## Evaluation and Reporting of Results

### Annex 1A

Full document title and reference:
Evaluatie en rapportage van resultaten – Annex 1A
Model Template for Failure Investigation of OOS Results
PA/PH/OMCL (14) 87

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The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
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.
### Sample Information
(name and laboratory code)

### Analytical Procedure / Test / Parameter (suspect OOS result)

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#### General
- ☐ ☐ weighing error
- ☐ ☐ inadequate ambient conditions (temperature, moisture, etc.)
- ☐ ☐ contamination from surfaces or glassware
- ☐ ☐ presence of interfering substances
- ☐ ☐ other possible reasons for OOS result:

#### Samples, Reagents, Solvents & Solutions
- ☐ ☐ use of wrong reagents/chemical form
- ☐ ☐ error during filtration
- ☐ ☐ wrong quality or purity of reagents and solvents
- ☐ ☐ inappropriate storage of samples
- ☐ ☐ inappropriate storage of reagents, solvents and solutions
- ☐ ☐ solutions or reagents expired
- ☐ ☐ abnormal appearance of samples, reagents solvents or solutions
- ☐ ☐ reagents not dissolved completely
- ☐ ☐ water of sub-standard quality

#### Reference Standards
- ☐ ☐ wrong reference standard or inadequate quality used
- ☐ ☐ error in weighing, dissolution and dilution
- ☐ ☐ reference standard expired
- ☐ ☐ inappropriate storage of reference standard

#### Dilutions & Pipetting
- ☐ ☐ glassware or pipetting device with wrong volume
- ☐ ☐ uncalibrated/leaking piston pipettes
- ☐ ☐ uncalibrated/sub-standard glassware
- ☐ ☐ dilution error
- ☐ ☐ pipettes with broken tip
- ☐ ☐ wrong dilution technique

#### Method Verification
- ☐ ☐ deviations from the specified (authorised) method
- ☐ ☐ values below limit of detection/quantitation
- ☐ ☐ imprecision of observations/results of sample higher than acceptable (RSD, 95%CI)
- ☐ ☐ blank value ignored
- ☐ ☐ imprecision of observations/results of reference standard higher than acceptable
- ☐ ☐ system suitability test or assay validity criteria (controls, statistics) missing/failed
- ☐ ☐ measurement outside linear/validated range
- ☐ ☐ trend of routine method (control chart, comparison with manufacturer in OCABR)

#### Equipment Verification
- ☐ ☐ wrong instrument used
- ☐ ☐ wrong instrument parameters
- ☐ ☐ instrument calibration missing or criteria not met
- ☐ ☐ computerised system (including software) inappropriate

#### Calculations
- ☐ ☐ calculation error
- ☐ ☐ data transfer error
- ☐ ☐ formula or factor wrong
- ☐ ☐ inappropriate validation of calculating software

☐ ☐ The reason(s) indicated above invalidate the results

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)

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<tr>
<th>Technician(s) (Signature, Date)</th>
<th>Supervisor (Signature, Date)</th>
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