



NUCLEAR ENERGY INSTITUTE

Anthony R. Pietrangelo
DIRECTOR, LICENSING
NUCLEAR GENERATION DIVISION

October 24, 1996

Mr. Thomas T. Martin
Director, Division of Reactor Program Management
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

PROJECT NUMBER: 689

Dear Mr. Martin:

On August 20, 1996, NEI and the NRC staff met to discuss items of mutual interest relative to the topics of the § 50.59 process and FSAR compliance. In our September 16 letter, we indicated our intent to develop point papers on many of the topics discussed in the August 20, 1996, meeting. Drafts of these papers are enclosed for NRC staff review. Further, we would appreciate meeting with the staff the week of November 4, 1996, to continue our dialogue on these matters.

If you have any questions or would like to set up a meeting date, please call Doug Walters (202-739-8093) or me.

Sincerely,

Anthony R. Pietrangelo

DJW/jes
Enclosure

9611050222 961024
PDR PROJ
689 PDR

PROJECT 689

2046
11

WHEN DO YOU ENTER THE §50.59 PROCESS?

DISCUSSION: 10CFR50.59 allows a licensee to make changes in its facility, procedures and tests described in the Safety Analysis Report without prior NRC approval unless the changes involve a change in the Technical Specifications or an unreviewed safety question. The types and number of changes that take place at a nuclear power plant site are numerous. One licensee identified over 100 separate change control processes and estimated that more than 100,000 changes are initiated at its site each year. So, how does an initiator of one of those myriad changes recognize its relationship to §50.59 and take appropriate action?

Changes that fall within the scope of the §50.59 are defined by the regulation. 10CFR50.59(a)(1) states that a licensee may i) make changes in the facility and as described in the safety analysis report, ii) make changes in the procedures as described in the safety analysis report, or iii) conduct tests or experiments not described in the safety analysis report as long as the proposed change, test or experiment doesn't involve a Technical Specification change or an unreviewed safety question. As defined, the scope of 50.59 is fairly straightforward, yet often anything but in its application.

As a result, a number of licensees have utilized items (i) through (iii) as a basic set of "screening" criteria that, when applied to proposed changes initiated by their various change processes, provide reasonable assurance that the proposed change will be properly dispositioned with respect to 50.59. However, licensees who have identified and linked only major change processes to 50.59, such as those that implement design modifications or that change procedures, may have inadequate change management controls in place and may have a number of change processes that lack the appropriate link to the 50.59 process.

As part of effective change management, it is incumbent on licensees to identify all processes that implement change at their facilities. The licensee should ensure that those processes having a reasonable likelihood for effecting the types of changes described by 50.59(a)(1) have within them a "link" that directs the change initiator to perform a 50.59 screening. One acceptable mechanism for establishing such a link is to ensure that administrative controls are in place that implement the "screening" concept. The specific wording for the screening criteria may vary, and can include criteria in addition to the basic set listed above. The effectiveness of such screening then turns on the ability of the individual performing the screening to recognize whether the proposed change involves an activity described in the SAR, and whether the proposed activity is, in fact, a change--two issues best addressed by training individuals to perform quality screenings.

In a broad sense, all changes to the facility are subject to §50.59. In practice, licensees may screen a proposed change and conclude that the type of change being proposed can be excluded from further 50.59-related activity. For example, the licensee organization responsible for a large, multi-volume document like the updated Final Safety Analysis Report requires reasonable flexibility in performing certain "editorial" functions typically

October 21, 1996

associated with documents of that size and scope. One type of editorial change is the trivial, or purely administrative, change. Such changes should be defined and documented within the licensee's administrative controls for its 50.59 process. By establishing that category of change, the licensee is then better able to focus its resources on those changes that may have potential safety significance.

October 21, 1996

ANALYSIS CHANGES AFFECTING 50.59 DETERMINATIONS

DISCUSSION: Section 3.8 of NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," addresses, in part, the effect of utilizing analysis methods, codes, uncertainties, etc., different from those used in the SAR to evaluate changes to the plant or procedures. Specifically, the guidelines state: "The licensee should apply the same methodology, with and without the proposed change, when evaluating a change to determine its effect upon the margin of safety." The guidelines also differentiate between cases where the analysis methodology was submitted to the NRC as part of the license application and cases where it was not submitted.

Discussions with the staff during the development of NSAC-125 (the predecessor to NEI 96-07) indicated that the licensing review for a license included consideration of the methods, assumptions, etc., that are part of the determination of accident analysis results and, therefore, the margin of safety. A review of a plant design or procedure change using refined methodology, for example, might result in offsetting the effect of the change on the safety analysis due to characteristics of the new methodology. The staff indicated that such a double change should be considered a USQ if the plant change, evaluated under the original methodology, resulted in a decrease in the margin of safety. If the details of the methodology were a part of the original submittal, the change in methodology itself would have to be reviewed under 50.59.

The guidelines also indicate that the reduction in margin should be determined by the analysis result rather than the detailed inputs. An example would be an increase in system operating temperature and a corresponding decrease in a protective setpoint such that the transient analysis results in the same peak pressure would not be considered a USQ.

Licensee procedures for 50.59 reviews should include an assessment of the analysis methodology. The methodology assessment should consider whether or not the codes, input assumptions, etc., were part of the original licensing submittal and whether or not that is documented in the SER. If it was part of the submittal and the change in methodology by itself reduces the margin of safety, it should be considered an USQ. If the methodology was not submitted, a comparison of the physical change using the old and new methodology should be made to determine if a reduction in margin of safety exists.

APPLICABILITY OF 10CFR50.59 TO NONCONFORMANCES/DEGRADED CONDITIONS

DISCUSSION: When is a 10CFR50.59 evaluation required as part of the dispositioning of nonconformances or degraded conditions (hereinafter referred to by the former term)?

The principal regulatory requirements associated with disposition of nonconformance are 10 CFR 50, Appendix B, Criterion XV and XVI. These can be summarized as requiring the identification and timely resolution of nonconforming conditions. Once identified, such items are tracked to resolution.

There are a number of related requirements. These include 'operability' assessments required for SSCs addressed in the Technical Specifications (GL 91-18 provides additional guidance) and 'reportability' assessment required by 10CFR 21, 50.72, etc.

Once these assessments are completed; corrective action(s) must be identified or planned following additional assessments (scope, root cause or other efforts). Ultimately the nonconformance must be corrected by changing the requirement not met, changing the condition of the SSC, or a combination of both. Both the 'operability' assessment and the corrective action plan must be done in an appropriately timely manner. Timeliness must be based on safety significance.

If the requirement is to be changed it must be evaluated in accordance with the applicable change control process:

- Exemptions from a rule are addressed by 10 CFR 50.12.
- Changes to certain plans generically incorporated into the Operating License (QA, Security, or Emergency Plans, are addressed in 10 CFR 50.54 (a), (p) or (q) respectively.
- If the change meets the requirements of 10 CFR 50.59 then it too may apply.

[The purpose of the two latter assessments is to determine if a change to the Operating License is required.]
- Amendments to the License are addressed by 10 CFR 50.90.

If the nonconforming condition is to be corrected by changing the condition of the SSC so that no change to the design or licensing basis is required; no change control process is generally applicable.

As noted earlier, the timing of corrective actions is driven by the safety significance of the item and can be influenced by other factors (mode required, resource availability, etc). If the

October 21, 1996

nonconforming condition is not completely corrected for an extended period of time then a de facto temporary change has occurred. Temporary changes are subject to the same change controls as are permanent ones (although it may be easier to justify a change on a temporary basis). Thus, a 10 CFR 50.59 (or other more appropriate) evaluations are required for situations allowed to remain uncorrected for extended periods of time.

The key issue is the definition of "extended." This should generally be based upon the safety and regulatory significance. There is general consensus that 30 days or less is not "extended" and that a year or more is. It is recommended that either the industry or NRC establish a common expectation. It is suggested⁴ that no longer than 180 days be adopted. Conducting the reviews before 180 days seems reasonable to allow routine corrective maintenance planning and scheduling or other similar actions which would preclude the need for such evaluations. If the situation is clearly significant from either a safety or regulatory perspective it should be pursued earlier. It is recognized that the justification of timeliness of corrective action plan and a 10 CFR 50.59 evaluation are different but can both be accomplished in one, sufficiently broad, assessment.

USE OF COMPENSATORY MEASURES IN THE 50.59 PROCESS

DISCUSSION: Draft NEI 96-07 has been revised to indicate that changes which are so small, or uncertain, may not be considered an increase in probability or consequences, or a reduction in margin of safety, provided that compensatory measures are taken which outweigh the potential increase or reduction, or offset the uncertainties (See Sections 3.4, 3.5, 3.6, and 3.8.) This clarification is consistent with the NRC Inspection Manual, Part 9900, "Interim Guidance on the Requirements Related to Changes to Facilities, Procedures and Test (or Experiments)." Specifically, page 3 states: "In considering the acceptability of a licensee's 10CFR50.59 evaluation, the staff has found compensating effects such as changes in administrative controls acceptable in offsetting uncertainties and increases in probability... the compensatory actions must clearly outweigh any potential increase in probability of occurrence or consequences or reduction in margin."

The acceptability of this practice is based on the concept of "bundling" a group of related changes and evaluating the combined effect of the integrated change package. This is similar to the practices employed by the NRC staff in evaluating proposed Technical Specification changes, or by licensees in evaluating potential changes in risk per the PSA Applications Guide. While individual aspects of the change may tend to drive the result in opposite directions, what is important is the overall effect of the integrated change package on the particular attribute being evaluated (e.g., probability, consequences, risk, etc.)

A question has arisen as to how closely related must changes and associated compensatory measures be to permit "bundling" in an integrated package for the purposes of 50.59 evaluations. It is suggested that the language of the 50.59 questions themselves provide the appropriate "boundaries" or limitations to ensure the validity of this approach. The following examples illustrate this point:

- 1) Increase in the Probability of an Accident previously evaluated in the SAR.

The term "accidents" refers to the anticipated operational transients and postulated design basis accidents that are analyzed to demonstrate that the plant can be operated without undue risk to the health and safety of the public (typically found in SAR Chapter 15). If the licensee were evaluating a proposed change to the Reactor Coolant pressure boundary which tended to slightly increase its susceptibility to failure, then that tendency could potentially be offset by increasing the frequency of inservice inspections. The acceptability of the compensatory measure (inservice inspections) is based on its direct effect on reducing the probability of occurrence of the accident of interest (Loss of Coolant Accident) which is potentially affected by the proposed change (change to reactor coolant pressure boundary.)

- 2) Increase in the Consequences of an Accident previously evaluated in the SAR.

Again, the term "accidents" is as defined in the previous example (reference: NEI 96-07, Section 3.3). "Consequences" refers to dose (NEI 96-07, Section 3.6). A proposed change to the operating pressure of the waste gas storage system which could result in a

slight increase in the amount of radioactive gas which could be released in the event of rupture of a storage tank, could potentially be offset by requiring testing of the auxiliary building ventilation filters to a higher efficiency. The acceptability of the compensatory measure (increased filter efficiency) is based on its direct effect on reducing the consequences of the accident of interest (release of contents of waste gas storage tank to the auxiliary building) which is potentially affected by the proposed change (higher operating pressure of waste gas storage system.)

3) Increase in the Probability of Malfunction of equipment important to safety.

The accident analyses assume the proper functioning of certain equipment important to safety. Changes to equipment important to safety can occur at the system, train, or component level. Compensatory measures may be directed at assuring that the overall effect of the change is neutral at the lowest level, or at higher levels. It is suggested that the Maintenance Rule system functional level provides the appropriate upper boundary for the application of compensatory measures. For example, a proposed change which could result in a slight increase in the failure probability of an auxiliary feedwater valve in Train A of a two-train system could potentially be offset by testing that valve at an increased frequency; by compensatory measures which reduce the failure probability of other Train A components; or by compensatory measures which reduce the failure probability of Train B. The acceptability of the compensatory measure(s) is based on its direct effect on reducing the overall probability of malfunction of the auxiliary feedwater system function.

4) Increase in the consequences of a Malfunction of equipment important to safety.

Again, the term "consequences" refers to dose. As in the previous example, compensatory measures may be directed at assuring that the overall effect on dose of the proposed change is neutral, at (or below) the Maintenance Rule system functional level. For example, a proposed change which could result in a malfunction which slightly increased the valve stroke time of a containment purge isolation valve could potentially be offset by improving the detection time (by changing sensitivity and/or setpoint) of the radiation monitor which actuates the valve. The acceptability of the compensatory measure (improved detection time) is based on its direct effect on reducing the consequences (dose) from the malfunction which resulted in longer valve stroke time.

5) Reduction in the Margin of Safety as defined in the Basis of any Technical Specification.

As discussed in NEI 96-07 Section 3.8, margins of safety are associated with the results of accident analyses. A potential increase in analysis results can be compensated for by lowering a setpoint, changing initial conditions, or reallocating analysis conservatisms. If the analysis results continue to be bounded by the acceptance limit, a reduction in margin is not involved. For example, a proposed change which tended to slightly increase the results of a PWR containment pressure analysis could potentially be offset by placing administrative limits on the cooling water temperature to the Containment Fan Cooler units (CFC's), which function to limit the containment pressure in the event of an accident. The acceptability of the compensatory measure (limitation on cooling water temperature)

October 21, 1996

is based on its direct effect of limiting the result of the accident analysis of interest (containment pressure) to within the acceptance limit.

Several cautions should be emphasized in applying the above guidance. First, the "compensatory measures" referred to are NOT intended to include actions taken to compensate for degraded or nonconforming conditions over an extended period of time; but rather are those measures initiated in an integrated manner with a proposed change. Second, appropriate administrative tracking processes must be established to ensure that the compensatory measures remain in place. Finally, as with all changes made by licensees under 10CFR50.59, the proposed changes and associated compensatory measures must not require a Tech Spec change (in that case, prior NRC approval is required.)

EVALUATIONS AND ANALYSES TO BE INCLUDED IN UPDATED FSARS

DISCUSSION: 10CFR50.71(e) makes several references to analyses and evaluations in discussing the information to be included in amendments to the updated Final Safety Analysis Report (FSAR):

(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the FSAR contains the latest material developed. This submittal shall *contain all the changes necessary to reflect information and analyses* submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR or, as appropriate, the last updated FSAR. The updated FSAR shall be revised to include *the effects of*: all changes made in the facility or procedures as described in the FSAR; *all safety evaluations* performed by the licensee either in support of requested license amendments or in support of conclusions that changes did not involve an unreviewed safety question; and *all analyses of new safety issues* performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the FSAR.

(1) The licensee shall submit revisions containing updated information to the Commission, as specified in [section] 50.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement.

(2) The submittal shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since he previous submittal, necessary to *reflect information and analyses* submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 50.59 but not previously submitted to the Commission.

In a literal reading of the above section the defining phrases are "...the changes necessary to reflect...", and "...the effects of..." which in turn refer, in part, to: "...analyses submitted to the Commission...", "...all safety evaluations ... in support of requested license amendment requests or ... conclusions that changes did not involve an unreviewed safety question...", and "...all analyses of new safety issues performed ... at Commission request."

The literal meaning of the regulation does not require that the analyses or evaluations themselves be included in the FSAR. Instead, the regulations require that the effects of the analyses be included and that the FSAR be changed to reflect the analyses. A question to be discussed later is which analyses and evaluations are being referred to. The first question is to what extent must the FSAR be revised to reflect and describe the effects of these analyses and evaluations. The federal register notice (45 FR 30614 of 5/9/80) which issued this regulation offers some insight (highlights added):

SUMMARY:...These revised pages will indicate changes which have been made to reflect information and analyses submitted to the Commission or prepared as a result of Commission requirement. The amendment is being made to provide an updated reference document *to be used in recurring safety analyses performed by the licensee, the Commission, and other interested parties.*

October 21, 1996

SUPPLEMENTARY INFORMATION:...These revised pages would indicate changes made in the facility or the procedures for its operation and any analyses affected by these changes.

...No analyses other than those already prepared or submitted pursuant to NRC requirements (either originally with the application, or as part of the operating license review process, or as required by § 50.59 or other NRC requirement, or to support license amendments) are required to be performed by the licensee because of this rule. However, *analyses existing in the FSAR* which are known to be inaccurate or in error as a result of new analyses performed by the licensee pursuant to NRC requirements, *would have to be revised*. Specialized studies provided in the FSAR, such as on volcanic hazards or quality assurance, should include the latest information that has been developed in response to NRC requirements. *New analyses (i.e., analyses not previously included in FSAR) which were required during consideration of unreviewed safety questions,... technical specification changes, or other licensing questions, may be incorporated as appendices or otherwise appropriate inserted within the FSAR.*

...The level of detail to be maintained in the updated FSAR should be at least the same as originally provided.

...Furthermore, the report required under § 50.59(b) is only "a brief description of such changes, tests, and experiments, including a summary of the safety evaluation of each." The §50.59(b) reporting may not be detailed sufficiently to be considered adequate to fulfill the FSAR updating requirement. *The degree of detail required for updating the FSAR will be generally greater than a "brief description" and a "summary of the safety evaluation."* However, there is nothing that precludes submitting the § 50.59(b) along with § 50.71(a). Parts of the FSAR submittal may be referenced by the § 50.59(b) report.

...The rule is only a reporting requirement to insure that an updated FSAR will be available. ...Thus, for example, approvals of license amendments and technical specification changes are independent of the FSAR updating process and once approved would not be subject to further consideration simply because the FSAR is updated.

Again, certain portions of this federal register notice are key in understanding how the FSAR should be updated to reflect the analyses and evaluations of concern. One key thought is that "[t]he level of detail ... in the updated FSAR should be at least the same as originally provided." This implies there was no intent to force licensees to describe new analyses or evaluations in greater detail than the original FSAR. This intent should apply to both the level to which an analysis or evaluation is described and whether a specific analysis needs be described at all. There are certainly evaluations performed to support "no significant hazards" determinations which have no impact on the existing FSAR descriptions and analyses and are a level of detail greater than the FSAR. In such cases, the regulation and the federal register notice support the conclusion that such an evaluation would not require a change to the FSAR (or in other words, the existing FSAR adequately describes the effects of the evaluation and adequately reflects the evaluation to the level of detail required in the FSAR).

The regulation does not give much detail on how to change the FSAR but the federal register notice provides some guidance. Specifically the notice states that changes which describe the effects of evaluations or analyses or which reflect evaluations or analyses "... may be incorporated as appendices or otherwise appropriately inserted within the FSAR." In other words, the existing

October 21, 1996

text, tables or figures in the FSAR may be revised or appendices may be added. In either case, as discussed above, the level of detail is not expected to necessarily be any greater than the original FSAR. The general expectation is that the changes will be incorporated in the existing text, tables or figures as this is probably the easiest and cleanest way to make the change and ensure that all the needed corrections are made. There may be some cases in which the subject of the evaluation or analysis is not addressed in the FSAR but is of a level of detail commensurate with the FSAR. In such cases, a licensee could revise the FSAR to reflect the evaluation or analysis by adding an appendix in an appropriate location.

The scope of analyses and evaluations to be considered in the updating of the FSAR are discussed in the regulation and federal register notice. The regulation states:

“...all safety evaluations ... in support of requested license amendment requests or ... conclusions that changes did not involve an unreviewed safety question; and all analyses of new safety issues performed ... at Commission request.”

The federal register notice also states:

“... analyses submitted to the Commission or prepared as a result of Commission requirement...”

“... changes made in the facility or the procedures for its operation and any analyses affected by these changes...”

“... analyses existing in the FSAR which are known to be inaccurate or in error as a result of new analyses performed by the licensee pursuant to NRC requirements...”

“... Specialized studies provided in the FSAR, such as on volcanic hazards or quality assurance, should include the latest information that has been developed in response to NRC requirements...”

“... New analyses (i.e., analyses not previously included in FSAR) which were required during consideration of unreviewed safety questions...”

“... New analyses (i.e., analyses not previously included in FSAR) which were required during consideration of... technical specification changes...” and

“... New analyses (i.e., analyses not previously included in FSAR) which were required during consideration of ... other licensing questions...”

It appears clear that all evaluations and analyses which are reflected in the FSAR must be updated to be correct (per the guidance on timing for the updates which is not specifically addressed in this paper). Any plant activity, including physical changes, procedural changes, tests or experiments, and the analyses and evaluations that go along with these activities, must be considered in making these corrections. Similarly, analyses and evaluations prepared for the NRC, such as NOV responses, license amendment requests, and generic letter or bulletin responses, must be considered for correcting the FSAR.

A more difficult task is determining which analyses and evaluations do not change existing descriptions in the FSAR but are required to be added to the FSAR because they can be summarized in a level of detail commensurate with the original FSAR and are consistent with the

October 21, 1996

scope of the original FSAR. Assessing the level of detail of a summary description which reflects the evaluation and analyses, and determining if it falls within the FSAR's scope is not a clear cut task and requires a degree of judgment.

An acceptable approach for dealing with some analyses and evaluations might best be explained through some examples.

EXAMPLE 1:

A licensee needs to perform maintenance and desires to install a temporary structure to provide shielding to reduce the radiation dose received by the workers. An evaluation is performed to confirm that this temporary structure will not have an adverse effect on any of the safety equipment in the vicinity. The structure will not be described in the FSAR because it is temporary and will be removed after a short period of time. The evaluation shows that all the acceptance criteria in the FSAR continue to be met. The discussion in the FSAR concerning the potential interaction of non-safety equipment and safety equipment remains valid. This change and the associated analysis will not require a revision to the FSAR.

EXAMPLE 2:

A licensee proposes a license amendment to change a setpoint in the Technical Specifications. The actual setpoint is not provided in the existing FSAR. The analysis and evaluation provide in the license amendment request conclude that all existing acceptance criteria continue to be met. The descriptions and analyses in the FSAR remain correct. This change and the associated analysis will not require a revision to the FSAR.

EXAMPLE 3:

In a generic letter, the NRC asks a group of licensees to assess the impact of a new technical development on the decommissioning costs of plants. A licensee performs the analysis and submits a response to the NRC. This analysis is not within the scope of the FSAR. This analysis will not require a revision to the FSAR.

SUMMARY:

Licensee perform many analyses and evaluations to support the continued operation of their units. Per 10 CFR 50.71(e) the FSAR must be corrected on a periodic basis including the corrections necessary to reflect these analyses and evaluations to the extent that the analyses and evaluations are within the scope of the FSAR and consistent with the level of detail of the original FSAR. The federal register notice that issued the regulation does state that some information such as minor differences between actual and projected population figures need not be reported unless the conclusions of safety analyses relative to public health and safety are affected and the licensee has prepared new analyses as a result of NRC requirements.