

NRC and Licensee Actions in Response to New Information from a Third Party

Lauren Gibson
Project Manager
NRR/DORL/LPL4

1. Introduction

Occasionally, a third party will release information that may affect the information that is currently in a plant's Final Safety Analysis Report (FSAR). The nature of the new or updated information and its potential impact on the licensee's facility will determine how and whether licensees and the U.S. Nuclear Regulatory Commission (NRC) must react to that information. This white paper discusses the potential sources of third-party information, the licensee's expected actions in response to the third-party information, and the NRC's options to ensure licensee consideration of third-party information. In order to serve as a convenient reference guide, this white paper consolidates guidance found in several relevant sources; it contains no new guidance.

2. Sources of Information

Licensees may receive new information from a variety of sources, some of which are considered to be a third party and some of which are not. The following is not considered to be third party information: information received from the NRC or industry groups; information received through NRC processes such as generic communications, reports under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," or reports under 10 CFR 50.73, "Licensee Event Report System"; or information received from the nuclear reactor owners' groups, Nuclear Energy Institute (NEI), Electric Power Research Institute, or the Institute of Nuclear Power Operations. The NRC generally expects licensees to

know about information that originates from these non-third-party sources. However, new information could also potentially come from a third party with no affiliation to the NRC or the licensee, such as a university or the U.S. Geological Survey. Examples of a third party releasing new information that could potentially affect a licensee include the U.S. Army Corps of Engineers issuing revised flood levels for a river basin or a new fault line being discovered near a nuclear power plant. In all cases of new third-party information, the appropriate response depends on the potential impact of the information on the facility.

3. NRC Expectations of Licensees

The NRC has no explicit requirement for licensees to determine whether the third-party information raises a safety issue. However, licensees may consider third-party information through several regulatory processes, including the following:

- corrective actions (Criterion XVI, “Corrective Action,” in Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”)
- operability determinations as described in NRC Regulatory Issue Summary (RIS) 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,’” Revision 1, dated April 16, 2008
- 10 CFR 50.59, “Changes, Tests and Experiments”

- NRC Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation),” Revision 2, issued February 1978 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML003739995)

Licensees should also consider updating their FSARs in accordance with 10 CFR 50.71(e).

Licensees typically use the corrective action program (CAP) when new information comes to light, but not all third-party information would necessarily fall into this program. According to Criterion XVI in Appendix B to 10 CFR Part 50, licensees use this program to identify and correct conditions adverse to quality, including failures, malfunctions, deviations, defective material and equipment, and nonconformances. For example, licensees would generally enter into the CAP new information calling into question the safety of a valve; however, the revision of flood levels around a plant may or may not lead to a condition adverse to quality.

Prior to or concurrently with entering the issue into the CAP, the licensee may perform an operability determination for nonconformance. This applies to structures, systems, and components (SSCs) and should be done if the new information casts doubt on the ability of an SSC to perform its safety function. NRC RIS 2005-20 provides more information on operability determinations.

The licensee may also consider performing an evaluation under 10 CFR 50.59. It would do so if the new information has the potential to prompt a change in the facility as described in the FSAR, which includes design and performance requirements for certain SSCs. The regulations in 10 CFR 50.59 establish the conditions under which licensees may make changes to the facility or procedures and conduct tests or experiments without prior NRC approval. NEI 96-07, “Guidelines for 10 CFR 50.59 Implementation,” Revision 1, dated November 17, 2000 (ADAMS

Accession No. ML003771157), provides an acceptable method for licensees to comply with 10 CFR 50.59, as the NRC staff stated in Regulatory Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," issued November 2000 (ADAMS Accession No. ML003759710).

The circumstances may also warrant licensee consideration of other, more narrow regulatory requirements. For example, licensees should consider whether the new information impacts their quality assurance programs, based on the requirements for such programs in Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50.

Licensees may also be required to consider the impact on their procedures of changes to their licensing or design basis. Most licensees are required by their technical specifications to have procedures in accordance with Regulatory Guide 1.33. This regulatory guide lists the systems for which procedures are required. It also states that licensees should have procedures for combating emergencies and other significant events. Therefore, if a licensee is aware of new, third-party information that could potentially affect a system for which procedures are required or a procedure used in combating an emergency, and the licensee has updated its licensing or design basis to reflect that information, then the technical specifications would require the licensee to evaluate its procedures and update them, as necessary, in accordance with the requirements of its quality assurance program.

The licensee must also determine whether it needs to update its FSAR in accordance with the requirements in 10 CFR 50.71(e), which states, in part, the following:

This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the applicant or licensee or prepared by the applicant or licensee pursuant to Commission requirement since the

submittal of the original FSAR, or as appropriate, the last update to the FSAR under this section. The submittal shall include the effects¹ 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.

¹ Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

Therefore, the licensee needs to update the FSAR in response to analyses and evaluations that were performed by or on behalf of the licensee under any of the regulatory processes discussed above or at the Commission's request. FSAR updates do not need to include any analysis prepared by the licensee that was not made under a regulatory process discussed herein or upon the Commission's request. The regulation at 10 CFR 50.71(e) does not state explicitly that a licensee must incorporate the results of a third-party study. However, if the licensee were required to evaluate an external study under any of the regulatory processes discussed above, then that evaluation would be captured under the licensee actions that would be included when it updates the FSAR.

Additional sources provide further explanation for when the agency expects a licensee to update its FSAR based on information from a third party. Specifically, the Statements of Consideration in the *Federal Register* (45 FR 30614; May 9, 1980) for 10 CFR 50.71(e) state, in part, the following:

Minor differences between actual and projected population figures or other such changes in the site environment need not be reported unless the conclusions of safety analyses relative to public health and safety are affected and the licensee has prepared new analyses as a result of NRC requirements.

Generic Letter 81-06, "Periodic Updating of Final Safety Analysis Reports (FSARs)," dated February 26, 1981 (ADAMS Accession No. ML031080517), includes questions and answers about the rule. One question asks whether a licensee must change its FSAR if references within the document are no longer in use or acceptable in industry. In response, the NRC staff stated the following:

New analyses do not have to be performed and new references do not have to be incorporated just to comply with this rule. Analyses should be revised if safety (i.e., 10 CFR § 50.59) or other considerations require such revision.

NEI 98-03, "Guidelines for Updating Final Safety Analysis Reports," Revision 1, issued June 1999, which the NRC endorsed in Regulatory Guide 1.181, "Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," issued September 1999 (ADAMS Accession Nos. ML003779028 and ML003740112, respectively), provides a similar understanding. Appendix A to NEI 98-03, Revision 1, states, in part, the following:

[L]icensees should evaluate potentially significant changes in the site environs, e.g., a new natural gas line within the site boundary or a major new industrial facility near the plant site, to determine if notification of NRC and appropriate update of the UFSAR are required. For example, 10 CFR 50.9 requires licensees to "notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security."

However, Section 6.1 of NEI 98-03 states that "...the intent of the rule [10 CFR 50.71(e)] is that licensees update only those portions that have been affected by licensee activities since the previous update." This document is, therefore, internally inconsistent with respect to the inclusion and consideration of third-party information in the FSAR.

An NRC staff position is stated in a nonpublic memorandum dated September 5, 1995 (Microfiche Location 72641:090-111), entitled, "Licensee Evaluations of Changes to the

Environs of Licensed Reactor Facilities,” from the director of the License Renewal and Environmental Review Project Directorate in the Office of Nuclear Reactor Regulation (NRR) to the NRR Office Director. The memorandum documents the results of inspections based on a temporary instruction whose purpose, as stated in the memorandum, was to “gather information considering the need for additional regulatory requirements to ensure that licensees are adequately evaluating changes to the facility environs and updating their Final Safety Analysis Reports.” The memorandum makes the following conclusion:

Section 50.71(e) of 10 CFR already requires that licensees maintain a current and accurate FSAR. This regulation provides sufficient regulatory basis for staff expectations that licensees review changes to the site environs along with the other changes to the facility for incorporation into the FSAR.

This is based on the inspection not identifying significant safety concerns that licensees had not taken into account when updating their FSARs. This may result more from encouragement from NRC staff rather than any apparent regulatory requirement.

The above guidance documents interpret the rule and are not regulatory requirements. While it is clear that the NRC expects licensees to update their FSARs in response to new safety-significant information, it is not a requirement. If existing regulatory processes require the licensee to evaluate the information, then the licensee may be required to update its FSAR as a result of those evaluations.

4. NRC Considerations if the Licensee Performs an Evaluation

If the licensee performs an evaluation based on third-party information under any of the applicable regulatory requirements discussed above, then the NRC has two main issues to consider (the case of a licensee not performing an evaluation will be discussed later):

(1) whether or not the NRC agrees with the licensee's conclusions and (2) whether or not the licensee updated its FSAR and procedures, if required.

The NRC would normally use inspection or evaluation, as appropriate, to determine whether adequate safety, security, and compliance are maintained with regard to the licensee's conclusions. If the NRC concludes that the licensee is not in compliance with regulatory requirements, it may take enforcement action in accordance with applicable regulatory procedures and the NRC Enforcement Manual, Revision 7, dated October 1, 2010 (ADAMS Accession No. ML102630150). Furthermore, if the NRC does not believe that the licensee has maintained adequate safety, security, and compliance, then the agency must issue an order to correct the safety issue.

The licensee and NRC staff may disagree on the need to update the FSAR. If the licensee was supposed to update the FSAR and did not, it would be considered a potential violation under traditional enforcement and the NRC Enforcement Policy should be followed. Potential violations of 10 CFR 50.71(e) are considered under traditional enforcement because the licensee's failure to update its FSAR could impact the NRC's ability to perform its regulatory function. The revised NRC Enforcement Policy, July 12, 2011 (ADAMS Accession No. ML093480037) provides two examples related to a violation of 10 CFR 50.71(e). The first is a Severity Level IV violation if the licensee fails to update the FSAR and "the erroneous information is not used to make an unacceptable change to the facility or procedures." If the erroneous information (i.e., not updated) is used to make an unacceptable change, however, it could become a Severity Level III violation, as described in the following example from the enforcement policy:

A licensee fails to update the FSAR as required by 10 CFR 50.71(e), and the un-updated FSAR is used to perform a 10 CFR 50.59 evaluation for a change to the facility or procedures, implemented without Commission approval, that results in a condition evaluated as having low-to-moderate or greater safety significance (i.e., white, yellow, or red) by the SDP [significance determination process].

The primary consideration is whether or not the licensee's failure to update the FSAR led to a condition of safety significance. If a licensee does not correct the issue after receiving the Notice of Violation, then the NRC may issue an order to change the licensing basis accordingly.

5. NRC Actions if the Licensee Does Not Perform an Evaluation

If the licensee does not perform an evaluation of the new third-party information, the NRC has several options. The following options derive from its regulatory authority.

The NRC may prompt the licensee to evaluate the information by issuing a letter under 10 CFR 50.54(f). 10 CFR 50.54(f) authorizes the NRC to require a licensee to provide information so that the agency may determine whether or not the license should be modified, suspended, or revoked. It requires the NRC to justify a request in some situations. Specifically, 10 CFR 50.54(f) states the following:

Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

NRR Office Instruction LIC-503, “Generic Communications Affecting Nuclear Reactor Licensees,” Revision 2 (ADAMS Accession No. ML043150304), provides additional guidance on the use of 10 CFR 50.54(f) and warns against the frequent use of this method without sufficient regard to safety significance.

The NRC may also use a generic letter to solicit responses if the new information applies to multiple plants. If the agency solicits responses, the regulatory authority for requiring a licensee to respond to a generic letter is also 10 CFR 50.54(f).¹ If the question is compliance with regulations, 10 CFR 50.54(f) does not require justification or consideration of safety significance. If the 10 CFR 50.54(f) request goes beyond verifying compliance, then the staff must justify the request in light of the potential safety significance. The staff need not be sure that the issue is safety significant. Rather, the staff needs to believe that the issue is potentially safety significant. In some cases, the issue may lack safety significance or sufficient risk to expend staff resources. In those cases, a 10 CFR 50.54(f) letter or a generic letter may not be appropriate.

Instead, the NRC may wish to issue an information notice (IN). The staff could then follow up on the licensee’s evaluation of the IN through its CAP. An IN can be issued relatively quickly. However, licensees do not necessarily have to enter the information into the CAP. The agency expects licensees to do a preliminary evaluation to decide whether or not the information is a potential condition adverse to quality that should be entered into the CAP. The CAP is used to address conditions adverse to quality; this designation may or may not apply, depending on the information. In addition, INs do not require a response. Consequently, it could be labor intensive for the NRC staff to follow up on the issue effectively and efficiently. The other forms

¹ For the purposes of this paper, the term “10 CFR 50.54(f) letter” refers to a letter sent to only one licensee, while a generic letter is its equivalent sent to multiple licensees. Both are requests under 10 CFR 50.54(f).

of generic communications, bulletins and Regulatory Information Summaries (RISs), may also be appropriate methods to address the issue. The agency uses bulletins for the most important and time-sensitive issues; they require a response. It uses RISs to communicate with the stakeholders on a wide variety of matters; they do not include a request for action or information unless it is strictly voluntary. Management Directive 8.18, "NRC Generic Communications Program," dated March 5, 2009, provides more information on generic communications.

6. Conclusion

The NRC expects licensees to address new information from a third party that could affect the plant, but it has no clear requirement that licensees address new third-party information of which they become aware. Licensees should determine whether the information should be considered under any of the existing, applicable regulatory requirements. Examples of such programs are operability determinations, 10 CFR 50.59 evaluations, corrective actions under Criterion XVI of Appendix B to 10 CFR Part 50, and quality assurance program requirements. The NRC may prompt a licensee to do an evaluation by using a 10 CFR 50.54(f) letter or, for multiple plants, generic communications.

Furthermore, the licensee should consider whether or not to update its FSAR as a result of new third-party information that could have a safety impact on the plant. The regulations in 10 CFR 50.71(e) do not specifically require a licensee to update its FSAR based on new third-party information. However, if the licensee (or its representatives) performs an evaluation or analysis of the new information to satisfy an NRC requirement or at the request of the NRC, the licensee may need to update the FSAR based on the results of the evaluation or analysis. If the NRC disagrees with the licensee's evaluation and believes that the licensee should make

changes to the FSAR in accordance with NRC requirements, including those in 10 CFR 50.71(e), regulatory processes are available to address the issue.

7. Path Forward

Appendix A contains references for the regulatory processes. Appendices B and C contain flow charts depicting the content of the White Paper. Appendix B describes “Licensee Actions to Address Third-Party Information” while Appendix C covers “NRC Response to Licensee Actions to Address Third-Party Information.”

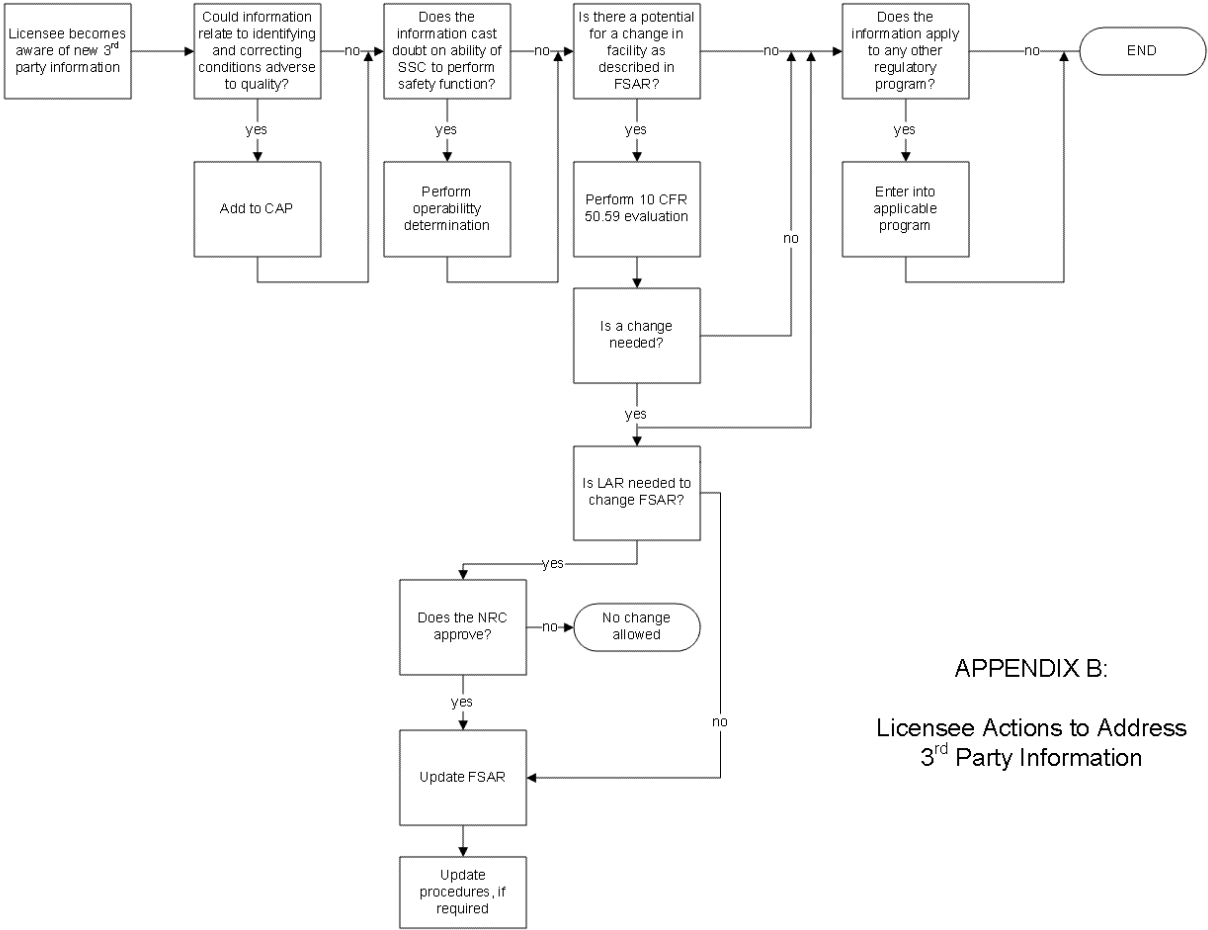
More comprehensive event tree(s) are now under development in the Office of Nuclear Reactor Regulation. The plan is for those to include all types of new information, not just third-party, and to further develop the key decision points.

Appendix A References for Regulatory Processes

The references below provide additional information on the regulations and guidance discussed in this paper.

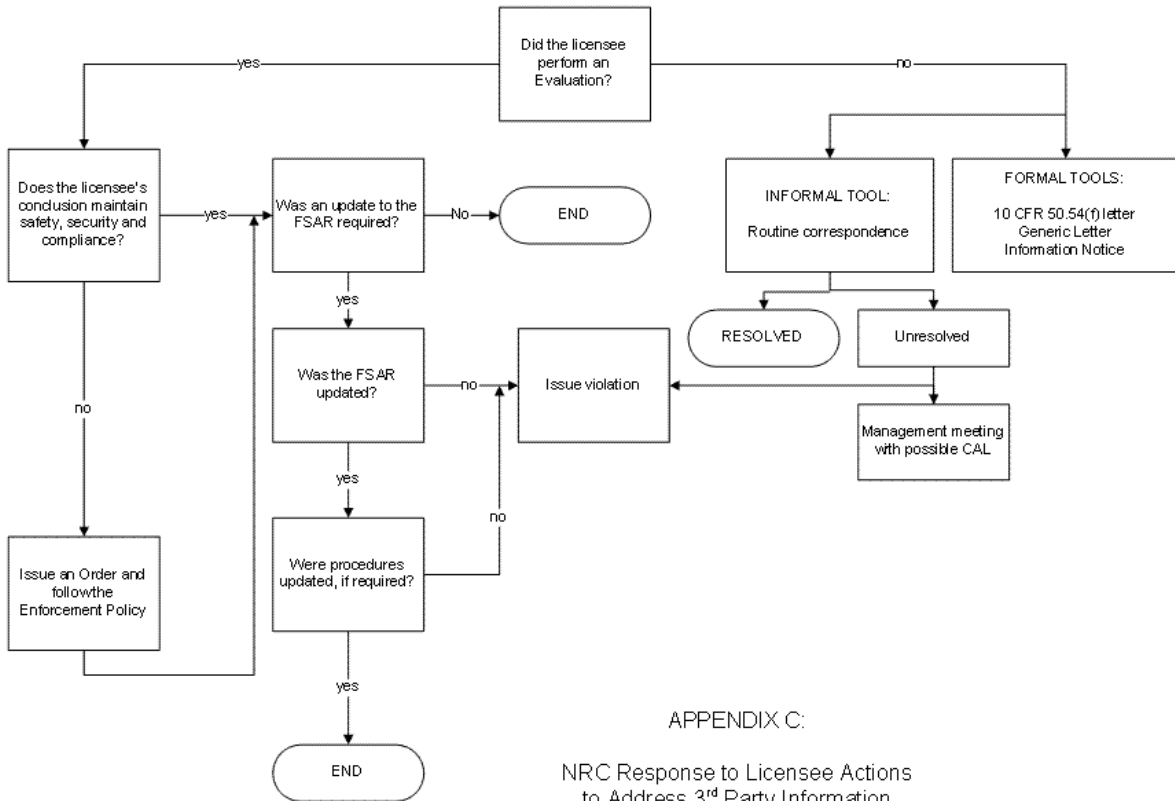
Corrective Action Program	<ul style="list-style-type: none"> • Criterion XVI, “Corrective Actions,” of Appendix B to 10 CFR Part 50 • NUREG-0737, “Clarification of TMI Action Plan Requirements” (ML051400209)
Operability Determinations	<ul style="list-style-type: none"> • NRC Regulatory Issue Summary 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)
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 this 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”

Appendix B Licensee Actions to Address Third-Party Information



APPENDIX B:
Licensee Actions to Address
3rd Party Information

Appendix C NRC Response to Licensee Actions to Address Third-Party Information



APPENDIX C:

NRC Response to Licensee Actions to Address 3rd Party Information