

# **How to Audit the Process-Based QMS**



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# How to Audit the Process-Based QMS

Dennis R. Arter, Charles A. Cianfrani,  
and John E. (Jack) West

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# Preface

This book is intended to help those involved in managing and conducting audits to ISO 9001:2000. It can be used as a guide to establishing a new audit program or for revitalizing one that has been operational for some time. It focuses on achieving an audit program that produces value-adding results for the organization.

To facilitate ease of use by the reader, this book consists of a general introduction followed by four parts:

- Part I Process-Based Internal Quality Auditing
- Part II Audit Program Management
- Part III The Process of Auditing
- Part IV Aids to Audit Program Implementation

## USING THIS BOOK

The user should first read the book in the order it is presented. As you read, refer to the items in part IV to understand how the concepts may look on paper. This gives a complete understanding of how the concepts can be adapted to a specific set of circumstances. Icons in the margins direct the reader to the appropriate items in Part IV. The items presented in Part IV include:



*Tools* (forms or worksheets) that can aid in accomplishing a recommended activity



*Checklists* that can be used to ensure that all activities have been considered.



*Questions* that should be considered when auditing processes, functions, or specific requirements of ISO 9001:2000.

We believe that the art and science of auditing quality management systems that have been designed and implemented following the process approach (the foundation of ISO 9001:2000) will be much more challenging and interesting than auditing 20 discrete elements to determine if documented procedures and records exist.

Auditing a process-based QMS, or even small elements of such a system, requires auditors to understand and integrate into an audit all aspects of organizational activities, from high-level planning through ensuring that customers are satisfied.

Indeed, the role of auditing is evolving, and the skills and competence required to do it well also need to evolve. We believe that the contents of this book will help auditors understand their role in the organization and to discharge their auditing duties in a way that is challenging to them and contributes to the success of the organization.

# Part I

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## **Process-Based Internal Quality Auditing**

### **INTRODUCTION—THE BASICS OF PROCESS-BASED INTERNAL QUALITY AUDITING**

Part I provides a broad overview of the basic elements of auditing, and specifically auditing ISO 9001:2000–based quality management systems. It discusses the concepts behind auditing, reviews audit principles, describes the process approach to quality management systems, addresses how to audit a process-based system, and reviews the two basic purposes for conducting audits.

This section is divided into four chapters. Chapter 1 addresses internal audit concepts, principles, and requirements. It defines auditing and provides a practical explanation of the principles that internal audit programs and auditors should use as their basic guides. It also covers the internal audit requirements of ISO 9001:2000 and discusses how those requirements should be applied.

Chapter 2 is dedicated to a detailed explanation of the process approach. It discusses the eight quality management principles that were used as key input for the development of ISO 9001:2000. It explains how organizations should use the process approach in developing their quality management systems. A complete understanding of these concepts is essential for auditors who will audit systems to the requirements of ISO 9001:2000.

Chapter 3 addresses auditing the process-based quality management system. It provides insight into the audit processes that can be used, and gives strategies for auditing a process-based system.

Chapter 4 provides an understanding of the distinction between auditing to ensure conformity to requirements and auditing for performance improvements.

# 1

## Internal Audit Concepts, Principles, and Requirements

**P**eriodic evaluations are essential to ensure the effective, ongoing implementation and improvement of any quality management system. Various types of evaluation techniques are used. Inspection, statistical process control (SPC), and product auditing are commonly used for products and processes. For quality management systems, the most common techniques are auditing, management review, and self-assessment.

*Auditing* is a process in which an objective and impartial evaluation is made of all or part of a quality management system's implementation against agreed-upon criteria. This chapter discusses the requirements for internal auditing as found in ISO 9001:2000, clause 8.2.2, *Internal audit*.

Internal quality audits are used to evaluate the adequacy of documents used to implement the quality management system, whether quality management system requirements are being met, and the effectiveness of system implementation. Audits can also be used to identify opportunities for improvement.

Internal audits are conducted by, or on behalf of, an organization for internal purposes and can form the basis for the organization's self-declaration of conformity. Supplier audits are conducted by customers of the organization or by other persons on behalf of a customer. Registration and government audits are conducted by external organizations outside of the typical customer-supplier relationship. All of these organizations can verify whether requirements, such as those of ISO 9001, are being met.

*Management review* of the quality management system is a process by which top management conducts regular, systematic evaluations of the

suitability, adequacy, effectiveness, and efficiency of the quality management system with respect to the quality policy and objectives. This review is the subject of ISO 9001:2000, clause 5.6, *Management review*. The review process also should verify that the quality policy and quality objectives are aligned with and support achieving overall business policy and objectives. It can include consideration of the need to modify the quality policy and objectives in response to changing needs and expectations of interested parties. The management review includes determination of the need for actions to improve products and processes. Audit reports are among the sources of information used for this review of the quality management system.

*Self-assessment* is a process for comprehensive, systematic, and regular review of the organization's activities and results. We use the term to mean an evaluation in which the organization's activities and results are compared to performance improvement criteria such as ISO 9004:2000 or a model of excellence such as the criteria for the Malcolm Baldrige National Quality Award. Self-assessment methodology can provide an overall view of the performance of the organization, and the degree of maturity of the quality management system. It can also help to identify areas requiring improvement in the organization, and to determine priorities. Such self-assessments typically go beyond auditing against detailed requirements. In doing so, they look for opportunities for the organization to improve its efficiency and performance. Self-assessment is discussed in ISO 9004:2000, clause 8.2.1.5, *Self-assessment*, and a process for self-assessment is given in ISO 9004:2000, Annex A. Sometimes the term self-assessment is used differently to mean corporate internal audits (as practiced by operational or financial auditors) or assessment of personal values.

Some have argued the merits of one approach over the others. Organizations may wish to use all three since each has its own advantages. By its very name we can assume that self-assessment is normally performed by and for the organization being evaluated. This means that those who have the most extensive knowledge of the processes conduct the evaluation. The insight gained by these "insiders" can form the basis for fundamental process changes. Self-assessments tend to be very detailed examinations using high-level criteria most pertinent to the organization, and involve judgments on the maturity of the quality management system. They are generally conducted less frequently than the other two types of evaluations. Management review, on the other hand, involves an organization's top managers making determinations of their own system's sufficiency, adequacy, and effectiveness. Management reviews can use the results of self-assessments and audits as well as other data such as process



performance trends and customer feedback. Audits are somewhat different in that they are, by definition, independent activities conducted against fixed requirements such as ISO 9001:2000 and methods used for local implementation. Management review and self-assessment are characterized by direct involvement of those responsible for the processes being examined. Audit, on the other hand, is characterized by the concept of independence. While the topic covered in this book is auditing, the authors believe that organizations should employ a mix of all three techniques.

## AUDIT DEFINED

The concept of audit is defined by ISO 19011:2002 and by ISO 9000:2000 as:

“systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled”

This is a very flexible and useful definition. This definition is general and does not mention quality. Let’s elucidate the definition. Auditing is a process:

- For obtaining evidence (facts supported by credible data) related to the system, process, area, subject, or activity being audited
- For determining the extent to which the system, process, area, subject, or activity being audited meets some specified criteria
- That is conducted objectively and impartially

This definition provides a foundation for many of the concepts needed to manage and conduct audits.

## AUDIT PRINCIPLES

Any quality management system internal audit program needs to be grounded in the principles that govern good auditing. There are a number of principles stated in ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*, that can be used to guide the internal audit program and the internal auditors.

The principles deal with the overall integrity and operation of the audit program and the integrity of the program’s auditors, as well as how audits are conducted.

- a) Ethical conduct: the foundation of professionalism  
Trust, integrity, confidentiality and discretion are essential to auditing.
- b) Fair presentation: the obligation to report truthfully and accurately  
Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities.  
  
Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported.
- c) Due professional care: the application of diligence and judgment in auditing  
  
Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.  
  
Further principles relate to the audit, which is by definition independent and systematic.
- d) Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions  
  
Auditors are independent of the activity being audited and are free from bias and conflict of interest. Auditors maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions will be based only on the audit evidence.
- e) Evidence-based approach: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process  
  
Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.

**Figure 1.1** Principles from ISO 19011.

Source: BSR/ISO/ASQ QE 19011-2002. Used by permission.

The audit program should be able to achieve consistent results regardless of which auditor conducts a specific audit. Internal audits are a key input into top management's determination of the suitability and effectiveness of the quality management system. Management should be able to rely on the audit results to give a fair, accurate, and comprehensive picture of the quality management system. To ensure this consistency and reliability, the leaders of the audit program need to ensure that it evidences certain characteristics:

- *Objectivity.* The audit process should be set up so that personal feelings, opinions, or interests do not influence it. This means that the assignment of auditors must ensure that the individuals assigned to a particular audit can be objective. Naturally, this must be a key consideration in the determination of the individuals who are suitable for inclusion in the "pool" of available auditors.

- *Impartiality.* The audit program must not favor one part of the organization, one manager, or one process over others. The audit process should treat each part of the organization impartially. This includes audit scheduling, audit frequency, assignment of auditors, conduct of audits, and reporting of audit results.

- *Evidence-based focus.* The audit process should be focused on determining the truth. As with the legal system, auditing should attempt to determine "the truth, the whole truth, and nothing but the truth." But auditors are faced with limited time and resources, and truth can be elusive. To determine the absolute truth, it is necessary to consider all points of view. This just may not be possible given the constraints placed upon a particular audit. It means that auditors need to place most of their effort in determining the facts. The definition of the term "audit" includes the idea of obtaining evidence and comparing that evidence against criteria in an objective and impartial matter. It may be impractical or even impossible for the audit program to determine the "truth"—but it must at least get the facts straight. The audit evidence should be made up of facts supported by credible data. The audit evidence should be sufficient to justify any conclusions drawn from it. While audit evidence may be based on sampling, it is often not feasible to draw sufficiently large sample sizes to achieve high statistical confidence levels. This means that the auditor training process needs to ensure that auditors are capable of making good judgments as to sampling results.

- *Competency.* The audit program should ensure that auditors have the requisite skills, training, educational background, and experience to perform their assigned audits. Auditors should never be assigned to audit processes for which they are not qualified. The relationship between the audit boss and the auditors needs to be such that an auditor can fully discuss and obtain resolution of any audit situation in which he or she feels uncomfortable. The audit boss is that individual in the organization responsible for managing and leading the audit process.

- *Cooperation and trust.* While it is not mentioned in most lists of audit principles, the idea of trust is central to auditing for performance improvement. The audit boss must facilitate an environment of cooperation between auditors and auditees. This environment is such that auditors really do have performance improvement in mind as they gather their evidence. Without compromising the other audit principles, they focus on that which is good for the entire organization. Auditees need to feel that they too are part of the team and recognize audit results as key inputs to improving their own work management activities.

In addition to these principles for the audit program, auditors must abide by certain ethical principles in their work:

- *Professionalism.* Auditors must be diligent, conscientious, and skillful in their work.
- *Honesty.* Auditors must always be responsible and not withhold reporting of issues, nonconformities, or violations when sufficient evidence indicates they exist. Auditors must never support or participate in any activity that violates customer, statutory, regulatory, or internal requirements. They also need to be honest with the auditees.
- *Ethics.* Credibility of the audit process is maintained only if auditors adhere to ethical standards. Auditors must remember that their role is to discover evidence, compare it to criteria, and to reach reasonable conclusions regarding how well the criteria have been met. The role is not one of a consultant or advisor. Regardless of the objectives of an audit, auditors should focus on identification of issues and gaps and never provide advice as to how these issues should be addressed or what action should be taken to close the identified gaps.
- *Confidentiality.* Auditors need to be prudent in their use and protection of information they obtain during audits. Information

gained in audits should never be used for personal gain in any way. Likewise, proprietary information that gives the organization a business advantage must be protected from unauthorized disclosure.

- *Duty to report.* Auditors may uncover evidence of fraud or other possible legal violations during their evaluations. They have a duty to report the matter to the audit boss, and to other officials inside or outside the organization (as appropriate) if action is not forthcoming. Of course, collected evidence should be protected for possible use in legal proceedings.

These audit principles are basic ideas or beliefs that must be observed in developing audit programs and in conducting audits. It is important for both auditors and those responsible for managing audit programs to keep these audit principles in mind. As we shall see, the internal audit requirements of ISO 9001:2000 reflect much of what is found in the principles stated above.

## **INTERNAL AUDIT REQUIREMENTS OF ISO 9001:2000**

The internal audit requirements of ISO 9001:2000 are found in clause 8.2, *Monitoring and measurement*, so we can think of auditing as an activity that measures the implementation of the quality management system or of the system's parts.

Even as we recognize internal audit as a form of measurement, it continues to be an essential process to provide confidence in the effective implementation of the quality management system. Part II will discuss how to manage the overall audit program to meet the requirements of ISO 9001:2000, and to focus it on both ensuring that the quality management system meets requirements and continual improvement.

## **REQUIREMENTS FOR THE AUDIT PROGRAM**

Auditing should be recognized as a valuable, ongoing process. A one-time set of audits to meet ISO 9001 requirements in order to obtain registration does not constitute an audit program. Internal quality audits should not be

performed solely to prepare for visits by outsiders. Nor is it sufficient to conduct internal audits only when there are suspected problems. Audits must be scheduled and carried out on a periodic basis and at planned intervals. They should be used to determine whether the requirements of ISO 9001:2000 are being met and the degree to which the quality management system has been effectively implemented and maintained. Indicators of problems with the effectiveness of the quality management system may include the occurrence of high numbers of customer complaints or of high levels of scrap and rework within the organization. Clause 8.2.1 of ISO 9001:2000 requires organizations to monitor customers' perceptions as to whether customer requirements have been met. Internal auditors often use this information to identify product realization processes that require further investigation regarding the extent to which they have been effectively implemented and maintained. In a similar fashion, scrap and rework information may be of value for identifying subject areas for the internal audit.

Audits must be planned. This planning must take into account a number of factors including the importance and status of the processes and areas to be audited. The results of previous audits also need to be considered. The audit scope, frequency, and methodologies must be defined.

Whatever factors are considered, internal quality audits may be performed on parts of the quality management system or on the entire system. Audits may be performed by functional area (often called vertical audits) or by process (often called horizontal audits). The scope of each audit should be clear, and the audit methodology and frequency of audits within the audit program should be identified.

The auditing process must maintain independence. This means that it must ensure objectivity and impartiality. Certainly, auditors cannot be the individuals who perform the activity being audited. Internal auditors should be qualified to do their work. This is particularly necessary for "guest" auditors or technical experts who do not normally perform audits but are used to provide technical product or process expertise and may be inexperienced at auditing.

A written procedure is required to describe how audits are planned, conducted, and reported. The procedure must also address the records to be maintained. Audit results should be documented in a written report and records should indicate audit results including any deficiencies found.

All of the above audit program requirements are discussed in greater depth in Part II.

## REQUIREMENTS FOR FOLLOW-UP ON AUDIT RESULTS

ISO 9001:2000 requires that managers of the areas audited follow up on audit results. If problems are identified, corrective action must be taken in a timely manner. If audit results are good, follow-up should assure acceptable ongoing performance and continual improvement. The management system should establish normal time periods for responding to audit findings, such as 30 days. These normal periods might be reduced or extended for special circumstances. Audit results are required input to management reviews.

Follow-up actions should be evaluated to assure the effectiveness of corrective actions. This effectiveness should be reported to top management. The follow-up need not be part of the audit system if it is accomplished by other means. Auditors are generally involved in some way, however.

It may be useful for those who have used ISO 9001:1994 to compare the internal audit requirements of that standard with those of ISO 9001:2000. As can be seen in Table 1.1, we find only minor changes. Perhaps the most noteworthy changes may be the addition of scope, frequency, methods, criteria, and use of prior audit results in planning. While some organizations may see these as new requirements, many have included all of these in their audit programs for years. Some organizations may find the change in wording regarding the independence of auditors to be significant. But for the most part, there is no requirement in ISO 9001:2000 to change the way auditing is done.

**Table 1.1** Comparison of ISO 9001-1994 and ISO 9001-2000 internal audit requirements.

<b>ANSI/ISO/ASQC Q9001-1994 (4.17, Internal quality audits)</b>	<b>ANSI/ISO/ASQ Q9001-2000</b>	<b>Comments</b>
<p>The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.</p>	<p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</p> <p>b) is effectively implemented and maintained.</p>	<p>Very similar requirements for establishing procedures and conducting audits.</p> <p>New requirement is for determination of implementation" rather than "determine the effectiveness of the quality system." ISO 9001:2000 leaves determination of effectiveness to top management as a part of management review.</p>
	<p>The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.</p>	<p>Very similar to ISO 9001:1994.</p>
<p>Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.</p>	<p>An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p>	<p>New requirements include:</p> <ul style="list-style-type: none"> <li>• Inclusion of previous audit results in planning</li> <li>• Audit scopes</li> <li>• Audit frequency</li> <li>• Audit methods</li> <li>• Audit criteria</li> </ul> <p>Focus is on objectivity and impartiality of the audit process rather than just independence of auditors.</p>

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<b>ANSI/ISO/ASQC Q9001-1994 (4.17, Internal quality audits)</b>	<b>ANSI/ISO/ASQ Q9001-2000</b>	<b>Comments</b>
<p>The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.</p> <p>Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).</p> <p>NOTES</p> <p>20 The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).</p> <p>21 Guidance on quality-system audits is given in ANSI/ASQC Q1001 1-1-1994, ANSI/ASQC Q1001 1-2-1994, and ANSI/ASQC Q1001 1-3-1994.</p>	<p>The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.</p> <p>Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p>	<p>New requirement is more succinctly stated but essentially the same.</p> <p>Requirements are essentially the same when read with ISO 9001:2000 clause 8.5.2.</p> <p>ISO 9001:2000 now requires that audit results be used as an input to management review.</p> <p>The ISO 10011 series will be replaced by ISO 19011.</p>

Sources: ANSI/ISO/ASQC Q9001-1994 and ANSI/ISO/ASQ Q9001-2000. Used by permission.

