HANDLING OF UNSTABLE OR DEVIATING SAMPLES

Requirements

ISO/IEC 17025:2017 lays down several requirements concerning the test of unstable and deviating samples. These requirements are:

- Clause 7.4.1: *“The laboratory shall have a procedure for the receipt, handling and storage of the test or calibration item to protect the integrity of the item. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item.”*
- Clause 7.4.3: *“Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the stability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the result of this condition. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified condition, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.”*
- Clause 6.2.3: *“The laboratory shall ensure that the personal have the competence to evaluate the significance of deviations”.*
- Clause 7.8.1.1: *“The results shall be reviewed and authorised prior to release”.*
- Clause 7.8.1.2: *“The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report, and shall include all the information’s agreed with the customer and necessary for the interpretation of the results and all information required by the method used”.*

Definitions

Unstable and/or deviating samples are samples that obviously do not reflect the original sample and where the test result is not representative of the tested consignment or the calibrated item. For example, samples subjected to chemical reactions or microbiological activity after sampling and prior to testing, if the correct precautions are not taken.
This is often due to the fact that the samples have not been handled properly during the sampling and transport to the laboratory according to the requirements stated in the standards or analytical methods or according to the agreement with the customer.
In addition, misunderstanding occurs when the correct information or instructions are not given to the laboratory about the expectations of the customer. This would include not advising the laboratory that a certain EU or National Standard method is expected to be performed and referenced.
Other deficiencies that may jeopardize the validity of the analytical result include but are not limited to:

- Improperly preserved samples (not cooled, not acidified).
- Exceeding of the maximum storage period (shelf life).
- Missing or insufficient sample information (place, time, tests).
- Denaturation by heat, light, or moisture.
- Spoiled or microbiological damaged.
- Contamination with other substances.
- Insufficient sample amount.

Background

During audits performed by NAB’s it is often identified that laboratories are performing tests on samples that are not stable and are not preserved to avoid deviations.
Laboratories do also perform tests on deviating samples without recording this or without contacting the customer for further instructions.
The NAB’s have therefore on several occasions requested that the laboratories must take corrective actions to take into consideration how to handle such samples.

Recommendations

According to the requirements in ISO 17025:2017 the laboratory must set up a sample reception where the samples are checked and assesses if they deviate from the specified conditions or requirements laid down in the standards or agreed with the customer or if the samples seem to have changed due to instability.

If the sample is taken by the customer or by a third party on behalf of the customer, the laboratory cannot be held responsible for verifying that the sample was taken according to the requirements or specifications, but nevertheless the laboratory shall validate the sample and if possible, identify any suspicious or unusual observations and deviation from the specified conditions if known and any improper sampling process. I.e., amount of sample, packaging, temperature, shipping conditions, etc.

The laboratory shall not just use the wording: “*The sample was tested or analysed as received*”, but state that the sample has been assessed when received and include information’s about the sample conditions in the analytical report including all identified deviations from known specified conditions. If no deviations have been identified this shall also be stated in the report.

Normally the laboratory shall react if a sample deviates from normal conditions or is affected by any instability or if the laboratory is suspicious about this.

If such samples are identified the laboratory shall contact the customer in a formal way with this information.

If the customer requires, in a similar formal way, that such a deviating sample shall be tested, the analytical report shall include a description of the general findings identifying in detail the deviations e.g., as described under “Definitions”.

The report shall also include a disclaimer that clearly states that deviations from the relevant standard were observed and that this might affect the validity of the test result.

Such a disclaimer could be: “*The sample/item ID no. xxx showed a deviation from the normal/original state (the state shall be described). Therefore, the sample should not be tested. According to an agreement with the customer (mail/letter xxx), the sample is tested with the disclaimer, that these deviations might affect the validity of the marked test result*”.

Conclusions

When a competent laboratory receives a sample, the laboratory shall always assess the sample and identify if possible, any deviations or instabilities from specified conditions. If so, the customer shall be contacted for further instructions, informing the customer, that this sample should not be tested. If the customer wishes that the laboratory shall perform the test the customer shall be informed in a formal and documented way that the laboratory is obliged to include a disclaimer in the analytical report. The laboratory shall also provide the customer with assistance to avoid such future cases.