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The ASQ Certified Quality Auditor Handbook

Fifth Edition

Lance B. Coleman Sr., Editor

ASQExcellence
Milwaukee, Wisconsin

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Foreword

Change is the only constant, and changes to the audit profession continue in order to improve effectiveness and efficiency, as well as to adjust to changes in technology. We are no longer just process and system auditors—rather, members of our profession are valued teammates, helping to drive continual improvement and manage risk. Management system standards such as ISO 9000–based management systems are now viewed as starting points for organizational excellence. ASQ Audit Division members are no longer considered compliance police. Rather, our membership has evolved to meet the challenges of the new millennium, just as Norm Frank predicted in his Foreword to the second edition of this handbook. We are no longer just auditors—we are assessors, and our chosen discipline has grown to include advising management on best practices toward organizational excellence. We are teachers in the true sense of the word.

Thank you does not begin to express my appreciation to the subject matter experts skilled in the audit profession that have grown the Body of Knowledge (BoK), working in tandem with the certification department of what is now known as ASQExcellence, and keeping it up to current expectations and in line with the current standards. This book reflects the latest revision to the BoK and has been edited to assure that the most recent auditing knowledge has been added. Teams of ASQ Certified Quality Auditors (CQAs), working on your behalf, volunteered long hours to ensure that the BoK, reflected herein, represents generally accepted, world-class audit practices. The editor and reviewers of this book spent many hours assuring the excellence of this new version was ready for release.

This book has become the text of choice for candidates sitting for ASQE's CQA examination. The handbook is written such that it is the leading source of information for the exam needed to attain the CQA credential. Please enjoy our latest edition and use the information to grow your expertise. As has been stated many times before, the professional path leading from compliance auditing to system assessing can take time and determination, but the rewards are worth the effort. I think you'll find this book to be an invaluable resource to help you along that path.

—BJ Johnson, Chair, ASQ Audit Division

Notes to the Reader

This handbook supports the Quality Auditor BoK, developed for the ASQ Certified Quality Auditor (CQA) program. The Quality Auditor BoK was last revised in 2012. The fourth edition of the handbook (2013) addressed new and expanded BoK topics, common auditing methods (quality, environmental, safety, and so on), and process auditing. The handbook is designed to provide practical guidance for system and process auditors. Practitioners in the field provided content, example audit situations, stories, and review comments as the handbook evolved.

In this fifth edition, many current topics have been expanded to reflect changes in auditing practices since 2012, with guidance from the recent 2017 update of ISO 19011. As CQA refresher courses are taught between updates to the BoK and associated handbook, areas in need of clarification and the occasional error in fact are identified. This fifth edition of the handbook is an attempt to capture all of those requested improvements. Some previous topics have been deleted, and several have been added. Topics remain written to promote the common elements of all types of system and process audits (quality, environmental, safety, and health).

The text is aligned with the BoK for easy cross-referencing. We hope that use of this handbook will increase your understanding of the Quality Auditing BoK.

THE USE

This handbook can be used by new auditors to gain an understanding of auditing. Experienced auditors will find it to be a useful reference. Audit managers and quality managers can use the handbook as a guide for leading their auditing programs. The handbook can also be used by trainers and educators as source material for teaching the fundamentals of auditing. It is not designed as a standalone text to prepare for the ASQ CQA exam. As with all ASQ/ASQE certification activities, you are encouraged to work with your local ASQ section or ASQ's Audit Division for preparation. *The ASQ Certified Quality Auditor Handbook* (previously *The ASQ Auditing Handbook*), when used in conjunction with other published materials, is also appropriate for refresher courses, and we hope that trainers will use it in that manner.

The handbook contains information to support all aspects of the CQA BoK and is not limited to what new auditors need to know. Hence, the amount of material in each part of the handbook is not directly proportional to exam emphasis.

The CQA exam is designed to test a candidate's basic knowledge of quality auditing. All the information in the handbook is important, but those preparing for the CQA exam should spend more time on their weakest areas and on those parts of the BoK receiving more emphasis on the exam. The number of questions and the percentage of CQA exam questions are indicated at the start of each part of the handbook.

THE CONTENTS

The handbook is organized to be in alignment with the CQA BoK. We have included the BoK at the back of the handbook as Appendix F. Since many concepts and practices of process and system auditing are still evolving, the BoK will continue to be revised from time to time. As changes to the BoK occur, the handbook will also be revised to remain current.

Terms and definitions are addressed throughout the text. Definitions are taken from ISO 19011:2018 and ISO 9000:2015, with definitions from the former superseding the latter. Definitions have undergone extensive peer review and are accepted worldwide. However, even the definitions of audit terms continue to evolve to meet the needs of the users of the standard.

The ASQ Certified Quality Auditor Handbook represents generally accepted audit practices for both internal and external applications. Thus, it may not depict the best practice for every situation.

The handbook uses generic terms to support broad principles. For clarity, specific industry examples and stories from CQAs are sometimes used to explain a topic from the BoK. The stories, depicted as sidebars, are a way for auditors to share their experiences. Industry examples incorporated into the text and presented in the appendices are not intended to be all-inclusive and representative of all industries. We are pleased to incorporate examples shared by audit practitioners as a means to add value to the text. Needless to say, this work cannot address the most appropriate practice for every industry or organization.

In some cases, CQA information needs are the same as other certified professional needs. Several sections in Part V, "Quality Tools and Techniques," are the same as similar sections for Certified Managers of Quality/Organizational Excellence. All sections and chapters are clearly marked and referenced.

This publication, which describes audit methods and their application, is not intended to be used as a national or international standard, although it references many existing standards. The conventions for writing standards and the use of the term *shall* to mean a requirement and *should* to mean a guideline do not apply to *The ASQ Certified Quality Auditor Handbook.*

WHO WROTE IT

The CQAs who supplied information for the handbook represent a broad spectrum of organizations in the United States and around the world. More than 120 individuals contributed material for the first, second, third, and fourth editions. Input from members and a number of published texts were also used to create and develop *The ASQ Certified Quality Auditor Handbook*. It represents internal

and external audits in a variety of product or service industries, regulated and nonregulated.

For each edition, a developmental editor gathered material to address the BoK topics and issued a manuscript to be reviewed by audit experts and practitioners in the field. Extensive peer review further strengthened the manuscript. The editor sorted, culled, augmented, and refined the manuscript to be turned over to the publisher.

WHY THE HANDBOOK?

The ASQ Audit Division sponsored the development of this handbook to promote the use of auditing as a management tool—our primary mission. We believe that the Audit Division's members possess the greatest concentration of theoretical and practical auditing knowledge in the world. In *The ASQ Certified Quality Auditor Handbook*, we have tried to give you the benefits of this collective expertise.

—Lance B. Coleman Sr., Editor

Acknowledgments

What an honor this is for me to serve as editor of the fifth edition of *The ASQ Certified Quality Auditor Handbook*. I would like to acknowledge my colleagues Denis Devos, Carl Douglas, Andrew Davison, and Paul Russell for their contributions to the review and revision of this manuscript. I would also like to acknowledge the late J. P. Russell, not only for his outstanding work as editor of previous editions of this handbook, but also for his many contributions to our profession as a whole. I hope to be a worthwhile successor to his legacy. I would also like to acknowledge the ASQ Audit Division for promoting knowledge sharing, cutting-edge auditing practices, and ethical conduct for all auditors for over 27 years.

I would like to further thank my wife of 33 years, Lorraine, who has always been my support, my inspiration, and my love; and my son, Lance Jr., who along with Lorraine helped keep the house running smoothly so that I could dedicate the time needed to successfully complete this important task. And, finally, to my dogs, Leo, Shii, and Uhura, who help me recharge by making my return home each day a celebration of head bobbing, tail wagging, and barking.

—Lance B. Coleman Sr., Editor

Overview

This handbook is organized in the same way as the ASQExcellence (ASQE) Certified Quality Auditor BoK, starting with Part I and ending with Part V. This section was written as an overview of auditing to better prepare readers for Part I of the handbook and is not meant to be an explanation of the BoK.

The word *audit* is associated with formal or methodical examining, reviewing, and investigating. Professional groups such as ASQ, ASQE, and the Institute of Internal Auditors (IIA) define preferred methods for conducting examinations and investigations (to audit). For product, process, and system audits, the Audit Division of ASQ has developed the BoK for auditing. ASQE also certifies individuals who meet the criteria for Certified Quality Auditor (CQA), Certified Food Safety and Quality Auditor (CFSQA), and Certified Medical Devices Auditor (CMDA). This handbook explains the topics listed in the BoK issued by ASQE.

Auditing is a prescribed work practice or process. There is a preferred sequential order of activities that should be performed to conduct a proper audit. Part II of the BoK ("Audit Process") follows the same preferred order. Audits must be prepared for (planning ahead), then performed (conducting the audit), the results reported (let everyone know what was found), and then the results responded to (feedback on what is going to happen next) by the organization that was audited. It is common to refer to these as phases of an audit: preparation, performance, report, and follow-up and closure. As with most service jobs, the outcome is influenced by how the service provider performs the job. That is why Part I of the handbook is about audit fundamentals, ethics, and conduct. Auditing is considered a profession; therefore, individual auditors need to know how to conduct themselves in a professional manner.

In the late 1980s, the Quality Auditing Technical Committee (now the Audit Division of ASQ) defined *audit* as

> a planned, independent, and documented assessment to determine whether agreed-upon requirements are being met.

For now, let us think of a quality audit as an assessment to determine whether agreed-upon quality requirements are being met and will continue to be met (whereas an environmental audit may be related to environmental requirements, a financial audit related to financial or accounting requirements, and so on). A distinguishing attribute of an audit is objectivity. The individuals performing audits must be able to evaluate the area being audited in an objective and unbiased manner. The degree of objectivity varies depending on the situation and type of audit

(purpose and scope). For example, auditors can audit within their own department, but they cannot audit their own jobs.

There are several groupings or classifications of audits, depending on the relationships (external and internal), the need for objectivity, and the reason for the audit (verification of product, process, or system). In Figure I.1, the circle represents an organization. Outside the circle are the organization's customer(s) and supplier(s). All organizations have customer-supplier relationships. Any audits done inside the circle are *internal* audits, and audits done outside the circle are *external* audits. We further classify the audits as first-, second-, or third-party audits based on relationships. *First-party* audits are ones within the organization itself (the same as internal audits or self-assessments) and are inside the circle. *Second-party* audits are audits of suppliers or of customers crossing into the circle to audit the organization (their supplier). *Third-party* audits are totally independent of the customer-supplier relationship and are off to the right in the diagram. Third-party audits may result in independent certification of a product or service, process, or system.

Auditors can focus the audit (examination and investigation) on different areas, depending on the needs. A product or service audit determines whether product or service requirements (tangible characteristics or attributes) are being met. The process audit determines whether process requirements (methods, procedures) are being met. A system audit determines whether system requirements (manual, policy, standards, regulations) are being met. The handbook discusses all types of audits, but most of the discussion is focused on system audits (being the most complex and having the greatest potential influence). A system can be thought of as a group of processes providing a product or service.

Figure I.1 Types of audits.

Source: J.P. Russell & Associates training materials. Used with permission.

When auditors are auditing, they are making observations and collecting evidence (data). They are seeking to verify that requirements are being met. They do this by collecting hard evidence, not hearsay or promises. Evidence produced as a result of the activity may be tangible objects or records, or personal observations.

Auditors must be familiar with auditing techniques and the criteria they are auditing to. What auditors observe is not always straightforward or obvious, so they must be able to judge whether the intent (reason for the requirement) is being met or addressed. The audit evidence and the method of collecting the evidence form the basis of the audit report.

The primary participants needed for conducting an audit are the auditor, the auditee, and the client. The person conducting the audit is called the *auditor*, *lead auditor*, or *audit team leader*. The organization being audited or investigated is called the *auditee*. There is also a *client*, the person or organization that has requested the audit. Audits are conducted only when someone requests one; they do not happen by accident. There has to be a *sponsor* or client with the authority to call for an audit.

Any type of organization can be audited against a set of standard requirements. The organization can produce a product or provide a service, such as government agencies or retail stores. An organization can be audited against almost any type of standards or set of criteria. The criteria or standards can be government regulations, ISO 9001 or ISO 14001 requirements, International Automotive Task Force (IATF) 16949, Malcolm Baldrige National Quality Award criteria, customer requirements, and so on. If there is a set of rules, auditors can compare actual practice with the rules.

While auditors are comparing actual practice with the rules or standards (determining conformity or compliance to requirements), they may also observe that certain practices and trends are not in the best interest of the organization being audited. Hence, auditors may report compliance and noncompliance as well as areas that are not effective or areas that can be improved as input for management consideration. Auditors may also include best practices or good practices as part of an audit report so that they can be shared with other areas of the organization.

Findings are the results of the investigation. They may be reported as nonconformities/conformities, findings, noncompliances/compliances, defects, concerns, and so on. The audit results can include both positive and negative issues identified. It is important for everyone to agree on the terminology that will be used in the audit report.

Recently there has been more emphasis on looking beyond conducting the audit steps to the management of the audit process. It is important to understand the objectives of the audit function and the potential benefits to the organization. This understanding and clarification has resulted in some audit programs being strictly limited to auditing for compliance and other audit programs seeking information about the effectiveness and efficiency of internal controls.

Auditing is a management tool used to verify that systems and processes are compliant/conformant, suitable to achieve objectives, and effective. For additional background information on auditing, continue to Part I.

AUDITS ARE NOT INSPECTIONS

All too often the term *audit* is used to describe an inspection activity. Inspection is a tool to detect errors or defects before a product or service is approved for release or distribution. It is normally part of the manufacturing or service approval process. An organization may form a quality control department to manage and conduct the inspections.

In other cases, some organizations may use the word *inspection* to describe an audit. Audits conducted by the government (such as the U.S. Food and Drug Administration) may be described as inspections in regulatory documents. For the purposes of this handbook, we will differentiate between audits and inspections on the basis of national and international standards such as the ISO 19011 guideline standard regarding management system audits.

As organization sectors (other than manufacturing) attempt to apply auditing principles, they may become frustrated due to some initial misunderstandings. One of these misunderstandings is the way they use the term *audit*. For example, in the insurance industry, claims (such as medical, property, and liability) are processed as a case file. This file contains the insured party's claim, the evidence, the adjuster's report, the offered compensation, the accepted compensation, and the closing statement. All this paperwork is subject to error and omission, so the managers will audit these case files before they are ultimately closed. Sometimes the audit is performed before a check is cut. In reality, this is an inspection and not an audit.

The general public associates quality with conducting an inspection. The irony is that using inspections to ensure quality has proved to be too costly and ineffective compared with using other quality tools and techniques.

For more information on the history of quality control and auditing, see Appendix E, "History of Quality Assurance and Auditing."

Part I

Auditing Fundamentals

[28 of the CQA Exam Questions or 19 percent]

The purpose of Part I is to present audit purpose, scope, types, and criteria as well as auditor roles and responsibilities. The last chapter addresses professional conduct and consequences for auditors. Ethics affect professional conduct, and professional conduct affects liability and audit credibility.

Chapter 1
Types of Quality Audits

METHOD

An *audit* is a "systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled."[1] Several audit methods may be employed to achieve the audit purpose. There are three discrete types of audits: product or service, process, and system. However, other methods, such as a desk or document review audit, may be employed independently or in support of the three general types of audits. Some audits are named according to their purpose or scope. The scope of a department or function audit is a particular department or function. The purpose of a management audit relates to management interests such as assessment of area performance or efficiency.

Integrated Audit

An *integrated audit* (combined or joint) may be conducted by a few individuals or a larger team of auditors and can be employed with all types of audits. Included in this audit may be *first-*, *second-*, and *third-party* auditors. These types of audits are used to add depth, minimize bias, and reduce time to complete an audit.

Combined audits allow multiple auditors to divide into smaller groups (or work as individuals) to assess different management systems during the same audit—quality, medical, environmental, automotive, and so on. Each auditor or audit team provides a report on their area of audit to the lead auditor.

Joint audits consist of two or more auditing organizations. Generally, a joint audit is done to mitigate risks of bias. To minimize bias, an external third-party auditing firm is included in the audit. All auditors will share auditing responsibilities of the same system and provide a single report to the lead auditor.

Product or Service Audit

A *product or service audit* is an examination of a particular product or service (hardware, processed material, software) to evaluate whether it conforms to requirements (that is, specifications, performance standards, and customer requirements). An audit performed on a particular service is called a *service audit*. Elements examined may include packaging, shipment preparation and protection, user instructions, product or service characteristics, product or service performance, and other customer requirements.

Product or service audits are conducted when a product or service is in a completed stage of production and has passed the final inspection. The auditor uses inspection techniques to evaluate the entire product and all aspects of the product characteristics. A *product quality audit* is the examination or test of a product that had been previously accepted or rejected for the characteristics being audited. It includes performing operational tests to the same requirements used by manufacturing, using the same test procedure, methods, and equipment. The product or service audit verifies conformity to specified standards of workmanship and performance. This audit can also measure the quality of the product or service going to the customer. The audit frequently includes an evaluation of packaging, an examination for cosmetics, and a check for proper documentation and accessories. This may include verification of proper tags, stamps, process certifications, use of approved vendors, shipment preparation, and security. Product audits may be performed on safety equipment, environmental test equipment, or product to be sent to customers. They can be auditing a service or be the result of a service such as equipment maintenance.

A product audit is the examination of the form, fit, and function of a completed item after final inspection. It is technical; it may involve special (sometimes periodic) examination, inspection, or testing of a product or service that previously passed final inspection and has been accepted for characteristics being audited to ensure that it has not degraded over time; and it can be customer oriented. The reference standard for a product quality audit is the product quality program and the product performance specification. One of its characteristics is a complete examination of a small sample of finished product. Sometimes a product audit includes the destructive test of sample product.[2]

A service audit is one type of product audit. For many services, an auditor can verify physical attributes of the service that was performed. For example: Was the label added? Is the area clean? Have records been completed? Are tools organized? For other services, there are few or no traces of the service that was performed and therefore it must be verified by a process audit—for example, tuning an engine, performing repairs, receiving education or training, and receiving some personal services (a haircut can be checked and verified but not a massage).

Process Audit

The process audit is performed to verify that processes are working within established limits. "The process audit examines an activity to verify that the inputs, actions, and outputs are in accordance with defined requirements. The boundary (scope) of a process audit should be a single process, such as marking, stamping, cooking, coating, setting up, or installing. It is very focused and usually involves only one work crew."[3] A process audit covers only a portion of the total system and usually takes much less time than a system audit.

A *process audit* is verification by evaluation of an operation or method against predetermined instructions or standards to measure conformity to these standards and the effectiveness of the instructions. Such an audit may check conformance to defined requirements such as time, accuracy, temperature, pressure, composition, responsiveness, amperage, and component mixture. It may involve special processes such as heat treating, soldering, plating, encapsulation, welding, and nondestructive examination. A process audit examines the resources (equipment,

materials, people) applied to transform the inputs into outputs, the environment, the methods (procedures, instructions) followed, and the measures collected to determine process performance. A process audit checks the adequacy and effectiveness of the process controls established by procedures, work instructions, flowcharts, and training and process specifications.

Auditors conducting process audits should naturally follow the process. The audit method of following process steps is a *process audit technique*. The process audit technique is an effective audit method and offers a good alternative to auditing by clause element or department or function. System auditors may use process audit techniques to the extent possible when auditing a management system. While performing a process audit, it is sometimes useful to have a subject matter expert (SME) on that process be a part of or assist the audit team. Without subject matter expertise, the process audit team may not be able to probe deep enough on the "adequacy" expectation of the process under review.

System Audit

An audit conducted on a management system is called a *system audit*. It can be described as a documented activity performed to verify (by examination and evaluation of objective evidence) that applicable elements of the system are appropriate and effective and that these elements have been developed, documented, and implemented in accordance and in conjunction with specified requirements.

A *quality management system audit* evaluates an existing organization through the quality program to determine its conformity to company policies, contract commitments, and regulatory requirements. It includes the preparation of formal plans and checklists that are based on established requirements, the evaluation of implementation of detailed activities within the organization, and the issuance of formal requests for corrective action where necessary.[4] Similarly, an *environmental system audit* examines an environmental management system, a *food safety system audit* examines a food safety management system, and *safety system audits* examine the safety management system.

Criteria contained in the American Society of Mechanical Engineers (ASME) codes, nuclear regulations, good manufacturing practices, or International Organization for Standardization (ISO) standards, for example, may describe a management system. Normally these descriptions state what must be done but do not specify how it must be done. The "how" is left up to the organization being audited. An auditor looks at the management systems that control all activities from the time an order comes into a company (that is, how the order is handled, processed, and passed on to operations, and what operations does in response to that order) through delivery of the goods; sometimes this even includes transportation to the site and other postdelivery activities.

A system audit looks at everything within the system (that is, the processes, products, services, and supporting groups such as purchasing, customer service, design engineering, order entry, waste management, and training). It encompasses all the systems of the facility that assist in providing an acceptable product that is safe and conforms to applicable local, regional, national, and international requirements.

Desk Audit or Document Review

A *desk audit* or *document review* is an audit of an organization's documents. It can be conducted at a desk as it does not involve interviewing people or observing activities. If auditing a new area, function, or organization, a desk audit must be conducted prior to a process or system audit to verify that documents meet requirements specified in the audit criteria or standards. The document review verifies that there is an adequately defined process or system prior to the full process or system audit. Findings from a desk audit or document review help ensure that audit program resources are used efficiently. It would be very costly if an audit team arrived to do a system audit, only to find out that the established system was not adequate. Also, a desk audit or document review may be conducted periodically or when documents or processes are changed to verify the appropriateness of the changes.

AUDITOR-AUDITEE RELATIONSHIP

First-, Second-, and Third-Party Audits

First-Party Audit

A *first-party audit* is performed within an organization to measure its strengths and weaknesses against its own procedures or methods and/or against external standards adopted by (voluntary) or imposed on (mandatory) the organization. A first-party audit is an internal audit conducted by auditors who are employed by the organization being audited but who have no vested interest in the audit results of the area being audited. The auditing management systems standard ISO 19011, paragraph 4e, states that the independence of the audit team members from the activities to be audited should be considered and that conflicts of interest when selecting audit team members should be avoided. Companies may have a separate audit group consisting of full-time auditors, or the auditors may be trained employees from other areas of the company who perform audits as needed on a part-time basis in addition to their other duties. One of the benefits of using part-time auditors is that the auditor learns the requirements by evaluating the objective evidence to determine conformity with the requirement beyond their normal work assignment.

In some cases, an organization may hire (outsource) an audit organization to conduct its internal audits. The benefits of hiring an external auditing organization are that internal employees do not have to take time from their day-to-day jobs, auditors may be more objective and impartial, and the organization may benefit from employing more experienced auditors. The downside of outsourcing is that contract auditors may not be familiar with company culture, strategic direction, employee concerns of the moment, and other factors that might impact audit results.

A multi-site company's audit of another of its divisions or subsidiaries, whether it is local, national, or international, is often considered an internal audit. If, however, the other locations function primarily as suppliers to the main operation or location, audits of those sites would be considered second-party audits.

Second-Party Audit

A *second-party audit* is an external audit performed on a supplier by a customer or by a contracted organization on behalf of a customer. A contract is in place, and the goods or services are being (or will be) delivered.[5] Second-party audits are subject to the rules of contract law as they are providing contractual direction from the customer to the supplier. Second-party audits tend to be more formal than first-party audits because audit results could influence the customer's purchasing decisions. A *survey*, sometimes called an *assessment* or *examination*, is a comprehensive evaluation that analyzes such things as facilities, resources, economic stability, technical capability, personnel, product or service capabilities, and past performance as well as the entire management system. In general, a survey is performed prior to the award of a contract to a prospective supplier to ensure that the proper capabilities, controls, and systems are in place. The scope of the survey may be limited to specified management systems, such as quality, environmental, or safety systems, or it may include the entire organization's management system.

> An auditor told of one case in which an organization wanted to acknowledge a supplier for the perfect product it had been receiving. However, during the award process, it was discovered that the supplier had absolutely no quality system in place! The supplier was able to ship an acceptable product simply because its employees were good sorters.

Third-Party Audit

A *third-party audit* is performed by an audit organization independent of the customer-supplier relationship and is free of any conflict of interest. Independence of the audit organization is a key component of a third-party audit. Third-party audits may result in certification, registration, recognition, an award, license approval, a citation, a fine, or a penalty issued by the third-party organization or an interested party. Third-party audits may be performed on behalf of an auditee's potential customers who cannot afford to survey or audit external organizations themselves or who consider a third-party audit to be a more cost-effective alternative. Government representatives perform mandatory audits on regulated industries such as nuclear power stations, airlines, and medical device manufacturers to provide assurances of safety to the public.

Internal and External Audits

An audit may be classified as internal or external depending on the interrelationships that exist among the participants. Internal audits are first-party audits while external audits can be either second- or third-party audits. *Internal audits* are audits of an organization's product or service(s), processes, and systems conducted by employees of the organization. *External audits* are audits of an organization's

product or service(s), processes, and systems conducted by individuals who are not employees of the organization. Figure 1.1 illustrates the classifications commonly used to differentiate between types of internal and external audits. The figure is provided as a guide to classifications, but there is no absolute rule because there are exceptions. The types of audits depicted in Figure 1.1 are not mutually exclusive. An audit can be a blend of the different types of audits. Third-party auditors (certification) could be joined by second-party auditors (customer auditors), or internal auditors could be joined by external auditors (customer).

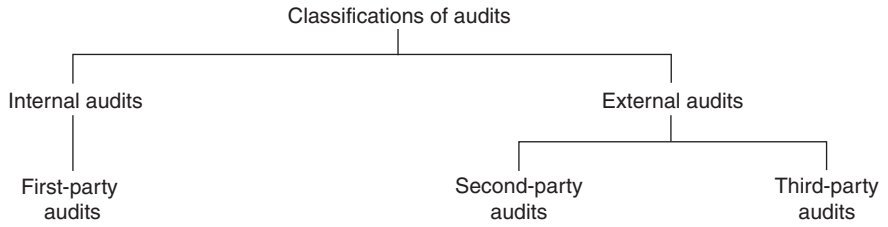

Figure 1.1 Classifications of audits.

PURPOSE

It is also common to refer to an audit according to its purpose or objectives. An auditor may specialize in types of audits based on the audit purpose, such as to verify compliance, conformity, or performance. Some audits have special administrative purposes, such as auditing documents, risk, or performance.

Another audit purpose is as a follow-up to a previous audit. A *follow-up audit* is conducted to verify closure of a previous audit finding. During a follow-up audit the auditor will verify the implementation of corrective and preventive (from risk-based audits) actions (such as through a Corrective and Preventive Action [CAPA] process) to determine, through evidence, that corrective action was implemented and that the finding was effectively resolved. A follow-up audit may be either on-site or at a desk, depending on the complexity and risk to the organization of the finding.

Certification Purposes

Companies in certain high-risk categories—such as toys, pressure vessels, elevators, gas appliances, and electrical and medical devices—wanting to do business in Europe must comply with Conformité Europeëne Mark (CE Mark) requirements. One way for organizations to comply is to have their management system certified by a third-party audit organization to international management system requirement criteria (such as ISO 9001).

Customers may suggest or require that their suppliers conform to ISO 9001, ISO 14001, safety criteria, and more. The U.S. Federal Acquisition Regulations (FARs) 48 Code of Federal Regulations (CFR) 46.202-4 replaced references to government specifications with higher-level contract quality requirements. Cited higher-level contract quality requirements include ISO 9001, AS9100, ANSI/ASQ

E4, and ANSI/ASME NQA-1. However, this does not preclude other federal government entities, such as the Department of Energy (DOE) or the Department of Defense (DOD), from having additional requirements for the specific work they do (for example, nuclear facility standards/regulations such as Federal Register 10 CFR 830 Subpart A). Many national standards have been canceled, and users have been referred to the U.S.-adopted ISO 9001 standard. A third-party audit normally results in the issuance of a certificate stating that the auditee organization management system complies with the requirements of a pertinent standard or regulation.

Third-party audits for system certification should be performed by organizations that have been evaluated and accredited by an established accreditation board, such as the American National Standards Institute's (ANSI's) and American Society for Quality's (ASQ's) National Accreditation Board (ANAB). As the U.S. accreditation body for management systems, ANAB accredits certification bodies for ISO 9001, ISO 13485, ISO/IATF 16949 QMSs, and ISO 14001 EMSs as well as for several other conformity requirements standards.

What's the difference between certification, registration, and accreditation?

The terms *certification* and *registration* are used interchangeably to refer to verifying the conformity of an organization's management systems to a standard or other requirements. The term *accreditation* is used when validating or verifying the conformity of a certification body to the requirements of national and/or international criteria. *Certification* also refers to the process of validating and verifying the credentials of individuals such as auditors.

A *certification body*, also known as a *registrar*, is a third-party company contracted to evaluate the conformity of an organization's management system(s) to the requirements of the appropriate standard(s) and issue a certificate of conformity when warranted.[6]

Performance Versus Compliance/Conformity Audits

There has been increased emphasis on how audits can add value. Various authors use the following terms to describe an audit purpose beyond compliance and conformance: *value-added assessments*, *management audits*, *added value auditing*, and *continual improvement assessment*. The purpose of these audits goes beyond traditional compliance and conformity audits. The audit purpose relates to organization performance. Audits that determine compliance and conformity are not focused on good or poor performance. Yet performance is an important concern for most organizations.

A key difference between compliance/conformity audits and audits designed to promote improvement is the collection of audit evidence related to organization

performance versus evidence to verify conformity or compliance to a standard or procedure. An organization may conform to its procedures for taking orders, but if every order is subsequently changed two or three times, management may have cause for concern and want to rectify the inefficiency.

All types of audits—including first-, second-, and third-party audits for products or services, processes, and systems—can include a purpose to identify and report performance observations. However, audits with an objective to identify risks and opportunities for improvement are more likely to be first-party, process, or system audits.

If an organization's audit program has an objective for audits to be a management tool for improvement, performance may be included in the audit purpose. The mission of the American Society for Quality (ASQ) Audit Division is "to develop the expectations of the audit profession and auditors. To promote to stakeholders auditing as a management tool to achieve continuous improvement and to increase customer satisfaction."

Follow-Up Audit

A product, process, or system audit may have findings that require correction or corrective action. Since most corrective actions cannot be performed at the time of the audit, the audit program manager may require a follow-up audit to verify that corrections were made and corrective actions were taken, if appropriate. Due to the high cost of a single-purpose follow-up audit, it is normally combined with the next scheduled audit of the area. However, this decision should be based on the importance and risk of the finding. An organization may not be willing to risk a fine due to a repeat sampling equipment failure or to risk sending customers a nonconforming product or service. An organization may also conduct follow-up audits to verify preventive actions were taken as a result of performance issues that may be reported as opportunities for improvement. At other times, organizations may forward identified performance issues to management for follow-up.

COMMON ELEMENTS WITH OTHER AUDITS

Regardless of the scope of a system or process audit, they all have some common elements. ISO 19011:2018, paragraph 3.1, defines an audit as a "systematic, independent, and documented process for obtaining audit evidence [records, statements of fact, or other information relevant to the audit criteria and verifiable] and evaluating it objectively to determine the extent to which audit criteria [set of policies, procedures, or requirements] are fulfilled."

Audits can address almost any topic of interest where activities or outputs result from defined plans. The scope of the audit might be product or service quality; environmental, marketing, or promotional claims; financial results and statements; health and safety conditions; equal opportunity compliance; internal controls for operations (e.g., Sarbanes-Oxley); post-product or service sales and service with feedback for improvement; and the like. Basically, if an activity or status is subject to planning or reporting, it can be audited.

The universality of auditing extends to most sectors of our society, including the American Civil Liberties Union, local building or fire inspectors, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), union representatives, critical customers, and the Internal Revenue Service, to assess and report how well organizations are performing.

Audit-like inquiries that do not fulfill all the technical requirements of an audit (such as an audit plan or avoiding conflicts of interest) are known as an *evaluation* or an *assessment*. Commonly, evaluations are fairly subjective audit-like activities that compare current performance with some potential status, like theoretical capacity or capability of a system or process, for example. Evaluations are judgments. Similarly, assessments are activities that more closely align with the definition of an audit but lack satisfying some known and identified requirement. Assessments are estimates or determinations of significance or importance.

A common type of assessment is termed *statutory and regulatory compliance audit*. While the auditors may be trained and informed in the relevant materials and documents, they need to be careful to avoid going beyond their competence in their reporting. For statutory issues, interpretation of laws is often required and can be viewed as the domain of lawyers who are members of the bar. Typically, determination of regulatory compliance lies solely in the domain of persons who are formally recognized by the regulatory agency as being competent to interpret regulations developed by statutory authorities—for example, the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Department of Transportation, the Federal Aviation Administration (FAA), and the Food and Drug Administration (FDA). Auditors may be qualified as technical SMEs but lack appropriate recognitions by interested bodies.

The key concept is that audits, regardless of form or name, are *processes*. Processes consist of a set of resources (materials, labor, finance, and so on) called *inputs* that are being transformed through interactions to create *outputs*. Outputs of processes are typically not just the desired product or service but also the nonconforming product or service, waste, pollution, and worn equipment or tooling.

In most cases, unless management specifically requests the associated negative or less positive results, only the desired positive outputs are emphasized, and management is provided with less than the total available data or information necessary to manage the organization and avoid risks.

For the audit process, we have inputs of competent auditors; an authorizing, supportive client; cooperative auditee personnel; defined auditee plans and procedures for satisfying requirements and accomplishing objectives; an identified audit purpose and scope; reference documents; and appropriate administrative and infrastructure support. These inputs, along with a planned sequence of audit activities, provide an output of accumulated data that are transformed into useful, actionable, information and presented to the auditee and the client in a formal report. Appropriate follow-up corrective or preventive actions are implemented to support improvements and mutual benefits.

Some common elements of audits include:

1. **Purpose and scope:** "Why are we doing this?" The answer will provide the purpose of the audit and lead to the proper scope (extent) of inquiry.
2. **Document review:** Documents are reviewed during the audit preparation phase to determine whether the auditee has developed a suitable (adequate and appropriate) set of comprehensive documents for the audited area or activities to satisfy all relevant goals and requirements.
3. **Preparation for review:** Details of who will be interviewed, at what location, and which aspects of the operations should be scheduled. Data collection plans are finalized.
4. **On-site or remote data collection (the audit):** Actual data collection activities may vary somewhat (for example, a shorter opening meeting) in internal and external audits due to the familiarity of auditor(s) and auditee; and auditor's knowledge of auditee's processes, product, services; and infrastructure. External audits are generally more formal. Collection of data, however, is the same for both internal and external audits.
5. **Formal audit report:** While most audit reports follow a prescribed format, sometimes the client (or an applicable standard) may require a unique format for the audit. Audit reports normally include an introduction, an overall summary, findings, and conclusions.
6. **Audit follow-up:** The auditee is responsible for implementation of the corrective action and its verification. An auditor may be assigned to perform a follow-up audit (an independent verification that the corrective action was implemented and effective).

The auditing community continues to move toward establishing common audit practices. ISO 19011 provides guidance on all management system audit types, such as quality, environmental, and occupational safety and health. The main differences among audits are the standards against which the organization is audited and the emphasis on certain techniques over others, depending on whether it is a quality, environmental, or safety audit.

NOTES

1. ISO 19011:2018, *Guidelines for Auditing Management Systems* (Milwaukee, WI: Quality Press, 2011), p. 16.
2. Akio Miura, taken from auditor training materials, provided July 11, 2005.
3. Dennis R. Arter, *Quality Audits for Improved Performance*, 3rd ed. (Milwaukee, WI: Quality Press, 2003), p. 15.
4. ASQC Energy Division, *Nuclear Quality Systems Auditor Training Handbook*, 2nd ed. (Milwaukee, WI: ASQC Quality Press, 1986), p. 2.
5. Arter, *Quality Audits for Improved Performance*, p. 6.
6. ANSI-ASQ National Accreditation Board, "Frequently Asked Questions: General," accessed July 7, 2005, http://www.anab.ansi.org/about-anab/faq.

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Note: Page numbers followed by *f* or *t* refer to figures or tables, respectively.