FRAMEWORK FOR THE CONDUCT OF PROFICIENCY TESTS AND COLLABORATIVE EXCERCISES WITHIN ENFSI

DOCUMENT TYPE:	REF. CODE:	ISSUE NO:	ISSUE DATE:
GUIDANCE	**QCC-FWK-004**	**001**	**10.05.2023**

NOTE: The previous Guidance was referenced QCC-PT-001 and was last issued as issue 001 on 27.06.2014. This document has revised the content of the previous Guidance and is referenced QCC-FWK-004 in order to conform with the correct naming nomenclature of ENFSI documents. Due to the change of references, this document is at issue 001.

1. INTRODUCTION

The ENFSI Memorandum of Understanding encourages co-operation between its members and other international organisations in the development of new scientific methods and procedures, standards of practice, training and quality assurance.

ENFSI wishes to promote consistent and reliable scientific evidence through the whole forensic process from scene of incident to court. The vision of ENFSI is to ensure that the quality of development and delivery of forensic science throughout Europe is at the forefront of the world.

In order to develop best practice, the ENFSI Expert Working Groups (EWGs) arrange or recommend proficiency tests and collaborative exercises in which members shall participate if it is applicable to their scope or planned extensions to scope.

2. AIM

The purpose of this document is to provide guidance for the EWGs on how to organise effective proficiency tests (PTs) and collaborative exercises (CEs) for their members. This guidance will apply to PTs or CEs conducted by the EWGs and to those outsourced by the EWGs to an external organisation. The framework also includes templates for Coordinator's PT/CE check list (appendix 1), feedback for participants (appendix 2), questions for participants' opinion on PT/CE (appendix 3), review report for the ENFSI Standing Committee for Quality and Competence (QCC) (appendix 4), annual summary of PTs/CEs organised by EWGs for the ENFSI Board (appendix 5).

3. REFERENCE DOCUMENTS

The following reference documents provide information on the conduct of PTs and CEs and are the basis for the guidance:

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories;
ISO/IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection;
ISO 9000	Quality Management Systems – Fundamentals and vocabulary;

ISO/IEC 17043	Conformity assessment – General requirements for proficiency testing;
ISO 13528	Statistical methods for use in proficiency testing by interlaboratory comparison;
ILAC-G19	Modules in a Forensic Science Process;
ILAC-P9	ILAC Policy for Participation in Proficiency Testing Activities;
EA-4/18	Guidance on the level and frequency of proficiency testing participation;
EA-4/21	Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation;
EURACHEM	Selection, Use and Interpretation of Proficiency Testing (PT) Schemes by Laboratories.

4. TERMS AND DEFINITIONS

Proficiency Tests (PTs) – tests designed to evaluate the participants' performance against pre-established criteria by means of interlaboratory comparisons.

Collaborative Exercises (CEs) – interlaboratory comparisons that are designed to address specific issues such as troubleshooting, method validation, characterization of reference materials or verification of results of a new developed method. CEs are not designed to monitor laboratory performance of analysis or interpretation, but CEs may include monitoring of laboratory performance and/or interpretation.

Provider – organization that takes responsibility for all tasks in the development and operation of a PT or CE scheme. The Provider could be an ENFSI member laboratory or a commercial company or a public body. The Provider appoints the Coordinator.

Coordinator – one or more individuals with responsibility for organizing/managing all the activities involved in the conduct of a PT or CE scheme.

Advisory Group (AG) – group who can advise on the design and implementation of the trial and on the assessment of the results. The EWG selects the AG when the Provider is a commercial or public body. When an ENFSI member is the Provider it usually selects its own AG that includes at least one specialist in the relevant field and a person with competence in setting PTs and CEs. When necessary, the AG should include a statistician.

Participant – organization or individual that receives test items as part of a PT or CE and submits results for review by the Provider.

Pilot Study – a trial run of the PT/CE organized by the Coordinator to ensure that the PT/CE is appropriate and fit for purpose prior to distribution to the participants. Any problems identified by the pilot study should be rectified before distribution.

The remaining definitions, not mentioned in this document, can be found in ISO 9000 Quality management systems – Fundamentals and vocabulary and ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing.

5. CODE OF CONDUCT FOR PROVIDER AND PARTICIPANTS

5.1 Provider, Coordinator and Advisory Group

The identity of the participants shall be anonymous unless the participant waives confidentiality All information supplied by the participant to the Provider shall be treated as confidential.

The trials should be fair and realistic and designed so that the participants get useful and timely information on their performance.

5.2 Participant

The analysis or examinations should be conducted in compliance with the participant's Standard Operating Procedures.

Any deficiency in the participant's performance should be addressed by the participant's according to internal procedures for nonconforming work.

6. TYPES OF PTs AND CEs

PTs and CEs may include:

a) qualitative identification;
b) comparison;
c) quantitative measurement;
d) data transformation;
e) interpretation.

PTs and CEs may be performed on test material supplied to all individual participants for concurrent examination or with the test material being provided for sequential examination by the participants on a round-robin basis. Sequential examinations can result in very drawn out exercises, problems with the stability or integrity of the material involved and delays in the overall assessment and reporting. Therefore, they should only be used when there is no alternative.

PTs and CEs can be conducted overtly (declared tests) or covertly (blind tests). It is unlikely that blind tests or exercises will be practicable within ENFSI for comparisons between laboratories.

7. RESPONSIBILITIES AND ROLE

7.1 Standing Committee for Quality and Competence (QCC)

The QCC is charged by the ENFSI Board to monitor the ENFSI PTs and CEs. The QCC is expected to provide an annual summary of PTs/CEs undertaken by the EWGs within the annual report to the ENFSI Board (see appendix 5, Annual summary of PTs/CEs organised by the EWGs).

7.2 Expert Working Group (EWG)

The EWG is responsible for the provision and promotion of PTs/CEs. The EWG identifies the purpose of the testing (see 8.2) and selects the Provider (member laboratory or commercial or public body). It is recommended to select the Provider, who operates in accordance with ISO/IEC 17043.

When the Provider is a commercial or a public body, it is recommended the EWG selects an Advisory Group (AG) who will liaise on its behalf with the Provider's coordinator.

When the design of the trial starts, the EWG must inform the QCC providing a partially filled report indicating the EWG, starting date of a trial design and a brief description of the purpose of the PT/CE (see appendix 4, Review report). After completion of the PT/CE the EWG must complete the full report for the QCC (see appendix 4, Review report) and attach the final report for the participants. If common problems are identified with the general performance of the participants, the EWG should describe its plan for follow up actions, e.g. another PT.

If individual laboratories experience difficulties with the PT/CE, they can ask for advice from the EWG.

7.3 Advisory Group (AG)

It is recommended that an AG be established with the following responsibilities:

a) Help define the objective of the trial and the expected results and to advise on the best way to organise the scheme and to prepare for the evaluation of participants' results.
b) Advise on the criteria for the participants (e.g. what techniques are needed) and whether prospective participants meet the criteria. This is particularly relevant given the diversity in expertise, experience and equipment in ENFSI laboratories.
c) Advise on the assessment of the results and the content of the feedback for the participants, either by carrying out these roles or delegating them to competent scientists.
d) Check that test materials, characterization and preparation details are clearly defined.
e) Check that criteria / fine details, which are required to be reported, are added.

When the Provider is a commercial body, the EWG appoints the AG. When a member laboratory is the Provider, the AG is usually within the laboratory.

7.4 Coordinator

The Provider appoints the Coordinator, who in cooperation with the AG has these responsibilities:

a) overall responsibility for the conduct of the PT or CE and for its planning, documentation and implementation and all related communication (for detailed process steps see appendix 1, Coordinator's PT/CE Check List);
b) selection of the AG (if the Provider is a member laboratory);
c) collaboration with the AG to define the objectives of the testing scheme and the measurand or characteristics to be determined as well as the criteria for the evaluation of performance;
d) designing the scheme and deciding on the timeframe;
e) obtaining and preparing the test material;
f) producing clear, concise, unambiguous instructions for participants on what they are required to do and how they are to report their results and be aware of the difficulties arising from participants who may not be highly proficient in the language;
g) packaging and transportation arrangements;
h) ensuring compliance with any legal, health and safety requirements in the design and distribution of the test or exercise;
i) establishing (if necessary) a team of qualified assistants to help monitor the progress of a particular test or exercise;
j) evaluation of participants' results (if possible in collaboration with the AG);
k) production of feedback report for the participants (see appendix 2, Suggestions for contents of feedback for participants);
l) reporting on the trial results to the EWG including the identification of any shortcomings in the trial or its results.

8. TRIAL ORGANISATION AND DESIGN

The PTs and CEs should be realistically designed to reflect the casework position as closely as possible. CEs could also be used to find the limitations of an examination or to support validation work that might include samples on the borders of what is encountered in ordinary casework. The purpose of CE should be clearly indicated. Where appropriate, the schemes should take account of the different legal frameworks in which participants may be working and the different requirements for their services.

The PTs and CEs should be focused on the priority issues (as identified by the EWG). They should reflect the work carried out routinely in that area and be neither too simple nor too ambitious.

The trial design includes:

a) identification of the purpose of the trial;
b) selection of the level(s) of difficulty of the trial;
c) identification of expected results (if appropriate) and identification of acceptable variation (if needed);

NOTE This should include a definition for the range of expected results and a definition of unexpected results.

d) estimation of time required by participant to do exercise;
e) identification of the supplementary information required to enable the evaluation of results and to help participants understand the results of other laboratories (e.g. methods employed);
f) selection of the most appropriate format for the results;
g) timescale for design, preparation, distribution to and return from participants, assessment of results and feedback to participants;
h) estimation of cost and decision if fee is required.

When the trial organisation and design starts, the EWG informs QCC by sending a partially filled report form (see 7.2 and appendix 4, Review report).

9. TRIAL PREPARATION

The Coordinator in cooperation with the AG organises the trial preparation including:

• Advance notice of the PT/CE that includes:

a) relevant details of the scope of the PT/CE scheme;
b) eligibility criteria for participants (if applicable) including specification of instruments or expertise required for the PT/CE;
c) any fees for participation;
d) confidentiality arrangements;
e) details on how to apply.

NOTE Participant's application should include the main contact person and his/her contact details.

• Pilot study, if required, and assessment of its results in collaboration with the AG. Ensure that any problems identified in the pilot study are addressed prior to distribution.

• Provision of a scenario when the participant requires background information for evaluation of findings.

• Documentation of how the results will be assessed. If applicable, the statistical design and data analysis methods should also be documented.

• Provision of clear, unambiguous instructions, in English, for the participants which includes:
  a) the necessity to treat the items in the same manner as routinely tested samples (unless there are factors that necessitate departure from this principle);
  b) if necessary, details of factors that could affect the test items (e.g. storage, limitations of test methods, timing of testing);
  c) instructions on handling of items if necessary (e.g. health and safety requirements, decontamination, disposal etc.);
  d) detailed instructions on recording and reporting test results (templates or forms are recommended);
  e) the latest date for the Provider to receive the test results;
  f) contact details of the Provider;
  g) instructions for return of test items (if applicable).

• Provision and preparation of the test materials (see 10).

• Compliance with any legal and health and safety requirements.

• Packing and transportation arrangements.

• Distribution of test materials (see 11).

10. PREPARATION OF TEST MATERIALS

Every effort should be made to ensure that all test materials provided are homogenous and stable (i.e. will not deteriorate), the Provider should guarantee their integrity. The procedures used to prevent contamination or deterioration of case samples should apply to the preparation of the test materials. (If this is not possible, it should be taken into account in the assessment criteria).

The expected result of the test and acceptable deviation needs to be defined.

The test materials may need to be checked by a competent practitioner (who was not involved in the design of the testing scheme) before distribution. This may occur as a part of a pilot study.

Extra test materials should be prepared to assist participants in resolving any issues that may arise in their laboratories. For example, a laboratory that got an incorrect result may need to rerun the test. There may also be situations where the test material was compromised or lost in transit. Extra test materials, when not needed for other purposes, could also provide useful basis for training purposes.

Details of the test materials and their preparation and characteristics should be fully documented.

Any possible health or safety considerations associated with the test materials or their examination should be identified and brought to the attention of the participants.

11. DISTRIBUTION

Test materials should be packaged in such a way as to ensure their integrity, stability and security whilst in transit. Any specific requirements for their handling or storage should be made explicit, particularly if this could affect the health or safety of anyone involved.

The distribution of some materials, such as drugs, firearms and explosive substances, is controlled by legislation. Import and export licenses may be required and attention will need to be given to any time limits associated with such licenses. The Provider should ensure that all the necessary requirements are in place.

Details of the packaging and distribution should be fully documented.

NOTE At least the following information should be included on the package: name of contact person, name of organization, full address. The main contact person should be informed about distribution of a PT/CE and the tracking number by e-mail.

The packaging should be labelled as official, not personal so that it will receive proper attention in case of absence of the main contact person. Clearly state in the letter of introduction that this is a PT/CE and identify the expert area that applies. Also in this letter ask for confirmation of the receipt of test materials.

12. PARTICIPANTS' RESULTS

It is important to identify how the results should be reported before the PT/CE is prepared. The Coordinator may choose to have different result sections, e.g. result of analysis or comparison and interpretation section. The use of standard forms greatly facilitates the analysis of the returns. The inclusion of a comment section may overcome the constraints imposed by a standard form.

When assessment of the strength of evidence is required, provision of a standard scale helps to assess the results.

Where measurement units are involved, there may be different national practices, so it is necessary to specify the units that should be used.

The Coordinator should specify the latest date for return of results. The policy for dealing with late returns can be left to individual EWG, but consideration should be given to discouraging late returns.

It is recommended to give instructions to the participant to archive the test material or to send it back with the results to the Provider.

Instructions should also include the requirement for the participant to inform the Provider whether they have retained or destroyed the test material, in instances where the material is not returned to the Provider.

13. ASSESSMENT OF PERFORMANCE

The purpose of the assessment in a PT is to identify those who achieve the expected results and those who did not. The purpose of the assessment in a CE depends on the objective of the CE.

An individual or panel may carry out the assessment. Ideally, the assessors should include the Coordinator and the AG. A Statistical analyt may be needed.

The basis for the assessment should be documented, and where appropriate, expert commentary on the performance of the participants should be provided with regard to the following:

a) variation between participants and comparisons with any previous PTs/CEs, similar schemes or published data;
b) variation between methods and procedures;
c) variation in interpretation of results;
d) possible sources of error and suggestions for improvement of performance;
e) advice and educational feedback;
f) conclusions.

Many PTs/CEs yield useful information that is incidental to the main objective. This should be collected and disseminated, but in such a way that it does not affect the primary issues.

14. FEEDBACK TO THE PARTICIPANTS

Full feedback (the individual feedback report and the collated final report) to the participants should be completed within the accepted timeframes but generally not later than six months after the deadline for the results.

If a participant's result was unexpected and could indicate a shortcoming, the Coordinator should ensure that the participant's main contact person is informed as soon as possible to allow the participant to take any necessary corrective action.

Ideally, the AG should approve the feedback report prior to its distribution to the participants.

To ensure anonymity, participants should be referred to by code, no country or other information shall be mentioned, and the feedback report should be carefully checked for any identifying information, particularly on photocopies of submitted material.

The feedback report should provide a summary and analysis of the returned results and should address performance against the declared objectives and any expected or desired outcomes. The report should also give an indication of the level(s) of difficulty of the trial. It may be appropriate to include any issues of concern and to identify matters requiring further consideration by the participant(s) and the EWG.

The feedback report should be objective, concise and constructive. It should provide all the information needed for the reader to understand the outcomes without having to refer to other documents. It should include the following information:

a) trial identifier;
b) date of feedback report;
c) table of contents;
d) number of participants;
e) code identifier for recipient laboratory (unless the Provider opts to send this separately to the feedback report);
f) details of the trial submitted to the participants;
g) details of the test sample preparation;
h) expected results;
i) summary of participants' results;
j) statistical analysis (if appropriate);
k) conclusions.

For more details see appendix 2, Suggestions for contents of feedback to participants.

The Coordinator should consider including copies of the participants' results, techniques used (if appropriate) and a summary of any additional feedback received. Information on time taken to conduct the test is also informative for the participants.

A copy of this feedback report should be submitted to the EWG along with any significant issues identified.

15. REVIEW ON ORGANISED PT/CE

All PTs and CEs should be reviewed at the earliest opportunity at a meeting of the relevant EWG. This review can be preceded by an exchange of information and views in writing, but this should not replace group discussion.

The EWG should consider:

a) how far the aims of the PT or CE have been met;
b) recommendations for improvement actions (if relevant and possible);
c) the timeframes for improvement actions to be implemented (if possible);
d) the provision of support to effect the improvements;
e) learning points for the future design of similar PTs or CEs;
f) the timing of any similar future PTs or CEs to ensure that the improvement actions arising from the current exercise or test has been implemented.

The EWG should submit a review report to the QCC (see appendix 4). The report should preserve the anonymity of the participants.

The QCC, considering review reports provided by EWG, on annual basis prepares annual summary of PTs/CEs undertaken by the EWGs (see appendix 5) and submits it to the Board.

16. STORAGE OF ENFSI PTs AND CEs

The Provider should store all documents related to the conduct of the trial (and extra samples if possible) for at least five years.

17. AMENDMENTS TO PREVIOUS VERSION

- This document replaces QC-PT-001 Guidance on the Conduct of Proficiency Tests and Collaborative Exercises within ENFSI in order to conform to the correct naming nomenclature of ENFSI documents. Due to the change of reference code, this document is at issue 001.
- General layout changed according to new version of BRD-FWK-004 Format and Approval of ENFSI Documents, issue 006, other small editorial changes (for ex., use of abbreviations, numbering of paragraphs) are made throughout the document.
- Paragraph "1. INTRODUCTION": deleted the second sentence.
- Paragraph "2. AIM": added the second sentence with references to all appendixes of this document.
- Paragraph "3. REFERENCE DOCUMENTS": updated the list of references, deleted the issue dates of the documents.
- Paragraph "4. TERMS AND DEFINITIONS": clarified definition of the term "Collaborative Exercises (CEs)".

- Paragraph “5. CODE OF CONDUCT FOR PROVIDER AND PARTICIPANTS”: clarified the second sentence of p. 5.2.
- Paragraph “7. RESPONSIBILITIES AND ROLE”: changed p. 7.1; added the second sentence in p. 7.2; added the requirement to inform the QCC about the start of trial design; added p. d and e in p. 7.3; editorial changes in p. 7.4 (the first sentence, p. a, c, d, k); deleted figure 1.
- Paragraph “8. TRIAL ORGANISATION AND DESIGN”: added sentence “The purpose of CE should be clearly indicated.” in the first paragraph; added new paragraph.
- Paragraph “9. TRIAL PREPARATION”: added the note.
- Paragraph “11. DISTRIBUTION”: added the note.
- Paragraph “12. PARTICIPANTS’ RESULTS”: deleted the second sentence in the second paragraph; added new paragraph.
- Paragraph “14. FEEDBACK TO THE PARTICIPANTS”: clarified paragraphs 1, 2 and 4.
- Paragraph 15: the title “15 Review of report” changed to “15. REVIEW ON ORGANISED PT/CE”; changed paragraph 3, added new paragraph.
- Appendix 1: small editorial changes; the line “Coding of participants” added in structural part “Trial distribution”.
- Appendix 4: the title “Form for report to QCC” changed to “REVIEW REPORT”; added new lines no1-6; added new lines “Trial design started”, “Deadline for submission of results”; deleted lines “Summary of results”, “Summary of EWG’s review (including any issues that arose)”, “Follow on actions (if required)”; added new lines “Evaluation of successfulness of the PT/CE”, “Issues that arose / follow on actions (if required)”.
- Appendix 5: new.

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APPENDIX 1: COORDINATOR’S PT/CE CHECK LIST

Activity	Responsibility	Date due	Date complete

Design and planning			
Purpose of PT/CE is based on the priority issues as identified within the EWG (8)	EWG		
Selection of Provider (P)	EWG		
Selection of Coordinator (C)	P		
Selection of Advisory Group (AG)	EWG/P/C		
Criteria to be met by participants (9.1)	C/AG		
Criteria for evaluation of performance of the participants (8.3)	C/AG		
Timeframe identified	C		
Estimation of cost. Determination of the fee	P/C		
Potential participants identified and informed of forthcoming trial (9.1)	C		
Identification of test materials	C		
Trial preparation			
Preparation of test materials (10)	C		
Pilot study completed (if needed)	C		
Assessment of pilot study	C/AG		
Modifications (if required) following pilot study	C		
Scenario (where appropriate) written (9.3)	C		
Instructions for participants (9.5)	C		
Results form designed with clear deadline for receipt of results (12)	C		
Trial distribution			
Health and safety issues considered	C		
Import/export licences if needed	C		
Package labelled as official	C		
Contents check • cover letter • instructions • scenario • test materials • form for results • participant's feedback form	C		
Coding of participants	C		
Assessment of performance			
Assessment of results (13)	C / AG		
Unexpected results reported to main contact person of participant (14.2)	C		

Report on performance against expected/desired outcomes (feedback report) (14.5)	C/AG		
Preparation of participant feedback report	C		
Participant feedback report approved by the AG (if possible)	C/AG		
Participant feedback report checked for participant anonymity	C		
Participant feedback report distributed to participants (as agreed timeframe)	C		
Coordinator's report (including participant's feedback report) to EWG	C		
Report on PT/CE to QCC (Appendix 4)	EWG		

APPENDIX 2: SUGGESTIONS FOR CONTENTS OF FEEDBACK FOR PARTICIPANTS

List of participants

Code of participant receiving the feedback
Names of Provider and Coordinator
Name(s) of the Advisory Group
Instructions that were sent to the participants
Copies of other documentation distributed with the trial, e.g. result proforma, feedback form, scenario and instructions
Information on sample and test preparation
Expected results
Results
Statistical analysis (if required)
Interpretations (if relevant)
Conclusion/summary (include number of satisfactory/unsatisfactory results and comment on issues raised by the trial / comment on any trends)
Table of techniques used (if relevant)
Table of participants' feedback results including time taken to complete exercise (see appendix 3)
Copy of individual results (ensure anonymity)

APPENDIX 3: SUGGESTIONS FOR QUESTIONS FOR PARTICIPANTS' OPINION ON PT/CE

1	Is this analysis, examination or interpretation part of your routine work?	
2	Is this analysis, examination or interpretation within the scope of your accreditation?	
3	Were the instructions clear?	
4	Accepting the limitations of an exercise of this type, is it an appropriate reflection of casework?	
5	If not, have you any suggestions for improvement?	
6	What did you think of the level of difficulty of the exercise?	
7	Approximately how much time did it take to complete this exercise?	
8	Approximately how long was the peer reviewer's check?	
9	Has the exercise raised any issues that you wish to share with the EWG?	
10	Any other comments?	

APPENDIX 4: REVIEW REPORT (TO QCC)

Expert Working Group	

Provider: member laboratory	No ☐ Yes ☐ Specify:
Provider: commercial or public body	No ☐ Yes ☐ Specify:
MP or other project funding	No ☐ Yes ☐ Specify:
Participation fee	No ☐ Yes ☐ Specify:
Number of participants	
Action:	**Date:**
Trial design started	
PT/CE issued to participants	
Deadline for submission of results	
Feedback issued to participants	
EWG review	
PT/CE objective	
Evaluation of successfulness of the PT/CE	
Issues that arose / follow on actions / trends (if required)	
Name and surname of the EWG Chair:	
Date:	

APPENDIX 5: ANNUAL SUMMARY OF PTs/CEs ORGANISED BY THE EWGs

ANNUAL SUMMARY OF PTs/CEs ORGANISED BY THE ENFSI EWGs	
Year	
Total number of PTs/CEs: organised and finished	
Started and finished[1]	
Started and ongoing	
Finished that started the previous year	
Specification of organisers:	
EWGs that organised PTs/CEs and a number of PTs/CEs in brackets	
Specification of providers:	
Member laboratories and a number of PTs/CEs in brackets	
Commercial or public bodies and a number of PTs/CEs in brackets	
Total number of participants	
Total number of PTs/CEs organised using MP or other project financing	
Evaluation of successfulness of the PTs/CEs	
Improvement actions taken	
Name and surname of the QCC Chair:	
Date:	

[1] Finished, i.e. feedback for participants and review report to the QCC are sent.