SCE&G
A SCANA COMPANY

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Rules and Directives Branch
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Gentlemen:

Subject: VIRGIL C. SUMMER NUCLEAR STATION
DOCKET NO. 50/395
OPERATING LICENSE NO. NPF-12
COMMENTS ON DRAFT REGULATORY GUIDE DG-1095,
GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59,
CHANGES, TESTS, AND EXPERIMENTS

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South Carolina Electric and Gas Company (SCE&G) submits the following comments on DG-1095. SCE&G endorses the generic response prepared by the Nuclear Energy Institute (NEI) on behalf of its members.

The comments provided by the industry to NEI are exhaustive, detailed and clarified with sufficient examples.

SCE&G appreciates the opportunity to comment on this draft regulatory guide and wishes to recommend the endorsement of NEI 96-07. Should you have any questions, please call Mr. Arnie Cribb of my staff at (803) 345-4346.

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IE47

NUCLEAR EXCELLENCE - A SUMMER TRADITION!

ADD: V. Weaver

May 22, 2000
Draft Industry Response to DG-1095

DG-1095 Position 1.1, SCREENING ON WHETHER A CHANGE AFFECTS DESIGN FUNCTION

DG-1095 Position 1.1.1

To implement the rule properly, "design function," as used in screening, is broad so that changes that have the potential to meet any of the evaluation criteria are evaluated rather than screened. Since the criteria include both the initiation and response to previously postulated events (including equipment performance), as well as introduction of new events, "function" extends beyond safety-related SSC and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses.

Industry Comment

The definition of "change" ensures that all changes that have the potential to meet one of the 10 CFR 50.59 evaluation criteria are appropriately reviewed. Indeed, any addition, modification or removal not controlled by another requirement is subject to 10 CFR 50.59, i.e., at least screened. The definition of "design function" provides the appropriate focus of these screening reviews. We agree that the definition of "design function" extends beyond safety-related SSCs and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses. We plan to clarify the phrases "credited in the safety analyses" and "supports or impacts SSC functions" consistent with the DG-1095 Position 1.1.4. See below.

DG-1095 Positions 1.1.2, 1.1.3 and 1.1.4

(1.1.2) For SSCs that have functions described in the FSAR, changes affecting such functions should be evaluated, not excluded from further review because the described function does not fit the definition. When the change is being made to an SSC that is not itself described in the FSAR, or whose functions are not, screening with respect to whether the change affects a design function for other SSCs is appropriate, as discussed in Section 4.2.1.1, with the clarifications in 1.1.3 and 1.1.4 below.

(1.1.3) The definition for design function is modified in Section 3.3. This modification is proposed to ensure that the definition is interpreted in a comprehensive manner when deciding whether changes require further evaluation with respect to the evaluation criteria. The definition of design function is to read as follows:

"Design Function" for an SSC is the information in the Final Safety Analysis Report (as updated) that describes what the SSC is intended to do, when it is to perform the function (e.g., modes of operation, conditions), and how it is supposed to perform. These functions include but are not limited to: (1) SSCs and their functions that are credited in safety analyses or required by regulation, (2) functions of SSCs that support or impact any credited SSC functions, or (3) functions of non-safety-related SSCs that, if not performed, would initiate a plant transient or accident. Design functions include the conditions under which intended functions are required to be performed, such as equipment response times, environmental and process conditions, equipment qualification, and single failure.

(1.1.4) Further, the staff is adding guidance that "credited in the safety analyses" means that, if the SSC were not to perform its intended function in the manner described, the assumed initial conditions, mitigative actions, or other information in the analyses would no longer be within the range evaluated. The "credit" may be implicit with respect to the analysis, for example, one of the functions described in the FSAR of the non-safety turbine bypass system may be to mitigate some overpressure transients, even though the code safety valves are what are explicitly credited in the transient analysis. The phrase "supports or impacts SSC functions" refers both to those SSCs needed to support other SSCs (cooling, power, environmental control, etc.) and to SSCs whose performance or malfunction could interact with SSCs that have functions described in the FSAR (for instance, offsite power, control systems, physical arrangements). The staff notes that "Safety analysis" includes demonstration of the ability to safely shut down the reactor, accident and transient response analyses, as well as supporting analyses that demonstrate that SSC functions will be accomplished.

Industry Comment

DG-1095 positions 1.1.2, 1.1.3 and 1.14 reflect a view that changes affecting any SSC function described in the UFSAR should be evaluated, not just screened. As discussed below, this position would result in licensees performing, documenting and reporting to NRC numerous unnecessary 10 CFR 50.59 evaluations for changes that clearly do not meet any of the criteria for requiring prior NRC approval.

Unless wholly controlled by another requirement, any change affecting an SSC function described in the UFSAR must, at a minimum, be screened. The 10 CFR 50.59 screening review is focused on the effects of the change on UFSAR-described design functions, methods used to perform or control design functions, and evaluations that demonstrate that intended design functions will be accomplished. "Design function" is defined broadly to encompass

functions that affect initiation as well as response to events the plant is required to withstand. For many changes, the 10 CFR 50.59 screening review is sufficient to determine that no prior NRC approval is required. This is because not all SSCs described in the UFSAR perform, support or impact functions credited in the safety analyses, i.e., not all SSCs have "design functions." Some SSCs have multiple functions, and screening may determine that the proposed change does not affect design functions. Changes have no nexus to SSCs or functions credited in the safety analyses if screening determines that they do not affect:

- design functions,
- methods used to perform or control design functions, or
- evaluations that demonstrate that intended design functions will be accomplished

Such changes cannot meet the criteria for requiring prior NRC approval and therefore do no warrant further evaluation under 10 CFR 50.59. Rather than expend resources on such changes to perform, document and report 10 CFR 50.59 evaluations to NRC, these changes should be screened out.

The NRC staff proposal to define "design function" in terms of information described in the UFSAR is helpful, and we have modified the definition in NEI 96-07, Revision 1, as indicated below. As discussed above, we have retained the focus on functions credited in the safety analyses (including those that support or impact safety analysis functions), rather than all functions that may be described in the UFSAR. The following additional changes were made to the guidance to reinforce the intended breadth of the design function definition:

- The definition was clarified to reflect that conditions under which intended functions must be performed are implicitly included within the meaning of "design function"
- Consistent with the guidance proposed in Position 1.1.4, we have added a paragraph following the definition to clarify terms used to define "design function." Rather than define the concept of "implicit credit with respect to the safety analyses" as proposed by the NRC staff, we have clarified the definition of "design function" (as discussed above) to include matters that are implicitly included within the meaning of "design function." The turbine bypass system example was not helpful in this regard[1] and was eliminated.

[1] The turbine bypass system is used to mitigate certain overpressure transients and avoid more significant transients (e.g., reactor trips, lifting of Code safety relief valves). Thus, although non-safety-related, we agree that certain functions of the turbine bypass system are "design functions" for purposes of 10 CFR 50.59 screening because they impact functions credited in the safety analyses, and a change that adversely affects these turbine bypass system design functions would screen in. However, these functions are not (as identified in DG-1095)

- Additional guidance is also provided in Section 4.2.1 that, consistent with historical practice, changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions. A 10 CFR 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function.

In defining "design function," we have specifically avoided use of the NRC staff phraseology, "These functions include *but are not limited to....*" First, such open-ended language is not helpful or appropriate for use in defining key terms. Second, the design function definition, modified and expanded as identified below, is sufficiently broad to encompass functions that affect initiation and response to events the plant is required to withstand.

Proposed NEI 96-07, R1, Clarification

In Section 3.3, replace existing definition of "design function" with the following:

Design function for an SSC means an SSC function described in the UFSAR that is credited in the safety analyses, or that supports or impacts any credited SSC function. UFSAR description of design functions may identify what SSCs are intended to do, when and how design functions are to be performed, and under what conditions. Design functions include: (1) functions performed by safety-related SSCs or non-safety-related SSCs, and (2) functions of safety-related or non-safety-related SSCs that, if not performed, would initiate a plant transient or accident. Implicitly included within the meaning of design functions are the conditions under which intended functions are required to be performed, such as equipment response times, ~~environmental and~~ process conditions, equipment qualification, and single failure.

To be added after the definition of "design function:"

As used in this definition, "credited in the safety analyses" means that, if the SSC were not to perform its design function in the manner described, the assumed initial conditions, mitigative actions, or other information in the analyses would no longer be within the range evaluated (i.e., the analysis results would be called into question). The phrase "supports or impacts SSC functions" refers both to those SSCs needed to support other SSC design functions (cooling, power, environmental control, etc.) and to SSCs whose operation or malfunction could adversely affect the performance of design functions (for instance, control systems and physical arrangements). Thus,

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considered "credited" in the safety analyses. Non-safety-related systems are typically not credited in safety analyses.

both safety-related and non-safety-related SSCs may perform design functions.

DG-1095 Position 1.1.5

The discussion in Section 4.2.1, beginning with the second sentence, is to be considered under the subheading of Section 4.2.1.1. Section 4.2.1 discusses whether an activity is a "change to the facility or procedures as described in the UFSAR." The discussion begins with reference to all three parts of the rule definition of change, but then the subsequent discussion in this section (as well as in subsection 4.2.1.1) is focused only on facility changes as they relate to design functions. Other subsections (4.2.1.2 and 4.2.1.3) give further guidance on screening with respect to procedures and evaluation methods. All parts of Section 4.2.1 need to be used, as applicable. Since the noted text under Section 4.2.1 is more germane to the heading of Section 4.2.1.1, this text is to be moved.

Industry Comment:

The purpose of Section 4.2.1 (modified as indicated below) is to present guidance common to the screening of changes to the facility (discussed in Subsection 4.2.1.1), procedures (discussed in Subsection 4.2.1.2), and methods of evaluation (discussed in Subsection 4.2.1.3). These points of common guidance are:

1. In determining whether a change screens in or out, the full range of effects—direct and indirect—of the change must be considered (examples provided).

2. Additions are subject to 10 CFR 50.59 and should be screened for their effects on the existing facility as described in the UFSAR.

3. (New) Changes affecting SSCs and functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions.

4. Adverse changes screen in; benign and beneficial changes may generally be screened out. Expanded guidance in Section 4.2.1 for determining whether there is an adverse effect, and thus that a 10 CFR 50.59 evaluation is required, is discussed in response to DG-1095 position 1.1.6.

Proposed NEI 96-07, R1, Clarification

Section 4.2.1 to be revised as follows:

To determine whether or not a proposed change affects a design function, method of performing or controlling a design function or an evaluation that demonstrates that design functions will be accomplished, a thorough understanding of the affected SSCs and the proposed change is essential. A given change may have both direct and indirect effects that the screening review must consider. The following questions illustrate the range of effects that may stem from a proposed change: ~~Only proposed changes that would, based on supporting engineering and technical information, have adverse effects on SSC design functions require evaluation under 10 CFR 50.59. A determination of whether adverse effects exist should consider both direct and indirect effects of the activity. Examples of questions that could be considered include the following:~~

- Does the activity decrease the reliability of an SSC design function, including either functions whose failure would initiate a transient/ accident or functions that are relied upon for mitigation?
- Does the activity reduce existing redundancy, diversity or defense-in-depth?
- Does the activity add or delete an automatic or manual design function of the SSC?
- Does the activity convert a feature that was automatic to manual or vice versa?
- Does the activity introduce an unwanted or previously unreviewed system or materials interaction?
- Does the activity adversely affect the ability or response time to perform required actions, e.g., alter equipment access or add steps necessary for performing tasks?
- Does the activity degrade the seismic or environmental qualification of the SSC?
- Does the activity adversely affect other units at a multiple unit site?
- Does the activity use equipment/tools that interface either directly or indirectly with an operable SSC?

- Does the activity introduce intrusive test equipment into the SSC such that an SSC design function is affected?

- Does the activity affect a method of evaluation used in establishing the design bases or in the safety analyses?

- For activities affecting SSCs, procedures, or methods of evaluation that are not described in the UFSAR, does the change have an indirect effect on electrical distribution, structural integrity, environmental conditions or other UFSAR-described design functions?

Per the definition of "change" discussed in Section 3.3, 10 CFR 50.59 is applicable to additions as well as to changes to and removals from the facility or procedures. Additions should be screened for their effects on the existing facility and procedures as described in the UFSAR and, if required, a 10 CFR 50.59 evaluation should be performed. NEI 98-03 provides guidance for determining whether additions to the facility and procedures should be reflected in the UFSAR per 10 CFR 50.71(e).

Consistent with historical practice, changes affecting SSCs or functions not described in the UFSAR must be screened for their effects (so-called "indirect effects") on UFSAR-described design functions. A 10 CFR 50.59 evaluation is required when such changes adversely affect a UFSAR-described design function, as described below.

(Revised Section 4.2.1 continues with expanded guidance on "adverse effects." See response to DG-1095 Position 1.1.6.)

DG-1095 Position 1.1.6

Section 4.2.1 (relocated to Section 4.2.1.1 per Regulatory Position 1.1.5) provides guidance on whether a change may (adversely) affect a design function. Guidance is added for deciding whether a function is affected when the change is with respect to some characteristic or value (response time, capacity) of an SSC. Whether the change affects the function is determined by whether the result remains within the bounds of existing analyses or FSAR information. If the nature of the change is such that engineering assessments or revised analyses are needed to determine whether an effect is adverse, the change requires an evaluation pursuant to 10 CFR 50.59, and not a screening.

Industry Comment

Because, to some degree, engineering assessments underlie essentially all proposed changes, tests and experiments, this proposed regulatory position would negate the screening process and require 10 CFR 50.59 evaluations for nearly all activities. We do not believe the NRC staff, which has recognized the appropriateness of 10 CFR 50.59 screening, intends this.

Each proposed change is supported by technical/engineering information, that may include but is not limited to, drawings, specifications, narrative description, design evaluations, installation and testing requirements, associated procedure changes (if any), revised analyses (if any) and similar information. This information, often referred to as the design change package, demonstrates the safety and effectiveness of the change and provides the basis for management approval of its implementation. The final rule and SOC highlighted the distinction between the engineering/technical (i.e., "safety") evaluation reflected in the design change package and the 10 CFR 50.59 regulatory review that determines whether a change requires prior NRC approval. Screening determinations are based on the technical/engineering information that supports proposed changes.

Screening is the first part of the 10 CFR 50.59 regulatory review and must be based on a thorough understanding of the design function(s) of affected SSCs and the effect(s) of the proposed change. As discussed above, where screening determines that a change does not affect SSCs that perform, support or impact functions credited in the safety analyses, i.e., that changes do not affect design functions, such changes may be screened out from further 10 CFR 50.59 evaluation.

In addition to screening out changes that have no effect on design functions, certain changes can be determined during the 10 CFR 50.59 screening review to have a positive (beneficial) effect on design functions and may also be screened out. This is so for two reasons:

(1) "Design function" is defined broadly to encompass functions that affect initiation as well as response to events the plant is required to withstand.

Per the definition of "design function," SSCs may have preventive, as well as mitigative, design functions. Adverse changes to either must be screened in. Thus a change that decreases the reliability of a function whose failure could initiate a transient or accident would be considered to adversely affect a design function and would screen in. Relaxing code or quality requirements for certain SSCs are examples of changes of this type. Similarly, changes that would introduce a new type of accident or malfunction result are in this category and would screen in. This reflects

an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 evaluation. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

and,

(2) Changes that have positive or no effect on design functions cannot increase the likelihood of malfunctions, increase consequences, create new accidents or malfunctions, or otherwise meet the 10 CFR 50.59 evaluation criteria.

Only changes that adversely affect design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished screen in because only adverse changes have the potential to meet the 10 CFR 50.59 evaluation criteria.

The screening process is not concerned with the magnitude of adverse effects that are identified. Any change that adversely affects a UFSAR-described design function, method of performing or controlling design functions, or evaluation that demonstrates that intended design functions will be accomplished is screened in. The magnitude of the adverse effect (e.g., is the minimal increase standard met?) is the focus of the 10 CFR 50.59 evaluation process.

Screening determinations are made based on inspection of the engineering/technical information supporting the change. The screening focus on design functions ensures the essential distinction between 10 CFR 50.59 screenings and evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR 50.59(c)(2) are met. Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect on UFSAR-described design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished may be used as basis for screening out the change. If the effect of a change is such that UFSAR safety analyses were, or must be, re-run to demonstrate that all required safety functions and design requirements are met (i.e., existing safety analyses are no longer bounding), the change is considered to be adverse and must be screened in. The revised safety analyses may be used to support the required 10 CFR 50.59 evaluation of such changes.

Changes that require update of safety analyses to reflect improved performance, capacity, timing, etc., resulting from a change (beneficial effects on design functions) are not considered adverse and need not be screened in, even though the change requires safety analyses to be updated. For example, a

change that improves filter efficiency of the main control room ventilation system reduces the calculated dose operators and requires UFSAR dose consequence analyses to be updated. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of main control room filters (to remove particulate radiation) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to begin providing power at 12 seconds. This change may be screened out because it is apparent based on inspection that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's readiness to accept load to 13 seconds would screen in because the change adversely effects the design function (to provide emergency AC power in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in determining whether any of the 10 CFR 50.59 evaluation criteria are met such that prior NRC approval is required for the change.

As indicated below, much of the above discussion has been added to Section 4.2.1 to provide expanded guidance for determining if there is an adverse effect due to a facility, procedure or methodology change. Also identified are modifications to Subsections 4.2.1.1, 4.2.1.2 and 4.2.1.3 to reflect the Section 4.2.1 guidance on screening for adverse effects. Additional specific guidance on determining if there is an adverse effect due to a procedure or methodology change is provided in subsections 4.2.1.2, and 4.2.1.3, respectively.

<u>Proposed NEI 96-07, R1, Clarifications</u>

Expanded Section 4.2.1 Guidance on "Adverse Effects"

New Subheading—Screening for Adverse Effects

A 10 CFR 50.59 evaluation is required for changes that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (i.e., "adverse changes"). Changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents or malfunctions, or otherwise meet the 10 CFR 50.59 evaluation criteria.[2]

Per the definition of "design function," SSCs may have preventive, as well as mitigative, design functions. Adverse changes to either must be screened in. Thus a change that decreases the reliability of a function whose failure could initiate a transient or accident would be considered to adversely effect a design function and would screen in. Relaxing code or quality requirements for certain SSCs are examples of changes of this type. Similarly, changes that would introduce a new type of accident or malfunction result are in this category and would screen in. This reflects an overlap between the technical/engineering ("safety") review of the change and the 10 CFR 50.59 evaluation. This overlap reflects that these considerations are important to both the safety and regulatory reviews.

If a change has both positive and adverse effects, the change should be screened in, and the 10 CFR 50.59 evaluation may focus on the adverse effects.

The screening process is not concerned with the magnitude of adverse effects that are identified. Any change that adversely affects a UFSAR-described design function, method of performing or controlling design functions, or evaluation that demonstrates that intended design functions will be accomplished is screened in. The magnitude of the adverse effect (e.g., is the minimal increase standard met?) is the focus of the 10 CFR 50.59 evaluation process.

Screening determinations are made based on inspection of the engineering/technical information supporting the change. The screening focus on design functions, etc., ensures the essential distinction between (1) 10 CFR 50.59 screenings, and (2) 10 CFR 50.59 evaluations, which focus on whether changes meet any of the eight criteria in 10 CFR

[2] The exception to this is that a change that has any effect—positive or negative—on design basis limits for fission product barriers must be screened in (see Section 4.2.1.1).

50.59(c)(2) are met. Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse effect on UFSAR-described design functions, methods of performing or controlling design functions, or evaluations that demonstrate that intended design functions will be accomplished may be used as basis for screening out the change. If the effect of a change is such that UFSAR safety analyses were, or must be, re-run to demonstrate that all required safety functions and design requirements are met (i.e., existing safety analyses are no longer bounding), the change is considered to be adverse and must be screened in. The revised safety analyses may be used to support the required 10 CFR 50.59 evaluation of such changes.

Changes that require update of safety analyses to reflect improved performance, capacity, timing, etc., resulting from a change (beneficial effects on design functions) are not considered adverse and need not be screened in, even though the change requires safety analyses to be updated. For example, a change that improves filter efficiency of the main control room ventilation system reduces the calculated dose operators and requires UFSAR dose consequence analyses to be updated. In this case, the dose analyses are being revised to reflect the lower dose for the main control room, not to demonstrate that GDC limits continue to be met. A change that would adversely affect the design function of main control room filters (to remove particulate radiation) and increase the existing calculated dose to operators would be considered adverse and would screen in. In this case, the dose analyses must be re-run to ensure that GDC limits continue to be met. The revised analyses would be used to determine if the increase exceeds the minimal standard and requires prior NRC approval.

To further illustrate the distinction between 10 CFR 50.59 screening and evaluation, consider the example of a change to a diesel generator-starting relay that delays the diesel start time from 10 seconds to 12 seconds. The UFSAR-described design function credited in the ECCS analyses is for the diesel to begin providing power at 12 seconds. This change may be screened out because it is apparent based on inspection that the change will not adversely affect the diesel generator design function credited in the ECCS analyses (ECCS analyses remain valid).

However, a change that would delay the diesel's readiness to accept load to 13 seconds would screen in because the change adversely effects the design function (to provide emergency AC power in 12 seconds). Such a change would screen in even if technical/engineering information supporting the change includes revised safety analyses that demonstrate all required safety functions supported by the diesel, e.g., core heat removal, containment isolation, containment cooling, etc., are satisfied and that applicable dose limits continue to be met. While this change may

be acceptable with respect to performance of required safety functions and meeting design requirements, the analyses necessary to demonstrate acceptability are beyond the scope/intent of 10 CFR 50.59 screening reviews. Thus a 10 CFR 50.59 evaluation would be required. The revised safety analyses would be used in determining whether any of the 10 CFR 50.59 evaluation criteria are met such that prior NRC approval is required for the change.

Additional specific guidance for identifying adverse effects due to a procedure or methodology change is provided in subsections 4.2.1.2 and 4.2.1.3, respectively.

To be added to Section 4.2.1.1 (on screening of changes to the facility) before the paragraph introducing the examples:

As discussed in Section 4.2.1, only proposed changes to SSCs that would, based on supporting engineering and technical information, have adverse effects on design functions require evaluation under 10 CFR 50.59. Changes that have positive or no effect on design functions may generally be screened out. The exception to this is that any change to a design bases limit for a fission product barrier—adverse or beneficial—must be screened in. This is because 10 CFR 50.59(c)(2)(vii) requires prior NRC approval any time a proposed change would "exceed *or alter*" a design bases limit for a fission product barrier.

Section 4.2.1.2 guidance on screening procedure changes to be revised as follows:

Changes to procedures are "screened in" (i.e., require a 10 CFR 50.59 evaluation) if the change adversely affects how SSC design functions are performed or controlled, as described in the UFSAR (including assumed operator actions and response times). Proposed procedure changes that are determined to have positive or no effect on how SSC design functions are performed or controlled may be screened out.

For purposes of 10 CFR 50.59 screening, changes that fundamentally alter (replace) the existing means of performing or controlling design functions should be conservatively treated as adverse and screened in. Such changes include replacement of automatic action by manual action (or vice versa), analog to digital upgrades, changing a valve from "locked closed" to "administratively closed," and similar changes.

Section 4.2.1.3 on screening methodology changes to be revised as follows:

> As discussed in Section 3.6, methods of evaluation included in the UFSAR to demonstrate that intended SSC design functions will be accomplished are considered part of the "facility as described in the UFSAR." Thus use of new or revised methods of evaluation (as defined in Section 3.10) is considered to be a change that is controlled by 10 CFR 50.59 and needs to be considered as part of this screening step. Adverse changes to elements of a method of evaluation included in the UFSAR, or use of an alternative method, must be evaluated under 10 CFR 50.59(c)(2)(viii) to determine if prior NRC approval is required (see Section 4.3.8). Changes to methods of evaluation (only) do not require evaluation against the first seven criteria.
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> Changes to methods of evaluation not included in the UFSAR or to methodologies included in the UFSAR that are not used in the safety analyses or to establish design bases may be screened out.
>
> Methods of evaluation that may be identified in references listed at the end of UFSAR sections or chapters are not subject to control under10 CFR 50.59 unless the UFSAR states they were used for specific analyses within the scope of 10 CFR 50.59(c)(2)(viii).
>
> Changes to methods of evaluation included in the UFSAR are considered adverse and require evaluation under 10 CFR 50.59 if the changes are outside the constraints and limitations associated with use of the method, e.g., identified in a topical report and/or SER. If the changes are within constraints and limitations associated with use of the method, the change is not considered adverse and may be screened out.
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> Proposed use of an alternative method is considered an adverse change that must be evaluated under 10 CFR 50.59(c)(2)(viii).

DG-1095 Position 1.2, INTERFACE OF 10 CFR 50.59 WITH THE MAINTENANCE RULE (10 CFR 50.65)

Sections 1.2.1, 3.3, and 4.1.2 of the NEI guidance discuss the relationship between 10 CFR 50.59 and 50.65(a)(4) with respect to maintenance activities, including associated maintenance preparatory activities (referred to in some instances as "temporary changes or alterations"). NRC agrees with the intent of this guidance that, for activities required to support and directly related to the maintenance, 10 CFR 50.59 does not apply for the duration of the maintenance on the basis that another regulation controls such activities.

To avoid confusion about the relationship of maintenance activities (which restore the facility to its original condition) and modifications (that change in some respect the facility), Section 4.1.2 is to read as follows:

> Maintenance activities are actions that restore SSCs to their as-designed state. Maintenance activities include troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, and similar activities that do not permanently alter the design or design function of SSCs. Maintenance activities, including alterations to the facility or procedures required to support and directly related to the maintenance, are not subject to 10 CFR 50.59 evaluations but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications.
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> Licensees should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."[1]
>
> When the facility is not restored to its original condition as a result of the "maintenance activity" (e.g., if SSCs are removed, if the design, design function, or operation is altered, or if a temporary change in support of the maintenance is not removed), both 10 CFR 50.65(a)(4) and 50.59 would apply as discussed below. In these circumstances, the activities under way are not limited to maintenance, but also involve some sort of design or licensing basis change. An assessment of the "maintenance activity" is required as well as review of the "change." This situation might occur when the original plan is to restore the facility, but during the course of the maintenance, it is determined that full restoration will not occur (at which time the applicability of 10 CFR 50.59 would arise).
>
> A design change would be subject to 10 CFR 50.59 evaluation with respect to its effect upon the facility and its operation (following installation). Further, licensees may include as part of the modification package an evaluation pursuant to 10 CFR 50.59 for the facility in various stages of implementation of a modification (as needed). The actual implementation of a design change, including associated activities, may be viewed as "maintenance" rather than a change under 10 CFR 50.59, and be assessed under 10 CFR 50.65(a)(4). Thus, in these cases, a 10 CFR 50.65(a)(4) assessment would be needed for the duration of the "maintenance activity" to implement the modification. Whether a 10 CFR 50.65(a)(4) assessment is required for the installation of a modification should be determined by the maintenance rule requirements and guidance for assessing and managing risk before maintenance activities.

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should be applied to maintenance activities if a temporary change in support of maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary change prior to implementation in the same manner as a permanent change.

Apply 10 CFR 50.59 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

Proposed NEI 96-07, R1, Clarification

We agree with the intent of the proposed NRC clarification. Section 4.1.2, Maintenance Activities, to be revised as follows:

> Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities include troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, ~~associated temporary changes,~~ and similar activities that do not permanently alter the design or design function of SSCs, and are thus not subject to 10 CFR 50.59. Maintenance activities, including alterations to the facility or procedures that directly relate to and are necessary to support the maintenance, are not subject to 10 CFR 50.59, but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications. Examples of alterations that support maintenance include jumpering terminals, lifting leads, placing temporary lead shielding on pipes and equipment, removal of barriers, and use of temporary blocks, bypasses, scaffolding and supports.
>
> Licensees should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, *Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.*
>
> In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should also be applied to maintenance activities in the following cases:

- A temporary alteration in support of the maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary alteration prior to implementation in the same manner as a permanent change. If the temporary alteration meets any of the 10 CFR 50.59 evaluation criteria, prior NRC approval is required to leave the temporary alteration in effect longer than 90 days.

- The plant is not restored to its original condition upon completion of the maintenance activity (e.g., if SSCs are removed, the design, ~~design~~ function or operation is altered, or if temporary alteration in support of the maintenance is not removed). In this case, 10 CFR 50.59 would be applied to the change in design.

Installation and post-modification testing of approved design changes is indistinguishable from maintenance activities that restore SSCs to their as-designed condition in terms of their risk impact on the plant. As such, installation and testing of approved design changes are maintenance activities that must be assessed and managed in accordance with 10 CFR 50.65(a)(4). This contrasts with historical practice whereby 10 CFR 50.59 reviews addressed the design, installation and post-modification testing of proposed design changes. Going forward, 10 CFR 50.59 will address the effect, following implementation, of proposed design changes to determine if prior NRC approval is required; the risk impact of actually implementing the change will be assessed and managed per 10 CFR 50.65(a)(4).

10 CFR 50.59 should be applied to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

DG-1095 Position 1.3, INCREASES IN LIKELIHOOD OF MALFUNCTION

In Section 4.3.2 of NEI 96-07, a quantitative value for "no more than a minimal increase" is a factor of 2 increase. This factor must be applied at the individual component level. If the guidance is not so limited, further guidance would be needed to limit the overall effects of the change at the system or train level. The NRC staff agrees with the NEI guidance that states that use of the factor of 2 may also be constrained by other evaluation criteria, depending upon the specific components or functions that the change involves.

Proposed NEI 96-07, R1, Clarification

Item 3 on page 42 (Section 4.3.2) is revised as follows:

3. The change in likelihood of occurrence of a malfunction is calculated in support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied ~~based on the nature of the activity, e.g.,~~ at the component level ~~for component changes~~. ~~System/functional level~~ Certain changes that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval, e.g., exceed the minimal increase standard for accident/transient frequency under criterion 10 CFR 50.59(c)(2)(i). For example, a change that increases the likelihood of malfunction of the Emergency AC system or Reactor Protection System by a factor of two would likely cause more than a 10% increase in the frequency of station blackout or ATWS, respectively.

DG-1095 Position 1.4, METHODS APPROVED BY NRC FOR THE INTENDED APPLICATION

DG-1095 Position 1.4.1 and 1.4.2

(1.4.1) NEI 96-07 refers to whether differences in plant configuration or licensing basis are "material to the NRC approval basis" in concluding whether the NRC approval of an evaluation method (reviewed for a plant-specific application) is still valid for use at another facility. The NRC staff believes that it will be difficult for a licensee to determine whether the differences meet this criterion; as for plant-specific reviews, the staff's evaluation may not discuss all aspects of the approval basis. Instead, the NRC staff has concluded the decision should be based upon whether the differences are relevant to the results obtained. If such relevant differences exist, the method is not "approved" and any modifications to NRC-approved methodologies should be evaluated using the "conservative or essentially the same" criteria in the definition of "departure."

(1.4.2) Section 4.3.8.2 states "slight modifications to the [NRC approved] methodology can be made and the methodology can still be considered approved for the intended application." The basis for acceptability of modifications to approved methods that is acceptable to the NRC staff is using the "conservative or essentially the same" criteria.

Industry Comment

We concur with the staff's conclusion that the decision as to whether a methodology approved for use at Plant A can be applied to Plant B should be based on the relevance of plant differences to the results obtained. It is important to note that adjustment of analysis input parameters is typically necessary to reflect plant differences, but such input differences (provided they are within the range of values for which the methodology is valid) do not affect the application of the methodology. It is incumbent upon the GL 83-11 qualified licensee to assess plant differences in an appropriate manner.

The staff proposal to use the "conservative or essentially the same" criterion to determine the acceptability of slight modifications to an NRC approved methodology that may be necessary is helpful and is reflected in the revised industry guidance below.

Proposed NEI 96-07, R1, Clarification

Last four paragraphs of Section 4.3.8.2 to be revised as indicated below:

- Is the facility for which the methodology has been approved designed and operated in the same manner as the facility to which the methodology is to be applied? Is the relevant equipment the same? Does the equipment have the same pedigree (e.g., Class 1E, Seismic Category I, etc.)? Are the relevant failure modes and effects analyses the same? If the plant is designed and operated in a similar, but not identical manner, the following types of considerations should be addressed to assess the applicability of the methodology:
    - How could those differences affect the methodology?
    - Are additional sensitivity studies required?
    - Should additional single failure scenarios be considered?
    - Are analyses of limiting scenarios, effects of equipment failures, etc., applicable for the specific plant design?
    - Can analyses be made while maintaining compliance with both the intent and literal definition of the methodology?
- Differences in the plant configurations and licensing bases could invalidate the application of a particular methodology. For example, the licensing

basis of older vintage plants may not include an analysis of the feedwater line break event that is required in later vintage plants. Some plants may be required to postulate a loss of offsite power or a maximum break size for certain events; other may have obtained exemptions to these requirements from the NRC. Some plants may have pressurizer power-operated relief valves that are qualified for water relief; other plants do not. Plant specific failure modes and effects analyses may reveal new potential single failure scenarios that can not be adequately assessed with the original methodology. The existence of these differences does not preclude application of a new methodology to a facility; however, differences must be identified, understood and documented. Slight modifications to the NRC approved methodology to address plant-specific features are acceptable provided the analysis results obtained are conservative or essentially the same with respect to the unmodified methodology.

DG-1095 GUIDANCE ON USE OF EXAMPLES

Revision 1 to NEI 96-07 includes examples to supplement the guidance. These examples are illustrative only, and the NRC's endorsement of NEI 96-07 (Revision 1) should not be considered a determination that the examples are applicable for all licensees. A licensee should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

Industry Comment

As important as the examples are, their appropriateness for purposes of illustrating and reinforcing the NEI 96-07, R1, guidance should be acknowledged in the final regulatory guide as indicated below:

> Revision 1 to NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in NEI 96-07, R1, ~~These examples are illustrative only, and~~ the NRC's endorsement of NEI 96-07 (Revision 1) should not be considered a determination that the examples are applicable for all licensees. A licensee should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

DG-1095 GUIDANCE FOR FSAR SUPPLEMENTS FOR LICENSE RENEWAL

The guidance in NEI 96-07 and in this regulatory guide is applicable to information added to the FSAR in accordance with 10 CFR 54.21(d), that is, for summary descriptions of the programs and activities for managing the effects

of aging and the evaluation of time-limited aging analyses. If necessary, the staff may provide further guidance or examples for use with respect to such programs and evaluations at a later date.

Industry Comment

We do not believe additional guidance is necessary with respect to applicability of 10 CFR 50.59 to supplemental license renewal information added to the UFSAR. If the NRC decides to provide further guidance or examples for use with respect to such information, we request the NRC provide opportunity for public comment on the proposed additional guidance.

Specific feedback requested by NRC

1. The NRC specifically seeks comment on the impact of not allowing screening of changes that affect functions that do not meet the definition of design function. In particular, examples of functions that might be described in the FSAR, but for which an evaluation under 10 CFR 50.59 would not be needed if that function were affected, would be helpful.

   Industry Comment

   See responses to DG-1095 Positions 1.1.1 – 1.1.6.

2. The NRC staff has proposed that NEI supplement the guidance with a few examples that are subjected to the entire evaluation process, including all of the eight evaluation criteria, to show some of the interrelationships. Commenters are invited to suggest examples of changes that would best demonstrate functioning of the overall process.

   Industry Comment

   Upon closure of DG-1095 issues[3], we will consider the need for including one or more comprehensive examples in the final guidance. It should be recognized that because criterion c(2)(viii) applies to methodology changes only, it is unlikely that any single change would be subject to all eight evaluation criteria.

3. Finally, the NRC is interested in the issue of documentation. The guidance notes the need for records of evaluations and for documentation of screening. The NRC staff believes that the guidance could be improved by direction about the level of detail to be documented about the considerations and questions contained in the NEI guidance. This is particularly true with respect to criteria 10 CFR 50.59(c)(2)(vii) and (viii). Comments on this subject are also requested.

   Industry Comment

   We have added the underlined sentence to Section 4.2.3, Screening Documentation:

[3] Consideration of additional examples would also be subject to disposition of the industry comment above concerning DG-1095 Guidance on Use of Examples.

Section 4.2.3

> 10 CFR 50.59 recordkeeping requirements apply to 10 CFR 50.59 evaluations performed for activities that screened in, not to screening records for activities that screened out. However, documentation should be maintained in accordance with plant procedures of screenings that conclude a proposed activity screened out (i.e., that a 10 CFR 50.59 evaluation was not required). The basis for the conclusion should be documented to a degree commensurate with the safety significance of the change. For changes, the documentation should include the basis for determining that there would be no adverse effect on design functions. Typically, the screening documentation is retained as part of the change package. This documentation does not constitute the record of changes required by 10 CFR 50.59, and thus is not subject to 10 CFR 50.59 documentation and reporting requirements. Screening records need not be retained for activities for which a 10 CFR 50.59 evaluation was performed or for activities that were never implemented.

Concerning documentation of 10 CFR 50.59 evaluations, Section 5.0 of NEI 96-07, R1, currently includes the following guidance:

> Each 10 CFR 50.59 evaluation is unique. Although each applicable criteria must be addressed, the questions and considerations listed throughout this guidance document to assist evaluating the criteria are not requirements for all evaluations. Some evaluations may require that none of these questions be addressed while others will require additional considerations beyond those addressed in this guidance.

We believe this guidance is adequate and appropriate with respect to documentation of 10 CFR 50.59 evaluations. However, we will consider further guidance based on public comments received on this subject and further discussion with the NRC staff.