System and Processes of Third Party Accreditation Bodies

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Specifying a Scheme

- Protects public health
- Provides oversight – (all levels)
  - For the Accreditation Body
  - For the Standard
  - For the Laboratory
- Provides confidence in the data
  - Review of the results (validation of the Scheme working)
- The public has confidence in results
- The labs have a level playing field

Third Party Accreditation Bodies

- Business Aspects
  - Organizations whose business is assessing and/or accrediting labs (cabs) against specified standards.
  - Customer Service
    - 5000+ accredited laboratories
    - Labs range from those with 1 person to 300+
    - Labs in all 50 states and foreign countries
    - Labs are Aerospace, Automotive, Federal, State, City, Medical, Product Certifiers, etc., etc., etc.

Third Party Accreditation Bodies

- Business Aspects
  - Contract Law
    - Contract with the Customer (the lab)
    - Allows AB's to Accredit, Suspend, and Terminate
    - Allows AB's to assure compliance (return)
    - Allows for other agreements (stakeholders)
      - Schemes specified by Government are agreed to by the AB at the recognition and accreditation level.

Third Party Accreditation Bodies

- **Business Aspects**
  - Impartiality
    - Third Party
    - Accreditation on the Merits
    - Credibility
    - Success
    - Monitoring
    - Recognition

Third Party Accreditation Bodies

- As a Business
  - Product
    - Scope of Accreditation
    - Certificate
    - Assessment Report(s)
    - Improvement
    - Fulfilling Agreements
    - Competence
    - Reputation
    - Scheme Requirements

Third Party Accreditation Process

- Application
- Assessment
- Accreditation Decision
- Maintenance

Application Stage

- Application Requirements
  - General Information
  - Scope of activities
  - Clearly defined scope
  - All locations
  - The number of technicians

Application Stage

- **Application Criteria**
  - Accurate information needed from lab to:
    - Ensure adequate resources
    - Ensure adequate assessment time
    - Ensure all areas of the scope are assessed and sufficiently witnessed

Assessment Stage

- Assessment Preparation
  - Document Review
    - For Completeness
    - Feedback
    - Records kept of the Review

Assessment Stage

■ Assessment Planning
- Assessors are assigned
  - Sufficient knowledge and experience
  - AB (s) ensure that teams are impartial
  - Labs have the right to decline assessors
  - Lead assessor submits plan/agenda
  - The plan includes all aspects of the assessment

Assessment Stage

- On-site Assessment
  - An opening meeting
  - All requirements and tests are assessed
  - Sufficient sampling to assure competence
  - Objective evidence to support findings
  - Nonconformities are reported and provided to the lab at the conclusion of the assessment
  - The next steps are explained and the lab is asked to respond

Assessment Stage

■ Post Assessment Activities

 – Review team convened

 – Closure of correction action

 – Completeness of assessment documentation

 – <u>Accreditation decision</u>

 – Decision makers are impartial and independent

 – Accreditation scope and certificate are issued

Accreditation Maintenance

- Maintenance of accreditation
  - On-going surveillance visits
  - Less extensive then the accreditation assessment
  - The AB assures the labs continually maintain their accreditation

Accreditation Maintenance

- Reassessment of the Accreditation
  - Based on the AB established cycle
  - Full system assessment
  - Full review through accreditation decision committee to renew accreditation
  - Certificate revised to reflect new approval and expiration dates

Accreditation Maintenance

- A lab's certificate may be suspended, withdrawn or reduced (established procedures)

- ABs assure labs continue to follow the standard and rules of the accrediting body

Third Party Accreditation Body Technical Competence

- Assessor Selection and Qualification
- Assessor Training and Development
- Evaluation of Performance
- Technical Advisory Groups
- Assessor Integrity
- ANSI/ISO/IEC 17011 and Peer Evaluation

Assessor Selection and Qualification

- <u>Education:</u> ABs require post-secondary qualification or equivalent in technical discipline

- <u>Work Experience:</u> Assessors have lab and quality management experience

- <u>Training:</u> ABs require successful completion of a training course(s) or equivalent

Assessor Training and Development

- ABs establish formal programs in which assessors progress

- Based upon successful completion of a certain number of assessments

Evaluation of Assessor Performance

- <u>Initial Evaluation:</u> ABs monitor and evaluate on-site initial assessment(s) of new assessors

- <u>Ongoing Evaluation:</u>
  - Formal Observation
  - Review of Assessor Reports
  - Feedback

Technical Advisory Groups

- ABs organize meetings for assessors, technical experts, and others in specific fields to discuss issues

- These meetings are used promote consistency in assessments

Assessor Integrity

- Conflict of Interest
- Confidentiality
- Integrity
- Impartiality
- Consultancy

ANSI/ISO/IEC 17011

- Each AB is required to comply with ANSI/ISO/IEC 17011: General requirements for accrediting bodies accrediting conformity assessment bodies

- Each AB undergoes a rigorous evaluation