March 6, 2015

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

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SUBJECT: REVIEW OF LESSONS LEARNED FROM THE SAN ONOFRE STEAM GENERATOR TUBE DEGRADATION EVENT

The purpose of this memorandum is to provide the staff evaluation of lessons learned from the San Onofre Nuclear Generating Station (San Onofre) steam generator tube degradation event and to provide a summary of the actions identified.

On January 31, 2012, San Onofre Unit 3 experienced a primary-to-secondary leak in one of the two steam generators. The affected steam generator was isolated and the unit was brought to cold shutdown on February 1, 2012. The licensee reviewed the amount of gaseous radioactivity released during the event and estimated a dose of approximately 0.00005 millirem (mrem) [.0000005 millisievert (mSv)] to a member of the public, a very small fraction of the 100 mrem (1 mSv) per year regulatory limit to a member of the public. A U.S. Nuclear Regulatory Commission (NRC) Augmented Inspection Team and followup inspections reviewed the causes of the event and the licensee's response. The NRC identified a performance deficiency associated with a violation of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," Criterion III, "Design Control," and issued a white finding, designating an issue of low-to-moderate safety significance under the Reactor Oversight Process.

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As directed by your tasking memorandum dated March 20, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14028A028), NRC staff evaluated the agency's response to the event under eight topics to identify enhancements to NRC processes and programs that could improve agency response to similar technically complex, highly visible events in the future.

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As a result of this comprehensive review, NRC staff identified 17 actions across the eight topics and is taking steps to implement them. The enclosure provides a complete discussion of each of these actions. Completion of the actions will be tracked by the agency processes appropriate to each action.

Enclosure:
San Onofre Lessons Learned Report

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SAN ONOFRE STEAM GENERATOR TUBE DEGRADATION LESSONS LEARNED REPORT

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ENCLOSURE

Executive Summary

The 2012 steam generator tube degradation at San Onofre Nuclear Generating Station (San Onofre) presented a variety of challenges to U.S. Nuclear Regulatory Commission (NRC) staff responding to the event. The sequence of events, the root cause of the degradation, and the results of the NRC evaluation of licensee performance are documented in a series of NRC inspection reports, starting with observations from the Augmented Inspection Team. The NRC issued a violation of design control requirements that was assessed as having low-to-moderate safety significance (White) for Unit 3.

In a March 20, 2014, tasking memorandum, the NRC Executive Director for Operations directed the NRC staff to evaluate the lessons learned from this event, apply appropriate process improvements, and clearly communicate the outcomes to all NRC stakeholders to improve NRC regulatory effectiveness and efficiency and meet the NRC's safety and security mission. As such, this review encompassed a variety of areas ranging from analysis of the specific degradation mechanism to interactions with the public. The NRC staff has identified a total of 17 actions across the eight topics. The most substantial of these actions are in the technical areas related to the actual cause of the tube degradation, and in the area of external communications.

As identified in the San Onofre root cause analysis, the cause of the steam generator degradation was tube-to-tube wear caused by in-plane fluid-elastic instability of the tube u-bends. A design error resulted in the actual steam generators having more severe thermal-hydraulic conditions than expected, which contributed, along with other factors, to the rapid steam generator tube wall degradation. Topic 3, "Steam Generator Technical Review," and Topic 8, "Vendor Inspection," of this report look at the technical aspects of the event and describe ongoing actions related to working with the nuclear industry and professional organizations to update standards and guidelines based on the experience at San Onofre and updating Reactor Oversight Process inspection procedures to flag major plant modifications that might require review and inspection by technical experts prior to operation.

In Topic 5, "Communication and External Interactions," the NRC staff reviewed responses from internal and external stakeholders to identify improvements for the communication of complex, technical subjects to the public. After reviewing the suggestions and concerns arising from experiences with the San Onofre event, the NRC staff identified actions for ensuring communications resources are available for future high-visibility events. These resources would be available to provide guidance and advice to technical staff to assist them in carrying out logistical details and allow the technical staff to focus on the technical aspects of external communications.

The NRC Office of the Inspector General (OIG) issued an event inquiry on October 2, 2014, that identified potential issues with the NRC's oversight of the 10 CFR 50.59 program at San Onofre. Topic 1 of this report, "10 CFR 50.59 Process," found that although there are improvements that can be made to NRC's oversight of the 10 CFR 50.59 programs in general, and at San Onofre in particular, the issues identified both by the NRC inspection process and by the OIG event inquiry were tangential to the technical cause of the problem. Process improvement actions to be taken include additional training and enhancements to internal NRC procedures.

Background

On January 31, 2012, San Onofre Nuclear Generating Station (SONGS, also referred to in this report as San Onofre), Unit 3, experienced a primary-to-secondary leak in one of the two steam generators. Although the leak rate was small, it was unexpected, and increased enough in a short period of time for Southern California Edison (SCE, also referred to in this report as the licensee) to perform a rapid shutdown in accordance with plant procedures. The affected steam generator was isolated and Unit 3 was brought to cold shutdown conditions on February 1, 2012. The licensee reviewed the amount of gaseous radioactivity released during the event and estimated a dose of approximately 0.00005 millirem (mrem) [.0000005 millisievert (mSv)] to a member of the public, which is a very small fraction of the 100 mrem (1 mSv) per year regulatory limit.

During followup inspections of the Unit 3 steam generator tubes, SCE discovered unexpected wear in both steam generators, including significant tube-to-tube wear in the U-bend free span areas of over 100 tubes. Pre-planned testing of 100 percent of the steam generator tubes at Unit 2 was already in progress as part of a regularly scheduled outage when the event occurred in Unit 3. Testing results from Unit 2 also revealed unexpected tube wear at the retainer bars. Additional analysis and testing ultimately resulted in identifying two tubes with tube-to-tube wear similar to that observed in Unit 3.

For both Units 2 and 3, this was the first cycle of operation with new replacement steam generators. SCE replaced the Unit 2 steam generators in January 2010 and Unit 3 steam generators in January 2011. All of the replacement steam generators were manufactured by Mitsubishi Heavy Industries.

On March 19, 2012, the NRC initiated an Augmented Inspection Team (AIT) reactive inspection to assess the circumstances surrounding the primary-to-secondary leak and unexpected wear of tubes in the replacement steam generators at San Onofre. The AIT report,[1] issued July 18, 2012, identified design control issues associated with the thermal-hydraulic modeling of the steam generators as the probable cause of the steam generator tube degradation that ultimately led to the tube leak in Unit 3. The AIT also assessed the licensee's response to the event and whether the licensee appropriately reviewed the design changes in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.59, "Changes, Tests, and Experiments." The AIT identified 10 unresolved items that warranted additional inspection and review.

In response to a letter from SCE dated March 23, 2012,[2] on March 27, 2012, the NRC issued a confirmatory action letter (CAL)[3] to the licensee to confirm the actions the licensee committed to take before returning Units 2 and 3 to power operation.

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1 Augmented Inspection Team (AIT) Report 2012-007, June 18, 2012, ADAMS Accession No. ML12188A748

2 San Onofre Nuclear Generating Station Letter, "Steam Generator Return to Service Action Plan," March 23, 2012, ADAMS Accession No. ML12086A182

3 San Onofre Confirmatory Action Letter (CAL) 4-12-001, March 27, 2012, ADAMS Accession No. ML12087A323

A followup inspection of the unresolved issues identified by the AIT was conducted from August 20 to September 28, 2012. The followup inspection report,[4] dated November 9, 2012, closed 8 of the 10 unresolved items.

On September 4, 2012, the NRC transitioned regulatory oversight for San Onofre Units 2 and 3 to the process described in Inspection Manual Chapter 0351, "Implementation of the Reactor Oversight Process (ROP) at Reactor Facilities in an Extended Shutdown Condition for Reasons Other Than Significant Performance Problems."[5] This action was taken to modify the inspection program for San Onofre, since many of the usual inputs to the ROP for assessing plant performance assume that the plant has been operating.

In its October 3, 2012, response to the CAL[6] (addressing Unit 2 only), SCE indicated that it desired to operate Unit 2 at no more than 70 percent power for no more than 150 days before conducting the next set of inspections of that unit's steam generator tubes.

On May 13, 2013, an NRC Atomic Safety and Licensing Board issued a decision finding that the CAL process used to determine the readiness of San Onofre for restart constituted a *de facto* license amendment, a decision which was later vacated by the Commission.[7]

On June 7, 2013, SCE announced plans to permanently retire the plants. In accordance with 10 CFR 50.82, "Termination of License," on June 12, the licensee submitted a certification of permanent cessation of power operations[8] to the NRC, certifying that SCE had permanently ceased power operations of San Onofre Units 2 and 3.

The NRC closed out the remaining two unresolved items from the AIT in an inspection report dated September 20, 2013.[9] This closeout included a violation of 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," Criterion III, "Design Control," for the failure of the licensee to verify the adequacy of the design for the replacement steam generators. This violation was later finalized as White[10] for Unit 3 under the NRC's Reactor Oversight Process, a finding with low-to-moderate safety significance. A violation of the same requirements issued to Unit 2 was determined to be Green, a finding with very low safety significance, since the performance deficiency at Unit 2 had not actually resulted in a steam generator tube leak.

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4 AIT Followup IR 2012-010, November 9, 2012, ADAMS Accession No. ML12318A342

5 IMC 0351, "Implementation of The Reactor Oversight Process at Reactor Facilities in an Extended Shutdown Condition for Reasons Other Than Significant Performance Problems," April 5, 2011, ADAMS Accession No. ML102770448

6 Southern California Edison CAL Response, "Actions to Address Steam Generator Tube Degradation," October 12, 2012, ADAMS Accession No. ML122850320

7 Southern California Edison Co. (San Onofre Nuclear Generating Station, Units 2 and 3), LBP-13-7, 77 NRC 307 (2013); vacated as moot, CLI-13-9, 78 NRC 551 (2013)

8 San Onofre Nuclear Generating Station, "Certification of Permanent Cessation of Power Operations," June 12, 2013, ADAMS Accession No. ML131640201

9 Confirmatory Action Letter Response IR 2012-009, September 20, 2013, ADAMS Accession No. ML13263A271

10 Final Significance Determination and Notice of Violation regarding IR 2012-009, December 23, 2013, ADAMS Accession No. ML13357A058

On March 20, 2014, the NRC Executive Director for Operations issued a tasking memorandum[11] directing a review of the NRC's actions with respect to the event and its aftermath to determine if there were any improvements that could be made to NRC processes. The tasking memorandum identified eight topics for review and specific, related items that should be examined. The review covered a broad range of issues and required input from 10 different NRC offices. The topics, listed below, are addressed sequentially in this report. Actions being taken related to the evaluation for each topic are included as part of the discussion within each topic.

A complete list of actions is included as Appendix A. The complete list of questions associated with each topic is included as Appendix B. Documents referenced in the material are footnoted throughout the report; a complete list of references used in developing the report is included as Appendix C. Appendix D provides the resolution of a non-concurrence that was submitted based on changes made to the input provided for Topic 4, "Organization/Roles and Responsibilities." The non-concurrence was satisfactorily resolved such that the non-concurring individual has concurred on this report.

Topic 1: 10 CFR 50.59 Process
Topic 2: Confirmatory Action Letter as a Regulatory Tool
Topic 3: Steam Generator Technical Review
Topic 4: Organization/Roles and Responsibilities
Topic 5: Communication and External Interactions
Topic 6: Commission Separation of Function Communication Challenges
Topic 7: Inspection Manual Chapter (IMC) 0351
Topic 8: Vendor Inspection

[11] NRC Memorandum, "Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event," March 20, 2014, ADAMS Accession No. ML14028A028

Topic 1: 10 CFR 50.59 Process

Issue Definition

The San Onofre steam generator tube degradation event in 2012 generated significant public and congressional interest in the U.S. Nuclear Regulatory Commission's (NRC's) requirements related to facility changes. Many questions focused on how a licensee could perform a replacement of major plant components without obtaining an NRC license amendment in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit," (except for technical specification changes), relying instead on the licensee's evaluation performed under the requirements of 10 CFR 50.59, "Changes, Tests, and Experiments."

10 CFR 50.59 permits licensees to make selected changes to licensed facilities without NRC prior approval provided certain conditions and criteria are met. Such approval, if needed, would be obtained through a license amendment in accordance with 10 CFR 50.90. The 10 CFR 50.59 process requires licensees to perform an evaluation applying the eight evaluation criteria included in 10 CFR 50.59 to determine if a license amendment must be obtained from the NRC before making the change. According to 10 CFR 50.90, whenever a licensee seeks to amend its license, or determines that such an amendment is otherwise required by 10 CFR 50.59, it must file an application for a license amendment with the NRC. The NRC provides public notice of the license amendment request, offering an opportunity for members of the public to request a hearing. The NRC staff reviews the license amendment request and documents its conclusions in a safety evaluation report explaining the reasons for approving or denying the license amendment.

NRC requirements, including regulations, technical specifications, license conditions, and orders, have been established to provide reasonable assurance of adequate protection, and licensee compliance with these regulations is presumed to provide this level of protection. The Commission established the criteria of 10 CFR 50.59 to provide a mechanism for determining when changes that might affect the basis on which it originally issued a license to operate the facility would require NRC approval before a licensee could implement the change. Thus, 10 CFR 50.59 provides a threshold for licensees to seek regulatory review for proposed activities—it does not constitute the final determination of safety, nor does it provide the determination of whether other regulatory requirements are met. Regardless of the outcome of the licensee's 10 CFR 50.59 evaluation as to whether or not a license amendment is required for a proposed modification, licensees are required to comply with all applicable NRC regulatory requirements, including, but not limited to, the requirements of 10 CFR 50 Appendix B, "Quality Assurance Program," covering design control, vendor oversight, technical specifications, and in-service inspections, as well as applicable American Society of Mechanical Engineers (ASME) codes outlined in 10 CFR 50.55a, "Codes and Standards."

Given that licensees make many changes to structures, systems, and components throughout the facilities' operational lifetime, the criteria in 10 CFR 50.59 are intended to focus NRC staff attention on those changes that have regulatory or safety significance.

In November 2000, the NRC issued Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments,"[12] endorsing an industry document, Nuclear Energy Institute (NEI) 96-07, Rev. 1, "Guidelines for 10 CFR 50.59 Implementation."[13] Taken together, these documents provide guidance that the NRC has found acceptable for implementing 10 CFR 50.59.[14]

NRC review and approval of license amendments is only one way in which the NRC provides oversight of reactor licensees. NRC oversight of modifications is also provided through the inspection process, regardless of whether prior NRC approval is required for the change. The NRC staff periodically inspects licensee implementation of the 10 CFR 50.59 process, as well as the design and configuration control processes, using a variety of Inspection Procedures (IPs) including, but not limited to, IP 71111.17T,[15] "Evaluations of Changes, Tests, and Experiments and Permanent Plant Modifications" and IP 71111.21,[16] "Component Design Bases Inspection."

In 2010 and 2011, Southern California Edison (SCE) installed replacement steam generators at San Onofre Units 2 and 3, respectively, following a 10 CFR 50.59 evaluation that concluded no license amendment would be required for installation of the replacement steam generators except for the relevant technical specification changes related to steam generator inspection and tube repair criteria and changes to the peak containment post-accident pressure. In preparation for the steam generator replacements, the NRC inspectors reviewed the 10 CFR 50.59 evaluation performed on Unit 2 by SCE as part of a baseline inspection of plant modifications and as part of the focused steam generator replacement inspection.[17] The inspection did not identify any issues with the licensee's 10 CFR 50.59 evaluation.

Following the January 2012 steam generator tube degradation event, the NRC conducted additional inspections[18] at San Onofre, including a review of the event, a review of the steam generator replacement process, and another review of the 10 CFR 50.59 evaluations. As part of this additional inspection and technical review, several issues were raised, including some specific to the San Onofre 10 CFR 50.59 evaluation.

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12 RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," November 2000, ADAMS Accession No. ML003759710

13 Nuclear Energy Institute (NEI) 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Implementation," November 17, 2000, ADAMS Accession No. ML003771157

14 Note: NRC letter to NEI dated November 5, 2013, "Summary of Concerns with NEI 01-01" (ADAMS Accession No. ML13298A787), describes a separate, unrelated effort to clarify the 10 CFR 50.59 guidance regarding digital instrumentation and control systems.

15 IP 71111.17T, "Evaluations of Changes, Tests, and Experiments and Permanent Plant Modifications," March 5, 2013, ADAMS Accession No. ML101340791

16 IP 71111.21, "Component Design Bases Inspection," November 29, 2013, ADAMS Accession No. ML13331B444

17 NRC Integrated IR 2009-004, November 5, 2009, ADAMS Accession No. ML093100051; NRC Steam Generator Replacement IR 2010-009, May 10, 2011, ADAMS Accession No. ML111300448

18 Augmented Inspection Team (AIT) IR 2012-007, June 18, 2012, ADAMS Accession No. ML12188A748; AIT Follow-Up IR 2012-010, November 9, 2012, ADAMS Accession No. ML12318A342

Subsequent to the completion of the NRC's inspection activities, on October 2, 2014, the NRC Office of the Inspector General (OIG) released an event inquiry report, "NRC Oversight of Licensees Use of 10 CFR 50.59 Process to Replace SONGS Steam Generators,"[19] which identified the following three issues:

1. There were missed opportunities during the NRC Region IV 2009 inspection to identify weaknesses in the SONGS steam generator 10 CFR 50.59 screening and evaluation package.

2. The 2012 Augmented Inspection Team (AIT) review of SCE's 10 CFR 50.59 evaluation did not document the answer to the question of whether a license amendment was required.

3. The NRC did not consistently apply oversight to the San Onofre updated final safety analysis report (UFSAR) following biennial UFSAR submittals.

The issues raised in the OIG event inquiry report have been incorporated into the evaluation of the broader issue of the 10 CFR 50.59 topic in this report.

Approach for Reviewing the Issue

To examine SCE's application of the 10 CFR 50.59 process at San Onofre, the NRC staff reviewed the history and application of the regulation, its relationship to other regulatory requirements, and documents specific to the event at San Onofre. This review included the following:

- selected documents from steam generator replacements at other sites
- 10 CFR 50.59 inspection results from major or complex component replacements at other U.S. nuclear plants
- NEI 96-07, Revision 1, "Guidelines for 10 CFR 50.59 Evaluations" (ADAMS Accession No. ML003771157)
- NRC Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments" (ADAMS Accession No. ML003759710)
- NRC inspection procedures that review implementation of the 10 CFR 50.59 process, including IP 71111.17T, "Evaluations of Changes, Tests, and Experiments and Permanent Plant Modifications," and IP 71111.21, "Component Design Bases Inspection" (ADAMS Accession Nos. ML101340791 and ML13331B444)
- NRC inspection reports for San Onofre that discussed the replacement steam generators (ADAMS Accession Nos. ML093100051, ML111300448, ML12188A748, and ML12318A342).

[19] OIG Event Inquiry Report, "NRC Oversight of Licensees Use of 10 CFR 50.59 Process to Replace SONGS Steam Generators," OIG Case No. 13-006, October 2, 2014, ADAMS Accession No. ML14276A478

- SCE 10 CFR 50.59 Screening and Evaluation for San Onofre Units 2 and 3 Steam Generator Replacement, Engineering Change Packages NECP 800071_702 and NECP 800071_703, respectively.

To address questions raised about the requirements for regulatory review of complex modifications, staff performed an evaluation of the 10 CFR 50.59 process summarized in "White Paper—10 CFR 50.59; the Process, Application to Substantial Modifications to Licensee Facilities, and NRC Staff Assessment of Licensee Implementation."[20]

The NRC staff also reviewed the OIG event inquiry for potential lessons learned related to the San Onofre event and incorporated appropriate response actions to these issues into this review. In addition to identifying the three issues, the OIG event inquiry highlighted varying NRC perspectives regarding the 50.59 process that the NRC staff considered as part of this lessons-learned effort. OIG Issues #1 and #2 relate to NRC inspections of 10 CFR 50.59 and are addressed under Item 2.b, which covers 10 CFR 50.59 guidance and information provided to NRC inspectors. OIG Issue #3 pertains to the NRC review of biennial UFSAR submittals and is addressed under Item 2.c, which covers 10 CFR 50.59 guidance and information provided to NRC licensing project managers responsible for this review.

Conclusions

1. Does the 10 CFR 50.59 rule continue to be adequate for major or complex component replacements?

Yes. NRC staff concluded that the 10 CFR 50.59 rule itself continues to be adequate, including for major or complex component replacements. No rulemaking actions are required or planned with respect to the 10 CFR 50.59 rule. However, Item 2 discusses some improvements that can be made related to the 10 CFR 50.59 process.

The San Onofre steam generator tube leak event generated significant public and congressional interest in the requirements related to facility changes. To address questions raised about the requirements for regulatory review of complex modifications, staff performed an evaluation of the 10 CFR 50.59 process summarized in the above-noted white paper. This white paper provides the NRC staff's assessment of the application of 10 CFR 50.59 for evaluating major modifications to licensee facilities, including steam generator replacements, by describing:

- the 10 CFR 50.59 process and process history
- the relationship of 10 CFR 50.59 to other regulatory requirements
- the application of 10 CFR 50.59
- the history of steam generator replacements in the United States
- the NRC staff's assessment of 10 CFR 50.59 inspection results, including those related to major or complex component replacements at other U.S. nuclear plants

[20] "White Paper—10 CFR 50.59; the Process, Application to Substantial Modifications to Licensee Facilities, and NRC Staff Assessment of Licensee Implementation," ADAMS Accession No. ML13066A266.

The NRC staff's review, documented in the white paper, determined that 10 CFR 50.59 continues to provide an appropriate threshold for determining which changes, tests, or experiments require prior NRC approval through a license amendment. Despite issues discovered in SCE's application of the 10 CFR 50.59 process at San Onofre, which are examined in more detail below, the 10 CFR 50.59 regulation continues to meet the spirit and intent of the objectives described in the statements of consideration issued with the 1999 final rule for 10 CFR 50.59[21] by establishing a threshold for prior NRC review of facility changes that might adversely affect the basis on which the NRC issued a license to operate the licensed facility.

The San Onofre steam generator tube degradation occurred as a result of issues introduced during the design phase that were unrecognized and, thus, were not considered in the licensee's 10 CFR 50.59 evaluation. 10 CFR 50.59 is not a process for verifying design adequacy. Rather, the engineering and technical design evaluations supporting the change are developed using the licensee's plant modification process that implements the requirements of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," Criterion III, "Design Control" which states,

> The [plant's] design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews…by individuals or groups other than those who performed the original design.

Furthermore, the required design control measures for verifying the adequacy of design are expected to be implemented before entering the 10 CFR 50.59 process. Specifically, the NRC-endorsed 10 CFR 50.59 guidance in NEI 96-07, Revision 1, states,

> After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR 50.59 process is applied to determine if a license amendment is required prior to implementation.

At San Onofre, the NRC identified violations of 10 CFR Part 50, Appendix B, Criterion III, for the failure to verify the adequacy of the thermal-hydraulic and flow-induced vibration design of the San Onofre replacement steam generators, resulting in excessive and unexpected steam generator tube wear after one cycle of operation. The 10 CFR 50.59 rule, NEI 96-07, Revision 1, and the results of the San Onofre 10 CFR 50.59 evaluation did not have any bearing on the underlying, unrecognized design control issue that actually caused the San Onofre steam generator tube leak event.

2. Does the agency need to provide additional 10 CFR 50.59 guidance and information?

   a. *Does the agency need to provide additional 10 CFR 50.59 guidance and information to licensees for large or complex component replacements*

Yes. Although not specifically related to large or complex component replacements, the NRC staff is developing a regulatory issue summary (RIS) to inform licensees of a potentially misleading sentence, described below, in the NRC-endorsed 10 CFR 50.59 guidance in Revision 1 to NEI 96-07, which was discovered during the review of this event. The staff is also

[21] Changes, Tests, and Experiments: Final Rule, 64 FR 53583 and 64 FR 53613 (October 4, 1999).

revising NRC Regulatory Guide (RG) 1.187 to add an exception to the NRC's endorsement of NEI 96-07, Revision 1, related to a statement that was specifically quoted in the San Onofre 10 CFR 50.59 evaluations, although it was not one of the causes of the identified shortcomings with the San Onofre evaluation and would not have identified the engineering flaw. A second RIS will also highlight important aspects of the 10 CFR 50.59 guidance related to issues identified in the San Onofre 10 CFR 50.59 screening and evaluation[22] performed for the steam generator replacement, as well as other issues relevant to 10 CFR 50.59 that have been found at other sites.

The first proposed RIS and revision to RG 1.187 will address guidance in NEI 96-07, Revision 1, related to 10 CFR 50.59(c)(2), criterion viii. Criterion viii requires the licensee to obtain a license amendment for changes that:

> Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

The definition in 10 CFR 50.59(a)(2) states (*emphasis added*),

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

The NRC staff determined that the following statement from NEI 96-07, Revision 1, provides potentially misleading guidance:

> By way of contrast, the following changes are not considered departures from a method of evaluation described in the UFSAR: Use of a methodology revision that is documented as providing results that are essentially the same as, or more conservative than, either the previous revision of the same methodology or another methodology previously accepted by NRC through issuance of an SER [safety evaluation report].

The NRC staff determined that this sentence from NEI 96-07, Revision 1, does not accurately reflect the definition in 10 CFR 50.59(a)(2) in that:

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[22] A "10 CFR 50.59 evaluation" is the documented evaluation against the eight criteria in 10 CFR 50.59(c)(2) to determine if a proposed change, test or experiment requires prior NRC approval via license amendment under 10 CFR 50.90. Screening is that part of the 10 CFR 50.59 process that determines whether a proposed activity requires a 10 CFR 50.59 evaluation. The definitions in 10 CFR 50.59(a) of "change," "facility as described…," "procedures as described…" and "test or experiment not described…" constitute criteria for the 10 CFR 50.59 screening process.

- It could be read to infer that "methodology revision" results could be compared to "the previous revision of the same methodology" instead of being compared to the revision currently specified in the FSAR which may be an earlier revision than the "previous revision;" and

- It could be read to infer that "methodology revision" results could be compared to "another methodology previously accepted by NRC through issuance of an SER" instead of being compared to the methodology currently specified in the FSAR.

The second RIS will also highlight important aspects of the guidance in NEI 96-07, Revision 1, related to observations identified during the NRC inspection of the San Onofre 10 CFR 50.59 screening and evaluation for the replacement steam generators. These observations were included in the subsequent OIG event inquiry under Issues #1 and #2. These observations include the following:

- NRC inspectors identified a minor violation of 10 CFR 50.59(d) for an inadequate 10 CFR 50.59 written evaluation for the San Onofre replacement steam generators related to whether the *change* from one computer code to another (ANSYS to ABAQUS) constituted a *departure* from the method of evaluation. The NRC inspection report stated that the licensee inappropriately evaluated this change against 10 CFR 50.59(a)(2)(i) (i.e., as a change to an element of a method) rather than against 10 CFR 50.59(a)(2)(ii) (as a change from one method to another method). As such, the licensee's 10 CFR 50.59 evaluation did not address 10 CFR 50.59(a)(2)(ii) for changing to another method by describing whether "that method [ABAQUS] *has been approved by NRC for the intended application*" [emphasis added].

  The OIG event inquiry discusses varying views among NRC staff as to whether the licensee was correct in its evaluation of the change from ANSYS to ABAQUS against 10 CFR 50.59(a)(2)(i) as a change to an element of a method. The 10 CFR 50.59 subject matter experts referenced in the OIG event inquiry agree that there was, in fact, a violation. As noted in the inspection report, this violation was dispositioned in accordance with the NRC's enforcement policy as a minor violation, as "there was no reasonable likelihood that the change would ever require NRC approval." The RIS will summarize this issue and ensure a clear documentation of the NRC's regulatory position on this matter.

- The OIG event inquiry stated that the closure of an unresolved item from the AIT report involved a change from a computer program to manual calculations. The RIS will clarify the NRC position that a manual calculation, no matter how simple, is considered a method of evaluation that in select cases is subject to evaluation under criterion 10 CFR 50.59(c)(2)(viii).

- The OIG event inquiry stated that at least 14 methods of evaluation listed in Section 3.9 of the San Onofre UFSAR, "Mechanical Systems and Components," were changed as a result of the steam generator replacement but were not mentioned in the 10 CFR 50.59 screening. The OIG event inquiry further states that, because of this, the San Onofre 10 CFR 50.59 evaluation did not discuss whether these changes in the method of evaluation meet the definition in 10 CFR 50.59(a)(2) of a departure from the method of evaluation that would require a license amendment. The RIS will describe the importance of addressing each applicable change in the UFSAR in the 10 CFR 50.59 screening.

This item from the tasking memo specifically asks whether additional guidance is needed to address "large or complex" component replacements. The NRC staff review determined that the guidance in NEI 96-07, Revision 1, specifically related to complex changes is clear and complete. There is one aspect of the 10 CFR 50.59 process that is affected by the size and complexity of a component replacement—namely 10 CFR 50.59 evaluation documentation. In accordance with 10 CFR 50.59(d), the licensee is required to maintain records that include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require a license amendment. Specifically, NEI 96-07, Revision 1, Section 5, "Documentation and Reporting," states:

> Thus the basis for the engineering judgment and the logic used in the determination should be documented to the extent practicable and to a degree commensurate with the safety significance *and complexity* of the activity [emphasis added].

The 10 CFR 50.59 regulations provide a threshold for determining when NRC approval is required to preserve the basis on which the license was issued and does not depend on the size or complexity of the modification under consideration.

b. Does the agency need to provide additional 10 CFR 50.59 guidance and information to inspectors for their review of 10 CFR 50.59 evaluations of large or complex component replacements?

Yes. The staff determined that the agency needs to conduct workshops and training with regional and headquarters staff, and provide additional continual training opportunities to ensure proper understanding of the 10 CFR 50.59 process. The staff is also evaluating possible updates to the inspection procedures related to the 10 CFR 50.59 process, including IPs for the inspection of steam generator replacements and other major plant modifications.

Most NRC inspections of licensee 10 CFR 50.59 screenings and evaluations occur under Inspection Procedure (IP) 71111.17T and IP 71111.21. These inspection procedures direct inspectors to review licensee implementation of the 10 CFR 50.59 process using the guidance in NEI 96-07, Revision 1, and as such, the above-described RIS will benefit NRC inspectors as well as licensees. To ensure that inspectors are prepared to effectively carry out their inspection activities, the NRC will be providing ongoing training on the 10 CFR 50.59 screening and evaluation process to its inspectors.

The OIG event inquiry Issue #1 states that there were missed opportunities during the NRC Region IV 2009 inspection[23] under IP 71111.17T to identify weaknesses in the San Onofre steam generator 10 CFR 50.59 screening and evaluation package. The NRC's inspection program is a sampling process and, therefore, is not designed to inspect every aspect of a particular licensee program. After review and consideration of licensees' 10 CFR 50.59 evaluation packages, inspectors select samples for further review as necessary to provide confidence in the licensee's ability to conduct its licensed operations safely and in compliance with regulations. When inspection results indicate safety-significant deficiencies in licensee performance, the program provides for expansion of the NRC's inspection effort as much as is necessary to ensure the proper implementation of 10 CFR 50.59 by a licensee.

[23] NRC Integrated IR 2009-004, November 5, 2009, ADAMS Accession No. ML093100051

OIG Issue #2 noted that the 2012 AIT review of the licensee's 10 CFR 50.59 evaluation did not document the answer to the question of whether a license amendment was required. The AIT review considered many issues, among which was whether or not the licensee correctly concluded that a license amendment was not required. The AIT and its followup inspections reviewed the licensee's 10 CFR 50.59 evaluations related to replacing the steam generators and determined that the licensee's conclusion that no license amendment was required was consistent with the requirements of 10 CFR 50.59.

The NRC staff also examined whether the NRC's Reactor Oversight Process (ROP) baseline inspection program allots sufficient inspection hours for the 10 CFR 50.59 screenings and evaluations. The NRC recently completed an in-depth review of its baseline inspection program as part of an ROP enhancement project[24] and did not identify a need to increase 10 CFR 50.59 inspection hours. Moreover, given that there are a finite number of NRC inspection hours allotted for completing the baseline inspection program, any increase in inspection hours for 10 CFR 50.59 would require either an increase in the resources budgeted to the inspection program or reduction of inspection hours in other areas. The NRC staff determined that the actions already proposed in this report will enhance the effectiveness of the inspection hours already allotted. Should a region identify a need for additional inspection hours to review the 10 CFR 50.59 evaluation for a particularly complex modification, processes do exist for allocating additional inspection hours on a case-by-case basis through the ROP.

c. Does the agency need to provide additional 10 CFR 50.59 guidance and information to project managers for their review of 10 CFR 50.59 evaluations?

Yes. The NRC staff determined that it needs to revise some internal processes to more clearly reflect the scope, depth, frequency, and timeliness expectations for the staff's review of licensee submittals required under 10 CFR 50.59 and 10 CFR 50.71, "Maintenance of Records, Making of Reports." Under 10 CFR 50.71(e), licensees are required to submit biennial updates to the UFSAR reflecting the current status of the facility. Under 10 CFR 50.59(d)(2), licensees are also required to submit information on a biennial basis concerning changes made under 10 CFR 50.59.

Responsibility for the review of selected licensee 10 CFR 50.59 screenings and evaluations rests with NRC's region-based inspectors, and the baseline inspection program allows for inspection hours to be dedicated to reviewing the licensee's conclusions. The project managers (PMs) at NRC headquarters are responsible for reviewing the summary of changes submitted in accordance with 10 CFR 50.59(d)(2).

Issue #3 identified in the OIG event inquiry stated that the NRC did not consistently review the San Onofre UFSAR submittals in a timely manner. Although licensees are required, under 10 CFR 50.71(e), to submit biennial UFSAR updates reflecting the current status of the facility so that the document can be used as a reference document in safety analysis, OIG concluded that the PMs in the Office of Nuclear Reactor Regulation (NRR) tasked to review these submittals did not always conduct the reviews within the 90-day timeframe specified by internal NRC procedures. Moreover, although under 10 CFR 50.59(d)(2) licensees also must biennially submit information concerning changes made under 10 CFR 50.59 without NRC prior approval, OIG found that PMs – although instructed by NRC procedures to consider this information

[24] "Reactor Oversight Process Enhancement Project—Baseline Inspection Program," April 4, 2014, ADAMS Accession No. ML14017A338

during their review of 10 CFR 50.71(e) submittals – do not always take the 10 CFR 50.59(d)(2) information into consideration during their reviews.

To address the OIG finding, the NRC staff has chartered a working group to provide comprehensive staff guidance for completing the 10 CFR 50.71(e) and 10 CFR 50.59(d)(2) reviews. In addition, the staff will update the relevant NRC procedures to include this guidance and provide applicable training. Evaluation of the licensee's UFSAR noted that there was a lack of detail concerning the design characteristics, functions, and acceptance criteria of the various components within the San Onofre steam generators. Since each vendor has established their design criteria and these criteria are generally considered or treated as proprietary information, minimal detail was described. The review guidance to be developed as discussed in Topic 3, "Steam Generator Technical Review," is intended to ensure that licensees have made the appropriate changes to the UFSAR to reflect the replacement steam generator design. The review guidance to be developed for NRC review of 10 CFR 50.71(e) submittals will provide further assurance that the UFSAR has the appropriate level of detail.

3. Does the agency need to clarify the commonly used phrase "like-for-like replacement" with respect to 10 CFR 50.59?

No. The NRC-endorsed 10 CFR 50.59 guidance in NEI 96-07, Revision 1, regarding the topic of component replacements is clear and complete. In its statements of consideration for the 1999 final rule, the Commission stated the following:

> In particular, the Commission finds that guidance would be useful on when "replacement" components must be treated as a change, as for instance because the replacement component has characteristics different from those described in the FSAR, compared to one that is "equivalent" and thus not a change.

This guidance was added to the NRC-endorsed 10 CFR 50.59 guidance in NEI 96-07, Revision 1. This issue involves the interface between the 10 CFR 50.59 process and the licensee's procurement process that implements the quality assurance requirements of 10 CFR Part 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services." NEI 96-07, Revision 1, uses the term "identical replacements," which is clearer in the context of 10 CFR 50.59 process. This term has the same meaning as the procurement process term "like-for-like replacements," which means "the replacement of an item with one that is identical." Replacement items are considered identical if purchased from the same vendor, provided all design, materials, and manufacturing processes are kept the same. Identical replacements are addressed in NEI 96-07, Revision 1, Section 4.1.2, "Maintenance Activities," which states the following:

> Maintenance activities are activities that restore SSCs [structures, systems, and components] to their as-designed condition, including activities that implement approved design changes. Maintenance activities are not subject to 10 CFR 50.59, but are subject to the provisions of 10 CFR 50.65(a)(4) as well as technical specifications. Maintenance activities include…identical replacements.

Licensee procurement processes specify that if a replacement item is similar, but not identical to, the item being replaced, an equivalency evaluation is necessary to determine if any changes in design, material, manufacturing process, safety, form, fit, function, or interchangeability could affect the alternative replacement item's ability to function. "Equivalent" components are

addressed in NEI 96-07, Revision 1, Section 4.2.1.1, "Screening of Changes to the Facility as Described in the UFSAR," which states the following:

> Equivalent replacement is a type of change to the facility that does not alter the design functions of SSCs. Licensee equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations and 10 CFR 50.59 evaluations.

The replacement steam generators at San Onofre Units 2 and 3 were not "like-for-like" (meaning identical) replacements, and they were not treated as such by the licensee. Statements to the contrary that appeared in industry and media publications were the result of the inaccurate use of a term that has a specific technical meaning. As the steam generator replacement did not constitute a "like-for-like" replacement, the licensee did perform a 10 CFR 50.59 screening and evaluation, as required by the regulations.

Following the San Onofre tube degradation event, there was public concern expressed about whether the licensee decided to design the new steam generators so they could be replaced under 10 CFR 50.59 to avoid NRC scrutiny provided by NRC review and approval of a license amendment. The staff evaluated whether it is acceptable for a licensee to intentionally design a facility change such that it could be implemented under 10 CFR 50.59 without the need for prior NRC approval and determined it does not represent a safety concern or a compliance concern. A change that conforms to the 10 CFR 50.59 criteria demonstrates the continued adequate protection of public health and safety due to the fact that it does not result in a more than minimal increase in the frequency or consequences of an accident or a system failure, does not affect fission product barrier limits, and does not involve a departure from the method of evaluation. The NRC-approved 10 CFR 50.59 guidance of NEI 96-07, Revision 1, Section 4.5, "Disposition of 10 CFR 50.59 Evaluations," states that if a licensee determines that a proposed activity would require prior NRC approval, it has the option to "[r]edesign the proposed activity so that it may proceed without prior NRC approval."

Actions

1. The staff is developing a RIS to inform licensees of a potentially misleading statement in the NRC-endorsed 10 CFR 50.59 guidance contained in NEI 96-07, Revision 1. Staff will develop a second RIS to highlight important aspects of the 10 CFR 50.59 guidance related to shortcomings identified in the 10 CFR 50.59 screening and evaluation process for the replacement steam generators at San Onofre. The NRC staff is also revising RG 1.187 to add an exception to the NRC's endorsement of NEI 96-07, Revision 1, related to the potentially misleading statement.

2. The staff is conducting workshops with NRC regional and headquarters employees to enhance their understanding of the 10 CFR 50.59 process, and will develop formal initial and continuing training on the 10 CFR 50.59 process. The staff is also considering an update to the inspection procedures governing inspectors' performance of 10 CFR 50.59 inspections, as well as inspections related to steam generator replacements and other major plant modifications to appropriately focus inspection reviews.

3. The staff will review and revise, as necessary, internal procedures providing guidance and direction for licensing PMs to clarify the scope, depth, frequency, and timeliness requirements for licensing PM reviews of documented 10 CFR 50.59 evaluation

summaries included in licensee submittals pursuant to 10 CFR 50.71(e) and 10 CFR 50.59(d)(2).

Topic 2: Confirmatory Action Letter as a Regulatory Tool

Issue Definition

A confirmatory action letter (CAL) is an administrative action where the U.S. Nuclear Regulatory Commission (NRC) issues a letter to a licensee to emphasize and confirm a licensee's agreement to take certain actions in response to specific issues. CALs are typically issued by the regions or relevant program offices, but oversight of the CAL process lies with the NRC's Office of Enforcement. The CAL process is described in the NRC Enforcement Manual[25].

Following the steam generator tube degradation at San Onofre, the NRC staff issued a CAL to Southern California Edison (SCE) on March 27, 2012[26]. The CAL confirmed commitments made by SCE to address steam generator issues before restarting Units 2 and 3.
A nongovernmental organization, Friends of the Earth (FOE), requested a hearing on the grounds the CAL, including the process for resolving the issues raised in the CAL, constituted a *de facto* license amendment proceeding under Section 189a of the Atomic Energy Act (AEA). The Commission referred the request to the Atomic Safety and Licensing Board (ASLB) Panel. The ASLB subsequently held that the CAL process constituted a *de facto* amendment proceeding. This decision was vacated by the Commission shortly thereafter in view of SCE's decision to permanently shut down the plant.[27] Notwithstanding vacatur of the Board's decision, the adjudicatory process raised concerns that served, in part, to prompt the lessons learned effort to examine the appropriateness of CALs as a regulatory tool.

During the adjudicatory process, the NRC staff was reviewing in parallel SCE's response to the CAL. As part of the NRC staff's review, Requests for Additional Information (RAIs)[28] were issued to SCE to seek more information about its proposed plan to return Unit 2 to operation. RAI 32 asked the licensee to clarify how the information it provided the NRC as part of its proposed plan to return Unit 2 to operation demonstrated that the structural integrity performance criterion in Technical Specifications (TS) 5.5.2.11.b.1 was met for operation within current licensed limits up to the licensed rated thermal power. In response to RAI 32, SCE submitted a license amendment request[29] on April 5, 2013, and a supplement[30] on April 9, 2013, requesting NRC approval to amend TS 5.5.2.11.b.1 to limit Unit 2's rated thermal power to 70%.

The NRC staff's review of SCE's response to the CAL resulted in the licensee's pursuit of a license amendment request through the licensing process. The review of the license amendment request was never completed by the NRC because SCE decided to cease

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25 NRC Enforcement Manual, December 5, 2014, ADAMS Accession No. ML102630150

26 San Onofre Confirmatory Action Letter (CAL) 4-12-001, March 27, 2012, ADAMS Accession No. ML12087A323

27 *Southern California Edison Co.* (San Onofre Nuclear Generating Station, Units 2 and 3), LBP-13-7, 77 NRC 307; *vacated as moot,* CLI-13-9, 78 NRC 551 (2013).

28 Request for Additional Information, "San Onofre Nuclear Generating Station, Unit 2 – Request for Additional Information Regarding Response to Confirmatory Action Letter," December 26, 2012, ADAMS Accession No. ML12361A065

29 Southern California Edison License Amendment Request, April 5, 2013, ADAMS Accession No. ML13098A043

30 Southern California Edison License Amendment Request, Supplement 1, April 9, 2013, ADAMS Accession No. ML13100A021

operation of San Onofre Units 2 and 3 and decommission the site before these issues were resolved.

Approach for Reviewing the Issue

The NRC staff reviewed the following documents:

- licensee event reports related to the San Onofre steam generator tube degradation, March 29, 2012, and May 10, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12090A153 and ML12136A065)

- NRC inspection reports from San Onofre following the steam generator tube degradation, July 18, 2012, November 9, 2012, and September 20, 2013 (ADAMS Accession Nos. ML12188A748, ML12318A342, and ML13263A271)

- CAL issued to SCE, March 27, 2012 (ADAMS Accession No. ML12087A323)

- SCE's response to the CAL, October 3, 2012 (ADAMS Accession No. ML122850320)

- request for additional information regarding SCE's response to CAL, December 26, 2012 (ADAMS Accession No. ML12361A065)

- license amendment request for San Onofre Unit 2 and its supplement, April 5, 2013 and April 9, 2013 (ADAMS Accession Nos. ML13098A043 and ML13100A021)

- *Federal Register* notice (78 FR 22576), "Application and Amendment to Facility Operating License Involving Proposed No Significant Hazards Consideration Determination; San Onofre Nuclear Generating Station Unit 2," April 16, 2013

- ASLB order for Southern California Edison Co. (San Onofre Nuclear Generating Station, Units 2 and 3), LBP-13-07, 77 NRC 307 (2013) (ADAMS Accession No. ML13133A323)

- Commission Order for Southern California Edison Co. (San Onofre Nuclear Generating Station Units 2 and 3), CLI-13-09, 78 NRC 551 (2013) (ADAMS Accession No. ML13339A952)

- Enforcement Manual – Part I, Section 3.4, "Confirmatory Action Letter" (ADAMS Accession No. ML102630150)

- OIG Audit Report 12-A-09, "Audit of NRC's Use of Confirmatory Action Letters," February 10, 2012, (ADAMS Accession No. ML120410534)

- NEI Letter, "Stakeholder Input on "Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event," November 12, 2014, (ADAMS Accession No. ML14317A233).

The NRC staff also engaged with a variety of internal and external stakeholders as listed below to inform its understanding and perspective on specific items:

- attorneys from the NRC's Office of the General Counsel
- Branch Chief from the Reactor Projects Branch in NRC Region IV
- Branch Chief from the Plant Licensing Branch in the NRC's Office of Nuclear Reactor Regulation
- enforcement specialists from the NRC's Office of Enforcement (OE)
- responsible personnel with analogous responsibilities in the NRC's Office of Nuclear Materials Safety and Safeguards
- various external stakeholders (via the Reactor Oversight Process working group public meeting)

Conclusions

1. Did the staff's actions in response to the event at San Onofre call into question the appropriateness of the use of CALs as a regulatory tool?

No. The NRC staff review found that the use of a CAL in the San Onofre case was appropriate. In addressing this question, the staff examined the appropriateness of the NRC staff's activities following the San Onofre tube degradation event in light of the issues raised in FOE's hearing petition. Specifically, the staff considered whether oversight activities undertaken during the CAL process could be mistaken for licensing actions requiring an opportunity for an interested person to request a hearing under the AEA.

The NRC staff review of SCE's response to the CAL[31] resulted in the licensee pursuing a license amendment request through the appropriate NRC licensing process independent of the CAL process. However, the review of the license amendment request was never completed by the NRC and the CAL was closed administratively because SCE permanently ceased operation of San Onofre Units 2 and 3 before these issues were resolved. Therefore, the NRC was engaged in both oversight activities, carried out as part of the CAL process, and licensing activities, which were in progress with the NRC review of the SCE's license amendment request. Given the significance of the distinction between these types of activities in the context of hearing rights, this review examined the appropriateness of the staff's actions relating to the CAL and looked for ways to clarify the distinction between licensing activities and other regulatory activities in agency guidance and documents. The discussion under Items 2 and 3 will consider actions the staff will be taking to ensure CAL guidance in the Enforcement Manual is clear.

[31] "Actions to Address Steam Generator Tube Degradation," October 12, 2012, ADAMS Accession No. ML122850320

The Commission has explained that, under section 189a of the AEA, hearing rights are required only for the granting, suspending, revoking, or amendment of any license. Because a licensee cannot amend the terms of its license unilaterally, agency approval or authorization is necessary to trigger an opportunity to request a hearing.[32] When determining whether agency action constitutes a *de facto* license amendment, the Commission considers two key factors: whether the approval (1) granted the licensee any greater operating authority or (2) otherwise altered the original terms of a license.[33] Applying these factors, the Commission has explained that NRC oversight activities conducted only for the purpose of ensuring compliance with NRC requirements, including those in an existing license, are not licensing actions for which an interested person may seek a hearing under the AEA.[34]

The staff received views related to this subject from the Nuclear Energy Institute (NEI) in a letter dated November 12, 2014. NEI expressed the concern that permitting hearings on CALs could have the effect of discouraging licensees from agreeing to them, adversely impacting the NRC's regulatory process. NEI contends that the contents of a CAL confirm licensee commitments to comply with existing requirements, and are separate and distinct from license amendments. The contents of a CAL would only constitute a *de facto* license amendment if NRC staff approval of licensee actions would grant the licensee greater operating authority than what is already granted under the existing license and NRC regulations. The NRC staff considered these views as part of this review.

2. Are changes needed to strengthen CAL guidance or implementation (e.g., when CALs are appropriate or not appropriate)?

No. However, while the NRC staff found that the CAL was issued appropriately and its implementation was in accordance with the guidance in the Enforcement Manual, the staff did identify some enhancements that could improve the guidance. As a result of the staff's review of the CAL process, the staff will clarify in the Enforcement Manual that CALs, or actions to close a CAL, are not license amendments, because CALs serve to commemorate actions taken to bring a facility or licensee into conformance with its existing license. An action that constitutes a license amendment will be handled separately under the license amendment process. This improvement to the guidance in the Enforcement Manual will help to ensure that the appropriate regulatory tools are used given the circumstances of a future event. The staff also plans on adding guidance in the Enforcement Manual for originators of CALs to coordinate and consult with regional counsel or the Office of the General Counsel, along with the Office of Enforcement, as needed to ensure appropriate implementation of the CAL process.

Discussions with staff members in Region IV and in the Office of Nuclear Reactor Regulation (NRR) identified an improvement to the Enforcement Manual guidance to help the staff handle the closing of future complex technical issues encompassed by a CAL. The staff will clarify in the Enforcement Manual that input is needed from any office(s) involved in the review of information necessary to close the action items in a CAL. For some complex technical issues, it may be appropriate for the staff to document its review in the form of a Technical Evaluation

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32 *Florida Power & Light Co.* (St. Lucie Plant, Unit 2), CLI-14-11, 77 NRC (Dec. 19, 2014) slip op. at 8-9

33 *Id.,* citing *Cleveland Electric Illuminating Co.*(Perry Nuclear Power Plant, Unit 1), CLI-96-13, 44 NRC 315, 326 (1996)

34 *St. Lucie*, slip op. at 9

Report or other equivalent document. This report should be included as part of an inspection report.

An Office of the Inspector General (OIG) audit report[35] on CALs was issued February 10, 2012, just before the CAL that was issued to SCE in response to the steam generator tube degradation event. This audit report highlighted areas of improvement and made four recommendations to improve the oversight and implementation of the CAL process, as described below:

- Designate a centralized control point to oversee and implement an effective agencywide CAL process.

- Assess and update the NRC Enforcement Policy, the NRC Enforcement Manual, and other associated guidance to ensure that NRC's approach for using CALs is consistent, effective, and efficient.

- Conduct periodic CAL audits that verify compliance with CAL policies and procedures.

- Implement a comprehensive, agencywide CAL tracking system.

The NRC staff agreed with all of the recommendations made by the OIG in its audit report, revised the applicable documents (i.e., Enforcement Policy, Enforcement Manual, and other associated guidance), and implemented an agencywide tracking system for CALs. The improvements made to the Enforcement Policy, Enforcement Manual, and other associated guidance as a result of the OIG audit are also applicable to this San Onofre lessons learned effort.

3. Is additional formal communication needed to licensees from the NRC regarding future use of CALs?

Yes. Additional formal communication, in the form of a regulatory issue summary (RIS) is needed to clarify the NRC's intention to continue using CALs. The CAL is a well-established and useful administrative tool used to supplement the enforcement program. The NRC staff agrees with NEI's comment in its letter on the need for formal communication, and plans on broadly disseminating formal communication to all stakeholders regarding future use of CALs.

Actions

1. The NRC staff submitted Enforcement Manual Feedback Form 208 to the NRC's Office of Enforcement, capturing the following enhancements to the Enforcement Manual:

    - Clarify that CALs, or actions to close a CAL, are not license amendments and should not be treated as such. An action that constitutes a license amendment will be handled separately under the license amendment request process.

[35] OIG Audit Report 12-A-09, "Audit of NRC's Use of Confirmatory Action Letters," February 10, 2012, ADAMS Accession No. ML120410534

- Add guidance for originators of CALs to coordinate and consult with regional counsel or OGC, as needed.

- Add guidance for originators of CALs to coordinate and consult with the Office of Enforcement, as needed, as OE is the centralized control point to oversee and implement the CAL process.

- Clarify that input is needed from any office(s) involved in the review of information necessary to close the action items in a CAL. For some complex technical issues, it may be appropriate for the staff to document its review in the form of a Technical Evaluation Report or other equivalent document. This report should be included as part of an inspection report.

2. The staff will issue a RIS to all stakeholders regarding the NRC's application of the Enforcement Manual as it relates to the continued use of the CAL process.

Topic 3: Steam Generator Technical Review

Background

In the first generation of commercial pressurized-water reactors (PWRs) (constructed in the 1960s and 1970s), the steam generators were manufactured primarily with Alloy 600 mill-annealed tubing material. Operating experience showed widespread degradation of the steam generator tubes manufactured from this material, and there were numerous forced outages caused by steam generator primary-to-secondary leakage. While corrosion of the Alloy 600 material was the predominant degradation mechanism, many units also experienced wear damage to the tubes at the interface with the tube supports.

Today, there are 65 pressurized-water reactor units operating in the United States. Only two units still have steam generators with Alloy 600 mill-annealed tubing. Degradation issues at each of these two units are effectively managed by the licensees' Steam Generator Programs, ensuring that tube integrity will be maintained. The NRC requires, via the licensee's technical specifications, that all PWR units maintain a steam generator program.

There are seventeen pressurized-water reactor units in service with Alloy 600 thermally-treated tubing. Alloy 600 thermally-treated tubing has enhanced corrosion resistance properties compared to Alloy 600 mill-annealed tubing, which has resulted in corrosion issues at these units being very minor to date. Mechanical wear at the tube supports has also been experienced at these units. Corrosion and wear in these units have been adequately managed under licensees' steam generator programs.

The remaining 46 pressurized-water reactor units in service have replacement steam generators with Alloy 690 thermally-treated tubing. Replacement steam generators with Alloy 690 tubing were first installed in the late 1980s. To date, there have been no reported instances of corrosion-related degradation affecting Alloy 690 thermally-treated tubing, a significant improvement over the original equipment performance. However, some of these reactors, particularly two-loop reactors with larger steam generators, have experienced wear degradation of the steam generator tubes at the interface with the tube supports. This wear initially developed during the first operating cycle at the affected units, indicating potential shortcomings in steam generator design and/or fabrication. However, until the recent event at San Onofre, all wear issues at these units have been managed successfully under the Steam Generator Program contained in the plant technical specifications, and they have continued to be managed effectively since the San Onofre event.

Issue Definition

Southern California Edison (SCE) and the vendor (Mitsubishi Heavy Industries) determined[36] that the mechanistic cause of the Unit 3 tube-to-tube wear was U-bend in-plane fluid-elastic instability associated with adverse thermal-hydraulic conditions in the steam generator, combined with a lack of effective in-plane tube support for the U-bends. Mitsubishi determined that the tube-to-anti-vibration bar contact forces used in the replacement steam generators were not high enough to prevent the in-plane motion, given the thermal-hydraulic conditions in the

[36] Mitsubishi Heavy Industries Technical Evaluation Report, October 1, 2012, ADAMS Accession No. ML12285A265

secondary side of the steam generators. Mitsubishi also found that its design models had not appropriately calculated the secondary side flow conditions for the design configuration of the San Onofre steam generators. As a result, there was significantly less margin to fluid-elastic instability in the actual steam generators than anticipated by the models.

Mitsubishi identified the root cause of the in-plane fluid-elastic instability of the tubes to be insufficient programmatic requirements for ensuring effective anti-vibration bar support that would prevent the in-plane fluid-elastic instability. The susceptibility to fluid-elastic instability was caused by the thermal hydraulic conditions that existed in certain parts of the San Onofre replacement steam generators during full power operations.

Approach for Reviewing the Issue

The working group members reviewed relevant documents and operating experience to address the questions raised by this event. These included:

- San Onofre Augmented Inspection Team (AIT) Report (ML12188A748) and AIT Followup Report (ADAMS Accession No. ML12318A342)
- SCE Root Cause Analysis (ADAMS Accession No. ML13057A013)
- Mitsubishi Heavy Industries Technical Evaluation Report (ADAMS Accession No. ML12285A265)
- American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (BPV) Code, Section III, Division 1, Non-Mandatory Appendix N[37]
- Regulatory Guide 1.20, "Comprehensive Vibration Assessment Program for Reactor Internals during Preoperational and Initial Startup Testing," March 2007 (ADAMS Accession No. ML070260376)

A complete list of references used by the working group is included in Appendix C.

In establishing the working group to review this topic, many of the members were chosen based on their detailed technical knowledge of steam generator design and operation, and their prior involvement with inspection activities related to the San Onofre tube degradation event. To ensure diversity of perspectives, the working group included NRC staff from the Office of New Reactors (NRO), the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Regulatory Research (RES) and Region IV.

Conclusions

The September 20, 2013, NRC inspection report[38] reviewing SCE's response to the confirmatory action letter closed out the final two unresolved items (URIs) from the original AIT

[37] Copies may be purchased from the American Society of Mechanical Engineers, Three Park Avenue, New York, NY 10016-5990; http://www.asme.org

report. Staff concluded that the root and contributing causes identified by Mitsubishi were programmatically and technically reasonable. The final significance determination[39] included a Notice of Violation with low-to-moderate safety significance (White) of the requirements of 10 CFR Part 50, Appendix B, Criterion III, "Design Control."

The finding, and in particular the performance deficiency it identified, forms the basis upon which the working group considered the following items of consideration.

1. Does the agency need to provide additional Standard Review Plan (SRP) guidance for steam generator designs for new reactors, steam generator replacements, or steam generator modifications?

Yes. The NRC established regulations to provide adequate protection of the public's health and safety. Regulatory guidance, including the SRP,[40] provides methods acceptable to the staff for meeting specific regulations. Given the lack of specifics in current review guidance related to steam generator tube vibration and wear, the staff has identified a need to clarify the appropriate scope and detail of the regulatory review guidance as it pertains to steam generator tube vibration and wear.

Current Review Guidance

Current review guidance that relates to the design of steam generator tubes includes the following SRP sections related to:

- Methods of analysis for seismic Category I components (Section 3.9.1)
- Review of design transients for ASME BPV Code Class 1 and core support components (Section 3.9.1)
- Dynamic testing and analysis of reactor internals and components making up the reactor coolant pressure boundary (Section 3.9.2)
- Structural integrity of pressure-retaining components (Section 3.9.3)
- Evaluation of adverse flow effects (Section 3.9.5 Appendix A)
- Thermal-hydraulic design (Section 4.4)[41]

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38 Confirmatory Action Letter Response IR 2012-009, September 20, 2013, ADAMS Accession No. ML13263A271

39 Final significance determination and notice of violation regarding IR 2012-009, December 23, 2013, ADAMS Accession No. ML13357A058

40 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," March 2007, ADAMS Accession No. ML070810350

41 Reactor core steady-state thermal-hydraulic reviews are performed subject to the regulatory requirements identified in this Section. Meanwhile, transient reactor coolant system analysis reviews in off-normal operating conditions are performed subject to the requirements identified in SRP Chapter 15. A similar subset of guidance details related to steam generator thermal-hydraulic analytic methods would be required if the staff were to review the computational methods, and associated results, used to evaluate shell-side thermal-hydraulic conditions.

- Steam generator materials (Section 5.4.2.1)

In 2007, the NRC staff issued revisions to the SRP and to Regulatory Guide 1.20, which clarified that although the SRP guidance addresses only analyses of the reactor internals; the vibration analyses of steam generator internals and tubes should be within the scope of the staff's evaluation. However, the guidance is vague about the degree to which the guidance for evaluating reactor internals should be applied to the evaluation of steam generator internals and tubes.

Operating experience has demonstrated that almost all types of corrosion and wear can be effectively managed through the Steam Generator Program currently required by each reactor plant's technical specifications. Manageable degradation in this context is degradation that occurs slowly enough that any flaws meeting reasonable acceptance criteria will generally not compromise the integrity of the tube before the next scheduled inspection.

Therefore, the staff focused on the development of guidance for degradation mechanisms that cannot be adequately managed through the current Steam Generator Program, and which could prove to be a substantial safety hazard. Based on these considerations, the staff evaluated the need to change the regulatory guidance related to tube vibration that can lead to tube damage from wear or high cycle fatigue in a manner that is not manageable by the Steam Generator Program, such as the in-plane fluid-elastic instability that occurred at San Onofre.

The working group evaluated the scope and depth that would be needed for new or updated review guidance, and considered two options:

- A detailed approach—Develop guidance for performing a detailed review of the steam generator thermal-hydraulic and vibration analyses and tests, including analytic methods, to the same level of detail as existing guidance for the reactor internals and thermal-hydraulic analytic methods.

- A general approach—Develop guidance for determining whether the steam generator design and fabrication details are within the envelope of previous successful experience. If the design were outside the envelope of previous successful experience, guidance for a followup evaluation would be needed.[42]

At present, the available analysis and design tools do not fully address U-bend in-plane fluid-elastic instability. This is partially the result of a lack of existing industry guidance, and also results from the current, limited state of knowledge for evaluating the effectiveness of the various U-bend tube support systems at resisting in-plane motion of the U-bends, for a given set of thermal-hydraulic conditions. As discussed under Item 4 below, the NRC staff is actively engaging the industry to address these issues.

[42] The working group also evaluated whether changes to the steam generator program were necessary to address mechanisms like certain forms of high-cycle fatigue and fluid-elastic instability. As discussed in subsequent sections of this report, the working group determined that steam generators need to be designed to prevent these degradation mechanisms from occurring; therefore, improved industry standards and NRC review guidance focused on ensuring steam generator designs that adequately preclude these phenomena are being recommended.

Despite the limitations of existing analysis methods and design tools for predicting the onset of U-bend in-plane fluid-elastic instability, no steam generators had experienced this condition until it occurred at San Onofre. A comparison between the San Onofre replacement steam generators and the replacement steam generators at other nuclear power plants, using the limited dataset of available evidence, suggests that the secondary side thermal hydraulic conditions of the San Onofre replacement steam generators were beyond the envelope of successful industry experience.

The NRC staff determined that the most appropriate approach to address this issue would be to issue two-tiered guidance. The first tier would identify qualitative considerations that a reviewer could use to determine whether a steam generator design is equivalent to, or a justified extrapolation of, a proven design. If the reviewer cannot readily verify using the first tier guidance that the steam generator is bounded by, or a justified extrapolation of, a proven design, the second tier would provide detailed guidance for review of those cases.

Use of the second tier guidance would be for those steam generator designs that are substantially outside the envelope of proven operating experience. These types of designs would require a more detailed review that could involve NRC evaluation of the computational methods used and a review of the analytic results.

The NRC staff continues to evaluate the most appropriate regulatory products for this guidance. The products, particularly the first tier guidance, would have to be versatile enough to permit its use not just during the licensing process, but also during the inspection process, in those cases where the licensee was not required by the regulations to submit detailed information about the steam generator design for NRC review and approval.

The proposed additional guidance would address the generic implications of the NRC finding that additional measures are needed to ensure U-bend in-plane fluid-elastic instability does not challenge NRC safety requirements.

Summary

- Develop general guidance to assist licensees, and the NRC licensing and inspection staff, in determining whether actions relating to steam generator modifications necessitate a detailed review. These reviews may be performed as part of a construction permit or operating license application, design certification or combined license application, a steam generator modification or replacement, or a request for licensing action related to steam generators operating under different conditions (e.g., power uprates). Although a steam generator replacement may not require a license amendment request, the availability of such guidance may be useful for supporting NRC oversight activities for verifying that the design remains within the envelope of successful experience, as described further in item 5 below.

- Develop additional guidance for a detailed review of a steam generator design if the initial review under the proposed general guidance indicates a detailed review is necessary.

2. Does the agency's steam generator program handle new steam generator degradation mechanisms effectively; if not, what modifications are needed?

Yes. The NRC staff reviewed operating experience and identified several examples demonstrating the effectiveness of the Steam Generator Program in identifying and managing degradation mechanisms during inservice inspections. Examples include:

- In 2011, steam generator tube inspections identified tube-to-tube wear at a unit with replacement once-through steam generators. Although not simple to detect, the degradation did not occur rapidly, and thus could be detected and evaluated before there was an effect on tube integrity (Information Notice 2012-07).[43]

- Since 2002, stress corrosion cracking has gradually emerged as a degradation mechanism in steam generators with Alloy 600 thermally-treated tubes. This degradation has been detected and evaluated through the Steam Generator Program at particular locations along the tube length in several steam generators, but tube integrity has been maintained (most recently, Information Notice 2013-11).[44]

Certain degradation mechanisms cannot be effectively managed through the normal inservice inspection process, so efforts are made to eliminate the potential for these mechanisms during the design of steam generators. Fluid-elastic instability is a phenomenon that can result in tube damage through degradation mechanisms such as wear or high-cycle fatigue, with the interval between flaw initiation and tube failure ranging from a few days to a few months. This timeframe is too short and too unpredictable to be effectively managed by the Steam Generator Program. Therefore, such phenomena should be addressed through steam generator design and reviewed by the staff, as necessary, using the proposed guidance described above.

The NRC staff has concluded that the technical specification Steam Generator Program effectively addresses new degradation mechanisms. As a part of the Steam Generator Program contained in their technical specifications, licensees are required to provide the results of their periodic steam generator inspections to the NRC. In addition to reviewing these results on an ongoing basis, the NRC staff periodically reviews domestic and international operating experience to identify any steam generator issues (including degradation) that may warrant additional action. The NRC staff will continue to perform reviews of domestic and international operating experience to ensure that the Steam Generator Program continues to address emerging degradation mechanisms adequately.

Summary

No modifications to licensee technical specification Steam Generator Programs are needed.

3. In light of the new steam generator degradation mechanism, fluid-elastic instability, does the Steam Generator Program effectively account for this phenomenon going forward?

Yes. The U-bend in-plane fluid-elastic instability experienced at San Onofre was the first known instance of this condition occurring in a steam generator in the nuclear industry, either in the United States or around the world. However, fluid-elastic instability in general is not a new

[43] NRC Information Notice (IN) 2012-07, "Tube-to-Tube Contact Resulting in Wear in Once-Through Steam Generators," July 17, 2012, ADAMS Accession No. ML120740578

[44] NRC IN 2013-11, "Crack-Like Indications at Dents/Dings and in the Freespan Region of Thermally-Treated Alloy 600 Steam Generator Tubes," July 3, 2013, ADAMS Accession No. ML13127A236

phenomenon, but rather, is a known phenomenon that is responsible for causing tube vibration that can lead to degradation from tube wear or high-cycle fatigue.

During its review of the Mitsubishi technical evaluation reports and root cause report, as part of the followup to the Augmented Inspection Team (AIT) inspection,[45] the NRC inspection team found that industry design practice for commercial reactors in both the United States and Japan (as well as other countries using nuclear technology), at the time the San Onofre replacement steam generators were designed, did not specifically address in-plane fluid-elastic instability of the U-bends. Rather, industry's practice relied on actively controlling out-of-plane fluid-elastic instability of the U-bends, which is a more likely form of instability. The assumption at the time was that measures taken to control out-of-plane fluid-elastic instability would be sufficient to control in-plane fluid-elastic instability.

Operating experience indicates that most corrosion and vibration-induced wear mechanisms are manageable under the Steam Generator Program. However, the Steam Generator Program was never intended to manage tube vibration phenomena that produce flaw growth rates that may be high or unpredictable, such that tube integrity may not be effectively managed. Because phenomena such as fluid-elastic instability can result in excessive tube degradation in a short period of time, either through wear or through high-cycle fatigue, the potential for these phenomena must be eliminated during the design and fabrication phase. If in-plane fluid-elastic instability or high-cycle fatigue occur unexpectedly, then corrective action must be taken to eliminate the condition. An example of such action is given in Bulletin 88-02, "Rapidly Propagating Fatigue Cracks in Steam Generator Tubes."[46]

Bulletin 88-02 describes a tube rupture event that occurred at North Anna Unit 1 in 1987, due to high-cycle fatigue. The high-cycle fatigue was caused by a combination of tube denting at the uppermost tube support plate, and out-of-plane fluid-elastic instability of the U-bend portion of the tube, which was caused by lack of anti-vibration bar support for the failed tube and locally high flow velocities. The high flow velocities were due to non-uniform insertion of the anti-vibration bars into the tube bundle. In response to the tube rupture event, the licensee stabilized and plugged tubes, reduced local fluid forces in the U-bend region, and improved leakage monitoring. In response to Bulletin 88-02, all pressurized-water reactor units reviewed their inspection data for evidence of tube denting at the top tube support plate. Units that had evidence of denting implemented enhanced leak rate monitoring programs, assessed anti-vibration bar locations, assessed stability ratios for the most limiting tube locations, and assessed flow peaking factors.

Summary

The NRC staff concludes that modifications to the Steam Generator Program are not necessary to address fluid-elastic instability, since this phenomenon should be precluded by design. Actions to address revising design review guidance, to ensure such effects are addressed in the design process, were discussed in Item 1; the need for improved industry standards and NRC oversight is discussed in Items 4 and 5.

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45 Confirmatory Action Letter Response IR 2012-009, September 20, 2013, ADAMS Accession No. ML13263A271

46 NRC Bulletin 88-02, "Rapidly Propagating Fatigue Cracks in Steam Generator Tubes," February 5, 1988, ADAMS Accession No. ML031220043

4. Does the agency or industry need additional standards or criteria for new steam generator designs or steam generator replacements?

Yes. As described in Item 1, the NRC staff is developing general guidance that can be used in evaluating steam generator designs, with respect to steam generator tube vibration issues. Currently, the guidance most commonly used in industry is Non-Mandatory Appendix N to Section III of the ASME BPV Code. With respect to industry standards or criteria, the guidance in Non-mandatory Appendix N to Section III of the ASME BPV Code does not sufficiently address in-plane fluid-elastic instability in the U-bend region of recirculating steam generators. Development of such guidance may require extensive laboratory testing.

The variables that determine the effectiveness of current U-bend support systems in resisting both in-plane and out-of-plane U-bend instability are not well-understood. The current methodology is largely based on advances made in the 1970s that have since been augmented by proprietary, vendor-specific design practices. Those specific design methods were developed over the years from open literature and proprietary in-house mock-up tests. Therefore, the experience of the vendor generally factors heavily into the effectiveness of the design in precluding fluid-elastic instability.

With the notable exception of the incident at San Onofre, industry design practices have been effective at ensuring acceptable margins to high flaw growth rate mechanisms, such as those that result from fluid-elastic instability. On August 13, 2014, the working group sent a letter[47] to the Executive Chairman of the Steam Generator Management Program (SGMP) to open a dialogue regarding possible changes to industry standards and NRC review guidance. The SGMP is an industry-run organization that developed many of the guidelines used by licensees in their Steam Generator Programs. The Steam Generator Programs are required by licensee technical specifications, and as such, they are subject to inspection under the NRC's reactor oversight process. Because portions of steam generators are designed to requirements of the ASME BPV Code, the Director of ASME Nuclear Codes & Standards was copied on the letter. In the letter, the NRC staff requested that the SGMP inform the NRC of specific actions that the industry is taking based on the San Onofre experience. This includes any plans to develop new design and fabrication standards and guidance, to modify or augment existing design and fabrication standards and guidance, and any actions underway to develop guidance on critical thermal-hydraulic parameters to eliminate the potential for in-plane fluid-elastic instability.

The SGMP Executive Chairman informed the NRC that the SGMP held a working group meeting at the end of August 2014 to discuss the topic. The topic remains on the agenda for future meetings and the NRC staff will continue to interact with the industry through correspondence and regular meetings with the industry's Steam Generator Task Force.

Summary

The staff will continue to engage the industry on design and fabrication standards and guidance to minimize the potential for in-plane fluid-elastic instability in steam generator design.

[47] Letter to the Executive Chairman of the Steam Generator Management Program regarding San Onofre Nuclear Generating Station Lessons Learned, August 13, 2014, ADAMS Accession No. ML14206A841

5. Should enhancements to the agency's steam generator inspection procedures be made to address experience gained at San Onofre?

Yes. The two-tiered guidance discussed in Item 1 could potentially be relevant to three Inspection Procedures (IPs). These include IP 50001, "Steam Generator Replacement Inspection"; IP 71111.17T, "Evaluations of Changes, Tests and Experiments and Permanent Plant Modifications"; and IP 71111.18, "Plant Modifications."

Inspection Procedure 50001 directs the development of a site-specific inspection plan for steam generator replacement, and directs inspectors to use IP 71111.17T and IP 71111.18 for completion of baseline inspections. Inspectors use the site-specific inspection plan to select and review the safety-related aspects associated with the major phases of the steam generator replacement project. Inspection Procedure 50001 also directs the inspector to confirm that the licensee completed engineering evaluations and design changes associated with steam generator replacements in conformance with the requirements of the facility license, the applicable codes and standards, licensing commitments, and the regulations.

Inspection samples of permanent and temporary plant modifications for the steam generator replacement project can be selected and reviewed as a part of the baseline inspection using IP 71111.17T, "Evaluations of Changes, Tests and Experiments and Permanent Plant Modifications," and IP 71111.18, "Plant Modifications." The inspectors also use IP 71111.17T to perform reviews of licensee 10 CFR 50.59 ("Changes, Tests and Experiments") screenings and evaluations, as discussed in this report under Topic 1.

The NRO Vendor Oversight Working Group also conducted a lessons learned review. Personnel from Region IV were involved on both the Vendor Oversight Working Group and the Steam Generator Technical Review Working Group, to ensure the consistency of any changes to IPs.

Enhancements to the vendor inspection program (VIP) are discussed in detail under Topic 8. The NRC VIP may involve inspections during manufacture of the steam generator. Because of the long lead times required to design and fabricate steam generators, these inspections can occur years before the steam generator fabrication is complete. Therefore, it may also be appropriate to revise the IPs used by the VIP to reference the proposed updates to general review guidelines discussed in Item 1.

Summary

As noted in Item 1, the NRC staff will develop and implement a set of general review guidelines, which could be used to determine the need for a detailed review of new steam generators, replacement steam generators, or steam generators that may be operated under different operating conditions (e.g., power uprates). In addition to these review guidelines, the staff will also revise the pertinent IPs to ensure the guidelines can be applied during the inspection and oversight process, even if the steam generator replacements themselves do not require NRC staff review and approval.

Actions

The staff is taking actions developed from consideration of each of the individual items above as follows:

1. The staff is developing general guidance to assist licensees, as well as the NRC licensing and inspection staff, in determining whether steam generators necessitate a detailed review. These reviews may be performed as part of a construction permit or operating license application, design certification or combined license application, a steam generator modification or replacement, or a request for licensing action related to steam generators that may be operated under different operating conditions, such as for a power uprate.

    - The staff will develop guidance to assist staff performing the review to determine whether the action is bounded by successfully operated projects, or if a detailed NRC evaluation is required.

    - The staff will develop guidance for staff performing a detailed review of steam generator design characteristics or modifications.

    - The staff will revise the relevant inspection procedures, in coordination with regional offices and the NRR Division of Inspection and Regional Support, to incorporate elements of the guidance into the inspection program, to assist NRC oversight of steam generator modifications or changing operating conditions that do not involve licensing actions.

2. The staff is continuing to engage the industry on standards and guidance for the design and fabrication of steam generators to eliminate the potential for fluid-elastic instability in the future.

Topic 4: Organization/Roles and Responsibilities

Issue Definition

During the inspection and technical review following the San Onofre steam generator tube degradation event, a number of issues were raised concerning organizational roles and responsibilities within the NRC including: the differentiation between inspection and licensing reviews; changes in signature authority; complications of review occurring in parallel with investigations; organizational changes; internal communications; legal assistance; and the use of common internal Web sites.

Approach for Reviewing the Issue

The NRC staff reviewed the following documents related to the events at San Onofre:

- Inspection Manual Chapter (IMC) 0350, "Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns," (ADAMS Accession No. ML063400076)

- IMC 0351, "Implementation of the Reactor Oversight Process at Reactor Facilities in an Extended Shutdown Condition for Reasons Other Than Significant Performance Problems," (ADAMS Accession No. ML102770448)

- Management Directive (MD) 8.3, "NRC Incident Investigation Program," (ADAMS Accession No. ML13175A294)

- IMC 0309, "Reactive Inspection Decision Basis for Reactors," (ADAMS Accession No. ML111801157)

- NRC Enforcement Manual (ADAMS Accession No. ML102630150)

- ADM-504, "Qualification Program," (ADAMS Accession No. ML13136A016)

- San Onofre Steam Generator Replacement Inspection Report dated May 10, 2011, (ADAMS Accession No. ML111300448)

- Confirmatory Action Letter (CAL), March 27, 2012 (ADAMS Accession No. ML12087A323)

- San Onofre Augmented Inspection Team (AIT) Inspection Report 2012-007, July 18, 2012 (ADAMS Accession No. ML12188A748)

The NRC staff preparing this report also discussed the issue of organization roles and responsibilities with representative NRC staff involved in the San Onofre event followup from the following offices: Region IV, the Office of Nuclear Reactor Regulation (NRR), the Office of New Reactors, the Office of Public Affairs, the Office of Investigations, and the Office of Congressional Affairs.

Summary and Assessment of Inquiry Responses

Interactions with internal stakeholders involved discussion of the specific items of the original tasking memo as outlined in Appendix B. It should be noted that no attempts were made to either validate or invalidate any of the perspectives offered. Additionally, it should be noted that feedback reflected in the discussion below represents, in many cases, a diversity of views and should not be taken as a consensus view. Nevertheless, recognizing the subjective nature of the perspectives offered, staff attempted to draw general conclusions, where possible, based on the majority views provided, but recognizes that others may draw different conclusions based on their personal perspectives. The following is a summary of the perspectives offered by the staff who were interviewed and the staff's assessment of any lessons learned.

1. Did the existing licensing and oversight processes help the staff respond with the appropriate priority to key events in the timeline (e.g., the Unit 3 steam generator tube leak, the Units 2 and 3 steam generator tube inspection results, and restart proposals for Unit 2 before the CAL and in response to the CAL)?

Yes. Most staff who were interviewed indicated that existing licensing and oversight processes helped the staff identify the appropriate response priority for key events. Examples of processes cited included MD 8.3 for the AIT, the NRC Enforcement Manual for issuance of the CAL, and IMC 0351 during the extended shutdown. However, some staff did indicate that processes could be enhanced by identifying triggers or thresholds that could be considered when determining if a management oversight panel should be established. Some triggers that were mentioned include: identification of a new or unique type of event; difficulty in reaching alignment on issues involving multiple offices; establishment of special projects branches; the potential for concurrent licensing and oversight activities; expectation of an extended shutdown period; and high levels of interest from external stakeholders. Establishment of the panel could help in providing additional management focus when complex issues arise.

During the followup to the steam generator tube degradation event at San Onofre, special projects branches were established prior to the formation of an oversight panel. Some staff interviewed indicated that the oversight panel provides a commensurate level of management oversight when special projects branches are deemed to be necessary.

Some staff also indicated that IMC 0350 contains provisions for the establishment of an oversight panel. IMC 0350 was considered for use during the San Onofre event followup but was not chosen since the extent to which licensee performance issues were a contributing cause of the event was not fully known at the onset.

Some staff emphasized that both IMC 0350 and IMC 0351 must clearly and cleanly accommodate circumstances such as were experienced at San Onofre.

2. For technical issues involving both regional inspection and headquarters technical review, does the agency have appropriate guidance to determine the roles and responsibilities of each office and how the decisionmaking process should work?

Interview responses on this topic did not support drawing a clear conclusion on this item. Some staff indicated, that for technical issues involving both regional inspection and headquarters technical review, the agency has appropriate guidance for determining the roles and responsibilities of each office and how the decision making process should work. However,

some staff indicated that they believed roles were not always adhered to before the establishment of the oversight panel, particularly in areas related to licensing activities.

In addition, some staff indicated that they encountered delays in securing active involvement from the appropriate offices and all of the necessary divisions within those offices.

3. Should there be a more concerted effort on the front end to gain alignment on scope of review and office lead?

Yes. While some staff indicated that it was understood which office had the lead for a given task, they also indicated that a discussion on the scope of review and office lead at the beginning of an event response would be beneficial.

Other staff indicated that before the establishment of the oversight panel, it was not always clear which office had the lead, or if all of the appropriate offices and the necessary divisions within the offices, were involved. There is a benefit to clearly establishing the scope of review and office lead, especially at the division and senior management level, early in the process.

4. Should there be guidance for Technical Evaluation Reviews?

No. Most of the staff interviewed indicated that developing specific guidance for Technical Evaluation Reviews (TERs) would not be practical due to the unique nature of each event. Some staff also indicated that the technical evaluation format largely follows the well-established safety evaluation format, and technical evaluations are largely conducted consistent with the relevant parts of the Standard Review Plan (NUREG-0800). Some stakeholders also indicated that IMC 0350 contains adequate guidance for addressing technical issues.

It should be noted that some staff did indicate that it would be beneficial if guidance for TERs could be developed. Some staff also indicated that there should be an office procedure for developing TERs (i.e. guidance on roles and responsibilities when reviews need to be developed).

5. For technical issues involving both regional inspection and headquarters technical review, is the agency's current approach and implementation of internal communications, especially at the middle and higher management levels, appropriate and effective?

Interview responses on this topic did not support drawing a clear conclusion on this item. Most staff indicated that communications were appropriate and effective, although some staff noted that issues arose occasionally when communications occurred outside the normal chain of command.

Some staff indicated that timeliness was an issue in addressing issues that were raised, particularly issues that involved differing views. However, some of the staff did indicate an understanding that the San Onofre tube degradation event was unique, and that progress was being made to resolve the differences.

Some staff indicated that prior to the establishment of the oversight panel, communications were not as effective, and it was more difficult to get upper level management alignment without the coordination structure of the panel.

6. During the SONGS followup, special projects organizations were established in NRR and Region IV, as well as a multiple-office oversight panel. One of the goals of the panel was to ensure consistent and clear communication. Were these organizational changes effective and what lessons can be learned for future high-profile and resource-intensive events?

Yes. Some staff indicated that the panel effectively ensured that roles and task leads were understood and improved communications. Some staff also indicated that the panel helped to ensure the appropriate level of management oversight and alignment at upper management levels. As stated in Item 1, staff did indicate that processes could be enhanced by identifying triggers and thresholds that could be considered when determining if a management oversight panel should be established.

Some staff indicated that the panel had a limited impact on communications, either positive or negative, but noted that setting up the panel earlier in the event would provide additional benefit.

7. During events that are high-profile and require involvement by multiple offices, are there lessons to be learned regarding internal communications such as the use of a common SharePoint site, establishment of review schedules, use of periodic group phone calls, use of periodic management briefings, etc.?

No. Most staff indicated that use of the SharePoint site and periodic status meetings helped to ensure that the staff involved were aware of the status of ongoing activities.

8. For technical reviews going on in parallel with investigations by the Office of Investigations (OI), are there lessons to be learned regarding internal coordination and communication?

No. Most staff indicated that there were no communication issues with OI and that any investigations by OI did not interfere with the NRC staff's efforts.

Summary

Many of the staff interviewed indicated that the establishment of an oversight panel during the San Onofre event helped to improve communications, affirm roles and responsibilities, or provide additional management oversight, and that establishing the panel earlier in the process could have been beneficial. In addition, guidance must clearly and cleanly accommodate circumstances like those experienced during the San Onofre event.

Actions

In order to promote effective communications and a clear understanding of roles and responsibilities during potential future events, the following action, which takes into account the various staff perspectives, will be taken:

1. The staff will develop guidance for determining when a management oversight panel should be considered. Examples of thresholds to consider include identification of a new or unique type of event; difficulty in reaching alignment on issues involving multiple offices; establishment of special projects branches; the potential for concurrent licensing and oversight activities; the expectation of an extended shutdown period; or high stakeholder interest. The guidance should also identify management oversight panel responsibilities.

Topic 5: Communication and External Interactions

Issue Definition

The steam generator tube degradation event at San Onofre generated significant external interest from a variety of stakeholders including congressional, State and local elected officials, the licensee, nongovernmental organizations, and members of the public. In responding to this interest, the agency conducted a number of externally focused communication efforts, including sponsoring multiple public meetings, hosting a dedicated Web site, posting to the U.S. Nuclear Regulatory Commission (NRC) Blog,[48] conducting periodic calls between NRC management and the licensee, briefing congressional staff, and responding to a variety of correspondence. To coordinate this effort, the agency formed a group focused on communication activities comprised of staff from the Office of Nuclear Reactor Regulation (NRR), Region IV, the Office of Public Affairs (OPA), and the Office of Congressional Affairs (OCA). The group spent significant staff resources and time implementing various communication activities and keeping information products up-to-date. These types of communication and outreach activities were not part of the NRC's routine oversight process, and available procedures provided limited guidance to staff as they implemented and coordinated these activities.

A number of issues have been raised concerning the agency's communications with external stakeholders during the NRC's response and evaluation of this event. A central theme is the question whether any improvements can be made to agency processes to ensure a more efficient use of agency resources in conducting more effective external outreach during future events.

Approach for Reviewing the Issue

Because the scope of this review centered on the agency's processes, most of the input reviewed came from NRC staff directly involved with communication activities during the extended shutdown. Interviews and focus groups were held with current NRC staff and managers from multiple offices, including Region IV, NRR, OPA, OCA, the Office of Information Services (OIS), the Office of the Executive Director for Operations (OEDO), and Commission staff. Interviews were also conducted with the former Region IV Regional Administrator, the former Region IV Deputy Regional Administrator, and a former NRC employee who served as one of the facilitators for several of the public meetings. Staff supplemented the insights gained from these interactions by reviewing relevant documents, including communication plans, Blog posts, press releases, the NRC's San Onofre public Web site,[49] and various public meeting documents, including agendas, presentation materials, and feedback forms. Staff also reviewed recordings of several of the NRC's San Onofre public meetings.[50]

The NRC staff reviewing this issue also sought to garner insights into the effectiveness of our communications with key stakeholders. Data collection from external sources focused on the activities that featured direct interactions with these individuals, including public meetings, the NRC Blog, and the NRC's San Onofre public Web site. As part of this effort, an online survey was conducted from August 19–September 22, 2014. The NRC staff sent survey invitations to

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48 NRC Blog postings for San Onofre; http://public-blog.nrc-gateway.gov/tag/san-onofre/

49 NRC Web site for San Onofre Steam Generator Tube Degradation; http://www.nrc.gov/info-finder/reactor/songs/tube-degradation.html

50 Archived webcasts of public meetings, which can be accessed at http://video.nrc.gov

approximately 140 individuals who had interactions or communications with the NRC during the extended shutdown for whom staff had contact information, and received 25 responses.[51] The NRC staff also reviewed additional written input beyond the survey responses that four individuals chose to provide. An external contractor who served as the main facilitator for several of the public meetings was also interviewed. Discussions with knowledgeable external stakeholders and interested parties at the October 27, 2014, NRC public meeting[52] on decommissioning were also considered.

Conclusions

The NRC staff consolidated the insights from the information sources discussed above for further analysis and evaluation.

1. With the large interest and turnout during public meetings, have any lessons been learned about format, focus, timing, location, security, and other logistics:

Yes. The agency held a total of eight public meetings during the extended shutdown, four in California and four at NRC headquarters.[53] They included both Category 1 and Category 3 meetings,[54] and the majority provided for remote participation (e.g., teleconference or Webcast). Staff input indicated that the planning and execution of these public meetings, particularly the ones in California, were very challenging and resource intensive. The level of effort needed to achieve a reasonably successful meeting had not been anticipated or budgeted in advance. NRC technical staff was heavily involved with planning these meetings, and this impacted their work on other activities. Many of the tasks, such as locating venues, arranging logistics, and developing communication products, could have been done by other staff so that the technical specialists could focus primarily on technical and inspection related work. In addition, obtaining assistance from individuals with specific meeting planning, coordinating, and logistics expertise could have resulted in an overall reduction in the time and effort expended and eased challenges encountered with some aspects of the arrangements.

Survey results and interactions with stakeholders indicated that most external stakeholders were generally satisfied with staff and facilitator performance, and that the meeting objectives were clear and were achieved. Suggestions for improvement included using venues that are more accessible and provide more suitable settings for federal public meetings, providing better notification of upcoming meetings, increasing the focus on relevant topics, taking measures to provide for equal participation among the different groups and viewpoints, providing more time and opportunities for questions and discussion, and better management of disruptive behaviors from members of the audience.

a. *Format* – Several different formats were used in the San Onofre public meetings. Several staff suggested that for similar situations in the future, the agency should consider

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51 SONGS communications external survey results and feedback for specific public meetings can be found under ADAMS Accession No. ML15014A091

52 NRC public meeting notice, October 9, 2014, ADAMS Accession No. ML14282A179

53 The full list of meetings along with supporting materials can be found at: http://www.nrc.gov/info-finder/reactor/San Onofre/San Onofre2/public-meetings.html

54 As defined in "Enhancing Public Participation in NRC Meetings; Policy Statement" (May 28, 2002, 67 FR 36920).

holding meetings using an “open house” format with the specific purpose of listening to attendees; NRC staff should not feel the need to always make a formal presentation. Such meetings allow more opportunity for dialogue and for participants to provide their views to the agency while conversing with NRC staff in a more informal setting. This could help reduce the likelihood for contentious interactions that are more likely to occur in large crowds. Such meetings could be done in combination with Category 1 meetings where the staff meets with the licensee to conduct business while the public observes.

Feedback from NRC staff recommended that for future panel discussions, the panel composition should ensure a broad, balanced spectrum of views directly relevant to the topic at hand. In addition, staff recommended bypassing the sometimes lengthy introductory statements and moving directly into a facilitated question and answer session to maximize the amount of time available for attendees to directly hear from the speakers on questions they have. Feedback from meeting attendees indicated that NRC presentations could be more informative for the general public with greater attention to the use of plain language, more graphics to illustrate technical concepts, and fewer acronyms.

Feedback from both NRC staff and survey respondents indicated that the facilitators worked hard to manage the meetings but at times were challenged when the size of the audience grew beyond a few hundred, or when faced with disruptive participants and contentious interactions. For future meetings with large audiences, the feedback from facilitators suggested using comment cards and/or asking people to sign in if they want to make comments. The facilitators could then manage the order of the comments to ensure a wide range of views are covered and the available time is used effectively. The facilitators also felt it was beneficial to conduct outreach in advance of meetings to better understand participants’ concerns and interests ahead of time. NRC staff feedback suggested that additional community outreach and relationship building could be helpful.

For the meetings that were held at headquarters, several members of the NRC staff indicated that it may have been better to follow the normal processes for setting up public meetings with the licensee. For the San Onofre meetings, NRC staff tried to keep more distance from the licensee than usual during the planning process, and so did not communicate with the licensee as much as they typically would in developing the agenda. NRC staff felt this led to both sides not being as clear on the focus and expectations for the meetings, which limited the effectiveness of the meetings.

The NRC staff providing feedback recommended that meetings with a technical focus should continue to be held at headquarters to minimize travel costs and maximize technical staff participation. Interested stakeholders can participate remotely. These technical meetings can then be complemented with meetings in the local community, with a focus on community outreach and communication.

b. *Focus & timing* – Feedback from NRC staff and from the survey responses emphasized the need for each meeting to have a clearly defined purpose. In this high profile case, many members of the public viewed the meetings as a type of hearing – they wanted to make statements “on the record,” and provide input to the NRC decisionmaking process for determining whether the plant was safe to restart. The intent of these meetings was to provide information on the event and NRC processes, and NRC staff was not in the position to take inputs for the decisionmaking process. Therefore, the NRC staff was challenged in carrying out the intended focus of the meetings. NRC staff responses during interviews indicated that meeting notices and introductory remarks should make it clear

when the purpose of the meeting is to focus on providing information on NRC processes and their status and that the agency is not seeking public input for decisionmaking purposes.

Some NRC staff also raised the related issue that there may have been too many public meetings. Holding meetings without a specific need may have actually been detrimental to outreach efforts. NRC staff being interviewed recommended basing the timing and the number of meetings on the availability of key pieces of new information to communicate.

c. *Location, security, & other logistics* - For the California meetings, the NRC staff expended significant effort to locate venues with capacities large enough to accommodate the expected audience. The high interest levels among large numbers of stakeholders presented challenges for coordinating security and finding venues willing to host these meetings.

Much of this effort fell to NRC technical staff, who had limited experience planning meetings and other work demands. A centralized agency resource to assist in coordinating public meeting logistics, particularly for remote locations, would have allowed the process to work more efficiently. In addition, challenges could have been reduced if there had been clearer agency guidance on specific details including: the types of facilities considered acceptable for hosting large meetings; coordination of security when contentious issues are expected in the discussion; facility capabilities required for a successful meeting; contingency measures that should be planned in case of overflow, and other supporting logistical details.

Meeting attendees noted that pre-registration could help staff to gauge whether larger accommodations might be needed. NRC staff involved in organizing meetings noted positive results from early interactions with the Office of Administration to enable security staff coordination with local officials. They also emphasized the need to coordinate with the venue about the potential for large or contentious crowds, and with the licensee about its expectations for crowd size and attendance of its own employees. The facilitators stressed the importance of advanced planning and coordination between themselves and with all the offices that would be involved.

Both NRC staff and survey feedback commended the ability to increase the reach of the meetings through webcasting, but NRC staff feedback noted that the agency could benefit from having a standard process in place for webcasting public meetings to make the process more efficient and less resource intensive.

2. Meetings with small groups of local stakeholders were planned to provide specific, targeted outreach in a more informal setting. Have any lessons been learned from this practice, including lessons about possible programmatic enhancements to encourage future consideration?

Yes. Nonpublic meetings had been planned with small groups of stakeholders including local and State government officials as well as nongovernmental organizations, but SCE announced its intention to decommission the San Onofre units before these meetings occurred. Most NRC staff interviewed had felt hesitant to schedule these meetings initially, particularly with the nongovernmental organizations, feeling that the format, where only certain groups would participate, detracted from the openness and transparency which the agency embraces to bolster public confidence in the regulatory process. The selection process for determining the attendees would pose additional challenges for ensuring fairness and diversity of

representation, though a few NRC staff members interviewed felt that such meetings could allow the agency to better understand various perspectives and allow outside stakeholders to feel that their opinions were heard and respected. Feedback from NRC staff noted that the decision to pursue such meetings in the future should require careful, deliberate consideration of the meeting's purpose and the groups to be invited. It would also require an understanding of the risk that these meetings could create a perception that runs counter to the NRC value of openness, and of the resources needed to ensure that the meeting objectives are met.

There was strong support for continuing government-to-government meetings with local and State governments.

3. The staff used the NRC Blog several times during the review of the licensee's restart readiness plan. Have any lessons been learned? Was this communication tool effective?

Yes. The NRC Blog proved to be an effective and valuable tool for posting updates and information in real time to which staff could direct interested parties. The posts related to San Onofre received a significant number of comments. NRC staff involved in posting to the Blog emphasized the need for NRC technical staff to coordinate closely with OPA to ensure the content is both accurate and presented appropriately in plain language so that it was understandable to the general public.

The downside to the public interest expressed in the Blog comments was the challenge to the NRC staff in responding to these comments, an effort that could be time-consuming and distract from the staff's technical assessment of the event. NRC staff noted that the majority of the comments were negative and often made by the same small group of people. While there were some instances where the moderator was able to provide additional information or correct inaccuracies in the comments, some of the Blog comments were not a useful source of dialogue on the topic, even while the postings themselves provided a useful format for sharing information. NRC staff responsible for maintaining the Blog did note that the presence of negative comments on the Blog added to its credibility and to the perception of the NRC as a transparent organization. Survey respondents who were familiar with it also indicated that the Blog had generally been a useful source of information.

4. The staff dedicated significant resources to updating the internal Communication Plan and external San Onofre website. Was this use of resources effective, was the information used, and have any lessons been learned for high-profile events going forward? Have any lessons been learned with respect to publicly posting technical information, including making sure it is accurate and determining if it could be misunderstood?

Yes. In general both NRC staff and survey respondents found the external Web site useful as a repository for background documents. However, ensuring that information was provided in a plain language format and in a timely manner presented time and resource challenges as this work was performed by technical staff involved in the review of the San Onofre event. The resulting product, though useful, could have made better use of plain language to be more easily understood by the general public.

The communication plans were a useful resource for communicating with external groups. Successful communication plans required close collaboration between the technical groups and staff involved in external outreach. The time and resources required to maintain the communication plan up-to-date need to be considered. In addition, although updated versions

of the plan were regularly posted to the agency's active communications plan Web site, not everyone who needed access to the plan knew how to locate it. Future frustration could be avoided if there is better awareness agencywide about where current communication plans are maintained and available.

5. The staff received significant external correspondence, multiple Freedom of Information Act requests, and numerous congressional requests during the staff review. Have any lessons been learned from how these were processed and how the staff responded, and are there ways to enable a more efficient and effective staff response to these activities? For example, is better coordination needed when processing e-mails to ensure that lead and support office guidance is clear, including coordination between allegation coordinators, to minimize duplication of work?

Yes. Response to Freedom of Information Act (FOIA) requests proved time-consuming for technical and project management staff. Suggestions for improving the FOIA response process focused on reducing the amount of redundant material provided, especially from e-mail chains, and flagging material that would be potentially subject to a FOIA request as it was produced to reduce the time spent conducting searches. Assigning a FOIA coordinator early in the process, and following a desktop guidance document produced substantial time savings over the course of the event.

For congressional correspondence, the Office of Congressional Affairs found that holding weekly calls for interested congressional staffers and being able to direct them to the updated Web site reduced the number of incoming congressional requests for information. NRC staff from several offices indicated that designating a single person in the Office of the Executive Director for Operations to track all congressional correspondence related to the issue was very useful.

6. The licensee arranged multiple weekly calls at different levels of management. Although this helped to keep NRC management informed, it also led to inconsistent messages and occasional confusion; have lessons been learned in this area?

Yes. The multiple weekly calls that the licensee arranged with different levels of NRC staff and managers presented challenges for communicating a clear and consistent message. Topic 4 discussed that the best way to maintain a consistent message was to ensure that roles and responsibilities were clearly delineated early in the process. Based on NRC staff feedback, the issue of unnecessary, redundant weekly phone calls could be addressed as well by ensuring that a single point of contact maintains responsibility for coordinating the calls with the licensee.

7. Often, both the Commission and NRC staff were engaged in communication with external stakeholders. Can efficiencies be gained by coordinating communication efforts on high-profile events using both Commission and staff communication experts to achieve a unified agency message?

Yes. Overall feedback from staff pointed to the importance of effective coordination between staff and the Commission. NRC staff interviewed for this report felt that Commission communication was most effective when staff provided the Commission with background information, context, and additional insights related to the issue. As discussed in Topic 4, the roles and responsibilities for these types of interactions are adequately defined in agency

procedures, and the most successful interactions occurred when these procedures were closely followed.

In addition, staff indicated that a more coordinated effort to engage in proactive communications, in a greater variety of formats, could have been beneficial. For future situations, staff encouraged the consideration of outreach methods beyond the traditional public meeting, including Webinars and meeting with media officials. Several staff provided positive feedback on the Regional Administrator offering and holding advanced discussions with selected reporters before one of the large public meetings. This resulted in news coverage that more accurately conveyed the context around the issues and the agency's message. More efforts such as this in anticipation of significant developments or emerging issues may have helped the agency better communicate key messages in a manner that anticipated and addressed areas of potential concern. Such efforts would have provided interested parties with a more complete understanding of the context surrounding any developments with San Onofre as they occurred. A greater emphasis on proactive and coordinated communications, through more varied formats, would have also reinforced the agency's commitment to transparency and might have reduced the number of external requests for information.

Summary

NRC Staff Input: The central takeaway from the evaluation of staff feedback was that communications efforts related to the steam generator tube degradation event at San Onofre consumed significant resources, especially from the technical staff, that exceeded what had been anticipated or budgeted. NRC technical staff had to perform most of the communications activities as collateral tasks, which often took them away from performing technical work. In addition, efficiencies could have been gained and more effective communication products could have been developed if individuals with specific communications expertise were used to assist in the efforts. Additional resources to aid with external messaging and meeting logistics, that could be flexed as needed to meet the demands of unique situations such as that experienced at San Onofre, would allow technical expertise to remain focused on the technical issues under consideration. They may also allow for more efficient and effective communication and outreach efforts.

Survey Feedback: In addition to the specific feedback described above related to public meetings, the Blog, and the public Web site, the majority of those who responded to the survey responded positively to questions about the overall amount of information provided by the NRC and the overall quality of that information during the extended shutdown. The survey also showed generally positive results for the quality, availability, and usefulness of additional communications activities, other than those specifically listed on the survey, including interactions with NRC staff. Some of the survey respondents expressed concerns about NRC communications; that there was too little opportunity for interactive communications, and that the timeliness for providing information could be improved.

One additional aspect of communications is the use of generic communications to ensure wide dissemination of information. When a generic communication is issued, over 7,000 stakeholders receive the final document by e-mail, and all generic communications (less any security related information) are available on the NRC public Web site. The NRC staff communications related to the San Onofre steam generator tube degradation event will continue with generic communications resulting from the assessment contained in two of the topics in this report.

Actions

Since the time of this tasking, a number of communication and outreach-related efforts have been started in various NRC offices, some independent of the San Onofre lessons learned tasking and some related. In developing these actions, an effort was made to coordinate with and leverage activities already underway to maximize efficiency and avoid duplication.

1. Develop additional communication resources:

   The agency could benefit from making communication resources available to assist technical staff when the need arises. NRC staff need to be aware of the resources available, and should be encouraged to seek out assistance when events or situations emerge that may be of high public interest. This will allow the staff to be more flexible and adaptive in leveraging available communications expertise, tailoring communication and outreach strategies from the beginning, and making adjustments as the situation develops. It will also allow technical staff to focus their time on the actual technical assessment of the event and necessary followup activities.

- The Office of the Executive Director for Operations (OEDO) will develop options for leveraging agency capabilities already available to assist in outreach and communication efforts when needed, and on a more proactive basis when possible, and using more varied formats when appropriate. This participation would be provided on a collateral basis, so careful consideration will be given to the potential level of need, the availability and flexibility of resources, and any additional training and developmental activities that might be needed.

- OEDO developed and awarded an enterprise-wide contract that can be tapped as needed for assistance with public meeting facilitation, planning, and outreach efforts. This contract can be used by any office throughout the agency on an as-needed basis and would supplement the agency's current In-House Meeting Facilitator and Advisor Program.

2. The staff feedback and survey results have been considered as part of the revisions to IMC 0351 that are also discussed under Topic 7 in this report. In particular, a Reactor Oversight Process (ROP) Feedback Form has been submitted proposing to add details to the procedure regarding the process for conducting small group meetings, maintaining the NRC Blog, and coordinating NRC calls with the licensee, as well as adding guidance on the availability of communications resources when the circumstances warrant more significant communication and outreach efforts.

3. Work with previously established "Enhancing Public Meetings" Task Group:

   The insights related to public meetings that have been collected during this evaluation, such as format considerations, logistical arrangements, use of facilitators, areas of further guidance needed, and challenges experienced, have been incorporated into the topics under consideration by the "Enhancing Public Meetings" Task Group. The Task Group's initial report was completed on January 29, 2015.[55]

[55] NRC Staff Memorandum, "Enhancing NRC Public Meetings Task Group Report," January 29, 2015, ADAMS Accession No. ML15029A460

4. OEDO communications staff will work with OIS to explore options for improving visibility of the Intranet Web page where current communication plans are stored. OEDO staff will also identify other opportunities for communicating its availability and encouraging its use, such as through the Communications Council, NRC Reporter, announcements, etc.

5. Improve FOIA response effectiveness:

   FOIA staff in the Office of Information Services (OIS) have worked with requestors to narrow the scope of their requests to provide more specifically targeted information, reducing time spent by both NRC staff and requestors on the collection and review of unwanted information. OIS is also implementing new procedures for handling large requests. Improvements include holding an initial meeting to ensure all staff responding to a request are targeting the same information, and establishing working relationships among FOIA counterparts in the different offices and FOIA specialists in OIS.

   In addition, the agency established a working group in July 2013 to develop recommendations based on recent experiences for promoting consistency in the treatment of sensitive information that is subject to FOIA requests. The working group identified a number of findings and recommendations in its initial report.[56] A subset of the recommendations has been endorsed for implementation over time as resources allow.

[56] NRC Staff Memorandum, "Report and Recommendations of the Sensitive Information Control Working Group," October 3, 2014, ADAMS Accession No. ML14268A313 (non-public)

Topic 6: Separation of Functions Communication Challenges

Issue Definition

Separation of functions refers to the restrictions that apply to communications between agency employees acting in an adjudicatory role and agency employees acting in an adversarial role in the same proceeding. In general, agency decisionmakers are prohibited from off-the-record communications with staff engaged in a litigating or investigatory role.[57] In June 2012, the nongovernmental organization Friends of the Earth submitted a hearing request relating to the San Onofre steam generator tube degradation event, triggering the separation of functions restrictions. At the same time, there was significant external interest from a variety of stakeholders, including State and local elected officials, nongovernmental organizations, and public citizens. The purpose of this review was to examine whether the separation of functions requirements resulted in any communication challenges for the Commission in effectively engaging with external stakeholders.

Approach for Reviewing the Issue

The team preparing this report interviewed U.S. Nuclear Regulatory Commission (NRC) staff members from Region IV and headquarters involved in briefings of the Commission on matters pertaining to San Onofre during the time when the adjudication was pending. The NRC staff also interviewed one Commissioner and several Commission staff members who had familiarity with internal and external communications during the San Onofre proceeding.

Conclusions

1. Were there instances in which the separation of functions requirements created communication challenges between the staff and Commission?

Yes. Interviews revealed communication challenges, both from the perspective of the Commission and from the staff, in applying a common understanding of the restrictions imposed by separation of functions when sharing information relating to the San Onofre adjudicatory proceeding. Specifically, interviewees recalled communication challenges with respect to:

- The potential implications on staff oversight activities during the adjudicatory process because of uncertainty in the regulatory community as to the hearing implications associated with the issuance of CALs;

- Providing briefings on technical issues relating to the San Onofre steam generators in sufficient detail to allow the Commission to respond to various stakeholders;

[57] The separation of functions restrictions are set forth in 10 CFR 2.348. Section 2.348(a) provides that covered employees may only advise Commissioners with respect to the disputed issues except as (1) witness or counsel, (2) through written communication served on all parties and on the record, (3) through oral communication made with reasonable prior notice to all parties and with reasonable opportunity to respond. Section 2.348(b) provides that this prohibition does not apply to communications from or to any adjudicatory employee on certain matters, including (1) status of the proceeding, and (2) generic issues not associated with resolution of the proceeding.

- Keeping the Commission abreast of significant developments in the staff's oversight activities, such as the status of the NRC staff's restart decision, in real time.

Because separation of functions restrictions do not typically create significant communication issues, the challenges identified during the San Onofre event appear to be the result of heightened public interest, which may have exacerbated communication challenges that normally are not an issue in other matters subject to adjudication. Because of heightened public interest, Commissioners were frequently asked questions in all types of settings that required an understanding of the underlying technical issues. At times, however, interviewees indicated that staff briefings and written products for Commissioners were, in their view, vague because of the staff's concern that more detailed information might violate separation of functions restrictions.

In addition, timely communication of significant developments was particularly important because Commissioners were continually questioned about, and expected to have detailed knowledge of, the staff's activities relating to San Onofre. On occasion, Commissioners were not aware of significant developments, such as the status of the staff's restart decision, until after it became public.

2. Is additional guidance to staff needed to help ensure common understanding of what information can and cannot be discussed with the Commission during adjudicatory processes?

Yes. Guidance on separations of functions is ordinarily provided by the Office of the General Counsel (OGC) orally, on an *ad hoc* basis, which allows OGC to tailor advice to the specific facts of the adjudication. While NRC staff who provided oral and written briefing materials to the Commission generally considered this approach effective, many interviewees believed that supplemental written guidance would also be beneficial.

OGC advice on separation of functions was provided orally to adjudicatory staff after the San Onofre hearing request was filed. For Commission briefings, staff was accompanied by OGC. In addition, OGC reviewed all written materials provided to the Commission. By all accounts, OGC was very effective at preventing improper communications. On the other hand, from the Commission's perspective, some of the technical information initially provided to the Commission was general and vague due to an overly cautious approach to separation of functions restrictions. Over time, the Commission perception was that the staff became more forthcoming as they became more comfortable with providing technical information under the separation of functions restrictions and relied on OGC to prevent potential violations.

Written guidance may give NRC staff a better understanding of and comfort with the restrictions, and therefore greater assurance in providing technical information when briefing the Commission in the future. Written guidance would also ensure that guidance is applied consistently, and that lessons learned are retained for future reference. Developing guidance would also offer an opportunity for OGC to consider whether the communication challenges identified during the San Onofre proceeding warrant any changes to the guidance for matters of higher public interest than has historically been provided.

Actions

1. OGC will develop written guidance on the separation of functions restrictions for staff providing information to the Commission on matters that are subject to adjudicatory hearings.

Topic 7: Implementation of Inspection Manual Chapter 0351

Issue Definition

The purpose of Inspection Manual Chapter (IMC) 0351[58] is to: (1) establish guidance for Reactor Oversight Process (ROP) implementation at plants in an extended shutdown condition for reasons other than significant performance problems; and (2) ensure that the NRC communicates unified and consistent oversight activities and actions in a clear and predictable manner to the licensee, public, and other stakeholders. Following the discovery of the steam generator tube degradation at San Onofre, Region IV, with concurrence from the Office of Nuclear Reactor Regulation (NRR), placed San Onofre Units 2 and 3 in the IMC 0351 process in September 2012.[59]

In January 2013, Region IV, in cooperation with NRR, established an Oversight Panel[60] to assist with the implementation of IMC 0351 objectives. During the implementation of IMC 0351 at San Onofre, the staff identified areas for improvement within IMC 0351. This topic was included within the scope of the lessons learned effort to ensure these enhancements, and any others that are more clearly recognized in hindsight, are incorporated in the manual chapter to facilitate any future applications of the process.

Approach for Reviewing the Issue

The NRC staff preparing this report reviewed the following documents:

- IMC 0351, "Implementation of the Reactor Oversight Process at Reactor Facilities in an Extended Shutdown Condition for Reasons other than Significant Performance Problems," April 5, 2011 (ADAMS Accession No. ML102770448)

- IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition due to Significant Performance and/or Operational Concerns," December 15, 2006 (ADAMS Accession No. ML063400076)

- IMC 0305, "Operating Reactor Assessment Program," November 20, 2014 (ADAMS Accession No. ML13178A032)

- San Onofre mid-cycle and annual assessment letters, September 4, 2012, March 4, 2013, and September 2, 2013 (ADAMS Accession Nos. ML12248A446, ML13063A574, and ML13246A435)

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58 IMC 0351, "Implementation of The Reactor Oversight Process at Reactor Facilities in an Extended Shutdown Condition for Reasons Other Than Significant Performance Problems," April 5, 2011, ADAMS Accession No. ML102770448

59 NRC staff memorandum, "NRC Oversight of San Onofre Nuclear Generating Station (SONGS) Units 2 and 3 during Extended Shutdown," September 4, 2012, ADAMS Accession No. ML12242A518

60 San Onofre Nuclear Generating Station Oversight Panel Charter, January 17, 2013, ADAMS Accession No. ML13017A346

- San Onofre augmented inspection team inspection report (IR) 2012-007, July 18, 2012 (ADAMS Accession No. ML12188A748)

- San Onofre Augmented Inspection Team Follow-Up IR 2012-010, November 9, 2012 (ADAMS Accession No. ML12318A342)

- Memorandum, "NRC Oversight of San Onofre Nuclear Generating Station Units 2 and 3 during Extended Shutdown," September 4, 2012 (ADAMS Accession No. ML12242A518)

- San Onofre Oversight Panel Charter, January 17, 2013 (ADAMS Accession No. ML13017A346)

- San Onofre Oversight Panel Closure, September 30, 2013 (ADAMS Accession No. ML13273A389)

The staff also engaged with a variety of internal and external stakeholders to understand the different perspectives involved in the implementation of IMC 0351 at San Onofre. This included numerous staff from the NRC's Region IV office and NRR, as well as external stakeholders during regularly scheduled public meetings of the ROP working group.

Conclusions

1. Were any lessons learned from implementation of IMC 0351 at San Onofre that could enhance future use of this manual chapter?

Yes. During its assessment of the implementation of IMC 0351 at San Onofre, the staff identified a number of enhancements that should be made to the manual chapter to improve its efficiency and effectiveness.

- Discussions with staff members in the NRC's Region IV office and NRR identified an improvement to the manual chapter to clarify the appropriate situations for the use of IMC 0351, as opposed to IMC 0350.

    - Changes recommended during staff interviews conducted in support of Topic 4 of this report are also included in this proposed change to IMC 0351.

    - The staff will change the numbering of IMC 0351 to help prevent confusion created by the similar numbering to IMC 0350, which can give the false impression that these very different processes are similar.

- During the implementation of IMC 0351 at San Onofre, an oversight panel was formed to help coordinate oversight activities and facilitate internal and external communication. As discussed in Topic 4, those involved in the event followup felt that establishing the panel earlier in the process could have reduced some of the communication challenges that staff faced initially. The action from Topic 4 to add guidance containing triggers or thresholds for considering the establishment of an oversight panel will also be considered during the IMC 0351 revision process, in addition to the actions taken as a result of the evaluation for this topic.

- Changes proposed following the evaluation of data as discussed in Topic 5 of this report, including guidelines for considering small group meetings, use of the NRC Blog, and coordinating communications with the licensee will be included among the changes considered for IMC 0351, in addition to the changes discussed in this topic.

- Many of the ROP performance indicators require a certain number of hours of critical reactor operation to be valid. This can cause confusion when a plant has been shutdown for an extended period of time. IMC 0351 provides limited guidance in this area. Prior to the event at San Onofre, the expectation was that the validity of performance indicators during extended shutdowns would be determined on a case-by-case basis. The NRC staff is currently engaging with industry and the Nuclear Energy Institute (NEI) to revise NEI 99-02, "Regulatory Assessment Performance Indictor Guideline,"[61] to include generic guidance for determining the validity of existing ROP Performance Indictor data for plants that are shut down for extended periods of time. Once the NRC-approved revisions to NEI 99-02 are complete, the NRC staff plans on capturing the revisions in IMC 0351.

- Discussions with NRC staff members in Region IV and NRR identified an improvement to the manual chapter to clarify when the application of IMC 0351 should be concluded.

- The NRC staff will clarify the process for documenting implementation of the manual chapter, to include providing template letter(s) and example inspection plan(s).

Actions

1. The NRC has established processes for routinely updating its IMCs to incorporate feedback and lessons learned. To ensure proper tracking and closeout of these items, the staff has submitted an ROP Feedback Form. In addition to the changes proposed in Topics 4 and 5 of this report, the feedback form also captures the following changes for improving the implementation of IMC 0351:

- Clarify the appropriate situations for the use of IMC 0351 as opposed to IMC 0350.

- Update the reference to NEI 99-02, "Regulatory Assessment Performance Indicator Guideline," to provide generic guidance for determining the validity of ROP performance indicators for plants in an extended shutdown.

- Clarify when application of IMC 0351 should be concluded.

- Clarify the process for documenting implementation of the manual chapter to include providing template letter(s) and example inspection plan(s).

[61] NEI 99-02, Revision 7, "Regulatory Assessment Performance Indicator Guideline," October 1, 2013, ADAMS Accession No. ML13261A116

Topic 8: Vendor Inspection

Issue Definition

At the time of the San Onofre steam generator modifications, the U.S. Nuclear Regulatory Commission (NRC) vendor inspection staff was operating under the vendor inspection program (VIP) that emerged following a 2003 review[62] of the vendor oversight process. That review had concluded that expansion of NRC nuclear component supplier oversight for currently operating reactors was not necessary. The basis for this determination was that the NRC could continue to rely on the licensee programs established to meet the regulatory requirements for quality assurance contained in Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," including requirements for design control, post-modification testing, and vendor oversight. Additional industry oversight of vendor activities occurs during audits by the Nuclear Procurement Issues Committee (NUPIC), which ensures adequate quality of vendor-supplied components. As part of its oversight role, NRC staff observes NUPIC audit activities at least twice a year. For major plant modifications (MPMs) such as replacement reactor vessel heads and steam generators, decisions on NRC staff oversight of fabrication, manufacturing, and testing at the vendor's facility have been handled on a case-by-case basis. Major plant modifications routinely have activities occurring at both the licensee site and the contracted supplier's (vendor) facility. Topic 8 is focused on NRC oversight related to the vendor facility.

The San Onofre replacement steam generators (RSGs) were designed in the 2004-2005 timeframe by Mitsubishi Heavy Industries (MHI) with design input and oversight by Southern California Edison (SCE). Fabrication was completed from 2006-2009. SCE maintained oversight of the vendor activities through the fabrication, shipping, and delivery phases. The NRC did not conduct any vendor oversight inspections of the San Onofre/MHI design scoping or fabrication during this timeframe. In general, inspections of suppliers associated with the operating reactor plants were limited to reactive inspections.

A vendor oversight working group (VOWG) was established to identify and respond to the lessons learned following issuance of the first 10 CFR Part 52 Combined Operating Licenses (COLs) in 2012 and following the San Onofre steam generator tube degradation event. The charter[63] for the working group directed the VOWG to provide recommendations to the appropriate managers in the Office of New Reactors[64] (NRO) on potential enhancements to the NRC's vendor oversight process. In addition, the charter included consideration of the following questions from the San Onofre lessons learned tasking memo:[65] (1) did the San Onofre steam generator tube degradation event expose any new or unique vendor lessons that the NRC's VIP

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62 NRC Review, "Vendor Inspections for Component Suppliers," October 17, 2003, ADAMS Accession No. ML032750012

63 NRC Vendor Oversight Working Group Charter, "Review of the Vendor Oversight Program in Response to the Part 52 and San Onofre Steam Generator Tube Degradation Event Lessons Learned," May 22, 2014, ADAMS Accession No. ML14128A267

64 NRO now leads and performs routine and reactive vendor and quality assurance implementation inspections for new and operating reactors under the Vendor Inspection Center of Expertise.

65 NRC Memorandum, "Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event," March 20, 2014, ADAMS Accession No. ML14028A028

should take into account; and (2) should the NRC's VIP should be more focused on the design aspects of major plant modifications (MPMs).

Approach for Reviewing the Issue

The VOWG, which consisted of NRC staff from the Region II and Region IV offices, the Office of Nuclear Reactor Regulation (NRR) and NRO, reviewed the issues raised relating to the San Onofre steam generator tube degradation event. The VOWG conducted a review of the VIP to provide recommendations on potential vendor oversight enhancements. The VOWG reviewed existing policy and practices for the NRC oversight of suppliers providing items and services to new plants under construction and the current fleet of operating reactors. During its review, the VOWG interviewed or held discussions with several NRC staff. The following documents were also reviewed:

- Post-COL Part 52 Working Group Charter (ADAMS Accession No. ML13066A739), Report (ADAMS Accession No. ML13196A403) and Status of Actions (ADAMS Accession No. ML13357A259)

- VOWG charter (ADAMS Accession No. ML14128A267) and report (ADAMS Accession No. ML14232A314)

- Review of VIP for Component Suppliers (ADAMS Accession No. ML032750012)

Conclusions

1. Did the San Onofre steam generator degradation event expose any new or unique vendor lessons that the NRC's VIP should take into account?

Yes. The San Onofre steam generator degradation event did expose vendor lessons that the NRC's VIP should incorporate. Routine vendor inspection of the replacement steam generator fabrication and design aspects had been conducted on a case by case basis since 2003. Based on the industry's successful replacement of steam generators at numerous sites under the existing regulatory framework, NRC vendor inspection engagement was not warranted at San Onofre. Enhancements to the NRC VIP reflecting lessons learned from the San Onofre steam generator tube degradation event are proposed.

The VOWG identified[66] two attributes of large component design and manufacture that were factors in the San Onofre event and that should be considered when selecting vendors for inspection. These attributes are not new or unique, and neither of the attributes individually led to the design issues that resulted in the steam generator tube degradation at San Onofre. Taken together though, they contributed to the licensee and the vendor failing to identify and correct weaknesses in the design before the degradation occurred. These attributes will be considered in the selection of a vendor for inspection,[67] and will weigh in the determination of an NRC vendor inspection priority. The attributes identified were:

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66 VOWG report, October 28, 2014, ADAMS Accession No. ML14232A314

67 The selection of vendors for inspection is based on several factors such as (1) significance to safety of the equipment or service being provided, (2) frequency and significance to safety of problems identified with vendor-supplied materials, equipment, or services, (3) performance history of a vendor, allegations, Part 21 reports, etc. More detailed information on process for

- The vendor used proprietary design software that had not been accepted as an industry standard or approved by a regulatory body.

- The analytic methods used to develop and evaluate the design lacked both rigorous acceptance criteria; and generally accepted best practices, such as the application of safety factors.

2. Should the NRC's VIP be more focused on the design aspects of major plant modifications?

Yes. The VIP verifies that new reactor applicants and existing nuclear power plant licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. The VIP has evolved since it started in the 1980s; in the mid-1990s, most NRC vendor inspections were reactive, "special" inspections of operating nuclear power plant vendors following discovery of demonstrated problems. These inspections were performed primarily based on operating experience, an incident, or an allegation concern. While the NRC expanded the VIP in 2007 in preparation for construction and procurement activities for new reactors, vendor inspections for operating reactors remained primarily reactive in nature, related to specific issues or circumstances.

Design-related aspects of vendor issues of the magnitude identified at San Onofre are infrequent. Performing pilot inspections at selected phases of the fabrication, manufacturing, or testing process for major plant modifications (e.g., steam generator replacement, reactor vessel head replacement) could inform a decision as to whether the NRC should place more focus on design-related aspects during the conduct of vendor inspections.

A key action would be the development of screening criteria and identification of guidelines that would establish a threshold to determine if a licensee's plant change would be considered a major plant modification. This action would be led by NRR and the Regions.

A second action would be the development of screening criteria and evaluation guidance that would establish a threshold to determine if a licensee's major plant modification would be considered an appropriate subject for NRC vendor inspection at the vendor facilities. This action would be led by NRR and the Regions, with support from NRO.

Once screening criteria and evaluation guidance have been established, the vendor inspection staff will perform pilot inspections at vendor facilities conducting fabrication, manufacturing, and testing activities in support of major plant modifications at a site, when requested by the Regions or NRR.

These pilot inspections would include a limited scope assessment using selected portions of Inspection Procedure (IP) 37805, "Engineering Design Verification Inspections,"[68] to assess the implementation of selected design-related aspects by the vendor responsible for fabrication, manufacturing, and testing.

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selecting vendors for inspection can be found in Appendix B, "Strategy for Vendor Selection," of the "Vendor Inspection Program Plan," Revision 10, dated November 2014, ADAMS Accession No. ML14329B345.

[68] Inspection Procedure 37805, "Engineering Design Verification Inspections," April 25, 2011, ADAMS Accession No. ML110871858

Results of inspections conducted will provide additional information in order to determine if such vendor inspections may be warranted on a recurring basis. These pilot inspections could be incorporated within the current vendor inspection resource estimates.

Actions

Based on its review, the VOWG is pursuing the following two actions related to vendor oversight involving enhancements to the existing VIP reflecting lessons learned from the San Onofre steam generator tube degradation event:

1. The staff will perform pilot design-aspect inspections at vendor facilities during the fabrication process for safety-related major plant modifications. The staff will evaluate the results from the inspections to determine if such inspection activities are warranted on a continuing basis. The initial inspections should use existing inspection procedures, such as IP 37805, "Engineering Design Verification Inspections." If the decision is made to continue, the existing procedures may need to be modified, or new procedures may need to be developed using lessons learned from the pilot design-aspect vendor inspections.

2. In support of the above action, the staff will develop and pilot screening and evaluation processes to determine if a plant change is a major plant modification, and whether such a modification should be subject to a vendor inspection. In coordination with NRR, the Regions, and NRO, and taking into account industry input and comments:

- The staff will develop identification guidelines and screening criteria to determine when a plant change can be considered to be a major modification. (NRR and Regions)

- The staff will develop evaluation/screening criteria to determine whether a major plant modification should be subject to a vendor inspection. (NRR, Regions, and NRO support)

Appendix A: Summary of Actions

Topic 1: 10 CFR 50.59 Process

1. The staff is developing a RIS to inform licensees of a potentially misleading statement in the NRC-endorsed 10 CFR 50.59 guidance contained in NEI 96-07, Revision 1. Staff will develop a second RIS to highlight important aspects of the 10 CFR 50.59 guidance related to shortcomings identified in the 10 CFR 50.59 screening and evaluation process for the replacement steam generators at San Onofre. The NRC staff is also revising RG 1.187 to add an exception to the NRC's endorsement of NEI 96-07, Revision 1, related to the potentially misleading statement.

2. The staff is conducting workshops with NRC regional and headquarters employees to enhance their understanding of the 10 CFR 50.59 process, and will develop formal initial and continuing training on the 10 CFR 50.59 process. The staff is also considering an update to the inspection procedures governing inspectors' performance of 10 CFR 50.59 inspections, as well as inspections related to steam generator replacements and other major plant modifications to appropriately focus inspection reviews.

3. The staff will review and revise, as necessary, internal procedures providing guidance and direction for licensing PMs to clarify the scope, depth, frequency, and timeliness requirements for licensing PM reviews of documented 10 CFR 50.59 evaluation summaries included in licensee submittals pursuant to 10 CFR 50.71(e) and 10 CFR 50.59(d)(2).

Topic 2: Confirmatory Action Letter as a Regulatory Tool

4. The NRC staff submitted Enforcement Manual Feedback Form 208 to the NRC's Office of Enforcement, capturing the following enhancements to the Enforcement Manual:

    - Clarify that CALs, or actions to close a CAL, are not license amendments and should not be treated as such. An action that constitutes a license amendment will be handled separately under the license amendment request process.

    - Add guidance for originators of CALs to coordinate and consult with regional counsel or OGC, as needed.

    - Add guidance for originators of CALs to coordinate and consult with the Office of Enforcement, as needed, as OE is the centralized control point to oversee and implement the CAL process.

    - Clarify that input is needed from any office(s) involved in the review of information necessary to close the action items in a CAL. For some complex technical issues, it may be appropriate for the staff to document its review in the form of a Technical Evaluation Report or other equivalent document. This report should be included as part of an inspection report.

5. The staff will issue a RIS to all stakeholders regarding the NRC's application of the Enforcement Manual as it relates to the continued use of the CAL process.

Topic 3: Steam Generator Technical Review

6. The staff is developing general guidance to assist licensees, as well as the NRC licensing and inspection staff, in determining whether steam generators necessitate a detailed review. These reviews may be performed as part of a construction permit or operating license application, design certification or combined license application, a steam generator modification or replacement, or a request for licensing action related to steam generators that may be operated under different operating conditions, such as for a power uprate.

    - The staff will develop guidance to assist staff performing the review to determine whether the action is bounded by successfully operated projects, or if a detailed NRC evaluation is required.

    - The staff will develop guidance for staff performing a detailed review of steam generator design characteristics or modifications.

    - The staff will revise the relevant inspection procedures, in coordination with regional offices and the NRR Division of Inspection and Regional Support, to incorporate elements of the guidance into the inspection program, to assist NRC oversight of steam generator modifications or changing operating conditions that do not involve licensing actions.

7. The staff is continuing to engage the industry on standards and guidance for the design and fabrication of steam generators to eliminate the potential for fluid-elastic instability in the future.

Topic 4: Organization/Roles and Responsibilities

8. The staff will develop guidance for determining when a management oversight panel should be considered. Examples of thresholds to consider include identification of a new or unique type of event; difficulty in reaching alignment on issues involving multiple offices; establishment of special projects branches; the potential for concurrent licensing and oversight activities; the expectation of an extended shutdown period; or high stakeholder interest. The guidance should also identify management oversight panel responsibilities.

Topic 5: Communication and External Interactions

9. Develop additional communication resources:

    The agency could benefit from making communication resources available to assist technical staff when the need arises. NRC staff need to be aware of the resources available, and should be encouraged to seek out assistance when events or situations emerge that may be of high public interest. This will allow the staff to be more flexible and adaptive in leveraging available communications expertise, tailoring communication and outreach strategies from the beginning, and making adjustments as the situation develops. It will also allow technical staff to focus their time on the actual technical assessment of the event and necessary followup activities.

- The Office of the Executive Director for Operations (OEDO) will develop options for leveraging agency capabilities already available to assist in outreach and communication efforts when needed, and on a more proactive basis when possible, and using more varied formats when appropriate. This participation would be provided on a collateral basis, so careful consideration will be given to the potential level of need, the availability and flexibility of resources, and any additional training and developmental activities that might be needed.

- OEDO developed and awarded an enterprise-wide contract that can be tapped as needed for assistance with public meeting facilitation, planning, and outreach efforts. This contract can be used by any office throughout the agency on an as-needed basis and would supplement the agency's current In-House Meeting Facilitator and Advisor Program.

10. The staff feedback and survey results have been considered as part of the revisions to IMC 0351 that are also discussed under Topic 7 in this report. In particular, a Reactor Oversight Process (ROP) Feedback Form has been submitted proposing to add details to the procedure regarding the process for conducting small group meetings, maintaining the NRC Blog, and coordinating NRC calls with the licensee, as well as adding guidance on the availability of communications resources when the circumstances warrant more significant communication and outreach efforts.

11. Work with previously established "Enhancing Public Meetings" Task Group:

    The insights related to public meetings that have been collected during this evaluation, such as format considerations, logistical arrangements, use of facilitators, areas of further guidance needed, and challenges experienced, have been incorporated into the topics under consideration by the "Enhancing Public Meetings" Task Group. The Task Group's initial report was completed on January 29, 2015.

12. OEDO communications staff will work with OIS to explore options for improving visibility of the Intranet Web page where current communication plans are stored. OEDO staff will also identify other opportunities for communicating its availability and encouraging its use, such as through the Communications Council, NRC Reporter, announcements, etc.

13. Improve FOIA response effectiveness:

    FOIA staff in the Office of Information Services (OIS) have worked with requestors to narrow the scope of their requests to provide more specifically targeted information, reducing time spent by both NRC staff and requestors on the collection and review of unwanted information. OIS is also implementing new procedures for handling large requests. Improvements include holding an initial meeting to ensure all staff responding to a request are targeting the same information, and establishing working relationships among FOIA counterparts in the different offices and FOIA specialists in OIS.

    In addition, the agency established a working group in July 2013 to develop recommendations based on recent experiences for promoting consistency in the treatment of sensitive information that is subject to FOIA requests. The working group

identified a number of findings and recommendations in its initial report. A subset of the recommendations has been endorsed for implementation over time as resources allow.

Topic 6: Commission Separation of Function Communication Challenges

14. OGC will develop written guidance on the separation of functions restrictions for staff providing information to the Commission on matters that are subject to adjudicatory hearings.

Topic 7: Implementation of Inspection Manual Chapter 0351

15. The NRC has established processes for routinely updating its IMCs to incorporate feedback and lessons learned. To ensure proper tracking and closeout of these items, the staff has submitted an ROP Feedback Form. In addition to the changes proposed in Topics 4 and 5 of this report, the feedback form also captures the following changes for improving the implementation of IMC 0351:

- Clarify the appropriate situations for the use of IMC 0351 as opposed to IMC 0350.
- Update the reference to NEI 99-02, "Regulatory Assessment Performance Indicator Guideline," to provide generic guidance for determining the validity of ROP performance indicators for plants in an extended shutdown.
- Clarify when application of IMC 0351 should be concluded.
- Clarify the process for documenting implementation of the manual chapter to include providing template letter(s) and example inspection plan(s).

Topic 8: Vendor Oversight

16. The staff will perform pilot design-aspect inspections at vendor facilities during the fabrication process for safety-related major plant modifications. The staff will evaluate the results from the inspections to determine if such inspection activities are warranted on a continuing basis. The initial inspections should use existing inspection procedures, such as IP 37805, "Engineering Design Verification Inspections." If the decision is made to continue, the existing procedures may need to be modified, or new procedures may need to be developed using lessons learned from the pilot design-aspect vendor inspections.

17. In support of the above action, the staff will develop and pilot screening and evaluation processes to determine if a plant change is a major plant modification, and whether such a modification should be subject to a vendor inspection. In coordination with NRR, the Regions, and NRO, and taking into account industry input and comments:

- The staff will develop identification guidelines and screening criteria to determine when a plant change can be considered to be a major modification. (NRR and Regions)

- The staff will develop evaluation/screening criteria to determine whether a major plant modification should be subject to a vendor inspection. (NRR, Regions, and NRO support).

Appendix B: Tasking Memo Topics

Topic 1: 10 CFR 50.59 Process

1. Does the 10 CFR 50.59 [Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, "Changes, Tests and Experiments"] rule continue to be adequate for major or complex component replacements?

2. Does the agency need to provide additional 10 CFR 50.59 guidance and information to:

    a) licensees for large or complex component replacements
    b) inspectors for their review of 10 CFR 50.59 evaluations of large or complex component replacements
    c) project managers for their review of 10 CFR 50.59 evaluations

3. Does the agency need to clarify the commonly used phrase "like-for-like replacement" with respect to 10 CFR 50.59?

Topic 2: Confirmatory Action Letter as a Regulatory Tool

1. Did the staff's actions in response to the event at San Onofre Nuclear Generating Station (SONGS) call into question the appropriateness of the use of confirmatory action letters (CALs) as a regulatory tool?

2. Are changes needed to strengthen CAL guidance or implementation (e.g., when CALs are appropriate or not appropriate)?

3. Is additional formal communication needed to licensees from the U.S. Nuclear Regulatory Commission (NRC) regarding future use of CALs?

Topic 3: Steam Generator Technical Review

1. Does the agency need to provide additional Standard Review Plan guidance for steam generator designs for new reactors, steam generator replacements, or steam generator modifications?

2. Does the agency's steam generator program handle new steam generator degradation mechanisms effectively; if not, what modifications are needed?

3. In light of the new steam generator degradation mechanism, fluid elastic instability, does the steam generator program effectively account for this phenomenon going forward?

4. Does the agency or industry need additional standards or criteria for new steam generator designs or steam generator replacements?

5. Should enhancements to the agency's steam generator inspection procedures be made to address experience gained at SONGS?

Topic 4: Organization/Roles and Responsibilities

1. Did the existing licensing and oversight processes help the staff respond with the appropriate priority to key events in the timeline (e.g., the Unit 3 steam generator tube leak, the Units 2 and 3 steam generator tube inspection results, and restart proposals for Unit 2 before the CAL and in response to the CAL)?

2. For technical issues involving both regional inspection and headquarters technical review, does the agency have appropriate guidance to determine the roles and responsibilities of each office and how the decisionmaking process should work?

3. Should there be a more concerted effort on the front end to gain alignment on scope of review and office lead?

4. Should there be guidance for technical evaluation reviews?

5. For technical issues involving both regional inspection and headquarters technical review, is the agency's current approach and implementation of internal communications, especially at the middle and higher management levels, appropriate and effective?

6. During the SONGS followup, special projects organizations were established in the Office of Nuclear Reactor Regulation (NRR) and Region IV, as well as a multiple-office oversight panel. One of the goals of the panel was to ensure consistent and clear communication. Were these organizational changes effective and what lessons can be learned for future high-profile and resource-intensive events?

7. During events that are high-profile and require involvement by multiple offices, are there lessons to be learned regarding internal communications such as the use of a common SharePoint site, establishment of review schedules, use of periodic group phone calls, use of periodic management briefings, etc.?

8. For technical reviews going on in parallel with investigations by the Office of Investigations (OI), are there lessons to be learned regarding internal coordination and communication?

Topic 5: Communication and External Interactions

1. With the large interest and turnout during public meetings, have any lessons been learned about:

    a) format
    b) focus
    c) timing
    d) location
    e) security
    f) other logistics

2. Meetings with small groups of local stakeholders were planned to provide specific, targeted outreach in a more informal setting. Have any lessons been learned from this

practice, including lessons about possible programmatic enhancements to encourage future consideration?

3. The staff used the NRC Blog several times during the review of the licensee's restart readiness plan. Have any lessons been learned? Was this communication tool effective?

4. The staff dedicated significant resources to updating the internal communication plan and external SONGS Web site. Was this use of resources effective, was the information used, and have any lessons been learned for high-profile events going forward? Have any lessons been learned with respect to publicly posting technical information, including making sure it is accurate and determining if it could be misunderstood?

5. The staff received significant external correspondence, multiple Freedom of Information Act requests, and numerous congressional requests during the staff review. Have any lessons been learned from how these were processed and how the staff responded, and are there ways to enable a more efficient and effective staff response to these activities? For example, is better coordination needed when processing e-mails to ensure that lead and support office guidance is clear, including coordination between allegation coordinators, to minimize duplication of work?

6. The licensee arranged multiple weekly calls at different levels of management. Although this helped to keep NRC management informed, it also led to inconsistent messages and occasional confusion; have lessons been learned in this area?

7. Often, both the Commission and NRC staff were engaged in communication with external stakeholders. Can efficiencies be gained by coordinating communication efforts on high-profile events using both Commission and staff communication experts to achieve a unified agency message?

Topic 6: Commission Separation of Function Communication Challenges

1. Were there instances in which the separation of functions created communication challenges between the staff and Commission?

2. Is additional guidance to staff needed to help ensure common understanding of what information can and cannot be discussed with the Commission during adjudicatory processes?

Topic 7: Inspection Manual Chapter (IMC) 0351

1. Were any lessons learned from implementation of IMC 0351 at SONGS that could enhance future use of this manual chapter?

Topic 8: Vendor Inspection

1. Did the SONGS steam generator degradation event expose any new or unique vendor lessons that the NRC's Vendor Inspection Program should take into account?

2. Should the NRC's Vendor Inspection Program be more focused on the design aspects of major plant modifications?

Appendix C: References

U.S. Nuclear Regulatory Commission (NRC) Inspection Reports (IRs) for San Onofre (05000361 & 05000362)

- Integrated IR 2009-004, November 5, 2009, Agencywide Documents Access and Management System (ADAMS) Accession No. ML093100051
- San Onofre Steam Generator Replacement IR 2010-009, May 10, 2011, ADAMS Accession No. ML111300448
- Augmented Inspection Team (AIT) IR 2012-007, June 18, 2012, ADAMS Accession No. ML12188A748
- AIT Follow-Up IR 2012-010, November 9, 2012, ADAMS Accession No. ML12318A342
- Confirmatory Action Letter Response IR 2012-009, September 20, 2013, ADAMS Accession No. ML13263A271
- Final Significance Determination and Notice of Violation Regarding IR 2012-009, December 23, 2013, ADAMS Accession No. ML13357A058
- NRC Inspection Report 99901030/2013-201 and Notice of Nonconformance for Mitsubishi Heavy Industries, September 20, 2013, ADAMS Accession No. ML13261A189

Licensee Event Report (LERs):

- LER 05000362/2012-001, “Unit 3 Manual Reactor Trip due to Steam Generator Tube Leak,” March 29, 2012, ADAMS Accession No. ML12090A153
- LER 05000362/2012-002, “Unit 3 Steam Generator Tube Degradation Indicated by Failed In-Situ Pressure Testing,” May 10, 2012, ADAMS Accession No. ML12136A065

NRC Inspection Procedures (IPs)

- IP 71111.08, “Inservice Inspection Activities,” November 23, 2011, ADAMS Accession No. ML11262A023
- IP 71111.17T, “Evaluations of Changes, Tests, and Experiments and Permanent Plant Modifications,” March 5, 2013, ADAMS Accession No. ML101340791
- IP 71111.18, “Plant Modifications,” December 21, 2010, ADAMS Accession No. ML101320542
- IP 71111.21, “Component Design Bases Inspection,” November 29, 2013, ADAMS Accession No. ML13331B444
- IP 50001, “Steam Generator Replacement Inspection,” November 8, 2011, ADAMS Accession No. ML11206B197
- IP 37805, “Engineering Design Verification Inspections,” April 25, 2011, ADAMS Accession No. ML110871858

Inspection Manual Chapters (IMCs):

- IMC 0350, “Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns,” December 15, 2006, ADAMS Accession No. ML063400076

- IMC 0351, “Implementation of The Reactor Oversight Process at Reactor Facilities in an Extended Shutdown Condition for Reasons Other Than Significant Performance Problems,” April 5, 2011, ADAMS Accession No. ML102770448

- IMC 0305, “Operating Reactor Assessment Program, October 18, 2013, ADAMS Accession No. ML13178A032

Regulatory Guides (RGs):

- RG 1.20, “Comprehensive Vibration Assessment Program for Reactor Internals during Preoperational and Initial Startup Testing,” March 2007, ADAMS Accession No. ML070260376

- RG 1.187, “Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments,” November 2000, ADAMS Accession No. ML003759710

Nuclear Energy Institute (NEI) 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” November 17, 2000, ADAMS Accession No. ML003771157

NRC Annual Assessment Letters for San Onofre 2012-2013:

- 2012 Mid-Cycle Assessment Letter IR 05000361/2012-006 and IR 05000362/2012-006, September 4, 2012, ADAMS Accession No. ML12248A446

- 2012 Annual Assessment Letter IR 05000361/2013-801 and IR 05000362/2013-801, March 4, 2013, ADAMS Accession No. ML13063A574

- 2013 Mid-Cycle Assessment Letter, Termination of Reactor Oversight Process, and Commencement of Decommissioning Inspection Program, IR 05000361/2013-006 and IR 05000362/2013-006, September 3, 2013, ADAMS Accession No. ML13246A435

NRC Staff White Paper, “10 CFR 50.59; the Process, Application to Substantial Modifications to Licensee Facilities, and NRC Staff Assessment of Licensee Implementation,” ADAMS Accession No. ML13066A266

NRC Staff Memorandum, “Reactor Oversight Process Enhancement Project—Baseline Inspection Program,” April 4, 2014, ADAMS Accession No. ML14017A338

San Onofre Confirmatory Action Letter (CAL) 4-12-001, March 27, 2012, ADAMS Accession No. ML12087A323

Southern California Edison CAL Response, “Actions to Address Steam Generator Tube Degradation,” October 12, 2012, ADAMS Accession No. ML122850320

San Onofre Unit 2 License Amendment Application No. 263, April 5, 2013, ADAMS Accession No. ML13098A043

San Onofre Unit 2 License Amendment Request, Supplement 1, April 9, 2013, ADAMS Accession No. ML13100A021

Federal Register Notices:

- 78 FR 22576, “Application and Amendment to Facility Operating License Involving Proposed No Significant Hazards Consideration Determination; San Onofre Nuclear Generating Station Unit 2,” April 16, 2013

- 64 FR 53582, “Changes, Tests, and Experiments (Final Rule),” October 4, 1999

Atomic Safety and Licensing Board Order for Southern California Edison Co. (San Onofre Nuclear Generating Station, Units 2 and 3), LBP-13-07, 77 NRC 307 (2013), ADAMS Accession No. ML13133A323

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[69] Copies may be purchased from the American Society of Mechanical Engineers, Three Park Avenue, New York, NY10016-5990; phone (212) 591-8500; fax (212) 591-8501; www.asme.org.

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