The accreditation : towards reference frame NF EN ISO CEI 17025

(Summary of the lecture given by M CHORIN – COFRAC - at CECALAIT's Annual General Meeting 2001)

According to regulation or customers wishes, there are continually more metrology and analysis laboratories, certification or inspection organizations seeking for accreditation. COFRAC is the French accreditation body. The reference frame they have used until now is decribed in standard NF EN 45001 (December 1989), which will be replaced by standard NF EN ISO CEI 17025 (May 2000) within a 2-year period (until January 2003). The new text is more complete and more precise on numerous points including metrology, uncertainty, sampling, interpretation and finally, the validation of methods.

The transition towards a new reference frame

Applying for accreditation at the COFRAC is a voluntary process which proceeds in several successive stages:

- official written request to the COFRAC
- reception of a file including an evaluation questionnaire, organization of the initial audit, carried out over 2 days by a quality control engineer and a technical expert.Before this step, there must have been :
  - proposal of team (*may be refused by the applicant)*.
  - schedule.
  - communication of the documents
- examination of the audit report by a Standing Committee of Accreditation and the permanent structure of theCOFRAC,
- decision.

The audit is based upon a reference frame. Until now, laboratories were accreditated to standard EN 45001, from December 1989. However, this text was replaced, in May 2000, by the standard EN ISO 17025, which :

- "extends its applicability to all laboratories,
- modifies the requirements relating to quality systems to put them in coherence with standards ISO 9001 and 9002. " (In AFNOR - standard NF EN ISO/CEI 17025, page 1)

The transition between the two reference frames took place from January to October 2001 as the laboratories had the possibility to be accreditated to either reference frame. From October 2001 to January 2002, the COFRAC began to use the new standard, except for some initial audits. As from January 2002, every COFRAC audit, *ie* initial or monitoring (conducted within 12 months after the initial audit) is conducted according to the new reference frame. All laboratories should be accredited to this text until January 2003. In the meanwhile, the monitoring audits will be carried out by a technical expert personnel and by a quality control engineer and not simply by a single expert.

The main differences between the two reference frames

➢ METROLOGY

In standard 17025, the requirements concerning metrology appear mostly in part 5: technical regulations, and in particular in paragraphs " 5.5 Equipment " and " 5.6 Traceability of measuring". To comply with these requirements, three stages are necessary :

- identification of any item of equipment likely to affect the accuracy or the validity of the test result, the calibration, the sampling,
- The set up of a programme of traceability for calibration standards and all relevant equipment to national standards. For this, the laboratories should specify in each case, the effective range and uncertainties of calibration and possibly, the conditions of use of the standard.
- Finally, ensurement of traceability.

The laboratory will later have to provide documentary evidence of the traceability to national standards by calibration or verification certificates issued by any assessed European laboratory accreditation body.

➢ UNCERTAINTY

In standard 17025, the requirements concerning uncertainty appear in part 5: technical regulations, and in particular in paragraph " 5.4.6 Estimating the uncertainty of measurement".

For the audits carried out according to the new standard, the assesment team will check that the laboratory started to identify and evaluate the various uncertainty components and to think of the calculations needed. Considering the volume of work necessary, the laboratories cannot be initially required to have calculated all uncertainties for all measurements ! However, the complete work carried out on uncertainties will be gathered from the audit reports and other local observations and examined by the Standing Committees of Accreditation, so that the COFRAC can draw doctrines from it. For example, it will specify if the calculations based on the reproducibility of the methods are sufficient or if it is necessary to take into account the propagation laws, all the significant factors... etc. Besides, the doctrines of the COFRAC are likely to evolve as additional information will be obtained from laboratory observations and calculations. Later, the assesment teams will have to verify how the laboratories set up the application of these doctrines.

Standard 17025 also specifies that the test report (paragraph 5.10.3) must include information on uncertainty in measurements in following cases:

- at the customer's request,
- when there is a declaration of conformity to some specification, if uncertainty affects its limits,
- when the method mentions limiting tolerances or thresholds to be reached,

- when the method gives a list of the components having an influence on the test results.

➢ SAMPLING

Sampling is discussed in paragraph 5.7 of the standard. But, it is only relative to the laboratories which deal, for themselves or for their customers, with sampling of substances or materials for further tests or calibrations. The sample must be representative of whole substance or material.

Then, the laboratories, that wish to include the procedure of sampling in the accreditation, must have a planning and a procedure of sampling, also available where sampling is done.

Planning must be based on adequate statistical methods. The procedures must take into account any factor to be controlled, so that the results of the tests and calibrations are valid. The most important information on planning and the procedure of sampling must be reported in the test report or the certificate of calibration.

However, most laboratories are not concerned, because their customers give them only a single sample. In this case, no sampling procedure can be set up and the laboratory cannot be accredited on this point. The test report will specify that the result is only valid for the analysed sample and cannot be extended to the whole batch. The laboratory cannot be held responsible when the sample is not representative. It remains that the laboratory can suggest sampling improvements to its customer.

➢ OPINION AND INTERPRETATIONS

The test reports (part 5.10) can contain opinions or interpretations, supplementing an analysis or calibration results. They must however be clearly identified. They may concern :

- Declaration of conformity or non conformity of the results compared to regulations,
- Respect of the contractual requirements,
- Recommendations on the use of results
- Recommendations to be followed for improvements.

In the same report, there may be opinions on tests that are accreditated or not, but they must be clearly separated. Opinions or interpretations can be communicated orally. However, it is necessary to keep a written formulation of them, in particular to specify on what they are based. In practice, it may be difficult to express any opinion or interpretation because the laboratory must not act as a consultant or an expert.

➢ VALIDATION OF METHODS

The validation of sampling, test or analysis methods is something new in this standard (part 5.4.5). However, over the last few years, the COFRAC has already included this requirement of validation of the internal methods in its reference frame for the accreditation of laboratories.

For the customer, this is a very important guarantee. For the laboratory, the validation will demonstrate the competence of those who :

- will have used non standardised methods,
- will have extended the domain of application of standardised methods,
- will have conceived or developed new methods.

In conclusion

The new reference frame NF EN ISO CEI 17025 is much more complete than the old standard EN 45001. The principal differences between the two texts relate to metrology, uncertainty, sampling, opinions or interpretations and validation of methods. The new reference frame thus covers the totality of the service, from sample taking to interpretations and is always directed towards the satisfaction of customers.

The list of abbreviations and bibliographic references are in « La Lettre de CECALAIT », page 10.