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## **POLICY ISSUE** (Notation Vote)

July 5, 1996

SECY-96-154

For: The Commissioners

From: James M. Taylor  
Executive Director for Operations

Subject: PROPOSED REVISION TO NRC ENFORCEMENT POLICY, NUREG-1600,  
ENFORCEMENT GUIDANCE FOR DEPARTURES FROM THE FSAR IN  
VIOLATION OF 10 CFR 50.59 AND FOR FAILURES TO UPDATE FSAR IN  
VIOLATION OF 10 CFR 50.71(e)

Purpose:

To obtain Commission approval to revise the NRC Enforcement Policy, NUREG-1600, to address violations of 10 CFR 50.59 and 50.71(e).

Background:

As a result of increased regulatory attention to Part 50 licensees' adherence to the Final Safety Analysis Report and the Updated Final Safety Analysis Report (these documents are referred to in this paper as the FSAR), both licensees and NRC have identified numerous failures to conform to these documents. Given these findings, the staff has reviewed the current Enforcement Policy to determine if additional guidance is needed to treat compliance issues associated with departures from the FSAR.

In accordance with 10 CFR 50.59, the Commission allows licensees to make changes to the facility or procedures described in the FSAR and to perform certain tests or experiments not described in the FSAR without prior NRC approval provided evaluations are performed to demonstrate that the change does not involve an unreviewed safety question and the change does not conflict with a technical specification. Specifically 10 CFR 50.59(a) provides:

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The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test, or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question.

If an unreviewed safety question or a change to a technical specification is involved, section 50.59(c) requires that the licensee submit an application for a license amendment pursuant to 10 CFR 50.90.

Section 50.59(b) requires that the evaluation be documented in writing and maintained and reports of the changes be submitted to the Commission. Periodic updates to the FSAR are required by 10 CFR 50.71(e) to reflect changes made under section 50.59.

Section 50.59 is primarily a prospective requirement. The regulatory process is predicated on the assumption that when the license is issued, the facility, procedures, tests, and experiments will be as described in the FSAR. Many operating licenses contain a finding which states that the licensed facility is as described in the FSAR, as amended and revised. Section 50.59 requires a process to be followed in evaluating proposed changes from the description of the facility and its procedures described in the FSAR. However, section 50.59 is also used to form the basis for citations when the facility or procedures are subsequently found to not meet the description in the FSAR. These cases are referred to as "de facto changes" from the FSAR or to the facility.

A failure of the facility to conform to the FSAR (including cases where the FSAR contains inaccurate or incomplete information) may be a violation of 10 CFR 50.9. In addition, failure to meet a specific commitment described in the FSAR may be a violation of a particular regulatory requirement<sup>1</sup>.

Thus, there are a variety of requirements that can be used to form the basis for enforcement action to address departures from the FSAR. Each potential enforcement case is reviewed on its merits to determine which requirement, or set of requirements, is an appropriate basis for the enforcement action. Given a violation of an NRC requirement, the next step in the enforcement process is to determine the severity level of the violation based on the safety and regulatory significance of the violation. The Enforcement Policy provides definitions of severity levels (Section IV, Severity of Violations) and examples (Supplements I - VIII) which are used in categorizing the severity levels of violations.

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<sup>1</sup> In some cases, the departure from the FSAR, if it does not involve a change to the facility, procedures, or tests or experiments described in the FSAR, may not cause the licensee to be in violation of any legal requirement. In such cases, the departure from the FSAR would not be a violation.

This paper only addresses enforcement issues. Separate papers will be submitted addressing other issues associated with FSAR and 10 CFR 50.59 issues.<sup>2</sup>

### Discussion:

Given the variety of current discrepancies from the FSARs, the staff has developed additional guidance to address violations of 10 CFR 50.59 and 50.71(e). In developing this guidance, the staff considered the following two principles: (1) the importance of licensees performing appropriate evaluations to ensure that there are not unreviewed safety questions or conflicts with technical specifications, and (2) the importance of maintaining and controlling changes to the FSAR so that both the licensee and the NRC understand the regulatory envelope that has been established for the facility. The changes to the Enforcement Policy described below should make it clear to licensees that the Commission believes that failures in either area can be significant and can justify substantial regulatory action.

It should be recognized that not every unreviewed safety question is necessarily a significant safety issue. However, until the question is reviewed and understood, there is an uncertainty in the basis for the Commission's safety decision in licensing the plant. Therefore, regardless of the actual safety significance of the change, when there is an unreviewed safety question or a conflict with a technical specification, the failure to follow the regulatory process established by 10 CFR 50.59, is a significant regulatory concern. Licensees must ensure that they are in conformance with the FSAR as it was a key element for the basis for the Commission's decision in licensing the plant and continues to be an important consideration in current licensing actions. The enforcement process is a tool that the staff proposes the Commission use to emphasize the importance of achieving this conformance and deter violations from continuing in this area.

To achieve this the staff believes that additional guidance is warranted to address severity levels associated with departures from the FSAR and reporting requirements, and the adequacy of corrective actions. In addition, the staff, as described below, is proposing a "carrot and stick" approach to provide clear incentives for licensees to ensure conformance with the FSAR in accordance with 10 CFR 50.59 and 50.71(e).

#### 1. Severity Levels

The definitions and examples of severity levels in the current Enforcement

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<sup>2</sup> On July 1, 1996, the Commission was sent a letter from the Nuclear Energy Institute (NEI) which transmitted its analysis of the regulatory significance of FSARs and implementation of 10 CFR 50.59. Based on a brief review of the NEI analysis, the staff believes that NEI's analysis of the FSAR on the whole is consistent with the staff's. The staff is evaluating NEI's analysis of 10 CFR 50.59 implementation and will address it as part of the Section 50.59 Action Plan.

Policy provide sufficient guidance to cover most potential violations. Additional guidance would be helpful to address violations of 10 CFR 50.59 and 50.71(e) which are the requirements that likely will most often be used to address departures from the FSAR. Currently, two specific examples are provided to categorize violations of 10 CFR 50.59 in Supplement I, Reactor Operations, and no examples specifically address violations of 10 CFR 50.71(e).

The first example, I.C.5, provides that a Severity Level III violation would involve:

A significant failure to meet the requirements of 10 CFR 50.59, including a failure such that a required license amendment was not sought.

This example includes changes involving unreviewed safety questions and conflicts with technical specifications. It also includes situations not involving an unreviewed safety question where the licensee would need to perform a detailed evaluation before it would have had a reasonable expectation that an unreviewed safety question was not involved. This type of violation is significant because of the importance of licensees using the required process for maintaining and operating the facilities in accordance with the design and procedures described in the FSAR when there is uncertainty as to whether an unreviewed safety question is present. An after-the-fact evaluation that demonstrates that an unreviewed safety question was not involved would, in general, not mitigate the regulatory significance of failing to perform an appropriate evaluation prior to implementation of the change.

The second example, I.D.2, provides that a Severity Level IV violation would be a failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation.

Consistent with the above two principles, the staff has developed the enclosed proposed changes to the Enforcement Policy to provide additional examples to categorize severity levels for violations associated with failures to meet the FSAR. The current two examples described above are deleted and the following ten examples are proposed:

#### Severity Level II

One example of a Severity Level II problem (the term "problem" is used here since more than one violation is involved) is proposed. Example I.B.4<sup>3</sup> addresses inspection findings involving a number of failures to meet section 50.59 including several unreviewed safety questions, and/or conflicts with a technical specification, involving a broad spectrum of problems affecting

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<sup>3</sup> The staff has numbered the examples in accordance with the numbering used in the proposed changes to the Enforcement Policy.



multiple areas, some of which impact the operability of required equipment. This situation is of very significant concern, the definition of a Severity Level II problem, because of the breadth of the process failures and the impact on equipment operability as well as the licensing envelope.

As a separate issue, the staff notes that the base civil penalty for a Severity Level II violation or problem is \$80,000. Section VII.A.1.a of the Policy provides that discretion should be considered for Severity Level II cases. In assessing civil penalties for violations meeting this example, the staff intends, consistent with the Policy, to consider the number and nature of the violations and the breadth of the problem that warranted the Severity Level II categorization in determining whether civil penalties substantially in excess of the base amount are warranted.

### Severity Level III

Four examples of Severity Level III violations are proposed which in the staff's view demonstrate significant regulatory concerns, the definition of a Severity Level III violation:

Example I.C.10 involves an unreviewed safety question, and/or conflict with a technical specification. Example I.C.11 addresses the failure to perform the required evaluation under section 50.59 prior to implementation of the change in those situations in which an extensive evaluation would be needed before a licensee would have had a reasonable expectation that an unreviewed safety question did not exist. The fact that a post-implementation evaluation demonstrated that no unreviewed safety question existed would not mitigate the regulatory significance of the failure to perform the required evaluation prior to implementation of the change. These two examples encompass the prior example I.C.5. Example I.C.11 is set out as a separate example to give clearer notice.

Example I.C.12 addresses programmatic failures (i.e., multiple or recurring failures) to meet the requirements of section 50.59 and/or 50.71(e) which show a significant lack of attention to detail resulting in a current safety or regulatory concern about the accuracy of the FSAR or a current concern that section 50.59 requirements are not being met. This example highlights a programmatic concern with a current impact on the regulatory process.

Example I.C.13 addresses the failure to update the FSAR as required by 10 CFR 50.71(e) where the failure to update the FSAR resulted in an inadequate decision that demonstrates a significant regulatory concern. This example addresses a significant failure associated with section 50.71(e) where the violation adversely impacted other decisions such as a decision by a licensee on whether a license amendment is needed or a decision by the NRC on a licensing issue. An example of such a violation would be the

failure to update the FSAR to delete a reference to equipment that had been properly removed from the facility. As a result an inadequate decision was made that an unreviewed safety question was not present for a subsequent change to the facility based on the presumed presence of equipment that the FSAR erroneously indicated was still present in the plant.

#### Severity Level IV

Four examples of Severity Level IV violations are proposed that in the staff's view demonstrate violations of more than minor concern which, if left uncorrected, could become a more significant concern, the definition of a Severity Level IV violation:

Example I.D.5 addresses relatively isolated violations<sup>4</sup> of section 50.59 not involving severity level II or III violations that do not suggest a programmatic failure to meet section 50.59. Example I.D.6 addresses a relatively isolated failure to document an evaluation where there is evidence that an adequate evaluation was performed prior to the change in the facility or procedures, or the conduct of an experiment or test. Example I.D.7 addresses a failure to update the FSAR as required by 10 CFR 50.71(e) resulting in an inaccurate FSAR where an adequate evaluation under 10 CFR 50.59 had been performed and documented. These three examples are, by their nature, less significant than a Severity Level III violation.

Example I.D.8 addresses a past programmatic failure to meet section 50.59 and/ or section 50.71(e) requirements not involving Severity Level II or III violations that does not reflect a current safety or regulatory concern about the accuracy of the FSAR or a current concern that section 50.59 requirements are not being met. This example is similar to example I.C.12. However, it is less significant because it does not involve a current performance issue nor does it have a current impact. This would address past programmatic issues where both the cause and the impacts have been corrected.

The determination of whether a violation or grouping of violations should be categorized at severity level III or IV will require exercise of judgement to determine if the failures are sufficiently broad and programmatic to warrant a finding of significant regulatory concern. To maintain consistency and fairness, the staff intends to modify the Enforcement Manual to provide for coordination with the Office of Enforcement on severity level IV cases where

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<sup>4</sup> Relatively isolated violations or failures would include a number of recently discovered violations that occurred over a period of years and are not indicative of a programmatic problem with compliance with sections 50.59 or 50.71(e).

there is a potential to categorize the violations at a severity level III.

#### Minor Violations

An example is proposed to address minor violations which are not subject to formal enforcement action under the Enforcement Policy and are not normally addressed in inspection reports. Example I.E addresses a failure to meet section 50.59 requirements that involves a change to the FSAR description or procedure, or involves a test or experiment not described in the FSAR, where there was not a reasonable likelihood that the change to the facility or procedure or the conduct of the test or experiment would ever be an unreviewed safety question. The example also addresses a failure to meet section 50.71(e), where a failure to update the FSAR would not have a material impact on safety or licensed activities.

This example is provided because 10 CFR 50.59 covers the complete FSAR. However, there are some descriptions in the FSAR of the facility or procedures that have very little or no relevance to safety and are of little or no regulatory concern. Nevertheless, by the specific terms of the regulation, departures from such descriptions must be evaluated. Violations in these areas are by definition minor and if included in an inspection report would be non-cited pursuant to section VI of the Enforcement Policy such as a change to the location of sanitary sewer lines (in contrast to natural gas pipelines) in owner controlled areas. The focus of this example is on plant equipment, procedures, tests, or experiments described in the FSAR that would not reasonably have any impact on safety regardless of the change. If the change is to, or the test is on, equipment or procedures that have some safety purpose, the violation should normally be considered to be of more than a minor concern.

#### 2. Corrective Action

In accordance with the Enforcement Policy, corrective action is a key element in considering the appropriate sanction. The discussion of corrective action in Section VI.B.2.c. of the Enforcement Policy should be expanded to provide that in response to violations of section 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee (1) makes a prompt decision on operability, and either (2) makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the as found condition, or (3) promptly initiates corrective action consistent with Criterion XVI of 10 CFR 50, Appendix B if it intends to restore the facility or procedure to the FSAR description. It is important for licensees to recognize the need for these actions because until such actions are taken the violation continues unabated.

#### 3. Reporting

Section IV.D. of the Enforcement Policy provides that unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have

been reported. It is appropriate to clarify the Policy to make it clear that failure to make a required report under 10 CFR 50.72 and 50.73, if the matter not reported involves (1) an unreviewed safety question, (2) a conflict with a technical specification, or (3) any other Severity Level III violation, is a significant regulatory concern. The NRC needs such information concerning significant issues to carry out its regulatory responsibilities. Therefore, the staff proposes the following additional example to Supplement I, Reactor Operations:

Example I.C.14: A failure to make a report required by 10 CFR 50.72 or 50.73 associated with a) an unreviewed safety question, b) a conflict with a technical specification, or c) any other Severity Level III violation.

#### 4. Old Design Issues

Section VII.B.3 of the Enforcement Policy addresses enforcement discretion for old design issues and may be applicable to some 10 CFR 50.59 violations to the extent that voluntary action by a licensee identifies a past problem, such as in engineering, design, or installation. This discretion addresses violations that would not likely be identified by routine licensee efforts such as normal surveillance or quality assurance activities. Identification of past violations through required efforts would be treated using the normal policy.

This provision was originally adopted to encourage voluntary initiatives to establish design reconstitution programs such as licensee initiated safety systems functional inspections to identify and correct past design errors. This section places a premium on licensees identifying issues before degraded equipment is called upon to work. Similarly, application of this provision in the policy to past FSAR issues could encourage licensees to establish programs with goals to ensure full compliance with the FSAR licensing basis and determine if there are unreviewed safety questions that have not been identified and addressed. To justify the exercise of VII.B.3 discretion, licensees must take comprehensive corrective action. The policy provides that licensees should expand their reviews, as necessary, to identify other failures from similar root causes. Thus, in applying this discretion, as with any significant violation associated with 10 CFR 50.59 and 50.71(e), the licensee should be taking broad corrective action to ensure that the licensee is meeting its licensing basis. The corrective action should have a defined scope and schedule.

The staff proposes to utilize Section VII.B.3 of the Enforcement Policy to provide incentives to encourage licensees to identify and correct violations which are not normally identified through current surveillance and quality assurance activities. Enforcement action would normally not be taken against a licensee if the licensee identifies violations up to and including Severity Level II associated with the FSAR by a voluntary initiative (including either a formal program or informal effort where issues are identified through a questioning attitude of an employee), provided the licensee takes comprehensive corrective action and appropriately expands the scope of the voluntary initiative to identify other failures with similar root causes. If



the staff utilizes this enforcement discretion with regard to FSAR departures, the licensee's voluntary initiative must be described in writing and be publicly available. The staff will reference and summarize the licensee's voluntary initiative, including the scope and schedule for corrective action, in an inspection report and will follow the licensee's corrective action until complete as an inspection report open item.

Since the reason for utilizing this discretion is to encourage positive licensee performance in identifying and correcting violations associated with departures from the FSAR, the staff would not normally apply the Section VII.B.3 discretion if:

- a) The NRC identifies the violation unless it was likely in the staff's view that the licensee would have identified the violation in light of the defined scope, thoroughness and schedule of the licensee's initiative (provided the schedule provides for completion of the licensee's initiative within two years of this policy change);
- b) The licensee identifies the violation as a result of an event or surveillance or other required testing where required corrective action identifies the FSAR issue;
- c) The licensee identifies the violation but had prior opportunities to do so (was aware of the departure from the FSAR) and failed to correct it earlier;
- d) There is willfulness associated with the violation;
- e) The licensee fails to make a report required by the identification of the departure from the FSAR; or
- f) The licensee either fails to take comprehensive corrective action or fails to appropriately expand the corrective action program. The corrective action should be broad with a defined scope and schedule.

Applying this discretion should further the objectives of the Enforcement Policy to encourage identification and correction of violations as well as provide deterrence for future violations. While the staff does not believe a change to the Enforcement Policy is needed to apply this discretion to FSAR issues, a change to the policy is proposed to address when this discretion would not normally be applied.

The staff recognizes it is important to provide licensees with incentives to embark on voluntary initiatives to identify and correct FSAR discrepancies. However, licensees should be designing and implementing their programs with goals to have these discrepancies identified in the near term. Therefore, staff does not believe it is appropriate to continue indefinitely the granting of enforcement discretion in cases where the NRC identifies the violations. As provided above in item a, for NRC identified violations use of Section VII.B.3 enforcement discretion for FSAR discrepancies will consider the schedule for the licensee's voluntary initiative and when NRC identified the violation (assuming the Commission approves this approach). The two year period will provide a reasonable time period and incentive for licensees to plan and conduct appropriate reviews to ensure that their facilities meet the

descriptions in the FSAR and take necessary corrective action. The staff will continue to document in inspection reports the results of its inspections against the FSAR and other than the exception noted in item a, above, intends to continue enforcement for NRC-identified violations.

Following this two year period, if a Severity Level II or III violation is identified, the Commission should use its discretion and assess civil penalties for each such violation or problem using a base penalty of \$100,000 which may be escalated considering the number and nature of the violations, the severity of the violations, whether the violations were continuing, and who identified the violations (and if the licensee identified the violation, whether exercise of Section VII.B.3 enforcement discretion is warranted), rather than the normal assessment factors and base civil penalties. This approach is intended to increase the incentive for licensees to take timely action to ensure that their facilities match the FSAR. For example, if a single Severity Level III violation is identified by the NRC and it lasted for more than one day, a civil penalty of \$200,000 could be assessed. If the licensee identified the same violation and application of enforcement discretion under Section VII.B.3 was not warranted, a civil penalty of \$100,000 could be assessed which will provide some recognition of the licensee's efforts. Section VII. of the Enforcement Policy is proposed to be amended consistent with this approach.

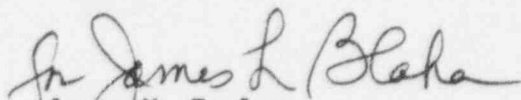
Coordination:

The Office of the General Counsel has no legal objection to this paper.

Recommendations:

The Commission approve the enclosed Federal Register notice for publication of revisions to the Enforcement Policy.

Note under the Small Business Regulatory Enforcement Fairness Act of 1996, the policy revision will need to be coordinated with OMB for its determination that this policy revision is not a major rulemaking and a copy provided to the Congress and GAO at the time of publication in the Federal Register.

  
James M. Taylor

Executive Director for Operations

Enclosure:

Draft Federal register  
Notice to change NUREG-1600

Commissioners' comments or cover it should be provided directly to the Office of the Secretary by COB Monday July 22, 1996.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT July 15, 1996, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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[NUREG - 1600]

Policy and Procedure for Enforcement Actions; Departures from FSAR

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: Revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its General Statement of Policy and Procedure for Enforcement Actions (Enforcement Policy) to address issues associated with departures from the Final Safety Analysis Report.

DATES: This revision is effective on [Date of Publication in the Federal Register]. Comments are due on or before (30 days after publication in the Federal Register).

ADDRESSEES: Send written comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch. Deliver comments to: 11555 Rockville Pike, Rockville,



Maryland 20852, between 7:45 am and 4:15 pm, on Federal workdays. Copies of comments may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301)-415-2741.

SUPPLEMENTARY INFORMATION:

As a result of increased regulatory attention to Part 50 licensees' adherence to the Final Safety Analysis Report and the Updated Final Safety Analysis Report (FSAR), both licensees and NRC have identified numerous failures to conform to these documents. Given these findings, the Commission has reviewed the current Enforcement Policy to determine if additional guidance is needed to treat compliance issues associated with departures from the FSAR. The Commission has concluded that the guidance in the current Enforcement Policy, NUREG-1600, published in the Federal Register (60 FR 34381; June 30, 1995) should be revised.

Many operating licenses contain a finding which states that the licensed facility is as described in the FSAR, as amended and revised. In accordance with 10 CFR 50.59, the Commission allows licensees to make changes to the facility or procedures described in the FSAR and to perform certain tests or experiments not described in the FSAR without prior NRC approval provided evaluations are performed to demonstrate that the change does not involve an

unreviewed safety question and the change does not conflict with a technical specification. Specifically, 10 CFR 50.59(a) provides:

The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test, or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question.

If an unreviewed safety question or a change to a technical specifications is involved, 10 CFR 50.59(c) requires that the licensee submit an application for a license amendment pursuant to 10 CFR 50.90, before making the change or departing from the FSAR.

Section 50.59(b) requires that the evaluation be documented in writing and maintained and reports of the changes be submitted to the Commission. Periodic updates to the FSAR are required by 10 CFR 50.71(e) to reflect changes made under 10 CFR 50.59.

The regulatory process is predicated on the assumption that when the license is issued, the facility, procedures, tests, and experiments will be as described in the FSAR. Thus, 10 CFR 50.59 is primarily a prospective requirement. Section 50.59 requires a process to be followed in evaluating

proposed changes from the description of the facility and its procedures described in the FSAR. However, 10 CFR 50.59 is also used to form the basis for citations when the facility or procedures never met the description in the FSAR. These cases represent de facto changes from the FSAR. A failure of the facility to conform to the FSAR may also mean that the FSAR may contain inaccurate or incomplete information, subjecting the licensee to enforcement action for a violation of 10 CFR 50.9.

In addition, failure to meet a specific commitment in the FSAR which describes how the licensee was to meet a regulatory requirement, may be a violation of that regulatory requirement. In some cases, the departure from the FSAR, if it does not involve a change to the facility, procedures, or tests or experiments described in the FSAR, may not cause the licensee to be in violation of any legal requirement. In such cases, the departure from the FSAR would not be a violation, and only a Notice of Deviation may be warranted.

Thus, there are a variety of requirements that can be used to form the basis for enforcement action to address departures from the FSAR. Each potential enforcement case is reviewed on its merits to determine which requirement, or set of requirements, is appropriate to base the enforcement action on. Given a violation of NRC requirements, the next step in the process is to determine the severity level of the violation based on the safety and regulatory significance of the violation. The Enforcement Policy provides definitions of severity levels (Section IV. Severity of Violations) and examples (Supplements I - VIII) which are used in categorizing the severity levels of violations.

regulatory process established by 10 CFR 50.59, regardless of the actual safety significance of the change, when there is an unreviewed safety question or a conflict with a technical specification, is a significant regulatory concern. Licensees must ensure that they are in conformance with the FSAR as it was a key element for the basis for the Commission's decision in licensing the plant and continues to be an important consideration in current licensing actions. The enforcement process is a tool that the Commission intends to use to emphasize the importance of achieving this conformance and deter violations from continuing in this area.

#### 1. Severity Levels

The definitions and examples of severity levels in the current Enforcement Policy provide sufficient guidance to cover most potential violations. Additional guidance is needed to address violations of 10 CFR 50.59 and 50.71(e) which are the requirements that likely will most often be used to address departures from the FSAR. Currently, two specific examples are provided to categorize violations of 10 CFR 50.59 in Supplement I, Reactor Operations and no examples specifically address violations of 10 CFR 50.71(e).

The first example, I.C.5, provides that a Severity Level III violation would involve:

A significant failure to meet the requirements of 10 CFR 50.59, including a failure such that a required license amendment was not sought.



## Revisions to the NRC Enforcement Policy

Given the variety of discrepancies from the FSARs that have been recently found, additional guidance has been developed to address severity levels to categorize violations of 10 CFR 50.59 and 50.71(e) and reporting requirements, application of the corrective action factor in Section VI.B.2.c. of the Enforcement Policy, use of Section VII.B.3 of the Enforcement Policy, Enforcement Discretion for Violations Involving Old Design Issues, and applying enforcement discretion to increase sanctions in this area under Section VII.A.2 of the Enforcement Policy.

In developing this guidance, the Commission considered the following two principles: (1) the importance of licensees performing appropriate evaluations to ensure that there are not unreviewed safety questions or conflicts with technical specifications, and (2) the importance of maintaining and controlling changes to the FSAR so that both the licensee and the NRC understand the regulatory envelope that has been established for the facility. The changes to the Enforcement Policy described below should make it clear to licensees that the Commission believes that failures in either area can be significant and can justify substantial regulatory action.

The Commission recognizes that not every unreviewed safety question is a significant safety issue. However, until the question is reviewed and understood, there is an uncertainty in the basis for the Commission's safety decision in licensing the plant. Therefore, the failure to follow the

## Severity Level II

One example of a Severity Level II problem (the term "problem" is used here since more than one violation is involved) is proposed. Example I.B.4<sup>1</sup> addresses inspection findings involving a number of failures to meet 10 CFR 50.59 including several unreviewed safety questions, and/or conflicts with a technical specification, involving a broad spectrum of problems affecting multiple areas, some of which impact the operability of required equipment. This situation is a very significant concern, the definition of a Severity Level II problem, because of the breadth of the process failures and the impact on equipment operability as well as the licensing envelope.

As to Severity Level II violations or problems, the Enforcement Policy provides that the base civil penalty for a Severity Level II violation or problem is \$80,000. However, Section VII.A.1.a of the Policy provides that discretion should be considered for Severity Level II cases. In assessing civil penalties for cases meeting the above example, discretion will be considered, consistent with the Policy, based on the number and nature of the violations and the breadth of the problem that warranted the Severity Level II categorization in determining whether civil penalties substantially in excess of the base amount are warranted. This will include consideration of assessing separate civil penalties for each violation that is aggregated into the Severity Level II problem.

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<sup>1</sup> The examples are numbered in accordance with the numbering used in the changes to the Enforcement Policy.

This example includes changes involving unreviewed safety questions and conflicts with technical specifications. It also includes situations not involving an unreviewed safety question where the licensee would need to perform a detailed evaluation before it would have had a reasonable expectation that an unreviewed safety question was not involved without the performance of a detailed evaluation. This is significant because of the importance of licensees using the required process for maintaining and operating the facilities in accordance with the design and procedures described in the FSAR when there is uncertainty as to whether an unreviewed safety question is present. An after-the-fact evaluation that demonstrates that an unreviewed safety question was not involved would, in general, not mitigate the regulatory significance of failing to perform an appropriate evaluation prior to implementation of the change.

The second example, I.D.2, provides that a Severity Level IV violation would be a failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation.

#### Revised Examples of Severity Levels

Consistent with the above two principles, the changes to the Enforcement Policy provide additional examples to categorize severity levels for violations associated with failures to meet the FSAR. The current two examples described above are deleted and the following ten examples are being added to the policy:

existed, b) the number of failures, c) whether one or more systems, functions, or pieces of equipment were involved and the importance of such equipment, functions, or systems, and d) the potential significance of the failures.

Example I.C.13. addresses the failure to update the FSAR as required by 10 CFR 50.71(e) where the failure to update the FSAR resulted in an inadequate decision that demonstrates a significant regulatory concern. This example addresses a significant failure associated with 10 CFR 50.71(e) where the violation adversely impacted other decisions such as whether or not a license amendment is needed or whether or not an NRC licensing action should be taken. An example of such a violation would be the failure to update the FSAR to delete a reference to equipment that had been properly removed from the facility. As a result an inadequate decision was made that an unreviewed safety question was not present for a subsequent change to the facility based on the presumed presence of equipment that the FSAR erroneously indicated was still present in the plant.

#### Severity Level IV

Four examples of Severity Level IV violations are added that demonstrate violations of more than minor concern which left uncorrected, could become a more significant concern, the definition of a Severity Level IV violation.

Example I.D.5 addresses relatively isolated violations<sup>2</sup> of 10 CFR 50.59

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<sup>2</sup> Relatively isolated violations or failures would include a number of recently discovered violations that occurred over a period of years and are not indicative of a programmatic safety concern with meeting the requirements



### Severity Level III

Four examples of Severity Level III violations are added that demonstrate a significant regulatory concern, the definition of a Severity Level III violation:

Example I.C.10 involves an unreviewed safety question, and/or conflict with a technical specification. Example I.C.11. addresses the failure to perform the required evaluation under section 50.59 prior to implementation of the change in those situations in which an extensive evaluation would be needed before a licensee would have had a reasonable expectation that an unreviewed safety question did not exist. The fact that a post-implementation evaluation demonstrated that no unreviewed safety question existed would not mitigate the regulatory significance of the failure to perform the required evaluation prior to implementation of the change. These two examples encompass the prior example I.C.5. Example I.C.11 is set out as a separate example to give clearer notice.

Example I.C.12 addresses programmatic failures (i.e., multiple or recurring failures) to meet the requirements of 10 CFR 50.59 and/or 50.71(e) which show a significant lack of attention to detail resulting in a current safety or regulatory concern about the accuracy of the FSAR or a concern that 10 CFR 50.59 requirements are not being met. This example addresses a current programmatic failure or past programmatic failure of current concern to meet 10 CFR 50.59 or 50.71(e). Application of this example requires weighing factors such as: a) the time period over which the violations occurred and

categorize the violations at a severity level III.

#### Minor Violations

An example is added to address minor violations which are not subject to formal enforcement action under the Enforcement Policy and are not normally addressed in inspection reports. Example I.E addresses a failure to meet 10 CFR 50.59 requirements that involves a change to the FSAR description or procedure, or involves a test or experiment not described in the FSAR, where there was not a reasonable likelihood that the change to the facility or procedure or the conduct of the test or experiment would ever be an unreviewed safety question. The example also addresses a failure to meet a 10 CFR 50.71(e) violation, where a failure to update the FSAR would not have a material impact on safety or licensed activities.

This example is provided because 10 CFR 50.59 covers the complete FSAR. However, there are some descriptions in the FSAR of the facility or procedures that have very little or no relevance to safety and are of little or no regulatory concern. Nevertheless, by the specific terms of the regulation, changes to the facility as described in the FSAR must be evaluated. Violations in these areas are by definition minor and if included in an inspection report would be non-cited pursuant to section VI of the Enforcement Policy such as a change to the location of sanitary sewer lines (in contrast to natural gas pipelines) in owner controlled areas. The focus of this example is on plant equipment, procedures, tests, or experiments described in the FSAR that would not reasonably have any impact on safety regardless of the

not involving severity level II or III violations that do not suggest a programmatic failure to meet 10 CFR 50.59. Example I.D.6 addresses a relatively isolated failure to document an evaluation where there is evidence that an adequate evaluation was performed prior to the change in the facility or procedures, or the conduct of an experiment or test. Example I.D.7 addresses a failure to update the FSAR as required by 10 CFR 50.71(e) where an adequate evaluation under 10 CFR 50.59 had been performed and documented. These three examples are, by their nature, less significant than a Severity Level III violation.

Example I.D.8 addresses a past programmatic failure to meet 10 CFR 50.59 and/or 10 CFR 50.71(e) requirements not involving Severity Level II or III violations that does not reflect a current safety or regulatory concern about the accuracy of the FSAR or a current concern that 10 CFR 50.59 requirements are not being met. This example is similar to example I.C.12. However, it is less significant because it does not involve a current performance issue nor does it have a current impact. This would address past programmatic issues where both the cause and the impacts have been corrected.

The determination of whether a violation or grouping of violations should be considered a severity level III or IV matter will require exercise of judgement to determine if the failures are sufficiently broad and programmatic to warrant a finding of significant regulatory concern. To maintain consistency and fairness, the regions will coordinate with the Office of Enforcement on severity level IV cases where there is a potential to

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of 10 CFR 50.59 or 50.71(e).

a required report under 10 CFR 50.72 and 50.73, if the matter not reported involves (i) an unreviewed safety question (ii) a conflict with a technical specification or (iii) any Severity Level III violation, is a significant regulatory concern. The NRC needs such information concerning significant issues to carry out its regulatory responsibilities.

#### 4. Old Design Issues

Section VII.B.3, Violations Involving Old Design Issues, of the Enforcement Policy addresses enforcement discretion for old design issues and may be applicable to some 10 CFR 50.59 violations to the extent that voluntary action by a licensee identifies a past problem, such as in engineering, design, or installation. This discretion addresses violations that would not likely be identified by routine licensee efforts such as normal surveillance or quality assurance activities. Identification of past violations through required efforts would be treated using the normal policy.

This provision was originally adopted to encourage voluntary initiatives to establish design reconstitution programs such as licensee initiated safety systems functional inspections to identify and correct past design errors. This section places a premium on licensees identifying issues before degraded equipment is called upon to work. Similarly, application of this provision in the policy to past FSAR issues could encourage licensees to establish programs with goals to ensure full compliance with the FSAR licensing basis and determine if there are unknown unreviewed safety questions that have not been identified and addressed. To justify the exercise of Section VII.B.3



change. If the change involves equipment, procedures and tests that have some safety purpose the violation should normally be considered to be of more than a minor concern.

## 2. Corrective Action

Corrective action is a key element in considering the appropriate sanction. The discussion of corrective action in Section VI.B.2.c. of the Enforcement Policy has been expanded to provide that in response to violations of 10 CFR 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee (1) makes a prompt decision on operability, and either (2) makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the as found condition, or (3) promptly initiates corrective action consistent with Criterion XVI of 10 CFR 50, Appendix B if it intends to restore the facility or procedure to the FSAR description. It is important for licensees to recognize the need for these actions because until such actions are taken the violation continues unabated.

## 3. Reporting

Section IV.D. of the Enforcement Policy provides that unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should be reported. The Policy has been clarified to make it clear that failure to make

from the FSAR if:

- a) The NRC identifies the violation unless it was likely in the staff's view that the licensee would have identified the violation in light of the defined scope, thoroughness, and schedule of the licensee's initiative (provided the schedule provides for completion of the licensee's initiative within two years of this policy change);
- b) The licensee identifies the violation as a result of an event or surveillance or other required testing where required corrective action identifies the FSAR issue;
- c) The licensee identifies the violation but had prior opportunities to do so (was aware of the departure from the FSAR) and failed to correct it earlier;
- d) There is willfulness associated with the violation;
- e) The licensee fails to make a report required by the identification of the departure from the FSAR; or
- f) The licensee either fails to take comprehensive corrective action or fails to appropriately expand the corrective action program. The corrective action should be broad with a defined scope and schedule.

Applying this discretion should further the objectives of the Enforcement Policy to encourage identification and correction of violations as well as provide deterrence for future violations.

The Commission recognizes the importance to provide licensees with incentives to embark on voluntary initiatives to identify and correct FSAR discrepancies. However, licensees should be designing and implementing their

discretion, licensees must take comprehensive corrective action. The policy provides that licensees should expand their reviews, as necessary, to identify other failures from similar root causes. Thus, in applying this discretion, as with any significant violation associated with 10 CFR 50.59 and 50.71(e), the licensee should be taking broad corrective action to ensure that the licensee is meeting its licensing basis. The corrective action should have a defined scope and schedule.

The Commission intends to utilize Section VII.B.3 of the Enforcement Policy to provide incentives to encourage licensees to identify and correct violations which are not normally identified through current surveillance and quality assurance activities. Enforcement action would normally not be taken against a licensee if the licensee identifies violations up to and including Severity Level II associated with the FSAR by a voluntary initiative (including either a formal program or informal effort where issues are identified through a questioning attitude of an employee), provided the licensee takes comprehensive corrective action and appropriately expands the scope of the voluntary initiative to identify other failures with similar root causes. If this enforcement discretion is utilized, the licensee's voluntary initiative must be described in writing and be publicly available. The staff will reference and summarize the licensee's voluntary initiative, including the scope and schedule for corrective action, in an inspection report and will follow the licensee's corrective action until complete as an inspection report open item.

Section VII.B.3 discretion would not normally be applied to departures

discretion under Section VII.B.3 was not warranted, a civil penalty of \$100,000 could be assessed which will provide some recognition of the licensee's efforts. Section VII.A.1 of the Enforcement Policy is being amended consistent with this approach.

#### Paperwork Statement

This policy statement does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0011. The approved information collection requirements contained in this policy statement appear in Section VII.C.

#### Public Protection Notification

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.

#### Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

programs with goals to have these discrepancies identified in the near term. Therefore, it is not appropriate to continue indefinitely the granting of enforcement discretion in cases where the NRC identifies the violations. As provided above in item a, for NRC identified violations use of Section VII.B.3 enforcement discretion for FSAR discrepancies will consider the schedule for the licensee's voluntary initiative and when NRC identified the violation. The two year period will provide a reasonable time period and incentive for licensees to plan and conduct appropriate reviews to ensure that their facilities meet the descriptions in the FSAR and take necessary corrective action. The staff will continue to document in inspection reports the results of its inspections against the FSAR and other than the exception noted in item a, above, will continue enforcement for NRC-identified violations.

Following this two year period, if a Severity Level II or III violation is identified, the Commission intends to use its discretion and assess civil penalties for each violation or problem using a base penalty of \$100,000 which may be escalated after considering the number and nature of the violations, the severity of the violations, whether the violations were continuing, and who identified the violations (and if the licensee identified the violation, whether exercise of Section VII.B.3 enforcement discretion is warranted), rather than the normal assessment factors and base civil penalties. This approach is intended to increase the incentive for licensees to take timely action to ensure that their facilities match the FSAR. For example, if a single Severity Level III violation is identified by the NRC and it lasted for more than one day, a civil penalty of \$200,000 could be assessed. If the licensee identified the same violation and application of enforcement



2. In Section VII., add the following language as paragraph h. at the end of paragraph A.1.g.:

VII Exercise of Discretion

A. Escalation of Enforcement Sanctions.\* \* \*

h. Severity Level II or III violations associated with departures from the Final Safety Analysis Report identified after two years from [date of this Federal Register Notice]. Such a violation or problem would be assessed using a base civil penalty of \$100,000 and consider the number and nature of the violations, the severity of the violations, whether the violations were continuing, and who identified the violations (and if the licensee identified the violation, whether exercise of Section VII.B.3 enforcement discretion is warranted).

\* \* \* \* \*

3. In Section VII. add at the end of paragraph B.3:

B. Mitigation of Enforcement Sanctions.\* \* \*

3. Violations Involving Old Design Issues.\* \* \*

\* \* \* \* \*

Section VII.B.3 discretion would not normally be applied to departures from the FSAR if:

a) The NRC identifies the violation unless it was likely in the

Accordingly, the NRC Enforcement Policy is amended as follows:

#### GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

1. In Section VI., add the following language at the end of paragraph B.2.c.

#### VI. Enforcement Actions

\* \* \* \* \*

B. Civil Penalty. \* \* \*

2. Civil Penalty assessment. \* \* \*

c. Credit for prompt and comprehensive corrective action\* \* \*

In response to violations of 10 CFR 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee

(i) Makes a prompt decision on operability; and either

(ii) Makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the as found condition; or

(iii) Promptly initiates corrective action consistent with Criterion XVI of 10 CFR 50, Appendix B if it intends to restore the facility or procedure to the FSAR description.

\* \* \* \* \*

\* \* \* \* \*

4. Failures to meet 10 CFR 50.59 including several unreviewed safety questions, or conflicts with technical specifications, involving a broad spectrum of problems affecting multiple areas, some of which impact the operability of required equipment.

C. Severity Level III - Violations involving for example:

\* \* \* \* \*

5. [Reserved]

\* \* \* \* \*

10. The failure to meet 10 CFR 50.59 where an unreviewed safety question is involved, or a conflict with a technical specification, such that a license amendment is required;

11. The failure to perform the required evaluation under 10 CFR 50.59 prior to implementation of the change in those situations in which no unreviewed safety question existed, but an extensive evaluation would be needed before a licensee would have had a reasonable expectation that an unreviewed safety question did not exist;

12. Programmatic failures (i.e., multiple or recurring failures) to

staff's view that the licensee would have identified the violation in light of the defined scope, thoroughness, and schedule of the licensee's initiative (provided the schedule provides for completion of the licensee's initiative within two years after [date of this Federal Register Notice;

- b) The licensee identifies the violation as a result of an event or surveillance or other required testing where required corrective action identifies the FSAR issue;
- c) The licensee identifies the violation but had prior opportunities to do so (was aware of the departure from the FSAR) and failed to correct it earlier;
- d) There is willfulness associated with the violation;
- e) The licensee fails to make a report required by the identification of the departure from the FSAR; or
- f) The licensee either fails to take comprehensive corrective action or fails to appropriately expand the corrective action program. The corrective action should be broad with a defined scope and schedule.

4. In Supplement I, paragraphs C(5) and D(2); are removed and paragraphs B(4), C(10), C(11), C(12), C(13), C(14), D(5), D(6), D(7), D(8) and E are added to read as follows:

#### Supplement I - Reactor Operations

B. Severity Level II - Violations involving for example:

meet the requirements of 10 CFR 50.59 and/or 50.71(e) that show a significant lack of attention to detail, whether or not such failures involve an unreviewed safety question, resulting in a current safety or regulatory concern about the accuracy of the FSAR or a concern that 10 CFR 50.59 requirements are not being met. Application of this example requires weighing factors such as: a) the time period over which the violations occurred and existed, b) the number of failures, c) whether one or more systems, functions, or pieces of equipment were involved and the importance of such equipment, functions, or systems, and d) the potential significance of the failures;

13. The failure to update the FSAR as required by 10 CFR 50.71(e) where the unupdated FSAR was used in performing a 10 CFR 50.59 evaluation and as a result, an inadequate decision was made demonstrating a significant regulatory concern; or

14. The failure to make a report required by 10 CFR 50.72 or 50.73 associated with (a) an unreviewed safety question, (b) a conflict with a technical specification, or (c) any other Severity Level III violation.

D. Severity Level IV - Violations involving for example:

\* \* \* \* \*

2. [Reserved]

\* \* \* \* \*



5. Relatively isolated violations of 10 CFR 50.59 not involving severity level II or III violations that do not suggest a programmatic failure to meet 10 CFR 50.59. Relatively isolated violations or failures would include a number of recently discovered violations that occurred over a period of years and are not indicative of a programmatic safety concern with meeting 10 CFR 50.59 or 50.71(e);

6. A relatively isolated failure to document an evaluation where there is evidence that an adequate evaluation was performed prior to the change in the facility or procedures, or the conduct of an experiment or test;

7. A failure to update the FSAR as required by 10 CFR 50.71(e) where an adequate evaluation under 10 CFR 50.59 had been performed and documented;  
or

8. A past programmatic failure to meet 10 CFR 50.59 and/or 10 CFR 50.71(e) requirements not involving Severity Level II or III violations that does not reflect a current safety or regulatory concern about the accuracy of the FSAR or a concern that 10 CFR 50.59 requirements are not being met.

#### E. Minor Violations

A failure to meet 10 CFR 50.59 requirements that involves a change to the FSAR description or procedure, or involves a test or experiment not described in the FSAR, where there was not a reasonable likelihood that the change to the facility or procedure or the conduct of the test or experiment

would ever be an unreviewed safety question. In the case of a 10 CFR 50.71(e) violation, where a failure to update the FSAR would not have a material impact on safety or licensed activities. The focus of the minor violation is not on the actual change, test, or experiment, but on the potential safety role of the system, equipment, etc that is being changed, tested, or experimented on.

\* \* \* \* \*

Dated at Rockville, MD, this day of \_\_\_\_\_, 1996.

FOR THE NUCLEAR REGULATORY COMMISSION

\_\_\_\_\_  
John C. Hoyle,  
Secretary of the Commission.