TPS 63

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UKAS Policy on Deviating Samples

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CHANGES SINCE LAST EDITION

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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, calibration and medical 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 The Laboratory Committee of the European co-operation for Accreditation (EA LC) has identified that too many accredited laboratories were not sufficiently critical about the samples they receive. Large numbers of deviating samples were being accepted, analysed (or calibrated) and reports issued without any remark. The EA LC concluded that this practice does not meet the requirements of ISO/IEC 17025 or ISO 15189 and it is not in the interest of the laboratories, their customers or other end-users of the result(s) to allow this practice to continue. Consequently, they have harmonised their interpretation of the aforementioned standards and directed EA signatory Accreditation Bodies, which includes UKAS, to strengthen their focus on the handling of deviating (or potentially deviating) samples during assessments of applicant/accredited laboratories.

1.4 This policy has been written in order to provide guidance on two distinct areas of the relevant international standards, namely; Handling of test and calibration items / Pre-examination procedures (ISO/IEC 17025 clause 5.8 / ISO 15189 clause 5.4) and Reporting the results (ISO/IEC 17025 clause 5.10 / ISO 15189 clause 5.8).

1.5 This document outlines the UKAS Policy for handling deviating samples and will assist laboratories in the formulation of effective policies and procedures for managing samples that are (or have become) deviating.

2 SCOPE

2.1 This document applies to applicant and accredited testing, calibration and medical laboratories. This document 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, lack the date and time of sampling and/or other relevant information, have not been retained at appropriate temperature, are presented in inappropriate containers/packaging, have inappropriate headspace, be denatured through heat, light or humidity, have rotted or suffered microbiologically, have become cross contaminated, been damaged in transit

have been supplied in insufficient quantity (or with incorrect dimensions) and so on. As a result, 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 may have been compromised prior to receipt and should therefore be defined as deviating.

3.2.2 Additionally, there may 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 shall define and document 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 may need to be developed and reviewed in consultation with its customers and/or relevant stakeholders.

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 as part of the contract review process, the procedure should include but not be limited to consultation with the customer 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 for further instructions (unless otherwise agreed during contract review).

4.4.3 If the customer 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 invalid.

4.4.4 In instances where the sample or item becomes deviating after the point at which the laboratory takes responsibility for the sample, steps 4.4.2 and 4.4.3 as detailed above shall be initiated. In addition, the laboratory shall initiate an investigation using its normal non-conforming work (or preventive action) procedures.

5 ADDITIONAL GUIDANCE

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

5.2 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 — Particular 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)