

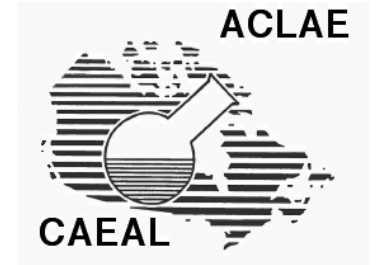
Specific Interpretations of CAN-P-4D

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Contents



- Data Validation (2nd set of eyes)
- From Non-Conformance to Corrective Action
- From Potential Non-Conformance to Preventive Action
- Traceability of Measurement

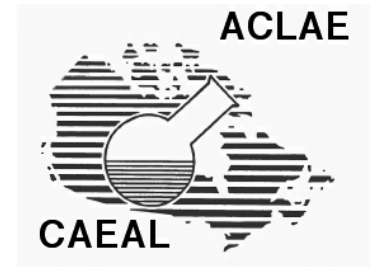




Validation of data and test results - requirements

- CAN-P-4D, 5.9 (...shall have quality control procedures for monitoring the validity of tests...)
- Trace of Tests Report, #8 (...validation includes checking transcription errors and comparison...)
- **MEANING:** Second set of eyes. This is not the same as the requirement to have an authorised person signing the reports. But both requirements could be accomplished by the same activity.





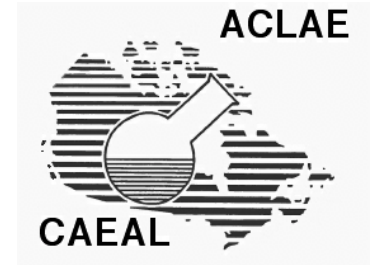
Non - conformances

- Definition: Non-fulfilment of specification
- Meaning - It has already happened and it has been identified and it is not good.

- CAN-P-4D requires labs to raise non-conformances from the following clauses
 - 4.8 complaints
 - 4.9 non-conformances
 - 4.13 internal audits
 - 4.14 management reviews
 - 5.9 QC



Corrective Action



- Root Cause
- Set of potential solutions
- Selection of solution
- Implementation of solution
- Documentation of this process
- Monitoring of implementation for effectiveness



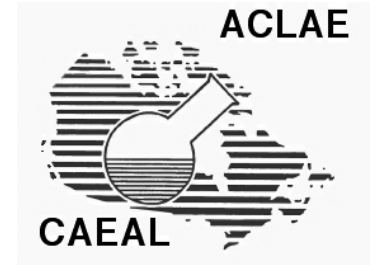


Potential Non - conformances

- Definition: Potential non-fulfilment of specification
- Meaning - It may happen or it has not yet been identified and it is potentially not good.
- CAN-P-4D requires labs to raise potential non-conformances from the following clauses
 - 4.8 complaints
 - 4.9 non-conformances
 - 4.13 internal audits
 - 4.14 management reviews
 - 5.9 QC



Preventive Action



- Root Cause
- Set of potential solutions
- Selection of solution
- Implementation of solution
- Documentation of this process
- Monitoring of implementation for effectiveness



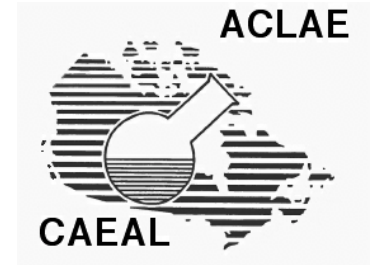


What is the Big Deal?

- Non-conformances and Potential Non-conformances (opportunities for improvement) differ in only ONE aspect -> Time! One has already occurred and the other has not yet occurred.
- Corrective and Preventive actions differ in only ONE aspect -> Time! One solves a problem already identified (prevents recurrence) and the other prevents a potential problem from occurring in the first place.

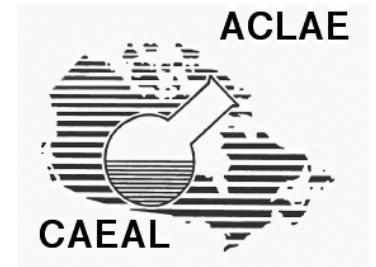


Internal Audits



- A laboratory internal audit **MUST** be completed at least once per year.
- It **MUST** include all aspects of laboratory operations.
- It may be done in many little steps or in **ONE BIG EFFORT**. Choice is theirs.

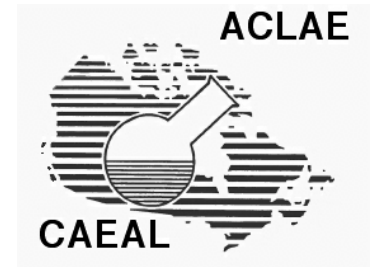




Management Review

- A laboratory management review **MUST** be completed at least once per year.
- It **MUST** include all topics listed in 4.14.1 of CAN-P-4D.
- It **MUST** include a mechanism for follow-up and close out of actions raised during the management review
- It **MUST** be chaired by the most senior person having **ANY** influence on the operation of the laboratory
- It may be done in many little steps or in **ONE BIG EFFORT**. Choice is theirs.





Traceability of Measurement

- See A61 - CAEAL and the SCC Policy on the Acceptability of Calibration Sources.
- For Traceability, or Calibration, or Uncertainty to exist at any point in the chain - they must **ALL** exist
- **NO CALIBRATION**
= **NO UNCERTAINTY**
= **NO TRACEABILITY**

