DEVIATING SAMPLES PROCEDURE

Outline

This procedure has been prepared to outline actions to be taken by the laboratory to ensure compliance with the requirements of ISO 17025:2017 (section 7.4.3) and UKAS document TPS 63 regarding deviating samples.

Definition

A deviating sample is one which has not been appropriately cared for resulting in a doubt existing on the suitability of the sample for testing. Examples where a sample would be considered deviating include those that have been received in inappropriate containers, those that have been compromised by being received in damaged packaging, those with inappropriate amounts of headspace for volatile samples, those that have no date or time of sampling (where required), those which have exceeded their holding time in the laboratory, those which have become cross contaminated, those containing an inappropriate request for work, those that have been inappropriately stored in the laboratory, those with descriptions differing from that observed by laboratory staff and also those which have, after test completion, been found to have out of control associated quality control results etc. This listing is not exhaustive.

Procedure

1. The laboratory will endeavour to be sufficiently critical of test samples received, for analysis or examination, to ensure that any derived results are fit for their intended purpose. Any damage to a test item observed on receipt (for example a leaking or broken container) or any other details relating to the item which could be relevant to the outcome of the tests, must be reported immediately to the appropriate Senior Analyst or Senior Technician. The details shall be recorded on the worksheet, or by recording the details in the laboratory workbook, and then be transcribed into LIMS using the description (Descript) determinand by the Senior Analyst or Senior Technician after assessment.

2. The laboratory will also ensure that samples received, for analysis or examination, are treated appropriately after receipt to reduce the likelihood that they will consequently need to be considered as a deviating sample.

3. Any samples received where it is considered that a fit for purpose result could not be generated will be considered as a deviating sample.

4. The laboratory shall, where necessary*, contact the customer if on receipt or during testing it has been found that a sample is a deviating sample. Customers will be asked if they wish to submit a replacement sample or wish the laboratory to analyse the deviating sample. All correspondence with the customer, including that relating to the deviating sample, will be stored in accordance with section 7.1.

*The exception to this process is when there has already been communication, that has been recorded as detailed in section 7.1 (contract review), between the laboratory and the customer on how the laboratory should treat such a deviating sample. The deviation must be similar in nature to the permitted deviation agreed with the customer.

5. Detailed instructions for the handling and storage of test samples received (including holding times) are detailed in procedure PP004. Any samples found to be out of adherence with the requirements of that procedure shall be considered as being a deviating sample.

6. In all cases where a deviation has been caused by the laboratory a nonconforming work investigation shall be commenced in accordance with section 7.10.