Workshop on Issues relevant for the Accreditation of the Current Quality Control Laboratories (QCL)

V

Discussion of Specific Aspects

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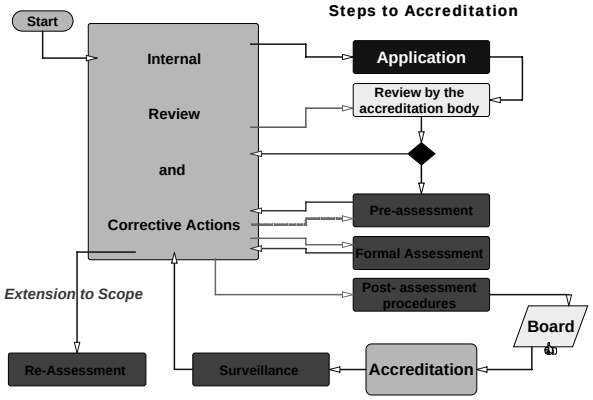
Steps to Accreditation



Steps to Accreditation

Stage in the Process		
Internal Review and corrective actions		
Global Activity	**Individual activities**	**Details**
Laboratory reviews its current system against ISO 17025.	**Review all management and technical processes and take corrective actions**	Current procedures and Documentation; special **focus on calibration processes**
Comment		
>90% perfection should b e achieved; estimated duration > two years		

Steps to Accreditation

Stage in the Process		
Application		
Global Activity	**Individual activities**	**Details**
Laboratory **provides basic, administrative and operating information with comprehensive cross-references** to relevant documents.	Laboratory submits **Application form**	Facilities Staff Activities for which accreditation is sought (**Scope**)
	Laboratory submits **Quality Manual.**	Sections 4 and 5 of the QM could be structured according to the clauses of the ISO standard 17025:2005
	Laboratory submits **results of proficiency tests** and inter-laboratory comparisons.	
Comment		
High precision required; Templates of QM are commercially available; quality highly variable!		

Steps to Accreditation

Stage in the Process		
Review by the accreditation body		
Global Activity	**Individual activities**	**Details**
Accreditation Body reviews Application and assigns the assessment to a lead assessor	Application form	Lead assessor evaluates suitability of the laboratory for pre-assessment.
	Quality Manual	
Comment		

Steps to Accreditation

Stage in the Process		
Pre-assessment		
Global Activity	**Individual activities**	**Details**
Pre-assessment creates better understanding of what the assessment visit will involve; key members of the laboratory staff who are aware of the procedure are available.	Discussion of the precise terms in which accreditation is to be defined.	**The Scope of the laboratory is defined**
	Review of the quality system and procedures with the management.	
	Review of the facilities and equipment	
	Definition of the areas to be addressed by the laboratory to prepare for formal assessment.	
Comment		
If more than a certain time span has passed before the formal assessment a new pre-assessment may be necessary		

Steps to Accreditation

Stage in the Process		
Formal Assessment		
Global Activity	**Individual activities**	**Details**
Involves discussions and observations of the laboratory's systems at work	Introductory meeting (Management including quality manager and relevant technical management participates on the side of the laboratory)	Assessors and laboratory's representatives become acquainted.
		Purpose of the assessment and what is expected of the laboratory during the visit is clarified.
		Discussion of the scope of testing and the terms in which the accreditation should be defined.
	Review of the assessment schedule.	

Steps to Accreditation

Stage in the Process		
Formal Assessment		
Global Activity	**Individual activities**	**Details**
Involves discussions and observations of the laboratory's systems at work	Examination of laboratory operations (general system and particular areas of work	Work in progress
		Trace back results of previous reports
		Filling out of detailed report form by assessors. Counter signature of head of laboratory
	Closing meeting	Verbal presentation of the findings
		Information on the assessment team's intended recommendation
		Corrective action required and time table for implementation
Comment		
Discussions in a professional atmosphere. Sections heads may **propose corrective actions** where required. Clarifications and factual corrections of errors in the		

Steps to Accreditation

Stage in the Process		
Post- assessment procedures		
Global Activity	**Individual activities**	**Details**
Actions and interactions before the decision of the accreditation body	The laboratory takes **all** corrective actions.	
	The laboratory reports on corrective actions and includes evidence.	
	[additional visit]	
	If all non-compliance cleared positive, recommendation by assessors to board.	
Comment		
At this stage: no choice but to comply within certain time limits. [Additional assessment only if necessary in cases of significant non-compliance at the time of assessment]		

Steps to Accreditation

Stage in the Process		
Surveillance and re-assessment		
Global Activity	**Individual activities**	**Details**
Monitoring of continued compliance	Regular surveillance and re-assessment visits.	First visit possibly shortly [6 months] after accreditation and annually thereafter
		Re-assessment [every 4 years] with new changed assessment team.
Comment		

Steps to Accreditation

Documentation for Assessment

- **Quality manual** [and record clearly identifying any amendments made to the quality manual since the last visit].
- **Schedule of all audits** (planned and completed audits)[since last visit]
- **Minutes of last Management Review meeting**(s)
- A **short** Summary Report of **performance in Proficiency Testing** schemes [and Inter-Laboratory Comparisons, where applicable]. This summary report should comprise:
  - The identity of the scheme
  - The number of rounds completed and the parameters tested [since the last visit]
  - The Organisation's performance in each round
  - Outlying results and brief summary of consequences and conclusions
- [Where applicable, a list of amendments to any accredited test methods since the last visit to include the reason for the amendment]

Where applicable, a list **detailing all instruments calibrated in-house**.

It is the policy of accreditation bodies that organisations provide this information several weeks prior to a scheduled assessment/surveillance/re-assessment visit.

Steps to Accreditation

Scope / Flexible Scope of Accreditation for Chemical Testing Laboratories

- Accreditation of laboratories is normally based on a ***defined scope of accreditation***. This is a precise description of the specific tests for which the laboratory is deemed competent.
- For each new test that is added to the scope an evaluation of the laboratory's competence is required.
- **Flexible scopes** allow a laboratory to undertake certain tests and to claim accreditation for these tests even though those tests may not be explicitly stated on their scope of accreditation.
- Additional tests, for which the laboratory claims accreditation via flexible scope, are to be listed within a defined category. **The matrix, parameters tested, reporting range, analytical technique and method are recorded in a document which is controlled and updated by the laboratory.**