

CAEAL ASSESSOR TRAINING 23 FEBRUARY 2003

RECORD OF DISCUSSION

This paper highlights the most prominent discussions of the large group during the CAEAL Assessor Training on 23 February 2003.

Recommended versus Required Actions

This issue has many facets and CAEAL will take it to the SCC's Task Group Laboratories (TG Labs) for resolution. Here are some of the considerations:

- “Recommended” could be interpreted to mean that it is not “required” to be addressed. This is not actually the case (in policy throughout all of PALCAN) but the words do not impart a necessity for action.
- One resolution may be to simply call them “A” and “B” actions without reference to “recommended” or “required.”
- Another is to put a due date against “B” actions (of two years) as opposed to the current practice of putting N/A in that column of the report.
- While “B” items may not be considered to adversely affect the ability of the laboratory to produce competent results – they are still non-conforming conditions recorded at the lab. So they need to be fixed or the lab cannot claim conformance to the standard. Labs that do not address these non-conformances, will themselves cease to conform to the requirements of the standard under Clause 4.9 – the clause requiring the laboratory to develop and implement procedures to address identified non-conformances.

CAEAL Decision: Until further notice, the definitions of “recommended” and “required” actions, will continue to be applied, as defined in current documentation. CAEAL is approaching TG Labs to open the discussion to redefine the approaches. Assessors are to be prepared to discuss the issue with laboratories during assessments and apprise them of the of the two year requirement to complete “B” items.

Assessment Team Handling of Recommended Actions from a Previous Visit

This issue was raised by some assessors who felt that the list of recommended actions from a previous visit was just one more checklist the team had to use in their assessment work – when this did not have to be the case.

- One option – put a due date against “B” actions (of two years) as opposed to the current practice of putting N/A in that column of the report. Have the lab respond, clear these response at CAEAL and have the assessment team examine any outstanding issues.
- Another option – provide the assessment team with the responses to these items prior to the visit.

Most probable approach will be to put the date on the “B” items and provide the team with the list as before. There can be no question that the assessment team is being asked to “close out” these items from the previous visit. The “B” items can, however, provide the team with an indication of where to lean in their assessment investigation. The team should, as the last document to review prior to the visit, cast an eye over the list of items raised and then be on the lookout for recurrence of these non-conformances.

Closing out Actions before the Closing Meeting

With the new regulations being introduced in Ontario, and with similar changes occurring in one or two other provinces, there is a great concern about the assessment report being considered a “Report Card” instead of its current role as a “list of things to do.” Laboratories are shifting their perception of an assessment to consider it more of a “pass-fail” exercise. This shifting perception changes the acceptability of the number of actions on the report.

One outcome is the “close out” of actions before the closing meeting, in an attempt to have that action removed from the report.

This approach contravenes both the spirit and the requirement of an assessment. There is no “pass-fail” and the lab is not penalised for having a series of required or recommended actions. While accreditation may not be granted to a new lab until the required actions have been addressed, a reassessment report with a number of required actions on it will not result in the suspension of a laboratory. Unless these actions are of such a grave nature as to call into serious question the conduct and/or capability of the laboratory, the reassessment report remains a “list of things to do” for an organisation that continues to maintain its accreditation.

Therefore, and in keeping with the understanding that the assessment “snap shot” is an accurate representation of the laboratory’s quality system, ALL findings noted during the visit shall appear on the report unless subsequent information indicates that the original finding was inaccurate.

Traceability

There have been a lot of misconceptions over the last 10 years about what a “quality” result is, and what “traceability” means. With the publication of ISO/IEC 17025, these two terms came to be interdependent. Today, we know that a “quality” result is not necessarily one with a higher “precision” or “accuracy” than another. In terms of determining what is “fit for purpose” (the 17025 definition of “quality”) the single most importance characteristic of a measurement is its associated uncertainty. Uncertainty can tell us enough about a measurement to help us decide whether or not it is “good enough.”

The concept of uncertainty requires that all traceable contributions to the measurement are quantifiable with their own uncertainties. To accomplish this,

they must be “traceable, ” an outcome of which is that the resulting measurement is also traceable.

ISO/IEC 17025 states a requirement that all measurements produced by a laboratory conforming to the standard are traceable. As a corollary, they must all have an associated uncertainty estimated for the measurement. Within the standard, these two concepts go hand in hand. There can be no uncertainty associated with a measurement, unless all of the instruments providing uncertainty contributions to that measurement are all traceable. A single result cannot be considered traceable unless all of the instruments contributing to the calculation of that measurement also have uncertainties associated with their measurement parameters.

No aspect of environmental testing is free of these requirements. Today, only mass, volume, and temperature are undergoing scrutiny for traceability in environmental laboratories, because SRMs, CRMs, and standard solutions do not yet all have uncertainties associated with them. In time, these will come too.

For now, assessors are being asked only to have laboratories demonstrate that their physical measurement devices – balances, masses, thermometers and pipettes – are traceable. And these only to the degree necessary to meet the laboratory’s own requirements for uncertainty of measurement.

Where a laboratory has not made such determination, then we are asking that laboratories provide a once yearly calibration of these reference and working measurement devices. When the laboratories are able to determine that their uncertainty requirements of an instrument are two or three orders of magnitude less demanding than what that instrument can currently deliver, then they have the basis on which to make a decision to lengthen the calibration cycle – not before.

In Rev 1.2 of A61 “*CAEAL and the SCC Policy on the Acceptability of Calibration Sources*,” the traceability chain is fully described. This document was supplied to all assessors during the Sunday session and should be the basis for discussions between the assessors and the laboratory on the issue of traceability.

Ontario Safe Drinking Water Act

The presentation by Ms. Cammy Mack of the MOE was an attempt to provide information to CAEAL assessors about the impact of the new legislation, prior to its coming into force and to make assessors aware of the type of observation that would be considered “reportable.” It is obviously a contentious topic.

The MOE has not yet provided SCC or CAEAL with a draft of an agreement.

While the new law requires reporting to the Ministry, some assessors commented that they understood that it would be OK to NOT REPORT. CAEAL does not support this approach. We must abide by the law and we must make our assessors aware of the requirement.

One outcome of the presentation was a general feeling that if CAEAL (and the SCC) are bound by law to report items that may have otherwise been confidential, then the affected laboratories must be made aware of the issue.

There were two members of the CAEAL Board of Directors present during this discussion and they were able to appreciate the concerns of the assessors. They will represent these concerns to the remainder of the Board when the issue comes before them again. The new Ontario Safe Drinking Water Act affects all laboratories conducting drinking water testing for communities in Ontario, regardless of the location of the laboratory. All of these laboratories fall under the new regulations. CAEAL will make every effort to remind all laboratories that it is every laboratory's responsibility to make themselves aware of the law of the land.