

NRC INSPECTION MANUAL

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PART 9900 10 CFR GUIDANCE

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10 CFR 50.59 CHANGES, TESTS AND EXPERIMENTS

A. PURPOSE

The purpose of this guidance is to clarify the specific 10 CFR 50.59 language relating to the type of proposed changes, tests and experiments (CTE) that require a record of the evaluation specified in Paragraph 50.59(d)(1). The guidance also clarifies the specific review criteria which must be used to identify whether a proposed change, test or experiment requires prior NRC approval. This Part supersedes previous Part 9900 guidance on 10 CFR 50.59.

B. BACKGROUND

This revision to this CFR Discussion is a result of a rulemaking that revised Section 50.59 in its entirety. The rulemaking was conducted in order to clarify requirements and to provide some limited flexibility beyond that provided by the previous version of the rule for licensee changes without prior NRC approval. The rulemaking was issued in final form on October 4, 1999. Licensees are to implement the revised requirements 90 days following publication of final regulatory guidance. See additional guidance on the transition to the revised rule contained in Regulatory Issue Summary (RIS) 2001-03, January 23, 2001 on "Changes, Tests, and Experiments."

Most licensees use implementation guidance that is based upon an industry guidance document NEI 96-07 (Revision 1, dated November, 2000). The NRC has endorsed this document in Regulatory Guide RG-1.187.

Other references of interest are:

Regulatory Guide 1.182 "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants" (May 2000)

Part 9900 "Guidance on Resolution of Degraded or Nonconforming Conditions" (GL 91-18, Revision 1) (October 1997)
RIS on Hazards Barriers (to be issued shortly)

Regulatory Guide 1.181 "Guidance on Updating of Final Safety Analysis Reports" (September 1999)

NRR Office Letter 807 "Control of Licensing Bases for Operating Reactors" (December 1999)

Inspection Procedures

71111.02 "Evaluation of Changes, Tests or Experiments"

71111.13 "Maintenance Rule Risk Assessment and Emergent Work Control"

71111.17 "Permanent Plant Modifications"

71111.23 "Temporary Plant Modifications"

C. DISCUSSION

10 CFR 50.59 is composed of several parts:

1. Paragraph (a) provides definitions for several of the terms used in the rule.
2. Paragraph (b) summarizes applicability of the rule, specifically production and utilization facilities licensed to operate (including power reactors and nonpower reactors), and power reactors and nonpower reactors whose licenses no longer permit operation.
3. Paragraph (c)(1) is permissive in that it allows a licensee to make changes to the facility and its operation as described in the final safety analysis report (as updated) without prior NRC approval, provided a change in technical specifications (TS) incorporated into the license is not involved, and the change does not satisfy any of the criteria for prior NRC approval specified in Paragraph (c)(2). If a change to the TS is required, or if any of the criteria in Paragraph (c)(2) are met, the licensee must apply for and obtain a license amendment in accordance with Section 50.90 prior to implementing the change, test or experiment.
4. Paragraph (c)(2) defines the criteria for prior NRC approval.
5. Paragraph (c)(3) states that for purposes of implementing Section 50.59, the FSAR (as updated) also includes those FSAR changes resulting from facility or procedure changes made pursuant to Sections 50.59 or 50.90 since the last FSAR update was submitted to NRC. Thus, it is not sufficient only to consider the updated FSAR as last submitted to NRC. The licensee must ensure that proposed subsequent changes take into account all changes made since the last FSAR update submittal.
6. Paragraph (c)(4) states that a Section 50.59 evaluation is not required for changes to the facility or the procedures where other regulations specify requirements for such changes. The intent is to remove any confusion that a duplicative 10 CFR 50.59 review is required for changes to the facility or procedure that may be described in the FSAR (as updated), but which are also subject to other change control requirements.
7. Paragraphs (d)(1) and (d)(3) require that the licensee maintain records of changes, tests and experiments made under the authority of Paragraph (c). These records must contain a written evaluation that provides the basis for the determination that prior NRC approval was not required.

8. Paragraph (d)(2) requires that a report be submitted at least once every 24 months of such changes, tests and experiments. The report shall contain a brief description of the change and a summary of the evaluation. Licensees may submit reports more frequently, but cannot exceed 24 months between submittals. Summary reports may be submitted separately, or along with the FSAR update submission.

It should be noted that the evaluation required by 10 CFR 50.59 is only one of the several evaluations and reviews required by the NRC. Most Technical Specifications require that onsite review groups review proposed procedures and modifications or changes to plant equipment or components affecting safety. These review requirements are applicable whether or not the equipment or component is described in the FSAR (as updated). Also note that preparation of an adequate Section 50.59 evaluation often requires looking at licensing and design information not included in the FSAR (as updated). Important sources of such information are NRC safety evaluations, docketed correspondence, and records of safety and transient analyses.

D. DETAILED GUIDANCE

1. Section 50.59 applicability determination guidance

All CTEs should be reviewed for Section 50.59 applicability. In the regulatory guidance and in this inspection guidance, this evaluation is referred to as the “Section 50.59 applicability determination.” Changes that may be determined to be not applicable to further evaluation under Section 50.59 include changes to procedures involved with the quality assurance plan that may be described in the FSAR (as updated), but where Paragraph 50.54(a) establishes criteria and reporting requirements for such changes. Other examples are emergency response facilities covered by Paragraph 50.54(q) and loss-of-coolant accident evaluation methods covered by Section 50.46. These changes are covered by other regulatory processes, and, as stated in Paragraph 50.59(c)(4), an evaluation in accordance with Paragraph 50.59(c)(2) is not required. In some instances, depending upon the nature of a particular change, more than one process may apply to address all aspects of the change.

Another category of changes for which a Section 50.59 evaluation is not required are maintenance activities. The basis is that Paragraph 50.65(a)(4) (as well as the TS) provides the process for evaluating such “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 evaluation. Removing non-TS equipment from service is covered by the requirements of the maintenance rule, Section 50.65, and a Section 50.59 evaluation is not required. One way to decide whether a particular activity is “maintenance” rather than a “change” is whether the plant will return to the same configuration following the activity.

The reliance upon the Paragraph 50.65(a)(4) assessment in lieu of a section 50.59 evaluation also extends to temporary alterations (or test activities) directly related to and required in support of specific maintenance activities. This guidance also applies to temporary alterations in support of implementation of a modification (the modification itself is subject to the Section 50.59 review process with respect to operation following installation). However, if the temporary alterations (including those affecting operator actions and procedures as described in the FSAR (as updated)) are not in support of maintenance, or are expected to remain in place for more than 90 days at power, a Section 50.59 review is to be performed in addition to the Paragraph 50.65(a)(4) assessment. Refer to the regulatory guidance (for Section 50.59 and for Paragraph 50.65(a)(4)) for further information.

Another example of applicability concerns changes to fire protection plans. As discussed in the guidance, for those licensees with the standard license condition that allows changes provided that they do not “adversely affect the ability to achieve and maintain safe shutdown in the event of a fire,” performance of an assessment demonstrating that this provision is met may be done in lieu of a Section 50.59 evaluation.

The Technical Specification Bases are not part of the FSAR (as updated), and thus as part of the rule, Section 50.59 does not apply to changes to them. As part of improved Standard Technical Specifications, many licensees have a TS section that specifies that the requirements of Section 50.59 be applied to changes affecting the TS bases, and thus, for those plants, a review under Section 50.59 (screening and if necessary evaluation) is required. (See also NRR OL 807 for additional information).

2. Screening Review

If a change, test, or experiment is not covered by another change control process, a review in accordance with Section 50.59 is required. The revised rule language allows for a licensee to screen changes as to whether a full evaluation with respect to the criteria in Paragraph 50.59(c)(2) is required, as discussed in more detail below. (see also NEI 96-07)

- a. Changes to the facility or procedures. The criterion for requiring a Section 50.59 evaluation is if it is a change to the facility as described in the FSAR (as updated) or a change to the procedures as described in the FSAR (as updated). The revised rule now defines “change,” “facility as described in the FSAR (as updated),” and “procedures as described in the FSAR (as updated).”

The intent of the definition of “change” as being those that affect design functions, method of performing or controlling functions, or method of evaluation, is to allow screening determinations to conclude that certain changes are administrative, or descriptive only, or do not (adversely) affect the functions of the SSC, such that a Section 50.59 evaluation is not required. The screening review is intended to cause proposed changes that might involve any of the evaluation criteria to be subjected to the Section 50.59 evaluation process (and not be “screened out”).

The guidance discusses licensee screenings as to whether a proposed change has “adverse” effects upon design functions, methods of performing or controlling functions or evaluations. If a change has no effect or only beneficial effects, it would not trigger any of the evaluation criteria concerning higher likelihood of malfunction or higher consequences, etc. If it cannot be concluded that there is no adverse effect, an evaluation is required. “Adverse” is to be judged with respect to accomplishment of design functions. Thus, changes reducing the SSC capability, performance, qualification, or reliability are adverse. Being outside the bounds of existing safety analyses or ranges described in the FSAR (as updated) is adverse.

The functions being affected by a change might be for a SSC other than the one to which the change is being made because of indirect effects. (Indirect effects include such items as environmental conditions, physical interactions, etc.) Therefore, the screening determination, if done only through a word search of the FSAR (as updated), might miss such effects. Refer to regulatory guidance for discussion about direct and indirect effects of changes.

The guidance also discusses those situations in which the existing safety analyses are not bounding and thus that those changes must be evaluated, and not

screened. In contrast, if a licensee decides to include a new analysis for future reference that documents the enhanced performance of SSC after a change, the creation of such analyses does not mean that an evaluation was needed.

A change to the facility does not have to be an actual hardware change to require a Section 50.59 evaluation. Changes to information in the FSAR (as updated) that provide performance or qualification requirements, or to the analyses and evaluations in the FSAR(as updated) that demonstrate that the facility meets requirements may also satisfy the screening criteria, as stated in the definitions.

SSC (or procedures) that are described in the FSAR (as updated) but are not safety-related should not be excluded from evaluation in accordance with Section 50.59 solely on that basis. If the Section 50.59 screening criteria are satisfied, then a Section 50.59 evaluation is required.

Equivalency of components - As discussed in the regulatory guidance, equivalency determinations provide the basis for screening such that a Section 50.59 evaluation is not required.

Additions to the facility or procedures must also be reviewed to determine whether there is any effect upon the facility as described in the FSAR (as updated). The next FSAR update shall reflect the effects of such additions, in accordance with RG 1.181, including, in most instances, a description of any added SSCs.

Each facility change is to be reviewed separately, unless they are interdependent, that is, linked to each other and not separable for functional reasons. The intent is that one change (that might add conservatism) not be used to preclude the NRC review of another change that would, on its own, satisfy the evaluation criteria.

Each criterion must be satisfied on its own, thus, a reduction in consequences cannot "offset" an increase in likelihood for a given change as a basis for meeting Section 50.59. Similarly, changes to evaluation methods must be considered separately from other facility changes, using the applicable evaluation criteria for each.

A temporary change to a SSC must be reviewed in accordance with Section 50.59, even though the change would not be permanent, unless the temporary change is associated with maintenance (see discussion above concerning maintenance; see also guidance in RG 1.181 with respect to FSAR updating requirements).

An unintended deviation of the facility/procedures from that described in the FSAR (as updated), whether in existence since initial licensing, or as the result of an error in a subsequent facility/procedure change or other activity that is not restored must be reviewed pursuant to Section 50.59 to determine whether the change requires NRC approval or a change in the technical specifications. For these types of changes, which rise to the level of requiring NRC approval, the NRC approval prior to implementation refers to the approval of the corrective action (i.e., of the change to the licensing basis as described in the FSAR (as updated)) before the nonconforming condition is resolved. Refer to the Part 9900 Guidance on Resolution of Degraded and Non-conforming Conditions for more information.

The way in which Section 50.59 is applied to changes in operator actions depends upon the context in which they are being made. Specifically, temporary alterations (including operator actions) associated with maintenance are to be covered by the

risk assessment required by Paragraph 50.65(a)(4). For temporary compensatory measures until degraded or nonconforming conditions are corrected, the Section 50.59 review is with respect to the compensatory measure itself, as discussed in the Part 9900 Guidance on Resolution of Degraded and Nonconforming Conditions (GL 91-18). Finally, other operator action changes are to be reviewed in accordance with the guidance on changes to procedures as established in the regulatory guidance.

Changes to the FSAR (as updated) itself, not associated with a change, test, or experiment, are considered part of the FSAR update process, in accordance with 10 CFR 50.71(e), and do not require a Section 50.59 evaluation. Thus, purely editorial changes to the FSAR do not require review under Section 50.59. However, care must be exercised in dealing with discrepancies between the descriptions in the FSAR (as updated) and the facility, or with conflicting information within the FSAR (as updated). In some instances, the resolution is an FSAR update per 10 CFR 50.71(e), but in other cases, the resolution actually involves a change to the licensing basis (by means of revision of the description in the FSAR (as updated)). Section 50.59 is applicable to such changes to the licensing basis.

- b. Tests or experiments. The screening criterion for requiring a Section 50.59 evaluation for the conduct of a test or experiment (not described in the FSAR (as updated)) is whether the test or experiment involves an activity under which any SSC is utilized in a way that it may not remain within the design bases and controlling parameters or in a way that is inconsistent with the safety analyses. If a test described in the FSAR (as updated) would be done in a different way, an evaluation pursuant to Section 50.59 is required. Consistent with the above guidance on temporary alterations associated with maintenance, a Section 50.59 review would not be required for a test in support of maintenance.

3. Evaluation Process

Even when the screening criteria are satisfied, a Section 50.59 evaluation would not be required if the change to the facility (or procedure) would involve a change to the technical specifications. If a technical specification change is involved, the licensee must apply for and obtain a license amendment in accordance with Section 50.90 before implementing the proposed facility or procedure change. Therefore, it is not necessary for a licensee to provide answers to the eight evaluation criteria noted below, as the need for NRC approval is already decided by the need for a change to the TS. Note that the licensee should always determine the effect of a facility or procedure change on the technical specifications regardless of whether the change satisfies Section 50.59 screening criteria (e.g., is described in the FSAR (as updated)).

Each Section 50.59 evaluation should consider the following:

- systems and components affected by the change (What is the effect of the change on their capability to perform their specified or intended functions?);
- parameters of the accident analysis affected by the change (Are all the relevant design basis accidents and transients identified?); and
- potential effects of system or component failure (i.e., the question, “what would happen if...” is explored and answered in the evaluation).
- how the evaluation criteria are met;

The actual implementation of a design change at the plant is to be assessed as a maintenance activity, in accordance with Paragraph 50.65(a)(4), as discussed above under applicability. Operation of the facility following implementation of a design change is subject to review under Section 50.59.

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, the licensee needs to review the partially completed status to determine whether a review in accordance with Section 50.59 is required or a change in the technical specifications is involved. These partially completed configurations should be treated as temporary alterations as discussed above in section D.1 with respect to when Section 50.59 applies. The licensee's control of the integration of the modification into interfacing systems should include positive control of system boundaries; full consideration of the effects of partial completion of the modification; and appropriate revisions to procedures.

4. Evaluation Criteria

- a. The first criterion is if the CTE would result in more than a minimal increase in the frequency of an accident previously evaluated in the FSAR (as updated). The intent of the criterion is to allow changes to be made without approval unless there is a discernible, attributable increase in frequency of an accident. There must be some reason to believe that the CTE would result in a more than minimal impact upon the accident frequency (as because it affects the integrity of the reactor coolant system, or the ability of SSC to remove decay heat, or makes an initiating event more likely to occur). Licensees must still meet applicable regulatory requirements. As noted in NEI 96-07, departures from the design, fabrication, testing and performance standards in the General Design Criteria are not compatible with a "no more than minimal increase" standard.
- b. The second criterion is if the CTE would result in more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety¹ previously evaluated in the FSAR (as updated). As for frequency, the intent is that there be some reason to conclude that the CTE has resulted in an increase in likelihood, rather than the licensee having to prove that it could not happen. In making these assessments, the licensee's evaluation should consider the effects of the proposed CTE on performance of all affected SSC and make a determination as to whether there has been an increase, and provide the basis for the determination. Specific guidance is included in NEI 96-07.
- c. The third criterion is if the CTE would result in more than a minimal increase in consequences of an accident previously evaluated in the FSAR (as updated). The term "consequences" refers to radiological consequences, and consequences are with respect to offsite release, and onsite release, to the extent that onsite releases are evaluated in the FSAR for a particular accident or location (as for example, the control room). As discussed in the implementation guidance, a CTE involves no more than a minimal increase in consequences if the resulting dose (with the change) is no greater than the current licensee-established value plus ten percent

¹ The criteria refer to SSC important to safety previously evaluated. There is no established definition of "important to safety", but this should not impair the ability to implement the criteria because the SSC are already described in the FSAR to the extent of consideration of their functions and requirements thereto with respect to whether they are important to safety.

of the difference between the regulatory value (specified in the regulations, e.g., GDC 19 or Part 100) and the current value, and provided that the result does not exceed the value established in the Standard Review Plan(SRP)² guidance for the particular design basis event if applicable. Applicability is with respect to the particular type of accident, not whether the plant was specifically licensed using the SRP. Also as noted, the intent is to require NRC review of changes with more than a minimal increase in consequences. Consistent with a “minimal” concept, small changes in predicted dose (on the order of 0.1 rem) do not require prior approval, even if the above guidelines are not met. One special case of consequences concerns doses to operators outside the control room, as assessed under the Three Mile Island (TMI) action plan, where the applicable standard for “minimal” is whether the GDC 19 values would continue to be met.

- d. The fourth criterion is similar to the third, and is if the CTE would result in more than a minimal increase in (radiological) consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR (as updated). The above discussion as to understanding of “minimal” also applies to consequences of malfunctions.
- e. The fifth criterion is if the CTE would create the possibility of an accident of a different type from any previously evaluated in the FSAR (as updated). The intent of this criterion is to require review of changes that would create conditions that would have been viewed as design basis events had the possibility existed before. Thus, the assumptions typically used for design basis events, such as no credit for non-safety-related systems, postulated loss of offsite power, single failure, etc. are applicable. On the other hand, accidents that may be theoretically possible once the CTE is made if multiple independent failures were postulated would not be viewed as creation of an accident of a different type.
- f. The sixth criterion is if the CTE would create the possibility of a malfunction of an SSC important to safety with a different result from any previously evaluated in the FSAR (as updated). This criterion focuses upon the “effect” of the CTE, and whether the result of any malfunctions that might have been created by the CTE has already been analyzed or bounded by the analysis in the FSAR (as updated). Only if the effect is different from those already considered would this criterion require prior NRC approval for a CTE involving a new type of malfunction. Note that the likelihood of malfunction may be increased if new failure modes are introduced (even if the effects have been previously evaluated in the FSAR (as updated)), and this situation would have to be evaluated under criterion (ii).
- g. The seventh criterion is if the CTE would result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered. As discussed in the implementation guidance, the determination of the need for NRC review is based upon whether the CTE results in exceeding or altering one of the design basis limits, established in the FSAR (as updated), for maintaining integrity of a fission product barrier. Effects of changes to SSC, including mitigation

² The use of the SRP guidance is for purposes of implementing the Section 50.59 criteria with respect to the need for NRC approval of a particular change with respect to “minimal increases in consequences.” For some plants or accidents, the NRC may already have reviewed and accepted consequences that do not fully conform with the SRP criteria. These previous reviews are unaffected by this guidance, but the overall impact would be that a change that results in any increase (beyond the de minimis value) would require prior NRC approval.

and support systems, need to be assessed with respect to whether the changes lead to exceeding or altering one of these limits. Depending upon the type of facility and its operational status, the particular fission product barriers and design basis limits may vary, but should be evident from the safety analyses presented in the FSAR (as updated). For operating power reactors, the barriers are the fuel clad, reactor coolant system boundary, and containment, and the design basis limits are the values for such parameters as DNB ratio, RCS design pressure, or containment design pressure. The parameters applicable to a specific facility should be ascertainable from review of the FSAR (as updated). Facility changes are judged in terms of whether the analysis results meet the criteria, such as not exceeding a design basis limit for any fission product barrier. There is not a “minimal” or amount of remaining margin standard to be applied. Effects under this criterion are to be judged using the methods described in the FSAR (as updated); methodology changes are evaluated using criterion (viii).

- h. The final evaluation criterion is if the CTE would involve a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses. Unlike the other seven criteria for evaluating CTE, this criterion is specifically directed at changes to evaluation methods. The implementation guidance discusses the meaning of “evaluation method,” and notes that the FSAR (as updated)(or documents incorporated by reference), must describe the method, and the change must affect this description, to require evaluation. Then, in accordance with criterion (viii), if the method is used in establishing the design bases, or in the safety analyses, prior NRC approval is required if there is a departure from the method as described in the FSAR (as updated). A departure occurs if some part of the method is changed, such that the result of the analysis using that method is not conservative or essentially the same. The “essentially the same” language is intended to allow licensees to benchmark revisions to methods for use without prior NRC review even if the results are not “conservative” when the changes are small, would have no effect upon the acceptability of the analysis, and the amount of change in the results is not used to justify that limits and requirements are met. “Conservative” is to be judged with respect to the results obtained from the method. If the result from the revised method is further from the established limit than under the previous method, the revised method is in the nonconservative direction. When judging conservatism of a change in methods, a predicted result closer to an established limit is conservative, in that there is less opportunity for other changes without triggering the need for NRC review and approval. (In contrast, a facility change, which when evaluated (with no change in methods) results in a value further from the limit, is a “conservative” facility change. The difference is that it is the facility change that causes “more margin” in the actual expected result, as contrasted to an analytical result arising from a change to methodology).

It is also not a departure if the licensee uses a different method that has already been reviewed and approved by NRC for the intended application, if used in accordance with the conditions and limitations specified in the approval. A different method must be used in its entirety to fall under this provision of the rule; changes to parts of methods are covered by the “essentially the same” standard noted above. Additional guidance for assessing whether a change to an evaluation method is a “departure” as defined in the rule is provided in the NEI 96-07 guidance.

The elements of the evaluation method include such items as treatment of uncertainties, correlations, and representations of phenomena. In contrast, items such as flows, temperatures, pressures, equipment response times that are

physical characteristics of the facility are viewed either as facility changes or input parameters that are to be evaluated using the other criteria, not as “methods of evaluation.” Changes to input parameters that are described in the FSAR (as updated), are to be evaluated as changes to the facility, and could be made without NRC approval as long as criteria (i) through (vii) and the TS are met.

Further, any changes to analyses and methods are also subject to design control process requirements in accordance with 10 CFR Part 50, Appendix B.

In sum, criterion (viii) is intended to preserve the basic assumptions of the evaluation method that provide the confidence that the analysis results are appropriately conservative, even if the results of the analysis are at the applicable limits or requirements. Use of different methods without specific NRC review is acceptable only if those methods have been previously found acceptable by NRC for the intended application, or the results are conservative or essentially the same.

5. Documentation, Records and Reports

Paragraph 50.59(d)(1) requires licensees to maintain records of CTEs made in accordance with Section 50.59 without NRC approval. It also requires that these records include a written evaluation that provides the basis for the determination that the CTE did not require prior NRC approval (i.e., the Section 50.59 evaluation). While the rule language was revised, this was for simplicity, there is no change in the requirement that evaluations be done for those situations that satisfy the applicability and screening review criteria.

Section 50.59 evaluations must be in writing and include the bases for the determination that the CTE did not require prior NRC approval. The NRC does not consider a checklist to be sufficient to meet the requirement for a written evaluation. However, depending upon the significance of the change, the Section 50.59 evaluation may be quite brief.

Each 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 consultation with the preparer. The documentation should identify the scope of the review (what documents were looked at), and any assumptions, engineering analyses or judgment, etc., that were used.

The documentation of evaluations for temporary modifications (for which Section 50.59 applies) should meet the same criteria regarding reviewability as for permanent changes. Summaries of evaluations for temporary modifications should be included in the periodic report to the NRC in accordance with Paragraph 50.59(d)(2).

Section 50.59 does not specifically require that Section 50.59 applicability or screening determinations for changes be documented. However, in accordance with its NRC-approved operational quality assurance program, the licensee should maintain records because determining the appropriate Section 50.59 review 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.

Paragraph 50.59(d)(3) requires that records of changes to the facility be maintained until the date of termination of the license (either the Part 50 license, or any license issued under Part 54), and that records of changes to the procedures and records of tests and

experiments be maintained for a period of 5 years. The administrative controls section of the technical specifications for some plants may contain additional requirements for record keeping.

Paragraph 50.59(d)(2) requires that the licensee submit a report containing a brief description of each CTE, including a summary of its supporting evaluation, implemented without prior NRC approval in accordance with Section 50.59. The reporting frequency has been revised to 24 months, but reports may be filed more frequently if a licensee so chooses. Reports are required only for those changes, tests and experiments for which evaluations against the criteria were required, not for CTEs screened out.

The Technical Specifications for some plants may contain references to terminology such as “unreviewed safety question” that is no longer used in the revised Section 50.59. These requirements may be for TS Bases Control Programs, safety review committee responsibilities, or record retention requirements. While the explicit language of the TS may not conform with the revised rule language, this is an administrative situation only with no substantive effect. As noted in the Statement of Considerations for the rulemaking, licensees are requested to include changes to these sections as part of another license amendment they might be requesting at a convenient opportunity. There is no obligation on the licensee to do so.

END