Guide on Building a Quality System for the Accreditation of a Conformity Assessment Body (CAB)
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This Section Is About the Process of Building a QMS
About the Author

Joseph Edgar John (Ned) Gravel, CD, PEng, CAE, CA-LS, IPL

Ned is an ILAC and APLAC evaluation team leader whose current role is to facilitate cultural change so that national accreditation programs can meet international requirements for APLAC and ILAC recognition. Ned is the Principal of MOTIVA Training Inc, a company whose mission is to help accreditation bodies develop and deliver training to their accredited CABs.

Ned won the Engineering Prize when he graduated as a Civil Engineer from the Royal Military College of Canada. He spent 22 years in the service of his nation and retired from the Canadian Army as a Major in the Royal Canadian Corps of Signals. His service included command of operational Signal Corps units.

After retirement, Ned became the quality manager for an acoustics and electronic testing and calibration laboratory. He created a quality system and underwent his first assessment 62 days after he became the quality manager. Today he works hard to help those who may also have to endure such a challenge. His company provides free webinars and quality system document samples so that others have better tools to work through the creation and implementation of a quality system.

Since that time, Ned has worked in four accreditation bodies in Canada and the USA and spent 10 years as the quality manager for one of the Canadian accreditation bodies. He helped create the ILAC signatory AB in Bangladesh and he works today in Myanmar to help them do the same.

Within the Asia Pacific Laboratory Accreditation Cooperation, Ned is a Lead Evaluator and the Convenor of the Evaluator Training Working Group (ETWG) - to train APLAC evaluators. He is also the Convenor of the Performance Monitoring Working Group (EPWG) - to document the monitoring of APLAC evaluators. Finally, Ned chairs the Calibration Sub Committee of the APLAC Technical Committee - responsible for all calibration laboratory policies within APLAC.

Ned is a trainer who believes that people are the solution to challenges in any organisation. His greatest joy is motivating dispirited teams of people to achieve difficult objectives under impossible circumstances - starting with believing in themselves. His company's motto is "Reaching People."

From 1997 to 2005, Ned was Canada's ISO/CASCO committee member for the creation and amendment of the laboratory accreditation standard, ISO/IEC 17025. He has created the QMS for a dozen laboratories and three ILAC signatory accreditation bodies. He is also the author of Ned's Rules of Engagement, a treatise on leadership and the author of the Principles behind ISO/IEC 17025.

Ned is a pilot, a sailor, a historian and a world traveller. In 1978 he married his best friend and their two sons are now married with families of their own.

Experience in Conformity Assessment

MOTIVA Training Inc. experience in this field includes:

- 22 years of leadership training and appointments in dangerous situations affecting the health and safety of operational teams,
- 25 years of standardization and accreditation work affecting over 1000 different conformity assessment bodies (CABs),
- 20 years of accreditation work in five internationally-recognised accreditation bodies, and
- 11 years of work in the recognition of national accreditation systems that include 72 nations worldwide.
Preface

This guide allows a conformity assessment body (CAB) considering the implementation of a QMS to determine the amount of work needed to design, develop, implement, and maintain it. It also gives some indication of the work to acquire accreditation of their conformity assessment activities.

This approach applies for any one of the international standards listed here:

- ISO/IEC 17025 for testing laboratories;
- ISO/IEC 17025; ILAC P14 for calibration laboratories;
- ISO/IEC 17020; ILAC P15 for inspection bodies (IBs);
- ISO/IEC 17043 for proficiency testing (PT) providers;
- ISO 17034 for reference material providers (RMPs);
- ISO 15189 for clinical laboratories;
- ISO/IEC 17065 for product certification bodies (CBs), and
- ISO/IEC 17011 for accreditation bodies (ABs).

The guide includes a questionnaire that a CAB can use to determine the amount of work needed for all stages from design, through development, implementation, maintenance and eventually, accreditation.

Instructions

1. Complete the questionnaire in Sections 2 through 7 in full. Green highlights identify the areas where a response is required.

2. Additional information and assistance may be obtained from the MOTIVA Training Website (https://www.motiva-training.com/tools-for-labs-qms).

3. Determine the amount of time, effort and external assistance that may be required from the answers provided in Sections 2 through 7.

4. The results of the questionnaire should be considered preliminary only and should serve only to provide a general idea on the work needed to create and implement a conformant QMS and have it accredited by an ILAC-Signatory accreditation body. No work of this type will ever succeed without discussion between the parties affected.

5. Examine Section 8 and follow the steps to implementation of a QMS for the accreditation of the specific conformity assessment disciplines involved.

6. Eventual award of any accreditation will be subject to the CAB meeting the requirements of the selected ILAC-signatory accreditation body, the listing of which can be obtained at (http://ilac.org/signatory-search/), and agreeing to and complying with the accreditation criteria of the applicable accreditation body. The meaning and scope of such accreditation criteria will be defined by the identified accreditation body in their published Terms and Conditions available on the accreditation body website shown in the ILAC listing.

7. MOTIVA Training Inc. does not impose any requirements on a CAB regarding the use of this guide. It is offered for free for the sole use of a CAB. Neither does MOTIVA Training Inc. accept any responsibility for a CAB making use of the results from the questionnaire unless formal signed contracts exists between the CAB and MOTIVA Training Inc.
Section 1 – Introduction to Creating a QMS

1.1 There are Five Factors Affecting the Success of QMS Operations

There are many ways to undertake the creation and implementation of an organisational tool, such as a quality management system (QMS) so as to assist a CAB in some aspect of its operation. Some of these ways are good and some are not so good.

CABs seeking to start along this path always ask: “What must we do?” The answer is fairly complex and only experience tells us which approach works and which approach does not really help. The short answer to the question is to follow the steps listed in Section 8 of this Guide. But that approach is not the most appropriate for the success of the CAB or of its effort to implement a QMS.

Common experience from within the conformity assessment indicates that the most important considerations in the successful implementation of a quality system for any CAB are:

- The leadership skills of top management of the CAB,
- The CAB’s reason for implementing the QMS,
- The level of understanding and knowledge of the people doing the work,
- The QMS tools available to the people doing the work, and
- How much QMS work has already been done.

1.2 Good Leadership

The single most important consideration in the successful implementation of a quality system for any CAB (or any system for any organisation for that matter) is the level of commitment of the people who actually work in the company. Motivated teams outperform those not motivated.

The single most important reason why some organisations can create this commitment and motivate its staff, and some cannot, is the leadership being exercised by top management. Good leaders enhance organizational performance and provide real motivation for success. This truth, more than any other, is the secret of success in CAB performance. See https://www.motiva-training.com/tools-for-labs-qms/leadershiptools.

QMS created in such CABs that are well led are easy to implement and manage and they actually help the CAB operate better, and produce more consistent technically valid results. When good leadership is missing, QMS implementation and use is more difficult for the staff and is often very costly to operate.

But we live in an imperfect world and not all top management / executive / ownership teams can attain this level of leadership skill.

1.3 Why a CAB Might Want a QMS

Besides leadership skill, the next most important factor for success in the implementation of a QMS is the reason it is being built. Why does the CAB need or want it?

To enhance successful implementation, leading to good outcomes, the most important expectations that matter are those of the people of the CAB. QMS are designed primarily to help the people doing the conformity assessment work of the CAB. Implementing any QMS just to meet the external (outside people) formal recognition needs of the market is the absolute worst reason for doing so.

The best reason for implementing a QMS is to provide the staff with the confidence that conformity assessment results are technically valid. This is the reason why good CABs do not accept second-best conditions because confidence in their own work is important to a motivated staff.

Accreditation or certification is good in and of itself. However, doing this to meet someone else’s (market/regulator/client) expectations will not produce a sustainable QMS environment associated with good and enduring results. In this circumstance, the requirements in QMS are often viewed as external rules imposed upon the CAB and its staff, to be followed by them only when necessary. Staff do not believe the QMS is actually helping them. They believe it is hindering them.
1.4 Understanding QMS Requirements.

“People who do not know what to do will have a great deal of difficulty doing it.”

Ned Gravel

The following are the most common skill sets for CAB staff to acquire when attempting to design, develop, implement and maintain a QMS:

- Understanding the organisational, structural, and impartiality requirements of the applicable standard.
- Understanding the competence, continual improvement, and stakeholder requirements of the applicable standards.
- Understanding the basic conformity assessment technical requirements of the standard:
  - Sampling
  - Preparation for conformity assessment tasks
  - QA
  - QC
  - Reporting
- Understanding the special conformity assessment technical requirements of the standard (for 17025):
  - Method Validation / Verification of CAB processes
  - Uncertainty of measurement
  - Traceability of measurement, including calibration
  - Proficiency testing
- Understanding the special accreditation body requirements related to the applicable standard or for the specific type of accreditation desired.
- Understanding the internationally accepted interpretations for the requirements contained in the applicable standard

Creating such understanding requires both formal/informal training and actual hands-on (including the-making-of-mistakes) practice. Training can be done relatively quickly. However, it is the practice of the use of acquired knowledge that takes the time and is the most important component in having staff gain sufficient confidence in the use of a QMS. The best method of doing this is mentoring by an expert in the field.

Staff practice of conformity assessment procedures based on correct understanding will lead to their competence and readiness to proceed to the next steps.

1.5 Resources Needed to Implement a QMS

“People who are not allowed to do the work required will have a great deal of difficulty completing it.”

Ned Gravel

Resource 1 - Staff (People) Available Time and Energy

It is very common for CABs to implement new approaches by simply adding to the workload of staff already doing other things. This approach has the advantage of making use of the current staff and saves the need to find new people for every new thing that is attempted. However, it is not ideal and there are some drawbacks to consider when using such an approach.

Complexity of the New Effort

The complexity of developing and implementing a QMS almost always outstrips the ability of the current staff. People who are assigned this work as a secondary duty, normally struggle a long time before the project delivers any real benefits to the CAB. Most often, the project is eventually abandoned because it is too difficult. To the people doing the work, it seems to take years to accomplish what might have been done in months. These outcomes adversely affect the productivity of the CAB, staff morale, and the perception of the usefulness of a QMS.
For example, a hospital that does not have a heart surgeon on staff will not attempt to perform heart surgery using the other surgeons. Designing, developing, implementing, and maintaining a QMS is much like this example because QMS work is very meticulous and it is best performed by people who love the detail involved in complex tasks. Without these dedicated and trained “champions” (= heart surgeons), no centre of expertise will be established within the CAB to bring the detail down to the level where it must be implemented in every day work by other staff.

Allocating responsibility to a meticulous staff person by shifting their current responsibilities will save the organisation much trouble later on. If this is not done, the work will only cause grief as this type of person struggles with the implementation of a system for which they are not allowed to dedicate time energy.

**Implementation Timelines**

Done as a secondary duty, the implementation of a QMS in a CAB always takes more time and that is OK. However, the longer implementation drags on, the less likely that staff will experience the benefits of a QMS and the less likely it will be used by staff when it is ready. Staff will eventually individually abandon any idea of using it without being forced to do so.

The people in a CAB will always determine the usefulness of a QMS for themselves long before it has actually been implemented. If staff does not experience progress leading to benefits in sufficient time, supporters among the staff will dwindle, regardless of how much top management pushes for it.

**Access to Expertise**

Allocating the work to create and implement a QMS to staff already working hard on other CAB operations prevents the creation of the CAB expertise to promote this work among staff while it is being built. Hiring temporary external expertise (consultant) is only a stopgap measure, because consultants do not stay with the company once the system is either designed, or developed, or implemented. Staff commonly perceives consultants as not “one-of-us” creating a divide that can be very difficult to overcome and establish the credibility needed for successful implementation.

As well, consultants normally write QMS from their own points of view – and not the point of view of the staff in the company who will actually use it. Experience has shown that the initial results of this approach will appear good, but the system will eventually fail to support the work of the people in the CAB and it will be perceived as an externally imposed impediment to their work.

In order to successfully design, implement and maintain a QMS that actually meets the needs of a CAB, top management must allocate the resources to create a “centre of expertise.” External help can certainly support such expertise, but the CAB’s own expert staff will be the driving force behind the success of the QMS, especially if top management cannot deliver the type of leadership described in 1.2 above.

**Resource 2 - Formally Documenting the Requirement for a QMS**

All conformity assessment activities require the creation and use of formally documented processes to be available to all who will work in such activities. This is also true for the implementation of a QMS.

No QMS (or any other system) can be implemented in any CAB based on ad-hoc decisions, sparse documentation and informal work. Staff will not undertake what is necessary to succeed in the implementation and use of a QMS, unless top management establishes the formal requirement for its implementation.

Therefore, the work that results in a successfully implemented QMS must be based on formally documented (recorded) decisions by top management to create the documentation that describes the QMS and how to implement it. Consultants can help create such documentation, but they can only be implemented by the people who will maintain the QMS.

**1.6 Building on Work Already Completed**

Most CABs have already implemented many of the components of a QMS, sometimes under a different name or for a different reason. That work is valuable to the successful implementation of a QMS as well and should be used to assist in overall implementation.
This guide accounts for QMS components already in place when estimating the work needed to implement a QMS for a specific purpose.

1.7 Timelines Recommended for Development of QMS

1.7.1 Timelines Recommended by International Regulatory Agencies for 17025

International specifying agencies such as the Food and Agriculture Organization (FAO) of the United Nations provide their own guidance on the time it takes to implement a QMS, such as ISO/IEC 17025 for a food-testing lab. FAO publishes their recommendation in Table 4.2 of “The Feed Analysis Laboratory: Establishment And Quality Control” published at http://www.fao.org/docrep/019/i3535e/i3535e.pdf.

An extract of that table is shown here for information purposes.

Note that many conformity assessment professionals consider this timeline to be very conservative. A lab QMS can be implemented and operating fully within two years – provided that all the elements are in place to ensure successful implementation in that time frame. See 1.1 above.

Timetable for the implementation of a QMS compliant with ISO/IEC 17025:2005 (from FAO)

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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.7.2 Timelines Recommended for other Conformity Assessment Activities.

Implementing a QMS for a lab is the most straightforward of all the ones listed in the Preface of this guidance. The QMS for all other activities differ in their complexity from a lab QMS and their activities are often not as straightforward as simple testing and calibration. All other CABs, with the exception of an RMP, make “conformity assessment decisions” requiring the use of professional judgement to provide an official recommendation on the conformance (or not) of the object of examination, based on the evidence obtained during their examination.

For example, an inspector working within an inspection body will determine the level of conformance of products and processes to inspection criteria and state this on an inspection report. A PTP must
determine the pass/fail condition of a participant in a PT scheme. A product certification body must make a formal decision on whether or not a product or process conforms to public requirements on the performance of products and services, judged primarily against regulatory safety standards.

As well, both inspection bodies and product certification bodies may make use of the results of a lab in their formal determination of the conformance of products, processes and services.

These are formal decisions made that go beyond the provision of primarily objective results of testing, calibration and reference materials.

As a result, these types of CABs will require more, or less time to implement a QMS than that of a lab:

- **Inspection body: a little less time** because inspection methods do not normally require validation and the inspection environment is normally at the client site. Rarely will an inspection body have its own on-site lab, but many inspection bodies may make use of the testing results from a lab as part of their inspection results.

- **Proficiency testing provider: a little more time** because proficiency testing requires more control of testing for the determination of the accepted value and for the analysis of PT results.

- **Reference material producer: much more time** because of the absolute control required to effectively characterize the materials produced so that they are suitable for the propagation of uncertainties.

- **Product certification body: much more time** because these organizations require a great deal of organizational infrastructure to ensure and demonstrate impartiality in their decision-making processes. As well, these certification bodies may also have in-house labs and inspection bodies to assist in their evaluation of products and services that form part of the certification process.

### 1.7.3 Timelines Recommended from this Guide

The amount of time required to implement a QMS by users of this Guide will depend on the answers they provide in Sections 2 through 7. Normally, a good laboratory QMS will take 12 months to design, train, and implement if the work is appropriately supported throughout the CAB.

It is the author’s experience that QMS built in less time will not be properly implemented and will fail to support the work of the conformity assessment staff. Following the steps shown in Section 8 will not change this.

### 1.8 Determining the Effort and Timelines for Implementation

The amount of work required for an Applicant to develop and implement a QMS conformant to a standard is dependent on a number of conditions that exist within the Applicant CAB.

These are:

1) The size and complexity of the CAB and its conformity assessment work. (See Section 2)
2) The amount of support to be provided by top management to remove impediments to the successful completion of the work. (See Section 3)
3) The amount of technical knowledge of the staff in the areas associated with the conformity assessment disciplines covered by the standards listed in the Introduction above. (See Section 4)
4) The amount of knowledge of staff in the operation of a QMS, regardless of where they have attained their experience. (See Section 5)
5) The amount of experience of staff in QMS operations and the QMS tools (documentation, procedures, equipment etc.) that may already exist in the CAB. (See Section 6)
6) The requirements imposed by an accreditation body that may include more than those contained in the standards listed in the Introduction above. (See Section 7)

Sections 2 through 7 are aimed at collecting information on these six components and providing recommendations on the effort and work to be accomplished within the CAB so as to implement an appropriate QMS. All of the information that is collected by the CAB is to be able to determine the amount of work required to develop and implement a QMS and is relevant to that effort.
Section 2 – General Information about the CAB

2.1 Identification of the CAB

- Name: ____________________________________________
- Postal Address: ___________________________________
- Post code: ________________________________________
- Telephone: __________________ Fax: ________________
- Website: _________________________________________
- E-mail: __________________________________________

2.2 Legal status of the CAB

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Owned by an individual or a partnership:</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>b. A public company or corporation or owned by one of these:</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>If the CAB is part of a larger organization, what is the relationship to that organization?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Owned by an academic or professional institution:</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>d. Owned by government or a government body:</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>If the CAB is part of government, please define the relationship within government.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Another category? If so, please specify:</td>
<td>☐</td>
<td>☑</td>
</tr>
</tbody>
</table>
2.3 People in the CAB

Indicate the numbers of staff employed by the CAB at the sites where the QMS is to be implemented.

| a. Management (Executive and Top Management) |
| b. Technical Management in the disciplines to be covered by the QMS |
| c. Technical staff in the disciplines to be covered by the QMS |
| d. Non-technical staff (including management staff not included in a. above) supporting the operation of the CAB such as HR, Admin, Finance, etc |
| e. QMS staff currently employed to manage the operation of any QMS that may currently exist in the CAB. |

2.4 Facilities of the CAB

Indicate the area occupied by the CAB at the sites where the QMS is to be implemented.

| a. Floor Area (m²) of all facilities to be covered by the QMS. |
| b. Floor Area (m²) all technical facilities to be used in conformity assessment. |
| c. Total Bench space to be used in testing/calibration/inspection. |

2.5 Type and Volume of Conformity Assessment Work in the CAB

2.5.1 Scope of CAB Work

All CABs must be able to define, with some precision, the exact type of conformity assessment work they carry out. This definition forms the basis of the design of the QMS and the technical procedures it must contain.

This requirement is so important that accreditation bodies use it to publicly describe, in a published scope of accreditation, the actual accreditation work for which the CAB has been accredited. Accreditation is specific to the scope of accreditation that lists the demonstrated competence of the CAB.

Each type of scope is discussed here, so that a CAB can complete the table below in Section 2.5.9 – Sample Scope of CAB Work.

2.5.2 Testing Laboratory

Specific tests are normally defined in the following manner:

- Chemistry testing (specify method + matrix + analyte)
- Biological testing (specify method + matrix + analyte)
- Physical testing (specify method + product + property)
- Mechanical testing + NDT (specify method + product + property)
- Electrical testing (specify method + product + property)

2.5.3 Calibration Laboratory

Specific calibrations are normally defined by making reference to the BIPM base units or a derived measurement unit of the calibration activity, such as:

- Light
- Voltage
- Mass
- Pressure
• Force
• Torque
• Amount of substance (chemistry)

Within each listing the calibration entry contains \((\text{product} + \text{range of measurement} + \text{uncertainty})\)

### 2.5.4 Medical Clinical Laboratory

Specific clinical tests are normally defined within each discipline, such as:

• Biochemistry
• Microbiology
• Haematology
• Cytology
• Molecular Biology
• Immunoassay

Within each discipline the entry includes \((\text{specific analyte} + \text{matrix} + \text{method})\)

### 2.5.5 Inspection Body

Inspections are not as specific as for laboratory tests and calibrations. They are normally specific to the regulation or specification that calls for inspection as a demonstration of conformance. Listings for assessment of conformity in inspection is normally defined in the following manner:

• Parameter examined \((\text{specify product} + \text{inspection criteria/standard})\)

### 2.5.6 Proficiency Testing Provider

PTP provide programs that serve tests and calibration laboratories. Their services are normally specific to a testing or calibration discipline and listings specify the target property/analyte as well as the target values of that property or analyte that can be provided.

Listings for PT and ILC services is normally defined in the following manner:

• Parameter examined \((\text{specify analyte or property} + \text{range of target values})\)

### 2.5.7 Reference Material Producer

Reference materials are very specific devices and materials used to propagate uncertainties to testing and calibration laboratories as well as specific to the scientific disciplines that make use of them.

As with calibration laboratories, RMPs list their conformity assessment activity with a focus on the uncertainties associated with their products. Reference materials are normally defined by making reference to the SI base units or a derived measurement unit, such as:

• Light
• Voltage
• Mass
• Pressure
• Force
• Torque
• Amount of substance (chemistry)

Within each listing the reference material entry contains \((\text{measurement parameter} + \text{range of measurement} + \text{uncertainty})\)

### 2.5.8 Product Certification Body

Certification body listings of CAB activity are generally defined by the International Classification for Standards (ICS) published by the ISO or by an industry-specific, or regulatory-specific classification for types of certifications.

### 2.5.9 Sample Scope of CAB Work

List the conformity assessment work to be conducted in the table below using the format of the Samples shown. See 2.5.2 to 2.5.8 above for guidance on completing the table.

<table>
<thead>
<tr>
<th>Product(s) / Material of activities</th>
<th>Specific activities performed</th>
<th>Method/Standard against which work is conducted</th>
<th>Range/Limits of detection</th>
<th>Uncertainty of Measurement (±)</th>
<th>Number of Samples per year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meat</td>
<td>Salmonella</td>
<td>Codex Alimentarius</td>
<td>5 – 500 ppm</td>
<td>3 – 200 VDC</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td></td>
<td>ICP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Household Appliances</td>
<td>Metalls</td>
<td>IEC 950</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low voltage electrical safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Calibration:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mass</td>
<td>Balances</td>
<td>OIML R-111</td>
<td>0.5 - 100 g</td>
<td>20 mg</td>
<td></td>
</tr>
<tr>
<td><strong>Inspection:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Gas Piping Systems</td>
<td></td>
<td>CAN/CSA Z305.1-92</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Systems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product Certification:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS No. 13.220.40</td>
<td>Performance</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

* When referring to publications such as ITU, ISO, IEC, USP, ASTM, AOAC etc. please cite the clause / chapter / page number, as appropriate.

Laboratories performing on-site testing (client site) should differentiate the specific tests on products(s) / material performed at the permanent laboratory and / or at the client site.

IBs are normally considered to do client site inspections exclusively.

RMPs and PTPs need not have their own testing/calibration facilities to be considered competent in their CAB disciplines. They may make use of contracted competent (accredited) facilities for this purpose.

### 2.6 Analysis of Results

#### Persons Dedicated to the QMS

The amount of persons needed to develop, implement and maintain a QMS are as follows:

- **One person for a whole year** is needed for any CAB with more than five persons (see 2.3 b and c) working on the conformity assessment activities shown above or for any CAB with more than ten conformity assessment activities (see 2.5.2 to 2.5.8). The person assigned to this role must be dedicated to the QMS and is often called the Quality Coordinator / Quality Manager / Management Representative. Further, as required by all QMS standards, this person will have direct access to Top Management for decisions related to the QMS.

- **Add another person for a whole year** for every 20 additional persons working on the conformity assessment activities shown above (see 2.3 b and c). This effort can be split a secondary duties among the conformity assessment staff. It accounts for the writing of procedures during the first year, and the maintenance of QC and QA after implementation.

#### CAB Decisions

- We should add _____ persons to our staff to implement a QMS.
- We already have people dedicated (sole responsibility) to the implementation of the QMS
- We understand that the soonest we can successfully implement a QMS is one year.
Section 3 – Top Management of the CAB

3.1 Top Management Vision

<table>
<thead>
<tr>
<th>Top Management Vision Item</th>
<th>Yes</th>
<th>Some</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Top Management envisions this effort to be part of our overall business strategy.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Top Management believes it will take significant effort, funding, and resources to attain this goal.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The function of Top Management is to ensure the success of the teams of people in our organization.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Top Management understands that a conformant QMS may change the way we do business.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Top Management understands that a gain in our revenues is not the aim of a QMS.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.2 Analysis of Results From Top Management Vision

If all answers are “Yes,” add no effort to that shown in 2.6 above. Add one half of a year if there are any “Some” responses. Add one full year if there are any “No” responses.

If all answers are “Yes,” the system can be implemented in one year. Add six months of development time if any responses are “Some” and one year if any responses are “No.”

Baseline Time to Build and Implement a QMS

The base amount of time needed for us to build and implement our QMS is _______ years.

3.3 Top Management Responsibility

<table>
<thead>
<tr>
<th>Top Management Responsibility Item</th>
<th>Yes</th>
<th>Some</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top Management will lead this effort by negotiating attainable goals with staff.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Top Management believes this work can be accomplished by using the current staff only if one of them (a dedicated person) is freed from current responsibilities and allocated the responsibility of coordinating QMS efforts (internal expertise) while remaining staff continue their current jobs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Top Management will review the progress of this work:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Daily...............................................................................................................</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Weekly...........................................................................................................</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Monthly..........................................................................................................</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our staff are delegated the authority to make decisions regarding their work.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.4 Analysis of Results from Top Management Responsibility

If all answers are “Yes,” add no effort to that shown in 3.2 above. Add one half of a year if there are any “Some” responses. Add one full year if there are any “No” responses.

If all answers are “Yes,” the system can be implemented in one year. Add six months of development time if any responses are “Some” and one year if any responses are “No.”

Additional Time to Build and Implement a QMS

The extra amount of time needed for us to build and implement a QMS is ____ years.

3.5 Rationale for Implementing a QMS

These are the reasons for the effort of creating a QMS.

<table>
<thead>
<tr>
<th>Why we Wish to Build and Implement a QMS</th>
<th>Yes</th>
<th>Some</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We wish to have more confidence in our results.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. We wish to show our competence to others and ourselves.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. We wish to access markets that require accreditation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. We are required to obtain accreditation to meet government regulation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.6 Analysis of Results from Reasons to Build a QMS

If the answer to question 1 is “Yes,” add no effort to that shown in 3.4 above. Add six months if it is “Some.” Add one year if it is “No.”

If the answer to question 1 is “Yes,” and any of the other answers are “Yes,” add six months of development time.

Additional Time to Build and Implement a QMS

The extra amount of time needed for us to build and implement a QMS is ____ years.
Section 4 – Knowledge/Experience in Technical Disciplines

4.1 This Section Is About Learning The Technical CAB Disciplines

This section deals with the amount of external training that may be needed by a CAB to learn about the technical testing, inspection, etc. disciplines required by a conformant QMS where one may not currently exist. Most CABs, whether or not they have implemented a QMS, have already taken some measures specific to their own technical disciplines to underpin their competence in their CAB work.

Remember that a CAB can be considered competent without being accredited. Accreditation, based on an appropriate QMS, is only formal recognition of competence from an external authority.

From the answers provided here, the CAB has a better understanding of how much external assistance they may need, if any at all, to ensure successful implementation of the technical disciplines required by their QMS as it applies to the conformity assessment work done in the CAB.

Only the technical disciplines used within the CAB should be addressed in these questions. The others can be marked as N/A.

4.2 Staff Knowledge of Technical Conformity Assessment Activities

<table>
<thead>
<tr>
<th>For Testing, Calibration and Medical Labs</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our staff can easily develop and validate new testing / calibration methods or verify currently published ones.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Our staff understand the JCGM-100 Document, Guide to the Expression of Uncertainty in Measurement.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Our staff can easily estimate uncertainties in any test or calibration results that are used in our CAB.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Our staff know the four components of an accredited calibration certificate.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Each member of our staff currently participates in one PT study per year.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Our staff understand the relationship between the uncertainty of our measuring instruments and the uncertainty of our results.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For Proficiency Testing Providers</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our staff understand ISO 13528 and how to determine the most appropriate scoring systems for PT studies.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Our staff know how to do Grubbs Test of PT results.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For Reference Material Producers</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our staff can easily develop and validate new testing / calibration methods or verify currently published ones.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Our staff understand the JCGM-100 Document, Guide to the Expression of Uncertainty in Measurement.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
</tbody>
</table>
### For Reference Material Producers (continued)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our staff can easily estimate uncertainties associated with the reference materials we produce.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our staff know the four components of an accredited reference material certificate.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Each member of our staff currently participates in one PT study per year.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our staff understand the relationship between the uncertainty of our measuring instruments and the uncertainty of our results.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### For Inspection Bodies

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our staff can easily develop and validate new inspection methods or verify currently published ones.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### For Product Certification Bodies

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our testing lab staff can easily develop and validate new testing / calibration methods or verify currently published ones.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our testing and calibration staff understand the JCGM-100 Document, Guide to the Expression of Uncertainty in Measurement.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our laboratory staff can easily estimate uncertainties in any test or calibration results that are used in our CAB.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our lab staff know the four components of an accredited calibration certificate.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Each member of our lab staff currently participates in one PT study per year.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our lab staff understand the relationship between the uncertainty of our measuring instruments and the uncertainty of our results.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our staff can easily develop and validate new evaluation methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Our staff can easily develop new certification schemes using ISO/IEC 17067</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 4.3 Analysis of Results from Knowledge of Technical Disciplines

**Additional Technical Training That May Be Required**

*For the CAB discipline desired, wherever the answer to any question is “No,” one two-day course and/or two weeks of consulting is recommended to upgrade knowledge in that technical discipline.*
CAB Decisions

☐ We already have training on the appropriate standard and the technical disciplines involved in our conformity assessment work.

OR

☐ We need training on the following Conformity Assessment disciplines:
  ☐ ________________ (cite the appropriate conformity assessment standard)
  ☐ Uncertainty of measurement
  ☐ Method validation and verification
  ☐ Traceability of measurement
  ☐ Internal Calibration
  ☐ Proficiency Testing and Inter-laboratory comparisons
  ☐ Control Charting
Section 5 – Staff Knowledge in QMS Disciplines

5.1 This Section Is About Learning The QMS Tools

This section deals with the amount of external training that may be needed by a CAB seeking to understand the QMS disciplines where there has been little or no experience in them to date. Most CABs, whether or not they have implemented a QMS, have already taken some measures in line with good business practice to implement procedures covered in most QMS.

From the answers provided here, the CAB will have a better understanding of how much external assistance they may need, if any at all, to ensure solid understanding of the QMS disciplines associated with the technical CAB work they already conduct.

5.2 This Describes our Understanding of QMS Disciplines.

<table>
<thead>
<tr>
<th>Demonstrated Understanding of QMS</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We have already implemented a QMS based on ISO 15189, ISO/IEC 17025, ISO/IEC 17020, ISO 17034, ISO/IEC 17043, or ISO/IEC 17065</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. We have already implemented a QMS based on ISO 9001, ISO 14001 ISO 45001, or ISO 13485</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. We understand document control systems</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. We understand systems to control records</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. We understand how to maintain records for staff competence</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. We understand how to identify and track issues such as non-conformances, potential non-conformances and opportunities for improvement</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. We understand how to receive and track all feedback, including compliments and complaints</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. (For IB, PTP, RMP, and CB only) We understand the difference between complaints and appeals</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. We understand how to conduct root cause analysis.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. We understand how to audit of all of our processes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. We understand how to conduct management review</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12. We formally track all samples received for CAB work</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13. We formally document the operation of all of our equipment used for CAB work</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

5.3 Analysis of Results from Knowledge of QMS Disciplines

Additional QMS Training That May Be Required

If the answer to Question 1 is “Yes,” a two-day course on the desired conformity assessment standard may be all that is needed or recommended.
If the answer to Question 2 is “Yes,” a two-day course on the desired conformity assessment standard and one week of transition mentoring (from a certification standard to an accreditation standard) may be all that is needed or recommended.

For each answer to any Question 3 through 14 is “No,” one two-day course is recommended to train and staff on the specific QMS discipline involved.

CAB Decisions

☐ We already have training on the necessary QMS disciplines.

OR

☐ We need training on the following QMS disciplines:
  ☐ Writing a Quality Manual
  ☐ Continual Improvement disciplines, including non-conformances, potential non-conformances, opportunities for improvement
  ☐ Feedback, including compliments and complaints
  ☐ Corrective and Preventive Action
  ☐ Root Cause Analysis
  ☐ Internal Audit
  ☐ Management Review
  ☐ Risk Management
Section 6 – QMS Tools

6.1 This Section Is About Help In Implementing QMS Tools.

This section deals with the amount of external support that may be needed by a CAB seeking to implement a QMS where one may not currently exist, or may not be working, or may not be appropriately implemented. Most CABs, whether or not they have implemented a QMS, have already taken some measures in line with good business practice to implement procedures covered in QMS.

From the answers provided here, the CAB will have a better understanding of how much external assistance they may need, if any at all, to ensure successful implementation of the QMS disciplines associated with the technical CAB work they already conduct.

6.2 This Describes the QMS Tools Already in Place in the CAB

<table>
<thead>
<tr>
<th>QMS Tools in Place</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We have a Quality Manual that meets the requirements of the applicable standard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. All of our technical procedures have been written and conform to the applicable standard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. All of our job descriptions have been written and agreed by the people whose functions they describe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. We have a master document list (paper or electronic) that tracks the location and status of all policies, procedures, instructions and external documents referenced in our system.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. We know which non-conformances need Corrective Action and which do not.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. We have a program for continual improvement in place, including identifying non-conformances, potential non-conformances, and opportunities for improvement, and addressing these with corrective or preventive action as needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. We receive and track all feedback, including compliments and complaints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. (For IB, PTP, RMP, and CB only) We receive and track appeals</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>9. We conduct root cause analysis leading to corrective- or preventive-action as needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. We audit of all of our processes every year or more often</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. One quarter of our CAB staff are formally trained to conduct our internal audits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. We conduct management review every year or more often</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Management review outputs are treated the same as all other instances of continual improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. We formally track all samples received for conformity assessment work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. We formally document the operation of all of our equipment used for conformity assessment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.2 Analysis of Results of Current QMS Tools in Place

Additional Writing And Mentoring That May Be Required

Wherever the answer to any of the Questions is “No,” one week of support / mentoring is recommended to help create, then train and mentor the implementation of the desired conformity assessment standard discipline not yet implemented.

CAB Decisions

- We already have all of the necessary QMS procedures in place and working.
  - OR
- We need help on writing and implementing the following QMS procedures:
  - A Quality Manual
  - Technical procedures
  - Job descriptions
  - Document control and control of records
  - Sample tracking and handling
  - Equipment records
  - Continual improvement including non-conformances, potential non-conformances, and opportunities for improvement, and addressing these with corrective or preventive action as needed
  - Root cause analysis leading to corrective- or preventive-action
  - Feedback, including complaints and compliments
  - Disputes and appeals (For IB, PTP, RMP, and CB only)
  - Internal audit
  - Management review
Section 7 – Staff Knowledge and Experience in Accreditation

7.1 This Section Is About Learning The Accreditation Requirements

This section deals with the amount of external support that may be needed by a CAB seeking accreditation for the first time. All CABs can request information from their selected or designated Accreditation Body on what extra requirements may exist and what is needed to meet them.

From the answers provided here, the CAB will have a better understanding of how much external assistance they may need, if any at all, to ensure solid understanding of the Accreditation requirements that will affect their own accreditation for the technical CAB work they already conduct.

7.2 This Describes our Understanding of Accreditation.

<table>
<thead>
<tr>
<th>Demonstrated Understanding of Accreditation</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. We are already accredited for ISO 15189, ISO/IEC 17025, ISO/IEC 17020, ISO 17034, ISO/IEC 17043, or ISO/IEC 17065</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. We are already certified to ISO 9001, ISO 14001, ISO 45001, or ISO 13485</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. We have already developed our requested scope of accreditation</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. We have already completed the Accreditation Body application form</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. We have already signed the Accreditation Body Terms and Conditions of Accreditation</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. (For Labs only) We already conform to the Accreditation Body traceability requirements.</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>7. (For Labs only) We already conform to the Accreditation Body proficiency testing requirements.</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>8. (For Labs only) We have already successfully participated in the required amount of PT.</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>9. (For Cal Labs only) We can trace all steps of the Traceability Chain back to the SI through an appropriate National Metrology Institute for all of our measurements, where such is not based on intrinsic standards.</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>10. (For PTP only) Our program scoring methods are based on either ISO/IEC 17043 or ISO 13528.</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>11. (For PTP only) We have access to expertise in statistical analysis</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>12. (For RMP only) We can trace all steps of the Traceability Chain back to the SI through an appropriate National Metrology Institute for all of our measurements, where such is not based on intrinsic standards.</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>13. (For PCB only) We have already established our service as a Type A, or Type B, or Type C service in accordance with ISO/IEC 17020</td>
<td>N/A</td>
<td>☐</td>
</tr>
<tr>
<td>14. (For PCB only) We have already established our “Mechanism to Safeguard Impartiality” as well as any Certification Committees relevant to the types of certifications we offer.</td>
<td>N/A</td>
<td>☐</td>
</tr>
</tbody>
</table>
7.3 Analysis of Knowledge of Accreditation Requirements

Additional Accreditation Program Training That May Be Required

If the answer to Question 1 is “Yes,” nothing more is needed or recommended.

For each answer to any Question 2 through 14 is “No,” two days of mentoring support to the CAB is recommended to better understand each requirement that is not currently being met.

CAB Decisions

☐ We already have training on the necessary AB requirements or the AB has already provided training on their requirements for our conformity assessment discipline.

OR

☐ We need training on the following AB requirements:
  ☐ An appropriate scope of accreditation
  ☐ Completing the Accreditation Body application form
  ☐ Understanding the Accreditation Body Terms and Conditions of Accreditation
  ☐ Understanding the Accreditation Body traceability requirements.
  ☐ Understanding the Accreditation Body proficiency testing requirements.
  ☐ Understanding the Traceability Chain back to the SI through an appropriate National Metrology Institute for all of our measurements, where such is not based on intrinsic standards.
  ☐ PTP program scoring methods based on either ISO/IEC 17043 or ISO 13528.
  ☐ PTP access to expertise in statistical analysis
  ☐ Inspection Body conformance to Type A, or Type B, or Type C requirements
  ☐ PCB establishment of a “Mechanism to Safeguard Impartiality”.
Section 8 – Steps to Implement a QMS for Accreditation

8.1 This Section Is About the Process of Building a QMS

This section deals with processes recommended for use by a CAB to implement a QMS, whether or not it seeks accreditation for its conformity assessment activities. In a normal business environment with all due diligence done to ensure success, it will take a good CAB about two years to be ready to apply for accreditation. If the CAB has superb leadership, previous experience in building and operating QMS, and/or current recognition in another QMS standard, that can be reduced to between six months and one year.

8.2 Step 1 – Decisions (One Month)

1. Top management determines the conformity assessment activities that will be conducted by the CAB. Top management makes use of the Table shown in Section 2.5.9 of this Guide.

2. Top management allocates the responsibilities for the creation and implementation of the QMS to a person in the CAB. See Section 1.5 of this Guide, Resource 1. Top management ensures this person is not being used for other duties and allows them the time to work on the Steps described in this Section 8 of this Guide. This person can now act as Quality Manager/Quality Coordinator.

8.2 Step 1 – Write the Requirement (One Month)

1. Top management formally documents a requirement (issues instructions) to create and implement a QMS, citing the standard it must conform to. See Section 1.5 of this Guide, Resource 2.

2. The newly-appointed Quality Manager/Quality Coordinator drafts a Quality Policy with associated Quality Objectives for review and approval by top management that will eventually be part of the QMS. The most common elements of a quality policy will also be used to define the contents of the Quality Manual. Use the samples shown here.

The CAB Quality Policy consists of three parts:

- CAB ensures the health, welfare and safety of all employees and visitors.
- CAB delivers services that embody only integrity, credibility, and technical validity.
- CAB adds value to client organisations in the delivery of its services

This policy is implemented through attainment of the Quality Objectives that follow.

CAB QUALITY OBJECTIVES

CAB Top Management Leads by Example:

CAB is appropriately structured for its business and CAB top management leads by example. All management personnel understand and have agreed to the implementation of the Corporate Quality Policy and Objectives. Management personnel take an active part of implementing CAB health, safety, environmental, and quality system requirements and support their teams in the attainment of these objectives.

CAB Delivers Only Competent Results

CAB delivers technically valid results on time, every time using approaches and environments that meet or exceed all applicable regulatory specifications. CAB reinforces this reputation through the maintenance of formal third-party recognition schemes, including accreditations from ILAC-recognized accreditation bodies, approvals from designated regulatory authorities, and formal recognitions of proficiency from accredited proficiency testing providers.

CAB Employees Demonstrate Competence and Safe Practices

CAB trains, supervises and demonstrates the continuing proficiency and safe working practices of the persons within CAB to carry out assigned activities. CAB establishes goals for this objective and tracks their attainment.
8.3 Step 2 – Acquire Resources (Two Months)

1. Top management formally allocates the QMS responsibilities for all CAB staff in a document that serves as a set of Job Descriptions. This can be drafted by the Quality Manager/Quality Coordinator, but it can only be approved top management.

2. Quality Manager/Quality Coordinator determines how much of the QMS is already in place from the examination of CAB capacity determined in Section 6 of this Guide.
3. Quality Manager/Quality Coordinator acquires a legal copy of the standard for use in the CAB. Only one copy is needed for each site because copyright laws allow as many copies from that one as are needed for use on that site. Each site will require its own copy.

4. Top management acquires any training for staff from the examination of CAB capacity derived in Sections 3 through 7 of this Guide in the following order:
   - Training on technical conformity assessment procedures from Section 4 of this Guide.
   - Training on QMS procedures from Section 5 of this Guide.

5. Top management acquires any external support for writing QMS policies, procedures and instructions from the examination of CAB capacity derived in Sections 6 of this Guide.

6. Top management acquires space to store documents and records and the IT support needed to write, store, transmit, modify and archive documents and records.

7. (For PTP) Top management acquires access to statistical expertise.

8. (For PCB) Top management acquires access to stakeholder expertise and acquires access to impartial persons to act as the “Mechanism to Safeguard Impartiality” as described in Clause 5.2 of ISO/IEC 17065.

8.4 Step 3 – Write the Technical Procedures (Three Months)

1. CAB conformity assessment staff writes the technical procedures with the assistance of the Quality Manager/Coordinator. These procedures must make reference to internationally published methods, standards, specifications, and procedures.

2. The CAB may have some of these already written and this will save time.

3. CAB conformity assessment staff writes the supporting technical procedures such as equipment maintenance, sample handling, review of reports, calibration, uncertainty, inspection decision-making, evaluation supporting procedures for product certification, etc.

4. Top management may wish to make use of external assistance in creating these procedures depending on the results of the examination of CAB capacity derived in Sections 6 of this Guide.

8.5 Step 4 – Validate and Use Technical Procedures (Three Months)

1. CAB conformity assessment staff validates all procedures used to generate results or conformity assessment decisions with evidence to demonstrate that the processes can produce technically valid results and conformity assessment decisions. The Quality Manager/Quality Coordinator can assist this work.

2. Top management may wish to make use of external assistance in creating these procedures depending on the results of the examination of CAB capacity derived in Sections 6 of this Guide.

3. CAB conformity assessment staff creates validation/verification records with statements from the appropriate authority within the CAB that each procedure is fit for its intended use.

4. CAB staff maintain records demonstrating the appropriate use of technical procedures.

8.6 Step 5 – Write the QMS Procedures (Two Months)

1. Quality Manager/Quality Coordinator creates the procedures used to provide instructions and guidance to CAB staff on the operation of the QMS. These must be documented (written) and made available to all persons who will need to access them. The CAB may have some of these already written and this will save time.

2. Top management may wish to make use of external assistance in creating these procedures depending on the results of the examination of CAB capacity derived in Sections 6 of this Guide.

3. Quality Manager/Quality Coordinator creates the document control procedure and creates the records that will demonstrate control of both internal and external documentation.
4. Quality Manager/Quality Coordinator creates the Quality Manual. There are many free templates available that can be used and some that are for sale. The MOTIVA Training Inc. template is free and is published on https://www.motiva-training.com/tools-for-labs-qms/free-publications-for-labs.

5. Top management ensures the Quality Manual includes a Quality Policy and Quality Objectives as in the examples shown in 8.1 of this Guide.

8.7 Step 6 – Formally Approve Quality Manual and QMS (One Month)
1. Top management formally approves, with their signature in the appropriate place, the implementation of the QMS and its documentation.

8.8 Step 7 – Implement Supporting Procedures (Two Months)
1. CAB staff now implement supporting technical procedures associated with uncertainty of measurement, proficiency testing, calibration, certification committee work, etc. Records are created and maintained to demonstrate their use.
2. CAB staff make use of the QMS procedure on the Control of Records for the creation, storage, protection, modification and archiving of such records.

8.9 Step 8 – Gather Evidence of Conforming Work (Three Months)
1. CAB staff gathers, maintain, and store records that demonstrate the conformance of the work done by the CAB. CAB staff makes use of the QMS procedure on the Control of Records.
2. CAB staff also gathers records from the supporting procedures in 8.8 of this Guide such as equipment maintenance, calibration, client requests, QA, evaluation for certification, decision making for all applicable conformity assessment disciplines etc.

8.10 Step 9 – Gather Evidence of Conforming QMS (Two Months)
1. The Quality Manager/Quality Coordinator and CAB staff gathers, maintains, and stores records that demonstrate the QMS is being used appropriately. CAB staff makes use of the QMS procedure on the Control of Records.
2. The Quality Manager/Quality Coordinator gathers the most important records, those associated with:
   • Feedback, complaints and appeals
   • Non-conformances, potential non-conformances, opportunities for improvement
   • Corrective- and preventive-action
   • Internal audit
   • Management review.
3. Top management ensures that at least one complete internal audit and management review are completed and close out in accordance with the requirement of the applicable standard. The Quality Manager/Quality Coordinator under the supervision of top management does most of this work. This is the final step for a CAB before it is ready to apply for accreditation.

8.11 Step 10 – Apply for Accreditation (One Month)
1. Top management determines the readiness of the CAB for application.
2. Top management may wish to make use of external assistance in establishing better understanding of local accreditation requirements depending on the results of the examination of CAB capacity derived in Sections 7 of this Guide.
3. Top management allocates and resources and funds needed to acquire accreditation.