



**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH**

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**GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59,
CHANGES, TESTS, AND EXPERIMENTS**

A. INTRODUCTION

In 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.59, "Changes, Tests and Experiments," contains requirements for the process by which licensees may make changes to their facilities and procedures as described in the safety analysis report, without prior NRC approval, under certain conditions. The rule was promulgated in 1962 and revised in 1968.

As a result of lessons learned from operating experience and other initiatives related to control of conformance of facilities with their final safety analysis report (FSAR) descriptions, the NRC determined that additional action was necessary to provide clarity and consistency in implementation of the rule. The staff recommended specific actions in SECY-97-205, "Integration and Evaluation of Results from Recent Lessons-Learned Reviews,"¹ dated September 10, 1997. In a staff requirements memorandum dated March 24, 1998,¹ the Commission directed the staff to initiate rulemaking to revise the requirements of 10 CFR 50.59 to clarify the requirements and to allow changes involving only "minimal increases" in probability or consequences to be made without prior NRC approval.

¹Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville MD; the PDR's mailing address is Mail Stop PDR, Washington, DC 20555; telephone (301) 415-4737 or (800)397-4209; fax (301)415-3548; email <PDR@NRC.GOV>.

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This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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The proposed rule was published for comment in October 1998. Following consideration of public comments, the NRC issued a final rule on October 4, 1999 (64 FR 53582) revising 10 CFR 50.59 that becomes effective 90 days after approval of regulatory guidance, which is contained in this Regulatory Guide (RG). The text of the revised rule is contained in Appendix A to this regulatory guide for convenience.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

B. DISCUSSION

OBJECTIVE

The objectives of 10 CFR 50.59 are to ensure that licensees (1) evaluate proposed changes to their facilities for their effects on the licensing basis of the plant, as described in the FSAR, and (2) obtain prior NRC approval for changes that meet specified criteria as having a potential impact upon the basis for issuance of the operating license. This regulatory guide, through its endorsement of a guideline document for licensees, provides guidance on complying with the revised requirements of 10 CFR 50.59.

DEVELOPMENT OF INDUSTRY GUIDELINE, NEI 96-07

Following publication of the revised rule, the Nuclear Energy Institute (NEI) submitted a guidance document for the implementation of 10 CFR 50.59 and requested NRC endorsement through a regulatory guide. Following a series of meetings between NEI and the NRC, a revised version of the guidance document was submitted by NEI on February 22, 2000. The NRC published a draft regulatory guide, DG-1095, which endorsed with certain clarifications, Revision 1 of NEI 96-07. As part of their comments in response to the draft RG, NEI proposed revisions to NEI 96-07 to respond to the issues raised by the NRC staff in its draft RG. Subsequently, NEI submitted a revised version of NEI 96-07, dated September 2000 for endorsement.

C. REGULATORY POSITION

1. NEI 96-07

Revision 1 of NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations,"² dated September 2000, provides methods that are acceptable to the NRC staff for complying with the provisions of 10 CFR 50.59.

²Copies of NEI 96-07 are available through NRC's web site, <WWW.NRC.GOV> through rulemaking, and through NRC's Electronic Reading Room at the same site, under Accession number xxxx. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301) 415-3548; email <PDR@NRC.GOV>.

2. OTHER DOCUMENTS REFERENCED IN NEI 96-07

NEI 96-07 (Revision 1) references other documents, but NRC's endorsement of NEI 96-07 (Revision 1) should not be considered an endorsement of the referenced documents.

3. USE OF EXAMPLES IN NEI 96-07

Revision 1 to NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in NEI 96-07, Revision 1, the NRC's endorsement of NEI 96-07 (Revision 1) should not be considered a determination that the examples are applicable for all licensees. A licensee should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

4. GUIDANCE FOR FSAR SUPPLEMENTS FOR LICENSE RENEWAL

The guidance in Revision 1 to NEI 96-07 and in this regulatory guide is applicable to information added to the FSAR in accordance with 10 CFR 54.21(d), that is, for summary descriptions of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses.

5. APPLICABILITY TO NON-POWER REACTORS

While most of the examples and specific discussion focus upon power reactors, the guidance contained in Revision 1 to NEI 96-07 is also applicable to evaluations performed by licensees for non-power reactors. Certain of the provisions in the guidance that discuss the relationship of other regulatory requirements to 10 CFR 50.59 may not be fully applicable to non-power reactors because of differences in those other requirements. For example, nonpower reactors are not subject to 10 CFR 50.65, and thus, the guidance concerning use of risk assessments for temporary alterations associated with maintenance in lieu of 10 CFR 50.59 reviews would not be applicable.

6. APPLICABILITY TO 10 CFR 72.48 EVALUATIONS

The guidance contained in Revision 1 to NEI 96-07 is also generally applicable to evaluations performed by licensees of independent spent fuel storage facilities (ISFSIs) or spent fuel storage cask design certificate holders for implementation of the revised 10 CFR 72.48. The NRC plans to issue guidance that would endorse (with comment if needed), a companion industry guidance document that has adjustments to the examples and other specific aspects as they pertain to 10 CFR 72.48.

7. APPLICABILITY OF PAST NRC COMMUNICATIONS

The NRC has issued a number of communications, such as Generic Letters or Bulletins that discussed or referred to 10 CFR 50.59. In considering whether the information in those documents remains applicable, it should be noted that these documents were based upon the rule requirements that existed at the time of issuance. To the extent that the discussion therein relates to specific aspects of the rule, such as evaluation criteria, which have been revised, these past documents may no longer be fully consistent and the new rule requirements would prevail. The status is unchanged of other parts of these documents that are not affected by the revisions to the rule.

8. USE OF OTHER METHODS

Licensees may use methods other than those proposed in Revision 1 of NEI 96-07 to meet the requirements of 10 CFR 50.59. The NRC will determine the acceptability of other methods on a case-by-case basis.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which a licensee proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used in the evaluation of licensee compliance with the requirements of 10 CFR 50.59.

APPENDIX A TEXT OF 10 CFR 50.59

§ 50.59 Changes, Tests, and Experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses* means (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) *Facility as described in the final safety analysis report (as updated)* means:

(i) The structures, systems, and components (SSC) that are described in the final safety analysis report (FSAR) (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(4) *Final Safety Analysis Report (as updated)* means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as updated per the requirements of § 50.71(e) or § 50.71(f), as applicable.

(5) *Procedures as described in the final safety analysis report (as updated)* means those procedures that contain information described in the FSAR (as updated) such as how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

(6) *Tests or experiments not described in the final safety analysis report (as updated)* means any activity where any structure, system, or component is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the final safety analysis report (as updated) or

(ii) Inconsistent with the analyses or descriptions in the final safety analysis report (as updated).

(b) Applicability. This section applies to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been amended to allow possession but not operation of the facility.

(c)(1) A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

(i) A change to the technical specifications incorporated in the license is not required, and

(ii) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A licensee shall obtain a license amendment pursuant to § 50.90 prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:

- (i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);
- (ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);
- (iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);
- (iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);
- (v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);
- (vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);
- (vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or
- (viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to § 50.90 since submittal of the last update of the final safety analysis report pursuant to § 50.71 of this part.

(4) 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.

(d)(1) The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR Part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

VALUE/IMPACT STATEMENT

A separate Value/Impact Statement was not prepared for this regulatory guide. The Value/Impact Statement that was prepared as part of the Regulatory Analysis for the rulemaking in May 1999 is still applicable. Copies of the Regulatory Analysis are available for inspection or copying for a fee in the NRC's Public Document Room at 11555 Rockville Pike, Rockville, MD, Washington, DC, as part of SECY-99-130, dated May 12, 1999. The PDR may be reached by telephone at (301)415-4737 or fax at (301)415-3548.

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