Presents

ISO 9001
Auditor Process Toolkit

By

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About the Company

Smithers Quality Assessments (SQA), founded in 1993, is an accredited quality, environmental and safety management systems certification body serving industrial, commercial, government, and service businesses.

We are accredited as a registrar for the following standards:

- **ISO 9001 Quality**
- **ISO 14001 Environmental**
- **ISO/TS 16949 Automotive**
- **AS 9100 Aerospace**
- **ISO 13485 Medical Device**
- **OHSAS 18001 Health & Safety**

Additional services include:

- **1st Party Internal Audits**
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- **GMP (Good Manufacturing Practices)**
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- **2nd Party Supplier or Special Audits**

For over 20 years, SQA has built its business on the philosophy of 'education and preparation leads to success" and a "no surprises" approach to customers. Every customer is important to us, regardless of size. We are always upfront, honest and fair in our business practices.

To best serve SQA's growing client base, we have our world headquarters located in Akron, OH and supporting offices in the United Kingdom and China.

There is a common weakness in internal audits. The old element-based checklist method was easy to use - just a series of checklist questions and answers. But over time, the checksheets became less effective. Audits focused on the same few questions, again and again. They ceased to uncover other issues and improvements.

The **ISO Process Approach** is much better. It follows audit trails through the process and into related linked processes, but it is much harder to perform well. The major weakness is without checksheets, auditors have little guidance as to what to audit.

A solution is to develop tools and worksheets that provide auditors with guidance, but not specific questions. Worksheets should outline the necessary parts of a good process audit without limiting the auditor to a few specific questions and paths.

ISO/TS-16949 and other ISO 9001 based standards require audits be performed using a "Process Approach." It is not enough to just audit the ISO standard, procedures or manufacturing. Audits must do more than check whether people "are following their work instructions." Each process (Core and Support processes) in your Quality System should be thoroughly assessed for **both** conformance and effectiveness. Audits must assess how each process is performing to determine improvements.

For example, is the process meeting objectives? Are customer needs being met? Are there bottlenecks? How effectively does it interact with other processes? Do people have good skills? Are work instructions clear? Are there areas where you can save time or money? Audits need to address these areas and more, if you want to improve your company's processes and performance.

To follow a Process Approach, audits must be scheduled according to the processes defined in your QMS. The schedule should not be based on the clauses of the ISO standard, or to your procedures.

Process Audits should address **3 important stages of process auditing –**

- **Stage 1** – Prep the Audit (Desk Review)
- **Stage 2** – Audit the Process and Linkages
- **Stage 3** – Write Executive Summary Audit Report

STAGE 1 - PREP THE AUDIT (DESK REVIEW)

Another key solution toward effectiveness is good prep and organization. Before auditing, **prepare thoroughly**! An hour preparing will make you a better auditor, and a **much more effective audit**.

Auditors frequently skip this step, and it strips much value from the audit. Taking time to prep and organize actually **saves** time.

Gather relevant documents and records for the process you are auditing, such as process metrics, instructions, turtle diagrams, flowcharts, etc. If applicable, collect Control Plans and FMEAs too. Review these documents **thoroughly,** and **mark what you plan to audit**. You can mark directly on the documents, and they become audit records.

Also, review relevant sections of the ISO standard. Your company documents may not include all the ISO requirements, and this is how you would discover that. If certain information is not available, it may become audit findings, even during prep.

Certain information and linkages should be audited. Some are required, some are simply good audit practice. Putting these sections into a worksheet format gives auditors a guide to follow, to ensure the relevant links are audited.

Following are examples of information that should be gathered and reviewed:

- **Audit Scope, Audit Objectives, Audit Criteria –** ISO requires this information be defined and documented. Usually, this is basic information - just document it and move on. But, when there are exclusions or unique situations, it can be significant. Be sure to record it in your audit plan.
    - **Audit Scope** defines what areas are included and excluded from the audit, what will be audited. Are there sections that are excluded, for example.
    - **Audit Objectives** define the purpose and what the audit should achieve.
    - **Audit Criteria** define what systems, standards, and documents will be audited.
- **Process Criteria, Metrics, Objectives and Performance –** Each process is required to define this in the QMS. Evaluate metrics and objectives to determine strengths and weaknesses. Compare actual performance to targets. This guides how you should allocate your audit time. If goals are not met, identify it as an audit trail. Where goals are met, focus more on other areas with greater issues.
- **Previous Audit Findings –** Verify if actions remain effective and closed. Review previous audit trails to see if there is more to review, or whether they should be audited again. Past problems areas may reveal more improvement opportunities.
- **Customer Complaints** and other **Corrective Actions** – Review previously identified problems and actions. Note what should be reverified to ensure problems and issues remain effectively closed. There could be incomplete actions, or new personnel that are not even aware of previous issues.
- **Process Inputs and Outputs, Internal Suppliers and Customers –** The QMS must define and document the Inputs and Outputs for each process. If your system uses flowcharts, turtle diagrams, process maps, etc., it should be documented there. Are inputs and outputs clearly defined? Do you see issues?

- **Relevant Sections of the ISO Standards –** Review sections in the applicable ISO Standard (ISO 9001, ISO/TS-16949, etc.) that are relevant to the assigned process. Print those pages and mark significant requirements to ensure they are documented correctly within the QMS, and that they get audited.
- **Flowcharts, Turtles, Procedures, Instructions, Records, Process Sequence –** Review the documents that describe and control the process. Review all the important steps and activities of the assigned process being audited. This info must be documented within the QMS. Evaluate how effectively the process flows through the steps. Do you see roadblocks or issues? Make notes directly on the company documents (saves time). During the audit, use them as checksheets, and audit the trails and notes you marked.
- **Links to Skills, Competencies and Training needed for each process –** must be documented. Should include Hourly and Salary. Review skill lists for the assigned process. Are there clear lists of skills for each position? Do they show enough detail? This is often a finding, where lists are generic with inadequate detail. Training is a key process of any system. Are there specific people or new hires you wish to review? Are there particular skills you want to evaluate? Collect names to review later.
- **Links and Interactions with other processes** – While it is key to audit relevant things about the assigned process, every process connects and interacts with other processes. It is also important to determine and audit relevant links other related processes. Often processes work well on their own, but don't "play" well with other processes. There may be areas to improve. These links must be documented in the QMS. Plan how you will audit the relevant links and interactions. Note: you won't audit the full linked processes, just the relevant linkages. Audit the parts that interact with the assigned process.

Prep these documents and audit materials well. It is quicker and easier to audit if you have all the information at hand, marked and organized. You will be more knowledgeable, confident, and prepared. You can make notes on worksheets or directly on the company documents. Mark the key requirements to be audited and use them for questions and audit trails. They will be a key part of your audit.

Are the documents clear, accurate and easy to understand? Do they clearly describe the process? Are there problems? Errors? Omissions? You can write directly on the documents to save time. This becomes part of the audit pages. Write answers and findings directly on the pages next to your questions. Your worksheets are a guide, and your company documents give specific details for your process. Two parts which together make the whole audit package.

Allow adequate time to perform this Prep Stage well. It will save you time later. It should provide a good understanding of how the process should run. Information and documents you prepped will become the questions and audit trails during the audit. They will guide your audit and show relevant process linkages. You will be more knowledgeable, confident, and productive. You may even know current performance

data as well as people working in that process. Prep well, it will save you a lot of time and make a better audit. Do your Prep at the computer and it will be neater. Gaps you find during Prep often become findings.

When you have finished Prep, print the pages you prepared, and organize it into a logical flow. Then you are ready to **move on to the Audit stage**.

STAGE 2 - AUDIT THE PROCESS AND LINKAGES

The actual audit will walk through the sequence of the process from start to finish; as well as the key linkages you identified during Prep. You will review the same sections, sequence and details described above. This is why prep and organizing is important. There are so many pieces. You will have many notes and important bits of the process you intend to follow and audit.

You will audit the notations and questions you documented and organized into a logical flow. Simply work through the pages and paths you identified. If you see something interesting, you can follow that trail to see if it leads somewhere. If all is well, return to your notes and continue where you left off. If the trail leads to issues, follow your lead. Using this method, you will have more than enough material to keep you busy. It will identify the important trails. It will lead you to relevant links and performance issues. You will have audited the main process, and review links to related and supporting processes.

Review metrics and performance with appropriate Managers, Supervisors, Operators. They should know how things are running, objectives, customer issues, problem areas. If they do not, the requirements were not met.

Audit the sequence of the process with the people actually performing the process. Do people know and follow the steps? Is what they do the same as what is written? Are best practices documented and followed? Do personnel have changes they would recommend. **This is the key part of the audit**, coming directly from the company documents you prepped. This info should be documented within the QMS. If it is not clear, it may be a finding (cl 4.1.b). Review all the relevant steps of the assigned process. Evaluate how the process flows through the steps. Are the process steps effective? Do you see roadblocks or issues? Notate and follow audit trails you find with the relevant personnel. Observe their work. Look for things that are not as they should be.

Training, Skills and Competencies are always a potential area for improvement. Training and competency is vital and you should always review whether training could be improved. Pay particular attention to newer employees or people who do not demonstrate good skills or competencies. But, put people at ease, so they aren't so nervous. If there are people who do not seem to be "up on their game," collect names to review with the Training Process Owner.

Linkages and Interactions with other processes are always important**.** As you audit the assigned process, you will see how it connects and interacts with other processes. As you audit, also audit the **relevant** links to related processes and support processes. These would include the input handoff from the previous process, and the output handoff to the next process (as discussed above). But, it also includes interactions with relevant supporting processes, such as Training, Quality, Maintenance, Calibration, Record and Document Control, etc. Often a process will work pretty well by itself, but it doesn't always "play well with other processes" at the handoff points. These linkages often have room to improve. They must be audited as to how they perform and interact with the main process. Audit the parts you marked during prep. Note: you won't audit each full linked process at this time. Only audit the pieces that interact with the assigned process. The full processes will get audited when they are the "assigned process."

Mark findings and issues as you go. When you finish auditing, you should have a collection of various findings to review. Organize the notes you made, these findings need to be reported to management.

STAGE 3 – WRITE THE EXECUTIVE SUMMARY AUDIT REPORT

Prepare a well written, typed report with good content for Management, so they can take actions on the findings. This is **the most important stage**. This is *why* you audit. The audit report must be clear so the Process Owner understands the auditor's impressions, findings, ideas and conclusions. What is written into the report is what is likely to improve.

As you moved through the audit, you should have noted the issues and improvements you saw. These should have been marked clearly so you are now able to quickly review and capture them as you write the report. A good summary report is the output which is the value of the audit. It deserves an appropriate amount of attention and effort.

When you have completed auditing, you will probably have findings. Some might be problems, some might be Opportunities for Improvement. Review your notes. Collect the findings into summary pages.

Audit teams should review findings with the Lead Auditor and Audit Manager. This is an important part to calibrate the findings, and serves as a learning process. Then your summary should be finalized. If there is disagreement over some findings, the Lead Auditor has the final vote.

Your audit report summary should describe findings objectively, provide **objective evidence to support** the findings, and determine whether they should be classified as Corrective Actions, Preventive Actions, or Opportunities for Improvement. Audits are a great source for Preventive Actions. That is not emphasized enough. The audit team should also summarize a couple paragraphs of their thoughts, impressions, observations and conclusions of this audit. These findings and conclusions should be formally documented as part of the Executive Audit Summary Report. Too often, the

audit report only recites back facts and data the managers already know. The value is in identifying issues and opportunities they **don't** know! This summary should be reviewed first with the Lead Auditor, then the Process Owner and Management Team. Make final revisions, and file the final audit report and all supporting audit materials and notes.

Because this is the primary audit report, the **Executive summary report should be typed!** It is more professional, easier to read, and allows you to edit your comments to make them more clear. The CA/PA's will also be copied from the report. Bundle the whole audit package together, in an organized order. (The rest of the Work Instructions, flowcharts, notes and relevant papers should be bundled into the audit package as supporting records and do not need to be typed.) Findings should also be documented on your CA and PA forms, per your organization's procedure for Corrective Action. The audit summary, and the CA and PA forms should be attached to the top of the audit packet and turned in as an audit record. Only the summary report and corrective actions need be given to the process owner as well. They don't need copies of the paperwork, though they are permitted to review it.

The audit report and closing meeting should include:

- **Auditor Thoughts and Summary:** An audit is only as good as the audit report. The report is the product, output, deliverable, from an audit. No matter how good the audit you performed, the audit report is what you deliver. The report is how you "report" back to the Process Owner, what problems you saw, and what improvements you observed.
    - **Noteworthy general GOOD observations** - (Note any particular good things observed, above average effort, excellent people performance, ideas, input, etc.):
    - **Noteworthy general POOR observations** - (Note any particular weak issues observed, below average effort, problems noted, people, ideas, performance, etc.):
    - **General summary and observations -** (Type two or three paragraphs describing auditors' overall opinions, comments, observations, ideas, based on what they saw. Note: Official Findings will be itemized on the next page, don't need to list them here. Keep this general.):
- **List of Findings:** This is a specific listing of the NC's, Preventive Actions, and OFI Improvements and other formal findings you issue.
- **Corrective or Preventive Action Forms:** (Auditor fills out 3 parts - Finding, specific Objective Evidence and Clause Ref. from the standard or SOP). Manager is responsible for the rest.
- **Audit Meeting**: Review findings with the Lead Auditor and then the Process Owner.