

**NRR Draft Evaluation Guide**

**Development of  
Graded Quality Assurance Programs**

**Draft - Revision 5  
January 1996**

**Attachment 1**

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1     **1.0    INTRODUCTION**

2  
3     Requirements related to quality assurance (QA) programs for nuclear power plants are set forth  
4     in Appendix B to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR 50). The  
5     general statements contained in Appendix B are supplemented by industry standards and NRC  
6     regulatory guides which describe specific practices that have been found acceptable by the  
7     industry and NRC staff. Although both Appendix B and the associated industry standards allow  
8     a large degree of flexibility, the licensees and the NRC staff have been reluctant to make major  
9     changes in established QA practices. Recently, however, changes in the nuclear industry have  
10    resulted in numerous proposals to revise QA practices. These changes include the completion  
11    of construction projects, establishment of programs related to plant operations and maintenance,  
12    maturing of licensee programs and personnel, and increased pressures to control plant operating  
13    costs.

14  
15    The Graded Quality Assurance (GQA) initiative jointly undertaken by the industry and the NRC  
16    staff is intended to (1) provide a safety benefit by allowing licensees and NRC to preferentially  
17    allocate resources to higher safety significant items, and (2) provide cost savings by reducing  
18    resources spent on lesser safety significant items. Background information about initial efforts  
19    to implement GQA is given in SECY-95-059, "Development of Graded Quality Assurance  
20    Methodology" (March 10, 1995).

21  
22    Licensees developing GQA programs will consider various methods and adjust their QA  
23    programs to accommodate their individual needs. Licensees' programs will affect different  
24    functional areas, such as procurement, records, or design control, varying according to perceived  
25    problems or cost control initiatives. The NRC conveyed its goals and expectations for an  
26    acceptable graded QA program to NEI on June 15, 1994. Irrespective of a licensee's specific  
27    approach, the NRC stated a graded QA program should have four essential elements:

- 28  
29       (1)    a process that determines the safety significance of structures, systems, and  
30              components (SSCs) in a reasonable and consistent manner  
31  
32       (2)    the implementation of appropriate QA controls for SSCs, or groups of SSCs,  
33              according to safety function and safety significance  
34  
35       (3)    an effective root-cause analysis and corrective action program  
36  
37       (4)    a means for reassessing SSC safety significance and QA controls when new  
38              information becomes available  
39



1     **2.0     EVALUATION GUIDE OBJECTIVES:**  
2

3     This is a preliminary guide for NRR and regional office staff evaluating volunteer licensees'  
4     graded QA programs. Such evaluations should ensure that the quality assurance provisions being  
5     applied to SSCs are consistent with the SSCs' safety significance. This guide will provide a  
6     framework for evaluating graded QA programs until the NRC develops its final guidance. The  
7     experience gained in using this guide will assist the staff in developing regulatory positions and  
8     the final guidance. Internal NRC procedures and regulatory guidance for licensees, if deemed  
9     necessary, will be completed in accordance with the NRR Action Plan for Graded Quality  
10    Assurance.  
11

12    Graded QA programs allow licensees and the NRC to preferentially allocate resources to higher  
13    safety-significant items and reduce resources spent on lesser safety-significant items. Licensees  
14    are expected to establish GQA programs that relax the documentation associated with the  
15    procurement and receipt inspection processes, the level of independent oversight of line  
16    organization activities, and the frequency of QA audits. The GQA programs will not change  
17    facility design bases or fundamentally change the activities of line organizations. NRC  
18    evaluations should ensure that a licensee's GQA program does not relax plant design bases or  
19    regulatory requirements. However, the NRC staff should recognize that the GQA programs will  
20    exercise the flexibility allowed by the regulations in adjusting QA provisions to the safety  
21    significance of equipment or activities. Some aspects of the GQA programs will require long-  
22    term followup to assess the effect of specific licensee changes to existing QA controls. If  
23    necessary, the final NRC internal guidance will address long-term followup requirements in  
24    documents such as routine or reactive inspection procedures.  
25

26    Briefly, NRC evaluations of GQA programs at the volunteer plants should consider the four  
27    essential elements: safety significance determination, QA controls, the corrective action program,  
28    and operational feedback. Each element is discussed in detail in a subsequent section of this  
29    evaluation guide.  
30

31    Safety Significance Determination: Evaluate the methods for determining safety significance for  
32    the SSCs within the scope of the graded QA program, including the use of probabilistic risk  
33    analysis (PRA) insights and deterministic considerations. Evaluate the effectiveness of the expert  
34    panel<sup>1</sup> in making safety significance classifications and in integrating PRA and deterministic  
35    considerations with reasonable confidence and consistency.  
36

37    QA Controls: Evaluate the effectiveness with which QA controls are assigned for SSCs that are  
38    within the scope of the graded QA program. The graded QA controls should maintain  
39    reasonable confidence in equipment performance and support the corrective action and feedback  
40    aspects of the program.

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41    <sup>1</sup> For the purpose of this guide, an expert panel is any of the various means used to perform a multi-disciplinary  
42    review related to the importance of SSCs or the grading of quality provisions.



1  
2 Corrective Action Program: Evaluate the effectiveness of the corrective action and root-cause  
3 analysis program related to the graded QA process.  
4

5 Operational Feedback: Evaluate the effectiveness of mechanisms to reevaluate SSC safety  
6 significance and QA controls in light of operating experiences, new information, or changes in  
7 plant design.



11  
12

1     **3.0   SAFETY SIGNIFICANCE DETERMINATION**

2  
3     Before QA practices can be graded, SSCs must be classified by safety significance. The  
4     classification can be based either on deterministic considerations or a combination of  
5     deterministic and probabilistic considerations. This evaluation guide is written in terms of the  
6     combined approach since it is the preferred method and has also been adopted by the volunteer  
7     licensees developing GQA programs. Future guidance may specify acceptable alternative  
8     approaches or such alternatives may be reviewed on a case-by-case basis.

9  
10    How much regulatory scrutiny is dedicated to the safety significance determination depends on  
11    the potential safety impact of the activity for which the determination is being made. The  
12    implementation of graded QA controls instead of maintaining existing QA controls is expected  
13    to have a minimal impact on the overall plant safety. This expectation is based upon each  
14    licensee defining a program that addresses each of the four fundamental elements described in  
15    this evaluation guide and that meets all other regulatory requirements. Although the GQA  
16    programs may reduce the availability or reliability of some systems or components, a meaningful  
17    assessment may not be possible until a GQA program has been in effect for several years. From  
18    the staff's experience with both PRA and deterministic analyses, some SSCs are obviously high-  
19    safety-significant and some are obviously low-safety-significant. However, there will also be  
20    SSCs that may reasonably be judged to be either high or low-safety-significant and for which  
21    the licensee's engineering judgment is a major factor in the classification. The staff should  
22    follow the guidelines below in evaluating safety-significance determinations made by licensees  
23    developing GQA programs.

24  
25    **3.1   Scope of Program:**

26  
27    Review the volunteer licensee's graded QA program description to determine the population of  
28    plant equipment to be considered for application of graded QA. Note that systems that contain  
29    safety-related components do not require that all components within the system be classified at  
30    the same level of safety significance or be assigned the same level of QA controls.

31  
32    The Maintenance Rule (10 CFR 50.65) lists broad classes of equipment that are considered  
33    within scope (see NUMARC 93-01 and 93-02 and Regulatory Guide 1.160). The initial graded  
34    QA programs proposed have defined the scope to be the same as the Maintenance Rule, which  
35    includes both safety-related and non-safety-related SSCs. However, note that non-safety-related  
36    SSCs, including those that are categorized as high-safety-significant, are not specifically covered  
37    by the provisions of 10 CFR 50 Appendix B except by the licensee's volition. However, the  
38    NRC expects that SSCs categorized as a high-safety-significant, including non-safety-related  
39    SSCs, would receive a level of attention and programmatic controls commensurate with the  
40    safety-significance categorization. Although perhaps not enforceable under Appendix B, any  
41    concerns with a licensee's treatment of a high-risk-significant non-safety-related SSC should be  
42    communicated to the licensee as a potential program weakness. The NRC will continue to  
43    evaluate the issue related to the appropriate scope of graded QA programs and the treatment of  
44    high-safety-significant/non-safety related SSCs. If deemed necessary, the final regulatory





1 guidance or rulemaking activities will be used to resolve concerns in these areas. Also, review  
2 the following services, activities, and SSCs to see whether they have augmented quality  
3 provisions and whether appropriate quality verification processes have been established:  
4

- 5 ● safety-related services and activities
- 6
- 7 ● seismic category II SSCs located in proximity to Seismic Category I SSCs (RG 1.29)
- 8
- 9 ● station blackout (SBO) equipment (10 CFR 50.63 and RG 1.155)
- 10
- 11 ● anticipated transient without scram (ATWS) equipment (10 CFR 50.62 and Generic  
12 Letter 85-06)
- 13
- 14 ● fire protection equipment (10 CFR 50.48, 10 CFR 50 Appendix R, and Branch Technical  
15 Position 9.5-1)
- 16
- 17 ● Post-Accident Monitoring (RG 1.97)
- 18
- 19 ● Class 1E Equipment Qualification (10 CFR 50.49 and RG 1.89)
- 20

21 Although these services, activities, and SSCs could be within the scope of the graded QA  
22 programs, evaluations should consider the current regulatory requirements and licensee  
23 commitments with respect to these items. The establishment of a graded QA program does not  
24 confer relief or exemption from any regulatory requirements associated with these items.  
25

26 This discussion of program scope assumes that the licensee is developing a broad-based GQA  
27 program. It is possible that future adjustments to QA practices will be developed for specific  
28 systems, activities, or tasks. Although situational applications would be expected to generally  
29 conform to this guide, the issue will be further discussed in the final regulatory guidance.  
30

### 31 3.2 Safety Significance Determination

32  
33 The safety significance determination identifies and ranks the plant equipment that has the  
34 greatest contribution, or potential contribution to plant risk.<sup>2</sup> Does the safety significance  
35 process carefully integrate deterministic and probabilistic considerations? Are functions related  
36 to both accident response and normal operations considered? Determining the safety significance  
37 of SSCs for GQA programs may be different than the categorizations for implementation of the  
38 Maintenance Rule which may have only considered maintenance preventable functional failures.  
39 Examine the methods or processes proposed for determining safety significance: how effectively

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40 <sup>2</sup> Core damage frequency (CDF) by itself is not a complete measure of risk. Containment  
41 failure, large release likelihood, and total dose must also be considered in determining  
42 risk importance.

1 does the expert panel combine PRA insights and deterministic insights in considering safety  
2 significance?

3  
4 The plant-specific PRA results are expected to play an important part in determining the safety  
5 significance of various SSCs. The relative importance of various SSCs can be estimated by  
6 using appropriate PRA importance measures. However, in using PRA results, the licensee must  
7 recognize that plant systems are modeled in varying degrees in the PRA. Does the expert panel  
8 consider limitations in the PRA modeling? Supplementary guidance and criteria should be  
9 available to the expert panel to ensure that such limitations are recognized and addressed in the  
10 safety significance determinations. Various considerations related to the use of PRA in safety  
11 significance classification are provided in Appendix D. Related guidance from the NEI PSA  
12 Applications Guide is given as Appendix E. The issues identified in these appendices are useful  
13 in evaluating whether a licensee is using the PRA insights appropriately. If practical, assess the  
14 validity and applicability of the NEI PSA Applications Guide to GQA programs.

15  
16 Supporting deterministic analyses are used to validate PRA insights, change initial  
17 categorizations to address limitations in PRAs, or to categorize those SSCs for which the specific  
18 PRA does not provide insights. Before categorizing an SSC as low-safety-significant, the expert  
19 panel should develop and consider additional deterministic screening criteria. In evaluating a  
20 GQA program, the panel's consideration of PRA limitations and deterministic factors is as  
21 important as their use of PRA importance measures in the safety significance classifications.  
22 Examples of deterministic considerations that should be included in licensee safety significance  
23 classifications are given in Appendix F.

24  
25 Regarding level of categorization, licensees may categorize SSCs at several levels. The  
26 Maintenance Rule approach is performed at the system level. Licensees may limit their  
27 evaluation to the system level and conservatively judge all components in a high-safety-  
28 significant system to be high-safety-significant, or they may further categorize components within  
29 systems. If the level of detail in PRA modeling is increased so that the major components  
30 within a system are modeled, licensees may be able to use PRA insights partly to distinguish  
31 between high-safety-significant and low-safety-significant components within a system.  
32 However, to provide a high-level perspective, system-level importances should be determined  
33 even when component-level importance measures are available.

### 34 35 3.3 Expert Panel:

36  
37 The expert panel plays an essential part in determining safety significance. In this guide, an  
38 expert panel is an actual multi-disciplinary review panel or any functionally equivalent group or  
39 process in which various perspectives are represented. The panel would nominally include  
40 experienced representatives from various disciplines such as operations, maintenance,  
41 engineering, safety analysis and licensing, and PRA. The composition of the expert panel  
42 should be augmented, if necessary, to support the purpose of the safety significance ranking.  
43 For example, because of the emphasis on QA considerations in the GQA process, QA and  
44 procurement personnel may be assigned to this panel.

1 The expert panel evaluates both probabilistic and deterministic information available regarding  
2 SSCs (or broad classes of functionally similar SSCs) within the defined scope to determine the  
3 safety significance of SSCs. The expert panel, needs to carefully weigh the PRA insights,  
4 recognizing the limitations of PRAs. PRA results should be augmented with information from  
5 other sources such as design bases documents, design specifications, analyses of failure modes  
6 and effects, plant operating procedures, normal and abnormal plant configurations and  
7 alignments, and plant licensing basis documents. Safety significance may be determined using  
8 criteria related to prevention or mitigation of core damage, containment integrity, or a reduction  
9 in the release probability or consequence to the public. Factors such as potential common-mode  
10 failures, human errors of omission and commission, defense in depth, and the maintenance of  
11 safety margins should also be considered. Both the high-safety-significant and low-safety-  
12 significant categories could include safety-related and non-safety-related SSCs.  
13

14 The licensee's expert panel safety significance determinations should be both scrutable and  
15 repeatable. To satisfy these key evaluation criteria (scrutability and repeatability), the licensee  
16 will need to establish procedures and guidance for the expert panel and sufficiently document  
17 expert panel activities to allow subsequent independent assessments of whether the safety  
18 significance determination process provided results with reasonable confidence and consistency.  
19 Evaluations of expert panel activities should answer the following questions:  
20

- 21 ● Are the expert panel's composition, its responsibilities, and its methods defined?
- 22
- 23 ● Does the panel use clear criteria in classifying SSCs within safety significance categories  
24 (Section 3.2)?
- 25
- 26 ● Does the panel have a means for addressing concerns through technical evaluations,  
27 sensitivity analysis, or actual classification of SSCs?
- 28
- 29 ● Does the panel consistently give SSCs of similar safety significance similar quality  
30 treatment?
- 31
- 32 ● Does the panel objectively consider deterministic and PRA information?
- 33
- 34 ● Does the panel use specific deterministic criteria to validate PRA importance measures?
- 35
- 36 ● Does the panel ensure continued compliance with existing regulations and commitments  
37 (including those that are plant specific)?
- 38
- 39 ● Does the panel incorporate lessons learned from its activities or the experiences of  
40 implementing line organizations?
- 41
- 42 ● Are expert panel activities documented so that the bases for important decisions and SSC  
43 classifications are recorded?
- 44



#### 4.0 GRADING OF QUALITY ELEMENTS

After classifying SSCs into two or more safety significance categories, the licensee must select appropriate QA requirements for the various categories. This is a critical factor in achieving the goals of the GQA initiative. To satisfy regulatory requirements and generally provide the staff with a reasonable explanation of the implementation of a GQA program, licensees are expected to prepare and submit changes to their QA programs. The revised QA plans should adequately describe the GQA program, including the safety significance determination process and how the program affects each of the elements within the QA program. Licensees will limit the descriptions to avoid detailed commitments that would trigger unwarranted submittals and staff reviews in accordance with 10 CFR 50.54(a). The staff should accept a limited level of detail in QA program descriptions.

For safety-related SSCs determined to be of the highest safety significance, the current QA practices would normally be retained. A certain number of SSCs currently classified as non-safety-related may fall into the high-safety-significant category. Has the licensee considered more rigorous quality assurance practices for these high-safety-significant non-safety-related SSCs than normal for non-safety-related SSCs (e.g., commensurate with the SSCs' relative importance to plant safety)? Non-safety-related SSCs, including those that are categorized as high-safety-significant, are not specifically covered by the provisions of 10 CFR 50 Appendix B, except by the licensee's choice. Although perhaps not enforceable under Appendix B, any concerns with a licensee's treatment of a high-risk-significant non-safety-related SSC should be communicated to the licensee as a potential program weakness. (see Section 3.1)

For those SSCs put in the lowest safety significance category, the licensee will develop reduced or graded quality assurance controls. What QA aspects and characteristics has the licensee selected for grading? In making this selection, the licensee should consider the safety function of the SSC and factors having to do with design, procurement, fabrication, construction, installation, maintenance, testing, and human performance. Grading of quality elements may reduce documentation and verification activities for low-safety-significant SSCs, but should maintain a reasonable level of confidence that each SSC will perform all intended functions with potential safety implications. Within the constraints of specific regulatory requirements, licensees have the flexibility to define the processes used to achieve reasonable confidence in SSC performance. In addition to providing reasonable assurance of SSC performance, the GQA program should include processes and documentation that support an effective corrective action program.

For graded QA programs that have more than two categories, the QA controls for the groupings between the highest and lowest safety significance categories are expected to mix elements from the current program and the graded program for low-safety-significant SSCs.



1     4.1    Evaluation  
2

3     Does the expert panel or the line organization consider appropriate QA factors when determining  
4     how much to adjust the existing 10 CFR 50 Appendix B program for low-safety-significant  
5     SSCs? How does the licensee's process establish the relationship between SSC safety function  
6     and the level to which QA controls are applied?  
7

8     Verify that the existing QA requirements have been maintained for the high-safety-significant  
9     systems. In reviewing any changes to the QA controls for high-safety-significant SSCs, use  
10    traditional review practices, including comparisons to the standard review plan, regulatory  
11    guides, and endorsed industry standards. Nevertheless, existing flexibilities within the traditional  
12    QA provisions and alternate approaches will not necessarily be found unacceptable and should  
13    not be discouraged.  
14

15    For the low-safety-significant category, does the program have an acceptable process for QA  
16    verification, including commercial grade item (CGI) dedication. Although QA verification for  
17    low-safety-significant SSCs may be graded, the process should continue to assure the design  
18    integrity and successful safety function performance of the SSC. Within this area, the technical  
19    requirements for CGI dedication (critical design and performance characteristics of an item for  
20    an application) are not subject to grading. However, for items of low safety significance, the  
21    verification of critical characteristics may be graded (e.g, by reduced sampling plans, alternate  
22    testing techniques, or correspondence with the vendor). Examples of graded QA controls for  
23    the procurement and dedication of CGIs are given in Appendix C.  
24

25    If available, examine the licensee's procedures or instructions for implementing its graded QA  
26    program. Do these documents adequately define the QA provisions to be applied to SSCs  
27    according to their relative safety significance and design requirements? Has the licensee  
28    established provisions for feedback mechanisms as discussed in Sections 5 and 6 of this guide?  
29    Areas in which quality assurance adjustments have been considered and found acceptable are  
30    discussed below. The list is not exhaustive but provides examples of the types of changes  
31    expected from implementation of GQA programs.  
32

- 33    ●     Procurement: Licensees may establish less stringent quality assurance requirements for  
34    the procurement of low-safety-significant components than for high-safety-significant  
35    components. In making these changes, licensees need to consider CGI dedication issues  
36    as well as possible 10 CFR 50 Appendix B requirements. Procurement is further  
37    discussed in Appendix C of this evaluation guide.  
38
- 39    ●     Level of Document Approval: Traditionally, QA plans have specified levels of licensee  
40    management authorized to approve documents such as procedures and design packages.  
41    GQA programs may reassign such approval authority to lower levels in the licensee  
42    organization.  
43



- 1 ● Independent Review: Existing QA programs require independent review of various  
2 licensee activities. For example, in the area of design control, licensee programs reflect  
3 the position in Regulatory Guide 1.64, "Quality Assurance Requirements for the Design  
4 of Nuclear Power Plants," that an immediate supervisor may not perform design  
5 verification functions. GQA programs may revise the independent review process to  
6 include review by peer personnel from line organizations, supervisors, or knowledgeable  
7 personnel from other licensee organizations. However, to be considered independent,  
8 the review should be performed by an individual not directly involved in the performance  
9 of the activity.
- 10
- 11 ● Frequency of Inspections: The licensee may choose to continue current practices related  
12 to specifying quality control "hold points" for activities involving SSCs considered high-  
13 safety-significant and to reduce such practices for low-safety-significant SSCs.  
14 Verifications by peer personnel in lieu of certified inspectors may be implemented for  
15 the low-safety-significant SSCs provided that the licensee designates individuals  
16 considered knowledgeable and qualified to do inspections.
- 17
- 18 ● Records and Documentation: Documentation, such as procedures and design packages,  
19 for low-safety-significant SSCs may be less detailed than for high-safety-significant items.  
20 This is likely already the case for existing documentation, but the GQA program may  
21 formalize this distinction. In assessing the level of detail specified in procedures or  
22 actual packages related to low-safety-significant items, there should be enough detail to  
23 maintain plant design and configuration control and to evaluate failures to determine  
24 corrective actions.
- 25
- 26 ● Audits: Processes and work associated with low-safety-significant SSCs could be audited  
27 less deeply and less frequently than high-safety-significant activities. Surveillances,  
28 performance monitoring, self-assessments, trend data or other activities may supplant  
29 formal audits in low-safety-significant areas.
- 30
- 31 ● Staff Training and Qualification Requirements: The licensees may establish different  
32 training and qualification requirements for personnel performing tasks on high-safety-  
33 significant and low-safety-significant SSCs.
- 34

35 Review the regulatory and licensing commitments that may be impacted by the implementation  
36 of a graded QA program. Do changes to any of the identified commitments involve license  
37 amendments, exemptions to regulations, or other NRC authorization apart from that of  
38 10 CFR 50.54(a). GQA programs should not result in either intended or effective changes in  
39 the design or configuration of plant systems. Such design or configuration changes occur when  
40 QA program reductions result in a loss of confidence in one or more SSC critical characteristics.  
41 An example of such a change might be reduction in procurement controls and a resulting lack  
42 of confidence in seismic or environmental qualifications of a component. The licensee should  
43 ensure that changes to technical requirements are performed in accordance with



1 10 CFR 50.59 and other applicable regulations. If such changes are identified, find out what  
2 actions the licensee has taken to address these issues. Evaluate the appropriateness of these  
3 actions.

4  
5 If a licensee concludes that a change to the program reduces a QA program commitment, has  
6 the licensee submitted or does it plan to submit a QA program change to the NRC in accordance  
7 with 10 CFR 50.54(a)? This change should describe what elements of the program will be  
8 revised and justify the conclusion that the program will continue to meet the requirements of  
9 10 CFR 50 Appendix B. For the purposes of the volunteer program, it is envisioned that the  
10 reviews of any proposed revisions to the licensee's QA program description will be performed  
11 by NRR.







1     **6.0    OPERATIONAL FEEDBACK**

2  
3     The evaluation should examine the GQA program or existing programs to ensure that a process  
4     exists to consider plant and industry operational experience and the potential need to revise SSC  
5     safety significance classifications or QA controls. Operating experience and plant modifications  
6     are two sources of information that could give insights about the effectiveness of a licensee's  
7     GQA program and feedback mechanisms.

- 8  
9     ●     Operating Experience: Review a representative sample of information, including  
10     performance indicators, NRC generic communications, Institute of Nuclear Power  
11     Operations (INPO) and Electric Power Research Institute (EPRI) design reliability data,  
12     Systematic Assessment of Licensee Performance (SALP) reports, licensee event reports  
13     (LERs), NRC inspection reports, equipment maintenance histories, plant performance  
14     reviews, reliability and unavailability data, equipment performance or condition trending  
15     data, Nuclear Plant Reliability Data System (NPRDS), and quality assurance audits.  
16     Review a sample of the PRA assumptions, system unavailabilities, and other plant-  
17     specific data used to justify safety significance classifications.
- 18  
19     ●     Plant Modifications: Plant modifications might affect the safety significance  
20     determination or selection of QA controls for low-safety-significant SSCs. Accordingly,  
21     review the pertinent aspects of the GQA program to determine if plant modifications are  
22     periodically reviewed with respect to their potential impact on safety significance  
23     determinations. Alternately, the design change process may include provisions to verify  
24     that changes do not affect SSC safety significance or required QA controls.

25  
26     Periodic audits of the QA program are performed as specified in the licensee's QA program.  
27     The evaluation should ensure either that the GQA programs will be included in the overall QA  
28     program audits or that special audits will be conducted to assess the GQA program. The audits,  
29     which could be accomplished in conjunction with similar requirements related to periodic  
30     evaluations of Maintenance Rule programs, should include the process for incorporating newly  
31     developed risk management insights and configuration management insights into the GQA  
32     program. The audits should evaluate deficiencies across the whole spectrum of plant activities,  
33     including operations, design, procurement, and maintenance. The audits should also determine  
34     whether the GQA program needs improvements and whether the bases for the safety significance  
35     classifications and assignment of QA controls (e.g., the PRA model and assumptions) continue  
36     to reflect plant design and operating practices.





1     **7.0 SAMPLE SSC REVIEW**

2  
3     **7.1 Safety Significance**

4  
5     Review the licensee's evaluation regarding safety significance of SSCs. Evaluate the factors  
6     discussed in Section 3 and the associated appendices. Evaluate the expert panel conclusions and  
7     its use of both PRA and deterministic considerations. Does the process used by the expert panel  
8     satisfy the key criteria of scrutability and repeatability? Assess the methodology and the actual  
9     categorizing of SSCs: has the licensee's process produced reasonable classifications for high and  
10    low safety significance.

11  
12    It should be recognized that engineering judgment plays a key role in the expert panel  
13    deliberations as well as the staff's evaluations. How deeply to review a licensee's justification  
14    for a specific safety significance determination and how much to expect of the licensee should  
15    depend on the possible safety impact of the activity. Implementation of graded QA controls  
16    instead of existing QA controls is expected to have little effect on the overall plant safety. Some  
17    speculate that GQA programs may lead to reduced availability or reliability for some systems  
18    or components. Whether this is so cannot be known until a GQA program has been  
19    implemented for at least several years. Some systems will obviously have high-safety and some  
20    low-safety significance. When engineering judgment is a major factor in classifying, the staff  
21    may ask questions or voice concerns, but the final classification of these systems should remain  
22    the licensee's. If deemed necessary, reviewers may escalate concerns to NRC management, who  
23    may, in turn, initiate interactions with licensee management.

24  
25    **7.2 Grading of Quality Assurance Elements**

26  
27    **7.2.1 High-Safety-Significant**

28  
29    **Safety-Related:** Verify that the level of quality assurance applied to these SSCs is consistent  
30    with the QA plan commitments.

31  
32    **Non-Safety-Related:** Review the SSCs considered in scope for the graded QA program and  
33    select several non-safety-related SSCs that the licensee classified as high-safety-significant (if  
34    applicable). Review the actions that were taken in accordance with the licensee's GQA  
35    procedures (e.g., increased quality assurance controls). Are the quality assurance controls  
36    imposed on these SSCs adequate considering their safety significance. Although perhaps not  
37    enforceable under Appendix B, any concerns with a licensee's treatment of a high-risk significant  
38    non-safety-related SSC should be communicated to the licensee as a potential program weakness.

39  
40    **7.2.2 Low-Safety-Significant**

41  
42    Select a sample of safety-related systems, structures, and components categorized under the  
43    licensee's graded QA program as low-safety-significant (including mechanical and electrical  
44    components). Review the licensee's evaluation regarding the level of quality assurance controls



1 to be implemented for each affected activity for the SSCs selected. Has the expert panel or the  
2 responsible line organization established adequate QA controls as discussed in Section 4? A  
3 useful assessment technique may be to compare the graded QA controls applied to a low-safety-  
4 significant SSC and the controls applied to a similar SSC assigned to the high-safety-significant  
5 category.  
6

7 For the SSCs selected in the sample, has the licensee taken other commitments or requirements,  
8 beside those of 10 CFR 50 Appendix B, into consideration in determining safety significance or  
9 grading of quality assurance controls. For example, grading of QA controls in the procurement  
10 processes should not result in changes in the seismic capability of plant components.  
11

### 12 7.3 Corrective Actions

13  
14 The licensee's GQA program should have elements specifically related to effective corrective  
15 actions. The licensee should have process controls to consider whether the specified graded  
16 quality assurance treatments of SSCs are sufficient. Failures of low-safety-significant SSCs  
17 should be identified by the licensee's corrective action or trending programs so that the licensee  
18 can tell whether the reduction of the QA controls unacceptably impairs an SSC's performance.  
19 In addition, corrective action programs should address the importance of failures of low-safety-  
20 significant components in terms of potential common-mode failure concerns or implications for  
21 similar components in high-safety-significant applications. Initial NRC staff evaluations may be  
22 limited to ensuring that the program descriptions or related procedures include corrective action  
23 processes similar to those discussed in Section 5.  
24

### 25 7.4 Operational Feedback

26  
27 Licensee programs should provide for revising quality assurance practices or controls and safety  
28 significance determinations on the basis of plant or industry operational experiences,  
29 performance trends, program reviews or audits, or other methods of assessing the GQA  
30 program. Initial evaluations may be limited to ensuring that the program descriptions or related  
31 procedures include feedback provisions similar to those discussed in Section 6.  
32  
33

### 34 7.6 Records Generated and Maintained:

35  
36 The licensee's program should specify the necessary procurement, design, installation, and other  
37 records that will be retained to document reasonable assurance that SSCs will perform their  
38 intended functions and to enable effective evaluations of SSC failures and corrective action  
39 determinations. Furthermore, the program should require that individual failures of low-safety-  
40 significant items be evaluated to address the common-mode failure issues and implications for  
41 similar SSCs in high-safety-significant applications. Documentation related to the expert panel  
42 activities should be sufficient to ensure that the determinations are both scrutable and repeatable.  
43



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Appendix A

DEFINITIONS

**Assessments:** A collective term covering reviews, monitoring, tests, surveillances, inspections, audits, or examinations.

**Basic Component:** A plant structure, system, component, or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite radiation exposures comparable to those referred to in 10 CFR 100.11.

**Critical Characteristics:** Those important design, material, and performance characteristics which, once verified, will provide reasonable assurance that the item will perform its intended safety function.

**Deviations:** A departure from a specified requirement or performance criterion.

**Engineering judgment:** A process of logical reasoning that leads from stated premises to a conclusion. The process should be supported by sufficient documentation to permit verification by a qualified individual.

**Expert Panel:** As used in this guide, a mechanism to achieve multi-disciplinary reviews such as a group of experienced and knowledgeable facility personnel that meet to determine the safety significance of SSCs based on PRA and deterministic considerations. The panel would typically include representatives from operations, maintenance, engineering, PRA, and quality assurance. The panel may also be responsible for specifying the graded QA provisions for SSCs and for determining the necessary performance monitoring criteria.

**Graded Quality Assurance:** The application of quality assurance controls to SSCs and/or activities according to their safety or risk significance.

**Industry Wide Operating Experience:** The information available in NRC, industry, and vendor equipment documentation shared within the nuclear industry to minimize adverse plant conditions or situations.

**Performance monitoring:** Continuous or periodic tests, inspections, measurement, or trending of the performance or physical characteristics of an SSC for use in determining corrective actions and the need to modify GQA controls.

**Q-List:** The licensee's list of SSCs required by Criterion II of 10 CFR 50 Appendix B, plus other SSCs within the explicit scope of other regulations (see definition of safety-related SSC).



1 **QA Topical Report:** A general report and description of the licensee's 10 CFR 50 Appendix  
2 B quality program and the corresponding standards. It constitutes the quality assurance licensing  
3 commitments associated with implementing 10 CFR 50 Appendix B.  
4

5 **Quality elements:** The quality attributes, controls, criteria, processes, or practices necessary  
6 to provide reasonable assurance that an SSC will be able to perform its intended safety function.  
7

8 **Safety-Related SSC (From 10 CFR Part 100 and 50.49/50/65):** A structure, system,  
9 component, or part thereof necessary to assure: (1) the integrity of the reactor coolant pressure  
10 boundary; or (2) the capability to shut down the reactor and maintain it in a safe shutdown  
11 condition; or (3) the capability to prevent or mitigate the consequences of accidents which could  
12 result in potential offsite radiation exposures comparable to the 10 CFR Part 100 guidelines.  
13

14 **High-Safety-Significant SSCs:** The set of SSCs (safety-related and non-safety-related) that is  
15 determined by an expert panel, considering both PRA and deterministic information, to have a  
16 relatively high safety significance.  
17

18 **Low-Safety-Significant SSCs:** The set of SSCs (safety-related and non-safety-related) that is  
19 determined by an expert panel, considering both PRA and deterministic information, to have  
20 relatively low safety significance.  
21

1 APPENDIX B

2  
3 REFERENCES

- 4
- 5 1. Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power  
6 Plants," June 1993.
  - 7
  - 8 2. NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance  
9 at Nuclear Power Plants," May 1993.
  - 10
  - 11 3. NRC Inspection Procedure 38703, "Commercial Grade Procurement Inspection."
  - 12
  - 13 4. Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently  
14 Marked Products."
  - 15
  - 16 5. Generic Letter 91-05, "Licensee Commercial Grade Procurement and Dedication  
17 Programs."
  - 18
  - 19 6. NUMARC 93-02, "A Report on the Verification and Validation of NUMARC 93-01,  
20 Draft Revision 2A, "Industry Guideline for Monitoring the Effectiveness of Maintenance  
21 at Nuclear Power Plants," May 1993.
  - 22
  - 23 7. NUMARC 93-05, "Guidelines for Optimizing Safety Benefits in Assuring the  
24 Performance of Motor-Operated Valves," December 1993.
  - 25
  - 26 8. SECY-95-059, "Development of Graded Quality Assurance Methodology."
  - 27
  - 28 9. NUREG/CR-5696, "A Process for Risk-Focused Maintenance," March 1991.
  - 29
  - 30 10. NEI, "Draft Pilot Project Guideline for Implementation of a Graded, Performance-Based  
31 Approach to Quality," September 1994.





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3 APPENDIX C  
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5  
6 GRADED QA FOR PROCUREMENT AND DEDICATION OF COMMERCIAL GRADE  
7 ITEMS  
8

9 The quality assurance requirements should be compatible with the type of item or service to be  
10 supplied. Certain items and services may require extensive QA controls throughout all stages  
11 of development, whereas others will require only limited controls in certain stages. The  
12 following factors should be considered in determining the extent to which quality assurance  
13 practices should be applied during the dedication.

14  
15 I. THE IMPORTANCE OF THE MALFUNCTION OR FAILURE OF THE ITEM TO  
16 PLANT SAFETY  
17

18 Each item to be procured must be evaluated to determine whether it is important to plant safety  
19 and whether it is of high or low safety significance. This determination should also consider  
20 applicable requirements of Appendix B to 10 CFR Part 50 (for CGIs to be dedicated for safety-  
21 related services applicable requirements from EPRI NP-5652, as endorsed by GL 89-02); the  
22 requirements should be specified in the procurement and CGI dedication process and in related  
23 procurement and dedication documents. The safety determination should be made by technically  
24 knowledgeable personnel who are thoroughly familiar with an item's functions and design  
25 parameters.

26  
27 II. THE COMPLEXITY OR UNIQUENESS OF THE ITEM  
28

29 In developing quality assurance requirements for an item, the complexity and uniqueness of the  
30 item should be considered. The extent of the controls needed to assure the quality of  
31 characteristics necessary for proper functioning and long-term performance may depend heavily  
32 upon the item's complexity and the industry experience, or lack of, in accomplishing the quality-  
33 related activity. Obviously, if a design effort is required to develop the item or accomplish the  
34 activity, design quality assurance requirements should be included in the procurement document.  
35 Items which require a complex manufacturing plan may require extensive control over critical  
36 characteristics. The control over critical characteristics should extend beyond the manufacturing  
37 phase when it is necessary to preclude damage to those characteristics during packaging,  
38 shipping, handling, and storage. In determining the extent of quality assurance to be applied,  
39 past experience in the development of similar items should be considered. An item developed  
40 for the first time will probably require much more control over critical characteristics than one  
which has a history of successful performance. The complexity or uniqueness of the item may  
also affect how much personnel training and indoctrination are required.



1 III. THE NEED FOR SPECIAL CONTROLS AND SURVEILLANCE OVER PROCESS  
2 AND EQUIPMENT  
3

4 Certain work operations may require the use of special processes such as welding, non-  
5 destructive examination, brazing and soldering, hardness and tensile testing, protective coating,  
6 and heat treatment. Special processes may also include certain in-process operations such as  
7 chemical batch process, plating operations, and electric insulation impregnation. These  
8 processes should be accomplished under specially controlled conditions. Controlled conditions  
9 include the use of appropriate equipment, suitable environmental conditions, definitive  
10 procedures, qualified personnel, and assurance that prerequisites have been satisfied.  
11

12 IV. THE DEGREE TO WHICH FUNCTIONAL COMPLIANCE CAN BE  
13 DEMONSTRATED BY INSPECTION AND TEST  
14

15 It may be possible to demonstrate certain characteristics of an item by an appropriate inspection  
16 or test. In such cases, the in-process controls (e.g., audits, surveys, and source surveillance)  
17 may be reduced if an appropriate inspection and test will provide an assurance of quality. An  
18 **end-product** test, for example, may eliminate the need for in-process controls.  
19

20 V. THE QUALITY HISTORY AND DEGREE OF STANDARDIZATION OF THE ITEM  
21

22 The usefulness of historical data in evaluating the quality experience of an item depends in part  
23 on the degree of standardization of the item. If a manufacturer has been producing a particular  
24 standard item for a long time, using essentially the same controls, and if the operational quality  
25 history of the item indicates that its critical characteristics perform satisfactorily, the quality  
26 assurance program may be tailored to reflect this satisfactory performance history. Conversely,  
27 if operational data shows certain characteristics to be unsatisfactory, additional quality assurance  
28 efforts may be required to correct deficiencies.  
29

30 CGI Dedication for Use in Low-Safety-Significant Applications  
31

32 The following dedication activities exemplify one approach for dedicating CGIs intended for use  
33 in low-safety-significant applications; these CGIs are relatively simple products and of standard  
34 design, and their critical characteristics may be verified by standard or automated inspections  
35 or tests.  
36

37 (1) Destructive and Nondestructive Testing  
38

39 For dedicated CGIs used in low-safety-significant applications, the licensee may perform  
40 destructive and nondestructive testing on shipments received using a reduced sample plan  
41 (relative to sampling plans used for dedicating CGIs designated for use in high-safety-  
42 significant applications). The testing would be performed at intervals determined by a  
43 supplier's performance history, the quantity of CGIs received, and information related  
44 to manufacturing processes. The licensee's test and performance results should be



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1 compared to similar results identified on any certifications provided by the supplier, and  
2 any abnormal variances should be evaluated. Substitute or alternate test methods (e.g.  
3 hardness testing of carbon steel to determine the approximate material strength in lieu of  
4 performing actual tensile tests, partial in lieu of full chemical analyses) may be used to  
5 verify critical characteristics provided that the basis for using the alternate test is  
6 documented.

7  
8 (2) Performance Testing  
9

10 Testing of low-safety-significant CGIs after installation instead of during receipt  
11 inspection may be acceptable for some products provided that the post-installation testing  
12 verifies the designated critical characteristics. Supplier testing may also be used to some  
13 extent if the supplier history is satisfactory.  
14

15 (3) Dimensional Inspection  
16

17 Any sample plan used by the licensee for accepting dimensions on low-safety-significant  
18 CGIs is product dependent and needs to provide reasonable assurance that the critical  
19 dimensions are correct. An acceptable supplier history may be used to justify reducing  
20 this sampling. For some products, a satisfactory supplier history may allow the licensee  
21 to eliminate dimensional inspection during receipt of the CGIs and may permit the  
22 licensee to rely on proper fit during the installation of the dedicated CGI.  
23

24 (4) Product Markings  
25

26 The licensee should determine if the manufacturer has the capability to have markings,  
27 such as the production run, serial number, batch number, or lot number, placed on each  
28 CGI. Although, by itself, this marking may not be sufficient to ensure homogeneity of  
29 the CGIs, it may provide additional assurance that the products were produced essentially  
30 at the same time, with the same materials and by the same method. The marking may  
31 also provide additional confidence that the CGIs were not from mixed production runs,  
32 heats, lots, or batches so that a further reduced sampling plan could be considered for  
33 accepting these products.  
34

35 (5) Sampling Plans  
36

37 The basis for selecting the sampling plan for dedicating low-safety-significant CGIs  
38 should be documented. Satisfactory supplier performance history, if used to reduce the  
39 sampling plan, should also be documented.  
40

41 For safety-related SSCs classified as low-risk significant, the following options appear to be  
42 acceptable alternatives to traditional methods of applying Appendix B QA requirements. These  
43 options alone, do not fully constitute an acceptable method for meeting graded Appendix B  
44 requirements. However, when used in combination with other graded QA program controls or



1 with traditional Appendix B controls, they may form the basis of an acceptable graded QA  
2 program.

3  
4 ● Option A  
5

6 In lieu of doing a traditional CGI survey or Appendix B audit, the licensee obtains copies of the  
7 manufacturer's QA program manual and of implementing procedures that control certain critical  
8 characteristics of the item being manufactured. After reviewing the manufacturer's QA program  
9 and implementing procedures, the licensee determines that, if properly implemented, the QA  
10 controls and procedures would provide reasonable confidence in some or all of the CGI's critical  
11 characteristics. The licensee could then use a reduced sampling plan (e.g., spot checking critical  
12 characteristics) to dedicate the CGI. The purchase order (PO) should clearly invoke technical  
13 requirements (e.g., specifications, codes, standards), and the QA controls should require the  
14 manufacturer's certification that the CGI was manufactured under these controls.

15  
16 ● Option B  
17

18 The manufacturer has established an International Standardization Organization (ISO) 9001 QA  
19 program (to control the manufacturing of a CGI) that has been accepted by a third party  
20 registrar. The licensee invokes technical requirements (e.g., specifications, codes, standards)  
21 and the manufacturer's ISO 9001 QA requirements in the PO to the manufacturer. The  
22 manufacturer certifies that the CGI was manufactured in accordance with the ISO 9001 QA  
23 program. When the CGI arrives, with the manufacturer's certification, the licensee reduces the  
24 CGI dedication activities for this CGI. Standard receiving inspection practices could then be  
25 applied on a sampling basis (e.g., part number, damage, some dimensions). The reduced  
26 dedication program could use post-installation testing to a large degree and use a much reduced  
27 sampling plan to overcheck selected critical characteristics (other than dimensions and part  
28 number).

29  
30 ● Option C  
31

32 Quality history and standardization were discussed in Section V above. The logical  
33 considerations outlined in Section V should apply to each procurement action. However, if these  
34 considerations have only limited applicability to a particular procurement action, unique graded  
35 procurement QA requirements will need to be developed.

36  
37 Acceptable supplier/item performance records should not be employed alone to justify the  
38 acceptance of a CGI unless:

- 39  
40 ● the established historical record is based on industry-wide performance data that  
41 is directly applicable to the critical characteristic being verified and the intended  
42 related application, and  
43





1           ● the manufacturer's measures for the control of design, process, and material  
2 changes have been adequately implemented, as verified by audit or by Options A  
3 or B above.  
4

5 In lieu of the above, performance history (see Section V) may be combined with other dedication  
6 methods and the options discussed above and used in dedicating CGIs. The use of and rationale  
7 for such combinations should be documented. When industry information (e.g., NRC  
8 information notices, bulletins, and generic letters; INPO SERs; NPRDS; LERs) identifies  
9 problems with equipment, the licensee should address the problems during the CGI dedication  
10 process.



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Appendix D  
PRA Considerations

The following considerations relate to the use of PRA in safety significance classification:

- Appropriate importance measures, including core damage frequency (CDF) contribution, risk achievement worth, and risk reduction worth, should be used.
- Since CDF is not a direct measure of risk, containment failure and large release must also be considered in the risk-ranking process to ensure that SSC risk importance is reflected, rather than solely CDF importance.
- Common-mode failures across system boundaries are not considered in PRA yet may be important as QA provisions are amended for components used in multiple systems.
- Dynamic risk management recognizes that risk is time dependent and is a function of plant operating practices. Operational insights should be fed back to the panel for consideration.
- Plant systems are modeled to varying degrees in PRAs. The fact that an SSC is not modeled in the PRA does not justify classifying an SSC as low-safety-significant. Deterministic factors need to be considered.
- The scope of plant PRAs should be taken into consideration. If the scope is that of a Level 1 study, containment performance provisions including containment isolation functions should be factored in. If the PRA scope is limited to internal events, external events like fires, earthquakes, floods, and high winds should also be considered. The internal flooding initiator should also be included in the evaluation of CDF and risk importance. Likewise, low- power, shutdown, and transitional modes of operation may not be addressed by plant PRAs but would nevertheless need to be considered in the determination of SSC safety or risk significance.
- The level of detail in PRAs determines how the results can be utilized. Licensees may limit their evaluation to the system level and conservatively judge all components in a high-safety-significant system to be high-safety-significant, or additional evaluations may be performed to further categorize components within systems. If the level of detail in PRA modeling is increased so that the major components within a system are modeled, PRA insights may be more valuable in distinguishing between high-safety-significant and low-safety-significant components within a given system.
- The failure modes modeled by the PRA may not be all-inclusive. Consideration should be given to the failure modes modeled and the potential for the introduction of new failure modes related to the application. For example, if



1 valve mispositioning has been assumed to be a low-probability event because of  
2 independent verification and therefore is not included in the PRA assumptions,  
3 any changes to such independent verifications should be evaluated for potential  
4 impact on the PRA results.

- 5
- 6 ● The type of data for equipment failure rates, unavailabilities, and initiating-event  
7 frequencies may be either plant specific or generic. If generic data is used, an evaluation  
8 is warranted to assure the appropriateness of using the generic data or updating the data  
9 with plant-specific experience.
- 10
- 11 ● Truncation of low-frequency sequences (beyond approximately 95% of CDF) may  
12 exclude some low-probability events from the dominant cutsets, making them unavailable  
13 for the subsequent determination of importance measures. Truncation levels need to be  
14 considered so that the safety significance of SSCs is not underestimated.
- 15
- 16 ● Plant-specific PRA modeling practices could skew the plant-specific PRA results in  
17 relation to the generic population of similar plant PRA results. Therefore, licensees  
18 would be prudent to compare plant-specific results to those for similar plants for  
19 additional insights.
- 20
- 21 ● Software driven-solid-state control and protection devices are not readily  
22 amenable to being analyzed by PRA.
- 23
- 24 ● PRAs normally address only 100% power operation. The effects of partial or low-  
25 power, shutdown, and refueling modes on plant safety also need to be considered.
- 26
- 27 ● Generally, fault trees are not developed nor generic event data used for modeling the  
28 switchyard and emergency diesel generator.
- 29
- 30 ● Containment performance, including containment isolation, may not be explicitly  
31 modeled, or the Level II PRA may be incomplete or may not have been reviewed.
- 32
- 33 ● Potential influences of aging on component reliability are not examined by the PRA.
- 34
- 35 ● Low-safety-significant components not required to support safety functions but whose  
36 failure could adversely impact safety function performance may not be addressed by the  
37 PRA models. Examples of such failures are seismic II/I system interactions, seismic-fire  
38 interactions, and the spurious operation of fire suppression systems.
- 39
- 40 ● Whether an uncertainty analysis has been done on the PRA results and whether the  
41 analysis (if done) confirms that an SSC is of low safety significance should be examined.
- 42
- 43



1 ● Initiating events may be modelled as single modularized events in the PRAs, masking  
2 the importance of the individual systems and components in these events. Examples of  
3 such initiating events are the loss of instrument air; the loss of HVAC/room cooling; the  
4 loss of offsite power (through local switchyard faults); the loss of AC or DC busses;  
5 small LOCAs (especially those involving pump seal failures and spurious or stuck open  
6 relief valves); interfacing system LOCAs (isolation valves and MOVs); and ATWS  
7 (electrical and mechanical portions of the RPS).

8  
9 ● Screening analyses are used to dismiss some initiators as insignificant. In many cases,  
10 credit for plant systems or structures is taken to bolster the arguments for redundancy  
11 and/or reliability. The importance of these systems and structures will not show up in  
12 the PRA results since the initiator is screened out. (Examples are the screening of  
13 certain containment penetrations because of the number of isolation valves involved; the  
14 screening of fire boundaries because of the existence of water curtains or fire suppression  
15 systems; and the screening of flood areas because of the presence of flood alarms.)

16  
17 ● When certain events dominate sequence importance, the importance of other events may  
18 be hidden. An example of this shadowing effect (for BWRs) is that during an automatic  
19 depressurization system (ADS) inhibit, the dominance of human error in the  
20 depressurization function will mask the failure of the ADS valves themselves or even the  
21 common-mode failure of the valves. An example (for PWRs) is that potential human  
22 errors will mask the failure of the PORVs or HPI pumps in the feed and bleed function.





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Appendix E  
NEI PSA Applications Guide

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5 **INITIATING EVENTS**

- 6  
7 ● Does the application introduce consideration of new initiating events?  
8  
9 ● Does the application address changes that lead to a modification of the initiating event  
10 groups?  
11  
12 ● Does the application necessitate a reassessment of the frequencies of the initiating event  
13 groups?  
14  
15 ● Does the application increase the likelihood of a system failure that was bounded by an  
16 initiating event group to the extent that it needs to be considered explicitly?  
17

18 **SUCCESS CRITERIA**

- 19  
20 ● Does the application necessitate modification of the success criteria?  
21  
22 ● Does the modification of success criteria necessitate changes in other criteria, such as  
23 system interdependencies?  
24

25 **EVENT TREES**

- 26  
27 ● Does the application address an issue that can be associated with a particular branch, or  
28 branches on the event trees, and if so, is the branching structure adequate?  
29  
30 ● Does the application necessitate the introduction of new branches or top events to present  
31 concerns not addressed in the event trees?  
32  
33 ● Does the application necessitate consideration of re-ordering branch points?  
34

35 **SYSTEM RELIABILITY MODELS**

- 36  
37 ● Does the application impact system design in such a way as to alter system reliability  
38 models?  
39  
40 ● Does the application impact the support functions of the system in such a way as to alter  
41 the dependencies in the model?  
42  
43 ● Does the application impact the system performance, and, if so, is that impact on the  
44 function obscured by conservative modeling techniques?



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1     **PARAMETER DATA BASE**

- 2
- 3     ●     Can the application be clearly associated with one or more of the basic event definitions,  
4           or does it necessitate new basic events?
- 5
- 6     ●     Does the application necessitate a specialized probability model (e.g., time-dependent  
7           model etc.)?
- 8
- 9     ●     Does the application necessitate modifications to specific parameter values?
- 10
- 11    ●     Does the application necessitate that the plant-specific (historical) data be taken into  
12          account, and can this be achieved easily by an update of the previous parameters?
- 13
- 14    ●     Does the application involve a change which may impact parameter values, and do the  
15          present estimates reflect the current status of the plant with respect to what is to be  
16          changed?

17

18    **DEPENDENT FAILURE ANALYSIS**

- 19
- 20    ●     Does the application introduce or suggest new common cause failure (CCF)  
21          contributions?
- 22
- 23    ●     Does the application introduce new asymmetries that might create sub-groups within the  
24          CCF component groups?
- 25
- 26    ●     Is the application likely to affect CCF probabilities?

27

28    **HUMAN RELIABILITY ANALYSIS**

- 29
- 30    ●     Does the application involve a procedure change?
- 31
- 32    ●     Does the application involve a new human action?
- 33
- 34    ●     Does the application eliminate or modify an existing human action?
- 35
- 36    ●     Is the application concerned with events that have been screened from the model, either  
37          in whole or in part?
- 38
- 39    ●     Does the application impact a particular performance shaping factor (PSF), or a group  
40          of PSFs, and are they explicitly addressed in the estimation approach? For example, if  
41          the issue is to address training, is training one of the PSFs used in the HRA?
- 42
- 43    ●     Does success in the application hinge on incorporating the impact of changes in PSFs,  
44          and if so, do the current estimates reflect the current status of these PSFs?



1 ● Is it possible that the particular group of human error events that is affected by the  
2 change being analyzed has been truncated?

3  
4 ● Does the change address new recovery actions?  
5

#### 6 QUANTIFICATION

7  
8 ● Does the application change any of the basic event probabilities?

9  
10 ● Does the application change relative magnitudes of probabilities?

11  
12 ● Does the application only make probabilities smaller?

13  
14 ● Is the new result needed in a short-time scale?

15  
16 ● Does the application necessitate a change in the truncation limits for the model?  
17

#### 18 ANALYSIS OF RESULTS

19  
20 ● Does the application necessitate an assessment of uncertainty, and is it be qualitative or  
21 quantitative?

22  
23 ● Are there uncertainties in the application that could be clarified by the application of  
24 sensitivity studies?

25  
26 ● Does the application strategy necessitate an importance analysis to rank contributions?  
27

28 ● Does the application necessitate that an importance, uncertainty, or sensitivity analysis  
29 of the base case PSA exist?  
30

#### 31 PLANT DAMAGE STATE CLASSIFICATION

32  
33 ● Does the application impact the choice of parameters used to define plant damage states?

34  
35 ● Do the Key Plant Damage States (KPDS) utilized adequately represent the results of the  
36 Level 1 analysis by including the plant damage states that have a significant frequency  
37 of occurrence?  
38

39 ● Have those plant damage states that have been eliminated in this process been assigned  
40 to KPDSs of higher consequence (e.g. likelihood of Large Early Release)?  
41

#### 42 LEVEL 2 (CONTAINMENT ANALYSIS PSA)

- 1 ● Have new containment failure modes identified by the application been addressed in the  
2 PSA? Are potential changes accounted for?  
3  
4 ● Are any dependencies among containment failure modes being changed?  
5  
6 ● Does the application involve mechanisms that could lead to containment bypass?  
7  
8 ● Does the application involve mechanisms that could cause failure of the containment to  
9 isolate?  
10  
11 ● Does the application directly affect the occurrence of any severe accident phenomena?  
12  
13 ● Does the application necessitate use of risk measures other than large early release?  
14  
15

16 LEVEL 3 (CONSEQUENCE ANALYSIS PSA)  
17

- 18 ● Does the application necessitate detailed evacuee doses?  
19  
20 ● Are individual doses at specific locations needed for this application?  
21  
22  
23 ● Are terrain features significant enough to impact local wind patterns?  
24  
25 ● Is evacuation or sheltering being considered as a mitigation measure?  
26  
27 ● Are long term doses a consideration in this application?  
28

29 EXTERNAL EVENTS PSA (HAZARD ANALYSIS)  
30

- 31 ● Will the changes introduce external hazards not previously evaluated?  
32  
33 ● Will the changes increase the intensity of existing hazards significantly?  
34  
35 ● Are design changes modifying the structural response of the plant being considered?  
36  
37 ● Does the change impact the availability and performance of necessary mitigation systems  
38 for an external hazard?  
39  
40 ● Does the application significantly modify the inputs to the plant model conditioned on the  
41 external event?  
42  
43 ● Are changes being requested for systems designed to mitigate against specific external  
44 events?



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- Does the application involve availability and performance of containment systems under the external hazard?

**SHUTDOWN PSA**

- 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?

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Appendix F

DETERMINISTIC CONSIDERATIONS

In addition to gaining insights from reviewing PRA results and related importance measures, licensees must consider certain deterministic factors in determining the safety significance and grading of quality elements for SSCs or activities. Following are some examples of deterministic considerations.

- Licensees should know if an SSC has multiple applications in the plant and is susceptible to generic or common-mode failure that could affect redundant trains or multiple plant systems. The potential consequences of such common-mode failures should be considered.
- When used in conjunction with PRA insights, the deterministic evaluations need to consider the scope of the PRA. For example, if the PRA is a Level 1 study, containment performance, including containment isolation functions, should be evaluated using deterministic factors. If the PRA scope includes only internal events, external events like fires, earthquakes, floods, and high winds should also be considered. Likewise, low-power, shutdown, and transitional modes of operation may not be addressed by plant PRAs but nevertheless need to be considered in determining SSC safety significance.
- The PRA may not provide insights related to some potential failure modes or may not model the failure of some SSCs on the basis of inherent reliability assumptions. Such assumptions need to be evaluated to ensure that the safety significance of passive systems or structures is not underestimated. In addition, certain failure modes, aging for example, may not be modelled as a result of credit taken for maintenance programs; in that case, licensees should consider whether the GQA program could invalidate the conclusions reached about SSC safety significance.
- The redundancy of systems able to fulfill a critically important function may have the result that each individual system is determined to be of low safety significance. It may be prudent to designate at least one system associated with critical safety functions as high-safety-significant. This approach is further discussed in Reference 9 and has been used at one of the volunteer plants in the development of GQA programs.
- PRA importance measures may not fully address the significance of SSCs that support operator actions. Such systems may include environmental controls, lighting, alarms, and annunciators. The importance of such systems should be considered by the expert panel. The panel should consider whether the loss of such systems could cause short-term or long-term problems, whether a system failure coincident with an accident is likely, and whether personnel could reasonably compensate for the loss of these support systems.



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- The expert panel should consider design and licensing basis information in its evaluations. System descriptions or other documentation may provide valuable insights into the design basis functions and the safety significance of various SSCs. A failure modes and effects analysis is another traditional deterministic design document that may have information valuable to the expert panel. An understanding of design basis functions may also be important in grading QA controls.
- Licensees may choose to develop GQA programs that reflect the multiplicity of regulations and programs to which some SSCs are subject. For example, one licensee has excluded SSCs from the reduced QA controls category if those SSCs are also governed by ASME Code requirements. Or an SSC may be subject to reduced QA controls except activities associated with specific regulations or activities necessary to provide adequate confidence for a specific SSC characteristic; such an SSC may have added QA controls for design features such as environmental qualification or ASME Code requirements. This "targeted" approach has been proposed by another licensee developing GQA programs.

