

**Energy Facility Contractors Group (EFCOG)
Software Quality Assurance Task Group**



White Paper

GUIDANCE FOR AUDITED ORGANIZATIONS

WP-2018-SAF-QA-SQA-001

Version 1.0

11/6/2017

Approved By: *Vicki L. Pope*
Vicki L. Pope, EFCOG SQA Chairman

November 8, 2018

Date

REVISION HISTORY

Document Version	Revision Date	Originator	Revision Description
1.0	11/6/2017	Art Young	Reviewed Final

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1. INTRODUCTION

A successful audit produces useful intelligence and credible conclusions – you believe it and you can act on it. Achieving that result is not entirely in the hands of the audit team. Like a coach that manages the game to put the players in the best position to win, the audit recipient can manage the audit process to get the best results.

Before the audit begins, focus on the end results you want to achieve:

- When the audit report comes out, there will be conclusions. Will you be able to explain and justify it to others?
- If there are findings, will the work required to resolve them be worthwhile?

These outcomes don't infer that you determine the audit conclusions and findings. The auditors do that. But once the auditors leave, you have to manage the results. Managing the results should guide your preparation and engagement before, during and after the audit.

2. PREPARING FOR AN AUDIT

An audit proceeds in accordance with a procedure, plan and checklist. Each of them is available to you. Knowing the rules of the audit can help you understand how the team operates. Briefly:

- An Audit Team Leader (ATL), certified to regulatory standards, leads the audit. There may be other auditors and technical experts on the team.
- The ATL prepares a plan and checklist and notifies the audited organization in writing of the audit scope and schedule.
- The audit team's intent is to find and document objective evidence on the checklist demonstrating that activities controlled by nuclear regulations have been effectively implemented.

So, the key to understanding what will be audited is the plan and checklist. *A well prepared audit recipient knows what's in the audit plan and checklist in advance of the audit team's arrival.*

3. THE AUDIT METHOD

Knowing what will be audited is one thing. Knowing how they audit is another. The key here is the part about "objective evidence."

Every auditor knows that objective evidence is documented proof that someone reviewing an audit report could see for themselves. The auditor needs to see this evidence in order to complete a checklist item. No evidence or insufficient evidence can mean only one thing – the activity was not done as required.

Audits typically assess evidence of compliance in two areas: program and implementation.

3.1. Program Assessment

Think of program documents as the interface between nuclear regulations and the tasks that individuals execute. Accordingly, program documents must:

- contain commitments to regulatory requirements
- explain the overall process for major activities
- identify organizational accountabilities for the process
- reference implementing procedures

Written commitments show that the organization knows which quality and technical standards apply to specific activities. Process descriptions, including organizational accountabilities and references to implementing procedures for each sub-process, provide evidence that the organization has an approved method for doing the work. By stating who is accountable for the process there is evidence of management control.

Auditors will then review implementing procedures to assure that the sub-processes and tasks required by the program document have been adequately described. The test here is whether an adequately trained individual can be expected to complete the steps and produce the requisite results and documentation required by the procedure.

Auditors will review the program documents and implementing procedures to verify they contain and correctly specify all of this evidence.

3.2. Implementation Assessment

Here auditors will look for records. Records result from following implementing procedures. The auditors will assess the adequacy of the forms and instructions specified in the implementing. They will then look for the completed records.

With an understanding of the audit method, you can anticipate what programs, procedures, and records the team will expect to see. *A well prepared audit recipient has assembled and reviewed the program, procedures, and records before the audit team arrives.*

4. THE AUDIT PROCESS

The ATL and team members start the audit with an entrance meeting. You're invited. They are required to introduce the team, the plan, and the checklist. They also establish lines of communication with the audited organization.

Communication with the audit team makes the difference between useful outcomes and needless effort on both parts. Even the auditors don't want to waste time. The better the communication between the team and the auditees, the less likely misunderstandings arise.

Oral communication is good, but written communication is better. Written words have the effect of forcing the author to be clear and forcing the reader to be aware. Auditees are well within the bounds of propriety to ask for a daily summary meeting with the audit team and to ask for a written summary of emerging issues and concerns. *A well prepared audit recipient communicates with the ATL everyday and asks for written progress reports during the audit.*

The audit team will conduct an exit meeting before they leave. They may or may not have the report written at that point. Usually audit reports are issued 30 days after the audit. They will certainly present their audit findings, if any, that require corrective action. And they should characterize their overall conclusions about the effectiveness of the activities they just audited.

The exit meeting is the wrong time to first learn about findings. You should have known about them before the exit. Thirty days after the exit is the wrong time to first learn of adverse conclusions and impressions in the audit report. You should have determined that at the exit meeting.

You have an obligation to assure that the auditors have the facts and that their conclusions are proper. Auditors are human and they can make mistakes about facts or confuse opinions with objective conclusions. *A well prepared audit recipient asks to see the facts and questions the conclusions drawn by the auditors before they submit their findings or the report.*

5. THE AUDIT RESULTS

So, now you have the audit report and possibly some findings. Regardless of the findings and conclusions, if you were prepared and engaged the team effectively the results are no surprise. The audit conclusions and findings should be valid.

Now you have great control over what happens next. You should realize that whether the results were favorable or not, you have work to do. Favorable results are cause for recognition. Your program works and independent auditors have said so. An audit with no findings is cause for celebration. You and your staff should be pleased that you've passed a nuclear grade compliance audit with flying colors. But you know that complacency is the enemy of excellence. There is always room for continuous improvement.

But even if the results indicate problems, you know that the corrective actions will be valuable because the conclusions were valid. Make sure you engage the corrective action program. It's there to guide you to fully correcting the problems and preventing their recurrence. You can also ask for help. The QA organization is a great resource. So is a well crafted self-assessment process. *A well prepared audit recipient demonstrates commitment to quality by promptly responding to the findings and being proactive about the corrective measures.*

6. SUMMARY

6.1. Before the Audit

- *Know what's in the audit plan and checklist in advance of the audit team's arrival.*

6.2. During the Audit

- *Assemble and review the program, procedures, and records before the audit team arrives.*
- *Communicate with the ATL everyday and ask for written progress reports during the audit.*
- *Ask to see the facts and question the conclusions drawn by the auditors before they submit their findings or the report.*

6.3. After the Audit

- *Demonstrate commitment to quality by promptly responding to the findings and being proactive about the corrective measures.*

A1. TEAM MEMBER BIOGRAPHIES

Art Young (ANL), Task Team Lead

D'Ann Bretzke (LANL)

Steve Gauthier (ANL)

Jennifer Turgeon (SNL)