Implementing ISO/IEC 17025:2017

Also available from ASQ Quality Press:

Practical Process Validation
Mark Allen Durivage and Bob Mehta

The Metrology Handbook, Second Edition
ASQ Measurement Quality Division

The Certified Quality Technician Handbook, Third Edition
H. Fred Walker, Donald W. Benbow, Ahmad K. Elshennawy

*Quality Risk Management in the FDA-Regulated Industry,
Second Edition*
José Rodríguez-Pérez

The Quality Toolbox, Second Edition
Nancy R. Tague

Root Cause Analysis: Simplified Tools and Techniques, Second Edition
Bjørn Andersen and Tom Fagerhaug

The Certified Six Sigma Green Belt Handbook, Second Edition
Roderick A. Munro, Govindarajan Ramu, and Daniel J. Zrymiak

*The Certified Manager of Quality/Organizational Excellence
Handbook, Fourth Edition*
Russell T. Westcott, editor

The Certified Six Sigma Black Belt Handbook, Third Edition
T.M. Kubiak and Donald W. Benbow

The ASQ Auditing Handbook, Fourth Edition
J.P. Russell, editor

*The ASQ Quality Improvement Pocket Guide: Basic History,
Concepts, Tools, and Relationships*
Grace L. Duffy, editor

To request a complimentary catalog of ASQ Quality Press publications,
call 800-248-1946, or visit our Web site at http://www.asq.org/quality-press.

Implementing ISO/IEC 17025:2017

SECOND EDITION

Bob Mehta

∞ Printed on acid-free paper.

Table of Contents

List of Figures and Tables

Acknowledgments

First, to my late parents, who both passed away when I was in India. Thank you to my mother for sacrificing her life to give birth to me. Since my mother passed away during childbirth, I depended on my dad until he passed away when I was in college. He taught me to believe in myself, work hard, and stay determined in everything that I do. I kept these values with me when I came to the United States in 1986. Since then, I never looked back. You both are the inspiration for my lifelong passion for learning and for sharing my knowledge with others. Your nurtured love and support make me what I am today.

To my wife for her love and support for over two decades. Your support while I wrote this book after working long hours as a consultant was invaluable to me.

To my son, Jay, for his love and support, including proofreading the manuscript for this book and sharing ideas as a quality professional.

My thanks to Ahmedabad Science College (Ahmedabad, India), where I earned a Bachelor of Science degree in chemistry; to Pepperdine University for helping me develop an understanding of business practices and use my learnings from my MBA degree toward professional goals; and to California State University–Dominguez Hills for helping me increase my competence in the field of quality and use my Master of Science degree in quality assurance to achieve my career aspirations. I would also like to acknowledge the adjunct faculty there, where I teach Master of Science in Quality Assurance classes, for their support and guidance.

And to the American Society for Quality sections around the world, members of the Orange Empire Section, to which I belong, and to all measurement and analysis professionals supporting and/or managing calibration functions.

Introduction

The focus of this book will be to demystify the requirements delineated within ISO/IEC 17025:2017, while providing a road map for organizations wishing to receive accreditation for their laboratories. For those of you who have read my first book, which focused on complying with ISO/IEC 17025:2005, this is essentially a second edition. AS9100, ISO 9001:2015, and ISO 13485:2016 are standards that have been created to support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system (QMS) for many diverse industries. Similar to these recognized QMS standards, ISO/IEC 17025:2017 for laboratory accreditation serves a unique purpose. It is not unusual for laboratories to retain dual certification in ISO 9001:2015 and ISO/IEC 17025:2017. However, ISO/IEC 17025:2017 does contain requirements specific to the laboratory environment that are not addressed by ISO 9001:2015. This book will highlight the differences between ISO 9001:2015 and ISO/IEC 17025:2017, while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO/IEC 17025:2017.

1
Scope

The scope of ISO/IEC 17025:2017 is essentially the creating of a sound functional platform for laboratories to operate in an environment that supports laboratory competency, impartiality, and consistency. Irrespective of a laboratory's size and the number of supporting personnel, the standard discussed in this book is deemed to be relevant. Not only can ISO/IEC 17025:2017 be employed to create the foundation for a laboratory, it can be used to assist customers, regulators, and other interested parties in their performance of assessment activities.

2
Normative References

There are two documents that are identified within ISO/IEC 17025:2017 that have content considered to be germane to any discussion associated with the understanding of this standard. According to ISO/IEC 17012:2017, these two documents are identified as: (a) ISO/IEC 17000 (Conformity assessment—Vocabulary and general principles) and (b) ISO/IEC Guide 99 (International vocabulary of metrology—Basic and general concepts and associated terms).

3
Terms and Definitions

According to ISO/IEC 17025:2017, the terms and definitions associated with ISO/IEC 17000 and ISO/IEC Guide 99 are applicable for this standard. However, ISO and IEC do maintain terminological databases that can be used in support of standardization. These two databases can be located at:

- ISO's Online Browsing Platform, https://www.iso.org/obp

- IEC's Electropedia: The World's Online Electrotechnical Vocabulary, http://www.electropedia.org/

Key terms and definitions referenced within the standard include:

Complaint: An expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.

Decision Rule: A rule that describes how measurement uncertainty is accounted for when starting conformity with a specified requirement.

Impartiality: The presence of objectivity.

Interlaboratory Comparison: The organization, performance, and evaluation of measurements or tests, on the same or similar items, by two or more laboratories in accordance with predetermined conditions.

Intralaboratory Comparison: The organization, performance, and evaluation of measurements or tests, on the same or similar items within the same laboratory in accordance with predetermined conditions.

Laboratory: A body that performs one or more of the following activities: (a) testing, (b) calibration, and (c) sampling associated with subsequent testing or calibration.

Proficiency Testing: The evaluation of participant performance against preestablished criteria by means of interlaboratory comparisons.

Reference Standard: A reference standard is a highly characterized, standardized, and validated reference material. It enables the measurement of the sensitivity, specificity, and accuracy of your assay or workflow.

Validation: The verification where the specified requirements are adequate for its intended use.

Verification: The provision of objective evidence that a given item fulfills specified requirements.

4

General Requirements

INTRODUCTION

It is imperative that laboratories complying with ISO/IEC 17025:2017 adhere to two fundamental concepts: (a) impartiality and (b) confidentiality. Not unlike a person's relationship with their family doctor or that inopportune time when a person ends up in traffic court, the expectation is that regardless of outcome, impartiality and confidentiality are appropriately maintained. Laboratories are required to adhere with those same principles. Because of the brevity of clause 4.1 (Impartiality) and clause 4.2 (Confidentiality) of ISO/IEC 17025:2017, both clauses will be reviewed in this initial chapter.

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—4.1 (IMPARTIALITY)**

- Laboratory activities must be carried out in a manner to ensure impartiality is maintained.
- Management shall be fully committed to the concept of impartiality.
- Commercial, fiscal, or other operational pressures should not influence impartiality.
- Laboratories are expected to review and identify potential risks to sustaining impartiality.
- When risks to impartiality have been identified, the laboratory is required to mitigate those risks.

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—4.2 (CONFIDENTIALITY)**

- Laboratories are to be responsible for carefully managing information with which they have been entrusted. If the information is not deemed to be public knowledge, then appropriate permission shall be in place to protect the confidentiality of information.
- When a laboratory is required by law to release confidential information, then this agreement must be defined within a contract.
- Confidential information shared between a laboratory and its clients, regardless of source, is still to be treated as confidential.
- Individuals acting on behalf of a laboratory (e.g., consultant) shall maintain the integrity of confidential agreements.

EFFECTIVE TOOLS FOR
IMPLEMENTATION AND COMPLIANCE

Clause 4.1 and clause 4.2 are essentially cornerstones for laboratories wishing to achieve compliance with ISO/IEC 17025:2017 requirements. Impartiality is rooted in a laboratory's ability to prioritize a customer's needs above those of the laboratory. It starts with the management making difficult decisions that may not be in the best interest of the laboratory but supports a customer's need for impartiality in the obtaining of accurate calibration or test results, regardless of the outcome. This becomes an extremely important task when supporting highly regulated industries such as aerospace and defense or med-tech. Regardless, impartiality is a top-down driven concept that is routed in laboratory integrity.

Tools for complying with clause 4.2 are less abstract as contracts and nondisclosure agreements (NDAs) can be scripted to ensure information is appropriately protected. Additionally, for med-tech clients, there is always the possibility for patient information to potentially be involved in failure investigations. As a result, there may be a need to address Health Insurance Portability and Accountability Act (HIPAA) requirements in support of protecting patient-related information. Regardless, a well-written contract and a signed NDA are a laboratory's best friend when addressing confidentiality concerns.

QUESTIONS TO CONSIDER DURING AN AUDIT

Questions placed at the end of this and subsequent chapters are relevant to the subject matter discussed in each chapter. However, the questions are intended to be an all-inclusive list. They can be used to populate an audit checklist or supplier questionnaire and used as part of the supplier assessment process:

1. Could the fiscal health of the laboratory impact the laboratory's ability to remain impartial?

2. Has someone reviewed a recent Dun & Bradstreet report that provides a general financial picture of the laboratory?

3. Is there ongoing litigation or other regulatory action potentially influencing the impartiality of the laboratory?

4. Are contracts required to be in place with all laboratory clients?

5. Are NDAs required to be signed for all clients?

CHAPTER REVIEW

For this initial chapter, maintaining impartiality and protecting the confidentiality of information is not rocket science. It is easy to pursue common-sense approaches that result in laboratories being able to provide accurate and impartial calibration or test results, while protecting the confidentiality of the information handled. It starts with management's commitment to these basic fundamentals—maintaining impartiality and confidentiality—at all costs. Customers demand it, ISO/IEC 17025:2017 requires it, and laboratories shall comply with it; all are requirements associated with maintaining impartiality and confidentiality.

5

Structural Requirements

INTRODUCTION

Similar to other ISO standards, identifying the salient requirements needed for establishing the foundation for an effective organization are delineated within clause 5 of ISO/IEC 17025:2017. If an organization is seeking accreditation to 17025, and an approved ISO 9001:2015 Quality Management System (QMS) has already been certified by a recognized registrar, then the chances are good an acceptable organizational infrastructure has already been established. It is imperative that the identification of the legal entity of the laboratory and its relationship to a parent organization or subsidiaries be clearly defined. Additionally, the laboratory's management system, policies, procedures, organizational structure, responsibilities of personnel, the interrelationships of laboratory personnel, identification of key management personnel, the handling of deviations from the QMS, methods of communication, and the reporting of the laboratory performance to management must be defined and developed in the context of complying with 17025. Further, the primary task of a laboratory is to perform testing and calibration activities in accordance with ISO/IEC 17025:2017. Finally, and arguably the most important point for a laboratory, is the ability to meet and hopefully exceed the expectation of their customers, including meeting all applicable regulatory and statutory requirements. This initial chapter will examine the requirements and the steps necessary for a laboratory to comply with clause 5 of ISO/IEC 17025:2017—Structural Requirements.

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—5 (STRUCTURAL REQUIREMENTS)

- An organization is classified as a stand-alone laboratory or the legal entity that is legally responsible for the laboratory.
- The management of the laboratory needs to be clearly identified and their overall responsibilities clearly defined.
- Laboratories need to define the range of activities and work performed within their facility in accordance with ISO/IEC 17025:2017 requirements. Compliance can only be claimed for the actual activities performed by the laboratory.
- Work performed within a laboratory shall be performed in a manner that complies with ISO/IEC 17025:2017 requirements. These requirements apply to other facilities, mobile facilities, or work being performed at client facilities.
- Laboratories, as defined by the standard, are required to:
  - Define the organizational structure, including the relationships between functional groups;
  - Clearly define the roles and responsibilities of all laboratory personnel; and
  - Establish (define, document, and implement) procedures that will result in consistent laboratory results.
- Laboratories are required to:
  - Retain adequate management and technical personnel with sufficient authority to support the implementation, maintenance, and improvement of the management system. When deviations from the established management system occur, these individuals will pursue corrective action to mitigate deviations, as appropriate;
  - Ensure management and personnel are protected from undue influences (internal and external) that may impact the quality of their work;
  - Establish policies and procedures to protect the confidentiality of customer data;
  - Establish adequate policies and procedures in support of the overall operational integrity of the lab;
  - Adequately define the organizational structure;
  - Delineate the authority, responsibility, and interrelationships of laboratory personnel;
  - Provide adequate supervision for all laboratory personnel;
  - Retain technical management responsible for technical operations;

> - Appoint a quality manager that has a direct reporting line to senior management;
> - When deemed appropriate, identify and appoint deputies for key management personnel; and
> - Ensure all personnel clearly understand the influence the execution of their day-to-day activities have on the management system.
> - Laboratory management is required to:
>   - Ensure the effectiveness of the management system is clearly conveyed to all stakeholders (individuals having a vested interest in the laboratory's success—e.g., a medical device manufacturer);
>   - Ensure the integrity of the management system remains intact when changes to the management system are planned and implemented.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Clause 5 is essentially an overview of elements required from laboratory management to maintain an effective management system. For example, the laboratory is required to retain adequate and properly trained resources to ensure the management system always remains in compliance with ISO/IEC 17025:2017. When deviations from the management system have been identified, management is tasked with correcting the deviation in accordance with clause 5.6(b) of ISO/IEC 17025:2017, discussed in Chapter 5 of this book.

For starters, the creation of an organizational chart is a fundamental requirement for laboratories considering accreditation. A well-constructed organization chart clearly delineates the functional structure of the laboratory. It is imperative that the roles of the laboratory's quality manager and technical manager are clearly depicted on the chart (see Figure 5.1).

The fundamental requirement is to ensure the roles, responsibilities, and the authority established within the laboratory is adequate and in compliance with 17025. The importance of having a job description will be discussed in greater detail later in this book; however, it is strongly recommended that the job description contain the reporting structure for each job. For example, the calibration technicians report directly to the test and calibration supervisor.

Additionally, it is also imperative that every laboratory employee is trained to understand the influence their functional duties have on the overall effectiveness of the laboratory's management system. Most organizations accomplish this task through initial employee orientation and training.
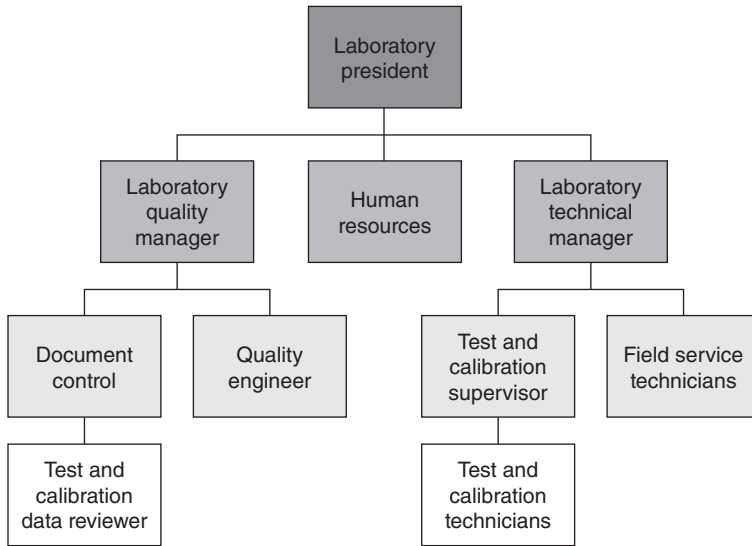
Figure 5.1   Typical laboratory organizational chart.

Regardless of the approach pursued, make sure the training is documented in accordance with clause 5.6 of ISO/IEC 17025:2017 (Chapter 6.2 of this book).

Further, it is important that the laboratory appoint a quality manager and a technical manager and delineate the specific roles and responsibilities for each of these positions. Once again, the job description will play a key role in definition of duties and responsibilities. For small organizations (e.g., less than ten individuals and in some cases one or two employees), team members will be tasked with wearing many hats. However, organizational size does not result in diminished levels of compliance with the standard.

Finally, laboratories must ensure the confidential nature of customer data. ISO/IEC requires that laboratories script a policy and procedure that defines the protection of confidentiality process. The procedure should be prescriptive when it comes to defining the security of confidential data.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Is the laboratory a stand-alone entity or part of a larger organization?

2. Is the laboratory currently accredited to ISO/IEC 17025:2017?

3. Is the certificate of accreditation current?

4. Does the laboratory have a documented management system that delineates all policies, procedures, and work instructions employed during testing and calibration?

5. Has the laboratory created an organizational chart?

6. Has a policy and procedure been established that protects the confidentiality of customer information?

7. Have the responsibility and authority level for each employee been established?

8. Does the laboratory have a designated quality manager?

9. Does the laboratory have a designated technical manager?

CHAPTER REVIEW

For this chapter, there are four fundamental requirements needed to achieve compliance with clause 5 of ISO/IEC 17025:2017: First, the laboratory should identify roles, responsibilities, and levels of authority for employees. The organizational chart is the perfect tool to accomplish this requirement. Second, ensure that job descriptions are clear and concise in regard to reporting relationships. Third, ensure that a procedure is scripted that delineates the laboratory's approach for protecting and securing the confidential nature of a client's data. Finally, make sure the laboratory appoints a quality manager and technical manager.

An expectation of all accredited laboratories is maintaining the effectiveness of the management system and employing corrective action and preventive action (CAPA) to correct deviations. It will become a daunting challenge to meet customer expectations without a deployed management system along with all the supporting policies and procedures to ensure ongoing effectiveness of the management system. Remember, meeting customer expectations is a fundamental requirement of ISO/IEC 17025:2017.

6.1
Resources Requirements: General

INTRODUCTION

Clause 6.1 of ISO/IEC 17025:2017 is nothing more than a direct statement requiring laboratories to obtain and implement the resources necessary to successfully carry out their day-to-day activities. In accordance with IOO/IEC 17025:2017, laboratories are required to have:

- Personnel
- Appropriate facilities and associated infrastructure
- Necessary equipment
- Systems
- Laboratory support

These elements are necessary to drive the overall success of the laboratory.

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—6.1 (RESOURCE REQUIREMENTS: GENERAL)

- There are numerous factors that influence a laboratory's effectiveness. Laboratories are required to have personnel, equipment, facilities, infrastructure, and adequate support to ensure it is capable of executing its duties in accordance with ISO/IEC 17025:2017.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Although clause 6.1 does not require an established procedure, it is recommended that a simple procedure be created that acknowledges the requirement. A procedure containing pointers that explain where each of the elements influencing measurement uncertainty can be found will suffice. For example, the following elements should be referenced in a high-level procedure:

- Personnel (6.2 of ISO/IEC 17025:2017);

- Facilities and environmental conditions (6.3 of ISO/IEC 17025:2017);

- Equipment (6.4 of ISO/IEC 17025:2017);

- Metrological traceability (6.5 of ISO/IEC 17025:2017); and

- Externally provided products and services (6.6 of ISO/IEC 17025:2017).

Getting down into the proverbial weeds with sufficient granularity can occur with the scripting of the individual procedures.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Has the laboratory implemented the appropriate infrastructure necessary to be successful?

2. Has an organizational chart been created, and does the chart reflect an appropriate level of resources necessary to sustain laboratory operations?

3. Has the equipment been appropriately identified and calibrated?

4. Have environmental conditions been appropriately identified?

5. Are environmental conditions being monitored?

6. If certain environmental conditions (e.g., particulate counts) do not influence laboratory activities, has rationale explaining that these conditions do not impact test or calibration results been scripted?

CHAPTER REVIEW

Laboratories are required to acquire and implement the appropriate resources to support laboratory operations. Qualified personnel, suitable equipment, adequate facility, qualified controlled environments, and calibrated equipment influence the overall effectiveness of laboratory operations. Without the appropriate infrastructure implements, it is not possible for laboratories to produce repeatable and reproducible results.

6.2

Personnel

INTRODUCTION

At the core of any successful organization are the people that support the day-to-day operations. Experience, skill, education, and training are important elements that need to be considered when working toward compliance with ISO/IEC 17025:2017's personnel (6.2) requirements. It is imperative that appropriate levels of competency are established for each function within the organization. Additionally, adequate supervision must be provided during the initial training of personnel until required competency levels for each employee are achieved. As a laboratory continues to grow, effective training programs and supervisory personnel must expand to ensure that employees keep pace with the ongoing evolution of technology. It is incumbent on laboratories wishing to achieve or retain ISO/IEC 17025:2017 accreditation to sustain continuous improvement opportunities that will be driven by a highly skilled and well-trained employee base.

EFFECTIVE TOOLS FOR
IMPLEMENTATION AND COMPLIANCE

A basic requirement for laboratories working toward accreditation or sustaining accreditation is the establishment of a documented policy/procedure that delineates the training requirements for all laboratory personnel. Employee training and competence drives the overall quality and performance of the laboratory. Laboratories are expected to ensure all personnel have the appropriate levels of skill, experience, education, and training in support of executing testing and calibration activities. In some instances, specific technical training may be required (e.g., operating a scanning electron microscope). This additional certification could be premised on an

---

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—6.2 (PERSONNEL)

The laboratory management team is responsible for ensuring the overall competence and impartiality of stakeholders (internal and external) that influence the work being performed.

Competency requirements, including the requirements for: (a) education, (b) qualification, (c) training, (d) technical qualifications, (e) skills, and (f) industry experience shall be documented.

Management is tasked with communicating roles, responsibilities, and authority to their staff.

Laboratory management is required to establish a written policy/procedure for training. At a minimum, the training program needs to address: (a) applicable education, (b) applicable training, (c) applicable skill set(s), and (d) verification of training effectiveness. The training program will also be applicable to contract labor and consultants employed by a laboratory.

Laboratories are responsible for the management and retaining of training records for all laboratory personnel, regardless of the function responsibilities or technical expertise.

---

industry standard or a regulatory/statutory certification requirement. Additionally, laboratory personnel tasked with the interpretation of test results or the authoring of test reports must possess:

- Relevant industry or technical knowledge as it pertains to the materials tested or the actual performance of a specific test

- An appropriate level of knowledge of applicable standards and regulatory/statutory requirements

- A thorough understanding of noted deviations associated with the materials tested and the overall testing process

One tool that should be employed in support of meeting the training requirement is a training matrix. The training matrix will assist laboratory management in the defining and management of training requirements for all laboratory personnel, including contract labor. It is recommended the training matrix include: (a) training to validated test methods; (b) training to industry standards, such as ASTM International; (c) training to quality system procedures; (d) training to applicable sections of ISO/IEC 17025:2017; and (e) training to applicable regulatory and statutory requirements. Table 6.2.1 contains an example of a basic training matrix.

Table 6.2.1 Sample training matrix.

ACME Test Labs' Training Matrix 6.2 of ISO/IEC 17025:2017	ASTM A370	ASTM D1708	ASTM D256	QPM0001	QSP0001	ISO/IEC 17025	ISO 9001:2015	TM0002	21 CFR § 820
Version/Section	−12	−10	−10	A	A	2017	2015	B	820.72
Employee									
J. Doe 1	X			X	X	X	X	X	
J. Doe 2	X			X	X	X		X	
J. Doe 3	X	X	X	X	X	X		X	X
J. Doe 4			X	X	X	X			
J. Doe 5			X	X	X	X			
J. Doe 6		X		X	X	X	X		X
J. Doe 7		X	X	X	X	X			X
J. Doe 8	X	X	X	X	X	X		X	X

Please keep in mind that the training record is a viable tool for managing the big picture of the laboratory's training; however, additional detail is required. Documented training is also required for all laboratory personnel. It is recommended that an individual training file be opened and maintained for each laboratory employee, regardless of their job function. The individual employee training records should contain documented evidence of previous (relevant) training, current training, certifications, applicable education, and evidence of competency testing (if deemed appropriate). Additionally, best-in-class training records for laboratory personnel will contain a resume and a job description. A well-written job description will support the overall training requirement for laboratory personnel.

Unlike ISO 9001:2015, which does not specify a requirement for a job description, clause 6.2.4 of ISO/IEC 17025:2017 requires laboratories to write and maintain job descriptions for laboratory personnel. There is some latitude granted regarding job description content; however, there are minimum requirements for defining responsibilities for management, technical

personnel, and key support personnel. For example, each job description should define the responsibilities:

- As they pertain to performing tests and calibrations

- As they pertain to planning tests and calibration

- As they pertain to evaluating test results

- As they pertain to the generation of reports that state opinions and interpretations of the test and calibration results

- As they pertain to test method validation (TMV) activities

Additionally, the job description needs to include expertise and experience required, qualifications, training programs, and managerial-specific duties. Table 6.2.2 depicts an example of well-written job description.

Table 6.2.2   Example of an ISO/IEC compliant job description.

ACME Test Labs
Laboratory Quality Manager Job Description   JD0001, REV A—08/08/12

1.0 Primary Job Function
The Laboratory Quality Manager is responsible for the laboratory's QMS and QMS implementation in accordance with ISO/IEC 17025. The Laboratory Quality Manager retains direct access to executive management, at which decisions are made in regard to laboratory policies, resources, practices, and direction provided to the laboratory's technical manager.

2.0 Education and Skills
The Laboratory Quality Manager is required to possess the following education, experience, and skills:
- Bachelor of Science Degree in a scientific/engineering field;
- A minimum of 10 years of experience in a laboratory environment;
- Proficiency in MS Word, Excel, Access, PowerPoint, and Project software; and
- Competency in employing the principles associated with ISO/IEC 17025 and ISO 9001.

3.0 Authority
The Laboratory Quality Manager reports directly to the president of ACME Test Labs and retains the authority to:
- Approve deviations from established procedures;
- Evaluate and determine the validity of customer complaints;

Table 6.2.2   Example of an ISO/IEC compliant job description. (*continued*)

- Evaluate and resolve calibration-related nonconformances;
- Review laboratory calibration results;
- Open corrective and preventive actions; and
- Issue certificates of conformance.

4.0 Responsibilities
The Laboratory Quality Manager is responsible for:
- Performing employee training as it relates to the QMS;
- Maintenance of the Quality Policy Manual;
- Managing the Internal Quality Audit Program;
- Entertaining audits for clients and regulatory bodies;
- Managing the CAPA program;
- Managing the QMS;
- Ensuring only approved documentation is released for use by ACME personnel;
- Managing the customer complaint process;
- Supplier selection and evaluation;
- Preparing the documentation for management review meetings; and
- Other duties and responsibilities deemed appropriate in support of sustaining quality operations at ACME Test Labs.

5.0 Training Requirements
- QPM0001—ACME Quality Policy Manual
- QSP0002—ACME Quality Policy
- QSP0006—ACME Purchasing Services and Supplies
- QSP0008—ACME Customer Complaints
- QSP0011—ACME Corrective Action
- QSP0012—ACME Preventive Action
- QSP0014—ACME Internal Audits
- QSP0015—ACME Management Reviews

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have a documented program for training?

2. Does the training procedure address the goals and requirements for specific levels of education, training, experience, and demonstrated skills?

3. Who is responsible for identifying the training needs for the laboratory?

4. Is there a requirement for verifying if the training performed is effective?

5. Does the training procedure address the requirement for supervision of employees in training?

6. Does the laboratory have training records, and do they maintain them for all employees?

7. Who is responsible for managing employee training records?

8. Is there an annual review process for training?

9. Does the laboratory have written job descriptions for all employees?

10. Are the job descriptions current?

CHAPTER REVIEW

Training is a fundamental requirement that is needed to ensure a laboratory is capable of providing repeatable and accurate quality testing and calibration services. Establishing a written procedure that delineates the content of the training program is a basic requirement of ISO/IEC 17025:2017. The creation of a training matrix is a sound concept that allows a laboratory to quickly ascertain the training status of laboratory personnel; however, the training requirement is more expansive than the matrix. It is recommended that a training file be opened for all laboratory personnel, regardless of their function or responsibilities. The training file will be a receptacle for all training-related documentation that is needed to support claims of compliance to clause 6.2 of ISO/IEC 17025:2017. Make sure each employee has a detailed job description. Remember, this requirement differs from ISO 9001:2015 in that it does not have a specific requirement for job descriptions. A well-written job description will support the laboratory's training program. One final thought for the reader: remember that the ultimate goal is to achieve and sustain accreditation to ISO/IEC 17025:2017. The best advice this author can offer is not to take shortcuts when establishing the management system. Compliance to all aspects of the standard—regardless of whether the requirement is physical (on paper) or virtual (online)—is mandatory.

6.3

Facilities and Environmental Conditions

INTRODUCTION

Similar to the infrastructure and work environment clauses delineated within ISO 9001:2015, ISO/IEC 17025:2017 has specific requirements nestled within clause 6.3 that relate to maintaining a proper laboratory environment. It is imperative that laboratories establish and maintain environmental conditions appropriate for the testing and calibration work being performed. Laboratories must ensure that environmental conditions never have an adverse effect on the results of testing and calibration. Not only is the establishment of a suitable laboratory environment required, but the laboratory is required to monitor, control, and record environmental conditions relevant to the performance of the test method and calibration methods. Specific requirements needing to be considered by laboratories are: (a) biological factors (sterility), (b) dust, (c) electromagnetic interference, (d) radiation, (e) temperature, (f) relative humidity, (g) source of electrical supply, (h) sound levels, and (i) vibration. Other factors needing to be considered to support compliance with ISO/IEC 17025:2017 are housekeeping practices, contamination control, and restricted access to work areas. In this chapter, industry standards for environmental control and monitoring, housekeeping practices, effective contamination control, and subsidiary practices necessary for establishing good laboratory practices (GLP) will be discussed.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

In support of obtaining accurate test and calibration results, laboratories are required to maintain adequate facilities, environmental controls, and good

---

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—6.3 (FACILITIES AND
ENVIRONMENTAL CONDITIONS)**

- Laboratories engaged in testing and calibration activities are required to maintain an appropriate environment to support the accuracy of testing and calibration performed. It should be considered a mission-critical activity to ensure that the operational environment does not adversely influence the accuracy of measurements being taken. A laboratory's environmental conditions are required to be monitored and the actual conditions documented, as appropriate.
- Laboratories are required to monitor, control, and record environmental conditions. Additionally, laboratories are required to monitor and control (as applicable) biological sterility, particulate, the influence of electromagnetic interference (EMI), radiation levels, relative humidity, consistency in laboratory electrical power, sound/noise, and levels of vibration to ensure that these environmental conditions do not negatively influence the results of testing and calibration. It is up to the laboratory to provide sufficient rationale when certain environmental requirements are not applicable for the work being performed (e.g., particulate counts when calibrating oscilloscopes).
- When functional areas within a laboratory are not compatible in regard to the type of activities being performed, then these areas must be segregated to prevent potential cross-contamination of results.
- Access to laboratory test areas shall be controlled as appropriate.
- Laboratories are required to execute good housekeeping practices. When deemed necessary, special housekeeping procedures shall be established (e.g., janitorial services cleaning of a controlled environment).

---

housekeeping. For example, temperature has a measurable effect on the accuracy of gage block calibration, so it is important that temperatures be controlled. The temperature associated with the dimensional calibration is typically 20°C +/− 2.0°C, so the laboratory would have to control and monitor the temperature for 20°C. The same would hold true for relative humidity (RH) if RH is a factor influencing test or calibration accuracy.

Environmental Conditions

The laboratory will need to establish a procedure for environmental controls. At a minimum, it is recommended that the procedure contain requirements for:

- Temperature (note that temperature ranges could vary dependent upon area utilization)

- Relative humidity

- Particulate count (for cleanroom environment)

- Positive pressure (required for cleanroom environment)

- Barometric pressure (if appropriate)

- Contamination control needed to meet sterility requirements (for cleanroom environment)

Additionally, (a) control limits, (b) action limits, (c) methods for sample collection, (d) environmental monitoring, and (e) environmental testing (including equipment) will need to be included into the procedure. For example, Magnehelic gages, needed to monitor the positive pressure of a cleanroom, will need to be included into the laboratory's calibration program.

Cleanroom/Controlled Environments

If the laboratory employs cleanroom environments for testing, the cleanroom will need to be properly validated. It is strongly recommended that ISO 14644 (Cleanrooms and Associated Controlled Environments) be employed for the validation process, as a reference. There are many organizations that specialize in the generation and execution of validation protocols needed to certify a cleanroom. For further clarification needed for cleanroom classification, it is recommended that Table 1 of ISO 14644–1 be referenced. Remember, it is important to retain the validation protocols and reports and have copies available, upon request, for review by laboratory clients and regulatory bodies.

If the laboratory employs a controlled environment such as a cleanroom, a procedure for gowning will also be required. The gowning procedure, depending on the cleanroom classification, may require a lab coat, a full gown, a hair cover, a beard cover, booties, hand washing, makeup removal, and/or jewelry removal. Access into the controlled environment will also need to be regulated. One final note: the high-efficiency particulate air (HEPA) filtration system, needed to support cleanroom operations, must be included into the laboratory's preventive maintenance (PM) program.

Housekeeping

Good housekeeping is essential for maintaining a clean environment capable of performing accurate testing and calibration. Housekeeping is another area of the laboratory where having an established procedure is essential. Housekeeping is much more than emptying trash bins, sweeping laboratory floors, and cleaning restrooms. Work benches, shelves, storage areas, desktops, chairs, benches, walls, and everything else within the laboratory must be kept clean and in good working order. For housekeeping requirements inside the cleanroom, the task becomes even more challenging, as contamination prevention and control are extremely important. It is important to create log sheets to document all the cleaning activities as a part of the housekeeping procedure. If a janitorial service is employed for the housekeeping, it is imperative that the janitorial staff be instructed in accordance with the laboratory's housekeeping procedure and that the training is documented.

Facilities

The laboratory is required to have a facility that is adequate to support test and calibration operations. For example, the source of facility power is expected to be stable. If power interruptions are frequent, then a backup generator would be a reasonable capital asset. If they can potentially influence test and calibration accuracy, then other facility requirements, such as (a) adequate lighting, (b) controlled access to restricted areas, (c) special shielding of laboratory areas from EMI, (d) radiation protection, or (e) use of lasers, will need to be considered. It is important to maintain records for all facility maintenance activities, including the inclusion of facility-related equipment into the laboratory's PM program, if appropriate (e.g., HEPA filtration system).

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Are the environmental conditions for the laboratory being adequately controlled?

2. Does the laboratory have an established procedure for the monitoring and control of the laboratory environment?

3. What environmental elements are being monitored?

4. Are records of environmental monitoring being maintained?

5. Does the laboratory have an established procedure for housekeeping?

6. Does the laboratory employ a janitorial service for housekeeping? If so, are the service's employees trained in the laboratory's housekeeping procedure?

CHAPTER REVIEW

The primary purpose of clause 6.3 of ISO/IEC 17025:2017 is to ensure that laboratories consider the impact good facility management, environmental controls, and housekeeping have on obtaining accurate test and calibration results. It is important for laboratories to outline adequate procedures for environmental controls, cleanrooms, and housekeeping. When appropriate, facility-related equipment that can influence the overall operational performance of the laboratory should be placed into the laboratory's PM program. It is an acceptable practice to outsource the validation of cleanrooms; however, make sure copies of the protocols and validation reports are retained and made available to clients and regulatory bodies. It is also an acceptable practice to outsource housekeeping. Make sure the janitorial service selected is trained in the laboratory's housekeeping procedure and that the training for the procedure is documented. Finally, it is the responsibility of all laboratory personnel to create a work environment suitable for the performance of test and calibration work. Regardless of whether housekeeping is outsourced or not, all laboratory personnel must take responsibility for keeping their functional areas clean and orderly.

6.4

Equipment

INTRODUCTION

ISO/IEC 17025:2017 requires laboratories to be properly equipped to support performance testing and calibration activities. The equipment and software selected for use by the laboratory must be capable of obtaining accurate measurements when employed in a testing and calibration environment. Additionally, laboratory equipment must always be calibrated against a defined specification or standard prior to its use. If a laboratory has the need to lease a piece of equipment for a specific purpose, the leased equipment must meet all the laboratory requirements and the ISO standard's requirements. Laboratories are also required to maintain records for their equipment. ISO/IEC 17025:2017 delineates specific requirements that laboratories must comply with regarding the record-keeping process. Record keeping, because of its overall impact to the performance of a laboratory, will be discussed in detail in this chapter. Further, ISO/IEC 17025:2017 incorporates requirements that are similar to ISO 9001:2015. For example, calibration labels that reflect calibration status and equipment that is being safeguarded from adjustments are mandatory requirements of clause 6.4.13 of ISO/IEC 17025:2017. Finally, the proper handling of equipment is necessary to ensure that improper handling does not influence the accuracy of the measurement results obtained. When there is evidence that equipment has been mishandled or failed to perform within the instrument's stated specifications, the laboratory must pursue appropriate action, including the immediate removal of suspect equipment from service. Practical guidance for complying with clause 6.4 will be the premise for the material provided in this chapter.

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—6.4 (EQUIPMENT)

- The laboratory must have in place all the essential equipment needed for sampling, measurement, and test equipment employed for the performance of testing and calibration.
- The equipment and its supporting software must be capable of providing the necessary measurement accuracy needed in support of testing and calibration.
- Equipment must only be operated by trained and authorized personnel. The manufacturer's operating instructions must be made available for use.
- All equipment and its supporting service must be properly identified with a unique number or serial number.
- Laboratories are required to maintain records of their equipment and its supporting software. Records should contain:
  – Equipment identity;
  – Manufacturer's name, equipment name, and serial number;
  – Evidence that the equipment functions within its operating parameters;
  – Location within the lab (e.g., equipment owner);
  – Manufacturer's instructions (e.g., manual);
  – Calibration date(s);
  – Calibration certificate(s);
  – Preventive maintenance records (as applicable);
  – Records of repairs; and
  – All other records relevant to the piece of equipment.
- Laboratories are required to have a written procedure(s) that delineate:
  – Proper handling of equipment;
  – Proper storage of equipment;
  – Proper transportation of equipment;
  – Proper use of equipment; and
  – Proper preventive maintenance.

Note: If equipment is used outside of the laboratory environment, a written procedure shall be generated to define the process.

- Equipment found to be nonconforming shall be removed from service and the nonconforming event investigated. Corrective action shall be pursued, as appropriate.

- Equipment requiring calibration shall be clearly labeled with a calibration label that reflects the proper calibration status, including the date that calibration is due.
- If equipment is removed from the laboratory (i.e., from direct control), the equipment will be evaluated prior to returning the equipment to use within the laboratory.
- When performance checks of equipment are required to maintain calibration consistency, a written procedure is required to identify the performance confirmation process.
- When correction factors are required in support of calibration(s), the laboratory is required to document the use of these factors in a procedure.
- Equipment employed for testing and calibration shall be safeguarded from adjustments that would invalidate the results of testing and calibration.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

It is expected that laboratories be fully equipped with the appropriate pieces of tools and equipment needed for the collection of samples and the execution of testing and calibration. The selected equipment and software (as applicable) must be capable of obtaining accurate and repeatable test and calibration results. Equipment range, accuracy, resolution, and measurement uncertainty are factors that laboratories need to consider when selecting laboratory equipment. All laboratory equipment, as applicable, is required to be calibrated prior to its use. In fact, it is extremely important that a laboratory have an effective calibration and PM program; this includes a requirement for measurement traceability of calibrated equipment to be traceable to the National Institute of Standards and Technology (NIST) or to the equivalent standard outside of the United States (see Figure 6.4.1).

Training and Operation

Training is extremely important when it comes to the operation of equipment employed for testing and calibration. It is imperative that each engineer, operator, and technician be properly trained in the use of laboratory equipment. In some cases, it may be necessary for the equipment manufacturer to provide the training because of equipment complexity. Regardless, the training
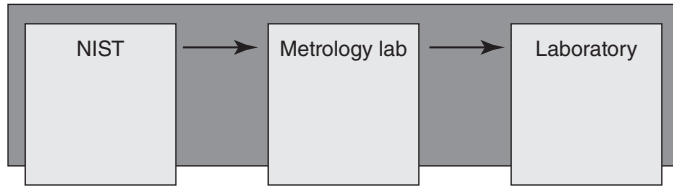
Figure 6.4.1   Traceability block diagram.

should be documented within the training folders for all laboratory personnel. Best practice would be to place the requirement to operate specific pieces of equipment into the laboratory's job descriptions. It is recommended that the operation manual for each piece of equipment be made available at their point of use. A practice that works extremely well is to build a kiosk in the laboratory that houses all the appropriate work instructions, procedures, and manuals relevant to the work being performed in the laboratory area.

Equipment Identification and Record Keeping

It is imperative that all equipment used in the pursuit of testing and calibration be properly identified. A common practice employed in many industries is to affix a label (see Figure 6.4.2) to each piece of equipment that contains: (a) an equipment identification number, (b) a calibration date, and (c) a calibration due date. For standards sent to a metrology for calibration, this is already a readily accepted practice.

When scripting the procedure for calibration and PM (Control of Monitoring and Measuring Devices), ISO/IEC 17025:2017 requires specific pieces of information to be collected and retained in each equipment file. At a minimum, the following pieces of information need to be included as part of each piece of equipment's master file (the following pieces of data can easily be managed through the use of state-of-the-art software solutions):

- The identification of equipment (including software, if applicable)
- The name of the manufacturer
- The equipment's serial number
- Verification and validation activities, including functional performance
- Equipment owner/location
- Manufacturer's operating instructions or manual or a pointer to the location of the manuals (e.g., a kiosk)

ACME Labs
Equipment ID #: ATL-0001
Cal Date: 03/21/18
Cal Due: 03/20/19
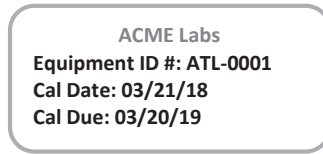
Figure 6.4.2   Equipment calibration label.

- Calibration records (reports, certificates, adjustments, acceptance criteria, and calibration due date)

- PM schedule (if applicable)

- History of equipment problems (damage, out-of-tolerance reports, malfunctions, modifications, and repairs)

Software Tools for Record Management

There are software solutions available that can assist with the management of calibration and PM records. For example, SIMCO Electronics has developed CERDAAC's Compliance Solution—a Title 21 Code of Federal Regulations (CFR) § 11 (the FDA's digital signature requirement) compliance tool for the management of calibration records. Other options on the market include GAGEtrak, Blue Mountain, and CATSWeb. These software solutions have the capability of managing all aspects of record management.

Handling and Storage

A section is needed to address the handling, storage, and transportation of laboratory equipment as part of the laboratory's procedure for calibration and PM. When not in use and when practical, laboratory equipment should be adequately protected in a suitable environment. Whenever possible, best practice is to store and transport laboratory equipment in its original carrying case. When equipment is in place on the laboratory floor, it is important to place the equipment in a manner where it cannot be accidentally dropped or damaged due to its location.

NONCONFORMING EQUIPMENT

When equipment has been identified as being mishandled or providing erroneous results or when it has been determined to be functioning outside of its specification limits, the equipment must be taken out of service

immediately. The first thing that the laboratory should do is tag the piece of suspect equipment with a nonconformance tag. The nonconformance should be handled in accordance with the guidance provided in Chapter 7.10 (Nonconforming Work), including the opening of the nonconforming report (NCR).

Additional Influencers

If laboratory equipment is moved outside of the laboratory's direct control, then the functional performance and calibration status must be verified prior to the return of the equipment to service. In a perfect world, metrology facilities never make mistakes and equipment is never damaged during routine transportation; however, the world is far from perfect. Upon receipt, the equipment should be checked to verify: (1) that a new calibration label has been affixed, (2) that the equipment is functional (it turns on), and (3) that the calibration certificate is accurate. Calibration results should be routinely compared to previous results to ensure that equipment performance remains consistent. If a piece of equipment was determined to be out of tolerance when received by the metrology lab, an adjustment to the calibration interval (in this case, shortening) is in order.

In some cases, correction factors may be needed to equipment or software. Again, the requirement should be documented in the calibration procedure. Correction factors should reside in the equipment file and be updated as required.

It is not unusual for some pieces of laboratory equipment to be dedicated to a specific test or calibration. This is particularly true when the setup of a test or calibration is time consuming. Most equipment has a feature or capability to lock potentiometers into place to prevent measurement adjustments. In these cases, it is often beneficial to lock adjustments into place through the use of lock-out tape or the application of an epoxy adhesive. If software is loaded into laboratory equipment prior to its use, the software must be controlled. Only the most current version of software and firmware should be available at its point of use.

TEST UNCERTAINTY RATIO/TEST ACCURACY RATIO 10:1

According to Rick Hogan:

> Test Uncertainty Ratio or TUR is a common term used in calibration. It is the ratio of the tolerance or specification of the test

measurement in relation to the uncertainty in measurement results. It is used to evaluate measurement risk and validate the suitability of calibration methods. The most common requirement for many calibrations is a 4:1 TUR. However, not all calibrations meet a 4:1 TUR.

USE OF CORRECTION FACTORS

A correction factor is any mathematical adjustment made to a calculation to account for deviations in either the sample or the method of measurement. Additionally, the application of correction factors will vary depending upon the test, instrument, or process being analyzed or calibrated. For example, correction factors used to calibrate an oscilloscope, waveform analyzer, or digital multimeter will vary considerably versus the determination used for assessing insulin sensitivity in a patient who is managing their blood sugar. Simply stated, the correction factors that are calculated will be specific to the task at hand.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have adequate measurement equipment to support testing and calibration?

2. Is equipment and supporting software capable of supporting the necessary accuracy needed for testing and calibration?

3. How is equipment capability determined (Test Uncertainty Ratio/Test Accuracy Ratio 10:1)?

4. Are instructions for the proper operation of equipment available for operatory use?

5. Is equipment being operated by trained operators?

6. Are training records available for the operators and are those records current?

7. Are records being maintained for each piece of equipment?

8. How are these records being maintained (e.g., GAGEtrak)?

9. What type of information do the equipment records contain?

10. Does the laboratory have an established procedure for addressing nonconforming equipment?

11. Does the laboratory permit use of its equipment outside of the laboratory environment?

12. How is equipment that is used outside the laboratory identified?

13. Is equipment that is used outside the laboratory environment evaluated prior to returning it to use inside the laboratory?

14. Is the laboratory employing correction factors in support of calibration?

15. Is test equipment being safeguarded from unauthorized adjustments that can influence measurement accuracy?

CHAPTER REVIEW

Laboratories are required to select and employ equipment capable of providing accurate and repeatable measurements. As part of the selection process, equipment range, accuracy, resolution, and measurement uncertainty must be considered. Laboratory personnel must be properly trained and the training must be documented prior to allowing laboratory personnel to operate equipment. Equipment must be properly identified, including its calibration status. To maintain equipment that is capable of obtaining accurate and repeatable measurement, the laboratory must script a calibration (control of monitoring and measuring devices) procedure that contains sufficient granularity that defines the laboratory's equipment calibration and PM program. When equipment is identified as being nonconforming, the equipment must be removed from service and the nonconformance processed in accordance with clause 7.10 of ISO/IEC 17025:2017.

6.5

Metrological Traceability

INTRODUCTION

The accuracy of the measurements obtained during testing or the performance of calibration can be directly attributed to the equipment employed as part of the measuring process. The cornerstone for measurement traceability is calibration. As mentioned in the previous chapter, all monitoring and measuring equipment must be properly calibrated. ISO/IEC 17025:2017 specifically requires laboratories to establish a program and procedure for calibration. Another requirement of the calibration process is to maintain traceability to a recognized standard. There are several nuances associated with the use of primary measurement standards, national standards, and international standards associated with calibration and specific to ISO/IEC 17025. The fundamental question to ask should be: "When is each standard appropriate for use?" Another challenge for laboratories is the traceability of calibrations and measurements to the International System of Units (SI) or the linking to SI units through the use of a reference made to a national standard. In some cases, the use of SI units is just not practical. Finally, the calibration, use, and management of reference standards are also a requirement of ISO/IEC 17025 requiring an established procedure. In this chapter, a proactive approach for ensuring laboratories can achieve and sustain compliance to clause 5.6 will be discussed, including examples of different approaches for managing calibration and reference standards.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Laboratories are required to calibrate their equipment prior to its use. As stated in Chapter 6.4 (Equipment), laboratories are required to establish a

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—6.5 (METROLOGICAL TRACEABILITY)

- Laboratories are required to establish a procedure that delineates their entire equipment calibration program, including how traceability is maintained for performed measurements (linking back to the appropriate reference or transfer standard).
- Calibration activities require traceability back to an SI. This can be achieved through:
  – Using a competent laboratory for calibration,
  – Using certified values or reference materials, and/or
  – Traceability back to a national standard.
- Not all calibrations can be performed and expressed in SI units. When it is not possible, traceability to an appropriate standard is acceptable. ISO/IEC 17025:2017 permits:
  – The employment of certified reference materials; and
  – The employment of consensus standards.
- When traceability to SI units is not possible, it is acceptable to employ certified reference materials and consensus standards.

Reference Standards

- Laboratories are required to calibrate their reference standards.

Intermediate Checks

- When deemed appropriate for ensuring the accuracy of standards (primary, reference, working, or transfer), performance checks of equipment will be performed.

Transport and Storage

- Laboratories are required to establish written procedures that delineate the proper handling of reference standards and reference materials.

Note: If reference standards are used outside of the laboratory environment, a written procedure shall be generated to define the process.

calibration program that is documented by a written procedure. Besides calibration, the program created by the laboratory must also include the laboratory's processes for:

- Checking equipment

- Controlling measurement standards

- Maintaining measurement standards

- Reference materials employed as measurement standards

SI Units (système international d'unités)

For laboratories dedicated to the execution of calibration work, equipment used must be capable of obtaining accurate measurement and calibration results while being traceable to the SI. SI units, premised on the metric system, have been universally adopted by most countries. However, the United States *has not* adopted the SI unit system. Figure 6.5.1 depicts the seven baseline SI units and their relationship among each other.

Calibration and Traceability

According to the ISO, "calibration" is the set of operations that establish, under specified conditions, the relationship between values as indicated by
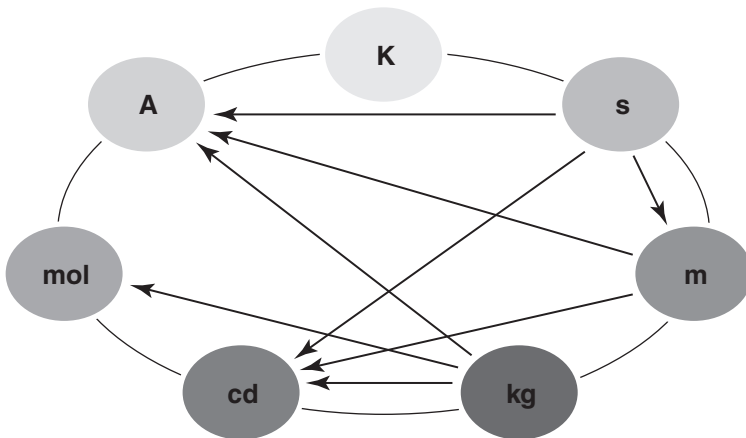

Figure 6.5.1   Seven baseline SI units.

Source: Dono, "File:SI base unit.svg," *Wikipedia*, February 16, 2010, https://en .wikipedia.org/wiki/File:SI_base_unit.svg.

**Issued by
ACME
Labs, Inc.**

(ACME is an accredited ISO/IEC 17025:2017 Laboratory)

Telephone: (123) 456-7890 Fax: (123) 456-7890

ACME

Date of Issue	: 20 March 2018
Type	: Mercury-in-Glass
Specification	: ASTM7C / IP5C
Manufacturer	: CD-USA
Identification	: 134689

Range	: –2 to +300°C
Smallest Division	: 1°C
Immersion	: Total

Approved Signatories

B. Mehta

Customer	: Blue Moon Testing
Address	: 123 Main Street
	: Any City, USA

Certificate Number

2012-03020-001

Order#   1234   Customer#: BMT-02011   ACME Reference #: 2012-0401A

REPORT ON A THERMOMETER

Date Received: 20 March 2018   Date Calibrated: 20 March 2018

Corrections Rounded to: 0.1°C

Uncertainty Corrections: ± 0.15°C (0° to 200°C) and ± 0.20°C (201° to 300°C)

Corrections Applied:

Temperature ITS-90	Thermometer Reading	Corrections to Thermometer Reading
0.0°C	0.0°C	0.0°C
75.0°C	75.0°C	0.0°C
150.0°C	150.0°C	0.0°C
225.0°C	225.0°C	0.0°C
296.0°C	295.0°C	+0.2°C

Corrections reported for liquid-in-glass instruments are standardized to an ambient pressure of 760mmHg. A full 'compliance with specification' check is not undertaken for liquid-in-glass thermometers in that physical dimensions and correctness of scale markings are not examined. All calibrations are by comparison in liquid or fluidized stirred baths. Ambient room temperature during the calibration procedure was monitored as 20°C ± 2°C.

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2, providing a level of confidence of approximately 95%. The uncertainty evaluation has been carried out in accordance with NIST requirements.

Note: This certificate has been created to meet the requirements denoted within ISO/IEC 17025:2017.

Figure 6.5.2   Example of calibration certificate.

a measuring instrument or a measuring system or as indicated by values represented by a material measure and the corresponding known values of a measurand (a quantity intended to be measured). Note: traceability is also a critical component of the calibration process.

According to a working paper developed by the United Nations Industrial Development Organization (UNIDO 2006), "*traceability" is the concept of establishing valid calibration of a measuring standard or instrument by step-by-step comparison with better standards up to an accepted national or international standard.*

Collectively, calibration and traceability are two terms that define a laboratory's calibration program. Basically, all equipment employed in the calibration process must eventually be traceable back to a national standard such as NIST through the use of primary and secondary (reference) standards. It is imperative that when a laboratory employs a metrology lab for the performance of equipment calibration, the metrology laboratory selected should be accredited to ISO/IEC 17025:2017. Compliance with ISO/IEC 17025:2017, although not a complete guarantee, reflects the organization's status of demonstrating technical competence, measurement capability, and measurement traceability.

Use of Independent Metrology Laboratories

As previously stated, when employing an independent metrology laboratory, it is imperative that the laboratory selected should be accredited to ISO/IEC 17025:2017. Prior to their addition onto the approved supplier's list (ASL), the laboratory should be evaluated by employing the tools mentioned in Chapter 5 (Subcontracting Tests and Calibrations) and Chapter 6 (Purchasing Services and Supplies). Make sure the metrology laboratory provides actual values associated with each calibration as part of the Certificate of Calibration (see Figure 6.5.2).

Calibration Procedure Content

Besides the mandatory content requirements specified in Chapter 6.4 (Equipment), best practice is to incorporate the requirements delineated within ISO 9001:2015 or ISO 13485:2016. As a minimum, the following requirements will need to be included and addressed within the laboratory's established calibration procedure:

- Laboratory equipment must be calibrated at predefined intervals against standards that are traceable to a national standard (e.g., NIST). Make sure the calibration intervals are placed into a table within the procedure.

- Laboratory equipment (if applicable) must be able to be adjusted or readjusted as necessary.

- Laboratory equipment will be properly identified in regards to calibration status.

- Laboratory equipment must be safeguarded against adjustments that would invalidate the results of obtained measurements.

- Laboratory equipment must be protected from damage and deterioration during handling, maintenance, and storage.

- Laboratories will need to perform a comparative analysis of calibration data versus the previous calibration data obtained. This is why it is extremely important to have metrology labs provide the actual calibration data.

- Laboratories must take action when nonconforming equipment has been identified.

- Laboratories need to maintain records of all calibration activities.

Testing

Testing within the laboratory still requires the employment of calibrated measuring equipment and includes the requirement for traceability. When equipment is employed for testing, the equipment must be capable of supporting the need for addressing measurement uncertainty. Additionally, testing must be performed within an adequate laboratory environment. For example, if the testing is being performed on biologics, then the expectation is that the laboratory performs these tests in a controlled environment (cleanroom).

Calibration of Reference Standards

Laboratories are required to establish procedures for all of their reference standards. Reference standards should be considered restricted-use standards as they should only be used for calibration. The metrology lab tasked with the calibration of reference standards must ensure the calibration is performed using equipment traceable directly to a national standard (e.g., NIST).

Traceability of Reference Materials

As part of the calibration procedure, the laboratory needs to define the requirements for the control of reference materials. Whenever possible, reference materials will need to be traceable to SI units (except in the United

States). It is always a best practice to employ certified reference materials; however, if certification is not possible, the laboratory will need to establish a procedure for validating the use of reference materials.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Is all laboratory measurement equipment employed in testing and calibration calibrated?

2. Does the laboratory have an established procedure documenting its calibration program?

3. Are measurements that are obtained by laboratories traceable to International System of Units (SI)?

4. If the laboratory is not employing traceability to SI units, has traceability to an appropriate measurement standard been established?

5. Does the laboratory employ reference materials in support of calibration?

6. Does the laboratory have an established procedure for the calibration of reference standards?

7. Does the laboratory have an established procedure for the handling, transportation, and storage of reference materials and standards?

CHAPTER REVIEW

Laboratories are required to establish a calibration program that is documented by an established procedure. All testing and calibration performed within the laboratory must be performed with calibrated equipment with traceability to a national standard (e.g., NIST) to ensure that measurements obtained are accurate and repeatable. Metrology facilities selected for equipment calibration (e.g., reference standards) should be ISO/IEC 17025:2017 accredited. It is always considered a best practice to employ certified reference material; however, if certification is not possible, validating the use of reference material would be the preferred path.

6.6

Externally Provided Products and Services

INTRODUCTION

Laboratories are required to retain only qualified sources for externally provided products and services. Due to the changing needs of a dynamic business environment that may influence laboratories, the use of a subcontracting laboratory facility may become necessary. ISO/IEC 17025:2017 recognizes the inevitable and has identified a few requirements associated with the subcontracting of work to other laboratories. It is incumbent upon the laboratory to ensure that all off-loaded work is sent to a competent subcontractor (e.g., compliant with 17025:2017). A point to keep in mind is that all work done at the subcontractor's location must be performed in accordance with the requirements delineated within 17025:2017. In fact, the facility or organization subcontracting the work is responsible for the accuracy and quality of the work. However, if the use of a specific subcontractor is delineated within a customer's contract, then the customer retains the responsibility for subcontractor performance and general oversight. However, best practice is to take some ownership in the work activities performed at the subcontractor's location, even if the selection process is made by someone else. In this chapter, the identification, selection, and use of qualified subcontractors will be discussed.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

When a laboratory needs to outsource work to another laboratory, the preferred path is to select a laboratory that is already accredited to ISO/IEC 17025:2017. For example, if the laboratory has a valid accreditation

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—6.6 (EXTERNALLY PROVIDED
PRODUCTS AND SERVICES)**

- Laboratories are required to ensure that only suitable, qualified services or products from external sources are chosen, as appropriate.
- Laboratories are required to script a procedure that delineates the requirements for evaluation selection and ongoing monitoring of externally used service or product suppliers.
- Laboratories are required to clearly communicate requirements to their suppliers.

certificate from a recognized accreditation body (e.g., The American Association for Laboratory Accreditation, or A2LA, as it is now known), then the laboratory should have the appropriate certificate and should have completed a brief questionnaire (see Figure 6.6.1). However, if the laboratory selected for outsourcing is not accredited, an on-site evaluation is probably warranted to determine the overall level of compliance to ISO/IEC 17025:2017. The NIST website has a complete supplier survey form that can be employed for the performance of a detailed laboratory assessment. The summary of changes provided in the appendix of this book is also a viable tool.

Another important point to remember pertains to responsibilities and customer notification. The laboratory is ultimately responsible for the performance of all outsourced work. It is also important to ensure the laboratory's customer is informed in writing about any work being outsourced. Hopefully, this will be captured during the initial contact review process.

Finally, there is a need to ensure that a laboratory's supplier base is appropriately qualified. From a QMS perspective, supplier qualification should be premised on risk. For example, a supplier selected to perform janitorial services will probably be considered low risk. Conversely, a supplier that is providing components to repair damaged equipment or that is selected to actually perform the repair work may be considered a medium- or high-risk supplier.

ACME Medical Laboratory Questionnaire—ISO/IEC 17025:2017		
Basic Laboratory Data		
Laboratory Name:		Date Completed:
Address: City: State/Province: Zip code: Country:		
Telephone Number:	Fax Number:	
Laboratory Contact Information		
Senior Supplier Official Name: Title: Email:		
Senior Quality Official Name: Title: Email:		
Senior Regulatory Official Name: Title: Email:		
Name of Management Representative: Title: Email:		
Applicable Certifications (attach copies of all certifications)		
ISO 9001:2015 Yes/No Certificate #: Exp. Date: Issuing Authority:		
ISO 13485: Yes/No Certificate #: Exp. Date: Issuing Authority:		
ISO 17025:2017 Yes/No Certificate #: Exp. Date: Issuing Authority:		
ISO 14001: Yes/No Certificate #: Exp. Date: Issuing Authority:		
FDA Registered Facility: Yes/No Registration #:		
List Additional Certifications (as applicable):		
Business Type		
Public Corporation (C Corp): Yes/No		
Privately Held Corporation (C Corp): Yes/No		
Limited Liability Partnership (LLP): Yes/No		
Laboratory Management Systems (LMS) Questions		
Management System Requirements		
1. Does the laboratory have a documented management system?	Yes	No
2. Does the laboratory have an approved quality manual?	Yes	No
3. Does the laboratory have a quality manager and technical manager?	Yes	No
4. Does the laboratory have a written quality policy?	Yes	No

Figure 6.6.1 Sample questionnaire.   (*continued*)

5. Does the laboratory have established quality objectives?	Yes	No
6. Does the laboratory have an established document control procedure?	Yes	No
7. Does the laboratory have an organization chart?	Yes	No
8. Does the laboratory have an established procedure for contract reviews?	Yes	No
9. Does the laboratory outsource testing and calibration work?	Yes	No
10. Does the laboratory have an established procedure for purchasing?	Yes	No
11. Does the laboratory have an established procedure for complaint management?	Yes	No
12. Does the laboratory have an established procedure for nonconforming product?	Yes	No
13. Does the laboratory have an established procedure for corrective action?	Yes	No
14. Does the laboratory have an established procedure for preventive action?	Yes	No
15. Does the laboratory have an established procedure for the control of records?	Yes	No
16. Does the laboratory have an established procedure for internal audits?	Yes	No
17. Does the laboratory have an established policy for management reviews?	Yes	No
Process and Resource Requirements		
18. Does the laboratory have an established procedure for training?	Yes	No
19. Do laboratory employees have written job descriptions?	Yes	No
20. Does the laboratory have an established procedure for environmental controls?	Yes	No
21. Are laboratory environmental conditions routinely monitored?	Yes	No
22. Does the laboratory employ only approved test and calibration methods?	Yes	No
23. Does the laboratory have an established procedure for test method validation?	Yes	No
24. Are all methods employed by the laboratory validated prior to their use?	Yes	No
25. Does the laboratory have an established procedure for measurement uncertainty?	Yes	No
26. Does the laboratory have an established procedure for data control?	Yes	No
27. Does the laboratory have an established procedure for equipment maintenance?	Yes	No

Figure 6.6.1   Sample questionnaire.   (*continued*)

28. Does the laboratory have an established procedure for measurement traceability?	Yes	No
29. Does the laboratory have an established procedure for the transportation and storage of equipment?	Yes	No
30. Does the laboratory have an established procedure for the handling of test and calibration items?	Yes	No
31. Does the laboratory have an established in-house calibration program?	Yes	No
32. Does the laboratory have an established procedure for quality control in support of monitoring the validity of testing and calibration results?	Yes	No
33. Does the laboratory have an established procedure for issuing test reports and calibration certificates?	Yes	No
QMS Exclusions and Clarifications		
Please list any QMS exclusions:		
Please explain any "no" answers from Questions 1 through 33:		
Additional comments:		
Name of individual completing this form:		
Title:		
Signature: Date:		
ACME Medical Use Only		
Reviewed by: Accepted: Yes/No Date:		
Signature:		

Figure 6.6.1   Sample questionnaire.   (*continued*)

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory subcontract to external suppliers test and/or calibration work?

2. Are the external suppliers employed for the performance of sub-contracted work in compliance with and/or accredited in accordance with ISO/IEC 17025:2017?

3. Does the laboratory notify customers, in writing, when all or part of their work is outsourced?

4. Does the laboratory maintain an ASL containing the names of their qualified subcontractors?

5. Does the laboratory have documented evidence that their subcontractors are either in compliance with or accredited to ISO/IEC 17025:2017?

6. Are suppliers being appropriately assessed premised on risk?

CHAPTER REVIEW

In review, it is a perfectly acceptable practice for laboratories to outsource work to qualified facilities. It is strongly recommended that outsourced work be shipped to an accredited ISO/IEC 17025:2017 laboratory. However, the actual requirement is for the selected facility to be in compliance with ISO/IEC 17025:2017. Regardless, there are tools available, such as questionnaires, to assist with the selection process. For laboratories that are accredited, the best practice is to have them complete a short supplier questionnaire and provide a copy of their ISO/IEC 17025:2017 certificate. For nonaccredited laboratories, an on-site evaluation is probably warranted. Remember, if the decision is made to outsource work, the laboratory outsourcing the work assumes the responsibility of the quality and integrity of the work performed. Finally, the laboratory must ensure that the customer is notified when the decision is made to outsource any part of a customer's testing or calibration work. Customer notification is required in writing when a decision is made to outsource work, and it is also considered best practice to do so.

7.1

Review of Requests, Tenders, and Contracts

INTRODUCTION

In attempting to break down the concept of "review of requests, tenders, and contracts," this chapter can easily be aligned with clause 8.2 of ISO 9001:2015 (Requirements for Products and Services). Similar to 9001:2015, ISO/IEC 17025:2017 requires laboratories to establish policies and procedures delineating processes associated with the review of customer requests, the identification of laboratory resources, and the selection of an appropriate test method or calibration method to be used for meeting customer requirements. Documented contract reviews are also a salient requirement of 17025:2017. It is not enough for laboratories to review customer and contractual requirements. These critical reviews, including the decision to accept or request a modification or to reject a customer order, must be documented. The use of a contractor must be incorporated into the review process and disclosed to the customer should the laboratory plan to subcontract activities in accordance with ISO/IEC 17025:2017, clause 7.1.1(c). It is inevitable that contract deviations are going to occur. It is imperative to recognize that 17025:2017 requires laboratories to notify their customers when deviations occur or when a decision is made to outsource work to another laboratory. Finally, ISO/IEC 17025:2017 recognizes a contract as being oral or written; however, it is always best to have a written contract that clearly defines customer requirements and expectations. This chapter will expand upon the importance of the review of requests, tenders, and contracts.

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.1 (REVIEW OF REQUESTS, TENDERS, AND CONTRACTS)

- The laboratory must establish a procedure that delineates the review and handling of requests, tenders, and contracts.
- The procedure employed for review must delineate:
  - Requirements (e.g., regarding procedures specific to testing and calibration);
  - The laboratory's capability to actually perform the test and/or calibration;
  - The capability of the selected test or calibration methods to achieve the stated requirements; and
  - The qualification of these external resources and the customer's agreement with their use.

Note: Contracts can be written or oral agreements.

- Laboratories are required to notify customers when their requested method for calibration or test is inappropriate or out of date.
- When requested by the customer, certification should be provided regarding the particular standard or rule that is applicable to the calibration and/or testing.
- All disparities noted within a contract are required to be resolved before the order is accepted and subsequent work is performed.
- All deviations from the contract will require a customer notification.
- Contract reviews are required to be performed when previously approved contracts are amended.
- Laboratories should be prepared to permit reasonable access to their facility upon customer request.
- Records associated with the review of requests, tenders, and contracts shall be retained.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Having an established procedure for contract review is a mandatory requirement for laboratories. The expectation is that the written procedure be prescriptive enough to support an effective contract review process.

Contract/Purchase Order Identification
- Has the correct business name of the customer been provided?
- Does the delivery address differ from the business address?
- Has the correct contact information been provided?
- Have all the necessary drawing and specifications been received?

Scope/Definition of Work or Services to Be Provided
- Is the scope of the work to be performed clearly and concisely listed?
- Are other proposals incorporated in the agreement?
- Is the customer going to provide equipment and materials to support its laboratory work?
- Does the laboratory have the ability to perform the work defined?
- Will any of the defined work need to be subcontracted to another source?

Payment/Terms
- Have the payment terms been clearly defined in the contract/purchase order?
- Has a review of the customer's Dun & Bradstreet rating been performed?

Schedule
- Does the contract/purchase order contain delivery dates?
- Can the laboratory meet those dates? If not, notify the customer and give them scheduling options.
- Does the contract/purchase order contain penalties for failing to meet the delivery dates?

Contract/Purchase Order Changes and Deviations
- Does the customer have a change order process?
- Is there a deviation notification clause in the contract/purchase order?
- If this is a change order, are the changes accurate?
- Will the change order impact the cost or delivery of the product/service?

Contract Claims and Disputes
- Does the contract/purchase order contain a clause for claims and disputes?
- Is there an arbitration clause for the handling of dispute resolution?

Requirements for Indemnity and Insurance
- Does the contract/purchase order contain an indemnity and insurance clause(s)?
- Has the laboratory identified the levels of risk it is willing to assume?
- Are responsibilities for the customer and the laboratory clearly defined?
- Is the laboratory's insurance adequate considering the level of work to be performed?
- Are the laboratory's subcontractors adequately insured?

Warranties
- Are there any warranties (expressed or implied) associated with the contract/purchase order? Note: Typical warranties include: (a) the quality of

Figure 7.1.1 Contract review checklist: Questions and elements to consider.
(*continued*)

materials employed; (b) the quality of work to be performed (e.g., defect free); (c) the conformity of work to the contract's requirements; and (d) the performance of work according to specified requirements or the achievement of a certain result.

Limitation of Liability
- Has the contract/purchase order been reviewed for limitations of liabilities— duties, damages, and defenses?
- Have certain damages—defined, eliminated, or limited-actual damages, consequential damages, liquidated damages—been defined?
- Does the contract/purchase order contain a no-damage-for-delay clause or other scheduling-related clauses that limit recovery?
- Is there a contingent payment clause?
- Is liability limited to insurance proceeds that are recoverable?

Contract Default and Termination
- Does the contract/purchase order contain a default or termination clause?
- Does the contract/purchase order contain a notice-and-opportunity-to-cure clause that is clear, concise, and reasonable?
- Are the rights of terminating party clear, concise, and reasonable?
- Does the contract/purchase order contain a clause for termination of convenience?
- Can wrongful termination be converted to termination for convenience?
- How is compensation determined?
- How are potential damages defined?
- Is there a force majeure clause?

Miscellaneous Requirements
- Does the contract/purchase order contain miscellaneous requirements?
- Are the miscellaneous requirements clearly defined and are they achievable?

Figure 7.1.1   Contract review checklist: Questions and elements to consider.
(*continued*)

One tool that can be implemented quickly is a contract review checklist. The elements noted in Figure 7.1.1 should be considered when construction the checklist.

Remember, it is requirement of the standard to retain all records associated with the contract review process. Additionally, when deviations are noted, it is imperative that the customer be notified and their approval of the deviation approved. Finally, contract changes received after work has commenced require the same level of scrutiny as the original contract/purchase order review.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for the review of requests, tenders, and contracts?

2. Does the review process entail a review of test methods required, an alignment of laboratory capabilities, and a determination regarding whether the customer requirement can be met?

3. Are records of the reviews of requests, tenders, and contracts retained by the laboratory?

4. Does the review entail an assessment for the need to outsource testing or calibration work?

5. Are customers notified of deviations from the contract?

6. Are contracts reviewed when amendments to the contract are made?

CHAPTER REVIEW

Understanding customer requirements is a fundamental requirement of ISO/IEC 17025:2017. Customers will use the contract or a purchase order to delineate their testing and calibration requirements. Attachments to contracts and purchase orders should contain relevant customer drawings, specifications, and, if applicable, test methods. When it comes to the actual contract review, it is strongly recommended to create a review checklist that is reflective of the laboratory's business model. Finally, remember to: (a) retain all records of the contract/purchase order review process, (b) notify customers and obtain their approval for all deviations, and (c) ensure all customer change orders receive an adequate review.

7.2

Selection, Verification, and Validation of Methods

INTRODUCTION

It is not enough for laboratories to perform testing and calibration services in an appropriate environment. ISO/IEC 17025:2017 requires substantial granularity in regards to procedures employed for testing and calibration. For example, established procedures are required to address: (a) sampling requirements, (b) handling, (c) transport, (d) storage, (e) the preparation of items to be tested or calibrated, and (f) the test methodologies employed. Measurement uncertainty and statistical techniques are also salient factors required to be considered as part of the analysis of test and calibration results. Another important tool driving the accuracy, reproducibility, and repeatability of measurement results is the TMV. Standard methods, laboratory-developed methods, and nonstandard methods that are used by a laboratory are required to be validated. The primary focus of the procedures and validated test methods is to support the obtainment of accurate measurement data using a stable measurement platform. Measurement range, accuracy, measurement uncertainty, detection limit, linearity, repeatability, reproducibility, industry-accepted practices for addressing measurement uncertainty, and measurement error will be explored as part of the discussion on compliance in clause 7.2.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Laboratories are required to employ documented procedures and test methods for all test and calibration activities. The test methods employed are required to be validated unless they are a recognized standard developed by

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.2 (SELECTION, VERIFICATION, AND VALIDATION OF METHODS)

General

- Laboratories are required to employ appropriate methods and procedures when performing testing and calibration activities. Procedures should address: sampling plans employed; the handling, transportation, and storage of test samples and equipment; and the preparation of test items and equipment for testing and calibration.
- Measurement uncertainty and statistical methodologies must also be considered. Laboratories are also required to develop and maintain adequate operational instructions for all equipment employed for testing and calibration. When deviations from established laboratory testing and calibration methods occur, not only shall such deviations be documented, but also written technical rationale shall be provided and the deviation shall be approved by the customer.

Note: Recognized standards that contain sufficient granularity are not required to be rewritten by laboratories.

Selection and Verification of Methods

- Laboratories are required to employ test and calibration methods that are appropriate for the testing or calibration being performed. These methods must support the needs of the customer. The expectation is that laboratories employ the latest revision of recognized standards when possible. For cases where the customer does not specify a particular test or calibration method, the laboratory will select and employ a test or calibration method that is appropriate. Test methods developed or adopted by the laboratory must be appropriately validated prior to use. Before selecting a specific test method, laboratories are required to ascertain if they can effectively execute the method selected. If standard methods are employed by a laboratory and changes to a standard method occurs, the laboratory is required to assess those changes and, if necessary, revalidate the standard prior to continued use. If a customer proposes a method that is out of date or not appropriate for the test or calibration to be performed, the laboratory is required to notify the customer of the issue.

- When laboratories decide to develop and implement test and calibration methods for internal use, then these activities must be adequately planned and executed by trained and qualified laboratory personnel. Plans are required to be documented and revised accordingly.
- There may come a point in time when a laboratory may need to employ a nonstandard method. Nonstandard methods require validation prior to their use. Additionally, customer approval is required. *When nonstandard methods are employed, these methods must align with customer requirements to ensure testing and calibration performed aligns with customer specifications.*

Validation of Methods

- Definition of validation: Validation is the conformation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
- Laboratories are required to validate not only nonstandard methods but also methods the laboratory has developed for their internal utilization. Validation activities shall be appropriate in depth and scale to ensure the accuracy and repeatability of each method in its intended use.
- Laboratories are required to assess the range and accuracy of values obtained when validated methods are employed for testing and calibration. Measurement uncertainty, detection limit, measurement repeatability and reproducibility, and measurement robustness must be gauged and assessed.

Estimation of Uncertainty of Measurement

- Laboratories performing their own calibrations are required to establish a procedure that details the calibration process, including measurement uncertainty.
- Laboratories are required to establish, retain, and apply the needed procedures in support of determining measurement uncertainty. The need to employ measurement uncertainty tools is premised on the robustness of the test method.
- When laboratories estimate measurement uncertainty, all sources of uncertainty that can influence measurement accuracy must be included as part of the analytical process.

a recognized organization such as ASTM International. Recognized standards should still be evaluated regarding their intended use within the laboratory. Additionally, all other test methods should be validated regarding their intended use. Further, written procedures and instructions should be generated to provide guidance for laboratory personnel that are tasked with performing the actual test and calibration work. Finally, controlled copies of released procedures and work instructions need to be available at their point of use. If documentation is not available electronically, best practice is to create a document kiosk within each functional area of the laboratory for the purpose of housing relevant procedures and work instructions.

Selection of Test Methods

Whenever possible, it is always recommended that recognized standards be employed for testing or calibration. For calibration of electronic equipment—such as oscilloscopes, voltmeters, RLC bridges, etc.—the manufacturer's calibration method should be adequate. For a gage block set, other factors come into play. Such factors include grade, which will drive the use of an appropriate reference standard to drive the calibration accuracy. The laboratory has the option of developing their own test method to support the mechanical or dimensional assessment and calibration of gage blocks. If the laboratory is tasked with testing the integrity of material or the assessment of biological products, then the chances are good that the laboratory or the laboratory's client will have developed a test method (including a sampling plan) for the products to be tested. Regardless of the test method selected for testing or calibration, it is imperative that the laboratory document the approach and notify the customer of the method employed.

Test Methods

It is not unusual for laboratories to develop their own test methods to support testing and calibration work. The practice is perfectly acceptable; however, laboratory-developed test methods require the same stringent oversight as standard test methods, so a performance of validation is required. Laboratory-developed test methods must be validated for their intended use prior to releasing the test method for general laboratory use. Similar to laboratory-developed test methods, nonstandard test methods require a validation prior to releasing the nonstandard test method for use.

Procedure Content

ISO/IEC 17025:2017 does require that each new procedure generated for test or calibration contain specific content. At a minimum, procedures scripted for testing or calibration should contain (as appropriate):

- Procedure identification

- Scope

- Description of test or calibration

- Test or calibration parameters

- List of necessary equipment to execute the test or calibration

- List of reference standards

- List of reference materials

- Detailed procedural steps

- Test or calibration acceptance or rejection criteria

- Data collection sheets and the data recording process

- Measurement uncertainty

- Process for documenting test or calibration deviations

Test Method Validation

Laboratories must validate all laboratory-developed methods, nonstandard test methods, and standard methods that have been modified for use, regardless of application. According to 21 CFR § 820 (the FDA's Quality System Regulation), validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. Additionally, validation is establishing documented evidence that provides a high degree of assurance a specific process will consistently produce a product that meets its predetermined specifications and quality attributes.

Although not specifically required by the standard, best practice is for a laboratory to script a stand-alone procedure for validation. There are also specific attributes and data quality objectives that ISO/IEC 17025:2017 requires to be considered in support of validation:

- Accuracy

- Precision

- Specificity

- Detection limit

- Limit of quantitation

- Linearity

- Range

- Ruggedness and/or robustness

If all the data quality objectives are achieved and premised on the review and analysis of the data, then the test method is considered to be validated in accordance with ISO/IEC 17025:2017.

The National Association of Testing Authorities (NATA) in Australia has developed a list of questions that can be employed to frame the scope of the method requiring validation:

- What is the purpose of measurement (what is to be identified and why)?

- What are the likely sample matrices?

- Are there interferences expected, and, if so, should they be determined?

- What is the scope (what are the expected concentration levels or ranges)?

- Are there any specific legislative or regulatory requirements?

- Are there any specific equipment accommodations and environmental conditions that need to be considered?

- What type of equipment is to be used?

- Is the method for one specific instrument, or should the method be used by all instruments of the same type?

- What is the method used for the preparation, subsampling, procedure, and included equipment? (NATA, Australia, 2012)

Measurement Uncertainty

To understand the concept of measurement uncertainty, one must first understand the measurement process. A measurement is nothing more than the output of a series of operations being executed to calculate or determine a value. The measurement process essentially transforms inputs into outputs.

Regardless of how well-defined a measurement process is, it is nearly impossible to obtain repeat observations that are identical. This is due to the introduction of variability into the measurement process. Variables introduced into the measurement process—such as laboratory environmental conditions, test methods employed, use of different technicians, materials employed, and equipment employed—each result in measurement uncertainty; each needs to be accounted for as part of the measurement process (Type-B estimates of uncertainty). Statistically, estimating uncertainty can be broken down into two categories: Type-A estimates (an estimate obtained from sample data) and Type-B estimates (uncertainty estimates for measurement process errors resulting from reference attribute bias, display resolution, operator bias, and computation and environmental factors)—also known as heuristic estimates.

For laboratories, it is essential that procedures are scripted and applied to the estimation of measurement uncertainty for all calibrations. It is important to remember that measurement uncertainty values are required to be stated within the calibration certificates and test reports.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Are testing and calibration methods employed by the laboratory documented within written procedures and/or work instructions?

2. Does the laboratory have an established procedure for TMV?

3. Are work instructions and procedures available at their point of use?

4. Have laboratory-designed test and calibration methods been properly validated?

5. Does the laboratory employ nonstandard test and calibration methods for testing and calibration?

6. Are nonstandard methods validated prior to their use?

7. Are range, accuracy, measurement uncertainty, detection limits, measurement linearity, reproducibility, and repeatability considered when validating test methods?

8. How does the laboratory evaluate measurement uncertainty?

9. Does the laboratory have an established procedure for addressing measurement uncertainty?

CHAPTER REVIEW

Since application of standard, laboratory-developed, and nonstandard test methods form the foundation for the performance of testing and calibration work, it is essential that test methods be validated for their intended use. Standard test methods, developed by a recognized body such as ASTM International, do not require formal validation, provided that the methods are employed for testing in their intended use. All other test methods are required to be validated by the laboratory. Identifying the factors of measurement uncertainty is also immensely important in support of obtaining accurate test and calibration results. In fact, measurement uncertainty is such an important influencer that ISO/IEC 17025:2017 requires laboratories to establish a procedure to address it. Finally, maintaining data accuracy and integrity is also a fundamental requirement for laboratories.

7.3

Sampling

INTRODUCTION

Laboratories are required to establish and implement procedures employed for the purpose of sampling materials, substances, and products being tested. It is imperative that the sampling plans be premised on recognized statistical methodologies and that such plans be made available at the point of use. The procedure established for sampling plans must delineate: (a) sample selection, (b) sampling plan, (c) sample withdraw, and (d) sample preparation. In support of achieving compliance with clause 7.3 of ISO/IEC 17025:2017 it is considered best practice to ensure that sampling plans can be directly correlated to a recognized sampling standard, such as the American National Standards Institute/American Society of Quality (ANSI/ASQ) Z1.4. It is essential that the approach to sampling does not influence the accuracy and validity of test and calibration results. In support of the sampling requirement, laboratories are also required to establish a procedure for the recording of data collected during the performance of testing and calibration activities.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Laboratories are required to have and employ sampling plans and establish procedures for the governance of sampling plans and/or delineating custom sampling plans. According to the NIST *Engineering Statistics Handbook:*

> A **sampling plan** is a detailed outline of which measurements will be taken at what times, on which material, in what manner, and by whom. Sampling plans should be designed in such a way that

---

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—7.3 (SAMPLING)**

- Laboratories are required to establish procedures covering the use of sampling plans and to ensure that such procedures are available at the point of use (where testing and calibration is performed). Sampling plans employed by the laboratories must be premised on valid statistical methodologies. The approach to sampling, delineated within a procedure, must identify and address factors requiring to be controlled to ensure that the result of testing and calibration remain valid.
- Laboratories are required to establish procedures supporting the recording of data collected during the use of sampling for testing and calibration. Examples of records needing to be considered and recorded are:
  - References to the sampling methods employed;
  - Date(s) and time(s) when the actual sampling occurred;
  - Data specific to the sampling (e.g., the size of the sample selected);
  - Name(s) of individual(s) participating in the sampling process;
  - Identification of equipment used (serial number, calibration status, etc.);
  - Environmental conditions;
  - Diagrams that support the clarification of sample location, as applicable; and
  - Deviations noted.

---

the resulting data will contain a representative sample of the parameters of interest and allow for all questions, as stated in the goals, to be answered. (NIST/SEMATECH 2012)

Sampling Plans

Depending on the type of test or calibration work being performed within the laboratory, established sampling plans, such as those authored by ANSI and ASQ, may be practical, depending on the application. Sampling plans—such as (a) attribute acceptance plans (e.g., ANSI/ASQ Z1.4); (b) zero acceptance number sampling plans ($C = 0$) (see Figure 7.3.1); and (c) variable acceptance plans (e.g., ANSI/AQS Z1.9)—have proven to be effective in a laboratory environment.

Lot size	.010	.015	.025	.040	.065	.10	.15	.25	.40	.65	1.0	1.5	2.5	4.0	6.5
2–8	All	All	All	All	All	All	All	All	All	All	All	All	5	3	3
9–15	All	All	All	All	All	All	All	All	All	All	13	8	5	3	3
16–25	All	All	All	All	All	All	All	All	32	20	13	8	5	3	3
26–50	All	All	All	All	All	All	All	All	32	20	13	8	7	7	5
51–90	All	All	All	All	All	All	80	50	32	20	13	11	11	8	5
91–150	All	All	All	All	All	125	80	50	32	20	13	13	11	9	6
151–280	All	All	All	All	200	125	80	50	32	29	29	19	13	10	7
281–500	All	All	All	315	200	125	80	50	48	47	29	21	16	11	9
501–1200	All	800	500	315	200	125	80	75	73	47	34	27	19	15	11
1201–3200	1250	800	500	315	200	125	120	116	73	53	42	35	23	18	13
3201–10,000	1250	800	500	315	200	192	189	116	86	68	50	38	29	22	15
10,001–35,000	1250	800	500	315	300	294	189	135	108	77	60	46	35	29	15
35,001–150,000	1250	800	500	490	476	294	218	170	123	96	74	56	40	29	15
150,001–500,000	1250	800	750	715	476	345	270	200	156	119	90	64	40	29	15
500,001 and over	1250	1200	1112	715	556	435	303	244	189	143	102	64	40	29	15

Figure 7.3.1 Zero acceptance numbering sample plan ($C = 0$).

Development of a Sampling Plan

There are eight salient steps that must be taken into consideration for the sampling plan to be statistically relevant (i.e., capable of providing a result that accurately reflects the population from which a sample is being selected) and effective:

1. The sampling plan must contain purpose and scope statements.

2. The sampling plan should contain references (as appropriate).

3. The sampling plan should contain a section for roles and responsibilities.

4. The sampling plan must contain: (a) the parameters selected to be measured, (b) the range of the values to be measured, and (c) the accuracy and resolution required to obtain these measurements.

5. The process for how and when samples will be taken and obtained must be specified.

6. Actual sample sizes need to be specified within the plan.

7. The sampling plan must contain requirements for data collection, data recording, and storage.

8. The sampling plan must be verified prior to its release for use within the laboratory.

Sampling Plan Deviations

If a laboratory is asked by their customer to deviate from established sampling plans, then such a deviation should always be documented. In some cases, a laboratory's customer may have their own sampling plans. These sampling plans should always be reviewed as part of the initial quotation request that is received from the customer and be built into the laboratory's testing and/or calibration documentation that is established for the customer. It is imperative that, when stating the results of testing or calibration work, the sampling data should be included in the test reports or within the calibration certificate.

Recording of Data

As stated within the "Development of a Sampling Plan," the process of recording data should be included. ISO/IEC 17025:2017 specifically requires:

- The sampling plan employed for sampling to be identified

- The environmental conditions to be recorded if it is relevant to the process

- The accurate identification of the location(s) of the samples taken

- The statistical plan the sampling plan is premised on (if appropriate)

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for the use of sampling plans?

2. Are sampling plans available at their point of use in support of testing and calibration?

3. Are deviations from the sampling plans documented?

4. Are sampling plans verified prior to their release?

5. Are the sampling plans statistically relevant?

CHAPTER REVIEW

Laboratories are required to establish procedures for sampling plan creation and sampling plan utilization. The sampling plans engineered by laboratories must be verified prior to their release. Remember, regardless of the approach for sampling, the sampling plans employed must be statistically relevant. ANSI/ASQ has well-established sampling plans that can be employed in the laboratory environment. If it is practical, it makes sense to use them. If a customer requires a laboratory to deviate from their documented procedures, or a customer has their own sampling plan procedure they would like the laboratory to use, then this deviation must be documented within the test report or calibration certificate. Finally, there are specific requirements relating to the process of data recording that are specific to ISO/IEC 17025:2017.

7.4

Handling of Test and Calibration Items

INTRODUCTION

Similar to clauses outlined in ISO 9001:2015, ISO/IEC 17025:2017 requires laboratories to establish procedures that delineate: (a) transportation, (b) receipt, (c) handling, (d) protection, (e) storage, and (f) retention and disposal of test and calibrated items, as applicable. Similar laboratory procedures are required to prevent damage, deterioration, or loss of test and calibration items during storage, handling, and preparation. The salient goal in mind for laboratories should be the fundamental protection of the integrity of the test item or the equipment submitted for calibration. Laboratories are also required to implement a process for identification and traceability test and calibrated items. Finally, laboratories must be able to reasonably assess items submitted for test and calibration and to ascertain the suitability of the item prior to the commencement of testing or calibration work.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Laboratories are required to establish procedures for the transportation, receipt, handling, protection, storage, and retention and/or disposal of test and/or calibration items. These elements can be placed into a number of different laboratory procedures, or the laboratory can choose to script a standalone procedure. As long as the requirements are documented in a procedure and the laboratory complies with the procedure, then compliance to clause 7.4 can be claimed.

**SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.4
(HANDLING OF TEST AND CALIBRATION ITEMS)**

- Laboratories are required to establish a procedure or set of proce-
dures that delineate how the laboratory manages the overall handling
of items received for test and calibration as well as how the labora-
tory ultimately returns the items to the customer. As a minimum, the
procedure(s) must address: transportation, receipt, handling, storage,
retention, and disposal processes.
- Laboratories are required to create and implement an effective system
for the identification and traceability of items tested and calibrated in
the laboratory. The system needs to support effective data retention
and traceability for the life of the items tested and calibrated.
- When laboratories receive items for test or calibration, and the ini-
tial assessment of these items reflects a nonconformance or sufficient
granularity is not provided regarding a test or calibration method, the
customer will be contacted for further instructions.
- Laboratories are required to establish procedures and operate within
an appropriate environment and facility to prevent damage, deterio-
ration, or loss to test or calibrated items. Additionally, when a con-
trolled environment is required to perform testing and calibration, the
environmental conditions must be monitored and controlled. Further,
laboratories are required to provide adequate storage and security
when such methods are required.

**Note: Best practice is always to treat samples and equipment received
from customers as if it were the laboratory's own.**

Designated Areas and Transportation

As part of the procedure, the laboratory should include a listing of the des-
ignated areas within the lab impacted by the procedure. For example, the
receipt and transportation of items by the laboratory will occur in one of
two ways: (a) it is collected by laboratory's personnel, at a customer site, and
transported back to the laboratory by employing a laboratory vehicle; or (b) it
is shipped to the laboratory through the use of a commercial shipping carrier
(e.g., UPS or FedEx). In any event, the entry point into the laboratory will be
the receiving dock. If the laboratory routinely performs customer pickup and
delivery of test and calibration items, then the transportation of these items

needs to be documented by procedure. It is also a best practice to document all shipping modalities, including packaging, into an established procedure.

Receipt and Identification of Test and/or Calibration Items

The laboratory should perform an initial assessment of the items received for damage relating to handling and transportation when the item is received by the laboratory. If the item is damaged, the event should be documented and the customer contacted for further instructions. It is recommended that laboratories have a holding area for items received as damaged. If the item is received as acceptable, the receipt should be logged into the laboratory's receiving log. Note: the receiving log can be electronic (e.g., a material requirements planning [MRP] system). It is important that receiving personnel are properly trained and are capable of documenting the "As Received Condition" of test and calibration items. As part of the receiving process, the laboratory will: (a) assign a unique work order number (employed for ID and traceability) to the item, (b) affix a tag or label to the item reflecting the work order number, and (c) print the work order that delineates all the processing steps. For electronic MRP systems, the work order may simply be a compiled number of sequential steps that contain a brief description of the work to be performed and a barcode.

Received Test and/or Calibrated Item Inspection

Depending on the type of test or calibration item received, a more thorough inspection may be required versus the typical identification and damage performed on receipt. All additional inspection and assessment activities performed on items as part of the inspection will need to be documented. In many cases, the inspection information can be recorded onto the work order. If a test or calibration item is found to be unfit for testing or calibration, the item should be placed on hold and the customer notified, which is similar to the receiving process. Since the test or calibration item has now entered into the laboratory's work stream, the nonconformance should be documented.

Handling and Protection of Test and/or Calibration Items

It is imperative that laboratories properly handle items to protect them from damage and deterioration while in the custody of the laboratory. For test items, the best practice is to place these items (if possible) into protective storage totes. For equipment sent to the laboratory for calibration, the best

practice is to use the manufacturer's carry case for each piece of equipment. The employment of adequate protection schemes is never optional.

Storage of Test and/or Calibration Items

It is inevitable that storage, even for very brief periods of time, will be required for test and calibration items. Storage is nothing more than an exercise in material handling assuming the laboratory has properly identified such items as they enter the laboratory and the items have been placed into protective bins or their cases. If there are environmental considerations associated with the storage of test samples, the requirements for the control of monitoring the environment must be delineated within a procedure. For example, if a storage area requires the control of temperature and relative humidity, these parameters must be defined in a procedure and evidence of the sustainability of the environment collected. Additionally, the storage of test and calibration items should be in a manner that facilitates the easy retrieval of these items. Further, security should always be a concern for laboratories. Storage areas should be considered restricted access areas, with access limited to laboratory personnel with functional responsibility of item storage.

Retention and Disposal of Test and/or Calibration Items

Retention and disposal pertains to test samples, as equipment sent to a laboratory for calibration will ultimately be returned to its owner (customer). Depending on the customer, some will want the samples returned with the test report. Sometimes the laboratory is asked to retain the samples. Since there is no predefined retention time denoted within ISO/IEC 17025:2017, the retention time for the samples will need to be defined by the laboratory. If the test samples do not degrade over time, then best practice would be to retain the sample for the same duration as the test report. If samples do degrade over time, then ninety days would be a reasonable duration to retain samples prior to their disposal. However, regardless of the approach for sample retention and disposal, the time frames must clearly be delineated within a procedure and the retention periods clearly conveyed to the customer.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for the handling, receipt, transportation, protection, storage, retention, and, if applicable, disposal of test and calibration items?

2. How does the laboratory identify test and calibration items?

3. Are items received by the laboratory evaluated on receipt for damage and operational performance anomalies?

4. Are laboratory customers promptly notified when items are received as damaged or in a nonoperational or degraded condition?

5. Does the laboratory have the appropriate facilities for avoiding deterioration, loss, or damage to the test or calibration item during storage, handling, and preparation?

6. Does the laboratory have an established procedure for handling items that are required to be secured?

CHAPTER REVIEW

Laboratories are required to establish procedures for the transportation, receipt, handling, protection, storage, and retention and/or disposal of test and/or calibration items. When test and calibration items are received by a laboratory, there must be an initial assessment for damage. This initial assessment must be documented (e.g., "as received condition"). Best practice is to place test items into protective totes or bins. Equipment sent to a laboratory for calibration and repair work should be placed into its original carry case to prevent damage. Laboratories are required to provide adequate storage conditions to protect and preserve tested and calibrated items. Retention and disposal time periods need to be defined in a procedure. The customer should be aware of the laboratory's test item disposal policy. If special environmental controls are necessary, the requirements for environmental controls must be documented in a procedure and the storage area monitored for compliance.

7.5

Technical Records

INTRODUCTION

Technical records have been given a stand-alone section within ISO/IEC 17025:2017 to place an additional emphasis on the importance of technical records. In general, technical records fall under the guise of clause 8.4 of ISO/IEC 17025:2017. They need to be adequately controlled, protected from deterioration, and retained as demonstrated evidence of compliance. As the title of this section suggests, these records are technical in nature. This brief chapter will discuss the importance of technical records and their proper management; however, it is not possible to separate this chapter from the chapter on control of records. Regardless of record construction or type, some level of control is required by this standard.

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—7.5 (TECHNICAL RECORDS)**

- Laboratories will retain technical records that document all testing and calibration activities. The records need to contain sufficient granularity to support an audit trail.
- Records should reflect the time, the date, the individual(s) performing the task, and the actual results.
- Original and amended copies (as appropriate) are required to be retained.

EFFECTIVE TOOLS FOR
IMPLEMENTATION AND COMPLIANCE

Effective tools for complying with the requirements for technical records are quite simple. The standard requires that a laboratory script a procedure that clearly delineates the steps that will be taken to comply with technical requirements. As part of the procedure, the data collection and storage should be adequately addressed. Additionally, the procedure should have the requirements for handling deviations and nonconforming results. It is acceptable to reference the procedure for control of records regarding the requirements for technical record retention. The primary technical record collection will be the report. The collection and recording of technical data are important steps in the technical record process. However, the final report is where the actual data are summarized and the final decisions made, premised on the data collected.

General Requirements

All relevant data collected as part of a laboratory's work is required to be appropriately recorded. For example, records should reflect (as appropriate) the following pieces of information:

- The actual measurement results

- Factors influencing the measurement results

- Influencers that impact measurement uncertainty

- Environmental conditions

- Equipment used to obtain measurement results (including calibration status)

- Individual(s) performing the actual work

- Date(s) and time measurements were obtained

- Deviations from test procedures and protocols

- Nonconforming results

- Additional actions pursued that are relevant to the report, and

- The actual report

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for technical records?

2. Does the procedure identify the appropriate content for technical records?

3. Have requirements for handling deviations and nonconforming results been defined?

4. Have record retention and storage requirements been defined for technical records?

CHAPTER REVIEW

Technical records are required to contain an appropriate level of content, as defined within clause 7.5 of ISO/IEC 17025:2017. The control of technical records can be merged with the control of records requirement delineated within clause 8.4 of ISO/IEC 17025:2017. However, it is imperative that technical records retain adequate granularity to support the measurements being taken and recorded, and that subsequent decisions made are based on the results. Remember, the outcome of the collection of measurement data is a report. The report becomes the prevalent technical record that will be retained by the laboratory.

7.6

Evaluation of Measurement Uncertainty

INTRODUCTION

NIST's definition for measurement uncertainty is:

> A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand (the measurand is the actual quantity that is being measured). (www.nist.org)

ISO/IEC 17025:2017 requires laboratories to identify the contributing factors that can influence measurement uncertainty. There are multiple factors that can influence measurement uncertainty, such as variations in temperature, accuracy of the equipment being used, and even the technical skills of laboratory personnel. It is important to remember that at the most basic level, a measurement is nothing more than the attainment of a value. For example, when performing a final test or a mechanical inspection and obtaining measurement values associated with measuring and monitoring equipment used, the values being obtained through measurement will include: (a) volts, (b) temperature, (c) centimeters, (d) grams, etc. However, once a measured value is obtained, it is important that the quality of the value obtained be determined. Measurement uncertainty is essentially the primary element that will influence the accuracy of the measurement(s) obtained.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

There are tools that can be used to mitigate the challenges associated with measurement uncertainty. For example, ensuring that the output of a measurement process is repeatable and consistently reproducible will drive

---

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.6 (EVALUATION OF MEASUREMENT UNCERTAINTY)

- Laboratories are required to identify all factors that can potentially influence measurement uncertainty. Sampling methodologies shall be included in the analysis.
- Laboratories that perform calibration (e.g., metrology laboratories) are required to evaluate measurement uncertainty *for all calibrations* that they perform. This requirement also applies to the calibration of their laboratory-owned equipment.
- Laboratories that perform testing activities are also required to ascertain measurement uncertainty for their test methods. Additionally, when a test method precludes any determination of measurement uncertainty, laboratories are required to provide an estimation of uncertainty premised on theoretical principles and/or the laboratory's knowledge and practical experience as they pertain to the method.

---

the reduction in measurement variability. TMV is a key ingredient needed to support the obtainment of accurate measurement results.

Additionally, ensuring that the measurement and monitoring of equipment is validated, maintained, and appropriate for the measurement value that is necessary to obtain is equally important. For example, the use of a caliper to obtain a measured value of ≤ 0.001 is not appropriate when a micrometer should be the tool of choice to obtain an accurate measured value.

Further, operator performance is essential when it comes to the use of measuring and monitoring equipment. All staff members tasked with using measuring and monitoring equipment are required to be appropriately trained. Simple concepts, such as knowing how to hold a component when measuring a mechanical parameter or selecting the correct tool to actually obtain a measurement value, requires experience and training.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Is the determination of measurement uncertainty being adequately addressed by procedure?

2. How is measurement uncertainty being determined?

3. Is measuring and monitoring equipment being calibrated?

4. Are calibration activities traceable to a national standard (e.g., NIST)?

5. Have personnel tasked with using measuring and monitoring equipment been appropriately trained?

CHAPTER REVIEW

NIST's definition for measurement uncertainty is: "A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (www.nist .org). It makes no difference if a laboratory calibrates its own equipment, calibrates equipment for others, or performs testing for clients; measurement uncertainty is still required to be ascertained. Challenges associated with measurement uncertainty can be mitigated by executing TMV, ensuring equipment is calibrated and maintained, and adequately training laboratory personnel.

7.7
Assuring the Validity of Results

INTRODUCTION

If one considers that obtaining and reporting accurate test and calibration results are the primary goals of testing and calibration laboratories, assuring the quality of the results should be considered a mission-critical activity. In support of compliance with ISO/IEC 17025:2017, laboratories are required to establish quality control procedures. The quality control procedures are needed to monitor and assess the validity of the data obtained from testing and calibration activities and from the identification of statistical trends. Similar to the requirement for sampling, the employment of applied statistical methodologies should be applied as a tool for data assessment. It is important to remember that the monitoring process must be planned. Elements such as the retesting or recalibration of retained items must be considered as part of the overall monitoring process. A final point that needs to be made pertains to the steps required when analyzed data falls outside of the pre-defined parameters. In this chapter, proactive steps that can be employed in support of achieving compliance with clause 7.7 of ISO/IEC 17025:2017 will be discussed.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Laboratories are required to establish quality control procedures to ensure that the data obtained during the execution of testing and calibration are valid. When developing new procedures for testing and/or calibration, laboratories shall consider carefully all requirements necessary for effective quality control. These requirements should be documented as part of the

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.7
(ASSURING THE VALIDITY OF RESULTS)

- Laboratories are required to establish written procedures in support of monitoring the validity of testing and calibration activities being performed. The recording of test and calibration data must be performed in a manner that facilitates data analysis to support statistical trend identification. The application of acceptable statistical methodologies is always considered a best practice when performing data analysis. The monitoring of laboratory data should always be planned and approved in advance. Elements to be considered as part of the overall approach to data monitoring are:
  - The employment of certified reference materials
  - The employment of certified reference standards
  - Participation in interlaboratory comparison programs
  - Establishment of a proficiency testing program
  - Test and calibration replication program (repeatability testing)
  - Verification of testing and calibration against laboratory retains (retained samples)
  - Correlation of results employing different operational/functional characteristics

Note: The approach selected must always be relevant to the type of testing or calibration being performed.

- The result of data should always be adequately analyzed for compliance against customer requirements, specifications, or established standards. When data are found to be outside of the defined requirements or operating parameters, corrective action must be pursued to ensure that only correct and accurate results are being reported.

quality control procedures. Where necessary, the existing quality control procedures should be assessed for their adequacy. The procedure scripted by the laboratory must contain sufficient granularity to prevent erroneous results of testing and calibration from being reported to the customer. When establishing a procedure, the following suggestions for monitoring the validity of results and detecting trends using planned and structured methods should be considered.

Regular Use of Certified Reference Materials

The definition for certified reference materials (CRM) is:

> reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (ISO 2008)

According to the Institute for Reference Materials and Measurements (IRMM):

> Public confidence in measurement results is important in many aspects of modern society, including consumer protection in food consumption, health-care, environmental protection, and fair trade. CRMs are cornerstones of modern analytical quality assurance because they allow calibration of instruments, validation of methods, and quality control of methods and laboratories based on traceability and comparability of measurement results. (IRMM 2015)

There are numerous CRMs available commercially that a laboratory can procure and quickly employ in support of testing and calibration activities. When a laboratory procures a CRM from a supplier, best practice is to have procurement specifications for each CRM purchased. It should be noted that some CRMs will require controlled environmental conditions for storage to ensure that the validity of the CRM is sustained. Special requirements for handling and storage should be documented within each CRM's procurement specification (as applicable).

CRM, when procured, should always be accompanied by a certificate. The certificate should state the property and values certified and the procedure by which traceability to SI units or a national standard has been established. Each value certified on the certificate should be supported by a statement of measurement uncertainty at a stated level of confidence.

Another source for CRMs is NIST. NIST maintains 1000 different high-quality reference materials that can be employed by laboratories in support of testing and calibration. There are also numerous commercial entities, such as Sigma-Aldrich, that are capable of providing high-quality standards. As the author of this book, I recommend visiting the Sigma-Aldrich website. It contains a plethora of information pertaining to CRM and links that can provide laboratories with relevant regulatory and statutory information.

Internal Quality Control Using Secondary Reference Materials

As previously stated, there are companies that provide detailed traceability and assay results with their standard reference materials (see Figure 7.7.1). Laboratories must ensure that traceability requirements for secondary reference materials are defined within the quality control procedure. Copies of all certifications for secondary reference standards must be retained. A requirement for certification retention, including retention periods, should be specified within laboratory procedures.

Proficiency Testing Program and Participation in Interlaboratory Comparison Program

According to NIST:

> A proficiency test (PT) is simply a method that you may use to validate a particular measurement process. The artifact's reference value is not known by the participating laboratory at the time of its measurement (test). In a well-designed proficiency test, the reference value for the artifact should be principally determined by a competent laboratory with appropriate traceability to the International System of Units (SI). The reference laboratory should also have demonstrated its competency though key comparisons, inter-laboratory comparisons, or proficiency tests appropriate to validate their measurement capability. It is also preferable that the laboratory has had its competency independently assessed through the process of laboratory accreditation. Lastly, in order to appropriately validate the measurement capability of the participating laboratory, the uncertainty assigned to the artifact by the reference laboratory should be sufficiently smaller than the
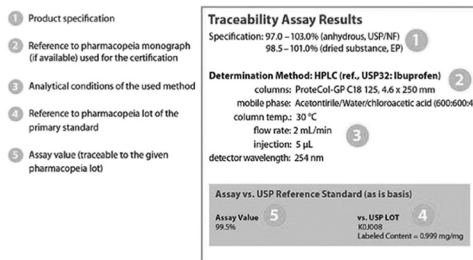
Figure 7.7.1 Example of traceability certification.

expanded uncertainty reported by the participating laboratory. (www.nist.org)

It is strongly recommended that a laboratory participate in at least two PT programs annually for each laboratory discipline. The PT program must cover all functional areas for which the laboratory has received accreditation. Failure to perform PT testing can result in the laboratory's loss of accreditation.

NIST recommends that laboratories develop and employ a proficiency testing plan (PTP) to substantiate the quality, accuracy, and repeatability of test and calibration results. Employing PTPs are an excellent way for laboratories to support the requirement of monitoring the validity of test and calibration results and the overall validation of a laboratory's measurement process.

According to the National Association for Proficiency Testing:

> Several different methodologies are used to evaluate and report the results of a proficiency test. ISO Guide 43, *Proficiency Testing by Inter-laboratory Comparisons—Annex A,* provides guidance. NCSLI Recommended Practice, *Guide for Inter-laboratory Comparisons*, is another excellent source of information. The most widely accepted method compares the measured data against established reference values. The result is the En (called E sub n) number. When the En is between +1 and –1 no corrective action is required. A second method for evaluating and reporting proficiency test results centers around determining the inclusion and/or overlap of a participant's measured values and associated uncertainties with that of the artifact's reported reference values and uncertainties. This evaluation is simply given as "Within," "In," and "Out." Both of these evaluations can be displayed using charts/graphs, making a relatively simple comparison. Besides being compared in the reference values, a report is also prepared showing the data from all participants. With this information it is relatively easy to note individual performance compared to that of peers within the industry. (NAPT 2015)

Test and Calibration Replication Employing Different Methods

According to ORA Regulatory Laboratories Laboratory Manual of Quality Policies:

> Replicate testing may be performed on samples which are found to be violative. The original sample results are verified by using an

alternative method or by rechecking results by the same method. A violative chemistry result may be verified by a second instrument, another method, a second analyst or repeated by the same analyst. A violative microbiology result by a rapid screening method is verified by a culture method. (US FDA Office of Regulatory Affairs 2014)

Retesting and/or Recalibration of Retained Items

The retesting of retained items is nothing more than the reintroduction of retained items into the normal testing and/or calibration environment to assess the ongoing performance of the laboratory. The expectation is to establish a history of repeatable testing and calibration results.

Correlation of Results for Different Item Characteristics

According to ORA Regulatory Laboratories *Laboratory Manual of Quality Policies:*

> Checking for correlation means evaluating the interrelated characteristics (analytes) of the sample. By comparing results from different analyses on the same test item, one checks for reasonableness (i.e., Does the data make sense or correspond as anticipated?). Certain characteristics within the sample will maintain an analogous relationship to one another with regard to the type of test being performed. If one characteristic is dependent on or at all indicative of another characteristic, they should be compared for consistency. The supervisor or designated reviewer should be able to anticipate and recognize an analogous relationship with different characteristics of the same sample. Any deviation such as the absence of expected primary characteristics or the sudden appearance of previously unobserved characteristics of the sample, signals the probability of error. (US FDA Office of Regulatory Affairs 2014)

Analysis of Quality Control Data

One way to accomplish this task is the employment of applied statistical methodologies for the analysis of data collected. Best laboratory practice is to ensure that all data sheets containing test results or calibration results should be assessed for accuracy and acceptability. Control limits

should be established by the laboratory and documented within a procedure. If, during the execution of testing or calibration, the measured data are found to fall within the control limits, then the data should be deemed acceptable.

Other tools, such as accuracy and control charts, can be employed to determine if the measurement system process employed by the laboratory is capable of providing accurate and repeatable results. Control charts are great tools that can be used for quickly identifying data patterns in support of identifying process variation and assignable causes.

Data Found to Be Outside Predefined Criteria

When data are found to be outside the predefined criteria "control limits" then corrective action is required to mitigate the out-of-tolerance condition. The first steps pursued should be verifying the data results for transcription, calculation errors, equipment set-up errors, or sample preparation errors. It may be necessary to use a new set of standards or recalibrate the instrument employed for the initial measurements.

Monitoring for Validity

It is important to note that reliable and valid results, although a limited relationship exists, are not the same when it comes to measurements. For example, a measurement process can be reliable in that repeatable results are obtained; however, these results may not be valid. For example, if a voltmeter is out of tolerance and producing repeatable results that are always one volt lower than the actual value, the measurement can be considered reliable but not valid. To ensure validity is sustained, it is imperative that the validity of the output is determined and continuously monitored.

Trending of Calibration Data

Trending of calibration data consists of tracking the results of calibration over time. For example, a calibration report/certificate should contain the results of the actual calibration, including the recording of all adjustments made. Upon receipt, the contracting establishment should review the certificate and determine if the results are acceptable prior to placing an instrument or gage back into service. Additionally, this data should be trended so the short-term and long-term predictability of instrument or gage performance can be determined.

Out-of-Tolerance Scenarios

For a manufacturing organization, the receipt of an out-of-tolerance event can be a scary proposition, especially if the manufacturer is a medical device establishment. Products already in use that are considered suspect have to be evaluated to ensure that the out-of-tolerance event has not resulted in device performance, safety, and efficacy issues. If devices are determined to be nonconforming, a market product withdrawal may become a reality for the manufacturer. In any event, the owner of the piece of equipment or gage found to be out-of-tolerance will be required to perform an investigation and pursue an appropriate level of corrective action to remedy the issue.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for monitoring the validity of testing and calibrations performed?

2. Are the results of testing and calibration recorded in such a manner so that trends in data can be assessed?

3. Does the laboratory apply statistical techniques in support of data review and analysis?

4. How does the laboratory handle data when the data show that the results obtained were outside the defined limits?

5. Is corrective action being pursued when incorrect results have been reported to a customer?

CHAPTER REVIEW

Laboratories must ensure that the results of testing and calibration are accurate and repeatable. There are a number of different tools that can be used by laboratories to ensure that consistency is achieved within the laboratory. ISO/IEC 17025:2017 makes a suggestion regarding five processes that have proven to be effective tools for assuring the quality of test and calibration results:

1. Regular use of CRMs and/or internal quality control using secondary reference materials

2. Participation in interlaboratory comparison or proficiency testing programs

3. Replication of tests or calibrations using the same or different methods

4. The retest or recalibration of retained items

5. The correlation of results for different characteristics of an item

Using control charts and statistical techniques for data analysis and having a dedicated laboratory resource to provide a thorough review of testing and calibration results will ensure that customers receive acceptable results, quantified by acceptable data, on a continuous basis.

7.8

Reporting the Results

INTRODUCTION

Reporting the results is as equally important as the importance of protecting the integrity of testing and calibration measurements and data noted in Chapter 7.7. In accordance with clause 7.8 of ISO/IEC 17025:2017, the results of testing and calibration activities must be: (a) accurate, (b) clear, (c) unambiguous, (d) objective, and (e) in accordance with instructions and methods employed for calibration. Depending on the structure of the contract, results may not actually be reported but retained by laboratories and made available on customer demand. Calibration certificates created and issued by laboratories have specific reporting requirements. Information such as title, laboratory name and address, and customer name and address are examples of some of the basic information required. Similar mandatory inputs are also required for test reports. The standard has very specific requirements that will be reviewed as part of this chapter's material. If testing and calibration was performed employing a subcontractor, this too must be reported. The good news is there are no set formats or style requirements for a test report or calibration certificate; however, it is strongly recommended that laboratories create a format or template for consistency. A sample of a test report and calibration certificate will be presented as part of this chapter's material.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

When all the test and/or calibration work has been completed, laboratories need to quantify the results and report them in a test report or calibration certificate. To ensure that customers are able to quickly find and review relevant information in test reports or calibration certificates, it is incumbent

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.8 (REPORTING THE RESULTS)

General

- Laboratories must report the results of testing and calibration work accurately.
- The results of testing and calibration should be reported employing a readable test report format or a calibration certificate.
- Depending upon the customer (internal or external), it is acceptable to simplify the report or to use the customer's report format. However, all data relating to the testing or calibration must be retained and made available on request.

Note: Typical names associated with reports and certifications are test reports, test certificates, calibration reports, and calibration certificates.

Note: Reports and certificates can be issued as hard-copy documents or electronic records.

Test Reports and Calibration Certificates

Reports and certificates documenting testing and calibration activities shall include:
- A report title
- Laboratory name and address
- Lab location, and, if work was performed elsewhere, the name and address of the additional location
- Report, test, and/or certificate number
- Customer name and address
- List of test or calibration method(s) employed
- Description and condition of items received
- Date received
- Date(s) laboratory work was performed
- Date report was issued
- Sampling plans employed
- Statement that results relate only to actual items tested
- Results of testing and calibration
- Deviations and exclusions from the standard
- Name and signature of person approving the report or certificate

- Statement of results
- Clear pointers to when test results are from an external service provider.

Note: Be sure to include page numbers.

Note: Be sure to add a disclaimer statement, such as: "Laboratory reports and certificates cannot be reproduced without prior approval for the laboratory."

Test Reports

Additionally, test reports may also require the following information to be included, as applicable:
- Deviations, exclusions, and pertinent information relevant to the test method employed or the environmental conditions in which a test was performed
- A statement of conformance or nonconformance to requirements
- A statement pertaining to measurement uncertainty
- Interpretations of the test data and results of testing
- Customer-specific information

If sampling plans were employed, the following bulleted points need to be considered:
- The date the sampling actually took place
- Clear identification of the sample(s)
- Sample location and supporting documentation
- Identification of the applicable sampling plan used
- Relevant environmental conditions
- A list of other relevant standards and procedures employed in support of sampling

Calibration Certificates

- When deemed appropriate, calibration certificates are required to contain this additional information:
    - Relevant environmental conditions
    - Measurement uncertainty
    - Conformity statement to a recognized standard
    - Proof of measurement traceability
- Calibration certificates should be specific to the work performed and reference only applicable requirements, standards, and clauses.

(*continued*)

- When the actual measurement results are not reported, this data must be retained and made available on request.
- Measurement uncertainty must always be considered when stating the results and overall compliance.
- All results, before and after, must be reported when equipment being calibrated is adjusted or repaired.
- Calibration labels and certificates should contain a calibration interval suggested by the customer.

Opinions and Interpretations

- Opinions and interpretations made by laboratories must be supported by written rationale, including the basis for the opinion and the interpretation.

Note: Opinion and interpretations are just that and should not be confused with the actual inspection or test results.

Note: Elements to be considered when offering opinions and interpretations in a test report are: (a) opinions pertaining to the results, (b) opinions pertaining to the contract, (c) opinions relating to recommendations, and (d) opinions relating to improvements.

Note: It is acceptable to communicate opinions and interpretations directly to the customer.

Testing and Calibration Results Obtained from Subcontractors

- Test results obtained from subcontractors must be clearly identified in test reports.
- Reports being issued by subcontractors can be hard copy or electronic.
- Subcontractors are required to issue calibration certificates when they perform the work.

Electronic Transmission of Results

- It is an acceptable practice to transmit the results electronically.

Format of Reports and Certificates

- The format should be suitable for ensuring that information delineated within the report and/or certificate is clear, concise, and unambiguous.

> **Note: Special consideration should be given to the construction and layout of calibration certificates. Once a satisfactory template has been created, stick with it.**
>
> **Note: Headers on the certificates should be standardized.**
>
> **Amendments to Calibration Test Reports and Calibration Certificates**
>
> - Amendments to reports shall be clearly documented. For example, terms such as "Amended Report" or "Corrected Report" should be part of the title or included in a statement that clearly reflects that the report being issued is a revision. If a completely new report is issued, this information needs to be reflected and include a statement to the effect that the new report replaces the original.

on laboratories to standardize the formats of these documents. If there are specific pieces of information a customer requires to be reported in a test report or calibration certificate, the requirement should be placed into the contract.

Test Reports

ISO/IEC 17025:2017 has specific requirements for information required to be placed into each test report. It is imperative that laboratories include this information. Once the test report has been printed and issued, the laboratory must ensure that the data used to populate the test report are retained for the time period specified within the laboratory's control of records procedure.

Calibration Certificates

ISO/IEC 17025:2017 has specific requirements for information required to be placed into each calibration certificate. It is imperative that laboratories include this information. Once the certificate has been printed and issued, the laboratory must ensure that the data used to populate the calibration certificate are retained for the time period specified within the laboratory's control of records procedure.

Amendments to Test Reports and Calibration Certificates

At some point in time, it may be necessary for a laboratory to revise a test report or calibration certificate or to issue a new (replacement) test report or calibration certificate. The process of revision or replacement cannot be performed informally. If a test report or calibration certificate is revised, the word "revised" must makes its way onto the report or certificate. If the test report or calibration certificate is replaced, a reference to the original report must be placed in the replacement report or certificate. Retention of records supporting all amendments must be retained.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. How does the laboratory report the work results of testing and calibration?

2. Do test reports contain information relevant to the testing performed and in accordance with requirements delineated in 5.10.3 of ISO/IEC 17025:2017?

3. Do calibration certificates contain information relevant to the calibration performed and in accordance with requirements delineated in 5.10.4 of ISO/IEC 17025:2017?

4. Are calibration certificates free of recommendations for calibration intervals?

5. If equipment has been repaired prior to calibration, is this information documented on the calibration certificate?

6. Does the laboratory offer opinions and interpretations of test and calibration results?

7. Are opinions and interpretations being made by qualified individuals?

8. When the laboratory employs subcontractors for testing and calibration, are the subcontractors required to provide test reports and calibration certificates?

9. Does the laboratory permit the electronic transfer of report and calibration certificates?

10. How does the laboratory handle the amendment of test reports and calibration certificates?

CHAPTER REVIEW

ISO/IEC 17025:2017 has specific requirements for information required to be placed into test reports and calibration certificates. It is imperative that laboratories ensure their reports and certificates comply with these requirements. Once test reports and calibration certificates have been generated, the data used to populate these documents must be retained in accordance with the laboratory's control of records procedure. Amendments to test reports and calibration certificates (revisions and replacements) must be adequately documented with traceability back to the original documents retained. The terms revised, amended, replacement, and other such terms must find their way into the new certificates and reports.

7.9

Complaints

INTRODUCTION

Having to deal with a complaint from a customer is never a pleasant ordeal. Unfortunately, laboratories are not immune from customer complaints and face perils similar to product manufacturers. ISO/IEC 17025:2017 requires laboratories to establish a policy supported by a well-written procedure to delineate the process of addressing customer complaints that also include the investigative process and subsequent corrective action. Although there are always negative connotations associated with complaints, world-class organizations have the ability to use critical feedback received from the customer to drive continuous performance and actually turn a customer complaint into an event with a positive outcome. The fundamental key is to treat each complaint event proactively while striving to resolve the concerns of the customer. In this chapter, proven methods employed by organizations to manage customer complaints will be reviewed in support of achieving compliance with ISO/IEC 17025:2017 requirements.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Complaints coming from a customer are never pleasant events. Regardless of fault, customers believe they are always in the right. This perception makes the handling of a customer complaint all the more challenging. There are a variety of different tools that can be employed to assist with the complaint mitigation process. Regardless of the approach pursued, the complaint management process needs to be a closed-loop event. Figure 7.9.1 contains an example of a closed-loop feedback process. The salient steps associated with

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.9 (COMPLAINTS)

- Laboratories are required to establish a policy and procedure for the handling of complaints. As part of the complaint management process, records of complaints, complaint investigations, and corrective actions pursued in support of complaint mitigation must be retained.
- A copy of the complaint management process shall be made available to interested parties on request.
- The complaint handling process shall include: (a) a detailed description of the complaint-handling process; (b) the tracking, recording, and mitigation of said complaints; and (c) assurance that complaint corrective actions are appropriate and complete.
- Laboratories receiving the complaint are required to take ownership of the complaint.
- Outcomes of complaint investigations shall be shared with the complainant.
- Laboratories shall provide final notice when a complaint has been closed, as is appropriate and recommended.

Refine changes

Collect data

Communicate feedback
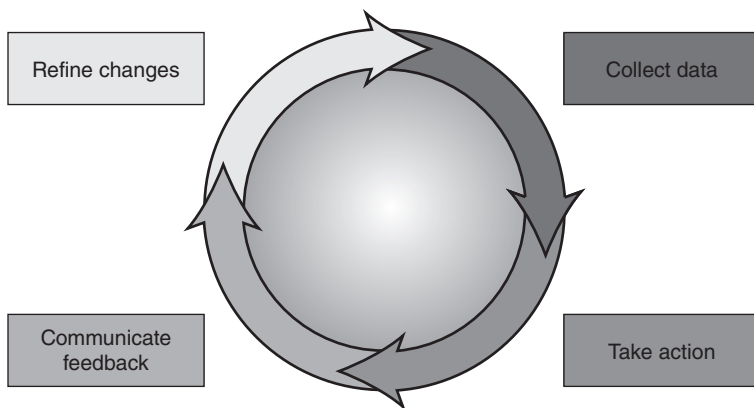
Take action

Figure 7.9.1   Four-step closed-loop process.

Figure 7.9.1 are: (a) collect data, (b) take action, (c) communicate feedback, and (d) refine changes.

Step 1. Collect Data

It is imperative that all relevant data be collected. A good source of data could be similar complaints from other customers or information gleaned from customer satisfaction surveys (the topic of Chapter 7.8). If the complaint information collected is insufficient, do not be afraid to contact the customer(s) to obtain as much useful information as possible.

Step 2. Take Action

It is not enough just to collect the data. Once collected, the data must be properly analyzed to hopefully draw a conclusion as to the root cause of the complaint. If the data are inconclusive, revisit step 1, "Collect Data," and collect more data. Tools such as the Eight Disciplines of Problem Solving and DMAIC (define, measure, analyze, improve, and control) are useful when they are employed as part of the investigative process.

Step 3. Communicate Feedback

Once the complaint investigation has been completed, it is important to communicate the results of the investigation back to the customer. If the results of the root-cause analysis are inconclusive, do not be afraid to state that fact to the customer. However, work should continue to determine the root cause. Typically, a failure to ascertain root cause should be a sufficient reason to open up a formal corrective action request (CAR) to further diagnosis the cause(s) behind a complaint. If step 2, "Take Action," results in a definitive root cause being determined, share the results with the customer(s) along with a solemn pledge to work hard to prevent such a recurrence.

Step 4. Refine the Changes

If the first three steps are executed properly, then it is important to implement the changes necessary to prevent a recurrence of the complaint. Until formal action is implemented and a Verification of Effectiveness (VOE) is performed, there is no guarantee that the issue causing the initial complaint has been resolved. Having a repeat complaint, after the customer has been notified that the problem has been resolved, will be a game changer.

Complaint Form
Customer complaint number: Date opened: Nature of the complaint: Name of complainant: Phone number: Complainant address:
Complaint received by: Title: Date received: By: ❑ Visit   ❑ Phone   ❑ Letter   ❑ Sales   ❑ Credit memo   ❑ Other
Complaint Issue   ❑ Testing accuracy: ❑ Missing certificate of conformance: ❑ Missing certificate of calibration: ❑ Equipment received damaged: ❑ Other (specify):
Received by QA manager: Date: Assigned to: Response due: Instructions: Distribution: ❑ Quality control   ❑ Engineering   ❑ Production   ❑ Sales
Analysis   CAPA required: ❑ Yes   ❑ No   CAR number: **Evaluation**   Date(s) evaluation performed: Evaluation results:
Action/Reply to Customer   ❑ None. Reason for no action: ❑ Replaced   ❑ Repaired   ❑ Credit   ❑ Letter sent   ❑ Sales follow-up
Final Disposition   Reviewed by QA: Date: Reviewed by Engineering: Date: Reviewed by Regulatory: Date:

Figure 7.9.2   Sample complaint form.

Formalize the Process

The management of complaints needs to be a formalized process. Clause 7.9 of ISO/IEC 17025:2017 requires laboratories to establish a policy and written procedure to delineate the complaint management process. It is essential that a complaint form be created to support the complaint process. Granted, even though the complaint form created will be tailored for use in a specific laboratory environment, there are going to be many similarities in regard to most complaint forms. Figure 7.9.2 contains a generic complaint form that contains information relevant to a laboratory environment.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for complaint management?

2. Are customer complaints thoroughly investigated?

3. When the results of an investigation support the need for corrective action, is corrective action actively pursued?

4. Are records of complaints being maintained by the laboratory?

CHAPTER REVIEW

No organization likes to receive negative, critical feedback. However, feedback critical of a laboratory should be treated as a gift. Chances are pretty good that a laboratory's customer(s) are unhappy; this may be the one and only chance to address and correct the complaint. Remember, the key is to be proactive. Not only is the customer expecting a root-cause analysis to prevent future problems with service, but they also want to be kept in the loop. It is *imperative* that the customer remain in the communication loop. If the results of an investigation are inconclusive, do not be afraid to say so. However, the work toward determining the root-cause analysis should continue. One final thought before closing out this chapter: "If a laboratory does not take care of its customer base, rest assured another laboratory will step in and gladly fill the role."

7.10

Nonconforming Work

INTRODUCTION

It is inevitable that at some point in time a nonconforming event will impact a test or calibration performed by a laboratory. Clause 7.10 of ISO/IEC 17025:2017 was scripted to provide laboratories a blueprint for working through nonconformances identified during the execution of testing and calibration services. A salient point that needs to be made is that a nonconformance can fall into two categories: (a) a nonconformance against a laboratories internal procedures and methods or (b) a nonconformance against failing to meet a customer-specified requirement. Regardless, once a nonconformance has been identified, the standard requires immediate and decisive action to resolve the problem. The laboratory is required to investigate the nonconformance, determine the appropriate action (e.g., accept the nonconformance or repeat the testing), notify the customer if such a notification is deemed appropriate, and pursue formal corrective action to prevent the recurrence of a nonconformance. This chapter will explore a proactive approach for complying with the management of nonconformance in a laboratory environment.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Similar to other salient requirements delineated in ISO/IEC 17025:2017, the management of nonconforming testing and calibration requires the establishment of a procedure. For readers familiar with the management of nonconforming product in the traditional sense (typically employed in support of an ISO 9001:2015 QMS), there are many similarities. It is always considered a best practice to establish a stand-alone procedure for the management of nonconforming testing and calibration.

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—7.10 (CONTROL OF NONCONFORMING WORK)

- Laboratories are required to establish a policy and procedure for managing nonconformance testing and/or calibrations when such events occur. As a minimum, the policy and procedure(s) shall address:
  - Management's responsibilities and their authority for managing nonconforming events
  - Initial actions taken, such as containment and risk assessment
  - Evaluation of the nonconforming work, including an impact assessment
  - Decisions made as they pertain to the nonconforming work and potential acceptability
  - Customer notification and recall activities, as applicable
  - Responsibility of work resumption activities
- All nonconforming work activities shall be documented.
- If the results of the investigation into the cause of the nonconforming event result in a determination that a recurrence is possible, laboratories are required to pursue formal corrective action in accordance with clause 8.7 of ISO/IEC 17025:2017.

Some of the elements that will need to be incorporated into the laboratory's procedure for the management of nonconforming testing and calibration are:

- A clear definition of the roles and responsibilities of all laboratory personnel tasked with the handling of nonconforming testing and calibration

- The detailed assessment of the nonconforming work and/or activity

- The pursuit of immediate corrective action

- The decision process for determining the acceptability of nonconforming work and/or activity

- The customer notification process

- The recalling of nonconforming work

- The process for authorizing the resumption of work and/or activities

Depending on the nature of the nonconformance, formal corrective action may be warranted. It can be a difficult task at best to identify what type of nonconformance warrants a CAPA. One way to streamline the process is to categorize the different types of nonconformances that should result in CAPA being pursued. For example, operator error, the use of out-of-tolerance equipment, or the use of past-due calibration equipment are worthy of consideration. If formal corrective action is required, clause 8.7 of ISO/IEC 17025:2017 should be employed for guidance.

There are two important pieces of documentation needed to assist with the identification and documentation of a nonconforming test and/or nonconforming calibration. These are the nonconforming tag (see Figure 7.10.1) and the NCR form (see Figure 7.10.2). For example, once a piece of equipment associated with a nonconforming calibration event is identified, a nonconforming tag should be affixed to it and the instrument quarantined. The form documenting the nonconforming calibration should be opened at the same time. As previously stated, if there is a need for formal corrective action, or if the nonconformance is premised on work outsourced to another laboratory, the form has the ability to document the corrective action decision.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure that governs the handling of nonconforming testing and calibration results?

2. Does the procedure delineate the responsibilities of the laboratory personnel tasked with the review and disposition of nonconforming work?

3. Are formal investigations pursued for nonconforming testing and calibration work?

Date NCR opened:_____ NCR number:_____

Test/Calibration number:_____ S/N:_____

Description:_____

Comments:_____

Figure 7.10.1 Sample nonconforming tag.

Nonconforming Testing or Calibration Information				
Test/calibration number:	Test description/calibrated instrument:	NCR #:	Date:	
Customer name:	PO #:	Date received:	Date:	Date rejected:

Nonconformance type: ❑ Testing   ❑ Calibration   ❑ Other

Item	Specification	Description of nonconformance	Test or calibration

Originator name:	Signature:	Date:

Disposition

❑ Accept—No problem found   ❑ Rework/repeat
❑ Rework/repeat test   ❑ Return to:

Responsibility: ❑ Laboratory   ❑ Contract laboratory

Item	Disposition code	Instructions/Comments

QA name:	Signature:	Date:
Engineering name:	Signature:	Date:
Customer service name:	Signature:	Date:

Closeout		

Corrective action required: ❑ Yes ❑ No	CA:
Supplier notification: ❑ Yes ❑ No	SCAR #:
Customer notification: ❑ Yes ❑ No	Date:

QA name:	Signature:	Date:

Figure 7.10.2 Nonconforming report.

4. What is the laboratory's process for correcting nonconforming work?

5. If nonconforming work has been shipped to the customer, what is the process for recalling the nonconforming work?

6. Is the customer notified of all nonconformances affecting their test or calibration?

7. How is the customer notified?

8. Which laboratory employee is responsible for the authorization for work to continue?

9. If it has been determined through the investigative process that a nonconformance has the potential for reoccurrence, is formal corrective action being pursued to remediate the potential for reoccurrence?

CHAPTER REVIEW

It is extremely important for laboratories to pursue immediate action once a nonconforming test or calibration is noted. Part of the remediation process may require the notifying the customer and potentially recalling nonconforming test articles or pieces of equipment. It is considered to be a best practice to ensure that nonconforming test and calibration events find their way into the laboratory's corrective action system. Corrective action is the only surefire way to prevent a nonconforming test or calibration from recurring in the future. Finally, nonconforming test and calibration events need to be thoroughly documented. The use of a nonconforming report is the appropriate tool. Whenever possible, the material associated with a nonconforming test, or the nonconforming instrumentation associated with a calibration, should be properly identified and quarantined.

7.11

Control of Data and Information Management

INTRODUCTION

Laboratories are required to validate their data control and information management systems. Considering that ISO and other regulators such as the FDA require documentation control systems to be validated and records protected from damage or loss, the fact that laboratories are required to validate their systems is not a foreign concept. Many of the systems employed by laboratories come with validation packages that include written protocols for installation of qualifications and user validations.

Additionally, if third-party service providers are retained (either for maintaining the information system platform or for hosting the actual software employed for data and information management), these suppliers shall be appropriately qualified and managed. Considering the expense associated with state-of-the-art information management systems, laboratories need to protect their investment at all costs.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Two thoughts come to mind when thinking about information management systems and the storage of data: (a) system reliability and (b) data security. State-of-the-art laboratories rely heavily on their technology. Data control and information management systems must be reliable to drive internal operations and must be able to provide reliable access through a secure intranet that allows customers access to their calibration and or test reports. Reliability is achieved through system validation and a robust PM program.

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—7.11 (CONTROL OF DATA AND
INFORMATION MANAGEMENT)**

- Laboratories are required to have access to needed documentation to execute laboratory duties.
- The laboratory information system used to manage documentation and data shall be appropriately validated for its intended use. Changes to software or its configuration shall be appropriately documented and validated prior to its release for use.
- The laboratory information management system (LIMS) shall be: (a) protected from unauthorized access, (b) protected from hacking and loss of data, (c) operated in accordance with its stated specifications, (d) properly maintained to sustain system functionality and data integrity, and (e) able to document system failures and actions taken to remedy system failures.
- If the system is managed by a third-party provider or hosted by a third-party provider (e.g., cloud based), the laboratory shall ensure that these service providers are appropriately qualified.
- User manuals for the system must be readily available for users and other personnel that need system access.
- System calculations and data transfers are required to be verified in a systemic manner.

Additionally, data backup is a fundamental requirement for all information systems. Without an effective way to: (a) store and retrieve data, (b) ensure data security, (c) ensure integrity, and (d) maintain record confidentiality, the information system will quickly lose its allure as an effective tool.

Control of Data

Data accuracy is a fundamental requirement for a laboratory. Laboratories should implement a system for verifying the accuracy of the data collected. If the process employed for data collection is automated or is used by a computer, the software needs to be validated. The equipment employed in support of an automated data collection system (including the computers) needs to be placed in an appropriate environment and maintained to preserve functional capabilities. The laboratory will be required to establish a procedure that clearly defines their entire process for data collection. In accordance with

ISO/IEC 17025:2017, the procedure generated for data control will need to include:

- Data protection
- Data integrity and confidentiality associated with data collection and date entry
- Data storage and backup
- Data retrieval
- Data processing
- Data accessibility
- Data transmission

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory perform a cursory review of obtained data for accuracy?
2. Does the laboratory employ computer software for testing and calibration?
3. Has the computer software been properly validated?
4. Does the laboratory have an established procedure for handling storage, transportation, and PM of equipment?
5. Is the information management system self-hosted or cloud based?
6. What types of security protocols have been implemented?
7. Are third-party service providers retained to service the information management system?
8. What types of supplier qualifications are required for third-party service providers?

CHAPTER REVIEW

It is imperative that laboratories select and qualify a robust information management system for the control of data. In this age of massive hacking attacks,

the security of data and the protection of record confidentiality have to be considered a fundamental requirement of an information management system. Additionally, information management systems need to be reliable. It makes no difference if the system is self-hosted or cloud based—the information management system must be reliable. System reliability is driven by retaining qualified third-party service providers and having a robust PM program to drive system reliability.

8.1

Options

INTRODUCTION

ISO/IEC 17025:2017 allows organizations to pursue two pathways regarding compliance with the establishment of an effective management system, or, as most industries recognize the term, QMS. The first pathway, which will be explored in greater detail within Section 8.0 of this book, is identified as "Option A." The second pathway, identified as "Option B" within ISO/IEC 17025:2017, entails achieving compliance with a known standard, such as ISO 9001:2015. However, for organizations that claim compliance with Option B, they have to demonstrate that the management system appropriately addresses the requirements delineating within ISO/IEC 17025:2015. Simply stated, Option A and Option B are nothing more than equivalent approaches to achieving an effective and compliance management system.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Most competent laboratories that I have assessed over the years have dual certifications: (a) ISO 9001:2015 and (b) ISO/IEC 17025. It is essentially a logical progression to have the management system, which aligns with recognized QMS standards, qualified to ISO 9001:2015. In fact, having an ISO 13485 accreditation would also be considered acceptable, because this standard clearly addresses all the management system elements required of ISO/IEC 17025:2017.

For organizations that do not have a QMS accreditation, the expectation is that the appropriate processes be established to meet Option A

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—8.1 (OPTION A)**

As required by ISO/IEC 17025:2017, laboratories are required to establish a QMS that contains the following elements:

- An appropriate level of QMS documentation shall be scripted
- A document control process shall be established
- Records shall be controlled and retained, as appropriate
- Actions shall be identified and pursued to mitigate risk
- Continuous improvement activities shall be identified and pursued
- Creation of an effective CAPA program as is mandated by the standard
- Creation of an internal audit program is a fundamental requirement
- Management reviews *must* be held and executive management *must* be fully engaged

---

requirements. This means that written procedures would be required to be scripted that address:

- Document control

- Control of records

- Management responsibility

- Management review

- Risk management

- Internal audits

- Continuous improvement

- CAPA

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory possess an ISO 9001:2015 or ISO 13485 accreditation from a recognized registrar or notified body?

2. Has the laboratory's management system been recently audited by their registrar or notified body?

3. What were the results of the laboratory's most recent audit?

4. Were any nonconformances (minor or major) issued?

5. What are the strengths of the laboratory's management system, and conversely, what are their weaknesses?

6. Is there demonstrated evidence that the laboratory strives for continuous improvement?

7. Does the CAPA system appear to be effective?

8. Are audits being performed in accordance with a published audit schedule?

CHAPTER REVIEW

Laboratories are required to establish an effective management system to govern all activities performed within the confines of the laboratory. ISO/IEC 17025:2017 sanctions two pathways for complying with the establishment of a management system requirement: (a) Option A, creating a dedicated management system that complies with this standard, or (b) Option B, obtaining a stand-alone accreditation for ISO 9001:2015 (ISO 13485 would also be a suitable selection).

8.2

Management System Documentation (Option A)

INTRODUCTION

A salient requirement for any organization operating in a regulated environment is the establishment of a fundamentally sound and effective QMS that complies with regulatory requirements, statutory requirements, and recognized standards, such as those authored by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). AS9100, ISO 9001:2015, and ISO 13485 are standards that have been developed to support the development and implementation of effective approaches to quality management. They are recognized blueprints for the establishment of a QMS for many diverse industries. Similar to these recognized QMS standards, ISO/IEC 17025:2017 serves a unique purpose: laboratory accreditation. One thing the reader should keep in mind is the importance of the link between ISO 9001:2015 and ISO/IEC 17025:2017. Laboratories that are accredited and operate in accordance with ISO/IEC 17025:2017 are expected to comply with clauses of ISO 9001:2015 as they pertain to the laboratory environment. It is not uncommon for laboratories such as a metrology lab to possess dual certification or accreditation in ISO 9001:2015 and ISO/IEC 17025. However, there are requirements unique to ISO/IEC 17025:2017 versus ISO 9001:2015. For example, the technical competency of laboratory personnel, the employment of validated testing methodologies, and ongoing proficiency testing for laboratory personnel are salient requirements specific to ISO/IEC 17025:2017. One way to view the differences between these standards is that ISO 9001:2015 provides guidance for an effective QMS while ISO/IEC 17025:2017 drives technical competency within a QMS.

The management system will form the fundamental foundation for any facility wishing to achieve accreditation to ISO/IEC 17025:2017. Similar to ISO 9001:2015, the quality manual becomes a core document employed for describing the management system. Other requirements that need to be

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—8.2 (MANAGEMENT SYSTEM
DOCUMENTATION)**

- Laboratories are required to establish and maintain an effective management system. Policies and objectives must align with the purpose of the organization and meet the requirements of ISO/IEC 17025:2017. Additionally, the policies and objectives must be communicated to all members of the organization and be implemented at all levels, as appropriate.
- Policies and objectives are required to address the need for impartiality, competency, and the sustainability of the ongoing efficiency of the organization.
- Management is required to demonstrate their commitment to establishing an effective management system, including their commitment to drive continuous improvement.
- All associated documentation (policies, procedures, records, processes, systems, etc.) needed to demonstrate compliance with the standard shall be linked under the management system umbrella.
- All the organization's personnel shall have the appropriate access to documentation needed to fulfill their primary duties within the organization.

addressed in support of complying with ISO/IEC 17025:2017 are: (a) written procedures; (b) creation of a concise quality policy statement; (c) management's commitment to develop, implement, and continuously improve the management system; (d) management's communication and reinforcement to the organization of the importance of meeting customer and regulatory requirements; (e) reference(s) to procedures placed into the quality manual; (f) the definition of the roles and responsibilities for technical management and the organization's quality manager; and (g) ongoing sustainment of the integrity of the management system by quality.

EFFECTIVE TOOLS FOR
IMPLEMENTATION AND COMPLIANCE

The path toward accreditation begins with the basic understanding that a laboratory must have an established QMS. Two of the main purposes driving

the need for an established QMS are: (a) the ability to provide accurate and repeatable testing results, supported by data, to the customer; and (b) the ability to maintain accurate records to support the quality of the data provided. Like regulatory requirements enforced by the FDA, the accreditation bodies (see *ISO/IEC 17011:2017—Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies*) require documented evidence of compliance.

The fundamental requirement for achieving compliance with clause 8.2 of ISO/IEC 17025:2017 is the establishment of an effective QMS, including: (a) policies, (b) procedures, and (c) work instructions. Additionally, a well-written and succinct quality policy manual is an excellent tool for linking all the requirements of QMS at a macrolevel. One tool that has proven to be effective in support of developing an effective QMS is the creation of a requirements matrix that maps an organization's QMS to ISO/IEC 17025:2017 (see Table 8.2.1).

The quality policy manual will become the cornerstone of the laboratory's management system. It is the umbrella document that links all the elements of the management system together. The laboratory's quality objectives and quality policy statement are extremely important pieces of information that are required to be embedded into the quality policy manual. The laboratory's objectives, once established, should be reviewed during the management review process (detailed in Chapter 8.9).

The quality policy, similar to ISO 9001:2015, should be appropriate for the organization and state a commitment to meeting the requirements of ISO/IEC 17025:2017, including a commitment by management to continuous improvement. Please note: this is a significant departure from the 2005 version of the standard, which was extremely onerous with specific compliant statements required to be embedded in the policy.

Additional requirements that need to be addressed by laboratory management to achieve compliance with this standard are:

- Evidence of commitment to the development and implementation of a management system

- Evidence of continuous improvement activities in pursuit of improving the management system

- The communication to laboratory personnel of the importance of meeting customer, regulatory, and statutory requirements

- The maintenance of management system integrity when changes to the management system are planned and implemented

These bullet points should be woven into the fabric of the laboratory's management system, with the processes specific to meeting these requirements

Table 8.2.1   Sample requirements matrix.

Document Number (example only)	Revision	Document Name	ISO/IEC 17025:2017	ISO 9001:2015
QSP0001	AA	Quality Policy	8.2	5.2.1
QSP0002	AA	Quality Objectives	8.2	6.2.1
QSP0003	AA	Control of Documents	8.3	7.5

placed in the quality system procedures. For example, management review, corrective action, preventive action, customer complaints, and continuous improvement are examples of tools employed to gauge the overall effectiveness of a laboratory's management system. ISO/IEC 17025:2017 requires written procedures to address these tools. Well-written procedures, employed to measure the overall effectiveness of the management system, will meet the intent of the requirements delineated within clause 8.2 of the standard.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Is the laboratory's management system adequately documented by written policies, procedures, and work instructions?

2. Does the laboratory have a released quality policy manual?

3. Does the laboratory have a documented quality policy?

4. Is the quality policy appropriate for the organization?

5. Has the quality policy been placed into the quality policy manual?

6. Have the laboratory personnel been trained to the quality policy? Is there documented evidence of the training?

7. Is there evidence of continuous improvement activities being pursued?

8. How does management communicate the importance of meeting customer requirements?

9. Does the quality policy manual contain a list of quality procedures or does it make reference to the location of the master list of procedures?

10. Has the role and responsibilities of the laboratory's technical manager been defined?

11. Has the role and responsibilities of the laboratory's quality manager been defined?

12. How is the integrity of the management system maintained when changes to the management system are planned and implemented?

CHAPTER REVIEW

First and foremost, the establishment of a compliant management system, supported by a well-written quality policy manual, is a basic requirement of an ISO/IEC 17025:2017 compliant management system. There are significant similarities between ISO 9001:2015 and ISO/IEC 17025:2017; however, the differences are rooted in technical competencies and in requirements specific to a laboratory environment (testing and calibration). Since the quality policy is often shared with the customer and is typically placed on the laboratory's website, much care should be taken when drafting the quality policy. Additional requirements that result in evidence of compliance, management system effectiveness, and the need to continually improve the management system will be supported by quality system procedures that are written, reviewed, and approved prior to their implementation. One final thought for the reader to remember is that the ultimate goal is to achieve and sustain accreditation to ISO/IEC 17025:2017. The best advice this author can offer is not to take shortcuts when establishing the management system. Compliance to all aspects of the standard, regardless of whether the requirement is written or virtual, is mandatory.

8.3

Control of Management System Documents (Option A)

INTRODUCTION

Organizations cannot place enough emphasis on the importance of the document control function. In a regulated environment, the control of documentation should be treated as a mission-critical process. It is not enough for organizations to just "control" documents; they must manage and control all aspects associated with effective document management. For example, the requirements delineated within ISO/IEC 17025:2017 include: (a) the establishment of documents and procedures, (b) the review of documents and procedures, (c) the approval of documents and procedures, (d) the issuance and control of documents and procedures, (e) the change-control process for documents and procedures, and (f) the removal of obsolete documents and procedures. Experienced quality professionals understand the importance of document control and realize that effective document control can be employed as a tool to facilitate successful internal and external quality audits. Although some organizations and laboratories continue to support a manual approach to a document control, there is an abundance of software platforms that can automate the document control process. Regardless of the approach pursued (manual or automated), this chapter will explore the essential requirements needed to comply with ISO/IEC 17025:2017, clause 8.3—Control of Management System Documents (Option A).

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

There is an abundance of commercial off-the-shelf software available that can be quickly implemented to solve the management of documents

---

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—8.3 (CONTROL OF MANAGEMENT SYSTEM DOCUMENTS)

- Laboratories must establish procedures to control all documents, including externally and internally generated documents.

Note: Documents are policy statements, procedures, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, and plans—regardless of the media employed.

- All documentation issued inside of the laboratory must be reviewed and approved. The laboratory shall create and maintain a master list of procedures (including revisions) and ensure that a process exists for the removal of obsolete documents from their point of use.
- The procedure employed for document control shall ensure that:
  - Only authorized copies of procedures are available for use
  - Documents are reviewed and revised, as appropriate
  - Obsolete documents are quickly removed from their point of use
  - Obsolete documents retained, regardless of purpose, are adequately identified
- Management system documents must be appropriately identified and controlled, either through the use of a date or a revision (e.g., Version AA).
- All document changes must be reviewed and approved.
- Where practical, changes to a document must be adequately identified.
- If a practice of redlining documentation is permitted by the laboratory, the practice must be documented by procedure.
- If a computerized system is employed as part of managing the document control process, a procedure describing the computerized approach must be established.

---

dilemma; however, a procedure still needs to be written. That being said, the most effective tool that can be employed in support of meeting the document control requirement is a well-scripted procedure. Key elements of the document control must include:

- The document numbering system
- The use of revision/version control

- Pagination

- Initial document review and approval

- A master document list

- Any document changes

- Control of external documents

- Document availability

- Document storage

- Redline changes

- Document obsolescence

The Document Numbering System

It is recommended that the document numbering system have some intelligence built into the number. For example, the use of prefixes such as SOP (Standard Operating Procedure), TM (Test Method), WI (Work Instruction), FM (Form), TP (Test Procedure), and QIP (Quality Inspection Procedure) should be considered. Since the functional structure and the industries served for each laboratory may differ, it is acceptable to create prefixes relevant to the laboratory. There is no set standard, although SOP is for the most part universally understood.

As for the physical number, this may be a sequence starting with 1001; for example, SOP-1001 "Document Control" would be an acceptable format. It is also acceptable to align high-level documents, such as a document control procedure with the actual standard. For example, SOP 8.3 "Document Control" would also be considered an acceptable approach.

Please keep in mind that there are some computerized document control systems that will not permit much flexibility, so extreme care must be taken if the laboratory is looking to purchase a software solution with a plan to migrate an already existing document numbering structure.

The Use of Revision/Version Control

The most widely accepted approach to revision control is the use of alphanumeric characters. Depending on the laboratory, the actual term employed may be either "revision" or "version." It is also an acceptable practice to control revisions through the use of a date, although this practice is not nearly as common. In fact, some organizations include both a revision and a date. Another practice needing to be considered is the use of alpha revision

characters for released documentation and numeric revision characters for developmental or engineering documentation. The following examples of revision control would be acceptable:

- SOP-1001 Revision A or SOP-1001 Version A

- SOP-1001, 02/24/18

- SOP-8.3 Revision A (02/24/18)

Initial Document Review and Approval

All documentation should require some level of oversight, review, and approval. For example, the inputting of a regulation or standard may be as simple as the person tasked with document control responsibilities logging the receipt date and entry date of this document into the document control system. For SOPs or TMs that are scripted by the laboratory, a detailed review and approval is probably warranted. Typically, a document change order (DCO) or an engineering change request (ECR) would be used to document this review (see Figure 8.3.1).

Master Document List

Although not required by the standard, it is a common practice to create a master list of documents (MDL). Many organizations choose to list the documents relevant to the QMS in the quality manual; however, all that is required is a pointer to where the list is located. The MDL is an excellent tool that can be used to quickly find a document. Make sure the MDL also contains a reference to the document revision. Remember, it is extremely important to have this type of document available for external audits. The auditor will ask for the MDL, as it really is a road map for the laboratory's document structure.

Document Changes

Similar to the initial review and approval of new documents, all revisions to documents require the same level of scrutiny. A detailed review and subsequent approval are core requirements of a document control system. Additionally, the laboratory needs to ensure that the reviews of document changes are performed by a cross-functional group. For example, if the document being changed is a test procedure, then engineering, quality, and operations are going to want to review it and, if appropriate, provide input into potential changes. In some cases, customer review and approval may be required, so it is important for the laboratory to remain vigilant when processing document

Document Change Request (DCR)			
Part/Drawing No.	**Part Description**	**DCR No.**	**Date** ▪/▪/▪
Reason for Change			
Description of Change			
Originator Name	**Signature**		**Date** ▪/▪/▪

Disposition		
▪ **Disapproved** **Reason for Disapproval**		
▪ **Approved**		**Due Date** ▪/▪/▪
CAT ▪ **I— Initial Release** ▪ **II — Must be implemented by due date**		
Quality Assurance Name	**Signature**	**Date** ▪/▪/▪
Engineering Name	**Signature**	**Date** ▪/▪/▪
Laboratory Name	**Signature**	**Date** ▪/▪/▪

Closeout			
Current Rev	**New Rev**	**Comments**	
Originator Name	**Signature**		**Date** ▪/▪/▪

Figure 8.3.1 Document change request form.

changes. Further, the standard requires a periodic review of documents. A common practice is to associate a planned review date with each document.

Control of External Documents

The document control system needs to be able to manage external standards as well; for example: (a) customer drawings and specifications; (b) standards, such as ISO/IEC 17025:2017; (c) regulatory and statutory documents, such as

21 CFR § 820; and (d) test methods, such as ASTM International that need to be input and tracked by the document control system. It is imperative that laboratories always have the latest version of a document on file. Companies like IHS Markit (2018) can augment the document control process by ensuring that laboratories have the latest and greatest version of a standard.

Document Availability

The most current version of a document must be made available at the point of use. Considering the abundance of available technology, laboratories should consider placing monitors or other remote terminals that are capable of accessing real-time documentation at each location to facilitate the ease of access. If a manual system is in place, build a kiosk to house the most current documentation and to ensure availability of the documents at the point of use. Remember, this is a requirement in accordance with clause 8.3.2(d) of ISO/IEC 17025:2017.

Document Storage
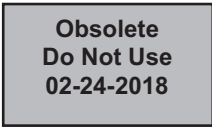
The established procedure must contain sufficient granularity to describe the document storage process. If an electronic system is employed for document control, then the process employed for scanning documents (e.g., PDF format) should be in the document control system. If the control is manual, then the storage location needs to be clearly identified—including levels of access granted to the document storage area. Do not forget about the preservation of these documents, as they need to be protected from damage during routine storage.

Redline Changes

Although the redlining of documents, in support of making document changes, is acceptable under ISO/IEC 17025:2017, it is better to dissuade laboratory personnel from the practice. This author has seen far too many cases of where redline changes were not properly accounted for when a revision to a document was made. The end result was a nonconformance from the accreditation body and/or a repeat of calibration work.

Document Obsolescence

Obsolete documentation needs to be clearly identified as such and removed from point of use as quickly as possible. If it is necessary to retain obsolete

**Obsolete
Do Not Use
02-24-2018**

Figure 8.3.2 Stamp showing a document's status.

documentation at the point of use for historical purposes, then employ a stamp that describes the status of the document (see Figure 8.3.2).

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for the control of documents?

2. Does the control of documents procedure address both internal and external documents?

3. Are documents reviewed and approved prior to their issuance for use within the laboratory?

4. Are procedures and work instructions available at their point of use?

5. What is the laboratory's approach to revising documents?

6. Are obsolete documents identified and removed from use?

7. Are obsolete documents retained as permanent records?

8. Are management system procedures uniquely identified?

9. Are document changes reviewed and approved by the same functional groups tasked with reviewing and approving the initial release?

10. Does the procedure employed for the use of documents allow for redline changes to documents?

11. Does the organization employ a computerized system in support of the control of documents?

CHAPTER REVIEW

Laboratories are required to establish a procedure that delineates their policy and processes for the effective management of documents. It is acceptable to employ an electronic approach to document control, provided that the requirements delineated under clause 8.3 of ISO/IEC 17025:2017 are achieved. It is important to ensure that laboratory-scripted documents are reviewed, approved, and released to their point of use. Additionally, the document control system must be capable of handling external documents. Further, an MDL, including the document revision, must be scripted and retained. Finally, obsolete documents need to be identified as such, and when practical, removed quickly from service.

8.4

Control of Records (Option A)

INTRODUCTION

The effective control of records is a salient requirement for organizations operating in a regulated environment. Similar to ISO 9001:2015, ISO 13485, and AS9100, ISO/IEC 17025:2017 has specific requirements for the control and management of records. The requirements delineated within clause 8.4 (*7.5 for technical records*) are prescriptive and require an established procedure that contains: (a) record identification, (b) record collection, (c) record indexing, (d) record access, (e) record filing, (f) record storage, (g) record maintenance, (h) record disposal, (i) quality records, and (j) technical records. Records falling under this clause can be in the form of a variety of different media; however, for most organizations records are typically in a hard-copy format (paper) or in an electronic format (e-file). Regardless, laboratories must implement adequate systems to preserve records and to retain records in accordance with regulatory, statutory, and customer requirements. First and foremost, the records must be protected and secured to preserve the confidential nature of record content. Establishing a policy for the implementation of good documentation practices (GDP) is paramount to establishing effective record control. Records must always be accurate, and, when errors are made, these errors must be corrected and remain legible. In this chapter, the control and preservation of records, the establishment of a table for record retention for quality and technical records, and the implementation of GDP will be discussed, and tools needed in support of 17025:2017 compliance will be presented.

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—8.4 (CONTROL OF RECORDS)

Control of Records

- Laboratories are required to establish a written procedure for the control and maintenance of all records (quality and technical).
- Records must be legible and stored in a manner that protects records from damage, deterioration, and loss. Records must be easy to retrieve.
- Records must be secure, and the confidential nature of records must be protected.
- Laboratories must have an established procedure for the backup of electronic records and the prevention of unauthorized access to electronic records.

Technical Records

- Laboratories will retain technical records that document all testing and calibration activities. The records need to contain sufficient granularity to support an audit trail. Calibration records should capture: (a) factors influencing measurement uncertainty, (b) the names of the laboratory personnel performing work, (c) observations, and (d) related calibration data.
- Data must be recorded at the time taken and linked to a specific task (test or calibration step).
- When errors or mistakes are made or noted, they must be corrected using GDP. GDP consists of the crossing out of the incorrect data and the addition of the correct data, supported by the date and initials of the person making the correction.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Because of the significant importance ISO/IEC 17025:2017 places on record legibility, record retention (times), record protection from deterioration, record security, data accuracy, reports, GDP, certifications, and electronic records, it is imperative that a laboratory establish a procedure with sufficient granularity to manage all records. As part of the procedure development process, it is important for laboratories to consider: (a) general

requirements, (b) record storage, (c) record retention periods, (d) GDP, (e) packaging and identification of records, (f) indexes of archived records, (g) shipment of records, (h) storage accessibility and security of records, and (i) record inspection and audits.

General Requirements

All laboratory records need to be maintained internally or at an approved off-site storage facility. It is important that laboratory records be readily available to laboratory personnel or customers and regulatory bodies on request. It is also important that laboratory records be adequately protected from deterioration. When deemed necessary, adequate security measures will be employed to protect the confidential nature of customer records.

Record Storage

All records must be legible and stored in appropriate filing containers to minimize deterioration and loss. Records stored electronically need to be backed up on a regular basis.

Record Retention Periods

Quality records and technical records need to have their retention periods specified in the procedure. It is recommended that a table be constructed for the purpose of listing each laboratory record and the records retention time. Table 8.4.1 contains an example of a table that can be employed to define record type and the retention period. Record retention periods should be linked to regulatory, statutory, and customer retention requirements.

Good Documentation Practices

Laboratories are required to implement GDP when it comes to corrections and revisions made to records.

Packaging and Identification of Records

When records are stored off-site, it is imperative that records are properly identified to facilitate their retrieval. Off-site storage facilities such as Iron Mountain will be able to provide guidance in support of the packaging and identification of records.

Table 8.4.1   Sample document matrix for a laboratory.

Document name	Record type	Maintained by	Retention period (minimum)
Approved Suppliers List	Quality	Quality	3 years
Audit Checklist (Internal)	Quality	Quality	2 years
Audit Reports	Quality	Quality	2 years
Calibration Certificates	Quality	Quality	3 years
Calibration Procedures	Technical	Technical	5 years
Calibration Records/Data	Technical	Technical	5 years
Complaint Form	Quality	Customer Service	3 years
Complaint Log	Quality	Customer Service	Permanently
Component Specifications	Technical	Technical	7 years
Contracts/Modifications	Quality	Sales	Permanently
Controlled Environment Monitor Log	Technical	Quality	5 years
Corrective Actions	Quality	Quality	7 years
Customer Drawings	Technical	Document Control	7 years
Engineering Change Order	Quality	Document Control	5 years
External Audit Records	Quality	Quality	5 years

Indexing of Archived Records

The laboratory will be required to index all records processed for archival storage. It is important that laboratories audit archived records to verify accuracy and integrity of the archived records process.

Shipment of Records

The laboratory will need to coordinate the movement of records to be archived and will act as liaison with the storage provider.

Storage Accessibility and Security of Records

All archived records need to be stored with a provider that will protect the integrity of the records and ensure protection against unauthorized access. Additionally, when external facilities are chosen for record storage, the record storage areas need to be maintained in a manner that prevents the deterioration and loss of records.

Record Inspection and Audits

Annual record inspection and audits should be scheduled as part of the internal audit program. The purpose of an annual record inspection and audit is to ensure that the archival record storage areas are adequately protecting the safety, integrity, and security of the records.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for the control of records?

2. Does procedure address the identification, collection, indexing access, filing, storage, maintenance, and disposal of quality and technical records?

3. Does the procedure contain a record retention requirement (length of record retention)?

4. Are records legible?

5. Are records being stored in a suitable environment capable of protecting the records?

6. Are records properly secured as to protect their confidentiality?

7. Does the laboratory have an established procedure for the storage of electronic records?

8. Does the established procedure for storage of electronic records contain a process for the backup, security, and access to electronic records?

9. When mistakes are made in records, does the laboratory employ GDP to correct the errors?

CHAPTER REVIEW

Maintaining the integrity of records (quality and technical) should be considered a mission-critical endeavor by laboratories. The procedure established for the control of records must contain sufficient granularity to ensure records are accurate, legible, preserved, stored under adequate conditions, and readily retrievable. If an off-site storage contractor is employed as part of the laboratory's control of records policy, it is considered a best practice to perform annual audits of the record storage facility. If records are stored electronically, a process for maintaining electronic media must be included in the procedure, including daily backups of electronic files. Finally, it is not practical to retain records forever. It is important to include a record retention table within the records control procedure. Record retention periods should be linked to regulatory, statutory, and customer retention requirements.

8.5

Actions to Address Risks and Opportunities (Option A)

INTRODUCTION

Preventive action is often viewed as one of those gray areas where organizations have some difficulty explaining preventive action or what constitutes preventive action. However, preventive action is also closely aligned with the concepts of risk management and risk mitigation activities. According to ISO/IEC 17025:2017, mitigating risk and employing opportunities to drive organizational improvements and identify potential sources of nonconformities before such nonconformities result in a nonconformance by negatively impacting the laboratory are essential requirements of a management system. It is not enough for the laboratory to simply identify potential opportunities for preventive actions; they must act by employing risk mitigation activities. Laboratories are required to draft preventive action plans, implement preventive action plans, and monitor the effectiveness of preventive action activities pursued. In support of achieving and sustaining compliance with clause 8.5 of ISO/IEC 17025:2017, a proactive approach to mitigating risk and driving opportunities for improvement will be discussed in this chapter.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

The continuous improvement piece is one that is often overlooked by organizations, since organizations move straight into corrective action when problems manifest so quickly. ISO/IEC 17025:2017 requires laboratories to establish a procedure for the mitigation of risks and continuous improvement. This is typically accomplished through preventive action. Although

> **SUMMARY OF ISO/IEC 17025:2017**
> **REQUIREMENT—8.5 (ACTIONS TO ADDRESS**
> **RISKS AND OPPORTUNITIES)**
>
> - Laboratories need to consider the risks and opportunities that may influence the laboratory environment. Risk management is driven by incorporating a preventive action system that: (a) drives management system compliance, (b) drives continuous improvement opportunities, (c) reduces the potential for failures within the laboratory environment, and (d) achieves the desired improvement goals.
> - Laboratories need to plan for improvement activities and opportunities for improvement through preventive action.
> - Actions taken in support of continuous improvement and preventive actions shall be appropriate for the level of risk.

there is no directive to do so, it makes perfectly good sense to marry the corrective action and preventive action/continuous improvement requirements into one procedure. Essentially, the steps taken for preventive action mirror the requirements for corrective action.

The Continuous Improvement Process

The fundamental goal of continuous improvement is to keep potential nonconformances from occurring while ensuring all potential risks are appropriately identified. Identification and mitigation of potential nonconformances are rooted in three basic concepts: (a) the identification of risk, (b) the identification of potential deficiencies, and (c) the prioritization of solutions to drive improvement. There is no better tool to drive these concepts that failure mode and effects analysis (FMEA). Figure 8.5.1 contains an example of a generic FMEA. There are some important things to be considered when creating an FMEA. The following bulleted points need to be considered when constructing an effective FMEA:

- The FMEA must drive design or process improvements as the primary objective

- The FMEA must address all identified high-risk modes

- The FMEA must consider all lessons learned—internal and external to the laboratory.

- The FMEA must identify key characteristic candidates as appropriate

	Function	Failure type	Potential impact	Severity	Potential causes	Occurrence	Detection mode	Detection	Risk priority number
Definition	Brief summary of the function	Describe the failure mode	Describe the potential impact of the problem	How severe is the effect?	What are the potential causes?	What is the frequency of occurrence?	What are the existing controls for detection?	How easy is the failure to detect?	Risk priority number
Example	Control of the mechanical lab temperature	Temperature is out of tolerance	Incorrect calibration values obtained	3	HVAC system failure	1	Temperature chart recorder	2	6

Figure 8.5.1 FMEA example.

- The FMEA should always be completed when it provides the most value and not after a nonconformance has occurred

- The FMEA requires input from subject matter experts to ensure that the FMEA content is adequate

- The FMEA should always be thoroughly completed, with no short-cuts taken

- The FMEA process should always be evaluated for effectiveness

Improvement projects supported by project plans are another approach that can be deployed for effective preventive action. When creating a project plan to support an improvement project, elements to be considered are:

- A clear definition of the actions to be taken

- A definitive time line for each activity

- Assignment of a resource to each activity

- Project reviews and status reports that delineate progress

- A guarantee that there are clear channels of communication for the dissemination of project information

- A formal review and closeout of each improvement project and plan

SWOT Analysis

A SWOT (strengths, weaknesses, opportunities, and threats) analysis may also be considered as an effective tool, albeit much simpler to implement, when it comes to driving continuous improvement. A SWOT analysis is a tool that allows organizations to quickly identify internal and external factors that could impact their ability to achieve tactical and strategic objectives.

Probability-Risk Matrix

Another tool to consider using is the probability-risk matrix. The risk matrix is a tool that can be used to allow organizations to have an increased visibility to risks that could adversely influence the organization. The matrix allows an organization to gauge not only the probability of occurrence but also the potential severity to each identified risk.

QUESTIONS TO CONSIDER
DURING AN AUDIT

1. Does the laboratory have an established procedure for continuous improvement?

2. Are preventive action plans developed when opportunities for improvement are identified?

3. Are records of continuous improvement activities being maintained by the laboratory?

CHAPTER REVIEW

It is a perfectly acceptable approach to marry the corrective action requirement and the continuous improvement (preventive action) requirement into one procedure. In fact, because the steps needed to pursue successful preventive action mimic those of corrective action (including the CAPA form), placing the two requirements together into one procedure makes sense. There are a variety of tools available to support the preventive action process. The FMEA (one of the author's favorite tools) is probably the best choice for the job. However, a SWOT analysis or a probability-risk matrix are also acceptable approaches. FMEAs, when properly constructed, are extremely powerful tools. Depending on the nature of the continuous improvement activity and the potential impact to a laboratory, the pursuit of an improvement project (supported by a project plan and team) may be a viable alternative. In any event, the pursuit of effective preventive action is always a laboratory's best defense to prevent nonconformances from reoccurring.

8.6

Improvement (Option A)

INTRODUCTION

Continuous improvement is a fundamental goal of proactive organizations. W. Edwards Deming, Kaoru Ishikawa, and Genichi Taguchi dedicated their lives to the development of tools to assist organizations in their drive for continuous improvement and to the implementation of quality-driven tools that were effective. The requirements delineated within clause 8.6 of ISO/IEC 17025:2017 reinforces the spirit of these quality pioneers by requiring laboratories to assess the effectiveness of the laboratory's management system. At a minimum, laboratories are required to employ a well-written quality policy, clearly defined quality objectives, results of internal and external audits, corrective action, preventive actions, and management reviews to drive continuous improvement. Proactively seeking customer feedback can also result in the obtainment of valuable critical feedback that can enhance a laboratory's pursuit of improvement. In this chapter, valuable tools needed to drive continuous improvement activities while supporting compliance with ISO/IEC 17025:2017 will be discussed.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

Clause 8.6 is essentially a catchall type of clause that reinforces the need for laboratories to employ all the tools afforded them in the pursuit of improving their management system. It is simply not enough to publish a quality policy, to assemble and publish a few quality objectives, to pursue corrective and preventive actions, to perform a critical assessment of collected data, or to hold an annual management review. Improvement is essentially the sum

---

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—8.6 (IMPROVEMENT)**

- Laboratories are required to invest in the continuous improvement of their management system. Tools deployed by the laboratory in support of management system improvement are: (a) the quality policy, (b) quality objectives, (c) audits (internal and external), (d) data analysis, (e) CAPA, and (f) management review.
- Laboratories are required to pursue feedback from their customers (good and bad).

---

of multiple salient elements required by ISO/IEC 17025:2017. Since most of these requirements are inputs into an effective management review, it is recommended that specific requirements delineated under clause 8.6 be included into the management review agenda. However, since the information is vital to effective laboratory management, reviewing this information annually is not sufficient to drive real-time laboratory improvement.

Quality Policy

The quality policy, although reflective of the laboratory's operating policies and principles, is typically cast in stone. However, it needs to be revisited from time to time and adjusted to reflect the current business environment. It is essential that laboratory employees also receive training for the quality policy, including training in policy meaning. Best practice is to retrain to the quality policy annually. This can be accomplished through an all-hands meeting.

Quality Objectives

The laboratory's quality objectives should be set early in the fiscal year. All laboratory personnel should be aware of the objectives, and the objectives should be posted throughout the laboratory. Quality objectives should be reasonable and be supported by collectable and objective metrics. Best practice is to update quality objective results at least monthly.

Audits (Internal and External)

Progress against an internal audit schedule and the results of internal audits are fairly easy to track. It is recommended that nonconformances identified

during internal audits be loaded into the CAPA system. External audits become a little more subjective, as input is coming from customers and regulatory bodies. However, the feedback coming from external audits should be treated as valuable advice that can be used to drive improvement of the management system. Nonconformances received as a result of external audits should definitely be loaded into the CAPA system.

Data Analysis

Information critical to the effective operation of the laboratory needs to be collected and analyzed for trends. For example, data collection associated with customer complaints, nonconforming testing or calibration, supplier CARs, and so on should analyzed and trended to ensure that performance expectations are being achieved. Without the collection and analysis of critical data, it is nearly impossible to ascertain the effectiveness of ongoing laboratory operations.

Corrective Action and Preventive Action

CAPA, when properly employed, is an effective tool to drive improvement. In fact, any adjustments that need to be made to improve the effectiveness of the management system will be driven by the CAPA program. When in doubt, it is always better to side with caution and ensure that CAPA is pursued for audit nonconformances, unfavorable data trends, nonconforming tests, nonconforming calibrations, and customer complaints.

Management Review

Management review is one of the important elements used to drive continuous improvement. Management reviews are required to be held at planned intervals. Common practice is to hold reviews annually. It is important to understand that, although management review is a mandatory requirement because of the annual requirement typically adhered to by laboratories, its value as an effective tool is limited. The primary purpose behind management review is for senior management to review and gauge the overall effectiveness of the management system for the preceding twelve-month period. Senior management may request that formal corrective action be assigned and pursued if concerns over the performance of the management system are noted.

Customer Feedback

It is imperative that laboratories query their customer base. Information can be gleaned from customer surveys, informal calls, and formal complaints received as part of the complaint management system. Laboratories can use this information to drive improvements in laboratory performance. For example, if there are errors in customer reports, it is incumbent on the laboratory to ascertain why these errors are occurring and to fix the problem. Direct customer feedback is an excellent forum to identify improvement opportunities.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory strive to continuously improve the management system?

2. What are the examples of the tools employed by the laboratory to drive improvement activities?

3. Are improvement activities included in the management review?

4. Are customer surveys being routinely issued to customers?

5. What tools are being used to collect customer feedback?

6. Is customer feedback being used to drive laboratory improvements?

CHAPTER REVIEW

Compliance to clause 8.6 is really premised on multiple requirements delineated within ISO/IEC 17025:2017. The expectation is that laboratories employ a variety of different tools and metrics to collect performance data associated with ongoing laboratory operations and use the subsequent data analysis to identify trends. When trends reflect performance issues with the laboratory's management system, CAPA needs to be pursued to drive corrections and improvements. Internal audits and external audits can also provide valuable insight into the effectiveness of the management system. It is always considered best practice for laboratories to employ all tools at their disposal to create a proactive environment to drive management system improvements.

8.7

Corrective Actions
(Option A)

INTRODUCTION

The ability for an organization to pursue corrective action for the reme-diation of nonconformances is a cornerstone for a QMS. Similar to ISO 9001:2015, establishing documented policies and procedures for corrective action is a salient requirement for ISO/IEC 17025:2017. While establishing a systemic approach to corrective action, inputs that need to be consid-ered are: (a) nonconforming work, (b) deviations from audits (internal and external), (c) customer feedback (typically complaints), and (d) observations made from laboratory employees. Another important influencer of a labo-ratory's approach to corrective action is the ability to frame the problem and to diligently work toward the identification of root cause. Pursuing effective actions to remediate the root cause of nonconformances will be a daunting task if an effective and exhaustive approach to root-cause analysis is not pursued. Once root cause has been established and corrective actions are implemented, it is imperative that these actions be monitored for effective-ness. If necessary, follow-up audits should be planned to preclude future nonconformances.

EFFECTIVE TOOLS FOR
IMPLEMENTATION AND COMPLIANCE

Laboratories are required to establish a policy and procedure to ensure that an effective approach to corrective action is pursued. As part of the policy and procedure, the laboratory must designate an individual(s) responsible for the oversight of the corrective action process. There are several software options available commercially that can be deployed to support meeting

---

**SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—8.7 (CORRECTIVE ACTION)**

- Laboratories are required to establish a policy and written procedure that delineates all activities associated with corrective action. The laboratory will ensure that sufficient authority is granted to a designee to manage corrective action and to act on behalf of management regarding decisions made.
- Corrective action requires a thorough investigation to determine root cause.
- When corrective action is deemed to be necessary, the laboratory will identify proposed corrective actions and implement them accordingly. Pursued corrective actions should be selected on the basis of their ability to resolve the problem originally identified and preclude the recurrence of similar problems in the future. All corrective action activities are required to be documented.
- If the corrective action requires that revisions be made to the management system, do not be afraid of revising the management system and its associated documents. Remember, the management system is a living collection of documents.

Note: Ensure that the corrective action pursued is appropriate for the nonconformances and for the actual risk!

- Laboratories are required to perform verification of effectiveness to ensure that corrective actions implemented are robust and effective.
- Records of pursued corrective action activities are required to be collected and retained—including the nature of the activities pursued and the outcome of the corrective actions pursued.
- When nonconformances are identified and corrective actions are pursued, laboratories are required to perform additional audits as deemed necessary and premised on elevated business risk to ensure that compliance to ISO/IEC 17025:2017 is sustained.

---

the requirements delineated within clause 4.11 of ISO/IEC 17025:2017. For example, CATSweb and Master Control are software products dedicated to a proactive approach for corrective action. If a laboratory is not inclined to spend money on a software solution, using basic software products such as Microsoft Word and Excel with secured and password-protected spreadsheet

access given only to the designate for oversight of the correction action process is an acceptable solution.

As part of the corrective action process, much emphasis must be placed on ascertaining root cause. There are tools available that can be implemented immediately to assist in the performance of root-cause analysis. Ishikawa's Seven Basic Quality Tools are an excellent place to begin. The application of tools such as: (a) cause-and-effect diagrams, (b) check sheets, (c) control charts, (d) histograms, (e) Pareto charts, (f) scatter diagrams, and (g) stratification are frequently employed in support of failure investigations. Regardless of the approach used in the pursuit of the root cause, the expectation set through ISO/IEC 17025:2017 is that a reasonable attempt be made in determining root cause.

When a laboratory has determined that corrective action is required to mitigate a nonconformance, the corrective action must be appropriate to the problem and include the assessment of risk. When corrective action has been taken, it is imperative that all proposed changes are documented, reviewed, and approved prior to implementing the changes. One area to be cognizant of when changes occur to procedures is the training piece. It is imperative that laboratory personnel are retrained, as appropriate, when changes occur to a procedure. In most cases, the retraining will be as simple as reviewing and understanding changes made to a procedure. Regardless of the level and detail of training as a result of corrective action activities, ensure that the training is documented.

An important piece of the corrective action process is the VOE. It is imperative that a laboratory verify not only that corrective action has been formally implemented but also that the corrective action taken was effective. Depending on the type of corrective action taken, the verification process will usually occur within thirty, sixty, or ninety days. It will be a rare event when the VOE is performed immediately. Once the VOE has been successfully completed, then and only then can the corrective action be closed.

In support of the corrective action process, Figure 8.7.1 depicts an example of a basic corrective action form. The same form can also be employed for preventive action and continuous improvement activities. Figure 8.7.2 depicts an example of a corrective action log sheet that can be used in concurrence with the corrective action form.

One final thought relates to performing additional audits as required to ensure that the nonconformances identified and the subsequent corrections implemented are not influencing potential compliance issues with the laboratory or ongoing compliance with ISO/IEC 17025:2017. It may be necessary to adjust the internal audit schedule to ensure that problems requiring corrective action receive additional oversight to be sure that nonconformances

Originator Data		
Name:	❏ Corrective action ❏ Preventive action	Date:
Subject:		
Description of problem/condition:		
Quality Assurance Review		
❏ Rejected Reason for rejection:		
❏ Approved Immediate action required (containment):		Due date:
Assigned to:	Department:	CAPA #:
Corrective Action/Preventive Action		
Analysis of root cause:		Date:
Corrective action/preventive action plan:		Due date:
Corrective action/preventive action taken:		Date completed:
Reviewed by:		Date:
Quality Assurance Follow-Up/Verification of Effectiveness		
Provide documented evidence of CAPA implementation/effectiveness:		
Corrective/preventive action notice status: ❏ Closed		Date:
Reviewed by:	Signature	

Figure 8.7.1   Example of a CAPA form.

CAPA Number	Date Opened	CAPA Owner	Target Date for CAPA Closure	Date Root Cause Is Completed	Date CAPA Plan Is Completed	Date Corrective Action Is Implemented	Date VOE Is Performed	Date CAPA Is Closed
18-001	1/21/18	J. Doe	4/21/18	1/26/18	1/28/18	2/4/18	3/4/18	3/5/18
18-002	2/23/18	S. Smith	5/23/18	3/10/18	3/12/18	3/15/18	5/15/18	5/16/18
18-003	3/10/18	R. Jones	7/10/18	4/1/18	4/15/18	5/07/18		
18-004	3/25/18	R. Jones	9/25/18	4/10/18	5/1/18			

Figure 8.7.2 Example of CAPA log sheet.

do not continue to manifest themselves within the laboratory. The internal audit program (discussed further in Chapter 8.8) should be flexible enough to add additional audits as required to drive laboratory compliance with its own policies, procedures, regulatory and statutory requirements, and ISO/IEC 17025:2017.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established policy and procedure for corrective action?

2. Does the corrective action procedure require inputs from: (a) nonconforming work, (b) noncompliances with policies and procedures, (c) internal audits, (d) external audits, (e) customer complaints/feedback, and (f) employee observations?

3. Does the corrective action process require root-cause analysis?

4. Is there evidence that adequate corrective actions are being pursued?

5. Is verification of effectiveness being performed for all corrective actions?

6. Is there a master log sheet for corrective actions?

7. Are all corrective actions current?

8. Are follow-up audits being performed when required?

CHAPTER REVIEW

Corrective action is an extremely important tool employed by laboratories to mitigate nonconformances while ensuring that QMS remains in compliance with internal policies and procedures, regulatory and statutory requirements, and ISO/IEC 17025:2017. There are key pieces of information required by ISO/IEC 17025:2017 to support the corrective action process. At a minimum, the procedure must contain: (a) root-cause analysis, (b) identification of proposed corrective action, (c) the corrective action implemented, (d) VOE, and (e) if deemed appropriate, the need for additional audits. It is imperative that the laboratory perform an adequate job of determining root cause of nonconformances. Without a clearly defined root cause, it will be an insurmountable task to implement effective corrective action(s). Allow ample time to transpire

prior to performing the VOE, as it may take a few months before changes that are made to a procedure can adequately be assessed for effectiveness. One final thought for the reader: remember that the ultimate goal is to achieve and sustain accreditation to ISO/IEC 17025:2017. The best advice this author can offer is not to take shortcuts when establishing the management system. Compliance to all aspects of the standard, regardless of whether the requirement is written or virtual, is mandatory.

8.8

Internal Audits (Option A)

INTRODUCTION

Internal audits, when properly implemented, are proactive tools for assessing an organization's ongoing compliance with a standard or regulation. Similar to ISO 9001:2015:2015, ISO/IEC 17025:2017 requires laboratories to periodically conduct internal audits to verify that continued laboratory operations are being performed in accordance with established policies and procedures and with ISO/IEC 17025:2017. Specifically, the internal audit program must be constructed to ensure all aspects of the management system are evaluated. Audits should be planned and a schedule created and published to support the internal audit program. Laboratory personnel tasked with performing audits must be trained and qualified. When deviations are noted during the performance of internal audits, corrective action should be pursued to remedy the nonconformance. In this chapter, implementing an effective internal audit program, including the creation of a viable schedule, will be presented.

EFFECTIVE TOOLS FOR IMPLEMENTATION AND COMPLIANCE

In an effort to successfully drive management system improvements, internal audits are an incredibly valuable tool to a laboratory. Enough emphasis cannot be placed on the importance of performing timely internal audits and when warranted, reaudits of laboratory functional areas that are identified as problematic. First and foremost, laboratories are required to establish an internal audit program documented by a written procedure. All elements of the laboratory's management system are required to be assessed at least once annually. When corrective action opportunities have been identified,

---

SUMMARY OF ISO/IEC 17025:2017
REQUIREMENT—8.8 (INTERNAL AUDITS)

- Laboratories are required to schedule and perform internal audits to ensure ongoing operations are performed in accordance with the documented management system and in compliance with ISO/IEC 17025:2017. Internal audits are required to address all elements of the management system, including testing and calibration activities.

Note: The recommended internal audit cycle is one year.

- The scope of each internal audit should be clearly defined and communicated.
- If findings are noted during the execution of audits, laboratories are required to pursue corrective action without undue delay.
- The results of internal audits shall be recorded.
- The results of audits should find their way into management review.
- When applicable, follow-up audits will be performed to verify the effectiveness of corrective actions taken. These activities will be recorded.

VOE of the instituted corrections must be performed. The results of internal audits need to be documented and retained as a quality record.

It is strongly recommended that an internal audit schedule be assembled and approved prior to the start of each year. This schedule should be published and qualified auditors assigned in advance. Note that ISO 19011 (Guidelines for Auditing Management Systems) should be reviewed prior to establishing an internal audit program and auditor requirements. Figure 8.8.1 depicts a typical internal audit schedule premised on a quarterly format. This schedule can be extrapolated to meet a monthly format. Another option would be for the laboratory to subcontract the internal auditing function to a qualified auditor or consulting firm.

From a trained auditor perspective, having a certified auditor, although preferred, is not a requirement of ISO 19011. Auditors must be appropriately trained and have adequate technical knowledge of the function or process they are auditing. Auditors must never have functional responsibility for the areas they are auditing to prevent any undue influence. Auditor objectivity and independence is crucial for the performance of an internal audit.

Department/Area		Primary Element(s)		Q1	Q2	Q3	Q4	Auditors
Management Systems Documentation	8.1	8.2		X				SMITH
Control of Management Systems Documents	8.3			X				SMITH
Control of Records	8.4	7.5		X				SMITH
Risk Management	8.5			X				JONES
Improvement	8.6				X			JONES
CAPA	8.7				X			SMITH
Internal Audits	8.8				X			ROGERS
Management Review	8.9				X			ROGERS
Complaints	7.9					X		SMITH
Reporting Results	7.8	7.8.1–7.8.8				X		SMITH
Review of Contracts	7.1					X		JONES
Technical Records	7.5						X	JONES
Verification and Validation Activities	7.2	7.2.1	7.2.2				X	ROGERS
Nonconforming Work	7.10						X	SMITH
Control of Data and Information	7.11						X	ROGERS

Figure 8.8.1 Example of an internal audit schedule.

Components of an Internal Audit

Unfortunately, execution of a successful audit is much more than having the auditor show up with a pencil and a pad of paper. A good audit takes planning and preparation to ensure that the audit is effective and beneficial to the laboratory. There are many components associated with an internal audit. Depending on the size of the laboratory, some of the components may be skipped or greatly reduced in scope.

Audit Planning

Prior to executing the actual audit, the auditor will need to become familiar with the area to be audited. The creation of an audit plan is nothing more than creating a road map for the audit. The audit plan will typically contain the scope, purpose statement, area/function to be audited, list of audit team members (if applicable), and the relevant documents. Depending on the scope of the audit and if multiple functional areas are being audited, it may be prudent to develop and audit agenda to support the plan. An audit checklist (Figure 8.8.2) should also be created to support the internal audit. To save time during the day of the audit, the auditor should request and review the relevant documents in advance.

Opening Meeting

The opening meeting is a useful tool for establishing the boundaries for the audit, reviewing the audit plan, reviewing the audit agenda, and discussing other issues influencing the audit. The dynamics of the audit, including the closing meeting, should be reviewed at this time. It is important that a sign-in sheet be employed to document attendance at the opening meeting.

Performing the Audit

Execution of the audit is nothing more than the execution of the audit plan. If a checklist has been created for the audit (see Figure 8.8.2), use the checklist as a guide. The checklist can be used to collect objective evidence of compliance and assist the auditor during the interview process. However, it is important to remember that the audit report will be the primary deliverable in support of providing objective audit evidence.

Date of internal audit: _____   **Lead auditor:** _____

Auditee: _____   **Area audited:** _____

Function audited: Organization, management, and personnel	Yes	No	N/A	Comment
Is a laboratory organizational chart or other information available listing staff organization and responsibilities? Does it identify the QA officer and all the relationships between the QA officer, technical operations, and support staff?				
If the laboratory is part of a larger organization, are there any organizational arrangements that could cause a conflict of interest?				
Does the laboratory have a health and safety program in place for all employees?				
Does the laboratory have policies or procedures to ensure client confidentiality and proprietary rights, including procedures for protecting the electronic storage and transmission of results?				
Do the laboratory managerial and technical personnel have the authority and resources needed to carry out their duties, to identify departures from the quality system, and procedures for performing environmental tests, and to initiate actions to prevent or minimize such departures?				
Are the education and technical background of all personnel documented?				
Does the QA officer have the authority to stop work and initiate action to prevent or minimize quality system variances?				
Is there a formal QA manual in place and does the QA officer maintain the current quality manual?				

Figure 8.8.2 Internal audit checklist example.

Collecting and Documenting Evidence

During the audit, it is important to collect objective evidence and to document compliance and, if applicable, nonconformances identified during the audit. Documented evidence will be needed to support the writing of nonconformances associated with the audit. Additionally, documented evidence of compliance is needed to support the audit report.

Writing Audit Nonconformances

If the audit results in a nonconformance from a policy, procedure, standard, or regulation, the nonconformance will need to be documented. When writing the nonconformance, it is important to specify the requirement (e.g., ISO/IEC 17025:2017, clause 8.9—Management Review) and the finding (no evidence of management reviews being performed). The nonconformance should always be clear and concise, with no evidence of subjectivity.

Closing Meeting

Similar to the opening meeting, the closing meeting may be deemed optional depending on the size of the organization. If a closing meeting is held, an attendance sheet should be circulated to capture attendance. During the closing meeting a review of the audit results are provided by the auditor. It is important to highlight the positives as well as the nonconformances noted. If a follow-up audit will be required, it should be noted during the closing meeting along with next steps to support the mitigation of nonconformances.

Audit Report

The audit report is a written detailed summary of the entire internal audit. It is strongly recommended that a written report be completed within seven days of the audit and no later than thirty days from the audit.

Pursuing Corrective Action

Nonconformances identified during the audit need to be corrected without undue delay. Depending upon the nature and severity of the nonconformance (e.g., systemic), formal corrective action may need to be pursued. Simple corrections can be performed and the correction documented in the audit report by the auditor.

Verifying Effectiveness of Corrective Action

The VOE of audit corrections typically occurs during the next audit cycle. However, if the audit nonconformance is systemic, and the nonconformance has been moved to the laboratory's CAPA system, VOE will be performed as part of CAPA. Even if the VOE is performed as part of CAPA, it will be incumbent on the individual selected to perform the next audit to verify that the nonconformance has been closed and that the action taken was effective.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure that governs the internal audit program?

2. Is there a published audit schedule?

3. Are internal audits being performed in accordance with the published schedule?

4. Is the laboratory employing auditors that have been properly trained or certified for the performance of audits?

5. When nonconformances have been identified, does the laboratory pursue corrective action to resolve the nonconformances?

6. Is the audit schedule being adjusted when there is evidence that a functional area within the laboratory requires additional oversight?

7. Is verification of effectiveness being performed to verify that corrections resulting from internal audits are effective?

8. Are records being maintained for internal audits?

CHAPTER REVIEW

Internal audits are vital tools needed in support of driving ongoing improvements in the laboratory's management system. For the internal audit program to be effective, the program must be well documented by procedure and an annual internal audit schedule created, reviewed, approved, and published. Audits require proper advance planning and trained auditors capable of executing internal audits. There are multiple components associated with an

internal audit. It is imperative that an audit plan, supported by an agenda (if applicable), and an audit checklist be created to assist in the facilitation of each audit. Finally, when nonconformances are identified during an audit, it is imperative that corrective action be pursued in support of mitigating all the nonconformances noted.

8.9

Management Reviews
(Option A)

INTRODUCTION

Management review is an important tool employed by organizations to ensure that the management system continues to remain effective. Included in the management review process—a process required to be held at planned intervals (common practice is to typically hold meetings at least once per year)—are a variety of quality records and collected records that capture the ongoing effectiveness of testing and calibration activities. Clause 8.9 of ISO/IEC 17025:2017 contains prescriptive requirements pertaining to specific metrics to be reported as part of the management review process. Similar to the management review inputs associated with ISO 9001:2015, ISO/IEC 17025:2017 requires the results of audits, customer feedback, and recommendations for improvement as a few of the requirements requiring incorporation into management review meetings. It is imperative that management reviews are well attended, that the results are recorded in detailed meeting minutes, and that, when deemed appropriate, the outcomes of the management review (such as corrective action) are documented. When actions are assigned, it is the responsibility of management to ensure that corrective actions are actively worked and completed. In this chapter, a review of best-in-class management review practices, including the creation of the agenda and signature sheet, will be discussed.

EFFECTIVE TOOLS FOR
IMPLEMENTATION AND COMPLIANCE

There is no question—a management review is a valuable tool needed by management to ensure that the laboratory's management system and the

SUMMARY OF ISO/IEC 17025:2017 REQUIREMENT—8.9 (MANAGEMENT REVIEWS)

- Laboratories are required to establish a procedure for management reviews. Management reviews are required to be scheduled and held to support the ascertainment of the effectiveness of the laboratory's management system and the testing and calibration work being performed—including the need for pursuit of corrective action when the results of management reviews reflect that improvements are necessary. Items to be considered for inclusion into the management review process are:

Review Input
- Changes in issues (internal and external) impacting the organization
- Achievement of quality objectives
- Ongoing suitability of policies and procedures
- Assigned actions during previous management reviews
- Results of audits (internal)
- CAPA
- Results of audits and inspections (external)
- Changes in the organization's workload (volume and structure)
- Feedback (customer and internal)
- Complaints
- Continuous improvement activities
- Resource adequacy
- Risk identification outcome(s)
- Validity of results and associated assurances
- Training needs
- Other relevant influencers on the organization

Review Output
- Discussion on the effectiveness of the management system
- Required improvements to sustain compliance with ISO/IEC 17025:2017
- Resource needs
- The need for changes to the management system

Note: It is recommended to hold management reviews at least once each year; however, quarterly is considered a best practice. Additionally, management review outputs should support planning, goals, and objectives.

- Management reviews, including action items identified, must be documented. Management is responsible for ensuring that action items are completed within the allotted time period.

application of tools needed to support the technical requirements are adequate and performing as expected. It is a generally accepted practice to perform management reviews at least annually; however, more frequent reviews will drive improved laboratory performance. Although holding management reviews monthly would be considered a best practice, quarterly reviews are effective and economically viable.

When establishing the procedure for management review, ISO/IEC 17025:2017 requires that specific elements be included in the procedure. The summary box for clause 8.9 lists all the review inputs and outputs that should be incorporated in the procedure for management review. These requirements are somewhat aligned with the review inputs and outputs delineated within ISO 9001:2015 and ISO 13485.

There are six succinct steps needed for the pursuit for management reviews to be successful: (a) a published schedule for management reviews, (b) an agenda for each management review, (c) a sign-in sheet for the management review meeting, (d) the actual management review meeting, (e) management review meeting minutes, and (f) a link to CAPA (should corrective action be assigned by the management team), premised on the data/results presented during the management review meeting. An example of a simple management review agenda is depicted in Figure 8.9.1.

Published Management Schedule

It is imperative that the schedule for management reviews be published at the beginning of each year. If the management review is held once annually, then the process is as simple as stating that the management review will be held in a specific month (e.g., January) for the preceding year. If reviews are held quarterly, reviews can be scheduled for the month following the close of a quarter. Since the laboratory owns the management system, the review schedule is premised on the laboratory's schedule. Note: if a quorum is not available to attend a management review, it is acceptable to reschedule the meeting. However, the rescheduling of the management review meeting should be documented.

Management Review Meeting Agenda

To ensure consistency in the management review agenda, the agenda items should be spelled out in advance and aligned with the minimum requirements depicted in clause 4.15 of ISO/IEC 17025:2017. It is considered a best practice to list the agenda items as inputs and outputs in the management review procedure. Doing so reduces the risk of omitting information from the management review that is relevant to the ongoing performance of the management system.

Date:

To: All ISO/IEC 17025:2017 Process Owners

Subject: **Management Review Meeting**

Please plan to participate in our Formal Management Review Meeting on [Day, DD Month YYYY], from [Start Time] to [End Time] in the [Location].

We will be addressing quality-related topics for this meeting, specifically prescribed, at a minimum, within the ISO 9001:2015 standard, as follows:

AGENDA

- Changes in issues (internal and external) impacting the organization
- Achievement of quality objectives
- Ongoing suitability of policies and procedures
- Actions assigned during previous management reviews
- Results of audits (internal)
- CAPA
- Results of audits and inspections (external)
- Changes in the organization's workload (volume and structure)
- Feedback (customer and internal)
- Complaints
- Continuous improvement activities
- Resource adequacy
- Risk identification outcome(s)
- Validity of results and associated assurances
- Training needs
- Other relevant influences on the organization

To help you prepare for the meeting, copies of or intranet links to the following materials are being provided:

- Copies of reports for internal audits completed since the last management review meeting
- The most recent customer feedback report and summary of warranty returns
- The most recent summary of outgoing product conformity data
- Summary of corrective and preventive action requests initiated and pending since the last management review meeting
- Minutes from the prior formal management review meeting
- Previously established quality objectives

Figure 8.9.1   Example of a management review agenda.

- Our *Quality Management System Manual*, which contains our current quality policy
- Proposed new quality objectives, indicating how each directly supports our quality policy and our organization's strategic business plan

In order to comply with the ISO/IEC 17025:2017 standard, the following meeting outcomes are required. It will be necessary to document these items, along with an attendance record:

1. Discussion on the effectiveness of the management system
2. Required improvements to sustain compliance with ISO/IEC 17025:2017
3. Resource needs
4. Need for changes to management system

Figure 8.9.1   Example of a management review agenda.   (*continued*)

Management Review Sign-in Sheet

Due to the confidential nature of the information, the content of management review meetings is not information that is required to be shared with laboratory customers or regulatory bodies such as FDA. However, evidence that the meetings are occurring is required. Management review meetings need to be supported by a sign-in sheet containing the name, function, and actual signature of each attendee. If a member of the management team is not in attendance, it is an acceptable practice to send an alternate. If more than 50% of the management team is absent, the meeting should be rescheduled.

Management Review Meeting

There is no industry standard for the duration of a management review meeting. The meeting should be long enough for the presentation, review, and discussion of each agenda item. Although not always practical, having the management review meeting off-site will reduce the number of potential interruptions, resulting in a more fruitful meeting.

Management Review Meeting Minutes

One individual should be assigned the task of taking a copious amount of notes and assembling them into the management review meeting minutes. Typically, the assignment is given to a member of the quality organization. It

is important to have the meeting minutes reviewed and published as quickly as possible. Once again, there is no industry standard that drives how long a time period should be before meeting minutes are issued; however, seven days should be a realistic goal, and thirty days should be the absolute maximum amount of time permitted for publication.

Management Review Corrective Actions

From time to time, management may decide that further actions are required to ensure that the management system remains in compliance with ISO/IEC 17025:2017. The action requested by management could be relatively benign and be handled informally (but still be documented). Typically, actions emanating from management review require formal corrective action. If formal corrective action is required, the request for action out of a management review should be placed into the CAPA system. It is much easier to track assigned actions that have been placed into the CAPA system versus those that are tracked informally. Regardless, actions taken must be reviewed at the next (immediate) management review. If reviews are being held annually, then one can now see how management oversight can lose some effectiveness.

QUESTIONS TO CONSIDER DURING AN AUDIT

1. Does the laboratory have an established procedure for management review?

2. How often are management reviews held?

3. Is there a published schedule for management reviews?

4. What information is presented and reviewed during management reviews?

5. Do outputs from management reviews feed into the corrective action and preventive action system when the result of management reviews dictate that corrective action is required to address an issue?

6. Is there a sign-in sheet that reflects attendees of management review meetings?

7. Are records of management reviews being maintained by the laboratory?

CHAPTER REVIEW

Establishing a procedure and holding at least one management review each year are mandated by ISO/IEC 17025:2017. The more frequent the management reviews, the more effective the management review process tends to be. As for management review content, an agenda is strongly recommended. Agenda items can be placed in a procedure to drive consistency in the management review process. Make sure an attendance sheet is used to document attendance. The attendance sheet can be used as documented evidence that the management review meetings are being held. If there is not a quorum available to attend the management review, the meeting should be rescheduled. However, rescheduling the meeting too many times can result in nonconformance from a regulatory body, aimed at management effectiveness. Make sure meeting minutes are posted as soon after the management review meeting as possible. Finally, if the management team decides corrective action is required, premised on meeting inputs, the corrective action process is better served by loading the request into the CAPA system. Finally, do not forget to review the status of assigned actions at the next (immediate) management review meetings.

Epilogue

I hope you have been able to glean value from this book. Quality and regulatory professionals are tasked with understanding so many regulations and standards, notwithstanding the bombardment of changes. It is a never-ending task trying to remain current with these requirements. ISO 9001:2015 and ISO 13485:2016 are quality system standards with which I am sure most of you work on a daily basis; however, ISO/IEC 17025:2017—probably not so much. That being said, understanding the basic concepts behind ISO/IEC 17025:2017 will only enhance your understanding of the calibration requirements delineated in ISO 9001:2015 and ISO 13485:2016. In closing, thank you for taking the time to read *Implementing ISO/IEC 17025:2017, Second Edition.*

Best Wishes,
Bob Mehta

Appendix A

Changes between the 2005 and 2017 Versions of the Standard

NEW REQUIREMENTS ASSOCIATED WITH ISO/IEC 17025:2017

Not unlike all the changes made between ISO 9001:2008 and ISO 9001: 2015, there have been significant changes made between the ISO/IEC 17025:2005 and the ISO/IEC 17025:2017 versions of the standard. During the research and writing of this book I found myself wondering why the members of the standard's committee could not leave well enough alone. There is no doubt that as technology continues to advance the state-of-the-art in any industry, there is a need for standards to adapt accordingly. However, it would be nice if the basic alignment with previous standards remained relatively consistent.

Table A.1 delineates the new requirements associated with ISO/IEC 17025:2017. As mentioned in the previous paragraph, the 2017 version of the standard was a significant departure from the previously released version.

Table A.1   Summary of changes to ISO/IEC 17025:2017.

ISO/IEC 17025:2017 Clause	Summary of Change
4.1.4	Laboratories shall identify risks to maintaining their impartiality.
4.1.5	Laboratories shall identify methods for the reduction or elimination of risks.

(continued)

183

Table A.1 Summary of changes to ISO/IEC 17025:2017. (*continued*)

ISO/IEC 17025:2017 Clause	Summary of Change
4.2.2	Laboratories shall be required to notify customers when confidential information is released.
4.2.3	Information pertaining to a customer obtained from other sources shall be kept confidential.
4.2.4	Lab personnel shall keep information obtained during laboratory work confidential.
5.3	Laboratories are required to document the activities it performs in support of complying with the standard.
6.6.3	Documented communications for external suppliers is required for: (a) products and services provided; (b) acceptance criteria; (c) personnel competencies; and (d) work performed by external service providers at their facilities.
7.1.3	The standard used and decisions made as a result of testing shall clearly be defined for the customer.
7.8.8.2	Laboratories shall be responsible for all report content that is laboratory generated and owned.
7.8.6.1	When laboratories claim compliance to a specific standard, the decision rule shall also be documented.
7.8.8.1	When a laboratory reports requiring a revision, the revision shall be clearly documented (including the reason for the revision).
7.9.2	Laboratories shall provide a copy (description) of their complaint management process upon request from the customer.
7.9.3	The complaint process shall include: (a) description of the initial complaint receipt; (b) complaint tracking and documentation; and (c) complaint remediation activities pursued.
7.9.4	When a laboratory is on the receiving end of a complaint, they are responsible for the subsequent complaint investigation and the actions taken.

Table A.1   Summary of changes to ISO/IEC 17025:2017. (*continued*)

ISO/IEC 17025:2017 Clause	Summary of Change
7.9.5	Laboratories are required to acknowledge complaint receipt, provide status reports, and provide final reports to customers.
7.9.6	Complaint outcomes shall be communicated to the complainant.
7.9.7	When a complaint investigation has completed, the laboratory shall notify the complainant.
7.10.2	Records are required to be created and retained for nonconforming work activities.
7.11.1	Laboratories shall have access to all information needed to successfully execute their work activities.
7.11.4	When LIMS is maintained by a third-party service provider, the laboratory shall ensure that the service provider complies with applicable clauses of the standard.
8.1.1	Laboratories are required to implement a management system that supports sustaining compliance with the standard.
8.1.3	Laboratories that comply with clauses 4 through 7 of ISO 9001:2015 fulfill the requirements associated with clauses 8.2 through 8.9 of ISO/IEC 17025:2017.
8.5.1	Risks and opportunities associated with day-to-day laboratory work activities shall be considered to: (a) ensure the management system is effective; (b) achieve objectives; (c) reduce or prevent nonconforming events; and (d) drive continuous improvement.
8.5.2	Laboratories shall plan for actions to mitigate risk and effectively use the management system to drive compliance.

Table A.1   Summary of changes to ISO/IEC 17025:2017. (*continued*)

ISO/IEC 17025:2017 Clause	Summary of Change
8.5.3	Actions pursued to mitigate risk shall be appropriate for the level of risk while ensuring the validity of laboratory results is not compromised.
8.9.2	New inputs to management review include: (a) changes in relevant internal and external issues; (b) fulfillment of objectives; (c) status of actions from previous management reviews; (d) effectiveness of any implemented improvements; and (e) results of risk identification.
Annex A	Metrological traceability
Annex B	Management system

Bibliography

American Association for Laboratory Accreditation (A2LA). 2018a. "F117—Technical Staff Matrix for Accreditation—ISO/IEC 17025" (MS Word file). American Association for Laboratory Accreditation, March 5. Available from https://portal.a2la.org/documents/resultspubdocuments.cfm.

———. 2018b. "R103—General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories." The American Association for Laboratory Accreditation, March 5. https://portal.a2la.org/requirements/A2LA_R103.pdf.

American National Standards Institute (ANSI) and American Society for Quality (ASQ). 2008. *ANSI/ASQ Z1.9–2003 (R2013): Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming.* Milwaukee, WI: ASQ Quality Press.

———. 2013. *ANSI/ASQ Z1.4–2003 (R2013): Sampling Procedures and Tables for Inspection by Attributes.* Milwaukee, WI: ASQ Quality Press.

AssurX. N.d. *CATSWeb* (blog). https://www.assurx.com/tag/catsweb/.

Bizmanualz. 2016. "What Is the Difference between Document Control and Record Control?" *Bizmanualz.com.* https://www.bizmanualz.com/implement-iso-quality/what-is-the-difference-between-document-control-and-record-control.html.

Bullen, Peroska B. 2013. "How to Choose a Sample Size (for the Statistically Challenged)?" *tools4dev.org*, October 18. http://www.tools4dev.org/resources/how-to-choose-a-sample-size/.

Carlson, Carl S. n.d. "Key Factors for Effective FMEAs." *ReliaSoft.com.* http://www.reliasoft.com/newsletter/v6i2/fmea_factors.htm.

Doiron, T., and J. Beers. 1991. *The Gauge Block Handbook.* Gaithersburg, MD: Dimensional Metrology Group, Precision Engineering Division, National Institute of Standards and Technology, September. http://xa.yimg.com/kq/groups/2573836/494330063/.

Dono. 2010. "File:SI base unit.svg." *Wikipedia.org*, February 16. https://en.wikipedia.org/wiki/File:SI_base_unit.svg.

Hogan, Rick. 2014. "How to Calculate Test Uncertainty Ratio." *ISOBudgets* (blog), October 27. http://www.isobudgets.com/calculate-test-uncertainty-ratio/.

Horizon. N.d. "What Are Reference Standards?" *Horizon Discovery*. https://www.horizondiscovery.com/reference-standards/what-are-reference-Standards.

IHS Markit. 2018. Website. https://ihsmarkit.com/index.html.

Institute for Reference Materials and Measurements (IRMM). 2015. *Certified Reference Materials 2015*. Geel, Belg.: IRMM. https://ec.europa.eu/jrc/sites/jrcsh/files/rm_catalogue_0.pdf.

International Organization for Standardization (ISO). 2008. *ISO Guide 30:1992/Amd 1:2008 Revision of Definitions for Reference Material and Certified Reference Material*. Geneva, Switz.: ISO, December. https://www.iso.org/standard/46210.html.

———. 2011. *ISO 19011:2011 Guidelines for Auditing Management Systems*. 2nd ed. Geneva, Switz.: ISO, November. https://www.iso.org/standard/50675.html.

———. 2015a. *ISO 9001:2015 Quality Management Systems—Requirements*. 5th ed. Geneva, Switz.: ISO, September.

———. 2015b. *ISO 14644–1:2015 Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*. 2nd ed. Geneva, Switz.: ISO, December.

———. 2016. *ISO 13485:2016 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes*. 3rd ed. Geneva, Switz.: ISO, March.

International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). 2017a. *ISO/IEC 17011:2017 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*. 2nd ed. Geneva, Switz.: ISO, November 2017.

———. 2017b. *ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories*. 3rd ed. Geneva, Switz.: ISO, November 2017. https://www.iso.org/standard/66912.html.

International Society for Pharmaceutical Engineering (ISPE). 2011. *GAMP Good Practice Guide: A Risk-Based Approach to Calibration Management*. 1st ed. North Bethesda, MD: ISPE, December.

Joint Committee for Guides in Metrology (JCGM), Working Group 1. 2008. "Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement." *JCGM 100: 2008*. Sèvres, Fr.: Bureau International des Poids et Mesures (BIPM), September. https://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf.

Leito, I., L. Jalukse, and I. Helm. 2018. "1. The Concept of Measurement Uncertainty (MU)." From the course "Estimation of Measurement Uncertainty in Chemical Analysis," University of Tartu, Republic of Estonia. https://sisu.ut.ee/measurement/introduction-concept-measurement-uncertainty.

Mind Tools Content Team. 2012. "Managing Complaints and Feedback: Improving the Way That You Do Things." *MindTools.com*. http://www.mindtools.com/pages/article/managing-complaints.htm.

Mistretta, Phil. 2014. "As-Found: Out-of-Tolerance—What to Do Next?" *InCompliance*, March 1. https://incompliancemag.com/article/as-found-out-of-tolerance-what-to-do-next/.

National Aeronautics and Space Administration (NASA). 2010. *Measurement Uncertainty Analysis Principles and Methods, NASA Measurement Quality*

Assurance Handbook—ANNEX 3. Washington, DC: NASA, Document No. NASA-HDBK-8739.19-3, July 13. https://standards.nasa.gov/standard/nasa/nasa-hdbk-873919-3.

National Association for Proficiency Testing (NAPT). 2015. "The Value of Proficiency Testing." St. Louis Park, MN: NAPT. http://www.proficiency.org/portals/0/pdfs/The-Value-of-Proficiency-Testing.pdf.

National Association of Testing Authorities (NATA), Australia. 2012. "Guidelines for the Validation and Verification of Quantitative and Qualitative Test Methods." *Technical Note 17.* Sydney, AUS: Commonwealth of Australia, June.

National Institute of Standards and Technology (NIST). 2010. "National Voluntary Laboratory Accreditation Program: On-Site Assessment Checklists." *NIST.gov*, February 4. https://www.nist.gov/nvlap/publications-and-forms/site-assessment-checklists.

———. 2018. "NIST Policy on Metrological Traceability." *NIST.gov*, July 23. https://www.nist.gov/traceability/nist-policy-metrological-traceability.

National Institute of Standards and Technology (NIST)/SEMATECH. 2012. *Engineering Statistics Handbook*. Gaithersburg, MD: NIST, April. http://www.itl.nist.gov/div898/handbook/index.htm.

QuestionPro. N.d. "Short Customer Satisfaction (CSAT) Survey Template." *QuestionPro.com*. http://www.questionpro.com/a/showSurveyLibrary.do?surveyID=227&mode=1.

Sheahan, Kyra. 2017. "What Is a Complaint Management System?" *bizfluent*, September 26. https://bizfluent.com/facts-6401656-complaint-management-system-.html.

Sigma-Aldritch. 2018. Website. http://sigmaaldrich.com.

Stimson, W. A. 2001. "Internal Quality Auditing: Meeting the Challenge of ISO 9000:2000." *Quality Digest*, November 1. https://www.qualitydigest.com/magazine/2001/nov/article/internal-quality-auditing.html.

SurveyMonkey. N.d. "How to Create Online Customer Satisfaction Surveys." *SurveyMonkey.com*. http://www.surveymonkey.com/mp/customer-satisfaction-surveys/.

Tague, N. 2004. *The Quality Toolbox*. 2nd ed. Milwaukee, WI: ASQ Quality Press.

TransCat Calibration Services. 2008. "Risk Management: The Critical Role of Measurement and Calibration." TransCat Services White Paper, Rochester, NY. http://www.transcat.com/media/pdf/Risk%20Management.pdf.

United Nations Industrial Development Organization (UNIDO). 2006. "Role of Measurement and Calibration in the Manufacture of Products for the Global Market." United Nations Industrial Development Organization Working Paper, Vienna, Austria. https://www.unido.org/sites/default/files/2009-04/Role_of_measurement_and_calibration_0.pdf.

———. 2009. *Complying with ISO 17025: A Practical Guidebook for Meeting the Requirements of Laboratory Accreditation Schemes Based on ISO 17025:2005 or Equivalent National Standard*. Vienna, Austria: United Nations Industrial Development Organization, October. http://www.unido.org/fileadmin/user_media/Publications/Pub_free/Complying_with_ISO_17025_A_practical_guidebook.pdf.

US Food and Drug Administration (FDA). 2014. "Corrective and Preventive Actions (CAPA)." FDA.gov, November 25. https://www.fda.gov/iceci/inspections /inspectionguides/ucm170612.htm.

US Food and Drug Administration, Department of Health and Human Services, 21 CFR Chapter I (2018). https://www.law.cornell.edu/cfr/text/21/chapter-I.

US Food and Drug Administration, Office of Regulatory Affairs. 2014. *ORA Laboratory Manual of Quality Policies.* Silver Spring, MD: US FDA, Document No. ORA-LAB.QM, version 2.0, May 2. https://www.fda.gov/downloads/ScienceResearch /FieldScience/UCM092012.pdf.

Watson-Price, Erin. N.d. "What Is Correction Factor?" *ItStillRuns.com.* https:// itstillruns.com/correction-factor-7268119.html.

Westcott, Russ. 2005. "Corrective vs. Preventive Action." *Quality Progress*, March. asp.org/quality-progress/2005/03/problem-solving/corrective-vs-preventive -action.html.

Index

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

T

V

Ask a Librarian

Did you know?

- The ASQ Quality Information Center contains a wealth of knowledge and information available to ASQ members and non-members

- A librarian is available to answer research requests using ASQ's ever-expanding library of relevant, credible quality resources, including journals, conference proceedings, case studies and Quality Press publications

- ASQ members receive free internal information searches and reduced rates for article purchases

- You can also contact the Quality Information Center to request permission to reuse or reprint ASQ copyrighted material, including journal articles and book excerpts

- For more information or to submit a question, visit **http://asq.org/knowledge-center/ask-a-librarian-index**

Visit www.asq.org/qic for more information.

ASQ
The Global Voice of Quality™

Belong to the Quality Community!

Established in 1946, ASQ is a global community of quality experts in all fields and industries. ASQ is dedicated to the promotion and advancement of quality tools, principles, and practices in the workplace and in the community.

The Society also serves as an advocate for quality. Its members have informed and advised the U.S. Congress, government agencies, state legislatures, and other groups and individuals worldwide on quality-related topics.

Vision

By making quality a global priority, an organizational imperative, and a personal ethic, ASQ becomes the community of choice for everyone who seeks quality technology, concepts, or tools to improve themselves and their world.

ASQ is...

- More than 90,000 individuals and 700 companies in more than 100 countries

- The world's largest organization dedicated to promoting quality

- A community of professionals striving to bring quality to their work and their lives

- The administrator of the Malcolm Baldrige National Quality Award

- A supporter of quality in all sectors including manufacturing, service, healthcare, government, and education

- YOU

Visit www.asq.org for more information.

ASQ
The Global Voice of Quality™

ASQ Membership

Research shows that people who join associations experience increased job satisfaction, earn more, and are generally happier*. ASQ membership can help you achieve this while providing the tools you need to be successful in your industry and to distinguish yourself from your competition. So why wouldn't you want to be a part of ASQ?

Networking

Have the opportunity to meet, communicate, and collaborate with your peers within the quality community through conferences and local ASQ section meetings, ASQ forums or divisions, ASQ Communities of Quality discussion boards, and more.

Professional Development

Access a wide variety of professional development tools such as books, training, and certifications at a discounted price. Also, ASQ certifications and the ASQ Career Center help enhance your quality knowledge and take your career to the next level.

Solutions

Find answers to all your quality problems, big and small, with ASQ's Knowledge Center, mentoring program, various e-newsletters, *Quality Progress* magazine, and industry-specific products.

Access to Information

Learn classic and current quality principles and theories in ASQ's Quality Information Center (QIC), *ASQ Weekly* e-newsletter, and product offerings.

Advocacy Programs

ASQ helps create a better community, government, and world through initiatives that include social responsibility, Washington advocacy, and Community Good Works.

Visit www.asq.org/membership for more information on ASQ membership.

*2008, The William E. Smith Institute for Association Research

TRAINING CERTIFICATION CONFERENCES **MEMBERSHIP PUBLICATIONS**

ASQ
The Global Voice of Quality™