



NRC and Licensee

Actions in Response to New Information From a Third Party

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March 14, 2012



Purpose

- Review the existing regulatory programs and guidance that licensees may consider when dealing with information from a third-party.
- Review potential actions that the NRC may take in response to those licensee actions

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Agenda

- Sources of Information
- Expected Licensee Actions
- NRC Response to Licensee Actions
 - When the licensee has addressed the information
 - When the licensee has not addressed the information

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Definition of Third-Party Information

- Third-Party Information is information that is not from the NRC or the Industry
- Examples
 - U.S. Army Corp of Engineers revising flood levels
 - Discovery of a new fault line by the US Geological Survey*

*Depending on who is sponsoring the study, it may not be independent of the NRC or industry.



Licensee Actions



Licensee Actions

- There is no explicit requirement for licensees to determine if there is a safety issue
- Applicable Regulatory Processes For Assessing Information:
 - Appendix B, Criterion 16, Corrective Actions
 - Operability Determination
 - 50.59
 - Quality Assurance Program
 - Updating the FSAR (10 CFR 50.71(e))



Corrective Action Program

- Regulatory criteria
 - 10 CFR Appendix B, XVI, Corrective Actions: "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."
- Applies to:
 - Anything with a significant condition adverse to quality
- Use when:
 - New information calls into question the quality

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Operability Determination

- Regulatory guidance:
 - Regulatory Issue Summary 2005-20
 - Attachment to RIS 2005-20, Operability Determinations & Functionality Assessments for Resolution of Degraded or Nonconforming Conditions Adverse to Quality or Safety, which is in the NRC Inspection Manual under Part 9900,
- Applies to:
 - Structures, Systems, and Components
- Use when:
 - New information calls into question the ability of an SSC to perform its specified safety function

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50.59 Evaluation

- Regulatory criteria
 - 50.59 prescribes when a licensee is able to make changes to the FSAR without prior NRC approval and when a license amendment request may be needed
 - NEI 96-07 provides an acceptable method of meeting 50.59
- Applies to (among other items):
 - Changes in the facility as described in the FSAR, which includes design and performance requirements for certain SSC
- Use when:
 - New information affects the performance requirements for certain SSC

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Quality Assurance Program Requirements

- Regulatory criteria:
 - Most licensees are required by tech specs to have procedures as recommended in Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)"
 - Lists of systems that must have procedures
 - Procedures for combating emergencies and other Significant Events
 - Includes "Acts of Nature (e.g., tornado, flood, dam failure, earthquakes)"
 - Applies to:
 - Procedures
 - Use if:
 - New information that could reasonably affect one of those systems or the procedures for combating an emergency

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10 CFR 50.71(e)

Requirements to Update the FSAR

"The submittal shall include the effects of all changes made in the facility or procedures as described in the FSAR;

all safety analyses and evaluations performed by the applicant or licensee

either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with 50.59(c)(2) or, in the case of a license that references a certified design, in accordance with § 52.98(c) of this chapter; and

all analyses of new safety issues performed by or on behalf of the applicant or licensee at Commission request."

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Guidance for Licensees

- Federal Register Notice for Issuance of the Final Rule (45 FR 30614) Requiring Periodic FSAR Updates:
 - The licensee **does not need** to report minor changes in the site environment unless the safety analysis is affected and a new analysis was performed as a result of NRC Requirements.
- Generic Letter 81-06, "Periodic Updating of Final Safety Analysis Reports (FSARs)"
 - The licensee **does not need** to update superseded references nor perform an analysis based on them just to comply with 10 CFR 50.71(e). However, if safety considerations require it, the licensee **should** perform an analysis.
- NEI 98-03, Rev. 1, "Guidelines for Updating Final Safety Analysis Reports"
 - "The intent of the rule is that licensees only update those portions that have been affected by licensee activities since the previous update"
 - "Licensees **should** evaluate potentially significant changes in the site environs."

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NRC Response to Licensee Actions

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If the Licensee does perform an evaluation. .

- The NRC may find out about it through reporting requirements or updates to the FSAR.
- Two issues to consider:
 - Whether or not the NRC agrees with the licensee's conclusions
 - Whether or not the licensee updated its FSAR, if needed.
- The NRC determines through inspection or evaluation, as appropriate, whether adequate safety and compliance is maintained with regard to the licensee's conclusions.
- If the NRC does not believe that adequate safety and compliance is maintained, then the matter may be subject to enforcement action in accordance with applicable regulatory procedures and the Enforcement Policy.
- The NRC may issue an order to correct any safety issues.
- The licensee is expected to update its FSAR as needed.

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Potential Violations

- If the licensee was supposed to update the FSAR and did not, it would be considered a potential violation.
- The failure of a licensee to update its FSAR could impact the NRC's ability to perform its regulatory function, therefore it is treated under traditional enforcement.
- If the licensee does not correct the issue after receiving the Notice of Violation, the NRC may issue an order to change the design basis accordingly.

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If the licensee does not perform an evaluation

- Issue an Information Notice (IN) and follow up on the licensee's use of the Corrective Action Program..
 - Licensees do not have to enter the information into their corrective action program—but they may do so anyway.
 - "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected." (10 CFR 10 CFR Appendix B, XVI)
 - No written response is required to an Information Notice.
 - It could lead to an FSAR update.

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Key Messages

- The NRC expects the licensee to address any new information from a third party that could affect the plant, but there is no requirement to address it solely because a third party originated it. Rather, the licensee should determine if the information should be considered under any of the existing, applicable regulatory processes.
- Applicable regulatory processes include operability determinations, 10 CFR 50.59, Corrective Actions, and Quality Assurance Program
- The NRC may prompt the licensee to do an evaluation issuing a 50.54(f) Letter or, for multiple plants, by using Generic Communications.
- The regulations in 50.71(e) do not require a licensee to update its FSAR based on new third-party information. However, if the licensee or its representatives perform an evaluation or analysis of the information, the licensee may need to include it in its corrective action program and updates to the FSAR and applicable station procedures.
- If the NRC disagrees with the licensee's evaluation and believes that changes should be made, regulatory tools are available to address this issue.

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Backup Slides

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References

Corrective Action Program	<ul style="list-style-type: none">• Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50• NUREG-0737, "Clarification of TMI Action Plan Requirements" (ML051400209)
Operability Determinations	<ul style="list-style-type: none">• NRC Regulatory Issue Summary 2005-20, "Revision to NRC Inspection Manual Part 9900 Technical Guidance, 'Operability Determinations & Functionality Assessments for Resolution of Degraded or Nonconforming Conditions Adverse to Quality or Safety'" (ML073440103)• Attachment to RIS 2005-20: "NRC Inspection Manual, Part 9900: Technical Guidance, 'Operability Determinations & Functionality Assessments for Resolution of Degraded or Nonconforming Conditions Adverse to Quality or Safety'" (ML073531346)
10 CFR 50.59 Evaluations	<ul style="list-style-type: none">• 10 CFR 50.59, "Changes, Tests and Experiments"• NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation" (ML003771157)



References

Quality Assurance Program Requirements (Regulatory Guide 1.33)	<ul style="list-style-type: none">• Refer to the individual plant's technical specifications to determine if Regulatory Guide 1.33 applies.• NRC Regulatory Guide 1.33, "Quality Assurance Program Requirements Operation)" (ML003739995)
Updating the FSAR	<ul style="list-style-type: none">• 10 CFR 50.71(e)• <i>Federal Register</i> notice for issuance of 10 CFR 50.71(e) (45 FR 30614; May 9, 1980)• Generic Letter 81-06, "Periodic Updating of Final Safety Analysis Reports (FSARs)" (Microfiche 07976:332-344)• NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports," Revision 1 (ML003779028)
10 CFR 50.54(f) Letter	<ul style="list-style-type: none">• 10 CFR 50.54(f)• NRR Office Instruction LIC-503, "Generic Communications Affecting Nuclear Reactor Licensees" (ML043150304)
Generic Communications	<ul style="list-style-type: none">• Management Directive 8.18, "NRC Generic Communications Program"• SECY-99-143, "Revisions to Generic Communications Program"



Acronyms

FSAR- Final Safety Analysis Report

RIS- Regulatory Information
Summary

NEI- Nuclear Energy Institute
