

1. **Thinking like a team (A)**

All Groups are to sit at their own table and draw triangles on hotel note pad paper under the following conditions:

- a. No talking, no signing, no blinking, no playing "footsies" - NO COMMUNICATION OF ANY SORT!!!
- b. Each person draws one straight line and then passes the piece of paper to someone else.
- c. At the end of ninety seconds STOP!

GENERAL DISCUSSION

2. **Thinking like a team (B)**

All Groups are to sit at their own table and draw as many triangles as they can on hotel note pad paper under the following conditions:

- a. Groups are to plan their activity for two minutes prior to the commencement of the exercise
- b. Once the planning period is over, no talking, no signing, no blinking, no playing "footsies" - NO COMMUNICATION OF ANY SORT!!!
- c. Each person draws one straight line and then passes the piece of paper to someone else.
- d. At the end of ninety seconds STOP!

GENERAL DISCUSSION

3. **"A" vs. "B" Ratings**

Scenario: ABC Laboratory has purchased thermometers from two different manufacturers which also arrange for "calibration" certificates to be included in the documentation supplied to the laboratory. The two certificates relating to the two thermometers are provided to each participant as "Calibration Certificate" and "Calibration Report." These exhibits demonstrate that the thermometers do not meet the requirements of CAN-P-4D with respect to traceability of measurement.

Requirement Each group has ten minutes to develop answers to the following questions:

- a. Are these non-conformances the same? Or different?
- b. Are these non-conformances "A" or "B" ratings? Why?

GENERAL DISCUSSION

4. **Method Validation**

CAN-P-4D defines Method Validation as "...confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use [of the Method] are fulfilled."

CAN-P-4D, cl. 5.4.5.1

Background Given the following information:

- a. Eurachem Guide on Method Validation - "*Fitness for Purpose of Analytical Methods*"
- b. CAEAL Appendix
- c. Interpretative note under cl 5.4.5 of D92.5-E3 - "*PALCAN Interpretations for Conducting Assessments of Testing and Calibration Laboratories*"
- d. One standard less than or equal to 10 times the detection limit may be part of the initial validation and/or calibration, but not necessarily required for every run....., and
- e. To ensure that a test method is validated based on performance, history or documented validation data, including: detection limit, precision, accuracy, and recovery, as appropriate.

Requirement Each group has twenty minutes is to develop answers to the following questions:

- a. Prioritise the main parameters that should be examined in order to determine whether a method has been appropriately validated against the definition above for:
 - i. Chemistry
 - ii. Microbiology
 - iii. Toxicology
- b. What level of objective evidence is required? Do these levels vary with the differences for each discipline? How?

GENERAL DISCUSSION

5. **Electronic Signatures**

Scenario A laboratory conducts hundreds of tests each day. It uses commercially available software to control the tests, store input parameters, gather resulting data, manipulate data to produce results, print and generate reports. The Quality Assurance Manager of the laboratory, in order to check for consistency and validity, has delegated the responsibility for spot-checking a statistically valid sampling of the results to the Senior Technicians. The QA Manager also receives a weekly report on the performance of resulting data and data trends, so as to follow how well the whole system is doing in the production of results.

The Quality Manual of the laboratory states that either the Laboratory Manager or the Quality Assurance Manager are the only authorised signatories of the reports. In order to accomplish this procedure, the commercially available software stores pictures of both of these signatures and they are printed on the reports, when these are produced.

The Quality Assurance Manager (or the Laboratory Manager) may actually see 5% to 10% of the reports produced that bear their signatures.

Requirement Each group has fifteen minutes to develop answers to the following questions:

- a. Do the actions of the laboratory meet the requirements of CAN-P-4D?
- b. What are the potential dangers of the laboratory's approach?
- c. What actions might the laboratory take, if any are needed, to both continue their "automated" approach to testing, and to meet the requirements of CAN-P-4D?

GENERAL DISCUSSION

6. **Equipment**

Within a fully developed quality system, a laboratory requires its staff to log the use of CRMs during testing. It does not require the staff to log the use of reagents. During the two previous reassessments, no mention was made of any requirement to log reagents. Last week, during the most recent reassessment, the new CAEAL Team Leader advised the lab that the list of required actions would include the following:

Develop and implement a procedure to log the use of all reagents during the conduct of tests for which the laboratory is accredited.

During a pointed exchange, the laboratory made its views clear on the unfairness of such an observation, given the lack of any such observation during the two previous assessments. The laboratory then indicated that it would appeal the Team Leader's decision to include this observation as a required action.

You are the Assessments Manager at CAEAL. Three days later you received the written appeal from the lab.

Requirement Each group has fifteen minutes is to develop answers to the following questions:

- a. Do you support the lab or the Team Leader?
- b. Why?

GENERAL DISCUSSION

7. **Sampling**

Scenario

Laboratory 1 receives water samples from clients for testing the presence of metals and other chemical compounds (non-organic).

Laboratory 2 receives sides of beef to test for PCBs in meat.

Requirement Each group has ten minutes to develop answers to the following questions:

- a. Do either of the two laboratories need to have procedures for sampling (in accordance with Section 5.7 of D92.5)?
- b. What do these procedures, if any, need to cover?

GENERAL DISCUSSION

8. **Challenging Situations**

Scenario

The Laboratory Manager and the Quality Manager of the laboratory have recently met to discuss what they feel is an unreasonable set of required actions raised by the CAEAL assessment team:

- a. The team has cited a need to log all reagents used in accredited testing, when the last two assessments failed to mention such a requirement.
- b. The team has cited a need to provide uncertainty statements with the internal calibration of the lab balances, which are normally calibrated from the set of masses held in the reference lab. Lab staff are not familiar with the derivation of uncertainties for masses and balances, and
- c. The team has cited a need to produce validation data on test methods that were last validated during the reassessment conducted four years ago. Digging out this data may take weeks for tests methods that are industry standards and considered acceptable.

There is a lot of work involved in these three actions and the laboratory staff do not feel that this work is an acceptable or justified expenditure of time and resources. They run a business and these requirements are "just plain silly."

The Team Leader now meets with the two managers and their discussion centres around whether the team will include these three required actions in the report to the CAEAL Assessment Manager.

Requirement Each group is to nominate three individuals to represent the two managers and the Team Leader and conduct a fifteen minute meeting on their differences of opinion.

GENERAL DISCUSSION

9. To Assess or not To Assess?

Scenario Last week an assessment team commenced its reassessment of XYZ Laboratory. Ten minutes into the opening meeting the Laboratory Manager presented a list of three tests that the lab seeks to have added to its scope of accreditation. The tests are for fecal coliforms, mercury and dissolved lead in drinking water. These tests, they explained, are now vital to the financial survival of the lab - given the Walkerton disaster. No one on the team was aware that the lab was going to ask to be accredited for these tests. The lab has successfully participated in the two most recent CAEAL PT studies for lead and mercury tests. Method validation data exists for only the mercury and fecal coliform tests

Situation 1 The Laboratory Manager has been arranging for the conduct of testing for mercury in drinking water samples for more than a year. All samples were drawn and logged from local water sources and the lab has successfully participated in the most recent PT study on this parameter. To date, the lab has not received any client samples, because they were not accredited for the test. Method validation data and recent PT results indicated that the method used in the laboratory is consistent with other CAEAL labs.

Situation 2 Contrary to the belief that the laboratory was going to drop "dissolved lead in water" from its scope of accreditation, because they had not actually done any testing on this parameter for more than a year, the laboratory requested that this test continue to be included on their published scope of accreditation. Historical data from previous tests and PT data showed reasonable results and the laboratory wanted to maintain this test on their scope of accreditation.

Situation 3 In another instance, the laboratory had not only not tested "real" client samples, but their equipment was not configured to conduct the coliform testing they now wanted to add to their scope. The incubator normally used during testing was set up for BOD testing and not coliform testing. There is no CAEAL PT program available for "presence/absence" of coliforms in water.

Requirement Each group has twenty minutes is to develop answers to the following questions:

- a. Which tests should or should not be assessed? Why
- b. What does the Team Leader have to do, if it is decided to assess any of these tests?
- c. What does the Team Leader have to do regarding those tests which should not be assessed?
- d. What do the members of the assessment team have to do?

GENERAL DISCUSSION

10. **Providing the "Solution"**

Scenario During a recent CAEAL-led reassessment of a joint lab, the following observations were made by the members of the entire assessment team.

Item	Detail
1.	Dimensions were missing from the floor plan that forms part of the Quality Manual
2.	The responsibility for the disposal of samples has been assumed by one of the key staff, but this responsibility has not been documented anywhere
3.	Organisation charts are not in, or referenced by, the Quality Manual
4.	The laboratory is recording average face velocity values of 24 m/min while the new CAN-P-27999 suggests 30 m/min.
5.	The lab has no centralised inventory of Reference Materials. Each section maintains their own inventory.
6.	The laboratory has no refractometer to conduct salinity measurements.
7.	The laboratory has no power monitor.
8.	The laboratory is not checking the temperature of the flame in the atomic absorption spectrophotometer.

Situation Select the person from each group that has the least assessment experience and "crown" them as Team Leader. During an in-camera session, the team is discussing these observations. While the Team Leader is solely responsible for the decisions of the team, teams should work towards consensus.

Requirement Each group has fifteen minutes to develop answers to the following questions:

- a. Which observations are "A", "B", or "C" ratings for this assessment?
- b. Does everyone in the group agree with the Team Leader's decision? If not, why not?
- c. How does the team ensure that they are not "forcing" the solution on to the lab?

GENERAL DISCUSSION