



Centerwide System Level Procedure

ISO 9001 - Ames Research Center

Document #:

53.ARC.0017

Rev:

11

Title:

Internal Quality Audit

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REVISION HISTORY

REV	Description of Change	Author	Effective Date
0	Initial Release	D. McDaniel	05/27/98
1	Clarifications based on 7/98 DNV Audit and 6/98 Internal Audit (see DCR 008)	M. Hines	9/2/98
2	Administrative change (see DCR 98-019)	R. Johnson	9/14/98
3	Clarifications based on 11/98 DNV Audit (DCR 98-070)	R. Serrano	12/18/98
4	Changes made in conjunction with the audit schedule, effectiveness of CARs, and consistency with 53.ARC.0014 (DCR 99-002)	Gail Pfeiffer & Mike Dudley	2/17/99
5	Add method of performing horizontal audits (DCR 99-003)	G. Pfeiffer	2/26/99
6	Define horizontal audits and the reason for performing horizontal audits (DCR 99-005)	G. Pfeiffer	3/17/99
7	Clarifications based on 4/99 DNV Audit and 1/99-4/99 Internal Audits (DCR 99-020)	G. Pfeiffer	8/2/99
8	Revised 6.3.2 to add reference to checklists location (DCR 99-037)	G. Miyahara	9/9/99
9	Changed observation process based on 11/99 DNV surveillance audit (DCR 00-005)	R. Serrano	2/25/00
10	Administrative change (see DCR 00-014)	J. Weller	5/9/00
11	Changes made to delete reference to checklists location (DCR 00-024)	J. Weller	9/21/00

REFERENCE DOCUMENTS

Document Number	Document Title
ANSI/ASQC Q9001	Quality Systems—Model of Quality Assurance in Design, Development, Production, Installation, and Servicing

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53.ARC.0000	Ames Research Center Quality Manual, Section 4.17
53.ARC.0014	Corrective and Preventive Action
53.ARC.0016	Quality Records

Documents referenced in this procedure are applicable to the extent specified herein.

1. Purpose

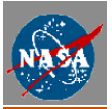
This procedure establishes the method by which internal quality audits are implemented within the Ames Research Center (ARC) Quality System.

2. Scope

This procedure applies to all ARC organizations within the ARC Quality System whose processes directly affect the quality of products and services delivered to customers.

3. Definitions and Acronyms

- | | |
|--|---|
| 3.1. Audit Report | Summary of audit scope and findings on form ARC 753 (Internal Audit Summary) |
| 3.2. Centerwide Corrective Action Request Coordinator (CWCARC) | Centerwide person responsible for processing CARs and administering the corrective and preventive action system |
| 3.3. Nonconformance | Nonfulfillment of a specific requirement |
| 3.4. Objective Evidence | Information which can be proven true based on facts obtained through observation, measurement, test, or other means |
| 3.5. Observation | Isolated nonfulfillment of a specific requirement that can be corrected on the spot (e.g., typo, missing word, one missing signature from a sample of objective evidence, etc.) |



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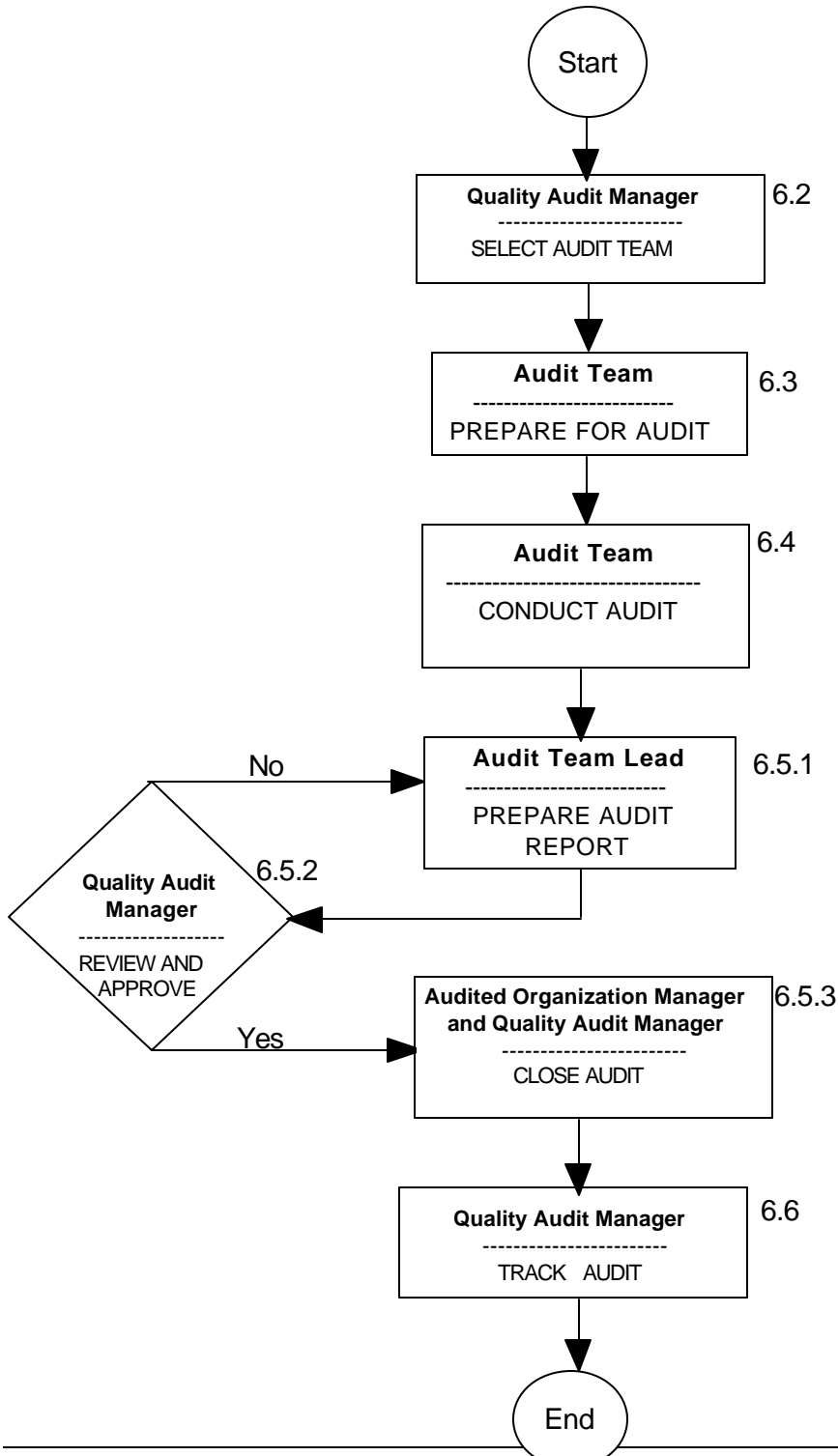
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
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
4. Flowchart



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5. Responsibilities

- 5.1. **Quality System Management Representative** shall:
- ? approve annual audit schedule and subsequent changes to the schedule.
- 5.2. **Director of Safety, Environmental, and Mission Assurance** shall:
- ? assign a Quality Audit Manager to plan, schedule, and manage the ARC internal quality audit process.
- 5.3. **Quality Audit Manager** shall:
- ? establish and maintain a dedicated audit team,
 - ? ensure that all auditors have received the required training,
 - ? ensure that the annual audit schedule is developed and updated,
 - ? ensure that internal quality audits are performed in accordance with this procedure and the approved audit schedule,
 - ? reconcile any disagreements between Audit Team Leads and audited organizations,
 - ? ensure that patterns of observations across audits are looked for and combined into nonconformances, and
 - ? review audit reports and distribute to audited organizations.
- 5.4. **Audit Team Lead** shall:
- ? plan audit,
 - ? perform audit in accordance with approved audit schedule,
 - ? conduct audit meetings,
 - ? prepare audit report, and
 - ? reconcile any disagreements between auditors and audited organizations and, when necessary, submit disagreements to the Quality Audit Manager for reconciliation.
- 5.5. **Auditor** shall:
- ? review documentation,
 - ? participate in the audit, including the verification of effectiveness of corrective actions taken,
 - ? collect objective evidence to support findings and CAR verifications, and
 - ? record findings.
- 5.6. **Audited Organization's Manager** or designee shall:
- ? inform area personnel of the time and scope of the audit,
 - ? assign knowledgeable guide(s) to accompany each audit team,
 - ? ensure that timely access to processes, products, and documentation needed by the auditor(s), including objective evidence is provided,
 - ? attend audit meetings, and
 - ? sign audit report.

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5.7. **Guide(s)** shall:

- ? escort audit teams to the correct areas,
- ? assist in communication between auditor and auditee, and
- ? inform management of audit progress prior to the formal audit report being issued.

6. Procedure

6.1. Audit Planning

6.1.1. The Quality Audit Manager shall ensure that the ARC internal quality audit schedule is developed. The audit schedule shall be reviewed and approved by the Quality System Management Representative.

6.1.2. The audit schedule shall:

- ? address all applicable elements of the Quality System during each 12-month period, and
- ? identify the depth and frequency of each audit based on prior audit history and operational status of the area to be audited.

6.2. Select Audit Team

The Quality Audit Manager shall select qualified Audit Team Lead(s) and Team Members for each area to be audited who are not directly responsible for the performance of the activity being audited.

Note: Auditors shall have received training in audit methods and objectives. The Audit Team Lead is required to have attended an accredited lead auditor course and possess experience leading audit teams in assessing quality management systems as determined by the Quality Audit Manager.

6.3. Prepare for Audit

6.3.1. The Audit Team Lead shall prepare an audit agenda that indicates specific audit dates, times, and team assignments.


6.3.2. The Audit Team shall:

- ? obtain corrective action requests (CARs) requiring verification of effective implementation from the Centerwide Corrective Action Request Coordinator (CWCARC),
- ? review previous audit reports and notes.

6.4. Conduct Audit

6.4.1. Each Audit Team Lead shall conduct the opening, wrap-up, and closing meetings with the Manager or designee of the organization.

6.4.2. The Audit Team shall:

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- ? interview appropriate personnel and determine whether actual practices conform to the requirements of the documented policies, plans, procedures, and work instructions, and
- ? verify the effectiveness of CARs closed since the last audit and complete the Verification section of the CAR forms (ARC 755). (If it is determined that the corrective action was not effective, see section 6.5.1.1, fourth bullet, below.) Forward CAR forms to the Quality Audit Manager.

6.5. Audit Closure

6.5.1. Prepare Audit Report

6.5.1.1. The Audit Team shall:


- ? categorize findings into nonconformance(s) and observations,
- ? complete the Originator section and the Responsible Directorate section of a CAR form for all nonconformances,
- ? in the event that a corrective or preventive action taken since the last audit was ineffective, initiate a new CAR, in accordance with 53.ARC.0014. The new CAR shall include the original CAR number, the original finding, the original action specified, and a statement as to the reason why the corrective action is ineffective,
- ? write observations to include the organization audited, the applicable ISO element, the requirement, the discrepancy, and the corrective action taken, and
- ? provide **audit notes, CARs and** observations to the Audit Team Lead.

6.5.1.2. The Quality Audit Manager shall:

- ? review the audit findings to ensure that complete and adequate descriptions of the discrepancies are documented, and forward CARs to the CWCARC. After the CWCARC assigns a number to the new CARs, the Quality Audit Manager shall provide the number to the Audit Team Lead for inclusion in the audit report.
- ? review any verified CARs to ensure that the verification is complete and adequate and that objective evidence is attached as needed, and forward the CARs to the CWCARC.

6.5.1.3. The Audit Team Lead shall:

- ? **combine observations that show a pattern of nonconformance into a nonconformance,**
- ? **forward all CARs to the Quality Audit Manager**

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? complete and provide the audit report to the Quality Audit Manager for review and approval.

6.5.2. Audit Report Review and Approval

The Quality Audit Manager shall review the audit report to ensure that it is complete, concise, consistent, and unambiguous, and that all nonconformances and/or observations are factual and traceable to elements of ANSI/ASQ Q9001.

6.5.3. Close Audit

- 6.5.3.1. The Quality Audit Manager shall distribute the audit report to the audited organization's Manager or designee within two weeks of the last day of the audit.
- 6.5.3.2. The audited organization's Manager shall sign the audit report, acknowledging the audit and receipt of the audit report.
- 6.5.3.3. The Quality Audit Manager will keep the audit report and objective evidence.
- 6.5.3.4. The Responsible Manager shall ensure that CARs issued are responded to in a timely manner and as required by 53.ARC.0014.

6.6. Track Audit

The Quality Audit Manager shall assign a unique number to each audit and maintain an audit-tracking log.

6.7. Audits of Closed CARs Only

When deemed necessary by the Quality Audit Manager because of the nature, risk, scope, or prevalence of problems documented by corrective actions, the Quality Audit Manager may schedule an audit to verify closed CARs. During these audits, the auditor need only:

- ? obtain the CAR forms to be verified from the CWCARC,
- ? audit the action taken for effectiveness,
- ? complete the Verification section of the CAR form for the actions audited, and
- ? issue CAR(s) if it is determined that additional action is required to correct the problem resulting from the ineffectiveness of the original CAR.

6.8. Horizontal and Special Audits

6.8.1. When deemed necessary by the Quality Audit Manager, a horizontal audit shall be scheduled to verify an ISO element center wide. Such audits will verify that procedures and activities are in conformance with a designated ISO element.



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6.8.2. A special audit shall be scheduled as determined by results from previous audits or if requested by an organization.

6.8.3. Horizontal and special audits will be performed in accordance with this procedure, with the exception of CAR verification and opening and closing meetings with the Responsible Manager.

7. Metrics

There are no metrics required for this document.

8. Quality Records

The following Quality Records shall be generated and managed in accordance with 53.ARC.0016.

Required Record	Custodian
Internal Audit Report	Quality Audit Manager
Corrective Action Request (ARC 755)	CWCARC

9. Form(s)

Forms required for this document:

Form Number	Title
ARC 753	Internal Audit Summary
ARC 755	Corrective Action Request