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THE AUDIT CHECKLIST
YOUR KEY TO AUDIT SUCCESS

J. H. Maday, Jr.

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# THE AUDIT CHECKLIST
## YOUR KEY TO AUDIT SUCCESS

Joseph H. Maday, Jr. (ASQC-CQA)
Technical Group Leader - Quality Verification Department
Pacific Northwest Laboratory [1]
Richland, Washington 99352

## ABSTRACT

As the old saying goes, "If you have no objective, any road will take you there." So it is with the audit checklist. The checklist is the primary tool for providing order to Quality Assurance audit activities. With a well-planned and well-defined checklist, success is achievable. Without a checklist, the auditor has a disjointed, disorganized activity and no place to document his or her failed efforts. A number of formal quality programs which include audits as one of their program elements require the audit to be performed using a checklist or procedures[2] to document what the auditor reviewed and what he or she found. It is the intent of this paper to provide the reader with some insight as to the value of the checklist; the varieties of checklists that can be constructed; the pitfalls of improper application; and the success that can be achieved when the checklist has been properly researched, developed, and deployed.

## "WHAT DOES THE CONTRACT SAY?"

While conducting an audit interview with one of my colleagues in Columbus, Ohio, I saw a quote that had been captured in a picture frame and mounted on the individual's wall. It said, "What does the contract say?" For a Quality Assurance Auditor, this could be the ensign around which we rally. Before you can sit down and develop your checklist, you must know what the governing requirements documents say. The source for such information will be located in the work authorization documents (i.e., a contract, a memorandum of understanding, or a statement of work). These items should be a standard bill of fare as the auditor researches before preparing the checklist.

It is my belief, and one shared by many experienced auditors that I know, that the amount of preparation given to an audit checklist will be directly reflected in the success of the overall audit. That is to say, the audit

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[1]   The Pacific Northwest Laboratory is operated by Battelle Memorial Institute for the United States Department of Energy under contract DE-AC06-76RLO 1830.

[2]   ANSI/ASME NQA-1-1989, Criteria 18. Audits; Basic Requirement, "...audits shall be performed in accordance with written procedures or checklists by personnel..."

checklist should ensure that the audit will be performed in a uniform manner; should provide the team participants with a common objective; and if constructed with comprehensive attention given to detail and technical criteria, should provide a level of confidence that the end product is acceptable. If this is not enough evidence of the value of a checklist, consider the following:

- The checklist not only serves as a road map, it acts as an organizer during the field activities by providing order to your investigation.

- A completed checklist provides objective evidence that an audit was performed.

- It provides a documented display that all applicable aspects of a quality assurance program were verified.

- It provides historical information on program, system, or vendor problems.

- If supplemented with copious notes, it provides the essence for the audit exit interview and the audit report.

- It also provides an information base for planning future audits.

In his book <u>The Quality Master Plan</u>, J.P. Russell states, "Quality audits are measurement tools that assist management and employees in gauging the status of the quality improvement process. Audits evaluate how consistently the business...is meeting customers' expectations and needs."[3] I cannot imagine that anyone could undertake such an exercise without a comprehensive checklist from which to work.

## CHECKLIST VARIETY - CUSTOM TAILORED OR "OFF THE RACK"

When it comes to checklist variety, the types and styles available are as diverse as the industries and services applying quality. "Canned" or "generic" checklists can be applied across a broad spectrum of activities. "Cockpit" or "criteria" checklists are an excellent assessment tool while the "open-ended" or "effectiveness" provide for more in-depth insights.

### "Cockpit" or "Criteria" Checklists

The "cockpit" type of checklist will give you only yes or no answers. In his book <u>Management Audits</u>, Allan J. Sayle refers to this type of checklist as a "criteria checklist." Sayle explains the advantages and disadvantages of the "criteria checklist."

Advantages:

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[3] Russell, J.P. 1990. <u>The Quality Master Plan</u>, p.77. ASQC Quality Press, Milwaukee.

- Provides ready assessment of compliance with the relevant code, standard or regulation of interest.

- Focuses auditor's mind on the words of the code/standard, etc., and not the auditor's opinion of their meaning.

- Saves argument with extrinsic auditors about inadequate questions.

Disadvantages:

- Inconvenient when auditing on departmental or individual task basis.

- Requires experienced, trained auditor to relate requirements to an individual department or work task.

- Doesn't tell an inexperienced auditee what you want.[4]

## "Open-ended" or "Effectiveness" Checklists

The auditor can develop a checklist designed around a quality system that asks open-ended questions. The answers to these questions will provide the auditor with enough information to determine the effectiveness of the quality program, such as it is being implemented, and the knowledge possessed by the entity being interviewed.

An example of a "cockpit" type of checklist question may go something like this:

"Does the auditee have an adequate program for the control of computer codes and related software?"

Obviously this can be answered one of three ways...yes, no, or indeterminate. It would be more appropriate to ask that question as a primary evaluation question for which the final answer is provided based on the auditor using open-ended questions obtained from supplemental evaluation criteria. These questions would be posed in the following manner:

### Control of Computer Programs:

"How does the QA Program specify the initial design, design change, verification and validation test, and documentation controls applicable to computer software?"

"How do you ensure that changes to computer software are justified and subjected to the control measures commensurate with the approval of the original software?"

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4    Sayle, Alan J. 1988. Management Audits - The assessment of quality management systems, 2nd Edition, p.8-4. ASQC Quality Press, Milwaukee.

One more "effectiveness" question:

"Are there adequate controls in place to ensure that quality objectives are not compromised by unsuitable working conditions or lack of procedures, instruction, or training?"

And the supplemental evaluation criteria:

### Quality Assurance Program:

"How do the QA Manual and QA Procedures or Instructions incorporate adequate provisions to ensure that activities affecting quality are accomplished under suitably controlled conditions?"

"When reviews of actual work in progress are performed to verify compliance to this requirement, what preparation and planning does the auditee undertake to accomplish this review?"

The answers to these questions will provide the auditor with sufficient information to determine the degree of compliance; the degree of implementation; the overall effectiveness of the quality program; and finally, the knowledge the auditee has of the applicable program elements as they may relate to the auditee's area of control. I would not recommend using these types of checklist questions for a pre-award survey of a vendor as the auditor is more interested in the program capability at that point in the business relationship. Checklist questions would be perfectly acceptable once the contract has been placed and the pertinent quality system elements have been rolled into the contract.

### "Generic" or "Canned" Checklists

The "generic" or "canned" checklist is what Sayle refers to as "the company standard checklist." These are ready-made checklists that the auditing organization keeps on hand to expedite the preparation. Here again, Sayle cites the advantages and disadvantages.

Advantages:

- Uniform questions for the company audit teams.

- Train auditors in company requirements.

- Evidence of consistency for extrinsic auditors.

- Economy of printing in bulk.

- Quick review by company personnel.

Disadvantages:

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- May not be suitable for all audits.

- Stereotyped auditors; inflexibility; problems in dealing with different audit objectives.[5]

My personal preference is for the "custom tailored" checklist using the "open-ended" or "effectiveness" style. This format seems better suited to auditee and customer needs and will more accurately reflect those special elements that may have been imposed through contractual or other work-authorizing documents. Whichever checklist you choose, keep in mind the words of Goethe: "Things which matter most must never be at the mercy of things which matter least." Stephen R. Covey refers to this as "getting caught up in the thick of the thin." In other words, decide what are the most critical attributes to evaluate during the audit and make sure the checklist reflects them.

## THE RIGHT CHECKLIST FOR THE JOB [6]

Those of us who have the ability to perform our own automotive repairs or tuneups can appreciate the need to have the proper tools when we undertake such a task. Trying to remove sparkplugs with a pipe wrench or replacing disk brakes with the drum type brake just is not going to get the job done as well as if we use the right equipment and replacement parts. Certainly using a Cadillac key will not get the old "Beemer" up and running either. Periodically, as quality assurance auditors, we have grabbed the wrong tool for the job, and the results have been less than satisfactory.

Not long ago, I was performing an assessment of several different tasks and had a prepared checklist at my disposal. During the planning stage I reviewed the checklist for applicability and adequacy for the job I was about to undertake. The questions seemed appropriate. I had used the checklist before with great success and felt comfortable using it for the upcoming assessment. As the assessment got under way, I applied the questions on the checklist to the various projects. The checklist seemed to be working well. The checklist was providing answers and even some indication of the degree to which the program was being implemented for those projects.

As the assessment progressed, I was beginning to feel somewhat euphoric about the success I was having with the "new" application of this checklist to the tasks being evaluated. However, my euphoria was to be somewhat short-lived. During my planning and checklist review, I failed to recognize that one of the projects included in the assessment had much more rigorous requirements than the others in the population. In fact, the checklist was designed to assess the bare minimums required for a given quality system. Although the checklist

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[5]    Ibid. p. 8-10.

[6]    Originally published as "The Right Checklist for the Job" by Joseph H. Maday, Jr., "QATC Newsletter" for the Quality Auditing Technical Committee of the American Society for Quality Control, April 1988, p.3. Revised and updated for the purposes of this paper.

was appropriate for the other projects, it became rather ineffective when applied to a task requiring an increased level of quality assurance. What was really needed was a checklist that provided a greater attention to detail and possibly also covered client-specific requirements. It was fortunate that I recognized this need and was able to expand the checklist accordingly.

## THE PARADIGM SHIFT

In his book The 7 Habits of Highly Effective People, Stephen Covey relates the story of Frank Koch as it was told in Proceedings, the magazine of the Naval Institute.

> Two battleships assigned to the training squadron had been at sea on maneuvers in heavy weather for several days. I was serving on the lead battleship and was on watch on the bridge as night fell. The visibility was poor with patchy fog, so the captain remained on the bridge keeping an eye on all activities.
>
> Shortly after dark, the lookout on the wing of the bridge reported, "Light, bearing on the starboard bow."
>
> "Is it steady or moving astern?" the captain called out.
>
> Lookout replied, "Steady, captain," which meant we were on a dangerous collision course with that ship.
>
> The captain then called to the signalman, "Signal that ship: We are on a collision course, advise you change your course 20 degrees."
>
> Back came a signal, "Advisable for you to change course 20 degrees."
>
> The captain said, "Send, I'm a captain, change course 20 degrees."
>
> "I'm a seaman second class," came the reply. "You had better change course 20 degrees."
>
> By that time, the captain was furious. He spat out, "Send, I'm a battleship. Change course 20 degrees."
>
> Back came the flashing light, "I'm a lighthouse."
>
> We changed course.[7]

Covey explains, "the power of the paradigm shift is the essential power of quantum change, whether the shift is an instantaneous or a slow and deliberate

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[7]    Covey, Stephen R., The 7 Habits of Highly Effective People, Fireside, 1990, p.33

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process."[8]  So it must be with checklists.  If you are a new auditor, your checklist preparation will evolve and, hopefully, this paper will aid in that evolution.  If you are an "old hand" and your audits have been less than effective, then perhaps it is time to make a paradigm shift in your audit program.  Regardless, consider the words of Eric Fromm:

> Today we come across an individual who behaves like an automaton, who does not know or understand himself, and the only person that he knows is the person that he is supposed to be, whose meaningless chatter has replaced communicative speech, whose synthetic smile has replaced genuine laughter, and whose sense of dull despair has taken the place of genuine pain.  Two statements may be said concerning this individual.  One is that he suffers from defects of spontaneity and individuality which seem to be incurable.  At the same time it may be said of him he does not differ essentially from the millions of the rest of us who walk upon this earth.

As you develop your checklists and present them to the auditee, be spontaneous yet reflective of the requirements.  Communicate those requirements and realize that someday you too will sit in the seat of the auditee.

## IN CONCLUSION

It makes no difference if you are a Fortune 500 company with tens of thousands of employees or a small sole proprietor, you can benefit from audits that are well prepared and executed.   Once completed, the checklist will identify strengths and weaknesses and give to you what J.P. Russell calls, "a renewed customer focus." Your key to that focus and success will continue to be the audit checklist.

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[8]    Ibid. p.32

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