Nuclear Regulatory Commission
Office of New Reactors
NRO Office Instruction

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Responsible Organization:	**NRO/DNRL/NRGA**

Summary of Changes: This is the initial issuance of NRO-REG-108, "Regulatory Audits." This office instruction (OI) defines how the U.S. Nuclear Regulatory Commission (NRC), Office of New Reactors (NRO) staff will conduct regulatory audits in support of new reactor licensing activities.

Training:	As needed to support specific audit teams
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Concurrences			
Primary Office Owner	Rulemaking and Guidance Development Branch		
Responsible Manager	William Reckley		01/27/09
Division Director(s)	PMDA	BGusack	07/25/08
	NRO Divisions	Distributed for Comment	07/08
OGC	OGC NLO w/ changes	JBiggins	12/19/08
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OFFICIAL RECORD

NRO Office Instruction
NRO-REG-108

Regulatory Audits

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1. PURPOSE

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

2. BASIC REQUIREMENTS

2.1 Definitions

Regulatory Audit

A regulatory audit is a planned, license or regulation-related activity that includes the examination and evaluation of primarily non-docketed information. A regulatory audit is conducted with the intent to gain understanding, to verify information, and/or to identify information that will require docketing to support the basis of the 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 responsible supervisor.

Audit Leader

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

2.2 General

The *Code of Federal Regulations* (CFR) requires applicants to provide written correspondence to the NRC. Additional requirements are provided for the applicant's maintenance and retention of documents. For example, Title 10 of the CFR, sections 2.101 (10 CFR 2.101), 10 CFR 50.4, and 10 CFR 52.3 require applications for permits and licenses, and 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 activities be maintained by the applicants and licensees.

In most circumstances, a regulatory audit is part of a larger regulatory action. Performing a regulatory audit may allow the staff to conduct its review more efficiently or gain insights on the applicants' processes or procedures. For example, when an application is reviewed by the NRC, the information that the staff relies upon to make the safety determination must be submitted. However, there may be supporting information retained as records under NRC regulations that, although not required to be submitted as part of the licensing action, would help the staff better understand information submitted by the applicant. 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 office. The audit leader should consider if coordination with other offices is appropriate to support technical consistency.

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

- applications for design certifications (DCs), combined licenses (COLs), or early site permits (ESPs),
- amendments or renewal of DCs, COLs, or ESPs,
- topical reports,
- qualification of alternate vendor support for COL applications referencing a certified design, and
- generic communications.

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 that is necessary for the applicant to supplement its application for the staff to reach a licensing or regulatory decision.

- Establish an understanding of an area where the staff has identified potential concerns to allow the staff to issue clear requests for additional information and for the applicant to provide quality and timely responses.

- Establish an understanding of potential concerns to inform future regulatory actions or decisions, such as generic communications.

- Enhance the staff's understanding of proposed modification(s) or resolution(s) in support of a regulatory action or decision.

- Confirm the applicant's implementation of programs or processes that track commitments, 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 information, and (5) computer code information.

2.3 Selection of Audit Leader and Members

The audit leader and audit team members are designated by the responsible supervisor. Audit team members may include project managers, 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 applicant's staff, and have completed allegation training. Additionally, the audit leader should possess the ability to coordinate small groups and interact with the applicant's staff and management. These skills are assessed by the supervisor when assigning members to perform audit activities.

At least one audit team member should be qualified through NRO OI PER-105, "Qualification and Training Program" or Inspection Manual Chapter (IMC) 1245, "Inspector Qualification." However, the selection is at the discretion of the supervisor.

3. SPECIFIC 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, project manager, and applicant, than a one-person audit of selected calculations.

3.1 Regulatory Audit Preparations

Regulatory audits may be conducted at any facility, including a plant site, applicant's headquarters, contractor or vendor site, and in NRC buildings. Regulatory audits conducted at reactor sites should be coordinated with the NRC project manager, the applicant, regional NRC office, and resident inspectors. The focal point for this coordination should normally be the NRO Project Manager (PM) for the subject nuclear power plant, ESP, or DC.

Once approved by the responsible supervisor, the audit plan should be shared with the audit team members and the applicant so they can prepare for the regulatory audit. The audit leader should consider holding a pre-audit meeting with the audit team members and responsible supervisor to discuss assignments and expectations. The audit leader or cognizant PM should discuss the plan with the applicant and request that the applicant provide space, documentation, access to subject matter experts, and other necessary items. To the extent possible, the audit leader should prepare a list of documents that are needed

and communicate the list to the applicant either orally or in writing, typically 14 days before the regulatory audit. The 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. The cognizant PM should, when needed, consult with the Office of General Counsel (OGC) to determine if communications associated with the audit preparations require OGC concurrence. Early interactions with the applicant should also address issues such as access controls, security requirements, and other policies and procedures affecting the audit team.

3.2 Regulatory Audit Plans

A regulatory audit plan should provide a clear, succinct overview of the regulatory audit activities. The audit plan should identify the applicant, 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 is normally 1-2 pages in length, and should include the following recommended sections as applicable to the audit:

a. Background.

This section provides a brief summary of the application and 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 is not limited to, sections of the COL, DC or ESP application, 10 CFR Part 52, 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 or material needed by the audit member(s) to complete the regulatory audit. This could include, but is not limited to, applicant reports, calculations, and computer codes.

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; entrance and exit briefing dates and times; and audit schedule.

g. Special Requests

This section may document any requests of the applicant by the team to support the audit.

h. Deliverables

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

i. References.

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

3.3 Conducting Entrance, Closing, Exit, and Status Briefings

For audits that require more than one day, an entrance briefing with the applicant is recommended. Entrance briefings should be scheduled in advance and should be conducted as soon as practicable. At the entrance briefing, the audit leader should review key elements of the regulatory audit plan with the applicant.

For multiple-day audits, the audit leader should consider status briefings with the responsible NRC supervisor and NRO project manager. As needed, the audit leader should also consider periodic status briefings with the applicant to discuss progress and potential issues identified. The audit leader should consider briefing the responsible supervisor on the preliminary audit results prior to the closing or exit briefing.

If a regulatory 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 regulatory audit. Preliminary results should be presented emphasizing that these are preliminary in nature and are subject to NRO management review. It should be noted to the applicant that the agency will communicate any significant changes between the preliminary audit results and the regulatory audit summary prior to issuance.

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

3.4 Conducting Regulatory Audit Activities

Audit member(s) activities during the regulatory audit and interactions with the applicant 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 is needed to support the staff's licensing or regulatory decision should be placed on the docket and in the Agencywide Documents Access and Management System (ADAMS). This may be accomplished through a RAI, formal correspondence from the applicant or staff action.

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

Audit team members may review controlled copies of the applicant's records and documents at any time during the regulatory audit. When the applicant uses a form to request controlled documents from its storage facility or document control clerks, the audit team members may fill out this form following the applicant's procedures. This documentation cannot be removed from the applicant's property or disposed of without the owner's permission.

Audit team members may remove copies of applicant-provided documents from the applicant's site, if necessary, to assist in writing the audit summary or for preparing safety evaluation report input. Prior to removing any of the applicant's documents that will be maintained, possessed, and controlled by the NRC, the applicant will have the opportunity to provide and mark the documents in accordance with 10 CFR 2.390(b). Applicant documents removed by the staff must be retained and entered into ADAMS if the criteria in Management Directive (MD) 3.53 (relating to NRC records and document management program) are satisfied.

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

3.5 Documenting the Regulatory Audit

At the completion of the regulatory audit, a regulatory audit summary should be developed in a timely manner. Depending on the scope of the audit, the regulatory audit summary may be documented as:

- a letter to the applicant,
- a detailed summary report, or
- an internal memorandum to the responsible supervisor or cognizant project management branch.

The regulatory audit summary should be placed on the docket and in ADAMS within 90 days of the completion of the audit. The regulatory audit summary may be publically available, as appropriate, given considerations such as those discussed in Section 4.6. If similar audits are conducted for multiple applicants, the audits should be consistently documented and provided to the applicants.

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

- identify the audit location and dates,
- list the audit team members,
- list applicant 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 applicant's document control process. This may include title, date, revision number, and supplement number.

If audit open items are necessary, a closure path should be provided. An exception would be in the case of planned multi-phase audits. If RAIs are necessary, they should be provided to the project manager with the technical supervisor's concurrence and in accordance with the audit plan schedule.

The staff should not make final licensing conclusions or staff findings in the audit summary. However, audit conclusions may be drawn. The staff may refer to the regulatory audit summary or include a discussion of the audit activities in a safety evaluation.

The audit leader is responsible for ensuring that the content of the regulatory audit summary is consistent with the audit activities and the content of the exit briefing. If the summary differs significantly from the exit briefing, the audit leader, NRO project manager, and responsible NRO management should discuss those differences with the applicant before issuing the regulatory audit summary.

3.6 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 Freedom of Information Act (FOIA) requests

- Handling sensitive unclassified non-safeguards information (SUNSI) (including proprietary information)
- Handling safeguards information (SGI)
- Handling draft applicant information
- Handling 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" and the Office of Information Systems website, http://www.internal.nrc.gov/ois/divisions/irsd/records-mgt/index.html#4, which has an interactive tool for determining whether or not something is an OAR.

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 applicant's site. NRO OI REG-105, "Support to Hearing Process," provides detailed guidance on the staff's responsibility to retain documents related to its reviews and audits if a hearing has been or may be requested.

Freedom of Information Act Requests

Audit team members have the responsibility to adhere to the guidelines for an FOIA request. Any document, docketed or not, in an NRC's employee's possession at the time of an FOIA request must be considered under the FOIA criteria. Further information may be found in MD 3.1, "Freedom of Information Act," and NRO OI ADM-101, "Freedom of Information Act (FOIA) Requests."

Proprietary, Sensitive, and SGI

Audit team members have the responsibility to protect the applicant's SUNSI (e.g., proprietary) and SGI. If information is removed from the audit site, all precautions to prevent the inadvertent release of proprietary and SGI should be followed. 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."

Draft Applicant Information

In general, draft information should not be invited or physically accepted by audit team members. If draft information needs to be reviewed as part of the audit, it should be treated consistent with other information gathered in support of the audit (e.g., preserved in ADAMS if removed from the site and meeting the criteria in MD 3.53) and should be clearly identified as preliminary or draft information.

Further information may be found in Office of Nuclear Reactor Regulation (NRR) OI COM-203, “Informal Interfacing and Exchange of Information with Applicants and Applicants” and NRR OI LIC-101, “License Amendment Review Procedures.”

If a hearing has been or may be requested, all communications between the staff and the applicant should be retained. NRO OI REG-105 provides guidance on the staff’s responsibility to retain NRC staff-applicant communications.

Working Files and Supporting Materials

True supporting materials are documents that are necessary to substantiate the final document or decision trail. Supporting materials are not working files. Supporting materials are part of the official record.

Working files consist of documents 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 that do not meet the requirements to be records and, thus, are not part of the agency's official record collections. However, working files are not exempt from FOIA consideration.

Working files should 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 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 otherwise specified, 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). Comments received during a formal review by outside experts and the public should be carefully documented for the record, either by keeping the original comments themselves, or if volume is extensive, keeping a summary of the comments, and how they were used.

Pre-Decisional NRC Information

Consistent with NRC policies, procedures, and regulatory requirements, audit team members should not show or physically provide to the applicant, or anyone external to the NRC, any portion of the audit summary before it is formally issued or the final licensing or regulatory decision has been made. Only the explicit written permission of the NRC Executive Director for Operations (EDO) can override this policy.

If an audit member inadvertently or improperly releases pre-decisional information, MD 3.4, "Release of Information to the Public," requires that the staff immediately inform the EDO in writing of the release and the facts about the release and that the responsible office take corrective action to retrieve the documentation and prevent recurrence of such a release.

Records Disposition

Information necessary to support the licensing or regulatory decision should be placed on the docket by the applicant or NRC staff. Applicant documents in the possession and control of the staff and not otherwise formally submitted by the applicant 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 applicant 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.

Materials created by an audit member for the audit member's own use in performing his or her job, and which are not shared (and are not otherwise required by NRC policy to be maintained), may be discarded at the audit member's discretion.

REFERENCES

1. Inspection Manual Chapter 0301, "Coordination of NRC Visits to Commercial Reactor Sites."

2. Inspection Manual Chapter 0620, "Inspection Documents and Records."

3. Inspection Manual Chapter 1245, "[Inspector] Qualification Program for the Office of Nuclear Reactor Regulation Programs"

4. NRC Management Directive 3.1, "Freedom of Information Act."

5. NRC Management Directive 3.4, "Release of Information to the Public."

6. NRC Management Directive 3.23, "Mail Management."

7. NRC Management Directive 3.53, "NRC Records and Document Management Program."

8. NRC Management Directive 12.2, "NRC Classified Information Security Program."

9. NRC Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program."

10. NRC Management Directive 12.7, "NRC Safeguards Information Security Program."

11. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants."

12. NRO OI PER-105, “Qualification and Training Program.”

13. NRO OI ADM-101, “Freedom of Information Act (FOIA) Requests.”

14. NRO OI REG-105, “Support to Hearing Process.”

15. NRR OI COM-203, “Informal Interfacing and Exchange of Information with Licensees and Applicants.”

16. NRR OI LIC-101, “License Amendment Review Procedures.”

17. Title 10 of the *Code of Federal Regulations* Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.”

18. Title 10 of the *Code of Federal Regulations* Part 9, “Public Records.”

19. Title 10 of the *Code of Federal Regulations* Part 50, “Domestic Licensing of Production and Utilization Facilities.”

20. Title 10 of the *Code of Federal Regulations* Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”

NRO-REG-108 - Change History			
Date	Description of Changes	Method Used to Announce & Distribute	Training
01/01/09	This is the initial issuance of NRO-REG-108, "Regulatory Audits." This OI defines how the U.S. Nuclear Regulatory Commission (NRC), Office of New Reactors (NRO) staff will conduct regulatory audits in support of new reactor licensing activities.	Posting on NRO website	NONE