

## Handling of deviating samples by competent laboratories / disclaimers in reports

Since 2003, extensive discussions took place within EA's Laboratory Committee regarding the handling of deviating samples by competent (i.e. ISO/IEC 17025 or ISO 15189 accredited) laboratories. In general it is clearly recognized that, in order to obtain valid test results, the quality within the whole chain *sampling – sample preservation and logistics – analysis – reporting* shall be ensured. However, only a limited number of competent laboratories is responsible (and accredited) for sampling; the far majority just receives samples to be analysed. Hence, the assessments by the accreditation bodies did not focus on sampling, preservation, transportation and receipt of samples.

Deviating samples are samples which are not (correctly) preserved, e.g. have exceeded their maximum preservation time, lack the date and time of sampling, are not cooled, etc, etc. As a result, deviating samples may jeopardize the validity of the reported test result.

Some years ago, accreditation bodies in EA observed that laboratories, in particular those operating in highly competitive markets, were not critical about the samples they receive. Large numbers of deviating samples were accepted, analysed and test reports were issued without any remark.

The EA Laboratory Committee members concluded that such practice is not in the interest of the laboratories, its customers or other end-users of the test result(s) (e.g. governmental organizations), nor of the accreditation bodies. At the end, it could even be a threat for the credibility of accreditation.

These findings have been discussed in the past years within the EA Laboratory Committee, and, also taking into account the requirements of the accreditation standards, the following conclusions were drawn:

- *Upon receipt of each sample, a competent laboratory shall assess whether the sample is suitable with regard to the requested test(s);*
- *When the sample is deviating, a competent laboratory shall contact the customer for further instructions;*
- *When the customer wants the deviating sample to be analysed, a competent laboratory shall include a disclaimer in the report, clearly stating that the sample was deviating and that, as a result, the test result(s) may be invalid;*
- *The accreditation bodies must, during their assessment at the laboratories, strengthen their focus on handling of deviating samples and the inclusion of disclaimers in the corresponding test reports.*

In 2004, several accreditation bodies reported immediate actions such as informing (lead) assessors and/or technical experts to put more emphasis on deviating samples and corresponding disclaimers in reports during assessments. From 2005 until 2007, the majority of the EA-MLA signatories have reported to the EA Laboratory Committee to have taken appropriate actions.

As a result, the general conclusion is that EA, by means of the EA Laboratory Committee, has harmonized its interpretation of the accreditation standards with regard to the handling of deviating samples and the inclusion of disclaimers in the corresponding test reports. In addition, accreditation bodies now better challenge their accredited laboratories for compliance with these requirements and significant improvements have been realized. The EA Laboratory Committee and the EA peer evaluation system should ensure the continuation of this focus as deviating samples play a role in many fields: environment, food, medicine, agriculture, etc.