

ARC ISO 9001 for SSA

Refresher for 2/24/00 Internal Audit

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AGENDA

- How is ISO 9K implemented at ARC?
- How does the Ames implementation of ISO affect SSA?
- How do we comply with ARC ISO9K: Summary
- How do we comply with ARC ISO9K: Calibration
- Tips for the upcoming audit
- Document guide, FAQ / Summary, Sample Audit Questions, and checklist
- Sample Quality Records Index

How is ISO 9K implemented at ARC? (1/3)

- At the highest (Center) level, ARC has written a Quality Manual, has coined a Quality Policy, and has written about 20 System Level Procedures (SLPs) and Work Instructions. (<http://dqa.arc.nasa.gov/iso9000/>)
- The Directorates have interpreted these SLPs into Standard Operating Procedures (SOPs) which detail what we need to do to comply with ISO 9K. (http://ace.arc.nasa.gov/cgi-bin/postdoc/get/postdoc/s/folder.ehtml?url_id=4607 for S directorate)
- These SLPs and SOPs specify Procedures and Work Instructions which we must follow in doing our work (research, instrumentation, etc.) and what Quality Records we must maintain in order to document our compliance with our procedures.
- Quality Records are very specific documents required by the ARC ISO 9K system to demonstrate our compliance with it. Objective Evidence of doing your work is “unofficial” documentation such as research notes, papers published, etc.

How is ISO 9K implemented at ARC? (2/3)

- What is the ARC quality policy?



“Ames will provide world class quality products and services that meet or exceed our customers’ requirements” (this will be on the test)

- Q: Where are all the Procedures and Work Instructions that we’re supposed to follow? A: On the Center and Code S ISO 9K WWW sites:
Center: <http://dqa.arc.nasa.gov/iso9000/>
Code S: http://ace.arc.nasa.gov/cgi-bin/postdoc/get/postdoc/s/folder.ehtml?url_id=4607
BOOKMARK AND BROWSE THESE SITES!!!
- Q: What Quality Records are we supposed to keep?
A: Approved proposals, approval letters, ARC310 (kept by branch office), NF1676 (Division office), calibration records (users), design review & verification docs, etc. (see 53.S.0016.1, SLPs, and SOPs for details)

How is ISO 9K implemented at ARC? (3/3)

- Changing the System

- 1) The ARC quality system is still changing. You can request that SOPs, WIs, and other controlled quality documents or data be added or modified by submitting a Document Change Request (DCR, ARC form 760; see 53.ARC.0005).

- 2) You can also submit a Corrective Action Request (CAR; ARC form 755) to report a nonconformance or a *potential* nonconformance to the ARC quality system. See 53.ARC.0014

- Audits and ISO 9K Certification

Ames passed its ISO9K Certification Audit 28 - 30 April 1999 by a licensed ISO Audit company, DNV. SSA will be internally audited on February 24 and again this spring in a surveillance audit which is required to maintain certification.

The auditors will ask you questions to determine whether you are aware of, are complying with, and are documenting your compliance to the ARC quality policy. If they find instances of non-compliance, then they will cite you with **CARs** or **NCRs**. These **CARS** and **NCRs** must be responded to as dictated by 53.ARC.0014. This will take effort on your part.

How does the Ames implementation of ISO affect SSA?

- The position descriptions of Civil Servants define the type of work we do. Details of how we are supposed to do our work are posted in center-level SLPs and Work Instructions and Code S Standard Operating Procedures.
- The Code S documents (53.S.00XX) apply most directly to us; they have been applied from the SLPs. At LEAST these Procedures, Work Instructions, and SOPs apply to SSA Civil Service Staff:

1. Ames Quality Policy (53.ARC.0000)
2. Quality Records (53.S.0016.1, 53.S.0016, 53. ARC.0016, and others below)
3. Management and Performance of Research (53.S.0009, 53.ARC.0009.2.1)
4. Calibration and Control of I, M, & T Equipment (53.S.0011, 53.ARC.0011)
5. Handling and Storage of Specialty Items - ESD, Storage (53.S/ARC.0015)
6. Design & Development of Hardware & S/W (53.ARC.0004.1, 53.ARC.0004.2)
7. ISO Document Control / Configuration Management (if required by your projects; 53.ARC/S.0005 and 53.ARC.0004.3)
8. Conformance to ISO9K itself (DCRs, response to CARs, etc. (53.S/ARC.0005.x, 53.ARC.0014, 53.ARC.0017)

How do we comply with ARC ISO 9K: Summary

- All SSA personnel should know their job title, have a copy of their position description (or NRC / contract / coop award letter), and know how they “fit” into the Ames / SSA organization.
- Look over the attached list of SLPs, Work Instructions, SOPs, and Quality Records. Figure out which apply to you (previous page) and browse over them on the WWW (no escaping from this!). See the SSA ISO Roadmap for help.
- Be sure that Lupe has your approved research proposals, their NRAs, & award letters (Since 6/98). Be sure that you have objective evidence of your research (papers -if 310s, logs) and / or technical (drawings, equipment maintenance procedures, etc.) work quality. Have all quality records for your current projects accessible (instrument calibration records, design review records, etc.). Know what forms of configuration management, document and materials (ESD etc.) controls are required by your projects. Show auditors published papers only if you have submitted ARC 310 and NF1676 forms.
- Become familiar with the concepts of DCRs and CARs. Read the attached FAQ and complete the checklist.

How do we comply with ARC ISO 9K: Calibration

- Each Researcher (PI or whatever) decides the calibration requirements for each piece of equipment he uses for research: **1)** Does not need calibration; **2)** Is user calibrated; **3)** Is calibrated by the Ames cal lab; **4)** Is calibrated by an outside lab.
- Each piece of equipment *must be labeled* as either: **1)** Calibration Not Required; **2)** User Calibrated; **3)** Calibrated (by Cal Lab; dates must not be expired); or **4)** Do Not Use Until Calibrated. See me or the cal lab for labels 1, 2, or 4.
- Self-calibrating equipment (e.g. FTIR spectrometers) should be labeled as “Calibration Not Required.”
- Prototype and experimental equipment is calibrated as you see fit. Other user-calibrated equipment must be calibrated as instructed in the OEM manual.
- Equipment users must maintain Calibration Records (logbooks or whatever) and OEM manuals for all User-Calibrated equipment as *quality records* - auditable!
- The auditors can also ask how you determined your calibration requirements: You must demonstrate (records or quantitative explanation) how you determined your calibration tolerance and how your methods meet that requirement.

Tips for the Upcoming Audit

- Read all of this material & browse the ARC ISO 9K documents!
- Make WWW Bookmarks for ARC and Code S ISO docs, other controlled documents, also NASA OSS Research Opportunities page (NRAs), etc.
- Become familiar with the concepts of SOPs, SLPs, WIs, SOPs, DCRs, and CARs.
- Make sure that your papers are in order - NRAs, research proposals, approval letters, have *instruments calibrated with calibration records*, copies of controlled drawings & procedures marked “*for reference only*”, design review documents (agenda, attendees, reports), CARs, etc.
- Read the attached FAQ and complete the checklist
- Remember that your *education and experience* qualify you to do your work and account for its quality (best practices).
- Be Discreet - don't volunteer any information to auditors that is not requested.