OFFICE OF NUCLEAR REACTOR REGULATION

LIC-111, Revision 1	Regulatory Audits	
Volume 100	Licensing Processes	
Approved By: Date Approved: Effective Date: Certification Date:	Eric J. Benner October 31, 2019 October 31, 2019 October 31, 2024	
Responsible Organizations:	DORL and DNRL	
Primary Contacts:	Mahesh Chawla Mahesh.Chawla@nrc.gov 301-415-8371	Allen Fetter Allen.Fetter@nrc.gov 301-415-8556
Summary: This revision was updated to capture NRR and NRO best practices for regulatory audits. The objective of this instruction is to provide guidance to staff who conduct regulatory audits. This issuance incorporates and rescinds the related NRO instruction "NRO-REG-108, Regulatory Audits."		
Training:	None	
ADAMS Accession No.:	ML19226A274	

TABLE OF CONTENTS

Office Instruction: LIC-111, Revision 1 “Regulatory Audits” Dated: October 31, 2019

ADAMS Accession No: ML19226A274

OFFICE	NRR/DORL/LPL3/PM	NRR/DORL/LPL3/LA	NRO/DLSE/PM	NRR/DMLR/MVIB/BC
NAME	MChawla	SRohrer	AFetter	DAlley
DATE	08/18/2019	08/15/2019	08/22/2019	08/28/2019
OFFICE	NRR/DMLR/MCCB/BC	DMLR/MRPB/BC	NRR/DRA	NRR/DSS/SNPB
NAME	SBloom	EOsterle	JRobinson	RLukes
DATE	08/27/2019	09/09/2019	08/26/2019	08/29/2019
OFFICE	NRR/DORL/BC	NRR/DORL/D	NRO/DLSE/D	NMSS/ENVCOE/D
NAME	DWrona	GSuber for CErlanger	ABradford	JTappert
DATE	09/06/2019	09/20/2019	09/10/2019	09/18/2019
OFFICE	NRR/DMLR/D(A)	NRR/DRA/D	NRR/DSS/D(A)	NRR/DIRS/D
NAME	ABilloch-Colon for JDonoghue	MFranovich	MWaters for JMarshall	CMiller
DATE	09/12/2019	09/17/2019	09/16/2019	09/11/2019
OFFICE	NRR/DAR/D	NRR/DE/D(A)	NRO/DESR/D(A)	NRR/DLP/D(A)
NAME	SLynch for JMonninger	BWittick for BSmith	KCoyne	HCruz for MJ Ross-Lee
DATE	09/15/2019	09/13/2019	09/17/2019	09/16//2019
OFFICE	NRR/DRMA	NRR/DD		
NAME	TGorham	EBenner for		
DATE	10/02/2019	10/31/2019		

OFFICIAL RECORD COPY

1. POLICY

As discussed in this guidance, regulatory audits are a tool available to the staff that can help to efficiently gain understanding, verify information, and/or identify information that will require docketing to support a staff decision. Consistent with the principles of good regulation, as modern, risk-informed regulators, NRR staff are encouraged to use regulatory audits as frequently as is appropriate to improve efficiency and effectiveness in their regulatory activities.

2. OBJECTIVES

This office instruction provides guidance to staff who conduct regulatory audits of information developed and maintained by licensees, applicants, vendors, and other entities related to nuclear reactor regulation (herein, referred to as licensees).

3. BACKGROUND

3.1 Definitions

Regulatory Audit

A regulatory audit is an effort by the staff to examine and evaluate information with the intent to gain understanding, verify information, and/or identify information that will require docketing to support the basis of a licensing or regulatory decision.

Audit Team Member

A staff member or contractor with the knowledge and skills necessary to effectively perform the regulatory audit activities who is assigned by the appropriate responsible supervisor.

Audit Team Leader

The staff member with the overall responsibility for the conduct of the regulatory audit who is assigned by the appropriate responsible supervisor.

Supporting Materials

Supporting documentary materials are documents supplied by the licensee or prepared by the NRC staff that are necessary to substantiate the final NRC document or decision trail. Supporting materials are not working files. Supporting materials are part of the official record, and when supplied by the licensee must be submitted on the docket.

Working Files

Working files are documents generated by the NRC staff over the course of the audit, such as personal notes, rough notes, calculations, or drafts assembled or created and used to prepare or analyze other documents. They can contain background files, such as worksheets, questionnaires, extra copies of articles,

reports, studies, information, and documentary materials. Working files may need to be considered official agency records as explained in Section 4.6. Working files that do not meet the requirements to be records are not part of the agency's official record collections. However, working files are not exempt from Freedom of Information Act (FOIA) consideration.

3.2 General

Title 10 of the *Code of Federal Regulations* (10 CFR) requires licensees to provide certain written correspondence to the NRC. Additional requirements are provided for the licensee's maintenance and retention of documents. For example, 10 CFR 2.101, 10 CFR 50.4, 10 CFR 54.17, and 10 CFR 52.3 require applications for permits and licenses, amendments to applications, and applications for amendment of permits and licenses to be sent to the NRC. The appendices to 10 CFR Part 52 and 10 CFR 50.71, "Maintenance of Records, Making of Reports," require that records connected to licensed or regulated activities be maintained by the licensee. 10 CFR 54.37, "Additional Records and Record Keeping Requirements," requires that license renewal applicants maintain documents demonstrating compliance with the requirements of 10 CFR Part 54 in auditable and retrievable form.

A regulatory audit is typically part of a larger regulatory action. Performing a regulatory audit may allow the staff to more efficiently conduct its review or gain insights on the licensee's programs or processes. For example, when an application or a licensing action request is reviewed by the NRC, the information that the staff relies upon to make the regulatory finding must be submitted on the docket. However, there may be other information that is not submitted on the docket but is retained by a licensee under 10 CFR 50.71 and/or 10 CFR 54.37, that would help the staff better understand the information submitted by a licensee. Examples of such material include detailed calculations and procedures.

A regulatory audit may focus on specific documents or may be performed by sampling analyses and information in support of the regulatory action. A regulatory audit may be conducted at one facility, all affected facilities, or a sampling, as necessary to support the regulatory action.

A regulatory audit may affect more than one NRC office. The audit team leader should consider if coordination with other offices is appropriate to support technical consistency.

The areas for which the staff may conduct a regulatory audit include, but are not limited to, the following:

- license renewal applications
- plant-specific licensing action requests or topical reports
- generic communications
- applications for design certifications (DCs), construction permits (CPs), operating licenses (OLs), combined licenses (COLs), or early site permits (ESPs), or manufacturing licenses

- amendments or renewal of DCs, COLs, or ESPs
- qualification of alternate vendor support for COL applications referencing a certified design

Regulatory audits allow the staff to do the following:

- Gain a better understanding of the detailed calculations, analyses and/or bases underlying the formal application and confirm the staff's understanding of the application
- Identify additional information necessary for the staff to reach a licensing or regulatory decision that the licensee should provide as a supplement to the application
- Establish an understanding of an area where the staff has identified potential concerns to allow the staff to issue clear requests for information and for the licensee to provide quality and timely responses
- Establish an understanding of potential concerns to inform future regulatory actions or decisions, such as generic communications
- Establish or enhance the staff's understanding of proposed modification(s) or resolution(s) in support of a regulatory action or decision
- Confirm the licensee's implementation of programs or processes that track commitments or industry initiatives, or other actions that might support a regulatory action or decision

The types of information that the staff may audit include, but are not limited to, the following: (1) process information, (2) procedures, (3) calculations, (4) design basis information, and (5) computer code information.

3.3 Selection of Audit Team Leader and Audit Team Members

The NRC audit team leader and audit team members are designated by the appropriate responsible supervisor. Audit team members may include project managers (PMs), technical reviewers, senior level staff, supervisors, contractors, and staff from other government agencies.

Audit team members should possess the technical and/or regulatory knowledge to work effectively and efficiently in the audit setting and interact with the licensee's staff. Additionally, the audit team leader should possess the ability to coordinate small groups and interact with the licensee's staff and management. These skills are assessed by the supervisor when assigning team members to perform specific audit activities.

It is the expectation that at least one audit team member will be qualified through a formal qualification program such as NRR Office Instruction (OI) ADM-504, "Qualification Program," or Inspection Manual Chapter (IMC) 1245, "Inspector Qualification." However, the selection is at the discretion of the supervisor.

4. BASIC REQUIREMENTS

The amount of detail included in the audit preparation, audit plan, execution of the audit, and audit documentation should be commensurate with the scope, complexity, and size of the audit. That is, a large team on-site audit should provide more details in the audit plan, as well as ensure more coordination with the Region, PM, and licensee, than a one-person audit of selected calculations. To foster agency openness and transparency, and ensure licensee preparedness for an audit, detailed audit plans should be sent to the licensee prior to the audit. In order to ensure the audit is effective and efficient, the audit plan should be issued at least 14 days prior to the beginning of an audit, or as early as practicable.

4.1 Regulatory Audit Preparations

Regulatory audits may be conducted at any facility, including a plant site, licensee's headquarters, contractor or vendor site, and in NRC buildings. Audits may also be conducted virtually, using licensee electronic portals, as discussed in Section 4.4. Regulatory audits conducted at reactor sites should be coordinated with the licensee, regional NRC office, and resident inspectors. The focal point for this coordination should normally be the NRR project manager (PM) responsible for the licensee. In the case of a license renewal regulatory audit, the NRC license renewal PM will coordinate with the licensee and the regional office and will inform the NRR operating reactor PM for the nuclear power plant or non-power reactor to provide appropriate awareness. In the case of an audit for a new unit, the audit team leader should coordinate with the project PM and PM of an associated operating unit, if applicable. For audits related to high-profile matters or issues under litigation, the cognizant PM should consult with the Office of General Counsel (OGC) to determine if communications (e.g., audit plans) associated with the audit preparations require OGC concurrence.

Once approved by the audit team leader's supervisor, the audit plan (described in Section 4.2 below) should be shared with the audit team members and the licensee, so that all participants can prepare for the regulatory audit. Note that audit plans need to be placed in Agencywide Documents Access and Management System (ADAMS) and made publicly available, with sensitive and proprietary information redacted, if applicable. The audit team leader should consider holding a pre-audit meeting with the audit team members and responsible supervisor to discuss assignments and expectations. The audit team leader or cognizant PM should discuss the audit plan with the licensee and request the licensee to provide space, documentation, access to subject matter experts, and other necessary items. To the extent possible, the audit team leader should prepare a list of documents, discussion topics, and any other special requests that are needed to support the audit. These items should be added to the audit plan (described below) and communicated to the licensee either orally or in writing, typically 14 days before the regulatory audit.

The audit information needs list does not take the place of a request for additional information (RAI) or otherwise change what information will ultimately need to be officially submitted to support the staff's licensing or regulatory

decision. Early interactions with the licensee should also address issues such as access controls, security requirements, and other policies and procedures affecting the audit team.

4.2 Regulatory Audit Plans

A regulatory audit plan should provide a clear, succinct overview of the regulatory audit activities. The audit plan should identify the licensees, describe the scope of the regulatory audit, discuss major areas of emphasis for the regulatory audit, identify key participants, and provide the basis, background, schedule, and logistics for the regulatory audit. The audit plan provides structure and organization for the regulatory audit and serves as an integral planning tool for the audit team member(s).

The level of detail of the regulatory audit plan should be commensurate with the desired audit scope. The audit plan should be comprehensive, yet concise and the page length should correspond to the complexity of a given audit. For example, a simple audit plan is normally 1 to 2 pages in length, while a more complex audit plan may be 8 to 10 pages or more. The audit plan should follow the recommended contents, as applicable, listed below:

a. Background. This section provides a brief introduction of the licensee and licensing action, application, topical report, generic communication, or program associated with or reason for the regulatory audit.

b. Regulatory Audit Bases. This section identifies the documents upon which the regulatory audit is based. This may include, but not limited to, sections of the licensing action request, COL, DC, or ESP application, 10 CFR Part 50, 10 CFR Part 52, 10 CFR Part 54, applicable sections of the Standard Review Plan (SRP), and/or regulatory guides.

c. Regulatory Audit Scope or Methodology. This section identifies the areas of focus for the regulatory audit (e.g., process information, calculations) or describes the method in which the regulatory audit will be conducted.

d. Information and Other Material Necessary for the Regulatory Audit. This section identifies known information (information needs) or material needed by the audit team member(s) to complete the regulatory audit. This could include, but is not limited to, licensee reports, calculations, and computer codes. Inclusion of discussion topics in this section helps ensure that a licensee has appropriate technical experts to support an efficient and effective audit.

e. Team Assignments. This section identifies the audit team members and their respective area(s) of responsibility.

f. Logistics. This section documents the date and location(s) for the regulatory audit, including phases (for extended or long-term audits); entrance and exit briefing dates and times; and audit schedule.

g. Special Requests. This section may document any requests of the licensee by the team to support the audit.

h. Deliverables. This section identifies the deliverables for the regulatory audit and establishes the target schedule for the deliverables. At a minimum, a schedule for issuance of the regulatory audit summary report should be provided.

i. References. This section identifies references that may be applicable to the regulatory audit.

4.3 Conducting Entrance, Closing, Exit, and Status Briefings:

Prior to the start of an audit, an entrance briefing with the licensee is recommended. Entrance briefings should be scheduled in advance and should be conducted as soon as practicable after arrival. At the entrance briefing, the audit team leader should review key elements of the regulatory audit plan with the licensee.

For multiple-day audits, the audit team leader should consider status briefings with the responsible NRC supervisor. As needed, the audit team leader should also consider periodic status briefings, including daily debriefing at the end of each day, with the licensee to discuss progress and potential issues identified. The audit team leader should consider briefing the responsible supervisor on the preliminary audit results and observations prior to the closing or exit briefing.

If an audit is conducted in several phases, at multiple locations and/or discontinuous time frames, the audit team member(s) should conduct a closing briefing at the end of each phase. The closing briefing should summarize the status of the audit at the time of the closing and detail the logistics of the subsequent audit phase.

An exit briefing should be conducted at the conclusion of the audit. Preliminary results should be presented emphasizing that these are preliminary in nature and subject to NRR management review. It should be noted to the licensee that the agency will communicate any significant changes between the preliminary audit results and the regulatory audit summary report prior to issuance.

Note: Similar to inspections, entrance and exit briefings are generally neither noticed nor conducted as public meetings.

4.4 Conducting Regulatory Audit Activities

Audit team members' activities during the regulatory audit and interactions with the licensee should be clearly linked to the staff's guidance, such as in the SRP, recognizing that much of the material discussed and audited may not require docketing. Information that will be relied on to make a regulatory finding should be placed on the docket and be in ADAMS. This may be accomplished via a response to an RAI, or through formal correspondence submitted voluntarily by the licensee, consistent with NRC rules and regulations.

Audit team members should use their time to audit detailed reports, design record files, and process information or procedures not required to be submitted by the licensee. Discussions with the licensee's staff may be held for the audit team members to gain a better understanding of how the information being audited was used by the licensee.

Audit team members may review controlled copies of the licensee's records and documents at any time during the regulatory audit. When the licensee uses a form to request controlled documents from its storage facility or document control center, the audit team members may fill out this form following the licensee's procedures.

As an expected practice, non-docketed licensee information (information that has not been formally submitted through the document control desk) should not be taken from the audit site, unless deemed merited by the circumstances. An example of a circumstance that merits taking information or material from the audit site is as follows: immediately obtaining material or information would be useful for the purposes of the agency mission (e.g., by helping expedite resolution of a safety significant issue) or enhancing review schedule efficiencies. Before any information is taken from an audit site, the audit team leader will determine if the request is reasonable and useful for the purposes of review efficiency, and then obtain the licensee's permission to remove the information. Prior to taking any of the licensee's documents, the NRC will give the licensee the opportunity to mark the documents in accordance with 10 CFR 2.390(b). Information taken from the audit site must be handled in accordance to federal records requirements and applicable NRC guidance, including Management Directive (MD) 3.53, "NRC Records and Document Management Program", and should be documented in the audit summary report. Note, however, that taking and properly handling information from an audit is not the same as informally "borrowing" material from the licensee. Information such as electronic data files, computer codes, and procedures cannot be "temporarily borrowed" by the NRC staff. If the staff requires time to work with such information, it must be done at the audit location, or the information must be requested for docketing.

Other tools, such as an online portal, may be used by staff to view non-docketed information. The online portal may be established by the licensees based upon a formal request from the respective NRR PM (example letter to licensee: ML102240060). The formal request should include the list of audit team members who may be granted access to the online portals. Also, it may include the list of documents needed by the audit team to be put on the portal for its review. The licensee should be instructed to establish measures to prevent the downloading, copying, or otherwise storing of any online portal documents by the staff or any contractors accessing the portal. These measures should be sufficient to preclude the staff from receiving, accepting, or collecting information posted on an online portal and prevent that information from becoming an official agency record subject to retention per MD 3.53.

During a regulatory audit, the staff may identify a potential inadequacy, programmatic deficiency, non-compliance, or operability concern. An issue that may be an immediate safety or operability concern should be reported to NRC management at once. Potential issues should be communicated to NRR and

regional management, the licensee, and/or resident inspectors, as appropriate. If a follow-up inspection is necessary, the regional staff may plan an inspection in accordance with NRC procedures.

4.5 Documenting the Regulatory Audit

At the completion of the regulatory audit, a detailed audit summary report will be developed and provided to the licensee. If sensitive information is involved, both public and non-public versions of the report must be prepared.

The regulatory audit summary report should be placed on the docket and in ADAMS within 90 days of the completion of the audit or before the regulatory action that the audit supports is completed, whichever is shorter. The regulatory audit summary report may be publicly available, as appropriate given considerations such as those discussed in Section 4.6. If multiple audits are conducted (e.g., license renewal audits), audit summary reports should be consistent in their structure and content. Specifically, if similar audits are conducted for multiple applicants, the audits should be documented consistently.

The regulatory audit summary report should provide a clear, succinct summary of the audit activities, and as applicable should:

- identify the audit location(s) and date(s),
- list the audit team members,
- list licensee staff that participated in substantive discussions,
- list documents that were audited,
- describe the audit activities,
- describe the closing or exit briefing,
- identify RAI(s) or potential RAI(s) that were discussed or that will be issued based on the audit,
- describe open item(s) and the proposed closure path(s), and
- describe deviations from the audit plan.

The list of the audited documents should be sufficiently detailed to retrieve the information through the licensee's document control process. This may include title, date, revision number, and supplement number.

If there are any open items at the end of an audit, a closure path should be identified in the audit summary report. An exception would be in the case of planned multi-phase audits. Multi-phase audits can be documented in a single comprehensive audit summary report. If RAIs are necessary, they should be prepared in accordance with the audit plan schedule or as identified on the audit summary report and issued in accordance with the latest RAI guidance.

The staff should not make final licensing conclusions or staff findings in the audit summary report because licensing and regulatory decisions cannot be made solely based on an audit. However, thorough documentation of audit observations and how audit items were addressed are important for the administrative record. The staff may refer to the regulatory audit summary report or include a discussion of the audit activities in a safety evaluation. As such, an

audit summary report documents facts and observations, and it should be prepared with this in mind. In other words, audit summary reports should be clear, logical, and "auditable."

The audit team leader is responsible for ensuring that the content of the regulatory audit summary report accurately reflects the audit activities and the information communicated in the exit briefing. It can be an effective practice to share a draft version of the audit summary report with the licensee, using secure methods, for a check of any factual errors, sensitive and/or proprietary information, as discussed in Section 4.6 below. This process should be done in accordance with guidance contained in the latest versions of NRR Office Instructions LIC-101, COM-203 (or COM-204), and MD 3.4.

4.6 Controlling and Disposing of Documents and Records

Audit team members have the responsibility to follow Agency and Office policies on handling documents, including guidance on:

- Retaining official agency records (OARs)
- Responding to FOIA requests
- Handling sensitive unclassified non-safeguards information (SUNSI) (including proprietary information) or Controlled Unclassified Information (CUI)
- Handling safeguards information (SGI)
- Handling draft licensee information
- Handling working files and supporting material/personal notes
- Handling pre-decisional information
- Dispositioning records

Official Agency Records

Audit team members have the responsibility to preserve OARs. They should not make documents or portions of documents that fall within the exempt categories, such as 10 CFR 2.390 and 10 CFR 9.13, publicly available. Further information may be found in MD 3.53, "NRC Records and Document Management Program." Provided below is excerpted guidance on determining OARs:

- Was it created or received by my organization to conduct agency business?
- Does it contain information that documents agency functions, policies, decisions, operations, procedures, mission or activities?
- Is it something on which an action was taken, or commented on behalf of the agency?
- Does it document business decisions, actions, advice, order of events, when something happened or who was involved in it?
- Is it an original document that doesn't exist elsewhere but is work-related?

If a hearing has been requested or if there is a potential for a hearing request, there are further requirements on documents removed from the licensee's site. Staff should follow the NRR OI on support of the hearing process (LIC-201 or successor OI, if applicable), as it provides detailed guidance on the staff's

responsibility to retain documents related to its reviews and audits if a hearing has been or potentially may be requested.

Freedom of Information Act Requests (FOIA)

Audit team members have the responsibility to adhere to the guidelines for a FOIA request. Any document, docketed or not, in an NRC employee's possession at the time of a FOIA request must be considered under the FOIA criteria. For more information see MD 3.1, "Freedom of Information Act."

Proprietary, Sensitive, and Safeguards Information (SGI)

Audit team members have the responsibility to protect the licensee's SGI and sensitive unclassified non-safeguards information (SUNSI), including proprietary information. If information is removed from the audit site (see Section 4.4), all precautions should be followed to prevent the inadvertent release of SUNSI and SGI. Further details may be found in MD 12.2, "NRC Classified Information Security Program," MD 12.6, "NRC Sensitive Unclassified Information Security Program," and MD 12.7, "NRC Safeguards Information Security Program" for more details.

Draft Licensee Information

In general, draft information should not be requested or physically accepted by audit team members. If draft information needs to be reviewed as part of the audit, it should be preserved as an OAR when it is needed to provide a complete record of the decision-making process. That is, if the draft licensee information was received by the agency in connection with the transaction of agency business, the draft information should be preserved if it is necessary for a proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities. Draft documents that are subsequently replaced by formal submittals need to be placed in ADAMS if they meet the criteria of MD 3.53. Further information may be found in NRR Office Instruction COM-203, "Informal Interfacing and Exchange of Information with Licensees and Applicants" and NRR Office Instruction LIC-101, "License Amendment Review Procedures."

If a hearing has been or may be requested, all communications between the staff and the licensee should be retained. NRR OI LIC-201 provides guidance on the staff's responsibility to retain NRC staff and licensee communications.

Working Files and Supporting Materials

As defined in Section 3.1, supporting materials are documents that are necessary to substantiate the final document or decision trail.

As discussed in MD 3.53, working files must be maintained and filed with the official record for the purposes of adequate and proper documentation if they meet both of the following conditions: (1) they were/are circulated or made available to employees, other than the creator, for official purposes such as approval, comment, action, recommendation, follow up, or to communicate with

agency staff about agency business, and (2) they contain unique information such as substantive annotations or comments included therein, that adds to the proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities.

Unless required to be maintained and filed with official records, working files, such as personal notes, informal comments, and drafts, can be destroyed/ deleted once they are incorporated into a final product. Special attention should be given to notebooks, calculations, and other background material that may contain information needed to supplement formal records (i.e., supporting material).

[Note: Working files are not exempt from FOIA consideration]

Exchange of Draft Information

In accordance with NRR COM-203, exchange of draft information is expected in the normal course of agency business activities, such as development of initial NRC staff regulatory or technical findings, preparation of bulletins and information notices, evaluation of events at facilities, inspection findings, or the collection, analysis, and verification of information. With prior approval authority, as specified in MD 3.4, pre-decisional information regarding initial NRC staff positions, license conditions, confirmation of action letters, inspection findings, enforcement actions, preparation of bulletins and information notices, and events at other facilities, may be communicated to licensees, vendors, industry representatives and other government agencies, for the purpose of (a) gaining factual information, (b) assessing the cost, feasibility and benefit of, or alternatives to, proposed actions or achieving settlements of actions, or (c) alerting licensees to initial staff positions or safety findings in order that corrective actions can be initiated promptly. Prior to the sharing of a draft audit summary report with a licensee, the report should go through the level of review and concurrence that is required for final release of the document. In addition to ensuring the information in draft audit summary reports is correct, exchange of draft information with licensees helps ensure against the public release and disclosure of sensitive and proprietary information.

In accordance with MD 3.4, the NRR Office Director has determined that approval authority for the sharing of draft audit summary reports on matters that are not high-profile, contentious, or under litigation is appropriate at the NRR Division Director level. For audits on high-profile, contentious matters or issues under litigation, approval authority is at NRR Deputy Office Director level, unless delegated otherwise.

Records Disposition

Information necessary to support the licensing or regulatory decision should be placed on the docket by the licensee or NRC staff. Licensee documents in the possession and control of the staff and not otherwise formally submitted by the licensee should be retained and placed on the docket and in ADAMS if the criteria in MD 3.53 are satisfied. The staff should properly dispose of licensee

and draft NRC documents as appropriate for the classification of the information. A list of the audited documents will be included in the regulatory audit summary, which becomes an OAR.

5. RESPONSIBILITIES AND AUTHORITIES

Director, NRR

Establish the policies contained within this office instruction related to the conduct of regulatory audits performed by the staff.

When necessary, responsible for approving the exchange of draft information with licensees for high-profile matters (consistent with NRR COM-203 and MD 3.4).

Division Directors and Deputy Division Directors (ALL)

Responsible for the oversight of all regulatory audits conducted within the auspices of their program/process.

When necessary, Division Directors, their Deputies, or designees, are responsible for approving the exchange of draft information with licensees for normal matters (consistent with NRR COM-203 and MD 3.4).

Branch Chiefs (ALL)

Responsible for the planning and implementation of regulatory audits conducted within the auspices of their programs and processes.

Responsible Branch Chief (or audit team leader)

Assigns individual as the audit team leader. Assigns or coordinates responsible individuals as audit team members. Approves audit plan. Ensures timely deliverables as established in the audit plan.

All NRR Staff Members

All NRR staff members are responsible for following the procedures in this office instruction. Staff members assigned to perform regulatory audit activities will follow the guidelines described in this office instruction and references.

6. PERFORMANCE MEASURES

None. Regulatory audits are generally performed as part of a larger program or as needed to support a regulatory and licensing decision.

Branch chiefs should ensure timeliness of deliverables established in the audit plan.

7. PRIMARY CONTACTS

Mahesh Chawla
Mahesh.Chawla@nrc.gov
301-415-8371

Allen Fetter
Allen.Fetter@nrc.gov
301-415-8556

8. RESPONSIBLE ORGANIZATION(S)

DORL and DNRL

9. EFFECTIVE DATE

October 31, 2019

10. CERTIFICATION DATE

October 31, 2024

11. REFERENCES

1. Title 10 of the *Code of Federal Regulations* Part 2, “Agency Rules of Practice and Procedure.”
2. Title 10 of the *Code of Federal Regulations* Part 9, “Public Records.”
3. Title 10 of the *Code of Federal Regulations* Part 50, “Domestic Licensing of Production and Utilization Facilities.”
4. Title 10 of the *Code of Federal Regulations* Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”
5. NRC Management Directive 3.1, “Freedom of Information Act.”
6. NRC Management Directive 3.4, “Release of Information to the Public.”
7. NRC Management Directive 3.23, “Mail Management.”
8. NRC Management Directive 3.53, “NRC Records and Document Management Program.”
9. NRC Management Directive 12.2, “NRC Classified Information Security Program.”
10. NRC Management Directive 12.6, “NRC Sensitive Unclassified Information Security Program.”
11. NRC Management Directive 12.7, “NRC Safeguards Information Security Program.”
12. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants.”
13. NRR Office Instruction ADM-504, “Qualification Program.”
14. NRR Office Instruction COM-203, “Informal Interfacing and Exchange of Information with Licensees and Applicants.”
15. NRR Office Instruction LIC-101, “License Amendment Review Procedures.”
16. NRR Office Instruction LIC-105, “Managing Regulatory Commitments Made by Licensees to the NRC.”
17. NRR Office Instruction LIC-201, “NRR Support to the Hearing Process.”
18. Inspection Manual Chapter 0301, “Coordination of NRC Visits to Commercial Reactor Sites.”

19. Inspection Manual Chapter 0620, “Inspection Documents and Records.”
20. Inspection Manual Chapter 1245, “[Inspector] Qualification Program for New and Operating Reactor Programs”

Enclosure:
Appendix A - Change History

Appendix A - Change History

Office Instruction LIC-111

Regulatory Audits

LIC-111 Change History - Page 1 of 1			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
12/16/2008	Initial issuance as ML082900195	E-mail to NRR staff	Offered presentation to all branches and divisions
10/31/2019	This revision was updated to capture NRR and NRO best practices for regulatory audits. The objective of this instruction is to provide guidance to staff who conduct regulatory audits. This issuance incorporates and rescinds the related NRO instruction "NRO-REG-108, Regulatory Audits."	E-mail to NRR staff	None

Enclosure