

June 29, 2000

MEMORANDUM TO: Kenneth Raglin, Associate Director  
for Training and Development  
Office of Human Resources

FROM: Cynthia A. Carpenter, Chief/**RA**/  
Generic Issues, Environmental, Financial  
and Rulemaking Branch  
Division of Regulatory Improvement Programs  
Office of Nuclear Reactor Regulation

SUBJECT: DEVELOPMENT OF TRAINING COURSE ON REVISION TO  
10 CFR 50.59

This memo transmits to you our initial "work-up" of background material to be used for further development into a web-based training course. The subject is as stated above. Please recall that staff from my branch met with you and members of your training staff in April, 2000, for discussions related to this needed course. The attachment to this memo is the document we indicated at the above meeting that we would prepare and provide to you. We are available to you for continued support in developing the course and look forward to working with your staff. We had discussed this coming November as an approximate target date for finalizing the course.

Please contact Joe Golla of my staff at 415-1002 to coordinate further development of the material as needed.

Attachment: As stated

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OFFICE	RGEB	SC:RGEB	C:RGEB
NAME	JGolla	SWest	CCarpenter
DATE	6/26/00	6/27/00	6/29/00

## Training on Revision to 10 CFR 50.59

Purpose of Training - to familiarize NRC staff with revisions to 10 CFR 50.59 rule requirements

Introduction- 10 CFR 50.59 is a change control process established by regulation for licensee's to determine if particular changes can be made, or tests or experiments performed, without prior NRC approval. It provides licensee's the statutory right, without prior approval to perform tests, operate and maintain the licensed facility, and make certain changes that do not impact the licensing basis. Integral to the 50.59 process are eight evaluation criteria to be utilized by licensee's to make the determination as to whether or not a change, test, or experiment would impact the licensing basis and therefore require prior NRC approval. Another important aspect of 50.59 is a provision that clearly states when it does *not* apply. That is, the 50.59 process is not to be utilized for proposed changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

The rule is applicable to power and non-power reactors that are licensed to operate and those undergoing decommissioning. A similar regulatory process exists for treating proposed changes, tests, experiments to independent spent fuel storage facilities. It is revised section 10 CFR 72.48. This section utilizes the identical eight evaluation criteria of 50.59 and the same provision for applying other regulations if they establish more specific criteria for accomplishing changes.

The 50.59 review process is one part of a larger framework for control of licensee activities, and in particular is a process for change control. The 50.59 review process does not constitute the sole determination of safety of a planned activity, nor the determination of whether other regulatory requirements are met. These determinations are treated within other established processes and practices. Examples include elements of procedure review, quality assurance (which includes design control and document control), and radiation protection program requirements, etc., which must also be adhered to by licensees.

Purpose of rule revision- The intended purpose of the revision to the 10 CFR 50.59 rule is to remove ambiguities in the existing rule about what constitutes a "change as described..." and to remove ambiguities about when the margin of safety as defined in the bases for a technical specification (TS), is reduced by a proposed change. This has been accomplished through the addition of definitions, eight specific evaluation criteria and other verbiage. There also exists a new revision to the complimentary industry guidance document, NEI 96-07, *Guidelines for 10 CFR 50.59 Evaluations*, Revision 1, which further clarifies issues such as those stated above.

It is also intended that the revision provide a limited degree of flexibility beyond that which currently exists for licensee's, without prior NRC approval, to make changes that involve only a "minimal" increase in consequence or probability of occurrence, or that create malfunctions of a different type (but not with a different result).

## ATTACHMENT

Revised Rule Outline- Paragraph (a) contains definitions. Definitions were not in the previous version of 50.59. These include such terms as "change," "facility as described in the FSAR (as

updated),” “tests or experiments not described in the FSAR (as updated),” a definition for “departure” with two principal subparts (i) for changes to parts of a method, and (ii) for changing from one method to another.

Paragraph (b) contains the Applicability Section. The term “applicability” here refers to the set of possible facilities for which the 50.59 process *might* apply to proposed changes, tests, and experiments. Below it will be explained that for a proposed change, test, or experiment at a facility under the purview of 50.59, that is, a facility defined by 50.59(b) to be regulated by 50.59 for proposed changes, tests, or experiments, each proposed change, test, or experiment must be reviewed to determine if the 50.59 process is applicable to that particular proposed change, test, or experiment.

Paragraph (c)(1) contains the text about licensee’s being able to make changes (or conduct tests) without obtaining a license amendment under specified conditions.

Paragraph (c)(2) contains the eight evaluation criteria previously mentioned. These have been derived from the three unreviewed safety question (USQ) criteria of the prior version of 50.59. These three criteria are now broken down into eight in the new revision and the terminology “unreviewed safety question” has been dropped. If any one of the eight criteria are satisfied (positive), then the licensee must obtain a license amendment for the change.

Paragraph (c)(3) is a “catch-all” statement that notes that in performing evaluations with respect to the FSAR, a licensee must consider other changes made but not yet reflected in the FSAR update as submitted to NRC.

Paragraph (c)(4) states, “The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.” This paragraph provides the explicit legal basis for not performing an evaluation under 50.59 for a proposed change, test, experiment; to a given SSC, parameter, or program, etc., for which applicable specific requirements exist in the regulations.

Paragraph (d) contains the record retention and reporting requirements. These include a requirement that licensees maintain records of their written evaluations which provide the bases for the determination that a change, test, or experiment does not require a license amendment. They are then required to provide to the NRC a summary report of changes at least every 24 months.

Summary of 10 CFR 50.59 Review Process- The process involves the application of four basic steps, these are:

- 50.59 Applicability Determination Process
  - this is done preliminarily to determine if the overall 50.59 process should be applied to a proposed change, test or experiment; that is, if the proposed change, test, or experiment falls within “50.59 space” [the requirement and method for doing this is not stated explicitly in the regulation but is supported by paragraph (c)(4)]
- 50.59 Screening Process
  - this is done to determine if a 50.59 evaluation is needed. (This step is not a specified requirement of the regulation.)

- 50.59 Evaluation Process  
-apply evaluation criteria
- 50.59 Documentation Process  
-activities the licensee intends to implement must be documented and reported to the NRC

50.59 Applicability Determination Process- The 50.59 change control process is neither applicable to all proposed changes nor the only change control process in the regulations. Other change control processes that may apply in a given situation instead of 50.59 are those that are specific to programs, e.g., fire protection, quality assurance, or parameters, e.g., peak cladding temperature, heat removal rate, etc. More than one of these more specific change control processes may apply to a given change or only one. It must therefore be determined up-front which change control process(es) should be applied to ensure the correct overall process is used and to avoid unnecessary burden. The provision in 50.59 that provides for this explicitly removes any requirement for redundant reviews. This provision is new within the revision of 50.59 and is stated in 50.59(c)(4).

An applicability determination then refers to determining if the 10 CFR 50.59 process is needed, not needed in lieu of another process, or if it and a complementary process such as the 10 CFR 50.90, *Application for Amendment of License or Construction Permit*, are needed. Note that the rule does not explicitly state a process that licensees are required to follow in determining applicability. It is however necessary prior to initiating a change and is a means by which licensees reduce or eliminate unnecessary expenditure of review effort. (Link to diagram on page 5 of NEI 96-07 here.) Some of the other change control processes that exist include:

Changes to Technical Specifications (10CFR 50.90) - changes to the facility or procedures that involve TS fall within the scope of 10 CFR 50.59. In practice, most licensees include within their process a check for whether TS are involved as an early step in the review, and if so, the need for a 50.90 submittal is thus identified.

Changes to Quality Assurance plans - refer to 10 CFR 50.54(a). Note that in accordance with 50.34(b), FSARs contain information about the QA plan (such as incorporation by reference). 50.59(c)(4) makes clear that such changes are covered by 50.54(a) and not by 50.59.

Changes to Emergency plans - refer to 10 CFR 50.54(q). Note that in accordance with 50.34(b), FSARs contain information about the Emergency Plan. 50.59(c)(4) makes clear that such changes are covered by 50.54(q) and not by 50.59.

Changes to Fire Protection plans - under the revised 50.59 rule and guidance, for plants that have adopted the “standard” license condition discussed in GL 86-10, determinations as to whether plan changes can be made without prior NRC approval are to be judged with respect to whether the change, as stated in the standard license condition, “adversely affects the ability to achieve or maintain safe shutdown.” If so, the licensee must get NRC approval. If the license condition is used to make the decision and is met, a separate 50.59 evaluation is not (also) required.

Temporary changes or alterations in support of maintenance - refer to RG 1.182.

Guidance within RG 1.182 is different from current practice, reflecting approval of 50.65(a)(4) as a new requirement for licensees to assess and manage risk of maintenance activities. Thus, for temporary alterations to the facility (or procedures) being implemented to support a maintenance activity, a 50.59 evaluation is not required. (If intended to be in effect for more than 90 days, then the activity should also receive a 50.59 evaluation, in addition to the 50.65(a)(4) evaluation.)

FSAR updates - changes to the FSAR not resulting from changes “to the facility...” being made under 50.59, are considered as update activities per 50.71e ( refer to RG 1.181 for guidance).

50.59 Screening Process- If it has been determined that 10 CFR 50.59 is applicable to a proposed change, test, or experiment a 50.59 “screening” is done to determine if the next step should be taken. That is, that a 50.59 evaluation be done.

Definitions that were added to the rule are intended to codify exact meanings of words in a specific “50.59 vernacular” to be used in the eight evaluation criteria of 50.59 (c)(2) and in applying the eight criteria. That way licensees, contractors, stakeholders, and the NRC will all be “speaking the same language” when applying or reviewing the 50.59 process. The definitions focus upon changes to “design functions,” “methods of operating or controlling the function,” and on methods of “evaluation.” The “change” definition explicitly includes additions, modifications, and removals. The “tests” definition covers things not presently included in the UFSAR. Thus, the evaluation process looks at whether facility changes affect design functions of SSCs, whether procedure changes affect methods of operating and controlling SSCs, and whether there is a change to an evaluation method (described in the SAR). The NEI guidance includes the concept of “adversely” affecting design function. That is, if the effect of a change is not detrimental to (does not “adversely” affect) any associated aspect(s) of a design function, then an evaluation of the degree of “loss of function” is not needed.

The screening is concerned with whether a proposed change to the facility or procedures adversely affects an SSC design function described in the UFSAR, or affects an SSC not described in the UFSAR, a change to which would adversely affect a design function of an SSC that *is* described in the UFSAR. The screening is also concerned with whether a proposed test or experiment is something “new.” That is, that the proposed test or experiment is or includes aspects not described in the UFSAR, that may introduce a process that is inconsistent with analyses or description that *is* in the UFSAR. Activities that “screen out” of further evaluation [evaluation using the eight evaluation criteria in 50.59(c)(2)] should be documented but are not required to be reported.

50.59 Evaluation Process- If a proposed change has been “screened in” to the 50.59 review process, the next step is to perform a 50.59 “evaluation” to determine if the change requires a license amendment (and therefore NRC approval). The change is evaluated using the eight evaluation criteria specified in 50.59(c)(2). (Link to eight criteria here) If any one criterion is satisfied (positive) then the need for a license amendment is established and the 50.59 evaluation is completed. That is, once one of the eight criteria is shown to be satisfied, the licensee need not continue to evaluate any remaining criteria.

Changes are expected to be examined individually as necessary to be sure the criteria are applied correctly. For example if a change is being made to the facility, and as part of the same modification a change is also being made to the method of evaluation (used to evaluate how the modified facility conforms with its safety analyses), then the facility change is to be assessed against the first seven criteria (the eighth criterion is not applicable) and the change to the method evaluated against the eighth criterion.

The first two criteria relate to whether a change involves “more than a minimal increase” in frequency of an accident (previously evaluated in the FSAR (as updated)), or in the likelihood of occurrence of a malfunction of a structure, system or component important to safety previously evaluated in the FSAR (as updated). The guidance discusses both qualitative and quantitative approaches to determining if an increase is “more than minimal”

The next two criteria relate to whether a change involves “more than a minimal increase” in consequences of an accident (previously evaluated in the FSAR (as updated)), or of a malfunction of a structure, system or component important to safety previously evaluated in the FSAR (as updated). The guidance discusses how to decide if an increase is “more than minimal” - in general, the approach involves 10% of the remaining margin to a regulatory guideline value (e.g., Part 100). That is, “an increase in consequences from a proposed activity is defined to be “no more than minimal” if the increase is less than or equal to 10 percent of the difference between the current calculated dose value and the regulatory guideline value (10 CFR 100 or GDC 10, as applicable). The guidance also notes that if an acceptance criterion established in the Standard Review Plan for a particular event would be exceeded as a result of a change, this is “more than minimal”

The fifth criterion involves the creation of a possibility for an accident of a different type. The guidance explains that accidents of a different type are credible accidents that the proposed activity could create that are not bounded by “UFSAR-evaluated accidents.”

The sixth criterion involves the creation of a possibility for a malfunction of an SSC important to safety with a different result from any previously evaluated in the UFSAR. The guidance defines a malfunction with a different result as one that involves an initiator or failure whose effects are not bounded by those explicitly described in the UFSAR. The guidance also indicates that malfunctions with a different result are limited by frequency, to those that are as likely to happen as those described in the UFSAR.

The seventh criterion concerns whether the change would result in a design basis limit for a fission product barrier described in the FSAR being exceeded or altered. The fission product barriers; fuel cladding, reactor coolant system boundary, and containment, of course, have design limits. This criterion is intended to protect the critical design parameters of the fission product barriers from proposed changes that may challenge those limits. Note that some design basis limits for fission product barriers may be controlled by another, more specific regulation or Technical Specification and would, per 50.59 (c)(4), not require 50.59 evaluation. The licensee’s ability to make changes affecting these parameters would be limited by the Tech Spec or regulation.

Fission product barriers for operating power reactors, as stated above, are the fuel clad, the reactor coolant system boundary and the containment. For nonpower reactors, there may be different and/or fewer barriers. For reactors undergoing decommissioning, the barrier may only be the fuel itself.

The final criterion concerns whether the change would result in a departure from a method of evaluation described in the UFSAR used in establishing the design bases or in the safety analysis. The guidance expounds greatly on this criterion.

50.59 Documentation Process- The licensee must satisfy the documenting, reporting, and record retention requirements detailed in 50.59(d) for all changes evaluated as not requiring NRC approval.

#### References

Regulations: 10 CFR 50.59, 10 CFR 72.48, 10 CFR 50.90, 10 CFR 50.54, 10 CFR 50.65, 10 CFR 50.71, 10 CFR 100

NEI 96-07, Revision 1, *Guidelines for 10 CFR 50.59 Evaluations*

GL 86-10, *Implementation of Fire Protection Requirements*

GL 91-18, Revision 1, *Information To Licensees Regarding NRC Inspection Manual Section On Resolution of Degraded and Nonconforming Conditions, Oct. 8, 1997*

RG 1.181, *Content of the Updated Final Safety Analysis Report In Accordance With 10 CFR 50.71(e)*

RG 1.182, *Assessing and Managing Risk Before Maintenance Activities At Nuclear Power Plants*

DG-1095, *Guidance for Implementation of 10 CFR 50.59 Changes, Tests and Experiments*

NUREG-1600 May 1, 2000, *General Statement of Policy and Procedure for NRC Enforcement Actions*