

TO: DISTRIBUTION LIST FOR DIVISION 1 REGULATORY GUIDES

SUBJECT: DRAFT REGULATORY GUIDE DG-1095, "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59, 'CHANGES, TESTS AND EXPERIMENTS'"

Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," is being developed to describe methods acceptable to the NRC staff for complying with the NRC's regulations with regard to the process for evaluating changes, tests, and experiments that a licensee wishes to make without prior NRC approval. In addition to comments on DG-1095, the staff would welcome specific comments in the following areas.

In NEI 96-07, NEI proposed a definition of "design function" to be used for screening changes from further evaluation. In the draft regulatory guide, the NRC staff did not use the definition of design function as a means to exclude functions from further evaluation for the functions of structures, systems, and components that are described in the final safety analysis report. In DG-1095, the NRC staff proposes to amplify the definition of "design function" so that it will be viewed in a broad sense of all the possible functions that might in some way involve the evaluation criteria. Further, the NRC proposes to revise the guidance concerning "affects" a function. The regulatory discussion is detailed to facilitate comment on the staff's position, but it is the NRC's intent to simplify the overall guidance in the final regulatory guide.

The NRC specifically seeks comment on the impact of not allowing screening of changes that affect functions that do not meet the definition of design function. In particular, examples of functions that might be described in the FSAR, but for which an evaluation under 10 CFR 50.59 would not be needed if that function were affected, would be helpful. The NEI guidance document contains a number of examples to illustrate the use of the evaluation process and the criteria. The NRC staff also seeks comments concerning whether there are other areas for which examples would be helpful. The NRC staff has proposed that NEI supplement the guidance with a few examples that are subjected to the entire evaluation process, including all of the eight evaluation criteria, to show some of the interrelationships. Commenters are invited to suggest examples of changes that would best demonstrate functioning of the overall process.

The NRC staff notes that the guidance related to whether a different method of evaluation is "approved for the intended application," and can thus be used by a licensee pursuant to 10 CFR 50.59(c)(2)(viii), has been developed from the Statement of Considerations (64 FR 53598), which stated that these methods needed to be "generally approved." The NRC concludes that the guidance provided in NEI 96-07 in Section 4.3.8.2, on determining whether a method is suitable for the intended application, provides the guidance necessary for changes in methods to be evaluated without restricting the use to "generic approvals," with minor clarifications as provided in DG-1095.

Finally, the NRC is interested in the issue of documentation. The guidance notes the need for records of evaluations and for documentation of screening. The NRC staff believes that the guidance could be improved by direction about the level of detail to be documented about the considerations and questions contained in the NEI guidance. This is particularly true with respect to criteria 10 CFR 50.59(C)(2)(vii) and (viii). Comments on this subject are also requested.

Comments should be submitted to the Chief, Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington D.C. 20555. Comments may also be provided via the NRC's interactive web site at WWW.NRC.GOV by following the path for current rulemakings. At this site, comments may be uploaded as files (any format) if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301)415-5905; e-mail CAG@nrc.gov.

The public comment period for the draft regulatory guide ends on MAY xx, 2000. Comments received after that date will be considered if it is practical to do so, but assurance cannot be given for late comments.

David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments may be submitted electronically through our web site, www.nrc.gov. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by

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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-1095

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.

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 proposed in this Draft Regulatory Guide DG-1095. The text of the revised rule is contained in Appendix A to this regulatory guide for convenience.

Regulatory guides are issued to describe to the public methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the staff in evaluating specific problems or postulated accidents, and to provide guidance to

¹Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273 or (800)397-4209; fax (202)634-3343; email <PDR@NRC.GOV>.

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applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in developing the regulatory positions. Draft regulatory guides have not received complete staff review; they therefore do not represent official NRC staff positions.

The information collections contained in this draft 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. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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, 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. This revision reflected comments provided by the NRC on November 4, 1999, and February 4, 2000.

C. REGULATORY POSITION

1. NEI 96-07

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

1.1 SCREENING ON WHETHER A CHANGE AFFECTS DESIGN FUNCTION

In Sections 3.3, 4.2.1, and 4.2.1.1, NEI has included guidance for screening changes to determine whether they affect a design function of a structure, system, or component (SSC). The NRC proposes clarifications about whether a change affects a design function

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. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273 or (800)397-4209; fax (202)634-3343; email <PDR@NRC.GOV>.

(and therefore, requires evaluation against the 50.59 evaluation criteria). In particular, the staff is proposing the following clarification with respect to the guidance offered by NEI:

1.1.1 To implement the rule properly, “design function,” as used in screening, is so broad that changes that have the potential to meet any of the evaluation criteria are evaluated rather than screened. Since the criteria include both the initiation and response to previously postulated events (including equipment performance), as well as introduction of new events, “function” extends beyond safety-related SSC and specific mitigation systems whose performance is explicitly modeled and discussed in the safety analyses.

1.1.2 For SSCs that have functions described in the FSAR, changes affecting such functions should be evaluated, not excluded from further review because the described function does not fit the definition. When the change is being made to an SSC that is not itself described in the FSAR, or whose functions are not, screening with respect to whether the change affects a design function for other SSCs is appropriate, as discussed in Section 4.2.1.1, with the clarifications in 1.1.3 and 1.1.4 below.

1.1.3 The definition for design function is modified in Section 3.3. This modification is proposed to ensure that the definition is interpreted in a comprehensive manner when deciding whether changes require further evaluation with respect to the evaluation criteria. The definition of design function is to read as follows:

“Design Function” for an SSC is the information in the Final Safety Analysis Report (as updated) that describes what the SSC is intended to do, when it is to perform the function (e.g., modes of operation, conditions), and how it is supposed to perform. These functions include but are not limited to: (1) SSCs and their functions that are credited in safety analyses or required by regulation, (2) functions of SSCs that support or impact any credited SSC functions, or (3) functions of non-safety-related SSCs that, if not performed, would initiate a plant transient or accident. Design functions include the conditions under which intended functions are required to be performed, such as equipment response times, environmental and process conditions, equipment qualification, and single failure.

1.1.4 “Credited in the safety analyses” means that, if the SSC were not to perform its intended function in the manner described, the assumed initial conditions, mitigative actions, or other information in the analyses would no longer be within the range evaluated. The “credit” may be implicit with respect to the analysis, for example, one of the functions described in the FSAR of the non-safety turbine bypass system may be to mitigate some overpressure transients, even though the code safety valves are what are explicitly credited in the transient analysis. The phrase “supports or impacts SSC functions” refers both to those SSCs needed to support other SSCs (cooling, power, environmental control, etc.) and to SSCs whose performance or malfunction could interact with SSCs that have functions described in the FSAR (for instance, offsite power, control systems, physical arrangements). The staff notes that “Safety analysis” includes demonstration of the ability to safely shut down the reactor, accident and transient response analyses, as well as supporting analyses that demonstrate that SSC functions will be accomplished.

1.1.5 The discussion in Section 4.2.1, beginning with the second sentence, is to be considered under the subheading of Section 4.2.1.1. Section 4.2.1 discusses whether an activity is a “change to the facility or procedures as described in the UFSAR.” The discussion

begins with reference to all three parts of the rule definition of change,³ but then the subsequent discussion in this section (as well as in subsection 4.2.1.1) is focused only on facility changes as they relate to design functions. Other subsections (4.2.1.2 and 4.2.1.3) give further guidance on screening with respect to procedures and evaluation methods. All parts of Section 4.2.1 need to be used, as applicable. Since the noted text under Section 4.2.1 is more germane to the heading of Section 4.2.1.1, this text is to be moved.

1.1.6 Section 4.2.1 (relocated to Section 4.2.1.1 per Regulatory Position 1.1.5) provides guidance on whether a change may (adversely) affect a design function. Guidance is added for deciding whether a function is affected when the change is with respect to some characteristic or value (response time, capacity) of an SSC. Whether the change affects the function is determined by whether the result remains within the bounds of existing analyses or FSAR information. If the nature of the change is such that engineering assessments or revised analyses are needed to determine whether an effect is adverse, the change requires an evaluation pursuant to 10 CFR 50.59, and not a screening.

1.2 INTERFACE of 10 CFR 50.59 WITH THE MAINTENANCE RULE (10 CFR 50.65)

Sections 1.2.1, 3.3, and 4.1.2 of the NEI guidance discuss the relationship between 10 CFR 50.59 and 50.65(a)(4) with respect to maintenance activities, including associated maintenance preparatory activities (referred to in some instances as “temporary changes or alterations”). NRC agrees with the intent of this guidance that, for activities required to support and directly related to the maintenance, 10 CFR 50.59 does not apply for the duration of the maintenance on the basis that another regulation controls such activities.

To avoid confusion about the relationship of maintenance activities (which restore the facility to its original condition) and modifications (that change in some respect the facility), Section 4.1.2 is to read as follows:

Maintenance activities are actions that restore SSCs to their as-designed state. Maintenance activities include troubleshooting, calibration, refurbishment, post-maintenance testing, identical replacements, housekeeping, and similar activities that do not permanently alter the design or design function of SSCs. Maintenance activities, including alterations to the facility or procedures required to support and directly related to the maintenance, are not subject to 10 CFR 50.59 evaluations but are subject to the provisions of 10CFR 50.65 (a)(4) as well as technical specifications.

Licenses should address operability in accordance with the technical specifications and should assess and manage the risk impact of maintenance activities per 10 CFR 50.65(a)(4) and NEI 93-01, “Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.”¹

When the facility is not restored to its original condition as a result of the “maintenance activity” (e.g., if SSCs are removed, if the design, design function, or operation is altered, or if a temporary change in support of the maintenance is not removed), both 10 CFR 50.65(a)(4) and 50.59 would apply as discussed below. In these circumstances, the activities under way are not limited to maintenance, but also involve

³ As noted in Attachment A, 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.

some sort of design or licensing basis change. An assessment of the “maintenance activity” is required as well as review of the “change.” This situation might occur when the original plan is to restore the facility, but during the course of the maintenance, it is determined that full restoration will not occur (at which time the applicability of 10 CFR 50.59 would arise).

A design change would be subject to 10 CFR 50.59 evaluation with respect to its effect upon the facility and its operation (following installation). Further, licensees may include as part of the modification package an evaluation pursuant to 10 CFR 50.59 for the facility in various stages of implementation of a modification (as needed). The actual implementation of a design change, including associated activities, may be viewed as “maintenance” rather than a change under 10 CFR 50.59, and be assessed under 10 CFR 50.65(a)(4). Thus, in these cases, a 10 CFR 50.65(a)(4) assessment would be needed for the duration of the “maintenance activity” to implement the modification. Whether a 10 CFR 50.65(a)(4) assessment is required for the installation of a modification should be determined by the maintenance rule requirements and guidance for assessing and managing risk before maintenance activities.

In addition to assessments required by 10 CFR 50.65(a)(4), 10 CFR 50.59 should be applied to maintenance activities if a temporary change in support of maintenance is expected to be in effect during at-power operations for more than 90 days. In this case, 10 CFR 50.59 would be applied to the temporary change prior to implementation in the same manner as a permanent change.

Apply 10 CFR 50.59 to temporary changes proposed as compensatory measures for degraded or non-conforming conditions, as discussed in Section 4.4.

1.3 INCREASES IN LIKELIHOOD OF MALFUNCTION

In Section 4.3.2 of NEI 96-07, a quantitative value for “no more than a minimal increase” is a factor of 2 increase. This factor must be applied at the individual component level. If the guidance is not so limited, further guidance would be needed to limit the overall effects of the change at the system or train level. The NRC staff agrees with the NEI guidance that states that use of the factor of 2 may also be constrained by other evaluation criteria, depending upon the specific components or functions that the change involves.

1.4 METHODS APPROVED BY NRC FOR THE INTENDED APPLICATION

Guidance has been included in NEI 96-07 for licensees to use in determining whether a change from one method to another is a “departure” (and thus requires NRC approval), or is a method “approved by NRC for the intended application.” The guidance in Section 4.3.8 is acceptable with two clarifications in Regulatory Positions 1.4.1 and 1.4.2.

1.4.1 NEI 96-07 refers to whether differences in plant configuration or licensing basis are “material to the NRC approval basis” in concluding whether the NRC approval of an evaluation method (reviewed for a plant-specific application) is still valid for use at another facility. The NRC staff believes that it will be difficult for a licensee to determine whether the differences meet this criterion; as for plant-specific reviews, the staff’s evaluation may not discuss all aspects of the approval basis. Instead, the NRC staff has concluded the decision should be based upon whether the differences are relevant to the results obtained. If such relevant differences exist, the method is not “approved” and any modifications to NRC-

approved methodologies should be evaluated using the “conservative or essentially the same” criteria in the definition of “departure.”

1.4.2 Section 4.3.8.2 states “slight modifications to the [NRC approved] methodology can be made and the methodology can still be considered approved for the intended application.” The basis for acceptability of modifications to approved methods that is acceptable to the NRC staff is using the “conservative or essentially the same” criteria.

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. These examples are illustrative only, and 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 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. If necessary, the staff may provide further guidance or examples for use with respect to such programs and evaluations at a later date.

5. 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 based upon this guidance with adjustments to the examples and other specific aspects as they pertain to 10 CFR 72.48.

6. USE OF OTHER METHODS

Licensees may use methods other than those proposed in Revision 1 of NEI 96-07, as clarified by this regulatory guide, 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.

This draft regulatory guide has been released to encourage public participation in its development. 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 method to be described in the final version of this guide, reflecting public comments, 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 2120 L Street NW., Washington, DC, as part of SECY-99-130, dated May 12, 1999. The PDR may be reached by telephone at (202)634-3273 or fax at (202)634-3343.