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Case study: How to establish a quality system acceptable to RMO

Jessica Chavarría, MSc

LACOMET Costa Rica

Bureau International des Poids et Mesures

Outline

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- How to establish a quality system acceptable to RMO
  - QMS is well established and working
  - How to build it?
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Background

- **MRA**
  - *The three fundamental elements leading to approval of an institute's CMCs are:*

1. *participation by the institute in reviewed and approved scientific comparisons;*
2. *operation by the institute of an appropriate and approved quality management system;*
3. *international peer-review (regional and inter-regional) of claimed calibration and measurement capabilities.*

Background

MRA

International Peer Review

Quality Management System (QMS)

✓ ISO 17025
✓ ISO 17034

Confidence in measurements

✓ ***Appropriate:***
Based on accepted standards

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How to establish a quality system acceptable?

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Acceptable, but first appropriate!

What is QMS appropriate?

HOW ?

Suitable for its use…

Fulfillment of

- ✓ ISO standard
- ✓ Country
- ✓ Economy
- ✓ NMI
- ✓ Internal
- ✓ External
- ✓ National Needs

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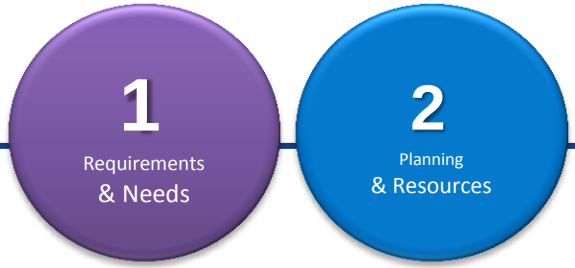
QMS is well established and working

- Establishing the QMS:

QMS is well established and working



- Identify requirements:
  - Customer
  - Legal
  - Standards
  - Internal
- Identify Needs of country:
  - Development
  - Magnitudes
  - Infrastructure

- Define the type of services that will be delivered to the customers
- Formulate these in the form of CMCs
- Quality management system must cover the claimed CMCs

- Planning of the QMS development
- Resources needed
  - Economics
  - Personnel
  - Information
  - Infrastructure

CMCs established!

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QMS is well established and working

- **Documental System**
  - Quality Manual
  - Procedures
  - Records
  - Process and interrelations
- **Responsibilities and roles**
  - Top management
  - Technical manager
  - Quality manager
  - Technicians
  - Support staff
- **Personnel**
  - Needs of training
  - Training process
  - Evaluation
  - Competences
- **Methods, standards & equipment**
  - Related to CMCs
  - Scope
  - Traceability
  - Control of equipment
  - Maintenance
  - Uncertainties
  - Calibration program

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How to build it?

- Involve the staff (motivation, training needs)
- Develop Procedures: Management & technical
- Document your performance (methods, staff, …)
- Build statistics (what you think have to be controlled?)
- Set a “friendly” way to access important information
- Keep documents and records updated

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Control, follow up & evaluation

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Controls, follow up & Evaluation

- Set mechanisms of control & follow up:

Management	Technical
✓ Control of non conforming works ✓ Customer complaints ✓ Internal audits ✓ Management review ✓ Implementation of actions	✓ CMCs review (uncertainties included) ✓ Results of Comparisons

Is everything Ok??

Follow up & Decisions →

PEER REVIEW

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Peer reviews

- Have QMS reviewed by RMO
  - Selection of Peer Reviewers
  - Definition of Scope
  - Resources & Requirements (Check RMO and MRA requirements)
  - Period of validity
  - Findings
  - Action plans
  - Follow up
  - Closing procedure

CIPM/2007-25

Planning is the key!

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Improvement & Vitality

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Improvement

- Keep trained and experienced staff in the lab
- Participate actively in relevant RMO and Consultative Committee programs, including:
  - workshops, education & training
  - pilot studies & Benchmarking
  - comparisons: key, supplementary & bilateral
- Review regularly and critically claimed CMCs
- Inform to the BIPM and the RMO in case of changes and interruptions
- Keep quality system updated, understood and implemented by every laboratory staff member

Publications, investigations, ….

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Submission for approval

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Submission for approval

- RMO QMS review could include:

  - review of the quality manual (questions, answers, corrective actions)

  - summary for presentation to the RMO, including results of on-site peer reviews, overview of complaints, corrective actions, etc.

  - names of peer reviewers

  - in case of accreditation disclosure of expert assessors (should be well reputed peers from other NMIs)

Check your RMO procedure to present

Fails during implementation…

- No clearly formulated mission, vision, policies...
- No continuity in: policy, management, laboratory staff, quality management
- Insufficient governmental financial support and commitment
- Discontinuity in active international participation

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Most common fails during the Peer Review…

- Document control
- Proposal times to action implementation
- Definition of scope
- Validity of Peer Review

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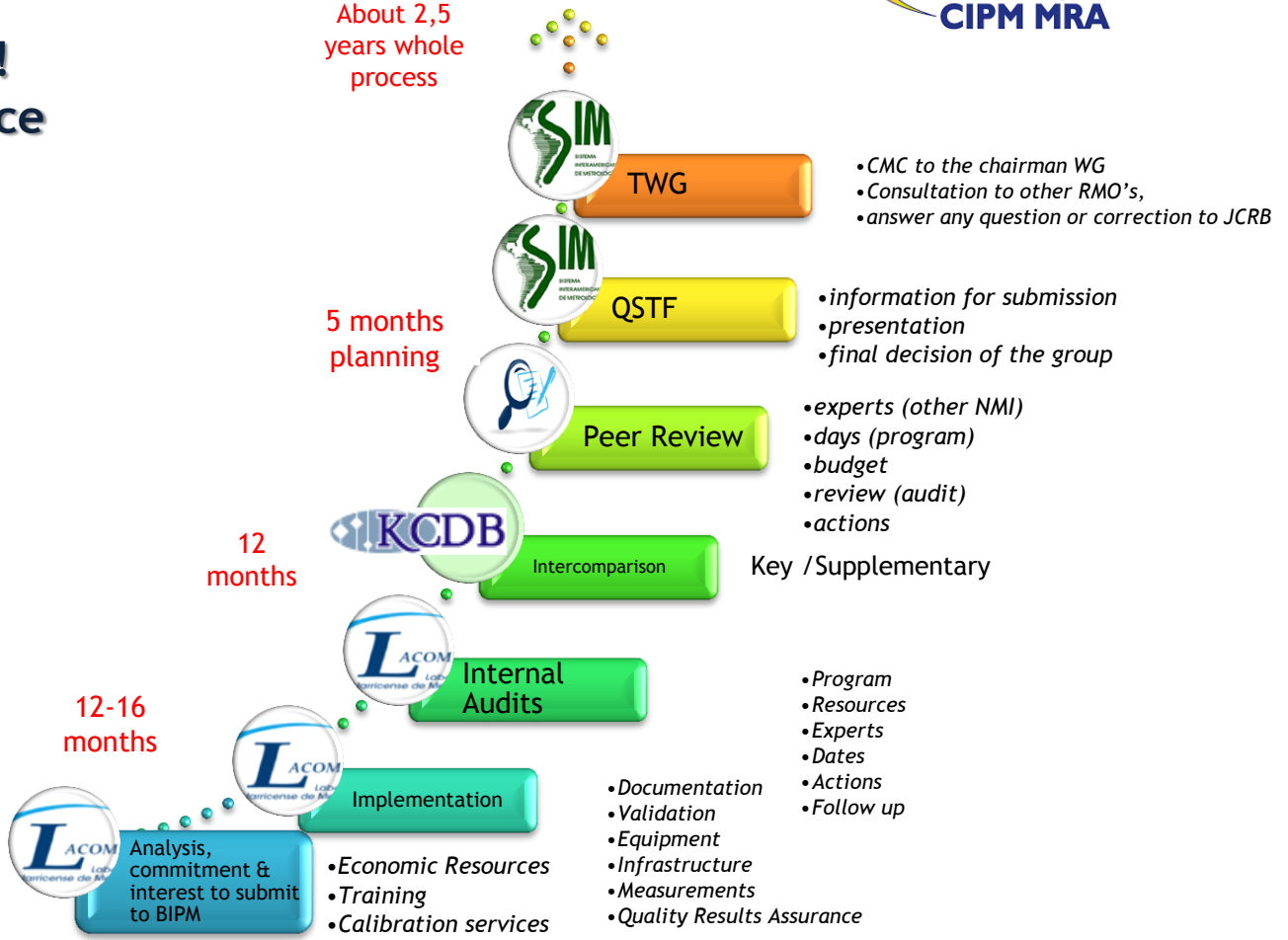
Way to CMCs!
First Experience

Appendix C
BIPM



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Challenges

Budget

- Financial resources of the process

Authorities change

- Decision takers

People involvement

- Importance of each one in the process

Keep vitality of the QMS

- It does not finish when the recognition is issued

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Lessons Learned

Planning Process:

- Review timeframes to fulfill RMO requirements

Selection of peer reviewers:

- Experience
- Feedback, action plan review and acceptance

Key/Supplementary comparisons:

- Support for CMCs

Prioritize Resources:

- Technical and management actions supporting QMS

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Conclusions

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Conclusions

- Remember to establish priorities in definition of CMCs
- Top Management has to be involved
- **Follow up** process as one of main points of the implementation
- Ask for feedback with other NMIs and peer reviewers
- Training, updates, R+D, innovation to keep vitality of CMCs
- **Good Luck!**

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jchavarria@lacomet.go.cr

+506 4060-1042

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