OMCL Network of the Council of Europe
QUALITY ASSURANCE DOCUMENT

PA/PH/OMCL (14) 91

Evaluation and Reporting of Results
Annex 2C

Full document title and reference	Evaluation and Reporting of Results – Annex 2C Re-test Programme for Qualitative Tests PA/PH/OMCL (14) 91
Document type	Guideline
Legislative basis	/
Date of first adoption	August 2014
Date of original entry into force	October 2014
Date of entry into force of revised document	/
Previous titles / other references / last valid version	/
Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	GEON

ANNEX II C OF THE OMCL NETWORK GUIDELINE

"EVALUATION AND REPORTING OF RESULTS"

RE-TEST PROGRAMME FOR QUALITATIVE TESTS

INTRODUCTION

This document is an Annex of the core document "Evaluation and reporting of results", *PA/PH/OMCL (13) 113*, in its current version, and it should be used in combination with it when planning, performing and documenting the evaluation process and when reporting the results of qualitative tests.

This document should be considered as a guide to OMCLs and should not be taken as a list of compulsory requirements. It is left to the professional judgment and background experience of each OMCL to decide on the most relevant procedures to be undertaken in order to prove that the evaluation and reporting of results has been well-managed.

Special care should be taken for the documentation of qualitative OOS results that are detected visually (e.g. TLC, pharmacognosy, appearance of the pharmaceutical dosage form). Photography or documented confirmation by a second qualified analyst should be considered.

FOCUS OF FAILURE INVESTIGATION

For qualitative tests, the focus of failure investigation should be adapted.
In case of non-detection of specified analytes, the focus should be on:

- influencing factors for possible analyte degradation (e.g. sample storage)
- confirmation of sample addition
- possible loss during extraction/sample preparation
- detection mechanisms of the equipment involved

In case of detection of unspecified analytes, the focus should be on:

- cross-contamination or carry-over from other samples, reference standards, surfaces, glassware or equipment.

RE-TEST PROGRAMMES

In cases where the failure investigation casts any doubts on the presence of an analyte or the absence of cross-contamination, the re-test programme should include an independent repeat test to exclude undetected errors. To consider a test result as independent, all analytical steps that may reasonably be expected to have an impact on the test result should be repeated.
The re-test strategy depends on the validation status of the test method according to the OMCL Guideline "Validation of analytical procedures (*PA/PH/OMCL (05) 47 DEF*)".

1. Pharmacopoeial (compendial) method (1.1)

For analytes that are described in Ph. Eur. and are analysed according to the respective monograph, no re-test programme is required, as long as the failure investigation does not cast any doubt on the reliability of the initial OOS result.

2. Method of a manufacturer (1.2)

According to ICH Q2, it is not always possible to demonstrate that an analytical procedure is specific for a particular analyte (complete discrimination). In this case, a combination of two or more analytical procedures is recommended to achieve the necessary level of discrimination. Therefore, the marketing authorisation dossier of an authorised method should include descriptions of alternative identification methods. The re-test should be performed with the alternative method(s) as described in the dossier.

If the MAH file has been approved, but without a description of alternative confirmation methods, the laboratory should prepare an adequate re-test programme, taking into account all the characteristics of the test in question and the results of the "initial OOS" investigation.

3. Other situations

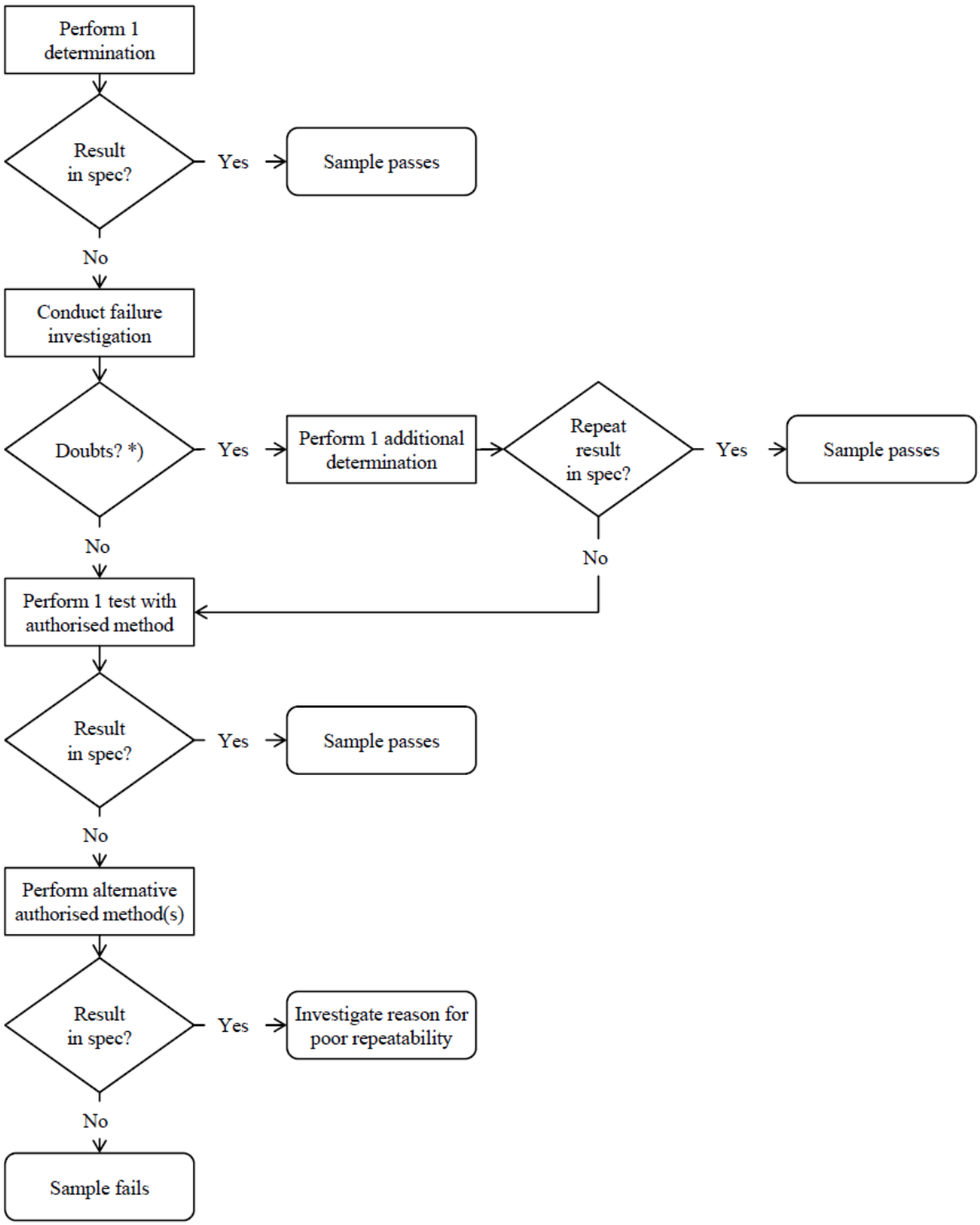
This approach is applicable for the following situations described in the OMCL Guideline "Validation of analytical procedures":

- non-compendial published method (1.3)
- method of one manufacturer used for a product from a different manufacturer (1.4)
- method of an active substance used for a medicinal product (1.5)
- screening for non-compliance (2.1)

The first step of the re-test programme should be the method described in the marketing authorisation dossier and approved by the National Competent Authority (authorised method), followed by any alternative method(s) as described in the dossier for the respective product, if applicable.

If the authorised and validated alternative methods lead to divergent results, the OMCL or the Competent Authority should discuss the situation with the marketing authorisation holder.

Figure 1 - Decision tree for qualitative methods



*) Any doubts regarding sample presence / cross contamination?