UKAS
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TPS 63

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UKAS policy on deviating samples

Contents

Changes since last edition

Minor editorial updates to bring in line with ISO 15189 terminology.

1. Introduction

1.1 Throughout this document, the term ‘sample’ should be taken to mean any item or sample requiring testing or calibration.

1.2 The international standards ISO/IEC 17025 and ISO 15189 require testing and calibration laboratories to have procedures in place to ensure that the integrity of samples they test or calibrate is maintained, and results are reported accurately, clearly, unambiguously and objectively and, where necessary, include comments upon the quality or adequacy of the primary sample which may have compromised the result.

1.3 This publication states UKAS policy on interpretation of the relevant international standards in two distinct areas, handling of test and calibration items / pre-examination procedures (ISO/IEC 17025 clause 7.4 / ISO 15189 clause 7.2.6) and reporting the results (ISO/IEC 17025 clause 7.8 / ISO 15189 clause 7.4.1) with respect to deviating samples. It will assist laboratories in the formulation of effective policies and procedures for managing samples that are (or have become) deviating and is primarily intended to apply to those laboratories testing or calibrating for chemical or biological parameters.

2. Scope

2.1 This document applies to applicant and accredited testing, calibration and medical laboratories. It also applies to inspection bodies that conduct measurements as part of their accredited activities.

3. Terminology

3.1 *Deviating*; an abnormality or departure from what is expected, a divergence from an accepted practice.

3.2 *Deviating samples*; Deviating samples can be defined as those which are not (correctly) cared for, for example they may have exceeded their maximum holding time, have not been retained at appropriate temperature, are presented in inappropriate containers/packaging, have inappropriate headspace, be denatured through heat, light or humidity, have deteriorated chemically or microbiologically, have become cross contaminated, been damaged in transit, have been supplied in insufficient quantity (or with incorrect dimensions) and so on. Such deviating samples may jeopardise the validity of the reported test or calibration result.

3.2.1 In certain circumstances, a laboratory may receive a sample or item where it is evident (or suspected) that integrity might have been compromised prior to receipt and should therefore be defined as deviating.

3.2.2 A laboratory might receive a sample or item for which evidence of sample integrity, critical to the testing or calibration requested, has not been provided, e.g. time/date of sampling where this is critical to stability. In such cases deviating status may be assumed without assurances provided by the customer. Additionally, there might be instances where a laboratory by its own actions (or inactions) allows a sample or item to become deviating after it has been received for analysis or whilst it is in transit where transport is the responsibility of the laboratory.

3.3 *Stability*; the ability of a property to remain unchanged, within a stated uncertainty, under given storage conditions and a specific timeframe

3.4 *Disclaimer;* a statement or assertion that abrogates responsibility for parts of the process

3.5 *Receiving laboratory*; the laboratory that initially receives the sample from the customer for analysis

3.6 *Subcontract laboratory*; the laboratory used by the receiving laboratory to carry out parts of the analysis required by the customer of the receiving laboratory

4. Policy

4.1 It is UKAS policy that all applicant and accredited testing, calibration and medical laboratories shall have appropriate and effective policies and procedures in place to address the requirements of ISO/IEC 17025 and/or ISO 15189 such that that the integrity of samples is maintained, and results are reported accurately, clearly, unambiguously and objectively and, where necessary, include comments upon the quality or adequacy of the sample which may have compromised the result.

4.2 A laboratory, with appropriate agreement of its customer/requester(s) and/or relevant stakeholders shall define and document as to what constitutes a deviating sample and this should include, but not be limited to, aspects such as stability periods (holding times), storage/transit conditions, availability of pertinent information relating to the sample or item (e.g. sampling date/time), use of appropriate sample containers and/or preservatives and whether it is of a type that the laboratory is accredited to analyse or calibrate. This definition shall be technically appropriate.

4.3 When a sample or item has been identified as deviating, a procedure shall be available to ensure consistent application of the actions to be taken. Where appropriate action to be taken has not previously been agreed with the customer/requester as part of the contract review/commissioning process, the procedure should include but not be limited to consultation with the customer/requester and recording of the discussions, initiation of non-conforming work

procedures (if the sample or item has been allowed to become deviating within the laboratory) and ensuring that reporting of any associated results is performed in an appropriate manner.

4.4 Specifically (and as a minimum) laboratories will be required to demonstrate that the following actions (or equivalent) have been taken:

4.4.1 Upon receipt of each sample or item, the laboratory shall assess whether it is suitable with regard to the requested test(s) or calibration(s).

4.4.2 When the sample or item is found to be deviating, the laboratory shall contact the customer/requester in a timely manner for further instructions (unless otherwise agreed during contract review).

4.4.3 If a sample is taken by the customer/requester or on their behalf by a third party and transferred to the laboratory, the laboratory is not responsible for verifying if the sample was taken in accordance with the relevant requirements. The laboratory however shall not ignore any observations concerning any potential adverse condition of a sample which might jeopardise the reliability of the test results. In such a case the laboratory shall contact the customer/requester for further instructions.

4.4.4 If the customer/requester confirms the request to the laboratory to proceed and test or calibrate the deviating sample, the laboratory shall include a disclaimer in the report, clearly stating that the sample was deviating and that, as a result, the test or calibration result(s) may be unreliable (or equivalent suitable wording).

4.4.5 In instances where the sample or item becomes deviating whilst under the laboratory's control, steps 4.4.2 and 4.4.4 as detailed above shall be initiated. In addition, the laboratory shall undertake an investigation using its normal non-conforming work procedures.

5. Additional guidance

5.1 If samples are not taken by the accredited laboratory, then it shall be made clear at the contract review stage or in the user information provided by the laboratory what conditions need to be applied for the sample to not become deviating prior to arrival for testing.

5.2 Laboratories shall ensure that disclaimers or caveats used on test or calibration reports relating to deviating samples are not misleading for customers/requesters.

5.3 The requirements of this TPS shall also apply to laboratories undertaking work under sub-contract arrangements. In this case, the customer of the sub-contract laboratory will be the original receiving laboratory that has provided the work. If the work is identified as deviating, the sub-contract laboratory will need to inform and consult with the original receiving laboratory. It is the responsibility of the original receiving laboratory to inform and consult with the end-user that originally submitted the sample(s) or item(s), for guidance on how to proceed (as in 4.3 / 4.4 above). The test or calibration reports from both the subcontract laboratory and the original receiving laboratory shall include appropriate disclaimers.

6. References

6.1 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

6.2 ISO 15189 Medical laboratories - Requirements for quality and competence

6.3 ISO 5667-3 Water quality - Sampling - Part 3: Preservation and handling of water samples

6.4 ISO 19458 Water quality - Sampling for microbiological analysis

6.5 ISO 5667-23 Water quality - Sampling - Part 23: Guidance on passive sampling in surface waters

6.6 ISO 18512 Soil quality - Guidance on long and short-term storage of soil samples

6.7 Eurachem - Accreditation for Microbiology Laboratories 3rd Edition, 2023