

DOCUMENTING 10 CFR 52
CONSTRUCTION AUDIT ACTIVITIES

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0614-01 PURPOSE

This manual chapter (MC) provides guidance on documenting construction audit activities. Specifically, this MC outlines the standard content, format, and style to be used for audit plans and reports to ensure that documents describe planned and executed activities in a clear, complete, and concise manner.

0614-02 OBJECTIVES

02.01 To ensure that audit plans:

- a. Identify the scope and bases for planned activities.
- b. Clearly designate responsibility for planned activities to audit team members. The audit team leader should be identified in the plan as well as all audit team members and their duties.
- c. Identify the expected deliverables that will result from the audit effort.
- d. Provide an outline of logistical considerations including lodging information, scheduled audit team meetings, per diem rates, and time and charge information.

02.02 To ensure that audit reports:

- a. Communicate observations in a clear, concise, and complete manner.
- b. Provide conclusions about the effectiveness of the programs or activities audited. The depth and scope of the conclusions should be commensurate with the depth and scope of the audit.

0614-03 DEFINITIONS

This section does not unnecessarily repeat terms defined in the associated construction manual chapters or terms defined in the NRC Enforcement Manual.

03.01 Audit. A planned and documented activity performed by the staff during predocketing phase to determine - by investigation, examination, or evaluation of objective evidence - the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation of the QA program used in the development of the application.

03.02 Audit Response Request. A request for additional information issued by the NRC to an applicant, or other audited party in response to a deficiency identified during an audit which could affect the completeness or accuracy of an application or activity.

03.03 Conclusion. As used in this manual chapter, an assessment that relates one or more observations to the broader context of an applicant program or process.

03.04 NRC Record. Any written, electronic, or photographic record under legal NRC control that documents the policy or activities of the NRC or an NRC licensee (see also the definition in 10 CFR Part 9).

03.05 Observation. As used in this manual chapter, a fact; any detail noted during an audit.

03.06 Requirement. A legally binding obligation such as a statute, regulation, license condition, technical specification, or an order.

03.07 Vendor. Any company or organization that provides products such as material, equipment, components, or services to be used in an NRC-licensed facility or activity. In certain cases the vendor may be an NRC licensee (e.g., a nuclear fuel fabricator) or the product may have NRC certificates (e.g., a transportation cask).

0614-04 RESPONSIBILITIES AND AUTHORITIES

Audit team leaders performing audit activities governed by this manual chapter are required to prepare audit plans and audit reports in accordance with the guidance provided in this inspection manual chapter. General and specific responsibilities are listed below.

04.01 General Responsibilities. Each audit shall be documented. This documentation includes the following:

- a. Audit Plan. Prior to the activity, a written plan (consisting of a cover page and audit plan) should be completed by or under the direction of the audit team leader.
- b. Audit Report. After completion of the audit, the audit team members will provide the audit team leader with written report input which documents the scope of their review, observations, and conclusions, in their assigned areas of review responsibility. The audit team leader will develop the audit report which shall consist of a cover letter, a cover page, and audit report details. Audit reports are written in paragraph format, as described in Section 6 of this manual chapter.

04.02 Audit Plan.

- a. Specific Responsibilities.
 1. The audit team leader has the responsibility for preparing the audit plan and working with the appropriate levels of management to establish the

audit scope and team member composition and audit review responsibilities. The audit team leader may designate a trainee or other audit team member to write the audit plan, but the audit team leader shall retain overall responsibility for completion of the document.

2. Audit team members responsible for writing audit plans should ensure that they follow the general format given in this chapter and outlined in Attachment 1.

b. Plan Review and Concurrence.

1. Before issuance, each audit plan will be reviewed at the branch chief level.

The audit plan serves as the justification for foreign travel, where applicable. Specific information pertaining to the approval, planning, and documentation required for international travel can be found in NRC Management Directive 14.1, "Official Temporary Duty Travel."

2. The branch chief with review responsibility should verify that team member composition and team member review responsibilities are commensurate with individual expertise and experience level and that the audit scope is appropriately focused.

c. Plan Issuance. The applicable branch chief is responsible for approving audit plan content, scope, and designation of team member assignments.

d. General Timeliness. Most audit plans should be issued no later than 14 calendar days prior to audit initiation (international audit plans should be issued approximately 60 days prior to audit initiation).

04.03 Audit Reports.

a. Specific Responsibilities.

1. Audit team members shall use audit observations to support conclusions about the programs or processes being audited, and issue audit response requests (ARRs) as necessary to draw attention to potential deficiencies in those programs or processes within the scope of the audit. Such deficiencies, if not promptly corrected, may affect the completeness and accuracy of the application and potentially impact the staff's acceptance review.
2. The audit team leader and individual audit team members are responsible for ensuring that observations and conclusions are accurately reported, that referenced material is correctly characterized, and that the scope and depth of conclusions are adequately supported by documented

observations. Advice, recommendations, and personal opinions are not to be included in audit reports.

3. The audit team leader and individual audit team members are responsible for ensuring that the content, as issued, is consistent with the content of the exit meeting presentation. When the report differs significantly from the exit meeting, the audit team leader and responsible NRC management should discuss those differences with the applicant before the report is issued.
- b. Report Review and Concurrence.
1. Before issuance, each audit report should, as a minimum, be reviewed by a member of NRC management familiar with regulatory requirements in the area being audited.
 2. Audit team members should complete report input and provide written report input to the audit team leader within 5 business days of audit completion to allow for compilation of the report in a timely fashion.
 3. The audit team leader should ensure that conclusions are logically drawn and sufficiently supported by observations, and that the observations, conclusions, and ARRs are consistent with NRC policies and requirements.
 4. The management designee assigned to review the audit report should ensure that assessments made in the report represent the judgment of the issuing organization and established NRC policy.
- c. Report Issuance. For reports written by audit team members from the NRC regional offices or NRO, the applicable branch chief is responsible for approving the report content, tone, conclusions, and overall regulatory focus.
- d. General Timeliness. Most audit reports should be issued no later than 45 calendar days after completion of the audit.

NOTE: Audit completion is normally defined as the day of the exit meeting.

0614-05 REQUIREMENTS – AUDIT PLANS

NRC audit plans should provide a clear, succinct overview of the activity to be performed, including the scope, key participants, bases, background, and logistics. This documentation provides structure and organization for the audit and serves as an integral planning tool for the audit team. The following paragraphs describe the appropriate format for audit plans.

05.01 Audit Plan Cover Page. The plan cover page provides a quick-glance summary of information about the planned audit. The plan is issued in memo format, and the cover page contains the following fields: date, memorandum to and from fields, subject, applicant name and contact, activity dates, location, report/project number, audit team members, and enclosures (the audit plan will likely be the only enclosure). See Attachment 1 for format.

05.02 Audit Plans. The audit plan is a brief document, normally 1-2 pages in length, in which the following topics are addressed:

- a. **Activity Bases.** This section should identify the documents upon which the audit is based. Typical examples are Appendix B to 10 CFR Part 50 and 10 CFR Part 21.
- b. **Audit Scope.** This section identifies the areas of focus for the audit (e.g., corrective action, 10 CFR Part 21 program, etc.). Attention should also be drawn to any follow-up actions that will take place as a result of previously identified issues.
- c. **Team Assignments.** Each audit team member is identified with his or her respective area(s) of responsibility.
- d. **Purpose.** This section explains the regulatory benefit of the audit.
- e. **Background.** The background includes a brief introduction to the inspected entity. This could include a summary of the audited party and its products, the applicant and its proposed project, etc.
- f. **Logistics.** The logistics section documents the date and locations for meetings, per-diem rates, audit schedule, and time charge information.
- g. **Deliverables.** The deliverables for each audit are identified in the activity plan with the related time frame allowed. Deliverables include any written input from the audit team members that is necessary to support the observations and conclusions documented for each area of review. Each audit team member should provide written input which consists of the audit scope, observations, including any ARRs, and a conclusion for each area of responsibility, to the team leader in draft format within five working days of audit completion for inclusion in the audit report.

0614-06 REQUIREMENTS – AUDIT REPORT FORMAT

Audit reports follow the paragraph format consistent with the structure and content to that of inspection reports described in IMC-0612. Each audit report is preceded by a cover letter and cover page.

06.01 Cover Letter. Audit reports are transmitted using a cover letter from the applicable NRC official (typically the projects branch chief, or lead project manager) to the designated applicant executive. Cover letter content may vary when ARR's are identified during audits. However, every cover letter generally uses the same basic structure.

- a. Date, Addressee, and Salutation. At the top of the first page, the cover letter begins with the NRC seal and address, followed by the date on which the report cover letter is signed and the report issued.

The name and title of the principle addressee are placed at least four lines below the letterhead, followed by the licensee's name and address. Note that the salutation is placed after the subject line.

- b. Subject Line. The subject line of the letter should state the type of report title in full capitalization.

EXAMPLE: "NRC AUDIT REPORT FOR XXXXXXXX PRE-COL APPLICATION REVIEW."

- c. Introductory Paragraph. The first paragraph of the letter should give a brief introduction, as follows:

EXAMPLE: "As part of the review of the combined license application (COLA), members of the Quality and Vendor Branches (CQV) performed an audit at the _____ facility during the period of August 20-24, 2007. The enclosed report presents the results of that audit."

- d. Body of the Letter. The ensuing paragraphs should discuss the most important audit results, including any ARR's and significant conclusions. In general, this portion of the cover letter should focus on clearly communicating a few main points (or a single point) that are well-supported by the report details, rather than attempting to deliver a large number of points or extensive detail. If no significant issues were raised by the audit, this section should briefly summarize the scope of specific audit activities performed to give perspective to the conclusion that no ARR's, deficiencies, or significant issues were identified.

The cover letter should clearly identify any significant observations and relate them to the effect they could have on application acceptance. In the event that significant observations are made or ARR's are issued, the cover letter should request the applicant provide a response to those ARR's before or as part of the Combined Operating License Application (COLA) submittal.

- e. Closing. The final paragraph consists of a statement regarding the public availability of the audit report and associated correspondence. The signature of the appropriate NRC official is followed by the list of enclosures and distribution.

06.02 Cover Page. The report cover page provides a quick-glance summary of audit information. It contains the report number, dates of audit, the names and titles of participating audit team members, and the name, signature, and title of the approving NRC official.

06.03 Audit Summary [Section 1 of Report]. The summary should begin with a one or two sentence introduction that identifies the audit purpose (i.e., the licensee programs or functional areas audited) and the name and location of the audited organization. The summary also includes a bulleted list of the audit bases (e.g., 10 CFR Part 21, Appendix B to 10 CFR Part 50).

Any ARRs or significant conclusions should be briefly introduced in the summary and include a reference to where the full discussion is located in the report.

EXAMPLE: “ARR-001 was identified and is discussed in Section 3.2 of this report.”

06.04 Status of Previous Audits [Section 2 of Report]. The status should begin with a listing of any previous audit observations or ARRs and identify the section of the audit report where the details regarding each previous observation or ARR are discussed. If there were no previous audits performed, a simple statement denoting this will be sufficient.

EXAMPLE: “There were no previous NRC audits in support of the APPLICANT’S COLA development.”

06.05 Audit Observations and Other Comments [Section 3 of Report]. This section contains the bulk of the audit details and consists of a separate scope, observations, and conclusions section for each area reviewed (e.g., 10 CFR Part 21 Program Implementation, Corrective Actions, Design Control, etc).

- a. Scope. The scope identifies the areas of focus for the audit and how the audit team examined these areas (document review, visual verification, etc.).

EXAMPLE: “The NRC audit team reviewed the implementation of the APPLICANT design control process for the APPLICANT COLA. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of the APPLICANT design control process, and reviewed selected draft completed portions of the COLAs, that have been reviewed and accepted by the APPLICANT.”

- b. Observations. This portion of each report section should be used to present, in a narrative format, the audit activities conducted by the audit team members. This should include a discussion of the policies and procedures governing the applicants programs for each area reviewed, a description of the audit sample evaluated by the audit team (e.g., portions of the COLA, test results, calculations, design packages, drawings, technical reports, etc.), and the results of the audit evaluations conducted. The auditor may choose to simply number

issues sequentially, with appropriate subheadings, or may use another method of organizing the observations.

- c. **Conclusions.** The Conclusions section will include a description of the program or functional area audited, identification of procedures and other documentation examined, and an explanation of observations and conclusions. This section will also define any ARR that were identified during the audit.

EXAMPLE: “The NRC audit team concluded that, with the exception noted above, the design control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant’s and its sub-supplier’s procedures to support the APPLICANT’S COLA development programs. The NRC audit team did identify an issue requiring additional action by the applicant prior to completion of the COLA (ARR-001).”

06.06 Management Meetings and Personnel Contacted [Section 3 of Report]. The final section of each audit report should include a brief summary of the entrance and exit meetings, a list of personnel contacted, and a list of documents reviewed.

- a. **Entrance and Exit Meetings.** The report should contain a brief paragraph that describes the entrance and exit meetings conducted in conjunction with the audit. Important information to relay is the date of the meeting, what was discussed, and who participated. Identification of participants should be on a generic level (e.g., XXX Company’s president and staff, NRC audit team members).
- b. **Personnel Contacted.** This portion of the report should identify the individuals who furnished significant information or were key points of contact during the audit. This subsection should be in tabular list format and include the name of each person contacted, his or her position, and his or her organization.

0614-07 GUIDANCE — AUDIT REPORT CONTENT

This section relates primarily to matters of content in the report details. As used in this chapter, the term “observation” refers to a fact—any detail noted during an audit. The term “conclusion” is used for an assessment that relates one or more observations to the broader context of a program or functional area. Finally, an ARR is a method available to identify an observation made during the audit which may affect the completeness and accuracy of the audit area documented or activity performed and is a method to request further explanation or clarification from the audited party. Effective use of ARRs should minimize unanticipated issues once the DC, ESP, or COL application is docketed and under review by prompting corrective action prior to submission.

07.01 Observations. The most basic results of an audit are the facts an audit team

member gathers through watching work activities, examining procedures and technical documentation, interviewing applicant personnel, reviewing records, and other audit methods. As documented, these observations should be factual.

When documenting an observation, use language that clearly identifies how the observation was discovered and verified. Identify all documents examined, and include other factual information as relevant, such as the time of discovery, the length of time the problem existed, the type, size, or model of the equipment, if it is germane to the issue. Observations are the basis for audit conclusions as well as ARR's.

07.02 Conclusions. Conclusions are general statements of assessment that relate one or more observations to the broader context of the applicant's program or functional area reviewed. The audit team leader's task is to match the scope of the conclusions to what the observations will support. Any conclusions included in a report should include a description of the related observation(s) and how they support the conclusion.

07.03 Audit Response Requests. Some observations identified during audits may warrant an ARR. An ARR is issued by the NRC to formally communicate an observation to an applicant which, based on the results of the audit, may affect the completeness and accuracy of the audit area documented or activity performed.

- a. The ARR is incorporated into the audit report and is used to draw attention to a deficiency in a program or process, a failure to meet commitments related to NRC activities, or a condition that might result in a lack of compliance with a legally binding regulatory requirement if not corrected prior to docketing.
- b. The observation or deficiency that initiated the ARR shall be identified in the body of the report (e.g., within the observation section of an area or topic under review), along with a description of the issue and any action already taken on the part of the applicant. The written response from the audited party should identify the cause(s) and extent of the condition and corrective actions that have been or will be implemented to correct the condition.
- c. Each audit response request will be numbered in the format "ARR-XXX," beginning with ARR-001 for the first response request in each audit report and increasing consecutively for additional requests in the same report.

0614-08 RELEASE AND DISCLOSURE OF AUDIT REPORTS AND ASSOCIATED DOCUMENTS

08.01 General Public Disclosure and Exemptions. Except for report enclosures containing exempt information, all final audit reports will be routinely disclosed to the public.

END

Attachments:

1. Audit Plan Format
2. Audit Report Format
3. Revision History

Attachment 1: Audit Plan Format

Audit Plan Cover Page

MEMORANDUM TO: Branch Chief Name
Branch
Division
Office

FROM: Team Leader Name
Branch
Division
Office

SUBJECT: Audit Plan for...

VENDOR/
APPLICANT: Name

CONTACT: Name
Company/Position
Phone
Email

[ACTIVITY] DATES:

LOCATION: Company
Address

PROJECT NUMBER: XXX-XXXXX

TEAM: Member Organization/Division/Branch Lead
Member Organization/Division/Branch

ENCLOSURE: Audit Plan

Audit Plan Format

i. *Cover Letter*

1.0 Audit Bases

2.0 Audit Scope

3.0 Team Assignments

4.0 Purpose

5.0 Background

6.0 Logistics

7.0 Deliverables

Audit Plan Sample

The following is an audit plan that has been written in the specified format and can be found in ADAMS via the listed accession number:

1. AUDIT PLAN FOR BELLEFONTE/LEE PROJECT COMBINED LICENSE APPLICATION DEVELOPMENT (ML072040450)

Attachment 2: Audit Report Formats

Cover Letter Outline

Date

Addressee
Company
Address

SUBJECT:

Salutation:

Introduction

Body

Closing

Sincerely,

Name
Division
Office

Enclosure:

Audit Report Cover Page Outline

Project No.:

Organization:

Contact:

Nuclear Industry:

Audit Dates:

Audit Team Leader:

Auditor:

Auditor:

Approved By:

Branch Chief
Branch
Division
Office

Date

Audit Report Content Outline

- i. Cover Letter
- ii. Cover Page
- 1.0 Audit Summary
- 2.0 Status of Previous Audits
- 3.0 Audit Observations and Other Comments
 - 3.1, 3.2, 3.3...Topic of Audit*
 - a. Scope
 - b. Observations
 - c. Conclusion
- 4.0 Entrance and Exit Meetings
- 5.0 Partial List of Persons Contacted
- 6.0 References

**Examples:*

- 10 CFR Part 21 Program
- Commercial Grade Dedication
- Quality Assurance Program
- Instructions, Procedures, and Drawings
- Control of Special Processes
- Handling, Storage, and Shipping
- Inspection, Test, and Operating Status
- Corrective Actions
- Nonconforming Materials, Parts, or Components
- Control of Measuring and Test Equipment (M&TE)
- Control of Purchased Material, Equipment, and Services
- Identification and Control of Materials, Parts, and Components
- Organization
- Design Control
- Procurement Document Control
- Document Control
- Test Control
- Inspection
- Records
- Audits

ATTACHMENT 3

Revision History for IMC 0614

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	10/03/07 CN 07-030	1. Initial issuance to provide direction for writing audit reports.. 2. Researched commitments for 4 years and found none.	None	N/A	N/A