Revision 0
(November 26, 1996)

INDUSTRY GUIDANCE FOR RESPONDING TO NRC REQUEST FOR INFORMATION UNDER 10 CFR 50.54(F) REGARDING ADEQUACY AND AVAILABILITY OF DESIGN BASES INFORMATION

Revision 0
11/26/96

Responding to NRC Request for Information Under 10 CFR 50.54(f)
Regarding Adequacy and Availability of Design Bases Information

This document provides a suggested approach for responding to the 50.54(f) letter. It has been developed using insights gained in discussions with various industry personnel, including senior licensee management, operations, engineering and licensing personnel, members of NEI's Issue Task Force on 10 CFR 50.59, and other NEI members.

Section I provides general guidance on addressing the principal NRC concerns discussed in the 50.54(f) letter. Section II is an outline developed for use in responding to the specific requests for information detailed in the letter.

I. General Guidance

Scope of the Response - Focus on Design Bases Information per 10 CFR 50.2

It must be emphasized at the start that there is no right or wrong response to the 50.54(f) letter. Rather, your response should fulfill the request for information that is detailed in the letter in a clear and thoughtful manner. The industry objectives are to be fully responsive to the NRC's concerns in providing the information requested, and to achieve general consistency with regard to the scope and level of detail in licensee responses.

The NRC's concerns are focused in three principal areas. They are:

- Licensee cognizance of the plant design bases;
- Licensee configuration control of plant and procedures consistent with the plant design bases; and
- Licensee actions to identify and correct conditions adverse to quality with respect to the plant design bases.

With respect to addressing the first concern, NUMARC 90-12, *Design Basis Program Guidelines*, provides industry guidance on the collation of design bases information. The key aspect here is to implement the term design bases, as defined in 10 CFR 50.2, in a straightforward manner (footnote 4 on page 4 of the NRC's 50.54(f) letter provides additional clarification on design bases as contained in the FSAR). This is important because it is that information that the licensee is responsible for under the current regulations. The amount of actual design bases

information required by regulation is relatively small compared with other design information, such as design input, process and output documents. While the process descriptions requested in the letter include much of this other design information, your response should focus on how these processes maintain the integrity of the plant's design bases. Therefore, a precise understanding of the design bases, focused on the 10 CFR 50.2 definition, directly addresses the NRC concern and is a fundamental element in responding to the 10 CFR 50.54(f) letter.

The second NRC concern involves maintaining the plant configuration (i.e., physical plant and procedures) consistent with the design bases information. Again, a precise understanding of the design bases information per 10 CFR 50.2 is fundamental to addressing this concern. NUMARC 90-12 stresses the importance of integrating design basis information into licensee design control and configuration control activities.

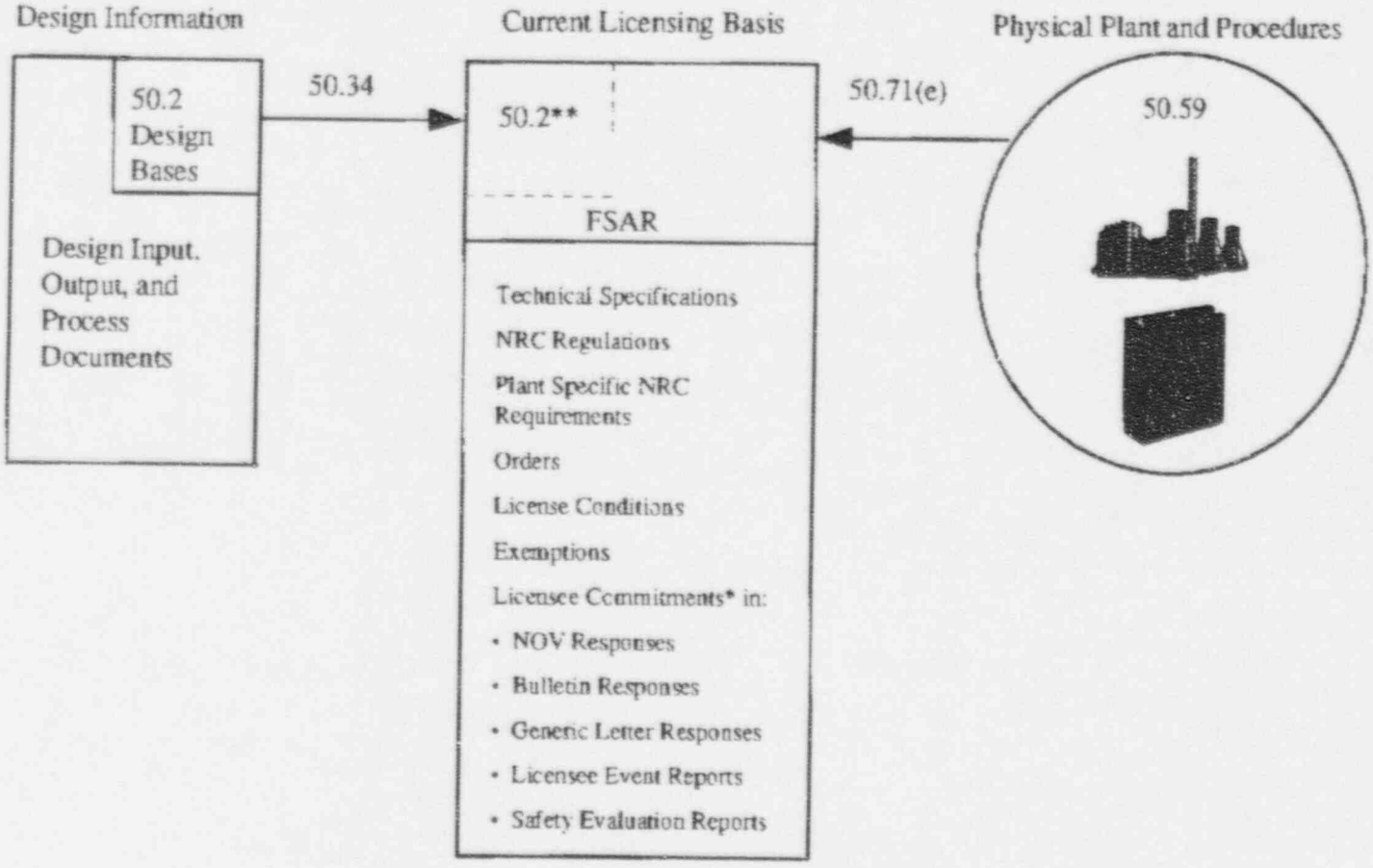
From a regulatory perspective, 10 CFR 50.59 is the mechanism for assuring that changes to the plant configuration are controlled such that the plant remains within its design bases, as described in the FSAR. 10 CFR 50.71(e) is the mechanism that assures that the effects of changes made to the plant or procedures, within the scope of 50.71(e), are appropriately reflected in the updated FSAR. Your response should focus on how these processes provide assurance that the plant configuration, including the FSAR, is maintained consistent with the design bases.

In addressing the first two NRC concerns noted above, it is important to understand licensee responsibilities with respect to design bases information and configuration control under the current regulations. The attached figure entitled, "Relationship of Current Regulations," was developed to aid in this regard.

The third NRC concern deals with the identification and correction of conditions adverse to quality (CAQs). NUMARC 90-12 provides guidance on a managed process for addressing discrepancies identified between the plant configuration and the design bases. This process includes discussion of both operability and reportability determinations under 10 CFR 50.72 and 50.73 as well as licensee responsibilities and actions with respect to technical specification compliance. In addition, licensee corrective action programs under Appendix B, Criterion XVI, assure that CAQs are appropriately tracked, dispositioned, and closed out. Note: Discrepancies, as discussed in NUMARC 90-12, are a subset of CAQs.

In summary, in responding to the five specified requests and supplemental inquiry in the 10 CFR 50.54(f) letter, the focus should be on the design bases, as defined in 10 CFR 50.2, and its consistency with the physical plant, procedures, and the FSAR. This focus will assure that the principal NRC concerns are addressed and that our response is directly tied to your responsibilities under the applicable NRC regulations. The guidance provided in NUMARC 90-12 should be utilized to the maximum extent.

RELATIONSHIP OF CURRENT REGULATIONS



* Those commitments that are necessary to comply with regulatory requirements

** Some design bases information, developed in response to new regulations, may exist outside the FSAR, but is still considered part of the current licensing basis.

Use of Industry Initiative Actions in the Response

With respect to the approved industry initiative to assess conformance with the licensing basis using the NEI 96-05 guidance, the implementation of the initiative entails actions and provides information that can be used in responding to the 10 CFR 50.54(f) letter. Specifically, your assessment of mechanisms that identify, evaluate, and/or process changes that could affect the design bases can support your rationale for concluding that the plant and procedures are maintained consistent with the design bases. Your response should cite and credit those actions where appropriate.

Use of Retrospective vs. Prospective Actions in the Response

The guidance in this document is primarily retrospective in that it focuses on using your established processes and the results of past activities to respond to the requests for information in the 50.54(f) letter. In general, the need to cite any prospective actions, such as vertical slice reviews or further design bases activities, should be examined following your assessment using NEI 96-05. It is recognized that some licensees may determine that further reviews of design bases information are warranted as a result of their preparations for responding to the 50.54(f) letter.

It should be noted that any prospective actions you cite in responding to the 50.54(f) letter will be regarded as commitments by the NRC and will become part of your licensing basis. The NRC will expect compliance with these commitments until they are changed. See NEI's *Guideline for Managing NRC Commitments* for additional information in this regard.

Use of NRC Findings in Your Response

The 50.54(f) letter asks each licensee to describe its processes and provide its rationale for concluding that design bases requirements are being maintained. Your response should therefore primarily focus on what you do to provide reasonable assurance that the plant is operating within its design bases.

As a supplement to your process descriptions and rationales, there should be a considerable amount of NRC findings from inspections and other activities (e.g., SSFIs, SSOMIs, SALP input, audits, etc.) that can be cited in your response in support of your conclusions. These findings should be used when they are relevant to the specific areas you are addressing in your response.

Use of Adequate Assurance/Confidence Standard vs. Absolute Statements

Design control and configuration management are complex administrative processes. Regardless of the integrity of licensee processes and reverification efforts, there will always be a potential for minor discrepancies to exist. While your responses should be factual and accurate, it would be difficult, given the legal nature of a 10 CFR 50.54(f) letter, to make any absolute statements in support of the conclusions drawn in your response. Rather, it is recommended that you consider the use of the adequate assurance or adequate confidence standard to support your rationale and conclusions. This usage would be consistent with the requirements set forth in 10 CFR 50, Appendix A, Criterion 1, *Quality Standards and Records*, and with 10 CFR 50, Appendix B, *Introduction*.

II. Responding to the Specific Requests for Information

The following outline is provided for your use in responding to the specific requests for information in the 10 CFR 50.54(f) letter. In general, descriptions should be concisely written, providing the reader with an overall understanding of the depth and breadth of your process or rationale. Your response can be supplemented with references to materials already on your docket or references to plant procedures that govern specific processes. The specific NRC requests in the letter are provided in bold type for your information.

(a) Description of engineering design and configuration control processes, including those that implement 10 CFR 50.59, 10 CFR 50.71(e), and Appendix B to 10 CFR Part 50.

Recommended Response: Provide a description of the processes used for maintaining the plant design and configuration consistent with the design bases. The description should include:

- Scope of the overall programs
- Level of reviews (managerial/committee)
- Integration with other change processes (e.g., commitment change process)
- Interfaces between the processes
- Organizational responsibilities and interfaces for implementing the processes

(b) Rationale for concluding that the design bases requirements are translated into operating, maintenance, and testing procedures.

Recommended Response: Discuss how the results of past and current activities provide assurance that maintenance, operations and testing procedures are consistent with the design bases. These activities may include:

- Initial licensing reviews
- Start-up verification activities, including testing
- 50.59 reviews of procedure changes
- Design basis review programs, including validation activities
- NRC conducted Safety System Functional Inspections (SSFIs)
- Utility self assessments, including Safety System Functional Assessments (SSFAs)
- QA audits and activities
- NEI 96-05 (industry initiative) reviews

(c) Rationale for concluding that system, structure, and component configuration and performance are consistent with the design bases.

Recommended Response: Discuss how the results of past and current activities provide assurance that SSCs configuration and performance are consistent with the design bases. These activities may include:

- Surveillance testing
- 50.59 reviews of plant changes
- Design basis review programs
- NRC conducted SSFIs
- Utility self assessments, including SSFAs
- QA audits and activities
- NEI 96-05 reviews
- DBD validation efforts
- Plant walkdowns

(d) Processes for identification of problems and implementation of corrective actions, including actions to determine the extent of problems, action to prevent recurrence, and reporting to the NRC.

Recommended Response: Provide a general description of the processes that identify conditions adverse to quality and the overall corrective action program at the plant. Items to include are:

- 10 CFR 50 Appendix B programs
- 10 CFR 21 process
- Discrepancy identification mechanisms (e.g., assessments, walkdowns, testing, etc.)
- Employee concern programs
- Discussion of root cause determination process
- Corrective action determination
- Tracking and closure of corrective actions
- Review for applicability of identified deficiencies to other plant SSCs/activities
- Discussion of operability determinations (NUMARC 90-12 and GL 91-18)
- Discussion of reportability - compliance with 10 CFR 50.72 and 50.73
- Organizational responsibilities and interfaces for program implementation

(e) The overall effectiveness of your current processes and programs in concluding that the configuration of your plant(s) is consistent with the design bases.

Recommended Response: The requested information is intended as a cumulative rollup of your responses to items (b) and (c), with a focus on how management assesses the overall effectiveness of the configuration control program. The response should summarize the efforts cited in items (b) and (c), and how management uses the results of those efforts. Specifically, the response should include management's use of the results to assess the effectiveness of the processes described in items (a) and (d), as well as to make any appropriate adjustments to those processes.

NRC Request for Information on Design Review/Reconstitution Programs

NRC also requests confirmation that design review or reconstitution programs have been or are being conducted and, if not, a rationale for not performing them.

If you have conducted or are currently conducting a design review or reconstitution program, or other type of design basis program consistent with NUMARC 90-12, your response should include the following:

- Program description, including principal objectives
- SSCs in scope
- Topical areas in scope (plant level design attributes, e.g., seismic, HELB, etc.)
- Implementation schedule if not complete
- Prioritization of SSCs/topical areas (e.g., risk-significant SSCs per Maintenance Rule)
- Verification and validation activities

If you have not conducted a design basis program, your rationale should be clear, concise and consistent with your responses to the NRC's requested information in items (a) through (e) of the 10 CFR 50.54(f) letter. Your rationale should be based on a conclusion that your plant's design bases information is adequate and available.