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PA/PH/OMCL (14) 87

Evaluation and Reporting of Results Annex 1A

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Concerned Network	GEON

ANNEX I A OF THE OMCL NETWORK GUIDELINE

“EVALUATION AND REPORTING OF RESULTS”

MODEL TEMPLATE FOR FAILURE INVESTIGATION OF OOS RESULTS

Introduction

The annexes of the Guideline “Evaluation and Reporting of Results”, *PA/PH/OMCL (13) 113* (in its current version) contain several examples of approaches to failure investigation and the re-test programme. Other approaches are possible if their scientific rationale is documented and the basic principles of the core document are followed.

The editable templates/calculation sheets are available on the EDQM Extranet in the OMCL Quality Documents section.

MODEL TEMPLATE FOR FAILURE INVESTIGATION OF OOS RESULTS

Sample information (name and laboratory code)			
Analytical procedure / Test / Parameter (suspect OOS result)			
Y N/NA		Y N/NA	
General			
<input type="checkbox"/>	<input type="checkbox"/>	weighing error	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	contamination from surfaces or glassware	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	inadequate ambient conditions (temperature, moisture, etc.)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	presence of interfering substances	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	other possible reasons for OOS result:	
Samples, Reagents, Solvents & Solutions			
<input type="checkbox"/>	<input type="checkbox"/>	use of wrong reagents/chemical form	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	error during filtration	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	wrong quality or purity of reagents and solvents	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	inappropriate storage of samples	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	inappropriate storage of reagents, solvents and solutions	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	carry-over	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	solutions or reagents expired	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	abnormal appearance of samples, reagents solvents or solutions	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	reagents not dissolved completely	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	water of sub-standard quality	<input type="checkbox"/>
Reference Standards			
<input type="checkbox"/>	<input type="checkbox"/>	wrong reference standard or inadequate quality used	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	error in weighing, dissolution and dilution	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	reference standard expired	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	inappropriate storage of reference standard	<input type="checkbox"/>
Dilutions & Pipetting			
<input type="checkbox"/>	<input type="checkbox"/>	glassware or pipetting device with wrong volume	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	uncalibrated/leaking piston pipettes	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	uncalibrated/sub-standard glassware	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	dilution error	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	pipettes with broken tip	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	wrong dilution technique	<input type="checkbox"/>
Method Verification			
<input type="checkbox"/>	<input type="checkbox"/>	deviations from the specified (authorised) method	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	values below limit of detection/quantitation	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	imprecision of observations/results of sample higher than acceptable (RSD, 95%CI)	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	blank value ignored	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	imprecision of observations/results of reference standard higher than acceptable	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	system suitability test or assay validity criteria (controls, statistics) missing/failed	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	measurement outside linear/validated range	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	trend of routine method (control chart, comparison with manufacturer in OCABR)	<input type="checkbox"/>
Equipment Verification			
<input type="checkbox"/>	<input type="checkbox"/>	wrong instrument used	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	wrong instrument parameters	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	instrument calibration missing or criteria not met	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	computerised system (including software) inappropriate	<input type="checkbox"/>
Calculations			
<input type="checkbox"/>	<input type="checkbox"/>	calculation error	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	data transfer error	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	formula or factor wrong	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	inappropriate validation of calculating software	<input type="checkbox"/>
<input type="checkbox"/>	The reason(s) indicated above invalidate the results		
<input type="checkbox"/>	During this failure investigation, no reason to invalidate the OOS result could be found		
Decision on the re-test programme:	(e.g. number of replicates, operator, reference material, equipment, methods / parameters)		
Technician(s) (Signature, Date)		Supervisor (Signature, Date)	