

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

# NRR OFFICE INSTRUCTION

# **Change Notice**

Responsible Organization:			
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Date Approved:	March 19, 2009		
Approved By:	Ben Ficks		
Effective Date:	March 30, 2009		
Office Instruction Title:	Managing Regulatory Commitments Made by Licensees to the NRC		
Office Instruction No .:	LIC-105, Revision 3		

Responsible Organization: NRR/DORL

**Summary of Changes:** Changes in revision 3 include (1) incorporation of additional guidance on charging time for audits, (2) incorporation of additional guidance on scope of review of licensee programmatic controls, (3) changes to the reporting requirements to be consistent with LIC-111, and (4) miscellaneous minor changes and edits.

Training:

E-mail announcement with recommended self-study for all staff. Posting in Knowledge Management Center.

ADAMS Accession No.:

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Effective Date: Approved By: Date Approved:	March 30, 2009 Ben Ficks March 19, 2009	
Primary Contacts:	Brendan T. Moroney 301-415-3974 <u>brendan.moroney@nrc.gov</u>	Sean C. Meighan 301-415-1020 <u>sean.meighan@nrc.gov</u>
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# NRR OFFICE INSTRUCTION LIC-105, Revision 3 Managing Commitments Made by Licensees to the NRC

# 1. POLICY

Although the terms "regulatory commitment" and "licensing bases" are not used in 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 Title 10 of the <u>Code of</u> <u>Federal Regulations</u> (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 about the use of regulatory commitments can be found in the following Commission papers:

- SECY-95-300, Nuclear Energy Institute's 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 these documents, the staff found that the Nuclear Energy Institute (NEI) document, NEI 99-04, "Guidelines for Managing NRC Commitments," (Ref. 4) contains acceptable guidance for controlling regulatory commitments made by power reactor licensees to the NRC.

Issues about the use of regulatory commitments usually center on the legal standing of the commitment and the 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 may not be "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 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 use of regulatory commitments when it is appropriate 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 (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.

To provide specific guidance to the NRC staff on conducting commitment management audits, LIC-105 was issued in May 2003. It has been revised subsequently to incorporate feedback from auditors and lessons learned from effectiveness and efficiency assessments in 2008 and 2009 (Refs. 8 and 9).

#### 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 licensing actions or other 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 relies on commitments in many instances and the NRC expects licensees to honor, in good faith, commitments that have a safety or regulatory purpose.

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 as part of the justification for a proposed licensing action or resolution of other licensing tasks should be docketed in formal correspondence from the licensee. The NRR staff should not

include in safety evaluations or other NRC documentation any statements regarding regulatory commitments made by the licensee 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. 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.

# 4.2 Handling of Licensees' Reported Changes to Regulatory Commitments

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 date(s) of previous regulatory commitments, consult with appropriate technical staff or lead PM for generic communications to

<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.

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) and the staff's conclusions in a memo to file. The DORL Technical Assistant (TA) should be copied on closeout documentation.

#### 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 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. 10), and constitute a regulatory audit plan for commitment management audits. 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.

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 technical assignment code (TAC) should be opened when the PM schedules the audit and starts to develop the audit sample. The assessments are to be completed under the planned accomplishment (PA) 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 basically 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 (e.g., procedure change or plant modification implemented vice procedure change request or modification request submitted).

In preparing for the audit, the PM should select a sample of approximately ten individual and unrelated commitments that were made by the licensee as part of a licensing action (amendment, exemption, etc.) or a licensing activity (bulletin, generic letter, etc.) during the previous 3 years. Selecting the sample should be relatively easy for licensees that specifically identify regulatory commitments in their correspondence. For those that do not, the PM should ask the licensee if they maintain a list of commitments and request a copy of the list. Otherwise, it may be necessary to review applicable documents, such as licensee submittals or staff safety evaluations, in detail to identify commitments.

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, procedures revisions, personnel training, and revised administrative controls.
- Check with the lead PMs or technical contacts for generic communications issued during the last 3 years to determine if they want 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.

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 will probably not be as convenient due to the need to have copies of numerous documents sent to the PM, and will probably 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 Branch Chief before adopting this approach.

When planning a site visit, the PM should coordinate with the site resident inspectors to ensure there will be no conflict with regional inspection activities. 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 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 should review LIC-111 for guidance on handling, control and disposition of documents provided for review by the licensee. In conducting the audit, the PM should review licensee commitment management records, work orders, revised procedures, NRC inspection reports, and other documentation that could demonstrate that the specific actions were completed in accordance with the stated commitment and related schedule. Having the site contact walk the reviewer through the commitment records and process documents should facilitate the review. Where appropriate, use actual physical verifications of affected equipment or procedures. The PM should determine the needed level of review to verify the implementation of each selected commitment. Whereas some commitments may be verified by a simple review of a revised procedure, training record or completed work order, verification of other commitments may require more extensive reviews of design documents and surveillance histories, actual configurations, and interviews with licensee personnel. The PM should work through the

<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, not the specific methods used.

point of contact to arrange discussions with other members of the organization (e.g., system engineering, maintenance, training) and plant tours, if needed.

For those commitments that require ongoing action, the PM should confirm that the licensee has integrated the commitment management system with other line organization functions to ensure traceability of the commitments following initial implementation. There should be a mechanism to ensure that licensee personnel are able to recognize that future 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> Commitments

The primary focus of this part of the audit is 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.

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 this 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 have 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 should request the licensee to provide a list of commitment changes (modifications or deletions) that were reported or will be reported to the NRC. From this list, select a sample of commitments for review. The PM may want to conduct informal discussions with appropriate technical and regional staff in developing the sample. The sample size should be sufficient to assess the licensee's program for controlling commitment changes.

Select commitment changes from as many of the following categories as practical:

- (1) Generic Letter Responses
- (2) Bulletin Responses
- (3) Licensing Actions (amendments, reliefs or exemptions)
- (4) Other Docketed Correspondence (e.g., responses to LERs or NOVs)

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 in the sample should 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 4.2 above) accurately described those changes that were reported. The PM should assess the licensee's technical justification for the changes. If necessary, appropriate technical and regional staff should be consulted.

Commitment Changes Not Reported to the NRC

The PM should request the licensee to provide a list of commitment changes (modifications or deletions) that it evaluated as not needing to be reported to the NRC and select a sample of commitments for review. 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 not to notify the NRC was not adequate, appropriate NRC technical and regional staff should be consulted to support this conclusion. Confirmed deficiencies should be handled in accordance with 4.3.3 below.

#### 4.3.3 Resolution of Deficiencies

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 be noted in the audit report.

Safety concerns or possible regulatory nonconformances that are discovered during this audit should be documented by the PM and referred to the appropriate Division of Operating Reactor Licensing (DORL) Branch Chief. The DORL Branch Chief will, as necessary, contact the appropriate regional Branch Chief 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 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.

For example, the NRC staff may issue an enforcement action (i.e., an Order) or may use the administrative enforcement tool of a Notice of Deviation (NOD) if a licensee fails to satisfy a commitment (See "NRC Enforcement Policy" and the NRC Enforcement Manual on the NRC web site). 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 attached 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 normally be documented in a letter to the licensee. However, following an initial satisfactory audit, it is acceptable to document subsequent audit results in a memorandum to file or a trip report if the PM's branch chief approves. In either case, the report should be placed in ADAMS as a publicly available record. The DORL TA, plant resident inspectors and the region branch chief 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>

The 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. The 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. The 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 periodic assessments 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 assessments. 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 periodic assessments of licensees' commitment management programs are performed and for assigning and scheduling the staff to perform the assessments. Branch Chiefs 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 Branch Chief 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 Branch Chief 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."

The DORL Branch Chiefs will review significant safety issues or potential NODs discovered during the audit and take appropriate action as discussed in 4.3.3.

# 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 to ensure that the outputs associated with these licensing activities are complete, accurate, and timely. Because the PMs serve as the primary contacts between NRR and the licensees, the PMs have the responsibility of ensuring that communications between the staff and licensees achieve 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 document. The PMs will coordinate the audit schedule with the licensee, resident inspector, and the appropriate regional staff to avoid scheduling conflicts and to minimize the burden on the licensee's operating staff.

Safety issues or potential NODs discovered during the audit that are considered significant will be reported to the DORL Branch Chief and, as appropriate, other NRR/Regional staff for final resolution as described in 4.3.3 above.

# 5.4 <u>Technical Staff</u>

The technical staff will ensure that licensing actions, including regulatory commitments, are complete and that appropriate consideration has been given to technical review (scope, depth, and quality), the office performance goals, and the most effective use of the different elements of the licensing bases for commercial nuclear reactors (see LIC-100).

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

As described in LIC-503, 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 CONTACT

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

NRR/DORL

#### 9. <u>EFFECTIVE DATE</u>

March 30, 2009

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

- 1. SECY-95-300, Nuclear Energy Institute's Guidance Document, "Guideline for Managing NRC Commitments," dated December 20, 1995.
- 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).
- 3. SECY 00-045, Acceptance of NEI 99-04, "Guidelines for Managing NRC Commitment Changes," 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).
- 7. Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000.
- 8. Memorandum from C. Haney (NRC) to B. Boger (NRC) dated February 14, 2008 (ADAMS Accession No. ML073310454).
- 9. Memorandum from J. Giitter (NRC) to B. Boger (NRC) dated February 26, 2009 (ADAMS Accession No. ML090560254).
- 10. NRR Office Instruction LIC-111, "Regulatory Audits."

#### Enclosures:

- 1. Appendix A: Change History
- 2. 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 1				
Date	Description of Changes	Method Used to Announce & Distribute	Training		
05/27/2003	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).		
09/07/2004	Changes in revision 1 include (1) discussion of regulatory commitments related to activities of industry groups [to address open item from Davis Besse LLTF], (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		
06/02/2008	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.		

Enclosure 1

03/19/09	Changes in revision 3 include (1) incorporation of additional guidance on charging time for audits, (2) incorporation of additional guidance on scope of review of licensee programmatic controls, (3) changes to the reporting requirements to be consistent with LIC-111, and (4) miscellaneous minor changes and edits.	E-mail to NRR staff	E-mail announcement with recommended self-study for all staff. Posting in Knowledge Management Center.

Audit Report Template

Enclosure 2

[Date]

[Address]

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

## Dear [Name]:

In Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000, the U. S. Nuclear Regulatory Commission (NRC) informed licensees that the Nuclear Energy Institute (NEI) document NEI 99-04, "Guidelines for Managing NRC Commitment Changes," 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.

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 w/encl: ListServe

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

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

ACCESSION No.: ML

NRR-<u>106</u>

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

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# 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

In Regulatory Issue Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," dated September 21, 2000, the U. S. Nuclear Regulatory Commission (NRC) informed licensees that the Nuclear Energy Institute (NEI) document NEI 99-04, "Guidelines for Managing NRC Commitment Changes," 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.

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.

NEI-99-04 defines a "regulatory commitment" as an explicit statement to take a specific action agreed to, or volunteered by, a licensee and submitted in writing on the docket to the NRC. 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.). The audit is to be performed every 3 years.

# 2.0 AUDIT PROCEDURE AND RESULTS

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] The audit consisted 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 program for managing changes to NRC commitments.

#### 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.

# 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 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, Technical Specifications (TSs), and Updated Final Safety Analysis Reports. 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. 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.

# 2.2.1 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.]

# 3.0 <u>CONCLUSION</u>

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]

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.]