions.

Specifically, the level of detail in the modeling of each SSC can be used to determine the following:

- If the SSCs are modeled at the basic event level, i.e., each SSC is represented by a basic event (or sometimes, more than one if different failure modes are modeled), risk insights from the PRA can be directly applied to the component modeled as long as the effects of the change are considered appropriately.

- If the SSCs are included within the boundaries of other components (e.g., the governor and throttle valves being included in the pump boundary); or if they are included in "black boxes" or modules within the PRA model; or they are modeled as part of the calculation of human error probabilities in recovery actions, risk insights from the PRA can be applied if the effects of the application can be mapped onto the events (e.g., modules, HEPs, etc.) in question. In these cases it should be noted that the mapping is relatively simple if the event is ORed with the other module or HEP events. However, if the logic involves AND gates, the mapping will be more complicated.

- If the SSCs are omitted from the model because of inherent reliability or if they are not modeled at all, risk insights on these components should be obtained from an integrated decisionmaking process (such as an Expert Panel) which revisits the assumptions or screening criteria which supported the initial omission.

II.3.2.4 Quality of a PRA for Use in Risk-Informed Regulation

The baseline risk profile is used to model the plant's licensing basis and operating practices that are important to safe operation and may provide insights into areas in which existing requirements can be relaxed without

unacceptable safety consequences. It is therefore essential that the PRA adequately represent the risk profile. To complement this, it is necessary not only to identify significant risk contributors, but also to identify those elements of the plant whose performance is responsible for reducing the risk to acceptable levels, and address these elements adequately in licensee programmatic activities.

Therefore, for risk-informed regulation, the following criteria should be satisfied.

- Reasonable assurance of PRA adequacy: The plant's current licensing basis and actual operating condition and practices are properly reflected in the plant PRA model.
- Robustness of results and conclusions: Results and conclusions must be robust, and an analysis of uncertainties and sensitivities should be carried out to show this "robustness".
- Key performance elements are appropriately classified and performance is backed up by licensee commitments: PRA results are dependent on plant activities. They reflect not only inherent device characteristics but also numerous programmatic activities, such as IST, ISI, GQA, and so on. Use of a PRA to justify relaxation of a requirement should therefore imply a commitment to whatever programmatic activities are needed to maintain performance at the PRA-credited levels that served as the basis for the proposed relaxation.

Review of PRA Quality

Quality in the licensee's technical analysis must be demonstrated in the licensee request. Guidance in this area is provided in Section 2.7 of DG-1061.

Staff review shall demonstrate that the PRA is of sufficient quality to support the decision. The reviewer should evaluate the licensee process to ensure quality. In addition, for each application, specific findings should be made regarding the quality of the PRA for that application. At a minimum, these findings should be based on a "focused-scope" staff review which will concentrate on application specific attributes of the PRA. This includes a review of the assumptions and elements of the PRA model that drive the results and conclusions.

Appendix A of this SRP provides more detailed guidance on several issues important to the application-specific reviews of probabilistic evaluations performed as part of risk-informed regulation.

In addition to the focused-scope review, the following factors should be considered in determining the need for a more detailed and larger scope staff review of the PRA.

- Staff audits of the licensee's process for conducting a PRA have identified practices which could affect the quality of the technical analysis detrimentally;
- Results of the licensee's analysis submitted in support of a licensing action are in some way counter-intuitive or inconsistent with results for similar plants on similar issues;
- The licensee's analysis is part of a pilot application of PRA in a regulatory activity;
- The PRA includes new methods that are unfamiliar to the staff.

Draft NUREG-1602 contains reference material that could be utilized to help in the larger scope staff review of PRAs.

Quality Assurance Requirements Related to the PRA

To the extent that a licensee elects to use PRA as an element to enhance or modify its implementation of activities affecting the safety-related functions of SSCs, appropriate quality requirements will also apply to the PRA. In this context, therefore, a licensee would be expected to control PRA activity in a manner commensurate with its impact on the facility's design and licensing basis. Section 2.7 of DG-1061 provides a description as to what quality elements are applicable to the licensee's PRA activities. The reviewer should determine that the quality of analyses and performance programs which affect safety-related equipment and activities, will meet the quality guidelines as described in draft guide DG-1061.

II.3.2.5 Risk Impact Including Treatment of Uncertainty

Determination of Risk Impact from the Application

For many risk-informed applications, a quantitative estimate of the total impact of a proposed action is expected to be performed. This includes the evaluation of the absolute and/or relative changes in risk measures such as core damage frequency (CDF) and large early release frequency (LERF). The necessary sophistication of this evaluation depends on the justification arguments and the magnitude of the potential risk impact. For those actions justified primarily by traditional engineering considerations and for which minimal risk impact is anticipated, a bounding estimate may be sufficient. For actions justified primarily by PRA considerations for which a substantial impact is possible or is to be offset with compensatory measures, an in-depth and comprehensive PRA analysis is generally needed.

The acceptance guidelines for changes to the plant's risk profile are discussed in section 2.4.2 of draft Reg Guide DG-1061. In the detailed evaluation of risk significance, the following should be considered: baseline

risk; change in the baseline risk; and risk in terms of CDF and LERF. It is necessary to address both internal and external events and all plant operational modes, but it may be possible to accomplish this without a full-scope PRA in all cases.

In accordance with DG-1061, it is expected that applications will result in a net decrease in ris or be risk neutral for plants with CDFs at or above 1E-4 per reactor year or .ERFs at or above 1E-5 per reactor year. In these cases, the reviewer should verify that proposed compensatory measures or plant improvements would clearly offset risk increases from proposed relaxation in current requirements. It is preferred that the net change in risk be quantified, however, risk improvements can also be demonstrated in a non-quantitative sense as long as it can be clearly justified that the risk decrease will at least offset any risk increases.

For plants with base CDFs of less than 1E-5 per reactor year and base LERFs of less than 1E-6 per reactor year, CDF increase of less than 1E-6 per reactor year and LERF increase of less than 1E-7 per reactor year is allowed subject to the principles and expectations as specified in Section II.1 of this SRP being met. In the review of where the plant stands in terms of the base risk, the staff should evaluate licensee justification of the base CDF and LERF. For PRAs that are full scope (i.e., those that include all probabilistically significant initiators and operating modes), the review could consist of the verification of PRA quality as described in Section II.3.2.4. For less than full scope PRAs, or in cases where the base risk is close to the acceptance guidelines (e.g., within a half order of magnitude of the guidelines), the reviewer should also consider the licensee's analysis of uncertainties as described later in this section of the SRP. For comparisons in the change in risk, the reviewer is referred to Sections II.3.2.1, II.3.2.2 and II.3.2.3 of this SRP.

In addition to the above guidelines, larger risk increases of 1E-5 in CDF and 1E-6 in LERF could be allowed subject to increased NRC management review. For this to apply, the base CDF should be less than 1E-4 per reactor year and the base LERF should be less than 1E-5 per reactor year. In the compilation of information for management review, the staff should include:

- the scope, quality, and robustness of the analysis (including, but not limited to, the PRA), including consideration and quantification of uncertainties;

- the base CDF and LERF of the plant;

- the cumulative impact of previous changes (the licensee's risk management approach);

- consideration of the Safety Goal screening criteria in the staff's Regulatory Analysis Guidelines, which define what changes in CDF and containment performance would be needed to consider potential

backfits;

- o the impact of the proposed change on operational complexity, burden on the operating staff, and overall safety practices; and
- o plant-specific performance and other factors, including for example, siting factors, inspection findings, performance indicators, and operational events.

Treatment of Uncertainties

The uncertainties in the PRA results should be taken into account in the assessment of the risk impact and in the risk-informed decisionmaking process to demonstrate the robustness of the results. The general approach to taking uncertainty into account is discussed in section 2.4.2 of draft guide DG-1061.

When required, the analysis of uncertainties should have the following attributes:

- It should reflect the uncertainties associated with each parameter and provide an assessment of the confidence with which any numerical guidelines are met.
- It should account for model uncertainties. There may be several alternate approaches to the analysis of certain elements of the PRA model. The licensee should document why the model or assumption used is appropriate both for the base case risk evaluation and for the analysis of the impact of the change. In certain cases, it may be necessary to perform sensitivity analyses using alternate models or assumptions to demonstrate the robustness of the conclusions.
- It should attempt to address uncertainty that is caused by potential incompleteness of the scope of the PRA model. The licensee should address the lack of completeness either by demonstrating that the impact of the missing parts on both the base case risk and the change to risk as a result of the application is bounded so that the overall result is acceptable, or by limiting the scope of the application to the SSCs for which the impact on risk can be evaluated (see section II.3.2.2).

In the review of the analysis of uncertainties, the staff should:

- review the types and sources of uncertainty that have been identified by the licensee, and how the uncertainties have been addressed with reference to the decision guidelines provided in DG-1061;
- identify if results are strongly impacted by the specific models or assumptions adopted for the assessment of important elements of the PRA, and whether the sensitivity analyses that have been performed (if any) are sufficient to address the most significant uncertainties with

respect to these elements. (Care should be taken when the characterization of a model uncertainty is such that the results fall into a bimodal or multi-modal distribution, and one or more of the modes exceeds the acceptance guidelines. The review of the results then should be based on an evaluation of the significance of the hypotheses associated with those modes that exceed the guidelines);

- determine whether the limitations in scope of the PRA, and other completeness issues have been addressed adequately by either limitation of the scope of the application, or by a demonstration that the impact of the unanalyzed portion of the risk on both the base case risk and on the change in risk is bounded or can be neglected.

Cumulative and Synergistic Effects from all Applications

The flexibility available to any given plant is not only a function of where it started in terms of base risk, but also a function of how much risk increase has taken place in preceding applications. As discussed in the next section, licensee risk management practices are expected to keep the cumulative increases low. The reviewer is expected to look at past changes in the plant to see if large increases are being accumulated. The reviewer should verify that:

- each application is carried out with reference to a model that already reflects previous applications;

- the cumulative changes from license amendments are being monitored; and

- the accumulation of applications has not created dominant risk contributors.

Beyond cumulative effects, synergistic effects are also possible, not all of which would emerge from a quantification of the PRA. For example, if conventional importance ranking approaches are employed to determine importance of SSCs, it would be possible that multiple requirements could be relaxed on certain "low" significant components under multiple applications. If the QA (potentially affecting the failure rate) and the test interval (potentially affecting fault exposure time) were to be relaxed for the same component, the component unavailability could increase more than expected (since failure rate and fault exposure time combine multiplicatively in the calculation of unavailability). If the effects of QA on failure rate could be quantified convincingly, this would be addressed explicitly, but this cannot presently be assured. As a result, there is potential for different applications to lead to unintended and unquantified synergistic effects on unavailability of a given component.

Synergistic effects on a given element can be addressed by showing that the basic event model adequately reflects the effects of programmatic activities and that the calculated unavailability, propagated through the PRA, is

consistent with the needed performance with regard to the risk indices and the defense-in-depth concept.

However, it is more straight-forward simply to not allow for the relaxation of multiple programmatic requirements on a given component, unless demonstrable justification is provided that the risk contribution from the component is negligible for conditions covered by the set of requirements. For example, if IST is relaxed on a given component, it would be preferable not to relax QA as well, unless good arguments are given for allowing this.

Risk Management

One of the goals of the review should be to ensure that in the course of the licensee's engineering evaluations, principles of risk management are applied appropriately in the process of evaluating changes to current regulatory requirements. For the purposes of this SRP, "risk management" will refer to an approach to decisionmaking about safety that seeks to allocate available resources and worker dose in such a way as to minimize the risk to public health and safety from plant operations. The staff recognizes that there is a point of diminishing returns in risk reduction and that some residual risk will be associated with plant operation, but expects that an effort will be made to identify reasonable measures to control this residual risk as part of the risk-informed regulatory process.

Therefore, as a staff expectation, the process of risk management in risk-informed decisionmaking should not be biased towards elimination of requirements to the exclusion of safety enhancements that would convey a worthwhile safety benefit. Licensees are expected to apply risk insights in an unbiased way, and licensees who do not satisfy subsidiary safety objectives (as defined in DG-1061) are expected to proactively seek safety enhancements in conjunction with any risk-informed applications.

Allowed increases in the CDF and LERF from proposed licensee applications should be small and any increases in the risk should not cause the NRC Safety Goals to be exceeded. The size of an allowable individual risk increase (per DG-1061) depends on the magnitude of the current plant risk. Net increases should generally not be considered without some evidence of licensee effort to identify measures to offset the risk increases caused by the proposed relaxations.

Finally, when risk increases are proposed, reviewers should consider plant performance and past changes to the licensing basis to ensure that there is no pattern for a systematic increase in risk. Insights on the licensee operational practices, management controls, risk management programs, plant configuration control programs, or performance monitoring programs from previous applications can be obtained from the NRC regional offices or from documentation of NRC inspection activities.

II.3.3 <u>Integrated Decisionmaking Process</u>

The acceptability of the proposed changes should be reviewed and determined in an integrated fashion. The reviewer should verify that the results of the traditional engineering analyses and the risk assessment have been used to ensure that the principles listed in section II.1 have been met. Due to the scope and quality of the engineering analyses, careful examination of the underlying assumptions in the analyses may be necessary to conclude with reasonable assurance that the principles were satisfied.

As part of the integrated decisionmaking process, implementation and monitoring strategies should be utilized to provide confidence in the results of the underlying engineering analyses. In addition, compensatory measures which reduce risk can be taken to offset incompleteness or uncertainties in the analysis. Compensatory measures can also be used to offset a quantifiable increase in risk with a non-quantifiable but expected improvements in safety.

To ensure that the underlying assumptions utilized in the PRA remain valid, the integrated decisionmaking process should ensure that an appropriate set of programmatic activities (e.g., IST, GQA, ISI, maintenance, monitoring) are maintained for important elements of the plant response capability. In addition, performance of compensating SSCs should be assured (through programmatic activities) when these SSCs are used to help justify the relaxation of requirements of other SSCs.

The process used by licensees to integrate traditional and probabilistic engineering evaluations for risk-informed decisionmaking is expected to be well-defined, systematic, repeatable, and scrutable. Appendix B of this SRP provides review guidance and staff expectations of licensee integrated decisionmaking process.

II.4 Element 3: Develop Implementation and Monitoring Strategies

Implementation and monitoring strategies are important in most risk-informed processes since they can provide early indication of SSC or other plant performance under the proposed changes. In addition, these strategies may be needed to ensure that the key assumptions or performance of key SSCs related to a proposed change are effectively maintained. Section 2.5 of DG-1061 provides guidance for the suggested process in this submittal element.

A key element in the performance monitoring process is the verification of the capability and availability allocated to SSCs which support the underlying basis for the decisionmaking. This process should also include non-safety related SSCs that are relied upon to justify the proposed change to the CLB.

The reviewer should evaluate the implementation and monitoring strategies based on findings of the traditional engineering and probabilistic evaluations.

When broad implementation is proposed over a short period of time, the

reviewer should verify that this is consistent with the traditional engineering evaluations, defense-in-depth (including common cause failure) considerations, and risk evaluation models and assumptions. When there is a need to gain additional performance insights given a change in requirements, the reviewer should verify that a phased approach to implementation has been proposed. If this phased approach involves plan implementation for different SSC groups at different times, the basis for the selection of the SSC groups and the timing should be reviewed.

When SSC or licensee performance can be affected by the proposed change, the reviewer should ensure that monitoring strategies are proposed to evaluate the performance over a period of time. This monitoring should be based on the reliability/availability and key modeling assumptions allocated to SSCs in the risk model (or on performance of operators, where appropriate) used to support the proposed change in regulation. As such, the reviewer should ensure that performance criteria chosen are consistent with the level of performance allocated in the risk analysis.

When monitoring that is already being performed as part of the Maintenance Rule implementation is also proposed for the current application, the reviewer should ensure that the performance criteria chosen are appropriate for the application in question.

Licensee proposed corrective actions should also be reviewed as part of the review on the monitoring program. If monitoring detects degradation, then there should be provisions for the SSCs to be refurbished, replaced, or tested/inspected more often (or a combination of these initiatives). The selected action should be based on a root cause analysis of the degradation, whether it is generic, age-related, etc. The reviewer should evaluate if the information gathered during monitoring activities is extensive enough to provide a timely indication of component degradation. Since many components are inherently quite reliable, the limited tests on a limited number of similar components may not provide adequate data, especially for newer plants where aging effects may not be detected until the proposed program is fully in place (and the advantages of a phased implementation are lost). One approach to ameliorate this concern would be to obtain performance data of similar SSCs at other plants with a range of operating times to expand the applicable database over a range of component ages. Such a program would be expected to provide a better chance of early detection of SSC reliability degradation.

A review (or evaluation) of the impact on plant risk and SSC functionality, reliability and availability given the proposed implementation and monitoring plan should also be carried out. The benefits from the implementation and monitoring programs should be balanced against any negative impact on risk.

Finally, the reviewer should also look at the criteria to be applied in deciding what actions are to be taken in cases where performance falls below that predicted by the supporting evaluations. Corrective action procedures should be in place before implementation of the proposed program.

II.5 Element 4: Staff Evaluation of Submittal

In order for the staff to make a conclusion of acceptability of the proposed CLB change based on review guidance provided in earlier sections, sufficient engineering and licensing information have to be submitted or be made available by the licensee. Furthermore, the data, methods, and assessment criteria used to support the regulatory decisionmaking should be available for public review.

In addition, appropriate regulatory action should be requested by the licensee. Requests for proposed changes to the plant's CLB typically take the form of requests for license amendments (including changes to or removal of license conditions), technical specification changes, changes to or withdrawal of orders, and changes to programs pursuant to 10 CFR 50.54 (e.g., QA program changes under 10 CFR 50.54(a)). The staff should determine if: (i) the form of the change request is appropriate for the proposed CLB change; (ii) the information required by the relevant regulation(s) in support of the request is submitted; and (iii) the request is in accordance with relevant procedural requirements. For example, license amendments should meet the requirements of 10 CFR §§50.90, 50.91 and 50.92, as well as the procedural requirements in 10 CFR §50.4. Where the licensee submits risk information in support of the CLB change request, that information should meet the guidance in Section 3 of draft guide DG-1061.

Licensees have a choice of whether to submit results or insights from risk analyses in support of their CLB change request. Where the licensee's proposed change to the CLB is consistent with currently-approved staff positions, the Staff's determination will be based solely on traditional engineering analysis without recourse to risk information (although the Staff may consider any risk information which is submitted by the licensee). However, where the licensee's proposed change goes beyond currently-approved staff positions, the Staff should consider both information based upon traditional engineering analysis as well as information based upon risk insights. If the licensee does not submit risk information in support of a CLB change which goes beyond currently-approved Staff positions, the Staff may request that the licensee provide this information. Such a request is not a backfit under 10 CFR 50.109. If the licensee chooses not to provide the risk information, the Staff will review the proposed application using traditional engineering analysis and determine whether sufficient information has been provided to support the requested change.

In risk-informed change proposals, licensees are expected to identify SSCs with high risk significance which are not currently subject to regulatory

requirements, or are subject to a level of regulation which is not commensurate with their risk significance, and propose CLB changes that will subject these SSCs to the appropriate level of regulation, consistent with the risk significance of each SSC. Specific information on the staff's expectation are set forth in the application-specific regulatory guides. The staff reviewer should assure that the application-specific guidance is followed. If there is no guidance, the reviewer should determine whether any assumptions from the risk analysis are reflected in the licensing basis, and that commitments for enhanced regulatory requirements/controls applicable to high risk SSCs not currently subject to regulatory requirements (or subject to a level which is not commensurate with their risk significance) are appropriate and reflected in the licensing basis.

Update of the Safety Analysis Report

Reviewers should assure that the proposed changes, when approved by the staff, will be appropriately included in future updates to the licensee Safety Analysis Report. In addition, important assumptions including SSC functional capabilities and performance attributes, which play a key role in supporting the acceptability of the CLB change, should be identified by the licensee. Since the continued satisfaction of these assumptions is necessary to maintain the validity of the safety evaluation, the reviewer should verify that such assumptions are reflected by licensee commitments which are incorporated into the Safety Analysis Report. The reviewer should verify that the licensee has submitted revised FSAR pages as necessary. This revision should include all the programmatic activities, performance monitoring aspects and SSC functional performance and availability attributes which form the basis of the request. This material should identify those SSCs whose performances should be verified (including nonsafety-related SSCs whose performance and reliability provide part of the basis for the CLB change).

NEPA Considerations

In accordance with 10 CFR Part 51, environmental protection regulations such as those from the National Environmental Policy Act (NEPA) would have to be addressed as part of the staff's review process. The reviewer should utilize NRR Office Letter 906, Revision 1 and 10 CFR 51.25 to determine how the NEPA requirements are to be addressed. If it is determined necessary, an environmental assessment (EA) should be prepared to assess whether an environmental impact statement (EIS) is required or whether a finding of no significant impact (FONSI) can be made. It is expected that, if all the guidance and acceptance criteria provided in DG-1061 is satisfied, the staff should normally be able to make a finding of no significant impact for the proposed CLB change.

Table II-1 (page 1 of 3)

Questions to Assist in Establishing the Cause-Effect Relationship[2]

LEVEL 1 (INTERNAL EVENTS PRA)

Initiating Events

- Does the application introduce consideration of new initiating events?
- Does the application address changes that lead to a modification of the initiating event groups?
- Does the application necessitate a reassessment of the frequencies of the initiating event groups?
- Does the application increase the likelihood of a system failure that was bounded by an initiating event group to the extent that it needs to be considered explicitly?

Success Criteria

- Does the application necessitate modification of the success criteria?
- Does the modification of success criteria necessitate changes in other criteria, such as system interdependencies?

Event Trees

- Does the application address an issue that can be associated with a particular branch, or branches on the event trees, and if so, is the branching structure adequate?
- Does the application necessitate the introduction of new branches or top events to represent concerns not addressed in the event trees?
- Does the application necessitate consideration of re-ordering branch points, i.e., does the application affect the sequence dependent failure analysis?

System Reliability Models

- Does the application impact system design in such a way as to alter system reliability models?
- Does the application impact the support functions of the system in such a way as to alter the dependencies in the model?
- Does the application impact the system performance, and, if so, is that impact on the function obscured by conservative modeling techniques?

Parameter Data Base

- Can the application be clearly associated with one or more of the basic event definitions, or does it necessitate new basic events?
- Does the application necessitate a specialized probability model (e.g., time-dependent model, etc.)?
- Does the application necessitate modifications to specific parameter values?
- Does the application introduce new component failure modes?
- Does the application affect the component mission times?
- Does the application necessitate that the plant-specific (historical) data be taken into account, and can this be achieved easily by an update of the previous parameters?
- Does the application involve a change which may impact parameter values, and do the present estimates reflect the current status of the plant with respect to what is to be changed?

Dependent Failure Analysis

- Does the application introduce or suggest new common cause failure (CCF) contributions?
- Does the application introduce new asymmetries that might create sub-groups within the CCF component groups?
- Is the application likely to affect CCF probabilities?

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[2] Information from section 3.3 of the EPRI PSA Applications Guide provided substantial input to this listing.

Table II-1 (page 2 of 3)

Questions to Assist in Establishing the Cause-Effect Relationship

Human Reliability Analysis

- Does the application involve a procedure change?
- Does the application involve a new human action?
- Does the application change the available time for human actions?
- Does the application affect the human action dependency analysis?
- Does the application eliminate or modify an existing human action?
- Does the application introduce or modify dependencies between plant instrumentation and human actions?
- Is the application concerned with events that have been screened from the model, either in whole or in part?
- Does the application impact a particular performance shaping factor (PSF), or a group of PSFs, and are they explicitly addressed in the estimation approach? For example, if the issue is to address training, is training one of the PSFs used in the HRA?
- Does success in the application hinge on incorporating the impact of changes in PSFs, and if so, do the current estimates reflect the current status of those PSFs?
- Is it possible that the particular group of human error events that is affected by the change being analyzed has been truncated?
- Does the change address new recovery actions?

Internal Flooding

- Does the application affect the screening analysis, for example, does the application result in the location of redundant trains or components into the same flood zone?
- Does the application introduce new flooding sources or increase existing potential flood inventories?
- Does the application affect the status/availability of flood mitigation devices?
- Does the application affect flood propagation pathways?
- Does the application affect critical flood heights?

Quantification

- Does the application change any of the basic event probabilities?
- Does the application change relative magnitudes of probabilities?
- Does the application only make probabilities smaller?
- Is the new result needed in a short-time scale?
- Does the application necessitate a change in the truncation limits for the model?
- Does the application affect the "delete terms" used during the quantification process? (More specifically, does the application introduce new combinations of maintenance actions or operating modes that are deleted during the base case quantification process using the delete function?)
- Does the application affect equipment that have been credited for operator recovery actions? Also, for recovery actions that credit inter-system or inter-unit cross ties, the effect on other systems or functions or on the operation of the other unit should be considered and addressed.

Analysis of Results

- Does the application necessitate an assessment of uncertainty, and is it to be qualitative or quantitative?
- Are there uncertainties in the application that could be clarified by the application of sensitivity studies?
- Does the application strategy necessitate an importance analysis to rank contributions?
- Does the application necessitate that an importance, uncertainty, or sensitivity analysis of the base case PRA exist?

Plant Damage State Classification

- Does the application impact the choice of parameters used to define plant damage states?
- Does the Key Plant Damage States (KPDS) utilized adequately represent the results of the Level 1 analysis by including the plant damage states that have a significant frequency of occurrence?
- Have those plant damage states that have been eliminated in this process been assigned to KPDSs of higher consequence (e.g. likelihood of Large Early Release)?

Table II-1 (page 3 of 3)

Questions to Assist in Establishing the Cause-Effect Relationship

Level 2 (CONTAINMENT ANALYSIS PRA)

- Have new containment failure modes identified by the application been addressed in the PRA? Are potential changes accounted for?
- Are any dependencies among containment failure modes being changed?
- Does the application involve mechanisms that could lead to containment bypass?
- Does the application involve mechanisms that could cause failure of the containment is isolate?
- Does the application directly affect the occurrence of any severe accident phenomena?
- Does the application necessitate use of risk measures other than large, early release?
- Does the application change equipment qualification to the point where it affects timing of equipment failure relative to containment failure?
- Does the application affect core debris path to the sump / suppression pool or to the other portions of the containment?
- Does the selected source term categories adequately represent the revised Containment Event Tree (CET) endpoints? Are CET endpoint frequencies changed enough to affect the selection of the dominant/representative sequence(s) in the source term binning process?
- Does the application affect the timing of release of radionuclides into the environment relative to the initiation of core melt? and relative to the time for vessel rupture?

LEVEL 3 (CONSEQUENCE ANALYSIS PRA)

- Does the application necessitate detailed evacuee doses?
- Are individual doses at specific locations needed for this application?
- Is evacuation or sheltering being considered as a mitigation measure?
- Are long term doses a consideration in this application?

EXTERNAL EVENTS PRA (Hazard Analysis)

- Will the changes introduce external hazards not previously evaluated?
- Will the changes increase the intensity of existing hazards significantly?
- Are design changes modifying the structural response of the plant being considered?
- Does the change impact the availability and performance of necessary mitigation systems for an external hazard?
- Does the application significantly modify the inputs to the plant model conditioned on the external event?
- Are changes being requested for systems designed to mitigate against specific external events?
- Does the application involve availability and performance of containment systems under the external hazard?

SHUTDOWN PRA

- Will the changes affect the scheduling of outage activities?
- Will the changes affect the ability of the operator to respond to shutdown events?
- Will the application affect the reliability of equipment used for shutdown conditions?
- Will the changes affect the availability of equipment or instrumentation used for contingency plans?

III. EVALUATION FINDINGS

The results of a reviewer's evaluation should reflect a consistent and scrutable integration of the probabilistic considerations and traditional engineering considerations provided by the licensee or applicant and developed independently by the reviewer. To make a finding of acceptability the reviewer will generally need to show that in light of a small or non-existent increase in risk and a reduced level of conservatism, defense-in-depth and sufficient safety margins are maintained. Findings of acceptability should be supported with logical bases built from an evaluation of the considerations given in section II.

The reviewer should confirm that sufficient information is provided in accordance with the requirements of this SRP and that the evaluation supports conclusions as specified below, to be included in the staff's safety evaluation report.

General

- The proposed change meets the current regulations. This principle applies unless the proposed change is explicitly related to a requested exemption or rule change (i.e., a 50.12 "specific exemption" or a 2.802 "petition for rulemaking").
- Defense-in-depth is maintained.
- Sufficient safety margins are maintained.
- Proposed increases in risk and their cumulative effect are small, and these changes do not cause the NRC Safety Goals to be exceeded.
- Performance-based implementation and monitoring strategies are proposed that address uncertainties in analysis models and data and provide for timely feedback and corrective action.
- All safety impacts of the proposed change are evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly and not just to eliminate requirements the licensee sees as undesirable. The approach used to identify reduced requirements was also used to identify if there are areas where requirements should be increased.
- The acceptability of the proposed changes have been evaluated in an integrated fashion that ensures that all principles are met;
- Increases in estimated CDF and LERF resulting from proposed CLB changes are limited to small increments.

- The scope and quality of the engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed CLB change are appropriate for the nature and scope of the change and are based on the as-built and as-operated and maintained plant.

- Appropriate consideration of uncertainty has been given to analyses results and interpretation of findings.

- The plant-specific PRA supporting licensee proposals has been subjected to quality controls such as an independent peer review.

- Data, methods, and assessment criteria used to support regulatory decisionmaking are available for public review.

Definition of the Proposed Change

- Adequate traditional engineering and probabilistic evaluations are available to support the proposed CLB change. Plant-specific and relevant industry data and operational experience also supports the proposed change.

- Cause-effect relationships have been identified to adequately link the application with the PRA model elements.

- The proposed risk models can effectively evaluate or realistically bound the effects of the proposed change.

- Information from engineering analyses, operational experience, plant-specific performance history have been factored into the decision process.

Evaluations of Defense-In-Depth Attributes and Safety Margins

- Defense-in-depth is preserved, for example: system redundancy, diversity and independence is maintained commensurate with the expected frequency and consequence of challenges to the system; defenses against potential common cause failures are maintained and the introduction of new common cause failure mechanisms is assessed; and defenses against human errors are maintained.

- Sufficient safety margins are maintained, for example: codes and standards approved for use by the NRC are met or deviations justified; and safety analysis acceptance criteria in the CLB are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty.

- Current regulations have been met or the proposed exemption is acceptable.

Scope of Risk Analysis

- The licensee's PRA satisfactorily addresses all mode/initiator combinations, **OR**

- The licensee's PRA does not need to analyze the following mode/initiator type combinations. [List combinations] In each instance, the licensee has demonstrated that:

  - suitably redundant and diverse plant response capability is maintained for significant initiators in these modes; and

  - sufficient elements of the plant response capability are subject to programmatic activities to assure suitable performance.

Level of Detail of Risk Analysis

- The PRA is detailed enough to account for important system and operator dependencies.

- Risk insights are consistent with the level of detail modeled in the PRA.

Quality of the PRA

- There is reasonable assurance of PRA adequacy as shown by the licensee process to ensure quality and by a focused scope application-specific review by the staff.

- Results are robust in terms of uncertainties and sensitivities to the key modeling parameters.

- Key performance elements for the application have been appropriately classified and performance is backed up by licensee commitments.

Risk Impact and Treatment of Uncertainty

- If the risk-informed application is based on the quantification of the change to risk, then the following applies:

  - The application is either risk neutral or results in a decrease in plant risk, **OR**

  - If an application results in an increase in risk, the increase is within the guidelines defined in draft guide DG-1061. The cumulative and synergistic effects on risk from the present and previous applications have been addressed. Licensee risk management practices are being followed to minimize the risk from plant operations.

- o In either of the above cases, an appropriate consideration of uncertainties is provided in support of the proposed application. The licensee showed that the uncertainty in the risk change was small compared to the margin between the estimated change and the allowable change. This argument was supported either by explicit propagation or by a qualitative and/or sensitivity analysis showing that no event contributing to the change in risk is subject to significant uncertainty.

- If the risk-informed application is based on a qualitative assessment of the change to risk, then the application is shown to result in a decrease in plant risk, or is risk neutral, or CDF and LERF increases are shown to be acceptable based on bounding evaluations or sensitivity studies. When this assessment is based solely on traditional engineering information or use of compensatory actions, then the application clearly shows a reduction in risk.

Integrated Decisionmaking Process

- Results from traditional engineering analyses and risk analyses have been used to ensure that the principles for risk-informed decisionmaking have been met.

- Potential analysis limitations, uncertainties and conflicts are resolved by use of conservative results, or by use of appropriate implementation and monitoring strategies, or by use of appropriate compensatory measures.

- The integrated decisionmaking process is well-defined, systematic, repeatable, and scrutable.

Implementation and Monitoring Strategies

- The implementation process is commensurate with the uncertainty associated with the results of the traditional and probabilistic engineering evaluations.

- A monitoring program which could adequately track the performance of equipment covered by the proposed licensing changes was established. It was demonstrated that the procedures and evaluation methods will provide reasonable assurance that performance degradation will be detected and that the corrective action plan will assure that appropriate actions can be taken before SSC functionality and plant safety is compromised. Data from similar plants will be used if needed.

- In addition to the tracking of performance of SSCs affected by the application, the performance monitoring process also includes the tracking of performance of SSCs which support the underlying basis for the decisionmaking.

Licensee Submittal

- The submittal includes sufficient information to support conclusions regarding the acceptability of the proposed change.

- The appropriate regulatory action was requested. In addition, pertinent information on the CLB change will be included in the Safety Analysis Report, technical specifications or license conditions as necessary.

- The licensee has appropriately committed to the important programmatic and performance assumptions in the PRA and engineering analyses which served as the basis of the CLB change. These include any enhancements to regulatory requirements necessary to preserve assumptions in the PRA and engineering analyses, and to reflect new regulatory requirements for high risk significant SSCs not otherwise subject to existing requirements, commensurate with their risk significance. These commitments are reflected in revisions to the Safety Analysis Report, technical specifications or appropriate licensee conditions have been imposed by the staff.

IV. IMPLEMENTATION

The following is intended to provide guidance to applicants and licensees regarding the NRC staff's plans for using this SRP section.

Except in those cases in which the applicant or licensee proposes a acceptable alternative method for demonstrating that a proposed CLB change is acceptable, the method described herein will be used by the staff in its evaluation of risk-informed changes to the CLB.

V. REFERENCES

1. "Status Update of t/ ; gency-Wide Implementation Plan for Probabilistic Risk Assessment", U.S. Nuclear Regulatory Commission, SECY-95-279, March 30, 1995

2. NRC Policy Statement on "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities", (60 Federal Register (FR) 42622, August 16, 1995.

3. "Framework for Applying Probabilistic Risk Analysis in Reactor Regulation", U.S. Nuclear Regulatory Commission, SECY-95-280, November 27, 1995.

4. "PSA Applications Guide", Electric Power Research Institute, EPRI-TR-105396, August 1995.

5. "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," Draft Regulatory Guide, DG-1061, XXXXX, 1997.

6. "Guidelines for Use of PRA in Risk-Informed Applications", Draft NUREG-1602, XXXXX, 1997

7. "Procedures for Treating Common Cause Failures in Safety and Reliability Studies", NUREG/CR-4780, January 1988

8. "Severe Accident Risks: An Assessment for Five Nuclear Power Plants," NUREG-1150, Volumes 1 and 2, December 1990

9. "Common-Cause Failure Data Collection and Analysis System", Draft Volumes 1 through 6, INEL-94/0064, December 1995

Appendix A GUIDANCE FOR A FOCUSED-SCOPE APPLICATION SPECIFIC PRA REVIEW

As stated in Section II.3.2.4 of this SRP and in draft guide DG-1061, PRAs that are used in risk-informed submittals to determine risk significance or risk impact should have been shown to be of adequate quality. Staff evaluation of a licensee risk-informed application submittal is expected to include a review of the licensee process for PRA quality assurance. Where necessary, this should be supplemented by an overall review of the following: event and fault tree models; data on SSC failures and common cause failures; mission success criteria; initiating event analysis; human reliability analysis; and result quantification including the analysis of uncertainties. These reviews should be of sufficient detail to provide the staff with confidence that the PRA properly reflects the plant's CLB and actual operating conditions and practices. Results from previous staff review efforts (e.g., from prior applications) should be utilized as appropriate.

In addition to the general overall review as described above, staff reviewers are also expected to perform a focused-scope review of the risk analysis on an application-specific basis. This appendix provides review guidance on the likely elements of a PRA which may affect or be affected by proposed changes to the CLB.

A.1 <u>Use of Appropriate Data</u>

a. Area of Review

In risk-informed applications it is important that appropriate SSC failure data is used. While plant-specific data is preferred, for plants with little operating history, the only choice is use of generic data. Furthermore, when the impact of the change is being modeled as a modification of parameter values, there may be no plant-specific data to support the modification. The data related issues are the following: a) if the impact of the application is to be modeled as a change in parameter values associated with basic events representing modes of unavailability of certain SSCs, these changes should be reasonable and should be supported by technical arguments; and b) the impact of the change is neither exaggerated nor obscured by the parameter values used for those SSCs unaffected by the change.

b. Review Guidance and Procedures

It is to be expected that, for a PRA that has undergone a technical review, parameter values will have been judged to be appropriate, whether they have been evaluated using generic or plant specific data. However, since the review was focused on the PRA as a base case model, a different perspective on the appropriateness of parameter values may be required for specific applications. Therefore, in reviewing PRA applications, the reviewer should focus on those parameter values that have the potential to change the

conclusion of the analysis. For example, parameters associated with SSCs that appear in the same cutsets as the affected SSCs have the potential to distort the conclusions by decreasing the assessed importance of the change if their values are too low, or by increasing it if their values are too large. Similarly, parameters that contribute to the cutsets that do not contain affected SSCs can decrease the importance of the change by being too large, or increase it by being too low.

Whether the data used is plant-specific, generic, or a combination of both, the parameter values are expected to be consistent with generally accepted values from PRAs of similar plants, or significant deviations should have been justified. Significant in this context can be defined as no greater than a factor of 3 for the mean values of the failure rate or failure probability. The focus of the review should be on those parameter values which both have a significant impact on the results as discussed above, and which deviate significantly from the generally accepted norm.

If it was decided that a more detailed review of the parameter values is appropriate, then the following guidance applies. For plant-specific data, the reviewer should determine how plant records were used to estimate the number of events/failures, the number of demands, and the operating hours or standby hours. The reviewer should verify the consistency between the definitions of failure modes and component boundaries used in the risk analysis and the definitions used in the plant records. When generic data are used, it is important to verify that the plant component is typical of the generic industry component. In cases where generic failure rates are used in combination with plant-specific data like test intervals, the reviewer should verify that the generic data are applicable for the range of plant data used.

When evaluating the impact of the change, it is important for the reviewer to recognize the assumptions that have gone into developing the PRA model. For example, two models are commonly used for events representing the unavailability of a standby component on demand; the standby failure rate model and the constant probability of failure on demand model. Using the former model can result in large differences between the unavailabilities of components whose test intervals differ significantly, given the same standby failure rate is used. The reviewer should be sensitive to this effect, and ascertain that appropriate models are used. As another example, in considering plant-specific failure data, poorly-performing individual components may have been grouped with other components, allowing their poor performance to be averaged over all components of that type. Poor performance may arise because of inherent characteristics of one member of what would otherwise be considered a uniform population, or may arise because components are operating in a more demanding environment. If these components are grouped together with others for which the operating conditions are more favorable, then the failure rates used for the poor performers could be artificially lowered. If requirements are relaxed based on the group failure rate, reduced programmatic attention to these poor performers could lead to a greater than expected probability of experiencing an in-service failure of one

of these components. The reviewer should be aware of such effects, and should make sure that components are grouped appropriately.

When the impact of the change is being modeled as a change in the parameter values associated with specific basic events representing modes of unavailability of SSCs, the reviewer should focus on whether the change in parameter values is appropriate and reasonable. The rationale behind the change in parameter values is expected to be documented and should be reviewed carefully.

If generic values are used for the base case parameter values which are candidates for being changed, it should be checked that the conditions under which the generic data are applicable do not correspond to those which would be more appropriate for a plant with the change incorporated. This should only be a real concern if the plant being changed is somewhat untypical with respect to the issue being addressed by the change. This would not be a concern if plant specific data were being used.

Finally, as a validation of the data used to justify CLB changes in risk-informed applications, monitoring of the performance of components affected by the application is important. This monitoring should be performed as the proposed application is phased in. For very reliable SSCs, it may be necessary for the licensee to review available operating experience at other plants for applicability to the licensee's plant to expand the operating experience database. The reviewer should ascertain that the monitoring program is capable of demonstrating that the performance of the components or systems is in accordance with what has been assumed.

c. Evaluation Findings

The reviewer verifies that information was provided to support the following conclusions:

- The failure rates and probabilities used, especially those that directly affect the proposed application, appropriately consider both plant-specific and generic data that are consistent with generally accepted values from PRAs of similar plants, and deviations (if any) have been justified.

- The licensee has systematically considered the possibility that individual components could be performing more poorly than the average associated with their class, and have avoided relaxation for those components to the point where the unavailability of the poor performers would be appreciably worse than that assumed in the risk analysis.

- The changes to the parameter values impacted by the application are both justified and reasonable.

- Data used to support changes to the CLB are supported by an appropriate

performance monitoring program.

A.2 Initiating Events

a. Area of Review

Whether or not a particular initiating event is included in a PRA depends on the scope of the PRA, the frequency of that event, the available plant systems or other features to mitigate the event, and the consequences of the event if unmitigated. Proposed plant changes could affect the frequency of initiating events, the probability of mitigation of event initiators and, in some cases, event consequences. In addition, plant changes could potentially introduce new initiating events or result in previously screened out events becoming more important.

b. Review Guidance and Procedures

For risk-informed applications, the staff should determine if initiating events and anticipated plant response are affected by the proposed changes. The reviewer should determine if the proposed changes: (i) can lead to an increase in the frequency of an initiator already included in the PRA; (ii) can lead to an increase in the frequency of an initiator initially screened out in the PRA; (iii) have the potential to introduce new initiating events; and (iv) can affect the grouping of initiating events. These are discussed further below.

Applications that result in changes to initiator frequency or the ability of the plant to respond to event initiators are relatively easy to model in the risk analysis if the initiators are already included in the base analysis. In these cases, the impact of the changes should be evaluated directly from the risk model.

In cases where initiators are not included in the original risk analysis based on screening evaluations, it is necessary to review whether initiating events previously screened out on grounds of low frequency, might now be above the screening threshold as a result of a proposed application. Plant changes could increase the frequency of initiating events that were relatively infrequent to begin with, or these changes could affect SSCs or operator actions that were credited with the satisfactory mitigation of initiating events. If initiating events increased in frequency as a result of an application to the point where it became important (i.e., could no longer be screened out), then the scope of the analysis would need to change to reflect this.

Usually, low frequency of an event by itself is not sufficient as a criterion for screening purposes. The consequences of non-mitigation of the events also play a big part in this process. For example, interfacing system LOCAs are often assessed as low frequency events, but because of their impact on public

health and safety, they can be important. Therefore, for potentially high consequence events, even if the event frequency is below a screening criterion, the features that lead to the frequency being low (for example, surveillance test practices, startup procedures. etc.) should be taken into account in reviews of PRA applications.

Proposed plant changes should be evaluated to determine if these changes could result in initiators not previously analyzed in the PRA. For example, changes might enhance the potential for spurious operation of components whose action may cause initiating events or changes might increase the likelihood for operator errors of commission which may result in plant trips. If mechanisms for producing new initiators have been identified, the reviewer should make sure that they have been added to the risk analysis so that the impacts from these initiators can be analyzed.

In PRAs, initiating events are usually grouped according to the systems required to respond to the transient. This implies that success criteria for plant systems and operator response are similar for all events in a group. In addition, events may be screened out when it can be shown that they are bounded in probability and consequence by other similar events. In the review of risk-informed applications that affect initiating events, the staff has to ensure that grouping criteria used in the base analysis have not been invalidated by the proposed plant changes or, in the case where this is not true, the licensee has made appropriate changes to the event groupings.

Finally, it should be noted that many PRAs model initiating events as single basic events or "black boxes". In risk-informed regulation, it is preferred that initiating events especially those that result from the loss of support systems, be modeled using a fault tree (or equivalent) approach so that system dependencies are fully understood and accounted for. If this is not the case, the reviewer should be aware of the combination of SSC failures or other events that could lead to the "failure" of the black box. This would lead to a better understanding of the risk contributors and is especially important in risk categorization applications.

c. Evaluation Findings

The reviewer verifies that the information provided and review activities support the following conclusions:

- The licensee has adequately considered the effects of proposed changes on the frequencies of initiating events analyzed and the frequencies of initiating events previously screened out.

- The changes have been shown to not result in new initiating events, or if new initiators are identified, these have been added to, and analyzed in the risk model.

- Proposed changes have been taken into account in the grouping of

initiating events.

- Dependencies between the initiating events and the plant mitigation systems have been considered in the decisionmaking process.

A.3 Determination of Success Criteria

a. Area of Review

Guidance in the PRA policy statement and in DG-1061 stipulates that realistic analysis should be used in PRA implementation. The following discussion is aimed at sorting out what is meant by "realistic" analysis of success criteria by reference to SAR analysis.

In order to fulfill its intended purpose, SAR analysis is ordinarily based on a set of assumptions containing significant embedded conservatisms. SAR analysis also reflects a postulated single active failure in addition to whatever event initiated the sequence. When a SAR analysis shows a successful outcome, then, there is good reason to believe that apart from beyond-single-failure scenarios, the system will meet or exceed performance requirements for the initiating event considered.

Applying the SAR mission success criterion in a PRA would be conservative, in the sense that the probability of failure to meet this standard of performance would be greater than probability of failure to meet a more realistic standard of performance. However, re-analyzing event sequences with conventional SAR tools would be too burdensome to apply to the large number of scenarios that are defined in the course of a PRA. In addition, the rather specialized computer codes used in SAR analysis may not be appropriate in beyond-single-failure scenarios. Traditionally, development of mission success analysis in PRAs has ranged from the use of faster running models that might not have the same level of quality assurance as the conventional SAR tools, to the extrapolation of results from analysis performed on similar plants.

In order to satisfy the Commission guideline, then, the staff should find that the applicable PRA insights have not been distorted by a systematic conservative bias in mission success criteria, and that mission success criteria used to justify changes to the CLB have a sound technical basis.

b. Review Guidance and Procedures

When it is determined that the results and conclusions of a risk-informed application are especially sensitive to the choice of mission success criteria, or if the modeling is particularly controversial, the staff should review the relevant success criteria and the basis for each. In cases where the basis is lacking, the reviewer should either request additional licensee justification or seek independent analysis.

If the basis is analytical, staff evaluation of the code used and the input data may be appropriate. When it is determined that the computer codes used have not received adequate licensee or other industry review, then closer examination of the models should also be considered.

The models, codes, and input used to determine mission success criteria should meet QA standards that are consistent with general accepted methods. This standard should include configuration control of the analysis input and results. The standard does not have to be the same as the standard applicable to SAR analysis, but it should be explicit (i.e., engineering calculations and codes should be verified and quality assured) and it should be formalized by the licensee as part of the licensee QA program.

Some mission success criteria can validly be extrapolated between similar plants when a firm basis for the criterion is created at the first plant and it is shown that plant-specific features do not invalidate the comparison.

On an application specific basis, the emphasis of the review should be on whether the definition of the system success criteria will be affected by the application specific elements or the elements required in the same minimal cutset as the application specific element. The reviewer should assure that the success criteria are not optimistic so as to underestimate the number of components required (i.e., overestimate the size of the minimal cutset).

c. Evaluation Findings

In cases where conclusions are sensitive to the mission success criteria, the staff safety evaluation report should contain findings equivalent to the following:

- a technical basis has been established for the mission success criterion used in the analysis. Analytical elements of the technical basis have been given an appropriate level of configuration control and quality assurance. Where comparison with analogous criteria from other plants is possible, this comparison has been justified.

A.4 <u>Modeling of Common Cause Failures</u>

a. Area of Review

Common cause failures (CCF) represent the failures of components that are caused by common influences such as design, manufacturing, installation, calibration or operational deficiencies. Since CCFs can fail more than one component at the same time and can occur with greater probability than would be predicted by the product of the individual component failure probabilities, they can contribute significantly to plant risk.

Risk-informed applications that cover SSCs as a group have the potential of

affecting the CCF probabilities of SSCs within that group. For the affected components, CCF probabilities could be low or might not even be included in the baseline PRA models based on the operational and engineering evidence driven by current requirements. With proposed changes there should be assurance that the CCF contribution will not become more significant. In addition, the assessment of the impact of the change can be affected by the CCF probabilities for other components, and can either be exaggerated or obscured depending on the CCF probabilities.

b. Review Guidance and Procedures

The reviewer should verify that potentially significant CCFs have been covered in the PRA and that, where applicable, the effects of the proposed changes have been incorporated into the CCF modeling. Staff evaluation should include a review of the process used for the selection of common cause component groups.

Acceptable methods for the modeling of CCF contributions are presented in NUREG-4780 (reference 7). Additional guidance can be found in an AEOD report "Common Cause Failure Data Collection and Analysis System" (reference 9), which also provides an extensive database of generic CCF probabilities that can be used to compare to those used in the risk-informed licensee submittal. Significant differences in CCF probabilities should be reviewed carefully to determine whether they are justified.

Specific review guidelines related to risk-informed applications and the assessment of the change are provided below.

- The reviewer should verify that industry and especially plant-specific experience which involve the failure of two or more components (especially for the application specific components) from the same cause was analyzed and incorporated into the risk model where appropria

- For relevant applications, reviewers should check that licensees have appropriately modeled CCF of groups of equipment that were proposed for the change. In cases where the effects of the application on CCF cannot be easily evaluated or quantified, reviewers should establish that performance monitoring is capable of detecting CCF before multiple failures are likely to occur subsequent to an actual system challenge. In addition, to reduce fault exposure times for potential common cause failures, phased or incremental implementation should be considered as part of the effort to protect against CCF.

- The reviewer should make sure that the impact of the change is not inappropriately made insignificant by the choice of CCF probabilities for SSCs unaffected by the change. This can occur in two ways. First, the cutsets containing events which represent failures of SSCs affected by the change may include CCF contributions from other SSCs which are too small. Second, the cutsets which do not contain affected SSCs may

be artificially increased in value by having CCF contributions that are too large so that the impact of the change is obscured. These cases will impact applications involving risk categorization by lowering the relative contribution (and importances) of the affected SSCs. An understanding of these effects can be obtained from sensitivity analyses performed by removing the pertinent CCFs or by using more realistic values for the CCFs.

- A common modeling approximation is to include CCF contributions only from that combination of SSCs which fails the function of the system. For example, if system success is defined as success of 1 out of 4 components, usually only a single term representing a CCF of all four components is included. If the success criterion were 2 out of 4, the corresponding CCF term would represent failure of any three or all four SSCs in the group. While probabilistically this usually corresponds to the dominant contributions, care has to be taken when the application relies on assessing the impact on risk of having one train unavailable. In this case, the effective success criterion of the remaining part of the system changes, so that in the case of the 1 out of 4 system, a CCF of three SSCs becomes a possible contributor. The impact of not modeling the lower order CCF contributors should be investigated. Note that this can impact applications for which the justification of the change relies on risk categorization as well as those that require an evaluation of changes to risk.

c. **Evaluation Findings**

Evaluation findings should include statements of the following effect:

- Common cause failure has been suitably addressed and that the licensee has systematically identified component groups sharing attributes that correlate with CCF potential and that affect the application.

- Where applicable, the licensee's performance monitoring program addresses a phased implementation approach to reduce the potential for increased incidence of CCFs due to the proposed change.

A.5 Modeling of Human Performance

a. **Area of Review**

The results of a PRA, and therefore the input it provides to risk-informed decisionmaking, can be very strongly influenced by modeling of human performance. Plant safety depends significantly on human performance, so it is essential that PRAs treat it carefully. However, the modeling of human performance, typically referred to as Human Reliability Analysis (HRA), is a relatively difficult area; significant variations in approach continue to be encountered, and these can result in significantly different estimates of

human error probabilities (HEPs) for what appear to be similar human failure events. The particular values used for HEPs can significantly influence results of the assessment of the impact of a proposed change. In addition to the quantification issue, there are questions related to what kind of human actions can appropriately be credited in the context of a particular regulatory finding. As an example, suppose that PRA results appear to support relaxation of requirements for a component based on the argument that even if the component fails, its failure can be recovered with high probability by operator actions outside the control room. The issues of concern here are whether the modeling of the operator action and the evaluation of the failure probability is appropriate, and whether this kind of credit is the sort of compensating measure that is intended by staff guidance to support justification of a relaxation. One further issue is the impact of human performance which is not explicitly modeled, but is implicit in certain parameter values. An example is the influence of human performance on initiating event frequency. The causes of initiating events are typically not addressed; their impact is included in the frequency in an implicit way.

b. Review Guidance and Procedures

The reviewer should have an understanding of the potentially significant human performance issues that might be affected by the application and how these are reflected in the PRA. This should include a review of the approach used to estimate human error probabilities. The human errors probabilities can impact the assessment of the change in one of three ways. First, HEPs unrelated to the change can obscure or exaggerate the impact of the change depending on their values by inappropriately increasing or decreasing the value of the cutsets unaffected by the change. Second, the HEPs may represent responses to failures of the SSCs impacted by the change. Third, the HEPs may be directly affected by the change.

Specific guidance related to the assessment of the impact of the change is provided below.

- The reviewer should make sure that the impact of the change is not inappropriately made insignificant by the choice of HEPs included in the PRA model. This can occur in two ways. First, the cutsets containing events which represent failures of SSCs affected by the change may include HEPs which are too small. Second, the cutsets which do not contain affected SSCs may be artificially increased in value by having HEPs that are too large so that the impact of the change is obscured. These cases will impact applications involving risk categorization by lowering the relative contribution (and importances) of the affected SSCs. An understanding of these effects can be obtained from sensitivity analyses performed by removing the pertinent HEPs or by using more realistic values for the HEPs.

- The reviewer should identify any human actions that compensate for events affected by the proposed application, and ensure that

inappropriate credit has not been taken for these events.

- Justification of proposed changes to the CLB that are based on taking credit for post-accident recovery of failed components (repair or other non-proceduralized manual actions, such as manually forcing stuck valves to open) should be reviewed carefully to ascertain whether the identified recovery action is an obvious one to take, and is feasible given the time and physical constraints.

  Credit may be taken for proceduralized implementation of alternative success strategies to work around a failed component. Licensees that take this kind of credit should demonstrate that these recoveries are feasible and are supportable by plant programs such as training, etc.

- For human actions that are used to compensate for a basic event probability increasing as a result of proposed CLB changes, licensee actions to ensure operator performance at the level credited in the risk analysis should also be a part of the CLB change.

- For human actions that represent responses to the unavailability of SSCs which are impacted by the change, an assessment should be made on whether the conditions under which the human actions are to be performed have changed significantly so that the HEP should be modified.

- For HEPs that are directly impacted by the change, e.g., as a result of a procedure or operating practice, the reviewer should make sure that the impact has been modeled appropriately. In particular, care should be taken to check whether HEPs that have been screened out of the model should now be reinstated.

- The reviewer should assess whether any dependencies between HEPs have been altered by the change.

- The reviewer should be assured that the set of HEPs used in the PRA is internally consistent, and that the proposed changes, if any, are made consistent with the changes in the performance shaping factors (PSFs) used by the analysts.

c. **Evaluation Findings**

The staff safety evaluation report should include language that is equivalent in effect to the following.

- The modeling of human performance is appropriate.

- Post-accident recovery of failed components is modeled in a defensible way. Recovery probabilities are quantified realistically. The formulation of the model shows decisionmakers the degree to which the apparently low risk significance of certain items is based on credit for

recovery of failed components (restoration of component function, as opposed to actuation of a compensating system).

- When human actions are proposed as compensatory measures as part of a proposed CLB change, licensee actions to ensure operator performance at the level credited in the risk analysis (e.g., by training, procedures, etc.) are also a part of the CLB change.

A.6 Effects of Truncation Limits Used

a. **Area of Review**

As a result of computer model and time limitations, the quantification process to evaluate CDF or LERF would involve cutset truncation either by use of a cutoff frequency or a maximum cutset order. Since the truncation process eliminates accident sequences from further consideration, care has to be taken to ensure that important sequences are not discarded and that the final results are not sensitive to the truncation limit chosen.

b. **Review Guidance and Procedures**

Acceptability of a truncation value used in the baseline PRA should be reviewed as part of the licensee review process. On an application specific basis, licensees should also demonstrate and reviewers should verify that the effects of the application on components modeled in the PRA is not restricted by the truncation criteria chosen. This could include sensitivity studies using different truncation levels (to selected parts of the model), or by the requantification of the base model from the beginning (as opposed to use of a pre-solved model) when evaluating the risk for the proposed applications.

It is preferred that the change in risk from the application is calculated by the requantification of the base model at the fault tree /event tree level so that the potential effects of originally truncated events could be accounted for should they become important as a result of an application. If model requantification was not performed or if the application depended on the risk ranking of SSCs from a pre-solved cutset equation, the reviewer should use the guidelines provided below.

The reviewer should be assured (either by documentation provided in the licensee review or by an independent analysis) that cutset truncation has not introduced errors into the application results or the logic of the PRA that affect the application. Staff review could also involve the performance of (or the review of) sensitivity studies where the truncation limit is lowered for the dominant sequences and event initiators, and a study of the resultant cutsets to see if there are any hidden dependencies or unusual/unexpected event combinations especially if these involve components affected by the proposed application.

Staff review could also include a comparison of a list of the events affected by the application that is in the final truncated cutset equations to the list of application-specific basic events used in the fault tree and event tree models. This will yield a list of events that did not make it past the truncation process. Documentation should be available that enables the reviewer to determine the reason truncated events are not important to the risk.

Finally, in PRA models where common cause failures and human dependencies are incorporated at the sequence level after a truncated set of minimal cutsets has been obtained, the reviewer should verify that the truncation criteria used in the PRA do not lead to cutsets involving application specific components being truncated that could be important if common cause failures, or human dependencies are considered.

c. Evaluation Findings

The staff review should conclude that the licensee has satisfactorily established that conclusions are not adversely affected by truncation, i.e.,

- the truncation criteria is sufficiently low to ensure stable results, that is, the magnitude of the CDF or release frequency will not change as a result of lower truncation limits, and the grouping of SSCs into risk categories will also not be affected.

- the components affected by the application are, for the most part, not truncated out of the model. In cases where they are, a qualitative assessment can demonstrate the reasons why they are unimportant to risk.

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Appendix B INTEGRATED DECISIONMAKING

Risk-informed applications are expected to require a process to integrate traditional engineering and probabilistic considerations to form the basis for acceptance. In order for this decisionmaking process to be effective in rendering accurate representations of plant safety and risk, it is expected that documented guidance be available to ensure consistent and defensible results. Such guidance would also allow staff reviewers to reconstruct the logic and events involved in the integration process.

This appendix discusses issues that should be addressed by the staff during reviews of the licensee integrated decisionmaking process (sometimes referred to as the "expert panel" process by licensees).

a. Area of Review

Staff reviewers are expected to evaluate all proposed changes to the CLB taking into account both traditional and probabilistic engineering considerations. For each proposed change, the reviewer should evaluate the licensee justification for the change. In cases where licensee results or conclusions are in some way counter-intuitive or inconsistent with results for similar plants on similar issues, the reviewer may also want to evaluate in detail the licensee documentation of the process by which the results were obtained. This would provide a better understanding of the reasons, assumptions, approaches, and information that were used in the licensee integrated decision process.

b. Review Guidance and Procedures

Since the licensee integrated decisionmaking process is responsible for the justification of acceptability of the proposed changes to the CLB, it is expected that the process will be documented in a relatively formal fashion. The staff may not routinely audit all of the licensee findings or recommendations, but the documentation should exist to support such a review, and should be maintained for the life of the plant or until such time when the recommendations are invalidated by later changes.

Staff expectations of the integrated decisionmaking process:

- The process should be well-defined, systematic, repeatable, and scrutable. This process should be technically defensible and should be detailed enough to allow an independent party to reproduce the major results.

- Deliberations should be application specific. The objectives proposed for the integrated decisionmaking process for a particular application (particularly, how the results are to be utilized) should be well defined and should be relevant to that application.

- Membership in the decisionmaking team should include experienced individuals with demonstrated skills and knowledge in relevant engineering disciplines (depending on the application), plant procedures and operations, system knowledge including operational history, system response and dependencies, operator training and response, details of the plant specific probabilistic risk assessment, and regulatory guidance.

- The decisionmaking team should have been advised of the specifics of all proposed changes and the relevant background information associated with the licensing action. In addition, since the judgement will be based in part on the results of a risk analysis, imparting to the team an interpretation of the results of the risk model and the potential limitations of this model is important.

- The process should take into account the principles and the NRC expectations as described in Section 2.1 of DG-1061.

- In the formulation of findings, both probabilistic and traditional engineering considerations should be taken into account. This should include information from the risk analysis, traditional engineering evaluations and insights, quantitative sensitivity studies, operational experience and historical plant performance, engineering judgment, and current regulatory requirements. Potential limitations of the risk model should be identified and resolved. SSCs that are affected by the proposed application but that are not modeled in the PRA should be considered individually and evaluated based on guidelines similar to those provided later in this appendix or in appendix C.2. Finally, conclusions should be robust to different plausible assumptions and analyses.

- When findings or conclusions are based in part on the use of compensatory measures, justification should be provided as to why the compensatory measures are an appropriate substitute for a proposed relaxation in current requirements. The compensatory measure should become part of the plant licensing basis.

Technical information basis:

In many risk-informed pilot applications, integrated decisionmaking panels have been utilized in cases where there are broad applications of PRA and traditional engineering results over a large number of plant SSCs to justify changes to the CLB. In cases such as these, it is expected that the information base supplied to the integrated decisionmaking panel is capable of supporting the findings that should be made in the context of the specific risk-informed application. For example, in risk quantification and risk categorization type of applications, the following should be applicable.

- At least the level 1 portion of the internal events PRA should be formulated in such a way as to support quantification of a change in risk (Δ CDF and Δ LERF) and importance measures, and should provide qualitative (minimal cutset) information adequate to support defense-in-depth findings.

- There should be an inventory of plant response capability for probabilistically significant operating modes and initiating event categories (internal, external, flood, fire, seismic, etc.). Given a full scope level 2 PRA, this requirement could be satisfied by an inventory of event tree success paths, with an indication of the mission success criteria, systems, and SSCs involved in each path. Lacking a full scope level 2 PRA, surrogate information should be developed for unanalyzed areas, along the lines described in Section II.3.2.2. This requirement is necessary in order to show the safety functions performed by SSCs affected by the application.

- Causal models (determination of cause-effect relationships) should be developed to support quantification of basic event probability as a function of the application. This is necessary in order to relate the application to actual risk indices.

Documentation of inputs to the decisionmaking panel should be part of the process. The reviewer should verify the scope and depth of the information base, especially information supplied regarding modes and/or classes of initiators unanalyzed in the PRA.

Treatment of SSCs not Modeled in the PRA:

PRAs do not model all SSCs involved in performance of safety functions for various reasons. However, this should not imply that unmodeled SSCs are not important in terms of contributions to the plant risk. For example, in some cases SSCs are omitted based on analysts taking credit for programmatic activities that ensure a low failure frequency for that item or a short fault exposure time in the event that it does fail. In such cases, when PRA results will not reflect the SSC at all, it would be inappropriate to conclude that the programmatic activity is unimportant.

It is one of the tasks of the integrated decisionmaking panel to extrapolate from the PRA and other information sources to draw conclusions about SSCs not modeled in the PRA. This does not mean that the panel is to impute to the PRA high-level results that were not generated in the analysis; it does mean that if a success path is modeled in the PRA, the panel is justified in reasoning that unmodeled SSCs in that path are relied upon. If items were screened from the PRA, the panel should be aware of the screening process, in order to avoid violating the basis for the screening.

For SSCs not modeled in the PRA, the reviewer should verify that the decisionmaking panel has performed the following:

- reviewed the PRA assumption base for instances in which initiators were screened out on the basis of credit for SSCs affected by the application;

- reviewed plant operating history for initiating events whose occurrence might have been prevented by the proposed application;

- reviewed plant operating history for failures of mitigating system trains as a result of events that might have been prevented by the proposed application;

- reviewed accident sequence modeling for instances in which early termination of the analysis obscured challenges to affected SSCs that would normally come into play later than the termination point.

Possible dispositions of the above include the following:

- the item will not affect initiating event frequency or mitigating system performance under reasonably foreseeable circumstances, and the proposed change is warranted;

- the item, although unmodeled, already receives and will continue to receive programmatic attention commensurate with its significance. In cases where reduced commitments are proposed, adequate justification is provided for this reduction;

- the item does not currently receive sufficient programmatic attention, and may be subject to tighter controls.

The reviewer should verify that the safety significance of SSCs not modeled in the PRA (but affected by the proposed application) are appropriately characterized and justified.

Addressing limitations of the risk analysis:

Part of the integrated decisionmaking process is to overcome certain limitations of the PRA. However, this does not include substituting the analyst's judgment for essential PRA results. One of the reasons for developing PRA models is that the complexity of many facilities makes judgment difficult in many contexts.

Generally, if PRA highlights a plant vulnerability, this should be taken seriously. This result should not be discounted on the basis of judgment. If the analyst can show that the PRA representation of a vulnerability is invalid, then the PRA should be modified, and the licensee should work with the results of the revised PRA.

To address the issue of credit for unmodeled systems that would change a PRA

result, the preferred method is to alter the PRA to take the credit. The reviewer should be aware that there are potentially cases in which credit for an unmodeled system would be seriously complicated by issues of shared support systems, environmental conditions, or other factors such as spatial interaction issues or operator interaction dependencies.

To address the issue of making decisions about SSCs that might influence plant response in unmodeled modes or to unmodeled initiators, the acceptable approach is to proceed on the basis of a structured representation of plant response that shows at least qualitatively what initiating events pertain, what systems are available to respond to each, functional dependencies of these systems at the train level, and in particular, what backups are available in the event of failure of any particular SSC. While it is possible to accept program reductions for SSCs that are explicitly shown to play no role in unanalyzed modes, it is much more difficult to accept reductions for components that do play a role in unanalyzed (e.g., shutdown) modes. For such instances, conservative methods will be considered prudent.

To address instances in which a PRA model exists but is considered misleading, caution is indicated. An example of this would be to down-classify SSCs (i.e., state that a high risk contributor is actually a low contributor) from a PRA result, based on panel judgment. It is not acceptable to place on the record both a PRA and a finding that clearly contradicts it. Although the panel is not expected to take the PRA as absolute truth, the test should be whether the record establishes a clear basis for a finding. A technical argument that begins with the misleading PRA result and furnishes supplementary information sufficient to justify a relatively minor change to a PRA result, or a qualified interpretation of a PRA result, is satisfactory. A cursory technical argument leading to a conclusion that qualitatively contradicts a major PRA result is an unsatisfactory record.

c. Evaluation Findings

The following language, or language substantially equivalent to this, should appear in the SER, or else exceptions should be noted and explained.

- The integrated decisionmaking process is appropriate. Appropriate information was available, suitable issues were raised, the disposition of these issues was systematic and defensible, and the documentation of the findings is traceable and reviewable in principle, so that the basis for conclusions and recommendations is available for scrutiny and review.

- The evaluation of risk significance represents appropriate consideration of probabilistic information, traditional engineering evaluations, sensitivity studies, operational experience, engineering judgment, and current regulatory requirements.

- The technical information basis was adequate for the scope of the application. In particular, the analysis of success and failure scenarios was adequate to identify the roles played by the SSCs affected by the application, the quantification of the frequency of these scenarios was adequate to establish the safety significance of the SSCs, and the causal models were adequate to establish the effects of the proposed changes in the program.

- The safety significance of components affected by the proposed application but not modeled in the PRA was evaluated in a systematic manner. This included a search of components that might contribute to initiating event occurrence, mitigating system components that were not modeled in the PRA because their failure was not expected to dominate system failure in the baseline configuration, and components in systems that do not play a direct role in mitigation but that interface with mitigating systems.

- The process applied by the licensee to overcome limitations of PRA was appropriate. Where decisions were made that do not follow straightforwardly from the PRA, a technical basis was provided that shows how the PRA information and the supplementary information validly combine to support the finding. No findings contradict the PRA in a fundamental way.

Appendix C CATEGORIZATION OF STRUCTURES, SYSTEMS, AND COMPONENTS WITH RESPECT TO SAFETY SIGNIFICANCE

For several of the proposed applications of the risk-informed regulation process one of the principal activities is the categorization of SSCs and human actions with respect to their safety-significance. The purpose of this Appendix is to discuss how to review approaches that may be used in this categorization process.

The first review consideration is the definition of safety-significance as applied to SSCs and human actions for a specific application. A related, but not identical concept, is that of risk significance. For example, an individual SSC can be identified as being risk-significant if it can be demonstrated that its failure or unavailability contributes significantly to the measures of risk, e.g., CDF and LERF. Safety-significance, on the other hand, can be thought of as being related to the role the SSC plays in the prevention of the occurrence of the undesired end state. Thus the position adopted in this SRP is that all the SSCs and human actions considered when constructing the PRA model (including those that do not necessarily appear in the final quantified model, either because they have been screened initially, assumed to be inherently reliable or have been truncated from the solution of the model) have the potential to be safety significant, since they play a role in preventing core damage.

In reviewing the categorization, it is important to recognize the purpose behind the categorization, which is, generally, to sort out the SSCs or human actions into two general groups: those for which some change is proposed; and those for which no change is proposed. It is the potential impact of the application on the particular SSCs and human actions and on the measures of risk which ultimately determines which of the SSCs and human actions should be regarded as safety-significant. Since different applications impact different SSCs and human actions, it is reasonable to expect that the categorization could be different for the different applications. Thus the question being addressed by the application is, for which groups of SSCs and human actions can the change be made such there will be no more than insignificant increase in the risk to the health and safety of the public. This impact on overall risk should be related back to the criteria for acceptable changes in the risk measures identified in draft guide DG-1061. It is those groups for which changes can be made that satisfy these criteria that can be regarded as low safety-significant in the context of the specific application. Thus, the most appropriate way to address the categorization is through a requantification of the risk measures. However, the feasibility of performing such risk quantification has been questioned for those applications for which a method for the evaluation of the impact of the change on SSC unavailability is not obviously available.

In the above case, an acceptable alternative to requantification of risk is to perform the categorization of the SSCs and human actions using an

integrated decisionmaking process (such as the use of an Expert Panel), based on the use of PRA importance measures as input. The issues that should be addressed by the reviewer for this approach are discussed in this appendix. Section C.1 discusses the technical issues associated with the use of PRA importance measures, and Section C.2 discusses the use of the importance measures by the decisionmaking panel.

C.1 Use of Importance Measures

a. Area of Review

In the implementation of the Maintenance Rule and in many industry guides for the risk-informed applications, the Fussell-Vesely Importance, Risk Reduction Worth, and Risk Achievement Worth are the most commonly identified measures in the relative risk ranking of SSCs. However, in the use of these importance measures for risk-informed applications, there are several issues that should be addressed. Most of the issues are related to technical problems which can be resolved by the use of sensitivity studies or by appropriate quantification techniques. These issues are discussed in detail in the sub-section below. In addition, there are two issues that the reviewer should insure have been addressed adequately, namely a) that risk rankings apply only to individual contributions and not to combinations or sets of contributors, and b) that risk rankings are not necessarily related to the risk changes which result from those contributor changes. When performed and interpreted correctly, component-level importance measures can provide valuable input to the integrated decisionmaking process.

b. Review Guidance and Procedures

Risk ranking results from a PRA can be affected by many factors, the most important being model assumptions and techniques (e.g., for modeling of human reliability or common cause failures), the data used, or the success criteria chosen. The reviewer should therefore perform an evaluation of the licensee PRA as part of the overall review process. Guidance for this review is provided in Appendix A.

In addition to the use of a PRA of appropriate quality for the application, the robustness of risk ranking results should also be demonstrated for conditions and parameters that might not be addressed in the base PRA. Therefore, when importance measures are used to group components or human actions as low safety-significant contributors, the information to be provided to the integrated decisionmaking process should include sensitivity studies and/or other evaluations to demonstrate the sensitivity of the importance results to the important PRA modeling techniques, assumptions, and data. Issues that should be considered and addressed are listed below.

Different risk metrics: The reviewer should ensure that risk in terms of both CDF and LERF is considered in the ranking process.

Completeness of risk model: The reviewer should ensure that, when determining safety significance contributions using an internal events PRA, external events and shutdown and low power initiators have also been considered either by PRA modeling or by the integrated decisionmaking process (as detailed in section C.2 and in Appendix B).

Sensitivity analysis for component data uncertainties: The sensitivity of component categorizations to uncertainties in the parameter values should have been addressed by the licensee. Reviewers should be satisfied that SSC categorization is not affected by data uncertainties.

Sensitivity analysis for common cause failures: CCFs are modeled in PRAs to account for dependent failures of redundant components within a system. As discussed in Appendix A, CCF probabilities can impact PRA results by enhancing or obscuring the importance of components. This should be addressed by the review. A component may be ranked as a high risk contributor mainly because of its contribution to CCFs, or a component may be ranked as a low risk contributor mainly because it has negligible or no contribution to CCFs. In RIR, removing or relaxing requirements may increase the CCF contribution, thereby changing the risk impact of an SSC.

Consideration of multiple failure modes: PRA basic events represent specific failure events and failure modes of SSCs. The reviewer should determine that the safety significant categorization has been performed taking into account the combined effect of all associated basic PRA events, such as failure to start and failure to run, including indirect contributions through associated CCF event probabilities.

Sensitivity analysis for recovery actions: PRAs typically model recovery actions especially for dominant accident sequences. Quantification of recovery actions typically depends on the time available for diagnosis and performing the action, training, procedure, and knowledge of operators. There is a certain degree of subjectivity involved in estimating the success probability for the recovery actions. The concerns in this case stem from situations where very high success probabilities are assigned to a sequence, resulting in related components being ranked as low risk contributors. Furthermore, it is not desirable for the categorization of SSCs to be impacted by recovery actions that sometimes are only modeled for the dominant scenarios. Sensitivity analyses can be used to show how the SSC categorization would change if recovery actions were removed. The reviewer should ensure that the categorization has not been unduly impacted by the modeling of recovery actions.

Truncation limit: The reviewer should determine that the truncation limit has been set low enough so that the truncated set of minimal cutsets contain the significant contributors and their logical combinations for the application in question and be low enough to capture at least 95 percent of the CDF. Depending on the PRA level of detail (module level, component level, or piece-part level), this may translate into a truncation limit from 1E-12 to 1E-8 per

reactor year. In addition, the truncated set of minimal cutsets should be determined to contain the important application-specific contributors and their logical combinations.

Multiple component considerations: As discussed previously, Importance measures are typically evaluated on an individual SSC or human action basis. One potential concern raised by this is that single-event importance measures have the potential of dismissing all elements of a system or group despite the system or group having a high importance when taken as a whole. (Conversely, there may be grounds for screening out groups of SSCs, owing to the unimportance of the systems of which they are elements.) There are two potential approaches to addressing the multiple component issue. The first is to define suitable measures of system or group importance. The second is to choose appropriate criteria for categorization based on component-level importance measures. In both cases, it will be necessary for the licensee to demonstrate that the cumulative impact of the change has been adequately addressed.

While there are no widely-accepted definitions of system or group importance measures, it is likely that some licensees will develop new system or group measures. If any are proposed, the reviewer should make sure that the measures are capturing the impact of changes to the group in a logical way. As an example of the issues that arise consider the following. For front-line systems, one possibility would be to define a Fussell-Vesely type measure of system importance as the sum of the frequencies of sequences involving failure of that system, divided by the sum of all sequence frequencies. Such a measure would need to be interpreted carefully if the numerator included contributions from failures of that system due to support systems. Similarly, a Birnbaum-like measure could be defined by quantifying sequences involving the system, conditional on its failure, and summing up those quantities. This would provide a measure of how often the system is critical. However, again the support systems make the situation more complex. To take a two-division plant as an example, front-line failures can occur as a result of failure of support division A in conjunction with failure of front-line division B. Working with a figure of merit based on "total failure of support system" would miss contributions of this type.

In the absence of appropriately defined group level importance measures, reliance should be made on the integrated decisionmaking process to make the appropriate determination (see section C.2).

Relationship of Importance Measures to risk changes: Importance measures do not directly relate to changes in risk associated with implementation of a set of changes proposed in an application. Instead, the risk impact is indirectly reflected in the choice of the value of the measure used to determine whether an SSC should be classified as being of high and low safety significance. This is a concern whether importances are evaluated at the component or at the group level. The PSA Applications Guide suggested values of Fussell-Vesely importance of .05 at the system level, and .005 at the component level for

example. However, the criteria for categorization into low and high significance should be related to the acceptance guidelines for changes in CDF and LERF. This implies that the criteria should be a function of the base case CDF and LERF rather than being fixed for all plants. Thus the reviewer should determine how the choice of criteria are related to, and conform with, the acceptance guidelines described in draft guide DG-1061. If component level criteria are used, they should be established taking into account that the allowable risk increase associated with the change should be based on simultaneous changes to all members of the category.

c. Evaluation Findings

The reviewer verifies that the information provided to the integrated decisionmaking process on the determination of risk importance of contributors for a specific application is robust in terms of model inputs and assumptions and "uncertainty" issues like common cause failure modeling and modeling of human reliability, and that the categorization addresses the effect of the on groups of components in a way that is compatible with the risk acceptance guidelines.

C.2 Role of Integrated Decisionmaking in Component Categorization

a. Areas of Review

While probabilistic importance analysis can provide valuable information on categorization, it should be supported and supplemented by an evaluation based on traditional engineering considerations. This will require using the qualitative insights obtained from the PRA, and the incorporation of the consideration of maintenance of defense-in-depth and the maintenance of sufficient safety margins. One important element of this integrated decisionmaking can be the use of an "expert panel". General review guidelines for the licensee integrated decisionmaking process are provided in Appendix B of this SRP.

b. Review Guidance and Procedures

Identification of functions, systems and components important to safety: The PRA can provide significant qualitative insights that emerge simply from consideration of whether and how systems are invoked in particular scenarios. If a front-line system is credited in success paths, then it is in some sense "important," and at least some of its SSCs must also be, in some sense, important, even if a given single-event importance measure does not reflect this. However, the real importance of a system is a function of whether there are alternate, diverse systems that could fulfil the same function, those systems which are the only means of providing the function being more important than those for which there are viable alternatives. A system that supports an important front-line system could also be important. This does not mean that all such systems cannot be candidates for relaxation in current

requirements, it does mean that components in system trains credited in the PRA should be explicitly considered during the integrated decisionmaking process.

The reviewer, either by evaluation of licensee documentation or by independent verification, should:

- identify all systems that are relied upon in plant response to an initiating event, whether explicitly modeled in the PRA or not (e.g., HVAC, I&C associated with indications rather than control), and identify the function(s) they perform or support; and

- check to see whether failure of components screened out on the basis that they are elements of "unimportant" systems could affect a system that is relied upon in plant response to an initiating event.

The reviewer should then verify that at least some elements of each of the important systems as identified above are considered "safety significant." If this is not the case, then the reviewer should ascertain what performance is allocated to these items in the PRA, and ascertain whether the programmatic activities allocated to these elements are commensurate with that performance level. If a system is identified as being important but none of its elements is, then licensee justification should be reviewed in detail.

As an example consider the case of a system that contains many redundant flowpaths. Single-event importance analysis will tend to dismiss the flowpaths one at a time, effectively dismissing the group as a whole. The focus of the above guidance is that the redundant flowpaths, considered as a subsystem, and recognizing the function they perform, are important and deserve some attention, even though conventional importance measures would not highlight them. However, in the case of redundant systems, the solution need not always be to assign every redundant path to the high risk contributor category. In this example, especially if the paths are essentially similar, it is arguably necessary to consider common cause failure and a program that addresses common cause failure potential by monitoring component performance may provide the necessary protection against loss of the function while still allowing a decrease in some level of commitment on the individual members of the group.

Verification of low safety significance: As part of the evaluation of the qualitative risk-informed categorization, the integrated decisionmaking process and criteria used by the licensee should be reviewed.

In reviews of the licensee determination of low safety significance for SSCs or operator actions, the staff should verify that risk importance measures have been applied appropriately and that results of sensitivity studies have been taken into account. In addition, the reviewer should verify that the licensee has considered and has compensated for factors such as potential inadequate scope and level of detail of the PRA (see sections II.3.2.2 and

II.3.2.3). Finally, the reviewer should verify that, in categorizing an SSC or operator action as low safety significance, the licensee has considered the defense-in-depth philosophy and available safety margins. Review guidance on these topics is provided in Section II.3.1 of this SRP.

For SSCs not modeled in the PRA, the reviewer should verify that the following conditions are applicable for each SSC that has been proposed as a candidate for relaxation or removal of current requirements:

- the SSC is not a part of a system that acts as a barrier to fission product release during severe accidents
- the SSC does not perform a support function to a safety function or does not complement a safety function
- the SSC does not support operator actions credited in PRAs for either procedural or recovery actions
- the failure of the SSC will not result in the eventual occurrence of a PRA initiating event
- the failure of the SSC will not result in unintentional releases of radioactive material even in the absence of severe accident conditions

If any of the above conditions are applicable, or if SSC performance is difficult to quantify, the licensee should have used a qualitative evaluation process to determine the impact of relaxing requirements on equipment reliability / performance. This evaluation should include an identification of those failure modes for which the failure rate may increase, and the failure modes for which detection could become more difficult. The reviewer should then verify that one or more of the following justifications (or similar) were provided by the licensee:

- a qualitative discussion and historical evidence why these failure modes may be unlikely to occur;
- a qualitative engineering discussion on how such failure modes could be detected in a timely fashion;
- a discussion on what other requirements may be useful to control such failure rate increases; and
- a qualitative engineering discussion on why relaxing the requirements may have minimum impact on the failure rate increase.

c. Evaluation Findings

The SER should incorporate language substantially equivalent to the following. Exceptions, if any, should be noted and explained.

- The categorization of the SSCs or human actions has adequately captured their significance to safety, and has been performed in such a way that the potential impact of the proposed application results in at most a small increase in the risk to the health and safety of the public. The input to the integrated decisionmaking process derived from Importance measures has been utilized taking into account the known limitations of importance calculations, and the results have been supplemented by appropriate qualitative considerations.

- The integrated decisionmaking process explicitly recognized systems invoked in plant response to initiating events, and ensured that components within these systems are considered for programmatic attention in areas (IST, ISI, etc.) appropriate to their performance characteristics and to the level of performance needed from them.