

NRC INSPECTION MANUAL

OTSB

INSPECTION PROCEDURE 37001

10 CFR 50.59 SAFETY EVALUATION PROGRAM

PROGRAM APPLICABILITY: 2515

SALP FUNCTIONAL AREA: ENGINEERING (ENG)

37001-01 INSPECTION OBJECTIVE

Ascertain whether the licensee is implementing a safety evaluation program that conforms to Title 10 of the Code of Federal Regulations, Section 50.59, 10 CFR 50.59, "Changes, Tests and Experiments" (CTEs).

37001-02 INSPECTION REQUIREMENTS

The primary focus of this inspection procedure is the licensee's performance implementing the requirements of Section 50.59. The principal measure of this performance is the quality of the safety evaluations prepared by the licensee in accordance with Section 50.59. NRC expects each Section 50.59 safety evaluation to address all safety issues pertinent to the associated CTE. When reviewing Section 50.59 safety evaluations in the performance of Section 02.03 of this procedure, the inspector should, as a minimum, determine whether the licensee resolved safety issues pertinent to the associated CTEs. A secondary focus of this inspection procedure is a programmatic review of the licensee's Section 50.59 procedures and training. The inspector should complete this programmatic review in accordance with the inspection requirements of Sections 02.01 and 02.02 as needed to support the completion of the performance-oriented inspection requirements of Section 02.03 of this procedure.

02.01 Procedures and Controls

- a. Verify that formal procedural guidance has been established for:
 1. Implementing the requirements of Section 50.59 for proposed changes, tests and experiments (CTEs). This should include guidance for --
 - (a) Assessing and documenting whether Section 50.59 applies (i.e., whether a Section 50.59 safety

evaluation to determine if the CTE involves an unreviewed safety question is required);

- (b) Assessing and documenting whether a change to the plant technical specifications or an unreviewed safety question is involved;

- (c) Maintaining records of CTEs made in accordance with Section 50.59 as required by 10 CFR 50.59(b)(1) and (3); and
 - (d) Formally reporting to the NRC the CTEs made in accordance with Section 50.59 as required by 10 CFR 50.59(b)(2).
- 2. Updating the Final Safety Analysis Report (FSAR) as required by Section 50.71(e) to describe the effects of (1) all changes made in the facility or procedures as described in the FSAR; and (2) all Section 50.59 safety evaluations in support of conclusions that changes did not involve unreviewed safety questions.
- b. Verify that the preceding guidance in Section 02.01.a.1 of this procedure assigns responsibility for:
 - 1. Evaluating all CTEs for Section 50.59 applicability;
 - 2. Preparing Section 50.59 safety evaluations for CTEs that require them;
 - 3. Reviewing and approving Section 50.59 safety evaluations as required by the technical specifications and the NRC-approved operational quality assurance program (Requirements for independent reviews and approvals are licensee-specific.);
 - 4. Reviewing and approving Section 50.59 applicability determinations;
 - 5. Formally reporting to the NRC CTEs made in accordance with Section 50.59 as required by 10 CFR 50.59(b)(2);
 - 6. Maintaining records of CTEs made in accordance with Section 50.59 as required by 10 CFR 50.59(b)(3); and
 - 7. Preparing and submitting the periodic update of the FSAR as required by 10 CFR 50.71(e).
- c. Verify that the licensee's formal procedural guidance for implementing its safety evaluation program conforms to Section 50.59 requirements.
- d. Verify that the licensee has established measures to ensure that design information necessary for preparing adequate Section 50.59 safety evaluations is available to licensee personnel that prepare Section 50.59 safety evaluations.

02.02 Training and Qualifications

- a. Verify that the licensee's training and qualification requirements are consistent with the licensee's commitments established in the NRC-approved operational quality assurance program including, as applicable, training and qualification

requirements for licensee personnel that prepare, review, or approve Section 50.59 safety evaluations and applicability determinations, and for personnel that conduct Section 50.59 training.

- b. Verify that training materials are consistent with the licensee's current procedural guidance for preparing Section 50.59 safety evaluations and making Section 50.59 applicability determinations.
- c. Determine whether the licensee has established a process for assessing training effectiveness.

02.03 Implementation

a. Section 50.59 Safety Evaluations. Select examples of Section 50.59 safety evaluations from the categories listed below.

1. Changes in the facility as described in the safety analysis report. As a rule of thumb, the number of Section 50.59 safety evaluations for facility modifications that the inspector should review is about 5 percent of the number of facility modifications the licensee last reported to the NRC as required by 10 CFR 50.59(b)(2). Focus on significant modifications implemented since the last NRC inspection of the licensee's Section 50.59 program, but also select approved modifications that are awaiting implementation. Other considerations for selecting Section 50.59 safety evaluations for facility modifications are the following:

- (a) Choose safety evaluations for changes to a variety of systems.
- (b) Choose safety evaluations involving a variety of engineering disciplines, such as nuclear, mechanical, civil, and electrical.
- (c) Choose safety evaluations for de facto design changes previously undiscovered deviations from the FSAR description of plant design that are purposely left uncorrected, either permanently or temporarily, during plant operation.
- (d) Choose safety evaluations for partially completed modifications.
- (e) Choose safety evaluations for temporary modifications. Included are original safety evaluations for maintenance and surveillance procedures that govern the periodic implementation of temporary modifications.
- (f) Choose safety evaluations for facility modifications being implemented during the inspection.

2. Changes in procedures as described in the safety analysis

report. As a rule of thumb, the number of Section 50.59 safety evaluations for procedure changes that the inspector should review is about 5 percent of the number of procedure changes the licensee last reported to the NRC as required by 10 CFR 50.59(b)(2). Focus on significant changes to procedures implemented since the last NRC inspection of the licensee's Section 50.59 program, but also select approved procedure changes awaiting implementation. Choose a variety of safety evaluations for changes in procedure from categories such as operations, engineering, maintenance, emergency operations, physics startup tests, surveillance tests, administrative controls, and health physics.

3. Tests or experiments not described in the safety analysis report. Focus on Section 50.59 safety evaluations for tests performed since the last NRC inspection of the licensee's test and experiments program (or equivalently, the licensee's Section 50.59 program), but also review approved safety evaluations of tests planned for the future. Since tests requiring a Section 50.59 safety evaluation occur infrequently, most, if not all, of the Section 50.59 safety evaluations for tests prepared since the last NRC inspection of the test and experiments program can usually be reviewed during the inspection.
- b. Section 50.59 Applicability Determinations. Review CTEs for which the licensee determined safety evaluations in accordance with Section 50.59 were not required. Choose the number and variety of such CTEs to review using the directions in paragraph 02.03.a of this procedure, as appropriate. Verify that the applicability determinations for these CTEs were made by conforming to the procedures and controls established in 02.01 of this procedure.
- c. Plant Onsite Review Committee (PORC). If the PORC plans to meet during the time the onsite part of the inspection is scheduled and plans to review and approve Section 50.59 safety evaluations and applicability determinations, then the inspector should try to attend the meeting and, by direct observation, verify that the PORC adequately performs the review and approval requirements of the licensee's Section 50.59 program established in 02.01 of this procedure.
- d. Updating the FSAR and reporting CTEs in accordance with Section 50.59(b)(2). Verify that the licensee is updating its FSAR by conforming with the formal requirements established in 02.01.a.2 and 02.01.b.7 of this procedure. Select about 5 changes in the facility and procedures made in accordance with Section 50.59 that were implemented in time to have been considered for inclusion in the most recent FSAR update submitted to the NRC. Verify that the Section 50.59 report includes these changes and that the updated FSAR accurately describes the effects of these changes and the associated Section 50.59 safety evaluations.

02.04 Use of risk insights. Consider risk significance as one |

input in the selection of a sample of inspection items.

37001-03 INSPECTION GUIDANCE

General Guidance

This procedure is intended to guide inspectors in evaluating licensee compliance with the requirements of Section 50.59. The procedure consists of three parts: procedures and controls, training and qualifications, and implementation. The first two parts are recommended to be done for the initial performance of this inspection procedure and every third SALP (systematic assessment of licensee performance) cycle thereafter. The third part, implementation, is recommended to be done each SALP cycle. Completion of the entire inspection procedure is also recommended whenever significant implementation problems are identified or the licensee has made significant changes in its Section 50.59 program.

It is intended that the facility's NRR project manager and another inspector (either from NRR or the region, possibly the facility's resident inspector) will participate in the inspection. Additional NRR, regional, and contractor technical assistance may be utilized if the CTEs to be inspected will require special expertise to ensure an effective review. The entire inspection procedure should normally take 4 to 5 days onsite to complete. Reviewing the licensee's Section 50.59 safety evaluation program procedures in the office will allow more time for implementation review while onsite. Choose the initial selection of Section 50.59 safety evaluations to be reviewed onsite in the office, using licensee-supplied lists of proposed and completed design changes and tests or experiments, and the annual report of changes made under Section 50.59. The week before the inspection inform the licensee which Section 50.59 safety evaluations have been selected for possible review so no time is lost the first day at the site waiting for the licensee to produce the necessary documentation.

The results of this inspection activity can be documented in the resident inspector's periodic inspection report, a regional inspection report, or an NRR-generated inspection report, depending upon the scope and depth of the inspection. If the inspection is performed by an NRR project manager, the inspection results will be a feeder report to either resident inspector or a regional based inspector. While onsite, brief the Senior Resident Inspector (SRI) daily on the progress of the inspection. Promptly discuss significant findings and concerns with the SRI, the regional section chief, and the NRR project director. As with any NRC inspection, hold an entrance meeting and an exit meeting with licensee management.

Guidance for inspecting Section 50.59 implementation has been included in the inspection program, in various inspection procedures, and in the guidance section of the NRC Inspection Manual but has never been the principal focus of any one inspection procedure. By providing that focus, this procedure emphasizes the importance of the requirements in Section 50.59 to safety and

promotes more consistent and effective NRC inspections of Section 50.59 implementation. The inspector should, however, be familiar with previous Section 50.59 guidance provided by the inspection manual because only part of it has been incorporated into this inspection procedure. The locations of this guidance is described below. Familiarity with the guidance pertaining to the facility modification process provided in these procedures may also be useful to the inspector, because inspecting Section 50.59 safety evaluations often involves reviewing design change documentation.

37700 Design, Design Changes, and Modifications; Issue Date: 08/29/88.

Item 02.01, paragraphs b, h, j, and k.
Item 02.02, paragraph a.
Item 03.01.
Item 03.02, paragraphs a, b, g, and h.

37702 Design Changes and Modifications Program; Issue Date: 12/04/87.

Item 02.01, paragraphs a.3, b.3, c, f, g, and k.
Item 02.02, paragraph a.
Item 03.01.
Item 03.02, paragraphs a, c.2, g, h, j, l, m, and n.

37703 Tests and Experiments Program; Issue Date: 06/10/85.

Item 02.01, paragraphs f and g.
Item 02.02.
Item 03.02, paragraphs c, d, e, and f.

42700 Plant Procedures; Issue Date: 06/25/84.

Item 02.03.
Item 02.04.
Item 03.02, paragraphs c, d, and j.

60710 Refueling Activities; Issue Date: 08/23/85.

Item 02.01, paragraph b.
Item 03.02, paragraph b.

Part 9900, CFR Discussions, 10 CFR 50.59, Changes to Facilities, Procedures and Tests (or Experiments); Issue Date: 01/01/84.

Note: Should any of these guidance documents be revised, the description of the location of the Section 50.59 related guidance within each document may no longer be accurate.

Specific Guidance

03.01 Procedures and Controls

a. The inspector should verify that the licensee has approved

procedures that include guidance for conducting the activities stated in 02.01.a of this procedure. Procedures for controlling activities affecting quality are required by Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, the NRC-approved operational quality assurance program, and the administrative controls section of the technical specifications. As part of the process for design control (Criterion III, "Design Control," of Appendix B to 10 CFR Part 50), the implementation of Section 50.59 requirements is an activity affecting quality.

1. Although the licensee should have a controlled process for implementing the requirements of Section 50.59, this process may not be confined to a single procedure or document. To satisfy inspection requirement 02.01.a.1, the inspector must, therefore, identify which procedures define the licensee's Section 50.59 implementation process. To do this, review and become familiar with as many of the following licensee procedures, guidance documents, and NRC requirements as needed for understanding how the licensee complies with Section 50.59:

(a) Section 50.59 implementation program procedure;

(b) Guidance for preparing Section 50.59 safety evaluations;

This should include controls for coordinating the preparation of Section 50.59 safety evaluations for design changes involving multiple engineering disciplines or diverse parts of the licensee's organization. Coordination of design activities is a requirement of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, and is usually included as a requirement of the licensee's NRC-approved operational quality assurance program.

For significant design changes that affect several plant systems, an integrated safety evaluation should be performed in addition to discipline specific safety evaluations to ensure a comprehensive review of the change against the design objectives of the affected system is conducted.

(c) Guidance for making Section 50.59 applicability determinations;

(d) Guidance for answering the questions in Section 50.59(a)(2) that define an unreviewed safety question;

(e) Procedures for making facility modifications;

(f) Procedures for making temporary facility

modifications;

- (g) The NRC-approved operational quality assurance program;
 - (h) Administrative controls section of the technical specifications;
 - (i) Procedures for preparing FSAR updates required by Section 50.71(e) and the Section 50.59(b)(2) report to the NRC;
 - (j) Procedures for making changes to procedures;
 - (k) Procedures for implementing PORC's review and approval requirements given by the technical specifications;
 - (l) Procedures for preparing and conducting tests (or experiments) not described in the safety analysis report; and
 - (m) Procedures for document control (procedures, design documents, etc.).
2. To satisfy inspection requirement 02.01.a.2 of this procedure, the inspector must identify the approved procedures that define the licensee's process for updating the FSAR with descriptions of the effects of changes in the facility and procedures as described in the FSAR made without NRC approval in accordance with Section 50.59.

Although Section 50.71(e) also requires updates describing the effects of changes made in accordance with Section 50.92 license amendments and analyses of new safety issues (performed by or on behalf of the licensee at Commission request), the focus of inspection requirement 02.01.a.2 is on changes made in accordance with Section 50.59. However, the inspector should verify that the licensee's process for updating the FSAR includes the scope of information required by Section 50.71(e).

- b. To satisfy inspection requirement 02.01.b of this procedure, the inspector should verify that the licensee's procedures (identified in 02.01.a of this procedure) for implementing Sections 50.59 and 50.71(e) clearly designate, by position title, the individuals in the licensee's organization responsible for the accomplishment of the activities listed in 02.01.b.1-7.

The individual responsible for the final approval of Section 50.59 safety evaluations is usually designated by title in the administrative controls section of the technical specifications (e.g., the Chairman of the PORC).

c. To satisfy inspection requirement 02.01.c of this procedure, the inspector should compare the licensee's procedures for implementing Section 50.59 to the guidance provided here for each of the four principal requirements of Section 50.59: reviewing all CTEs for applicability; evaluating applicable CTEs for involvement of unreviewed safety questions; documentation and record keeping; and reporting.

1. Section 50.59 applicability determination guidance. All CTEs must be evaluated (or screened) for Section 50.59 applicability. In this inspection procedure, this evaluation is referred to as the "Section 50.59 applicability determination."

(a) Changes in the facility or procedures. The criterion for requiring a Section 50.59 safety evaluation for a change in the facility (or procedure) is "a change in the facility or procedures as described in the safety analysis report." This criterion means that a change in a structure, system, or component (SSC) or a procedure requires a Section 50.59 safety evaluation only if the following statements are both true:

(1) The SSC (or procedure) being changed is described in the most recently updated FSAR submitted to the NRC in accordance with Section 50.71(e).

(2) The FSAR description of the SSC (or procedure) being changed would be affected by the change.

Even when this applicability (or screening) criterion is satisfied, a Section 50.59 safety evaluation would not be required if the change in the facility (or procedure) as described in the FSAR would involve a change in the technical specifications. The inspector should verify that the licensee's screening process requires a determination of the effect of facility (or procedure) changes on the technical specifications. If a technical specification change is involved, the licensee must obtain an operating license amendment, in accordance with Section 50.92, before implementing the proposed facility (or procedure) change. Note that the licensee should always determine the effect of a change in a SSC (or procedure) on the technical specifications regardless of whether the change satisfies the Section 50.59 applicability criterion.

The FSAR description of a SSC or procedure must be affected by the change in order for a Section 50.59 safety evaluation to be required. For example, changing a procedure just listed in the updated FSAR would not require a Section 50.59 safety evaluation.

However, a temporary change to a SSC that would affect its FSAR description must be evaluated in accordance with Section 50.59, even though the change in the FSAR description would not be permanent.

SSCs (or procedures) that are described in the FSAR but are not safety-related should not be excluded from evaluation in accordance with Section 50.59 just because they are not safety-related. If the Section 50.59 applicability criterion is satisfied and the technical specifications are not affected, then a Section 50.59 safety evaluation is required.

Temporary modifications (e.g., jumpers and lifted leads) of SSCs that are described in the FSAR that are routinely implemented by periodic maintenance or surveillance procedures do not need to be evaluated in accordance with Section 50.59 each time the procedure is performed. The original Section 50.59 safety evaluation for the procedure should remain valid as long as the precautions and limitations of the procedure are observed.

An unintended deviation from the design of a SSC as described in the FSAR, whether in existence since initial licensing, or as the result of an error in a subsequent modification, installation, or maintenance activity, is considered a de facto design change to the facility. Plant operation with a de facto design change must be evaluated pursuant to Section 50.59 to determine whether the change involves an unreviewed safety question or a change in the technical specifications. Facilities undergoing design basis reconstitution have frequently identified de facto design changes.

Removing equipment from service (making it inoperable) for maintenance for the technical specification (TS) allowed outage time does not require a Section 50.59 safety evaluation. However, if the plant's safety analysis as described in the FSAR depends on the functioning of non-TS equipment, then removing that equipment from service (i.e., disabling its function) for maintenance during plant operation should be evaluated in accordance with Section 50.59 for involvement of an unreviewed safety question.

If an SSC to be added to the facility would affect the FSAR description of another SSC, then a Section 50.59 safety evaluation of the indirect change to the FSAR-described SSC must be done. A description of the new SSC must be included in the next FSAR update.

- (b) Tests or experiments. The criterion for requiring a Section 50.59 safety evaluation for the conduct of a test (or experiment) is that the test not be described in the most recently updated FSAR submitted to the NRC in accordance with Section 50.71(e). However, if conduct of the test would involve a change in the technical specifications, the Section 50.59 safety evaluation would not be required.

If a test described in the SAR will be done in a different way, then a Section 50.59 safety evaluation is required.

Additional guidance related to the applicability of Section 50.59 to changes in the facility (or procedures) as described in the FSAR and the conduct of tests (or experiments) not described in the FSAR is provided in Part 9900, CFR Discussions, "10 CFR 50.59, Changes to Facilities, Procedures and Tests (or Experiments)."

2. Unreviewed safety question evaluation guidance. In this inspection procedure, the evaluation of applicable CTEs for involvement of unreviewed safety questions is referred to as the "Section 50.59 safety evaluation."

The inspector should verify that the licensee's guidance for preparing Section 50.59 safety evaluations requires answering the three questions for determining if an applicable CTE involves an unreviewed safety question (USQ) given by 10 CFR 50.59(a)(2). An USQ is involved if any of the three questions can be answered yes.

Note that the Section 50.59 safety evaluation is only one of several evaluations and reviews the NRC requires. Most technical specifications require that the PORC review all proposed procedures and modifications or changes to SSCs affecting safety. These review requirements are applicable whether or not the SSC is described in the FSAR. Also note that preparation of an adequate Section 50.59 safety evaluation often requires looking at licensing and design information not included in the FSAR. Important sources of such information are NRC safety evaluation reports, docketed correspondence, and records of safety and transient analyses.

Because precise meanings of the USQ criteria are not provided in Section 50.59, the thresholds for USQ involvement will be interpreted differently from licensee to licensee. The inspector must review the licensee's guidance for interpreting the USQ criteria and decide if it satisfies the intent of Section 50.59, which is to limit CTEs not requiring prior NRC approval to those that do not exceed the bounds of the licensing and design basis of the facility as described in the FSAR.

If concerns regarding the adequacy of the licensee's

guidance for interpreting the USQ criteria are identified, the inspector should first discuss them with the SRI. If a concern remains unresolved, it should then be referred to the appropriate manager at the region or NRR. An important measure of the adequacy of a licensee's guidance for addressing the USQ criteria is whether the licensee's Section 50.59 safety evaluations consistently reach the correct conclusions and are appropriately documented. (Guidance on what constitutes appropriate documentation required by Section 50.59 is discussed in 03.01.c.3. of this procedure.)

3. Documentation guidance. Section 50.59(b)(1) requires licensees to maintain records of CTEs made in accordance with Section 50.59 without prior NRC approval. It also requires that these records include a written safety evaluation that provides the bases for the determination that the CTE does not involve an USQ (i.e. the Section 50.59 safety evaluation).

Section 50.59 safety evaluations must be in writing and include the bases for the determination that the CTE did not involve an USQ. The NRC does not consider a checklist to be sufficient to meet the requirement for a written safety evaluation. However, depending

upon the significance of the change, the Section 50.59 safety evaluation may be quite brief.

Although Section 50.59 does not specifically require that Section 50.59 applicability determinations be documented with written bases for the determination that a Section 50.59 safety evaluation was not required, the licensee should maintain a record of these determinations in accordance with its NRC-approved operational quality assurance program. This record is needed because determining whether Section 50.59 applies to a CTE is an activity affecting quality covered by Criterion V of Appendix B to 10 CFR Part 50. As part of the process for design control (Criterion III, Design Control, of Appendix B to 10 CFR Part 50), the implementation of Section 50.59 requirements is an activity affecting quality.

Section 50.59(b)(3) requires that records of changes in the facility be maintained until the date of termination of the license and that records of changes in procedures and records of tests and experiments be maintained for a period of 5 years. No distinction is made by this requirement between changes made with or without prior NRC approval or between changes that did or did not require a Section 50.59 safety evaluation. The administrative controls section of the technical specifications for most plants contains additional requirements for record keeping.

4. Reporting guidance. Section 50.59(b)(2) requires

that the licensee submit a report containing a brief description of each CTE, including a summary of its supporting safety evaluation, implemented without prior NRC approval in accordance with Section 50.59. It states that the report may be submitted annually or along with FSAR updates as required by Section 50.71(e), or at such shorter intervals as specified in the license.

- d. Inspection requirement 02.01.d of this procedure (to verify that design information is available) is based on requirements in the licensee's NRC-approved operational quality assurance program and Criterion III, Design Control, of Appendix B to 10 CFR Part 50. Having necessary information available assures that Section 50.59 safety evaluations will be based on a consideration of all relevant design information.

03.02 Training and Qualifications

- a. Most NRC approved operational quality assurance programs contain a commitment to establish a training program based on an industry standard such as ANSI/ANS 3.1-1978 or N18.1-1971, "American National Standard for Selection and Training of Nuclear Power Plant Personnel." To satisfy inspection requirement 02.02.a of this procedure, determine what the licensee is committed to, and then review the licensee's training program for consistency with that commitment. Adherence to the NRC-approved operational quality assurance program is a condition of the operating license. Failure to satisfy the quality assurance program would therefore constitute a violation of the operating license.

Interview one of the licensee's Section 50.59 training program instructors for general information regarding the program. Focus on refresher training and how additional training needs are identified.

Determine if a feedback process is used for identifying training weaknesses and discuss how identified weaknesses are resolved.

- b. To satisfy inspection requirement 02.02.b of this procedure, review the licensee's lesson plans, training materials, tests, etc., and determine whether they are consistent with the licensee's current controls, procedures, and guidance for preparing Section 50.59 applicability determinations and safety evaluations.
- c. Although a feedback process is not a specific requirement of the regulations, the auditing of the licensee's training program, in general, is usually included in the licensee's NRC-approved operational quality assurance program (through a commitment to an industry standard such as ANS-3.2 or ANSI N18.7). If a recent training program audit report is available, the inspector should consider reviewing it.

03.03 Implementation. The implementation area of the inspection assesses the licensee's performance implementing its Section 50.59 safety evaluation program and the effectiveness of its Section 50.59 training. Section 50.59 safety evaluations can involve all technical disciplines associated with a nuclear plant. Few inspectors are expert in every nuclear-related discipline. Therefore, the inspector should recognize when technical assistance is needed to effectively review a safety evaluation or resolve a safety concern. The need for assistance can be anticipated based on the safety evaluations selected for review. But, also acceptable is simply identifying and documenting (in the inspection report) technical concerns for follow-up at a later date (either by the region or NRR). Make every effort, however, to reach a conclusion about a safety issue or concern in time to discuss it with the licensee at the exit meeting. Recognizing failures of the licensee to comply with the administrative control requirements of its plant modification program, including the requirements of Section 50.59, is important. However, recognizing failures of the licensee to adequately assess how a change will affect plant operational safety is more important. Without regard to 10 CFR 50.59, the licensee must ensure that plant modifications do not compromise safety. The safety evaluation serves as a check on the scope of the engineering safety analysis that should accompany any design change to the plant. Usually the safety evaluation is integral to and relies heavily on the engineering safety analysis because the three questions (10 CFR 50.59 (a)(2)) that define an unreviewed safety question are fundamental to safety analysis.

The focus of the implementation part of the inspection should, therefore, be on safety. Compliance with the administrative aspects of Section 50.59 should be enforced; but let the safety significance of administrative deficiencies guide the level of concern expressed to the licensee. For example, if you agree that a CTE was safe and believe it would not involve an unreviewed safety question (based on your review of the documented engineering analysis in the design change package), failure to prepare a Section 50.59 safety evaluation would not be a significant concern, unless errors in screening were a frequent occurrence or the failure was caused by inadequate guidance in the licensee's procedures. By contrast, a Section 50.59 safety evaluation that failed to address an obvious safety consideration, such as identifying all the relevant accident and transient scenarios, would be more significant. Failure to recognize that a CTE involved a change to the technical specifications would also be significant.

- a. Section 50.59 Safety Evaluations. To satisfy inspection requirements 02.03.a.1,2 and 3 of this procedure, review each selected safety evaluation against the requirements and guidance established in the licensee's procedures, if these procedures were found adequate, and the guidance in the following items 1 through 6. The licensee is required by Criterion V of Appendix B to 10 CFR Part 50 and its NRC approved operational quality assurance program to follow its own procedural guidance for activities covered by Appendix B.

1. Each safety evaluation should consider the following:
 - o the unreviewed safety question criteria;
 - o systems and components affected by the change (What is the effect of the change on their capability to perform their specified or intended functions?);
 - o parameters of the accident analysis affected by the change (Are all the relevant design basis accidents and transients identified?); and
 - o potential effects of system or component failure (i.e., the question, "what would happen if..." is explored and answered in the safety evaluation).

2. Each safety evaluation should be documented in accordance with the licensee's procedural requirements. As a minimum, the documentation should be sufficiently detailed with the conclusions logically supported so that independent review by persons designated in the licensee's procedures is possible without extensive reference to other documents and consultation with the preparer. The documentation should identify the scope of the review (what documents were looked at), responses to the items noted in 03.03.a.1 of this procedure, and any assumptions, engineering analysis or judgement, etc., that were used. In cases where the safety evaluation relies on the associated engineering safety analysis, the inspector should review that analysis and other relevant documents in the associated design change package.

The documentation of safety evaluations for temporary modifications should meet the same criteria regarding reviewability as for permanent changes. Scope of the safety evaluation for a temporary modification is a likely weak spot. Additional guidance on temporary modifications (in particular, jumpers and lifted leads) is provided by item 03.02.m of Inspection Procedure 37702, item 03.02.h of Inspection Procedure 37700, and Part 9900. Summaries of safety evaluations for temporary modifications should be included in the periodic report to the NRC in accordance with Section 50.59(b)(2).

The inspector should verify the validity of the original safety evaluations (selected as required by 02.03.a.1.(e) of this procedure) for maintenance and surveillance procedures that govern the periodic implementation of temporary modifications.

3. For changes not yet implemented, verify that the process for updating the safety evaluation, because of other changes that are being planned or implemented, is being applied to the change. Application of this process should be reflected in the documentation. See Inspection Procedure 37700 for additional guidance.

4. For changes being implemented, verify that field changes include a review of the safety evaluation to ensure that it remains valid. Verify that the process of implementation has not created an unreviewed safety question or that the licensee has taken appropriate action (e.g., by implementing a temporary modification or administrative control) to ensure that an unreviewed safety question is not involved .
5. For design changes that are partially completed, either by plan (e.g., hardware installed during one outage, but electrical hookup is not scheduled until the following outage) or unforeseen circumstances, verify that the licensee has reviewed the partially completed status to determine whether a safety evaluation in accordance with Section 50.59 is required or a change in the technical specifications is involved. Also verify that the licensee's control of the integration of the modification into interfacing systems includes positive control of system boundaries; full consideration of the effects of partial completion of the modification; and appropriate revisions to procedures.
6. For tests and experiments not previously described in the safety analysis report, focus on the adequacy of the prerequisite plant conditions for conducting the test. Verify that the scope of the safety evaluation is adequate. Sometimes a safety evaluation is done to change the acceptance criteria of an FSAR-described test. Try to review such a safety evaluation, if available, and especially if the change was made after the test was performed. Detailed guidance on safety evaluations of tests and experiments is provided by Inspection Procedure 37703, "Tests and Experiments Program."

Performing inspection requirement 02.03.a.3 of this procedure (using inspection guidance 03.03.a.6 of this procedure and Inspection Procedure 37703) as a regional initiative should also be considered whenever the licensee plans to conduct a significant test not previously described in the FSAR.

- b. Section 50.59 Applicability Determinations. To satisfy inspection requirement 02.03.b of this procedure, the inspector should review each negative applicability determination selected to verify that:
 - o The associated CTE does not meet the applicability criteria of Section 50.59(a)(1); and
 - o Its documentation conforms to the licensee's procedural guidance and logically supports the conclusion that a safety evaluation is not required.

Some licensees have developed additional screening criteria that are more detailed than the applicability criteria in Section 50.59(a)(1). Such screening criteria must not

conflict with Section 50.59(a)(1), but may be more stringent.

- c. Plant Onsite Review Committee. No inspection guidance.
- d. Updating the FSAR and reporting CTEs in accordance with Section 50.59(b)(2). To satisfy inspection requirement 02.03.d of this

procedure, the inspector should select 5 CTEs as described in 02.03.d, and for each CTE:

- o Compare the summary of the safety evaluation in the licensee's most recent Section 50.59(b)(2) report to the corresponding safety evaluation; and
- o Compare the associated safety evaluation and safety-evaluation summary in the Section 50.59(b)(2) report to the corresponding FSAR update for consistency, completeness, and accuracy.

The inspector should also verify the completeness of the Section 50.59(b)(2) report by comparing it to the licensee's list of CTEs implemented during the period covered by the report.

03.04 Use of risk insights. The inspector should refer to IMC 2515 Appendix C for guidance on the use of PRA insights to help in the selection and prioritization of items to inspect. If necessary, contact NRC PRA specialists (e.g., Senior Reactor Analysts or the NRR Probabilistic Safety Assessment Branch) for assistance.

37001-04 RESOURCE ESTIMATE

The initial completion of this procedure is estimated to require at least 60 onsite inspection hours by the inspector (usually an NRR project manager) and one additional inspector, preceded by approximately 8 hours in the office spent reviewing licensee procedures to prepare for the onsite inspection. Subsequent performance of Section 02.03 of this procedure is estimated to require at least 32 onsite inspection hours by the project manager each SALP cycle, but may require an additional inspector for reasons discussed at the beginning of Section 03 of this procedure.

END