APPROVED BY THE BOARD ON 27 JUNE 2014

STANDING COMMITTEE
FOR QUALITY AND COMPETENCE (QCC)

GUIDANCE ON THE CONDUCT OF PROFICIENCY TESTS AND COLLABORATIVE EXERCISES WITHIN ENFSI

DOCUMENT TYPE:	REF. CODE:	ISSUE NO:	ISSUE DATE:
GUIDANCE	QCC-PT-001	001	27/06/2014

Supported by EU project ' General Programme on Security and Safeguarding Liberties/specific programme on prevention of and fight against crime (ISEC)' HOME/2009/ISEC/MO/4000000798. Theme: Sustainable quality with European Forensic Science (SQWEFS)

APPROVED BY THE BOARD ON 27 JUNE 2014

1 Introduction

1.1 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. It is the policy of ENFSI that all members shall have achieved or be taking steps towards ISO/IEC 107025 accreditation as defined in Standards for Accreditation QCC-ACR- 001.

1.2 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.

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

2 Aim

2.1 The purpose of this document is to provide guidelines for the ENFSI Expert Working Groups (EWGs) as an aid on how to organise effective proficiency tests (PTs) and collaborative exercises (CEs) for their members. These guidelines will apply to PTs or CEs conducted by the EWGs and to those outsourced by the EWGs to an external organisation. The guidelines also include templates for reporting results to participants and the QCC.

3 Reference documents

3.1 The following reference documents provide information on the conduct of proficiency tests and collaborative exercises. The guidelines are based on these documents.

ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
ILAC G19: 2002	Guidelines for Forensic Science Laboratories
ISO/IEC 17020:1998	General criteria for operating of various types of bodies performing inspection.
IAF/ILAC-A4: 2002	Guidance on the Application of ISO/IEC 17020
EA 5/03	Guidance on the implementation ISO/IEC 17020 to the work at the scene of crime
EA-4/18: 2010	Guidance on the level and frequency and of proficiency testing
ILAC - P9: 11/2010	ILAC Policy for Participation in Proficiency Testing Activities
ISO 9000: 2005	Quality Management Systems – Fundamentals and vocabulary
ISO 17043:2010	Conformity assessment – General requirements for proficiency testing
ISO 13528	Statistical methods for use in proficiency testing by interlaboratory comparisons– 2005
EA-03/04 2011	Use of Proficiency Testing as a Tool for Accreditation in Testing

APPROVED BY THE BOARD ON 27 JUNE 2014

4 Definitions

- **Proficiency Tests (PTs)** – tests designed to evaluate the participants' performance against pre-established criteria by means of interlaboratory comparisons.
- **Collaborative Exercises (CEs)** – these are interlaboratory comparisons that are designed to address specific issues such as troubleshooting, method validation or characterization of reference materials. 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** – 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 PT/CE Provider shall be treated as confidential
- The trials should be fair and realistic and designed so that the participants gets useful and timely information on their performance

5.2 Participant

APPROVED BY THE BOARD ON 27 JUNE 2014

- The analysis or examinations should be conducted in compliance with the organisation's Standard Operating Procedures
- Any deficiency in the participant's performance should be addressed by the participant's organisation.

6 Types of proficiency tests and collaborative exercises

6.1 Proficiency tests and collaborative exercises may include:

a) Qualitative identification
b) Comparison
c) Quantitative measurement
d) Data transformation
e) Interpretation.

6.2 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.

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

7 Responsibilities and role

7.1 Quality and Competence Committee

The Quality and Competence Committee (QCC) is charged by the ENFSI Board to monitor the ENFSI PTs and CEs and to provide advice and support to the Expert Working Groups (EWGs) on their design and conduct. The QCC is expected to provide an annual report to the ENFSI Board on the content and effectiveness of the PT/CE schemes.

7.2 Expert Working Group

The Expert Working Group (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 body).

When the Provider is a commercial or a public body, it is recommended the EWG selects an Advisory Group who will liase on its behalf with the company's Coordinator.

After completion of the PT/CE the EWG must complete a report for the QCC (see appendix 4 for requirement for report content). If 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.

APPROVED BY THE BOARD ON 27 JUNE 2014

7.3 Advisory Group

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

- help define the objective of the trial and the expected outcomes and to advise on the best way to organise the scheme and to prepare for the evaluation of participants' results.
- 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.
- 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.

When the Provider is a commercial organisation, the EWG appoints the Advisory Group. When a member laboratory is the Provider, the Advisory Group is usually within the laboratory (figure 1)

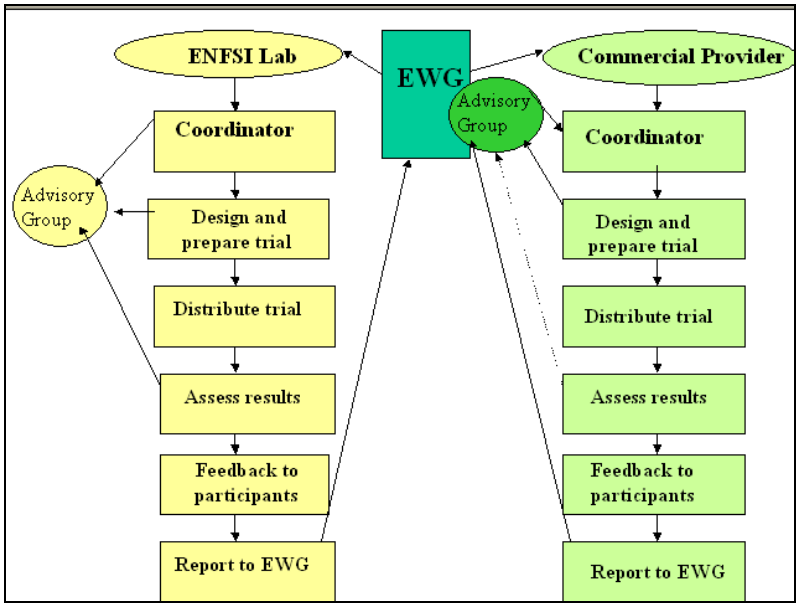

Figure 1 Relationship between Advisory Group and Coordinator for ENSFI laboratory and commercial provider

7.4 Coordinator

The Provider appoints the Coordinator whose responsibilities include:

- overall responsibility for the conduct of the PT or CE and for its planning, documentation and implementation and all related communication
- selection of the Advisory Group (if the Provider is a member laboratory)
- collaboration with the Advisory Group to define the objectives of the testing scheme and its expected outcome as well as the criteria for the participants
- designing the scheme and deciding on the timelines

APPROVED BY THE BOARD ON 27 JUNE 2014

- obtaining and preparing the test material
- 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
- packaging and transportation arrangements
- ensuring compliance with any legal, health and safety requirements in the design and distribution of the test or exercise
- establishing (if necessary) a team of qualified assistants to help monitor the progress of a particular test or exercise.
- evaluation of participants' results (if possible in collaboration with the Advisory Group)
- production of feedback report for the participants
- report on the trial results for the EWG including the identification of any shortcomings in the trial or its results.

8 Trial organisation and design

8.1 Proficiency tests and collaborative exercises 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. 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.

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

8.3 Trial design
The trial design includes:

- Identification of the purpose of the trial
- Selection of the level(s) of difficulty of the trial.
- Identification of expected results (if appropriate) and identification of acceptable variation (if needed). This should include a definition for the range of expected results and a definition of unexpected results
- Estimation of time required by participant to do exercise. Generally, it should not exceed the equivalent of 2-3 days work by an individual.
- 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).
- Selection of the most appropriate format for the results
- Timescale for design, preparation, distribution to and return from participants, assessment of results and feedback to participants
- Estimation of cost and decision if fee is required

APPROVED BY THE BOARD ON 27 JUNE 2014

9 Trial preparation

The Coordinator organises the trial preparation including:

9.1 Advance notice of the PT/CE that includes

- Relevant details of the scope of the PT scheme
- Eligibility criteria for participants (if applicable) including specification of instruments or expertise required for the PT/CE
- Any fees for participation
- Confidentiality arrangements
- Details on how to apply
  - Participant's application should include the name of the Quality Manager and his/her contact details

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

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

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

9.5 Provision of clear, unambiguous instructions, in English, for the participants which includes:

- The necessity to treat the items in the same manner as routinely tested samples (unless there are factors that necessitate departure from this principle)
- If necessary, details of factors that could affect the test items (e.g. storage, limitations of test methods, timing of testing)
- Instructions on handling of items if necessary (e.g. health and safety requirements, decontamination, disposal etc)
- Detailed instructions on recording and reporting test results. Templates or forms are recommended.
- The latest date for the Provider to receive the test results
- Contact details of Provider
- Instructions for return of test items (if applicable)

9.6 Provision and preparation of the test materials (see 10)

9.7 Compliance with any legal and health and safety requirements

9.8 Packing and transportation arrangements

9.9 Distribution of test materials (see 11)

APPROVED BY THE BOARD ON 27 JUNE 2014

10 Preparation of test materials

10.1 Every effort should be made to ensure that all test materials provided are homogenous and stable (i.e. will not deteriorate). They should be prepared by a competent test provider who can 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)

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

10.3 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 part of a pilot study.

10.4 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 material for training purposes.

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

10.6 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

11.1 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.

11.2 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.

11.3 Details of the packaging and distribution should be fully documented.

11.4 The packaging should be labelled as an official rather than a personal communication so that it will receive attention in the event of the Quality Manager being absent from the laboratory. Clearly state in the letter of introduction that this is a PT/CE and identify the expert area that applies. The procedure used should enable confirmation of the delivery of items.

APPROVED BY THE BOARD ON 27 JUNE 2014

12 Participants' Results

12.1 It is important to identify how the results should be reported before the test or exercise 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.

12.2 When assessment of the strength of evidence is required, provision of a standard scale helps to assess the results. Ideally, the same verbal scale should be used for all areas of casework and for all tests and exercises.

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

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

12.5 Consideration should be given to the need for the test materials themselves or working documents/materials to be returned with the results.

13 Assessment of performance

13.1 The purpose of the assessment in a PT is to identify those who got the expected results and those who did not get a satisfactory result. The purpose of the assessment in a CE will depend on the objective of the CE.

13.2 An individual or panel may carry out the assessment. Ideally, the assessors should include the Coordinator and the Advisory Group. Statistical analysis may be needed.

13.3 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:

- variation between participants and comparisons with any previous PTs/CEs, similar schemes or published data
- variation between methods and procedures
- variation in interpretation of results
- possible sources of error and suggestions for improvement of performance
- advice and educational feedback
- conclusions

13.4 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.

APPROVED BY THE BOARD ON 27 JUNE 2014

14 Feedback to the participants

14.1 Full feedback to the participants should be completed within a short period but generally not later than two months after the deadline for the results

14.2 If a participant's result was unexpected and could indicate a shortcoming, the Coordinator should ensure that the laboratory's Quality Manager is informed as soon as possible to allow the organisation to take any necessary corrective action.

14.3 Ideally, the Advisory Group should approve the feedback report prior to its distribution to the participants.

14.4 To ensure anonymity, participants should be referred to by code and the feedback report should be carefully checked for any identifying information, particularly on photocopies of submitted material.

14.5 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 participating organization(s) and the EWG.

14.6 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

- Trial identifier
- Date of report
- Table of contents
- Names of participants (if a large group)
- Code identifier for recipient laboratory (unless the Provider opts to send this separately to the report)
- Details of the trial submitted to the participants
- Details of the test sample preparation
- Expected results
- Summary of participants' results
- Statistical analysis (if appropriate)
- Conclusions

14.7 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.

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

APPROVED BY THE BOARD ON 27 JUNE 2014

15 Review of report

15.1 All proficiency tests and collaborative exercises should be reviewed at the earliest opportunity at a meeting of the relevant Expert Working Group. This review can be preceded by an exchange of information and views in writing, but this should not replace group discussion.

15.2 The Expert Working Group should consider:

- how far the aims of the test or exercise have been met
- recommendations for improvement actions (if relevant and possible)
- the timetable for improvement actions to be implemented (if possible)
- the provision of support to effect the improvements
- learning points for the future design of similar tests or exercises
- the timing of any similar tests or exercises after the improvement actions arising from the current exercise or test has been implemented.

15.3 The EWG should submit a report on their review to the QCC (appendix 4). The report should preserve the anonymity of the participants. The feedback report to the participants should accompany the EWG's review.

16 Storage of ENFSI PTs and CEs

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

APPROVED BY THE BOARD ON 27 JUNE 2014

Appendix 1 Coordinator's PT/CE Check List

Activity	Responsibility	Date due	Date complete
Design and planning			
Purpose of PT/CE is defined 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		
Expected effort required - not more than 2-3 days	C/AG		
Timelines identified	C		
Estimate of cost. Fee required?	P/C		
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	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		

APPROVED BY THE BOARD ON 27 JUNE 2014

Coordinator's PT/CE Check List continued

Activity	Responsibility	Date due	Date complete
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		
Assessment of performance			
Assessment of results (13)	C / AG		
Unexpected results reported to QM for relevant organisation (14.2)	C		
Report on performance against expected/desired outcomes (14.5)	C/AG		
Preparation of participant feedback report	C		
Participant feedback report approved by the Advisory Group (if possible)	C/AG		
Participant feedback report checked for participant anonymity	C		
Participant feedback report distributed to participants (within 2 months of result deadline)	C		
Coordinator's report (including participant's feedback report) to EWG	C		
Write report on PT/CE and send to QCC (Appendix 4)	EWG		

APPROVED BY THE BOARD ON 27 JUNE 2014

Appendix 2 Suggestions for contents of feedback for participants

List of participating laboratories

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 information 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)

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)

APPROVED BY THE BOARD ON 27 JUNE 2014

Appendix 3 Suggestions for questions for participants'opinions on the PT/CE

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

Appendix 4 Form for report to QCC

APPROVED BY THE BOARD ON 27 JUNE 2014

Action	Date
PT/CE issued to participants	
Feedback issued to participants	
EWG review	

PT/CE objective

Summary of results

Summary of EWG's review (including any issues that arose)

Follow on actions (if required)

Name Chair EWG:	
Signature Chair EWG:	Date: