

# U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation

Managing Regulatory Commitments Made by Licensees to

# NRR OFFICE INSTRUCTION

# Change Notice

LIC-105, Revision 5

September 16, 2013

Office Instruction No.:

Office Instruction Title:

Effective Date:

Approved By:

Susan Abraham

the NRC

Date Approved: September 5, 2013

Primary Contacts:

John D. Hughey 301-415-3204 john.hughey@nrc.gov Tracy J. Orf 301-415-2788 tracy.orf@nrc.gov

Responsible Organization: NRR/DORL

**Summary of Changes:** Revision 5 updates Section 4.3, and the audit report template in Enclosure 4, with the requirement for DORL PMs to open a not fee billable technical assignment code (TAC) to track final disposition of an identified misapplied commitment that requires actions to be completed after the audit report is issued. Minor editorial corrections were also made.

Training: E-mail announcement with recommended self-study for all staff.

ADAMS Accession No.: ML13193A358



# U.S. Nuclear Regulatory Commission Office of Nuclear Reactor Regulation

Managing Regulatory Commitments Made by Licensees to

# NRR OFFICE INSTRUCTION

# **Change Notice**

Office	Instruction	No ·
Onice	monucuon	NU

LIC-105, Revision 5

Office Instruction Title:

Effective Date:

September 16, 2013

the NRC

Approved By: Susan Abraham

Date Approved: September 5, 2013

Primary Contacts:

John D. Hughey 301-415-3204 john.hughey@nrc.gov Tracy J. Orf 301-415-2788 tracy.orf@nrc.gov

Responsible Organization: NRR/DORL

**Summary of Changes:** Revision 5 updates Section 4.3, and the audit report template in Enclosure 4, with the requirement for DORL PMs to open a not fee billable technical assignment code (TAC) to track final disposition of an identified misapplied commitment that requires actions to be completed after the audit report is issued. Minor editorial corrections were also made.

Training: E-mail announcement with recommended self-study for all staff.

ADAMS Accession No.: ML13193A358

NRR-071

				email	
OFFICE	Primary Contact	LPL1-2/LA*	LPL1-2/BC	NRR/DORL:D	NRR/PMDA/AD
NAME	JHughey	ABaxter	VRodriquez (Acting)	MEvans	SAbraham
DATE	08/26/2013	08/06/13	08/23/2013	09/03/2013	09/05/2013

OFFICIAL RECORD COPY

#### NRR OFFICE INSTRUCTION LIC-105, Revision 5 Managing Commitments Made by Licensees to the NRC

# 1. <u>POLICY</u>

Although the terms "regulatory commitment" and "licensing bases" are not used in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, they are nevertheless used frequently in the context of interactions between the U.S. Nuclear Regulatory Commission (NRC or Commission) and licensees for commercial nuclear reactors. The terminology was reflected in 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," in the definition of "current licensing bases" (see 10 CFR 54.3). Additional information about the attributes of various elements of the licensing bases for operating reactors can be found in NRR Office Instruction LIC-100, "Control of the Licensing Bases for Operating Reactors."

The policy considerations concerning the use of regulatory commitments can be found in the following Commission papers:

- SECY-95-300, Nuclear Energy Institute's (NEI) Guidance Document, "Guideline for Managing NRC Commitments," dated December 20, 1995 (Ref. 1)
- SECY-98-224, "Staff and Industry Activities Pertaining to the Management of Commitments Made by Power Reactor Licensees to the NRC," dated September 28, 1998 (Ref. 2)
- SECY-00-045, "Acceptance of NEI 99-04, 'Guidelines for Managing NRC Commitments,'" dated February 22, 2000 (Ref. 3)

As described in SECY-00-045, the NRC staff found that the Nuclear Energy Institute document, NEI 99-04, "Guidelines for Managing NRC Commitment Changes," (Ref. 4) contains acceptable guidance for controlling regulatory commitments made by power reactor licensees to the NRC.

Issues concerning the use of regulatory commitments usually center on the legal standing of the commitment and the NRC staff's ability to enforce the action committed to by a licensee. The staff determined that keeping regulatory commitments as an element of licensing basis information should continue because, when handled properly, the commitments support the overall licensing process by adding flexibility, improving efficiency, and maintaining the flow of information between the staff and licensees. These advantages usually outweigh concerns that a licensee is not "legally bound" to fulfill and subsequently control an action appropriately classified as a regulatory commitment. Various assessments performed by the NRC staff supported this view. See, for example, the "Assessment of Regulatory Processes That Utilize Regulatory Commitments," dated November 26, 2008 (Ref. 5).

# 2. <u>OBJECTIVES</u>

This office instruction provides NRR staff guidance on managing regulatory commitments. The guidance is consistent with available industry guidance and is intended to ensure common understanding (by the staff, licensees, and other agency stakeholders) of the handling of regulatory commitments. Specific objectives include the following:

- Ensure the protection of public health and safety and the environment, and the secure use and management of radioactive materials, by the effective use of NRC's regulatory processes, including the appropriate use of regulatory commitments made by power reactor licensees.
- Ensure effectiveness, efficiency, realism and timeliness in licensing actions by establishing a common understanding of the control of regulatory commitments, by promoting the appropriate use of regulatory commitments to achieve the desired results, and by establishing a vehicle for periodically assessing licensees' processes for implementing and managing subsequent changes to regulatory commitments.
- Ensure openness of the licensing process by establishing a common reference for processes, communications, and decision-making involving regulatory commitments.

#### 3. BACKGROUND

Various activities undertaken by the staff and the nuclear industry in the early 1990s culminated in the issuance of SECY-95-300, which contained the NEI guidelines for managing NRC commitments. The industry document and related Commission paper contained guidance for handling licensing basis information that was not subject to controls defined in NRC regulations. The NEI guidance describes a process that licensees can use to modify or delete regulatory commitments and provides criteria to decide if and when changes to regulatory commitments should be reported to the NRC. The use of this guidance was intended to clarify the standing of regulatory commitments and give licensees the confidence and flexibility to modify or delete regulatory commitments shown to be inefficient or ineffective.

In SECY-98-224, the staff described its activities related to commitment management strategies, audits of commitment management programs at power reactor facilities, and discussions with stakeholders. In SECY-98-224, the staff also: (1) discussed its rationale for maintaining regulatory commitments as an element of the licensing bases for power reactors, and (2) described the expected management of regulatory commitments by licensees' administrative processes and the proposed internal guidance for the NRC staff. Following the plan described in SECY-98-224, the staff worked with NEI and licensees as they revised the industry guidance document. These efforts were reflected, along with the insights from participating licensees, in the development of NEI 99-04.

The staff's review of NEI 99-04, including its finding that the revised guidance remained useful for controlling regulatory commitments, is described in SECY-00-045, and in the letter from S. Collins (NRC) to R. Beedle (NEI) dated March 31, 2000 (Ref. 6). In Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," (Ref. 7) the NRC informed licensees that NEI 99-04 contains acceptable guidance for controlling regulatory commitments and encouraged licensees to use the NEI guidance or similar administrative controls to ensure that regulatory commitments are implemented and that changes to the regulatory commitments are evaluated and, when appropriate, reported to the NRC.

LIC-105 was issued in May 2003 to provide specific guidance to the NRC staff regarding the appropriate use of regulatory commitments and the conduct of commitment management audits. It has been revised, subsequently, to incorporate feedback from auditors and lessons learned from effectiveness and efficiency assessments in 2008, 2009 and 2011.

#### 4. BASIC REQUIREMENTS

The basic requirements for NRR's management of regulatory commitments made by power reactor licensees can be divided into three major areas:

- (1) Routine creation of regulatory commitments by the licensees as part of the processes associated with various licensing tasks.
- (2) NRC handling of commitment changes that are reported to the NRC in accordance with licensees' administrative procedures.
- (3) NRC's periodic review (audit) of licensees' commitment management programs.

Each of these areas is described below.

#### 4.1 <u>Creation of Regulatory Commitments</u>

Regulatory commitments are appropriate for matters that are of significant interest to the staff, but do not warrant either legally binding requirements or inclusion in Updated Final Safety Analysis Reports (UFSARs) or programs subject to a formal regulatory change control mechanism. Nevertheless, the regulatory process appropriately utilizes commitments in many instances and the NRC expects licensees to honor these commitments in good faith.

Because regulatory commitments are implemented by the licensee, the licensee is responsible for creating and maintaining configuration control of all regulatory commitments made to the NRC. Control of such commitments, in accordance with licensee programs, is acceptable provided those programs include controls for evaluating changes and, when appropriate, reporting them to the NRC. The staff's review of licensees' commitment management programs is discussed later in this instruction.

All regulatory commitments made by the licensee to the NRR staff are to be docketed in formal correspondence from the licensee. The NRR staff should not include any statements regarding regulatory commitments made by the licensee in safety evaluations or other NRC documentation unless those commitments were expressly made by the licensee in writing. In some cases, licensees may choose to allow a third party (e.g., an owners group or NEI) to work with the NRC staff on their behalf to resolve generic issues or issues germane to a vendor type. Licensees and the NRC staff should ensure that regulatory commitments related to third party submittals are well understood and documented (i.e., the submittal should state that the group is authorized to make the regulatory commitment on behalf of the licensees or each licensee should separately submit a regulatory commitment related to the generic document).<sup>1</sup>

A frequently asked question is when to accept an action to be completed by a licensee as a regulatory commitment versus making the action a license condition, another regulatory requirement, or incorporating the action into a mandated licensing basis document such as the UFSAR. As described in LIC-100, "Control of Licensing Bases for Operating Reactors," the inclusion of actions or programs into the operating license, including technical specifications and license conditions, creates an obligation or regulatory requirement upon the licensee. This should only be used if the staff deems that the commitment is essential for ensuring the health and safety of the public. Such obligations include actions that form the basis for the NRC staff's reasonable assurance finding on a licensing action. LIC-100 defines obligations as follows:

Conditions or actions that are legally binding requirements imposed on licensees through applicable rules, regulations, orders, and licenses (including technical specifications and license conditions). The imposition of obligations (sometimes referred to as regulatory requirements) during routine interactions with licensees should be reserved for matters that satisfy the criteria of 10 CFR 50.36 or are otherwise found to be of high safety or regulatory significance. The major distinction between obligations and other parts of the licensing bases is that changes generally cannot be made without prior NRC approval.

Since commitments made by a licensee in support of a license action, such as a license amendment request, are not legally binding, the staff's safety evaluation (SE) should not rely on commitments as a basis for any part of the staff's approval of a proposed licensing action. Therefore, if the NRC staff needs to rely on a regulatory commitment in an SE, then the staff must escalate the commitment to an obligation, or incorporate it into a mandated licensing basis document.

<sup>&</sup>lt;sup>1</sup> This item was added in response to Davis-Besse Lessons Learned Task Force (LLTF) Recommendation, LLTF No. 3.1.2(2) that states NRC should establish review guidance for accepting owners group and industry resolutions for generic communications and generic issues. Such guidance should include provisions for verifying implementation of activities performed by individual owners groups and licensees.

#### 4.2 <u>Handling of Licensees' Reported Changes to Regulatory Commitments</u>

Licensees using the industry guidance in NEI 99-04 will periodically report changes in commitments that they have made using their administrative processes. The NEI 99-04 guidance also includes criteria to determine if a more immediate report to the NRC staff is appropriate. Upon receipt of a report of multiple changes or a letter on a change to a specific regulatory commitment, the project manager (PM) should perform a brief assessment to determine if additional reviews and/or interactions with the licensee are warranted. If the brief review identifies safety concerns, then follow-up with the appropriate technical staff and interfacing with the licensee are necessary to resolve the concerns. For changes to implementation dates of previous regulatory commitments, consult with appropriate technical staff or lead PM for generic communications to determine if the changes are acceptable. The formality of the staff's response will depend upon the circumstances and can vary from a telephone call acknowledging a revised commitment date to a formal letter. If a formal letter is not issued, the PM should document other contacts (e.g., phone call or e-mail) and the staff's conclusions in a memo to file. The Division of Operating Reactor Licensing (DORL) Technical Assistant (TA) should be copied on closeout documentation.

#### 4.2.1 Regulatory Commitments Within The License Renewal Process

The Division of License Renewal (DLR) accepts regulatory commitments made by the licensee during the course of a license renewal application review. These commitments are captured in the license renewal safety evaluation report that is issued as an NRC technical report (NUREG). Many of the commitments for license renewal are no longer commitments, since they are subsequently incorporated into the plant's UFSAR or reconstituted as license conditions.

The regional inspectors verify completion of commitments (including those that have been escalated) for license renewal using inspection procedure IP 71003, "Post-Approval Site Inspection For License Renewal" (ADAMS Accession No. ML082830294). Therefore, DORL PMs will typically not include these commitments in the triennial commitment audit sample. However, if there are a limited number of commitments initiated by a licensee since the last triennial commitment audit, the DORL PM should consider adding more commitments from license renewal to the triennial commitment audit sample population.

The criteria for assessing commitment changes provided in NEI 99-04 (see Enclosure 3 of this office instruction) may also apply to licensee modifications to commitments for license renewal. However, a majority of the commitments associated with license renewal are incorporated as part of the UFSAR supplement, and therefore, managed in accordance with the requirements of 10 CFR 50.59. In a few cases, commitments associated with license renewal were referenced in the license conditions for license renewal, but not incorporated as part of the UFSAR. As a result, these commitments were elevated to legal obligations via the license conditions.

Modification of actions that have been elevated from commitments to license conditions can only be accomplished through NRC approval of a license amendment, since they are no longer commitments but have been reconstituted as regulatory obligations. However, these elevated actions have historically continued to be incorrectly referred to as commitments in various NRC documents, including the associated license renewal safety evaluation reports that are issued as NUREGS. Therefore, DORL PMs should exercise caution when reviewing licensee changes to commitments for license renewal and ensure that: (1) modifications to commitments are made in accordance with the change process described in NEI 99-04, (2) modifications to commitments incorporated in the UFSAR are made in accordance with 10 CFR 50.59, and (3) modifications to actions that have been elevated to obligations are made in accordance with 10 CFR 50.90.

# 4.3 <u>Periodic Reviews</u>

Every 3 years, NRR PMs are required to audit the licensee's commitment management program by assessing the adequacy of the licensee's implementation of a sample of commitments made to the NRC in past licensing actions (amendments, relief requests, exemptions, etc.) and activities (bulletins, generic letters, etc.). For the purpose of this office instruction, every 3 years may be interpreted to mean calendar years. Thus, an audit conducted in 2009 should be followed up by an audit before the end of 2012. With proper planning, this schedule should be readily achievable. However, if it appears that the schedule cannot be met, the PM and the appropriate branch chief (BC) should make alternate plans and notify the DORL TA.

The procedures in this office instruction are consistent with NRR Office Instruction LIC-111, "Regulatory Audits" (Ref. 8), and constitute a regulatory audit plan for commitment management audits. Therefore, a separate audit plan, as described in Section 4 of LIC-111, is not required. For the purpose of verifying licensee commitments, the commitment management audit is a structured, pre-planned activity that is most appropriate for long-term verification of licensee actions. It is not structured to support short-term verification of important assumptions, methodologies, configurations, or other licensing information. For situations requiring short-term verification, the PM should refer to LIC-101, "License Amendment Review Procedures," and LIC-503, "Generic Communications Affecting Nuclear Reactor Licensees," for guidance.

It is estimated that approximately 60 hours, including travel time, will be expended in performing a commitment management audit. The time will consist of an in-office review of process descriptions, procedures, and documentation related to commitment changes that have been provided by the licensee in support of the audit and preparation of the report; an onsite portion that will involve interviews, review of supporting documentation for commitment changes, and verification of implementation of specific commitments; and the in-office development of the audit report.

The Office of Inspector General (OIG) audit report (OIG-11-A-17) issued in 2011 (Ref. 9) identified that the definition and use of commitments were not consistently understood throughout the NRC. As a result, the OIG audit determined that the NRC staff may have accepted licensee-proposed commitments rather than the necessary regulatory requirement or obligation, such as a license condition, order, rule or regulation. This is especially true of older commitments that were established in the years before NEI 99-04 was developed and endorsed by the NRC. The guidance in NEI 99-04 recognizes this possibility and provides guidelines in Section 4.2 to assess items that were previously implemented as commitments, but were in fact obligations. NEI 99-04, Step 3 of Section 4.2 notes that methods used by licensees to ensure compliance with obligations will not normally be considered commitments.

Recommendation No. 4 of the OIG audit proposed that DORL determine the extent to which commitments have been misapplied to actions that are safety significant and/or necessary for approval of proposed licensing actions. DORL's implementation of this recommendation includes the establishment of the following criteria to be applied when reviewing licensee commitments reviewed during the audit:

- (1) Determine if the commitment reviewed involves actions that were safety significant (i.e., commitments used to ensure safety).
- (2) Determine if the commitment reviewed involves actions that were necessary for approval of a proposed licensing action.

Should any commitments be identified that meet either of the criteria above, PMs are to notify their BC and the DORL commitments subject matter expert (SME) to determine what actions should be taken to address the misapplied commitment. The DORL PM will generate an internal branch memorandum (or e-mail placed in ADAMS) that describes the misapplied commitment and any actions taken to resolve the misapplication. This information will also be documented in the commitment audit report (see audit report template in Enclosure 4). There may be some instances when the actions required to resolve a misapplied commitment cannot be completed by the conclusion of the audit. In these cases, the DORL PM will open an Other Licensing Tasks docket-specific technical assignment code (TAC) (Activity Code "RO – not fee billable") to track final disposition of the misapplied commitment. The TAC number will also be documented in the commitment audit report. Note that this TAC is separate from the TAC opened for the commitment audit. The TAC opened for the commitment audit is a fee billable TAC, as described below.

For greater efficiency, commitment management audits should be combined with site visits for other purposes, when practicable, and time and travel charges should be prorated between these activities. A docket-specific TAC should be opened when the PM schedules the audit and starts to develop the audit sample. The audits are to be completed under the planned accomplishment code "Other Licensing Tasks," and are fee billable. Care should be taken to ensure charges to these TACs are accurate so that the budget assumptions can be verified. Only the PM or other person(s) that materially contribute to the audit should charge to these TACs. Personnel who participate as

observers or as part of a training function (e.g., Nuclear Safety Professional Development Program candidates), should charge to their normal TACs. If a planned audit is cancelled or significantly postponed, the TAC should be closed and a new one opened when the audit is rescheduled.

This audit consists of two major parts: (1) verification of the licensee's implementation of NRC commitments that have been completed, and (2) verification of the licensee's programs for managing commitments and, in particular, for managing changes to NRC commitments. The following describes these activities in greater detail:

#### 4.3.1 Verification of Licensee's Implementation of NRC Commitments

The primary focus of this part of the audit is to confirm that the licensee has implemented those commitments made to the NRC as part of past licensing activities. The audit should, therefore, ensure that the sample of completed commitments was implemented in a manner that satisfied both the action committed to and the overall intent of the commitment. For example, particular attention should be paid to determine if the committed action was to perform an action (e.g., revise a procedure or implement a plant modification), or to only initiate an action (e.g., submit a procedure change request or modification request).

# Sample Selection:

A selection of at least 10 licensee commitments comprising open, closed and modified/deleted commitments from the previous 3 years are to be reviewed. The PM may want to conduct informal discussions with appropriate technical and regional staff in developing the sample. The sample size will be a minimum of 10 commitments in total. However, as necessary, the sample size may be increased, if the PM determines that review of additional commitments is required to ensure that a sufficiently broad spectrum of commitments is audited.

In addition, the PMs will review all license amendment safety evaluations, exemptions and relief request safety evaluations that have been issued for a facility during the previous 3 years and identify if any misapplied commitments exist in these documents per the criteria in Section 4.2 of this office instruction. These documents will have been issued recently enough such that they are readily available in ADAMS and PMs will already be reviewing these documents to identify commitments for the audit sample selection. The additional effort needed to evaluate the context and use of these commitments, in order to determine if a commitment has been misapplied, makes efficient use of limited resources by focusing efforts on commitments made in connection with safety and regulatory determinations. See Enclosure 2 of this office instruction for guidance regarding triennial commitment audit sample selection to be applied by DORL PMs. Enclosure 2 also includes an example e-mail that DORL PMs may use for the initial document request from the licensee.

The audit report will also state that the review for misapplied commitments as described above was completed and note that none were identified, or describe any misapplied commitments and their resolution. (See Enclosure 4 of this office instruction).

#### Planning the On-Site Audit:

The sample selection will normally be done at NRC headquarters, and verification of commitment implementation will normally be done during a site visit. Although many audit activities can be done from NRC headquarters, this may not be as convenient due to the need to have copies of numerous documents sent to the PM, and may require additional communication by telephone or email to obtain clarifications. It may also create an additional burden on the licensee. The PM should consult with his or her BC before adopting this approach.

The PM will coordinate scheduling of the on-site audit with the site resident inspectors to ensure that there will be no conflict with regional inspection activities, site visits or other planned events. The principal point of contact should be the site licensing staff, unless the licensee has assigned the responsibility elsewhere within the organization, such as a corrective action program coordinator. The PM will request that the licensee provide a list of all open commitments in the licensee's commitment tracking database. In addition, the list of commitments that have been closed, modified or deleted since the previous audit will also be requested. These requests should be made approximately 4 to 6 weeks prior to the on-site audit. This information will be used in determining the audit sample (see Enclosure 2). Once the audit sample has been selected, the PM will request that the licensee prepare copies of the plant implementation records for the selected commitments to be reviewed during the on-site audit.

The regulatory commitments or aspects of commitments being verified and the information needed to perform the verification should, as much as possible, be identified and communicated to the licensee at least 14 days prior to the site visit in order to give the licensee adequate time to prepare and to minimize time spent waiting for information. Entrance and exit briefings are not required, but if the PM will be meeting with site management for other reasons, a brief discussion of the audit plan is appropriate.

The PM will request a copy of the licensee's commitment management procedure or program documents and copies of evaluation documentation related to changes to the program/procedure since the last audit. Prior to the onsite audit, the PM will assess the licensee's program/procedures for any deviations from the commitment change control process guidelines provided in NEI 99-04. The PM should request that the licensee prepare copies of any supporting documentation related to the identified deviations for review during the on-site audit.

#### **Commitment Implementation Verification:**

Commitments in the audit sample that the licensee has identified as completed will be reviewed for proper implementation. The PM should review LIC-111, "Regulatory Audits," for guidance on handling, control and disposition of documents provided by the licensee for review. PM's will verify that audit sample commitments have been properly implemented by direct inspection of the implementing records. Implementing records include the following items:

- 1. Procedure revisions;
- 2. Completed work orders and/or plant walkdowns;
- 3. Issued training plans;
- 4. Plant design calculations;
- 5. Plant drawings;
- 6. Issued memorandums;
- 7. Initiated licensing actions; and
- 8. NRC inspection reports.

The PM will request that the licensee prepare copies of the plant implementation documentation for the completed commitments in the audit sample. The PM will review the implementation documentation during the on-site audit. The review will confirm that all appropriate plant documentation has been revised and that the changes accurately and fully implement the commitment. Special attention should be given to fleet procedures and program documents to ensure that necessary site-specific implementing documents have also been revised.

In some instances, on-site physical verifications may enhance the audit. For example, the licensee may have updated plant procedures that require that certain equipment be staged in the field with charged power supplies. The PM may choose to physically verify that the staged equipment is in place and maintained appropriately. The PM should work through the point of contact to arrange discussions with other members of the organization (e.g., system engineering, maintenance, training) and plant walkdowns/tours, if needed.

For those commitments that require ongoing action, the PM will confirm that the licensee has integrated the commitment management system with other line organization functions to ensure traceability of the commitments following initial implementation. The PM should verify that a mechanism exists to ensure that licensee personnel are able to recognize that future proposed changes to the affected procedures, design documents or operating practices require evaluation

of the proposed change to ensure that the commitments are not inappropriately changed or deleted.

## 4.3.2 <u>Verification of Licensee's Program for Managing Changes to NRC</u> <u>Commitments</u>

The primary focus of this part of the audit is to assess the licensee's performance related to implementing controls for modifying or deleting commitments made to the NRC. The audit should ensure that changes to commitments (modifications or deletions) are evaluated in accordance with the licensee's programs and procedures, that the licensee's technical evaluations adequately justify the change, and that the NRC is informed of commitment changes that have safety or regulatory significance. The PM should, as a minimum, determine whether the licensee has used the NEI guidelines or an equivalent alternative process to resolve safety issues pertinent to the associated commitment and has informed or will inform the NRC of the change if the notification threshold of the licensee's process is exceeded. Guidance on applying the NEI 99-04 commitment change criteria is provided in Enclosure 3 of this office instruction.

The PM should also verify that revised commitments have not had an adverse effect on safety or security, or led to noncompliance with applicable regulations. If the PM agrees that a commitment change was safe and believes it would not introduce issues of compliance with any regulations, questions or concerns regarding the change process can simply be documented in the audit report. By contrast, a commitment change evaluation that failed to address an obvious safety or regulatory consideration would be more significant. Failure to recognize that a commitment change required assessment by regulations such as 10 CFR 50.59, 50.54, or 50.65 may also be significant. Section 4.3.3 of this procedure discusses follow-up actions for safety concerns or possible regulatory nonconformances that are discovered during this audit.

The two aspects of this part of the audit are: (1) change control procedure verification, and (2) procedure implementation assessment.

# A. Change Control Procedure Verification

The PM should verify that the licensee has established administrative controls for modifying or deleting commitments made to the NRC. The controls for changing commitments made to the NRC may be included in a stand-alone commitment management system or may be incorporated into other licensee administrative programs.

The PM should verify that the programs provide guidance regarding the evaluation of proposed changes to commitments in terms of safety and regulatory significance. The licensee's guidance should likewise include criteria for determining when it would be appropriate to notify the NRC of a commitment change. The NEI guidance document is an acceptable guide for licensees to

follow for managing and changing their commitments to the NRC. For those licensees that have not adopted the NEI methodology, the PM should document a comparison of the licensee's process, including criteria for evaluation of changes and NRC notification, to that recommended in the NEI guideline and evaluate whether the licensee's process is acceptable. If the licensee has not implemented a program for commitment management that includes NRC- endorsed features, this should be identified in the audit report. Section 4.3.3 of this procedure discusses follow-up actions for safety concerns or possible regulatory nonconformances that are discovered during the audit.

If an audit determines that the licensee has a satisfactory process that meets the NEI guidelines, the scope of this portion of the audit may be reduced to an evaluation of any changes to the process since the previous audit.

#### B. Procedure Implementation Assessment

Procedure implementation assessment is the process whereby the PM assesses the licensee's performance with regard to commitment changes reported to the NRC, commitment changes not reported to the NRC, notification requirements, and traceability. As previously noted, licensee programs that conform to NEI 99-04 guidelines will include controls for making and reporting changes to commitments. The following describes this process in greater detail.

<u>Commitment Changes Reported to the NRC</u>

The PM will request that the licensee provide a list of commitment changes (modifications or deletions) from the previous 3 years that were reported or will be reported to the NRC. From this list, the PM will select a sample of commitments for review as described in Enclosure 2 of this office instruction.

Since changes to the UFSAR and other programs are, or will be, assessed in NRC inspection procedures, this review should exclude commitments integrated into the UFSAR, Quality Assurance Program, Site Security Plan, Emergency Plan, or other documents governed by a change control mechanism contained in regulations such as 10 CFR 50.59 or 50.54.

Each commitment change in the sample will be reviewed to determine if the licensee's commitment change process has been followed and adequately documented. The PM should assess whether the licensee's periodic report (see Section 4.2 above) accurately described those changes that were reported. The PM will assess the licensee's technical justification for the changes. If necessary, appropriate technical and regional staff should be consulted.

#### <u>Commitment Changes Not Reported to the NRC</u>

The PM will request that the licensee provide a list of commitment changes (modifications or deletions) from the previous 3 years that it evaluated as not needing to be reported to the NRC. From this list, the PM will select commitment changes for inclusion in the audit sample for review as described in Enclosure 2 of this office instruction. The identification of such changes may be dependent on how a licensee handles such changes within its commitment management tracking system. Each selected commitment change should be reviewed to determine if it was evaluated in accordance with the licensee's process and adequately documented in a plant record that will be maintained in the licensee's record keeping system. If the PM feels that the licensee's determination to not notify the NRC was inadequate, appropriate NRC technical and regional staff should be consulted to support this conclusion. Confirmed deficiencies should be handled in accordance with Section 4.3.3 below.

# 4.3.3 Resolution of Deficiencies

The PM will request that the licensee enter any discrepancies identified during the audit into the licensee's corrective action program (CAP). The associated CAP item identification numbers, and any other audit findings, will be documented in the audit report. A licensee's choice to adopt an approach that differs from the approach recommended by NEI and accepted by the NRC is not subject to enforcement action. However, this should also be noted in the audit report.

Safety concerns or possible regulatory nonconformances that are discovered during the audit should be documented by the PM and referred to the appropriate DORL BC. The PM should also identify the issues to the resident inspectors while on-site. The DORL BC will, as necessary, contact the appropriate regional BC and the Office of Enforcement to discuss resolution of the issues. If appropriate, enforcement action will be taken in accordance with the NRC Enforcement Manual after a thorough review of the issue. Enforcement activities are outside the scope of the audit and should not delay issuance of the audit report or closing the TAC. As noted in Section 4.3 of this office instruction, any misapplied commitments will be identified to the DORL PM's BC and the DORL commitments SME to determine if any actions should be taken.

For example, the NRC staff may issue an enforcement action (e.g., an Order) to address any regulatory deficiencies identified during the audit or may use the administrative enforcement tool of a Notice of Deviation (NOD) if a licensee fails to satisfy a regulatory commitment, which is legally non-binding. (See the NRC Enforcement Manual, Ref. 10). In addition, issues regarding completeness and accuracy of information submitted to the NRC may warrant consideration of the requirements of 10 CFR 50.9, "Completeness and accuracy of information."

# 4.3.4 <u>Reporting Requirements</u>

Within 90 days following the site visit, PMs should document the results of the audit in an audit report that summarizes the licensee's commitment management process, specific reviews performed, and other pertinent information (recent changes in programs, planned changes in programs, etc.). A template for preparing an audit report letter is provided in Enclosure 4 of this office instruction and an electronic version is contained in the DORL Common Documents folder on the G:\ drive. Avoid unnecessary detail. If the results are satisfactory, it is only necessary to list the documents reviewed. Additional detail is appropriate if deficiencies in the licensee's program or its implementation were identified. The PM should provide suggestions for improvement, if appropriate. The report should inform the licensee if there are any issues requiring followup (e.g., additional inspections or potential enforcement action).

The assessment will be documented in a letter to the licensee. The report should be placed in ADAMS as a publicly available record. The DORL TA, plant resident inspectors and the regional Division of Reactor Projects BC should receive copies.

# 5. **RESPONSIBILITIES AND AUTHORITIES**

All NRR staff supporting the formation or revision of the licensing bases for commercial nuclear reactors are responsible for reading, understanding, and applying the guidance in this office instruction. They also are responsible for identifying possible improvements to the guidance and submitting suggestions for such improvements to their management or to the assigned contacts for this office instruction. The following paragraphs describe these responsibilities in greater detail.

# 5.1 <u>Division Directors</u>

Division Directors routinely ensure that their organizations are properly carrying out the overall licensing program for commercial nuclear reactors, including the use of regulatory commitments. Division Directors are responsible for ensuring that their organizations resolve technical issues, develop approaches, and take actions to meet the objectives established in the operating plan. Division Directors will escalate proposed solutions to problems and proposed process improvements to the Executive Team when circumstances require the involvement of senior managers.

The DORL Division Director is responsible for ensuring that the audits of licensees' commitment management programs are properly included in NRR's budget and operating plan. The DORL Division TA will track the status of commitment management audits. The Director will also ensure that PMs in DORL are given adequate guidance and training to conduct the audits. This will normally be accomplished by training sessions during the PM qualification program, by presentations at DORL staff meetings, or by individual coaching.

# 5.2 Branch Chiefs

Branch Chiefs in DORL are responsible for ensuring that audits of licensees' commitment management programs are performed and for assigning and scheduling the staff to perform the audits. BCs are responsible for ensuring that staff are appropriately trained, provided with necessary tools, and appropriately managed during their reviews of specific licensing actions or other licensing tasks.

In limited cases, the DORL BC may request that the regional office verify completion of certain regulatory commitments or other key information used in the review of a licensing action. If necessary, the DORL BC will request support from the appropriate regional office. The request will identify the information to be verified, whether there is a need to document the verification (in a memorandum or inspection report), and a proposed schedule. Refer to NRC Inspection Procedure IP71005, "Inspector Review of Licensing-related Information," (ADAMS Accession No. ML032190054).

DORL BCs will review significant safety issues or potential NODs discovered during the audit and take appropriate action as discussed in Section 4.3.3 of this office instruction.

# 5.3 Project Managers

PMs are responsible for the general oversight and coordination of NRR activities related to the processing of licensing actions, generic issues, or policy issues and for ensuring that the outputs associated with these licensing activities are complete, accurate, and timely. Because the PMs serve as the primary contact between NRR and the licensees, the PMs have the responsibility of ensuring that communications between the staff and licensees facilitate mutual understanding of any regulatory commitments that a licensee makes. Therefore, PMs will periodically (every 3 years) perform an audit to assess the licensee's commitment management program in accordance with the requirements specified in Section 4 of this office instruction. The PMs will coordinate the audit schedule with the licensee, resident inspectors, and the appropriate regional staff to avoid scheduling conflicts and to minimize the burden on the licensee's operating staff.

Safety issues, misapplied commitments or potential NODs discovered during the audit that are considered significant will be reported to the DORL BC and, as appropriate, other NRR/Regional staff for final resolution as described in Section 4.3.3 of this office instruction.

# 5.4 <u>Technical Staff</u>

The technical staff will ensure that regulatory commitments that are utilized in safety evaluation inputs are properly characterized. Specifically, technical staff will ensure that actions that are proposed by licensees as regulatory commitments, and form the basis for a finding of public health and safety, are appropriately elevated to legal obligations as discussed in Section 4.1 of this office instruction.

### 5.5 Lead Project Managers for Multi-Plant Actions

As described in LIC-503, "Generic Communications Affecting Nuclear Reactor Licensees," lead PMs for multi-plant actions are responsible for assessing the need for long-term verification of licensee actions in response to generic communications, which could be accomplished through the PM audits. Lead PMs should determine if it would be appropriate to issue guidance directing the plant PMs to verify the implementation of a regulatory commitment during the periodic audit.

#### 6. **PERFORMANCE MEASURES**

No performance measures are proposed beyond those related to the NRR Operating Plan.

#### 7. PRIMARY CONTACTS

John D. Hughey NRR/DORL 301-415-3204 john.hughey@nrc.gov Tracy J. Orf NRR/DORL 301-415-2788 tracy.orf@nrc.gov

#### 8. **RESPONSIBLE ORGANIZATION**

NRR/DORL

# 9. EFFECTIVE DATE

September 16, 2013

#### 10. <u>REFERENCES</u>

- 1. SECY-95-300, Nuclear Energy Institute's Guidance Document, "Guideline for Managing NRC Commitments," dated December 20, 1995 (ADAMS Accession No. ML060270189).
- 2. SECY-98-224, "Staff and Industry Activities Pertaining to the Management of Commitments Made by Power Reactor Licensees to the NRC," dated September 28, 1998 (ADAMS Accession No. ML992870043).
- SECY-00-045, "Acceptance of NEI 99-04, 'Guidelines for Managing NRC Commitments," dated February 22, 2000 (ADAMS Accession No. ML003679799).
- 4. NEI 99-04, "Guidelines for Managing NRC Commitment Changes," July 1999 (ADAMS Accession No. ML003680088).

- 5. Memorandum from J. Giitter (NRC) to B. Boger (NRC) dated November 26, 2008 (ADAMS Accession No. ML083150618).
- 6. Letter from S. Collins (NRC) to R. Beedle (NEI) dated March 31, 2000 (ADAMS Accession No. ML003696998).
- Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000 (ADAMS Accession No. ML003741774).
- 8. NRR Office Instruction LIC-111, "Regulatory Audits," dated December 16, 2008 (ADAMS Accession No. ML082900195).
- 9. Memorandum from S. Dingbaum (OIG) to W. Borchardt (NRC) dated September 19, 2011 (ADAMS Accession No. ML112620529).
- 10. "Nuclear Regulatory Enforcement Manual," Revision 8, February 1, 2013 (ADAMS Accession No. ML102630150).
- 11. Memorandum from M. Galloway (NRR/DLR) to M. Evans (NRR/DORL) dated February 27, 2012 (ADAMS Accession No. ML12027A026).
- 12. NRR Office Instruction LIC-101, "License Amendment Review Procedures," Revision 4, dated May 22, 2012 (ADAMS Accession No. ML113200053).

#### Enclosures:

- 1. Appendix A: Change History
- 2. Triennial Commitment Audit Sample Selection Guidance
- 3. Guidance for Reviewing Licensee Changes to Commitments
- 4. Audit Report Template

# Appendix A - Change History Office Instruction LIC-105 Managing Regulatory Commitments Made By Licensees to the NRC

LIC-105 Change History - Page 1 of 2				
Description of Changes	Method Used to Announce & Distribute	Training		
The objective of this office instruction is to provide NRR staff and their stakeholders with a common reference for handling regulatory commitments made by licensees to the NRC staff. The guidance in this office letter is consistent with the industry guidance prepared by the Nuclear Energy Institute (NEI) NEI 99- 04, "Guidelines for Managing NRC Commitment Changes."	E-mail to NRR staff	E-mail announcement with recommended self-study for all staff. Specific training session for Project Managers (Training as needed prior to specific audits).		
Changes in revision 1 include: (1) discussion of regulatory commitments related to activities of industry groups [to address open item from Davis Besse LLTF], and (2) minor changes to audit procedure to reflect lessons learned from recent audits.	E-mail to NRR staff	E-mail announcement with recommended self-study for all staff. Specific training session for Project Managers during routine DLPM division meeting		
Changes in revision 2 include: (1) incorporation of additional details on performing audits that previously were located in a separate guide, (2) incorporation of feedback and best practices from completed audits, (3) changes to the objectives section to reflect the current NRC strategic plan, (4) changes to the responsibilities section and other locations to reflect the current NRR organization, and (5) miscellaneous minor changes and edits.	E-mail to NRR staff	E-mail announcement with recommended self-study for all staff.		
	Description of Changes           The objective of this office instruction is to provide NRR staff and their stakeholders with a common reference for handling regulatory commitments made by licensees to the NRC staff. The guidance in this office letter is consistent with the industry guidance prepared by the Nuclear Energy Institute (NEI) NEI 99- 04, "Guidelines for Managing NRC Commitment Changes."           Changes in revision 1 include: (1) discussion of regulatory commitments related to activities of industry groups [to address open item from Davis Besse LLTF], and (2) minor changes to audit procedure to reflect lessons learned from recent audits.           Changes in revision 2 include: (1) incorporation of additional details on performing audits that previously were located in a separate guide, (2) incorporation of feedback and best practices from completed audits, (3) changes to the objectives section to reflect the current NRC strategic plan, (4) changes to the responsibilities section and other locations to reflect the current NRR organization, and (5) miscellaneous	Description of Changes         Method Used to Announce & Distribute           The objective of this office instruction is to provide NRR staff and their stakeholders with a common reference for handling regulatory commitments made by licensees to the NRC staff. The guidance in this office letter is consistent with the industry guidance prepared by the Nuclear Energy Institute (NEI) NEI 99- 04, "Guidelines for Managing NRC Commitment Changes."         E-mail to NRR staff           Changes in revision 1 include: (1) discussion of regulatory commitments related to activities of industry groups [to address open item from Davis Besse LLTF], and (2) minor changes to audit procedure to reflect lessons learned from recent audits.         E-mail to NRR staff           Changes in revision 2 include: (1) incorporation of additional details on performing audits that previously were located in a separate guide, (2) incorporation of feedback and best practices from completed audits, (3) changes to the objectives section to reflect the current NRC strategic plan, (4) changes to the responsibilities section and other locations to reflect the current NRR organization, and (5) miscellaneous         E-mail to		

Enclosure 1

LIC-105 Change History - Page 2 of 2			
Date	Description of Changes	Method Used to Announce & Distribute	Training
09/10/12	Revision 4 incorporates enhancements in response to the Office of Inspector General (OIG) audit report OIG- 11-A-17. Changes in revision 4 include: (1) incorporation of additional guidance on commitment audit sample selection, (2) incorporation of additional guidance on commitment implementation verification, (3) incorporation of new guidance on identifying misapplied commitments, (4) incorporation of additional guidance on reviewing licensees' commitment management program, (5) incorporation of additional guidance on reviewing commitment modifications, and (6) miscellaneous changes and edits.	E-mail to NRR staff	Training presentations to DORL, DLR and Regional staff. In addition commitment management briefings provided to DORL PMs.
09/05/13	Revision 5 updates Section 4.3, and the audit report template in Enclosure 4, with the requirement for DORL PMs to open a not fee billable technical assignment code (TAC) to track final disposition of an identified misapplied commitment that requires actions to be completed after the audit report is issued. Minor editorial corrections were also made.	E-mail to NRR staff	E-mail announcement with recommended self-study for all staff.

Triennial Commitment Audit Sample Selection Guidance

Enclosure 2

#### **Triennial Commitment Audit Sample Selection Guidance**

The following sources are to be reviewed by DORL PMs when developing a commitment management audit sample:

- 1. The licensee's list/database of commitments;
- 2. License amendment requests and NRC-issued Safety Evaluations;
- 3. Licensee responses to NRC Generic Letters;
- 4. Licensee correspondence related to NRC Bulletins and Information Notices;
- 5. Other licensee-docketed correspondence (e.g., responses to Licensee Event Reports or Notice of Violations).

Commitments related to the sources listed in items 2 through 5 above can be found through an ADAMS search of the last 3 years. The licensee's tracking list of commitments, described in item number 1 above, is to be requested at the inception of audit planning as follows:

- List of all open regulatory commitments (see Note).
- List of all commitments that have been initiated or closed in the last 3 years (see Note).
- List of commitments that have been changed (i.e., modified or deleted) in the last 3 years that were reported or will be reported to the NRC (see Note).
- List of commitments that have been changed (i.e., modified or deleted) in the last 3 years that were evaluated as not needing to be reported to the NRC (see Note).
  - Note: For each commitment, as a minimum, the list should include the licensees' tracking number and a description of the actual commitment.

PMs are to review the licensee's full list of all open regulatory commitments noting commitment descriptions that appear to be associated with license amendment requests, exemptions and relief requests, as these documents involve regulatory decisions made by the NRC staff. PMs will consider the item descriptions on this list that may indicate safety significance or a regulatory requirement for inclusion in the audit sample. This effort will apply a first level screening for potential misapplied commitments to the full scope of all open commitments tracked by the licensee. For licensees with multiple sites, the PM should request that the commitment lists being provided include any commitments that may be tracked by corporate systems, separate from the site tracking system.

PMs will also request that the licensee provide a list of all commitments that have been initiated, modified or closed in the last 3 years. The purpose for this sub-set of the licensee's commitment list is to select sample items to evaluate commitment changes and to confirm that all of the commitments included in the audit sample have been appropriately entered into the licensee's tracking system.

The audit sample should contain commitments that have been implemented, those that are awaiting completion of implementation and those commitments that have been modified (i.e., revised or deleted). Closed commitments will be selected to verify that they have been properly and completely implemented and dispositioned. Open commitments will be selected to confirm that they are properly documented, tracked and scheduled for implementation. Modified commitments will be selected to determine if the licensee properly evaluated the commitment change or deletion, and whether timely notification was made to the NRC, as appropriate.

There may be instances where it is appropriate to select more than 10 commitments for the audit sample. For example, several commitment items such as a procedure change, a training plan revision, or an initiated plant modification, may be implemented together to address a single issue. In this instance, it is appropriate to consider multiple items to support the audit of a particular commitment issue. In such cases, more than 10 commitments may need to be reviewed to ensure that a sufficiently broad sample of commitments is audited.

In defining the audit sample, the PMs should consider the following:

- Choose commitments related to a variety of systems.
- Choose commitments involving a variety of engineering disciplines, such as nuclear, mechanical, civil, and electrical.
- Choose commitments that involve a variety of licensee actions, such as design modifications, temporary modifications, procedure revisions, personnel training, and revised administrative controls.
- Verify with the lead PMs or technical contacts for generic communications issued during the last 3 years to determine the need for DORL PMs to verify, during the periodic audit, the licensees' implementation or control of specific regulatory commitments, including commitments to adopt an approach submitted by an owners group or other industry organization.
- To the extent practical, identify commitments for verification that have not been
  previously addressed by NRC inspections or audits.<sup>2</sup> In preparation for the audit,
  the PM should have informal discussions with the regional staff and other NRC
  staff members to gain potential insights pertaining to the licensee's commitment
  performance history.

<sup>&</sup>lt;sup>2</sup> Licensee Event Reports (LERs) and responses to Notices of Violation (NOVs) will normally be followed up through the NRC inspection process but may be included in a commitment audit if needed to develop an adequate sample. LERs and NOVs may state a licensee's intent to take certain actions. In these cases, the regulatory commitment is normally considered to be the promise to restore compliance with a violated obligation by a certain date (i.e., scheduling), not the specific methods used.

The audit sample will exclude the following types of commitments that are internal to licensee processes:

- Commitments made on the licensee's own initiative among internal organizational components.
- Commitments that pertain to milestones of licensing actions/activities (e.g., response to an NRC request for additional information by a certain date). Fulfillment of these commitments was indicated by the fact that the subject licensing action/activity was completed.
- Commitments made as an internal reminder to take actions to comply with existing regulatory requirements such as regulations and Technical Specifications (TSs). Fulfillment of these commitments was indicated by the licensee having taken timely action in accordance with the subject requirements.

# EXAMPLE INITIAL LICENSEE DOCUMENT REQUEST E-MAIL

[Licensee Contact],

As I am sure you are aware, NRR/DORL project managers are expected to periodically perform an audit of the licensee's commitment management program. The last audit at [Facility] was completed on [Date of last audit report letter] (ADAMS Accession No. ML[xxxxxxxx]).

I am starting the preparation for the [Facility] audit. Some of the initial activities (audit sample selection, review of program) will be done at my office in Rockville and some will likely be done on site (e.g., review of documentation associated with implementation of a closed commitment).

To facilitate the initial stage of the audit, I would appreciate if your staff could provide me the following information:

- 1) Copy of the commitment management procedure or program documents used at [Facility] and copies of evaluation documentation related to changes to the program/procedure since the last audit (i.e., since [Date of last audit report letter]).
- 2) List of all open regulatory commitments (see Note).
- 3) List of all commitments that have been initiated or closed in the last 3 years (see Note).
- 4) List of commitments that have been changed (i.e., modified or deleted) for the last 3 years that were reported or will be reported to the NRC (see Note).
- 5) List of commitments that have been changed (i.e., modified or deleted) for the last 3 years that were evaluated as not needing to be reported to the NRC (see Note).
  - <u>Note</u>: For each commitment, as a minimum, the list should include your tracking number and a description of the actual commitment.

Please let me know if you have any questions.

Thank you,

[DORL PM Name] 301-415-[xxxx] Guidance for Reviewing Licensee Changes to Commitments

Enclosure 3

#### **Guidance for Reviewing Licensee Changes to Commitments**

Section 4.3.2 of this office instruction notes that PMs are to verify that modified commitments have not been inappropriately altered or changed so as to result in an adverse effect on safety or security, or led to non-compliance with applicable regulations. In cases where an adverse effect on safety or security has occurred, the original commitment may have been changed into an action that is required to meet an obligation. In these cases, the action may need to be submitted to the NRC as a proposed license condition or other regulatory requirement.

The PM will review the licensee's evaluation of the commitment change and associated conclusion regarding the need for NRC staff notification or prior approval of the change. Figure A-1 of NEI 99-04, "Guidelines for Managing NRC Commitment Changes," outlines deterministic steps for assessing commitment modifications. Section 4.2 of NEI 99-04 provides assessment criteria to determine if a commitment change requires NRC staff notification or prior approval. These criteria are summarized and addressed below:

#### 1. Determine if a codified change process exists for the commitment.

The following changes will be evaluated by NRC staff outside of the commitment management audit: changes to commitments that have been embodied in the facility Updated Final Safety Analysis Report (UFSAR) will be evaluated and reviewed by the NRC staff pursuant to 10 CFR 50.59; changes to commitments incorporated into the Quality Assurance Plan, Physical Security Plan, Cyber Security Plan, Safeguards Contingency Plan or Emergency Plan will be evaluated and reviewed by the NRC staff pursuant to 10 CFR 50.54.

The applicability/screening criteria associated with 10 CFR 50.59 can be applied to any proposed change to a regulatory commitment. The resulting determination will direct either further assessment of the proposed change under 10 CFR 50.59 or make clear that the regulatory commitment change process should be used to evaluate the commitment modification.

#### 2. Determine if the change is significant to safety.

The first step in determining the safety significance is to evaluate if the change could negatively impact the ability of a safety significant system or component (SSC) to fulfill its intended safety function. If the change does affect an SSC's ability to fulfill its intended safety function, then an assessment applying the criteria of 10 CFR 50.92(c)(1) through (c)(3), should be performed to determine if the change involves a significant hazards consideration. If the evaluation determines that a significant hazards consideration exists, a separate evaluation to determine the safety significance of the change is required. Prior NRC notification of the commitment change is required and this will be determined by the NRC staff when the commitment change is reviewed prior to implementation. Figure A-2 of NEI 99-04 outlines these deterministic steps.

# 3. Determine if the original commitment was designed to achieve compliance with an obligation.

Historically, the NRC may have accepted some commitments from licensees that prescribed methods to restore compliance with regulatory requirements. The guidance of NEI 99-04 (also endorsed by the NRC per Reference 3) describes a change in the use of regulatory commitments. NEI 99-04, Step 3 of Section 4.2 notes that methods used to ensure compliance with obligations will no longer be considered commitments. Rather, Section 1 of NEI 99-04 describes that the methods prescribed to restore regulatory compliance should reside and be tracked in the licensee's corrective action program. However, the use of regulatory compliance. If the proposed change revises the licensee's schedule to achieve compliance, then the NRC is to be notified prior to the original commitment implementation date.

If the change under review involves a commitment that was used to prescribe specific methods to achieve compliance with an obligation, then the PM should notify his or her Branch Chief and the DORL Commitment Subject Matter Expert (SME) for assistance in evaluating the commitment change and determining if any additional actions are necessary. Refer to the criteria regarding the identification of misapplied commitments provided in Section 4.3 of this office instruction.

# 4. Determine if the NRC relied upon the original commitment being considered for change.

Historically, the NRC may have relied upon some commitments from licensees as the basis for a regulatory decision. This practice is not in accordance with the guidance contained in NEI 99-04 and endorsed by the NRC staff. The following categories of historical commitments may have been relied upon by the NRC staff as the basis for a regulatory decision:

- 1. Any commitment that was relied upon by the NRC staff in a Safety Evaluation as the basis for a finding of public health and safety;
- 2. Some commitments provided in correspondence related to NRC Generic Letters, Bulletins or Information Notices; and
- 3. Some commitments provided in response to requests for information under 10 CFR 2.204, "Demand for information," or 10 CFR 50.54(f), "Conditions of licenses."

If the change under review involves a commitment that was used by the NRC staff as the basis for a regulatory decision, then the PM is to notify their BC and the DORL Commitment SME for assistance in evaluating the commitment change and determining if any additional actions are necessary. Refer to the criteria regarding the identification of misapplied commitments provided in Section 4.3 of this office instruction.

5. Determine if the original commitment was made to minimize recurrence of a condition adverse to quality.

Commitments made to minimize the recurrence of conditions adverse to quality are appropriate because they are by definition, "adverse," as opposed to safety significant. Often such commitments are associated with long-term corrective actions made in Licensee Event Reports to minimize the recurrence of adverse conditions. Licensees are provided with flexibility in assessing and modifying these types of commitments based on the following considerations:

- The committed corrective action may have been determined to be ineffective;
- A more effective method of minimizing recurrence may have been determined;
- Changing conditions in the plant may have made the committed action unnecessary;
- Experience may have revealed that the committed action was never necessary to minimize recurrence of the adverse condition; and
- The commitment may have been subsequently captured as part of an on-going program or administrative control that is subject to a revision review process.

If the changed commitment is necessary to minimize recurrence of an adverse condition, the NRC should be notified by the licensee of the change in a periodic summary report. If the commitment is no longer considered necessary to minimize recurrence of an adverse condition, the licensee may change the commitment without notifying the NRC.

Audit Report Template

Enclosure 4

[Date]

[Address]

# SUBJECT [PLANT NAME] - AUDIT OF THE LICENSEE'S MANAGEMENT OF REGULATORY COMMITMENTS (TAC NO. **MXnnnn**)

Dear [Name]:

The U.S. Nuclear Regulatory Commission (NRC) informed licensees in Regulatory Issue Summary (RIS) 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000, that the Nuclear Energy Institute (NEI) document NEI 99-04, "Guidelines for Managing NRC Commitment Changes," contains acceptable guidance for controlling regulatory commitments. RIS 2000-17 encouraged licensees to use the NEI guidance or similar administrative controls to ensure that regulatory commitments are implemented and that changes to the regulatory commitments are evaluated and, when appropriate, reported to the NRC.

The NRC Office of Nuclear Reactor Regulation has instructed its staff to perform an audit of licensees' commitment management programs once every 3 years to determine whether the licensees' programs are consistent with the industry guidance in NEI 99-04, and that regulatory commitments are being effectively implemented.

An audit of [Plant Name]'s commitment management program was performed at [LOCATION, i.e., plant site or corporate office] during the period [Insert Dates]. The NRC staff concludes, based on the audit, that: [Provide brief summary of results, e.g., (1) [Plant Name] has implemented NRC commitments on a timely basis, and (2) [Plant Name] has implemented an effective program for managing NRC commitment changes]. Details of the audit are set forth in the enclosed audit report.

[If the audit revealed any nonconformance with NRC requirements or potential safetyrelated deficiencies, briefly summarize the issue and state that it was referred to the appropriate NRC organization (e.g., Region, NRR) for follow-up action. ]

Sincerely,

[ ], [Senior] Project Manager Plant Licensing Branch [ ] Division of Operating Reactor Licensing Office of Nuclear Reactor Regulation

Docket No(s). 50-[ (and 50- )]

Enclosure: Audit Report

cc: Listserv

DISTRIBUTION: PUBLIC RidsNrrPM[ ] RidsAcrsAcnwMailCenter [Region Branch Chief]

LPL [ ] R/F RidsNrrLA[ ] RidsRgn[]MailCenter [Plant Resident Inspector] RidsNrrDorlLPL[ ] [DORL TA]

ACCESSION No.: ML

OFFICE	LPL[ ]\PM	LPL[ ]\LA	LPL[ ]\BC	LPL[ ]\PM
NAME				
DATE				

**OFFICIAL RECORD COPY** 

# AUDIT REPORT BY THE OFFICE OF NUCLEAR REACTOR REGULATION

# LICENSEE MANAGEMENT OF REGULATORY COMMITMENTS

# [PLANT NAME], UNIT NO[S]. 1 [AND ]

# DOCKET NO[S]. 50-[ (AND 50- )]

# 1.0 INTRODUCTION AND BACKGROUND

The U.S. Nuclear Regulatory Commission (NRC) informed licensees in Regulatory Issue Summary (RIS) 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000, that the Nuclear Energy Institute (NEI) document NEI 99-04, "Guidelines for Managing NRC Commitment Changes," contains acceptable guidance for controlling regulatory commitments. RIS 2000-17 encouraged licensees to use the NEI guidance or similar administrative controls to ensure that regulatory commitments are implemented and that changes to the regulatory commitments are evaluated and, when appropriate, reported to the NRC. NEI 99-04 describes a "regulatory commitment" as an explicit statement to take a specific action agreed to, or volunteered by, a licensee by a certain date and submitted in writing on the docket to the NRC.

The NRC Office of Nuclear Reactor Regulation (NRR) has instructed its staff to perform an audit of licensees' commitment management programs once every 3 years to determine whether the licensees' programs are consistent with the industry guidance in NEI 99-04, and that regulatory commitments are being effectively implemented. An audit of the [Plant Name] commitment management program was performed at [LOCATION, i.e., plant site or corporate office] during the period [Insert Dates]. The audit reviewed commitments made since the previous audit on [DATE]. [Note: If this is the first audit, note the fact and use the period approximately 3 years prior to the audit]

NRR guidelines direct the NRR Project Manager to audit the licensee's commitment management program by assessing the adequacy of the licensee's implementation of a sample of commitments made to the NRC in past licensing actions (amendments, reliefs, exemptions, etc.) and activities (bulletins, generic letters, etc.).

# 2.0 AUDIT PROCEDURE AND RESULTS

The audit consisted of three major parts: (1) verification of the licensee's implementation of NRC commitments that have been completed, (2) verification of the licensee's program for managing changes to NRC commitments, and (3) verification that all regulatory commitments reviewed were correctly applied in NRC staff licensing action reviews.

# 2.1 Verification of Licensee's Implementation of NRC Commitments

The primary focus of this part of the audit is to confirm that the licensee has implemented commitments made to the NRC as part of past licensing actions/activities. For commitments not yet implemented, the NRC staff determines whether they have been captured in an effective

program for future implementation. The audit also verifies that the licensee's commitment management system includes a mechanism to ensure traceability of commitments following initial implementation. This ensures that licensee personnel are able to recognize that future proposed changes to the affected design features or operating practices require evaluation in accordance with the commitment change control process.

# 2.1.1 Audit Scope

The audit addressed a sample of commitments made during the review period. The audit focused on regulatory commitments (as defined above) made in writing to the NRC as a result of past licensing actions (amendments, exemptions, etc.) or licensing activities (bulletins, generic letters, etc.). Commitments made in Licensee Event Reports or in response to Notices of Violation may be included in the sample, but the review will be limited to verification of restoration of compliance, not the specific methods used. Before the audit, the NRC staff searched the Agencywide Document Access and Management System (ADAMS) for the licensee's submittals since the last audit [or during in the last 3 years] and selected a representative sample for verification.

The audit excluded the following types of commitments that are internal to licensee processes:

- (1) Commitments made on the licensee's own initiative among internal organizational components.
- (2) Commitments that pertain to milestones of licensing actions/activities (e.g., respond to an NRC request for additional information by a certain date). Fulfillment of these commitments was indicated by the fact that the subject licensing action/activity was completed.
- (3) Commitments made as an internal reminder to take actions to comply with existing regulatory requirements such as regulations and Technical Specifications (TSs). Fulfillment of these commitments was indicated by the licensee having taken timely action in accordance with the subject requirements.

# 2.1.2 Audit Results

The attached Audit Summary provides details of the audit and its results.

The NRC staff found . . . . [provide summary of audit results regarding implementation of commitments.].

[If the audit revealed any nonconformance with NRC requirements or potential safetyrelated deficiencies, briefly summarize the issue and state that it was referred to the appropriate NRC organization (e.g., Region, NRR) for follow-up action.]

# 2.2 Verification of the Licensee's Program for Managing NRC Commitment Changes

The primary focus of this part of the audit is to verify that the licensee has established administrative controls for modifying or deleting commitments made to the NRC. The NRC staff

compared the licensee's process for controlling regulatory commitments to the guidelines in NEI 99-04, which the NRC has found to be an acceptable guide for licensees to follow for managing and changing commitments. The process used at [Plant Name] is contained in [Licensee's Procedure Name(s)]. The audit reviewed a sample of commitment changes that included changes that were or will be reported to the NRC, and changes that were not or will not be reported to the NRC.

# 2.2.1 Audit Results

The attached Audit Summary also provides details of this portion of the audit and its results.

The NRC staff found .... [Provide staff evaluation of conformance of the licensee's procedure to NEI 99-04 guidelines for commitment tracking, commitment change process, traceability of commitments, reporting requirements, etc. Provide staff conclusions as to how well the licensee followed the process, with particular emphasis on handling of changes to commitments. Include any constructive comments or suggestions for improving the process, if identified.]

[If the audit revealed any nonconformance with NRC requirements or potential safetyrelated deficiencies, briefly summarize the issue and state that it was referred to the appropriate NRC organization (e.g., Region, NRR) for follow-up action.]

#### 2.3 <u>Review to Identify Misapplied Commitments</u>

The commitments reviewed for this audit were also evaluated to determine if they had been misapplied. A commitment is considered to be misapplied if the action comprising the commitment was relied on by the NRC staff in making a regulatory decision such as a finding of public health and safety in an NRC safety evaluation associated with a licensing action. Reliance on an action to support a regulatory decision must be elevated from a regulatory commitment to a legal obligation (e.g., license condition, condition of a relief request, regulatory exemption limitation or condition). A commitment is also considered to have been misapplied if the commitment involves actions that were safety significant (i.e., commitments used to ensure safety).

Each of the commitments selected for the audit sample were reviewed to determine if any had been misapplied. [Provide a description of the findings and what actions were taken to address any misapplied commitments that were identified. Include any TAC numbers opened to track final disposition of an identified misapplied commitment that requires actions to be completed after the audit report is issued.]

#### 2.3.1 <u>Review of Safety Evaluation Reports for Licensing Actions since the Last Audit to</u> <u>Determine if They Are Properly Captured as Commitments or Obligations</u>

In addition to the commitments selected for the audit sample, all license amendment safety evaluations, exemptions and relief request safety evaluations that have been issued for a facility since the last audit were identified. These documents were evaluated to determine if they contained any misapplied commitments as described above.

[Provide a description of the findings and what actions were taken to address any misapplied commitments that were identified. Include any TAC numbers opened to track final disposition of an identified misapplied commitment that requires actions to be completed after the audit report is issued.]

#### 3.0 CONCLUSION

The NRC staff concludes, based on the above audit, that .... [Provide brief summary of results, e.g., (1) [Plant Name] has implemented NRC commitments on a timely basis, and (2) [Plant Name] has implemented an effective program for managing NRC commitment changes].

#### 4.0 LICENSEE PERSONNEL CONTACTED FOR THIS AUDIT

[Insert Names]

Principal Contributors: [Insert Names of audit team members]

Date:

Attachment: Summary of Audit Results

# AUDIT SUMMARY

[The summary may be in the form of a table or narrative at the discretion of the auditor.]

# **IMPLEMENTATION OF COMMITMENTS:**

[Provide a brief list of the commitments sampled and list the documents that were reviewed to verify implementation. If the results were satisfactory, a simple list of the document name, revision number (if applicable) and date would be sufficient. Additional detail may be needed if deficiencies are found.]

# **MANAGEMENT OF CHANGES TO REGULATORY COMMITMENTS:**

[Provide a brief list of the change documents sampled. If the results were satisfactory, a simple list of the document name, revision number (if applicable) and date would be sufficient. Additional detail may be needed if deficiencies are found.]