IECEx TLs participation in the IECEx Proficiency Testing Program

ExTAG Training Workshop
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Introduction

- ✓ This presentation is intended to be a guide to planning, enrolling and undertaking proficiency testing topics organized by PTB with support from IECEx Secretariat.
- ✓ It will also remind the current requirements for participation.
- ✓ This presentation should be useful to laboratories and explain how to get the most from the programs.

Content

- ✓ What is the purpose of the PTP and who must participate ?
- ✓ How an ExTL prepares itself and registers to participate ?
- ✓ How test results are communicated to the Program provider, PTB ?
- ✓ What can an ExTL expect as feedback from the Provider, PTB ?
- ✓ What does IECEx expect the ExTLs to do with this feedback ?

What is the purpose of the PTP ?

- ✓ What is Proficiency Testing ?
  - Scheduled part of laboratory quality assurance where a group of laboratories compare their results of a test with many others who have tested the same materials.
  - Mechanism by which a laboratory can demonstrate competence based on practical evaluation.
  - Also called inter-laboratory comparison test.

What is the purpose of the PTP ?

- ✓ Chapter 7.7 of ISO/IEC 17025 related to validity of test results implies that the laboratory have quality control procedures for monitoring the validity of tests undertaken.
- ✓ Among the quality control procedure, the inter-laboratory comparison or proficiency-testing programs are considered as the best statistical techniques to determine the real capability and reliability of testing laboratories.
- ✓ In addition the purpose is to increase the "mutual confidence" between the ExCBs/ExTLs in the field of the IECEx 02 Scheme and related recognition of IECEx Certificates of Conformity.

Why perform Proficiency Testing ?

- ✓ Build mutual confidence between laboratories in the IECEx 02 scheme
- ✓ Show competence to authorities and/or clients
- ✓ Increase technical competence within laboratories
- ✓ Opportunity for increasing understanding of quality issues in a test
- ✓ Opportunity for comparison of methodologies with other laboratories
- ✓ Opportunity to learn and train
- ✓ Increase confidence of laboratory personnel

Why perform Proficiency Testing ?

- ✓ Requirement of certification and accreditation bodies :
  - Comply with quality assurance requirements of ISO/IEC 17025
  - Comply with scheme rules : IECEx 02 and OD 202

- ✓ ISO/IEC 17025 requires that the laboratory has a process that ensures the quality of test results. ISO/IEC 17025 also requires that success of training, adequacy of procedures and methods are monitored and that all these activities are planned.

- ✓ Quality assurance is a critical component of laboratory functions and performance of PT should also take priority.

Who must participate ?

- ✓ Requirements of IECEx 02 (clause 11.2.1 – Conditions for acceptance)
  - "The Ex testing laboratory shall participate in the IECEx proficiency testing program"

- ✓ Requirements of IECEx OD-202 (clause 6 – Participation)
  - "In accordance with IECEx ExMC Decision 2014/53, participation in the Proficiency Testing Program is mandatory for all accepted and applicant IECEx ExTLs and any Additional Testing Locations (noting that this does not include laboratories operating under the provisions of IECEx OD 024). Laboratory participation is according to their scope of acceptance in the IECEx System and is a condition for continued acceptance."

Who must participate ?

- ✓ Mandatory participation for :
  - IECEx ExTLs,
  - IECEx Applicant ExTLs,
  - IECEx Additional Testing Facilities (ATFs)
  - IECEx Applicant ATFs

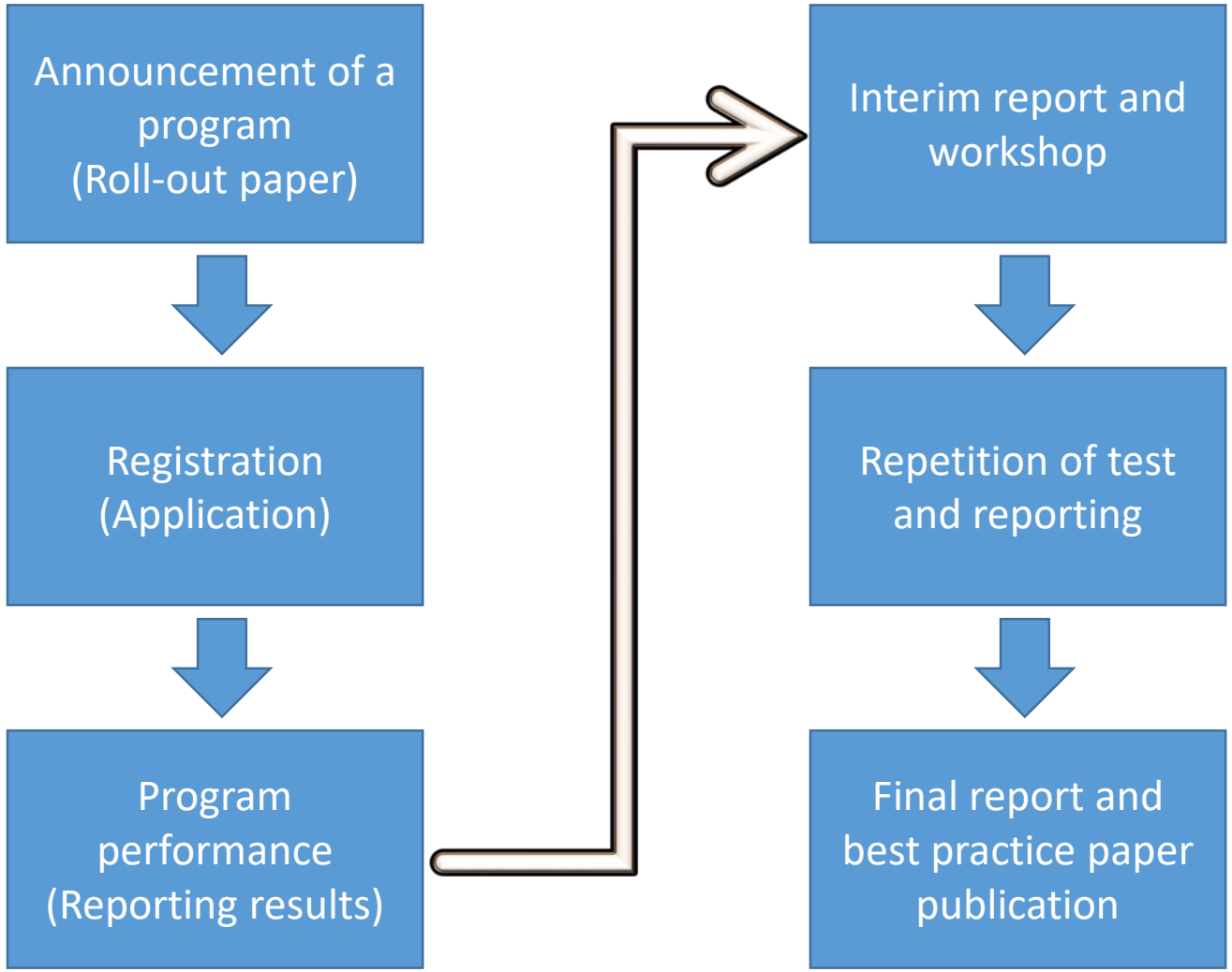
- ✓ Participation not requested for :
  - Manufacturer laboratories
  - Suppliers / subcontractors (not ATF)

Preparation by the laboratory

- ✓ OD 202 requires each laboratory participates in all topics within their scope, with the priority being given to new topics
- ✓ A laboratory may be required to conduct more than one program per year (or two programs every 2 years cycle) in the case of repeating a test as a result of “unsatisfactory results” in previous programs.
- ✓ Laboratory with satisfactory results will not be required to repeat participation in that particular program for at least three years.

- ✓ The IECEx Secretariat :
  - ensure that each accepted ExTL laboratory and applicant ExTL participates in the applicable Ex PTPs that fall within the testing scope of the laboratory.
  - monitored the participation of laboratories

PTP general process



Announcement of programs

- ✓ PTP provider announces when PT programs are planned
- ✓ PTP provider notifies all laboratories of new plans
- ✓ All notifications from PTP provider occur by email.
- ✓ To ensure your laboratory is notified :
  - Register your company and the correct contact details with PTP provider
  - Promptly update PTP provider with changes in Company address and contact details
- ✓ At any time, Laboratories can check the information on PT Program Status on the PTP provider web-page : https://www.ex-proficiency-testing.ptb.de/general/

Participation scheduling

- ✓ Laboratories create a PT programs plan in accordance with ISO/IEC 17025

- ✓ The PT programs plan should consider :
  - the PT activities the laboratory conducted over the previous 3 years
  - The results obtain in past programs
  - the PT programs available in the following years
  - The scope of the laboratory

Registration to programs

- ✓ PTB announces enrolment is available. A rollout paper is published at the beginning of a new program, which includes :
  - General information
  - Design of test sample
  - Time schedule
  - Application form

- ✓ The laboratory shall :
  - check whether it is on the laboratory's PTP plan
  - download the available documents (roll-out papers) available on the dedicated webpage
  - initiate enrolment by completing the application form attached to the roll-out paper.

Program performance

- ✓ Participant is registered when “Declaration of participation” is received from the PT provider.
- ✓ For carrying out the program, the laboratory follows the detailed instructions prepared by the PT provider : equipment analysis, reception of samples, testing instructions, report of results, due dates.
- ✓ However, the laboratory carries out the program in compliance with its own internal procedures. The laboratory carries out the PTP tests according to the same quality procedures as for certification tests
- ✓ According to the current scheduling (2 programs each two years cycle) it is expected to return the results before due date.

Program performance

- ✓ The results are send to the PTB by upload on the website
- ✓ Each laboratory get its own access and can download / upload all documents relevant to the program to which it has registered.
- ✓ The results are reporting on specific sheets prepared by PTB.
- ✓ Samples of reports are available for guidance to better understand the process for completion.

Reception of reports

- ✓ Actions for laboratories
  - Read the report
  - Compare the laboratory's performance with the evaluation criteria
  - Highlight the results to determine the type of unexpected results, if any : random or systematic
  - Share the information with the quality manager and also with the laboratory staff
  - Encourage all relevant people to read the report
- ✓ If results are not satisfactory
  - Evaluation of the nature of the problem
  - Cause analysis
  - Solution building
  - Perform new test for phase II
  - Measure success of solution implementation

Reception of reports

- ✓ Check that the results reported were actually those obtained, as errors may be in reporting :
  - Sample mix-up
  - Decimal or separators (“,” , “.”)
  - Typing mistake
  - Graph reading
- ✓ Check that the equipment and methodology were relevant
  - Method used
  - Respect of instructions
  - Equipment calibrations
  - Staff competence (training)

Repetition of tests

- ✓ In any case, for unsatisfactory results, the test should be repeated by the laboratory.
- ✓ Advantages of repeating the test :
  - Restore confidence if results are positive
  - Confirm more investigation needed if still unsuccessful

- ✓ The method of reporting is similar than for initial test round.
- ✓ When a laboratory does not provide additional results, the results of initial test round are used for the final report.

Provider responsibilities and feedback

- ✓ The PT provider is responsible for :
  - Ensuring samples meets specified criterias for performance homogeneity and stability
  - Report all data
  - Report reasons for variation
  - Provide means of assessing performance
- ✓ In addition to global reports, the provider is available for individual support in case of unsuccessful program
- ✓ The provider also initiate personal communication if necessary

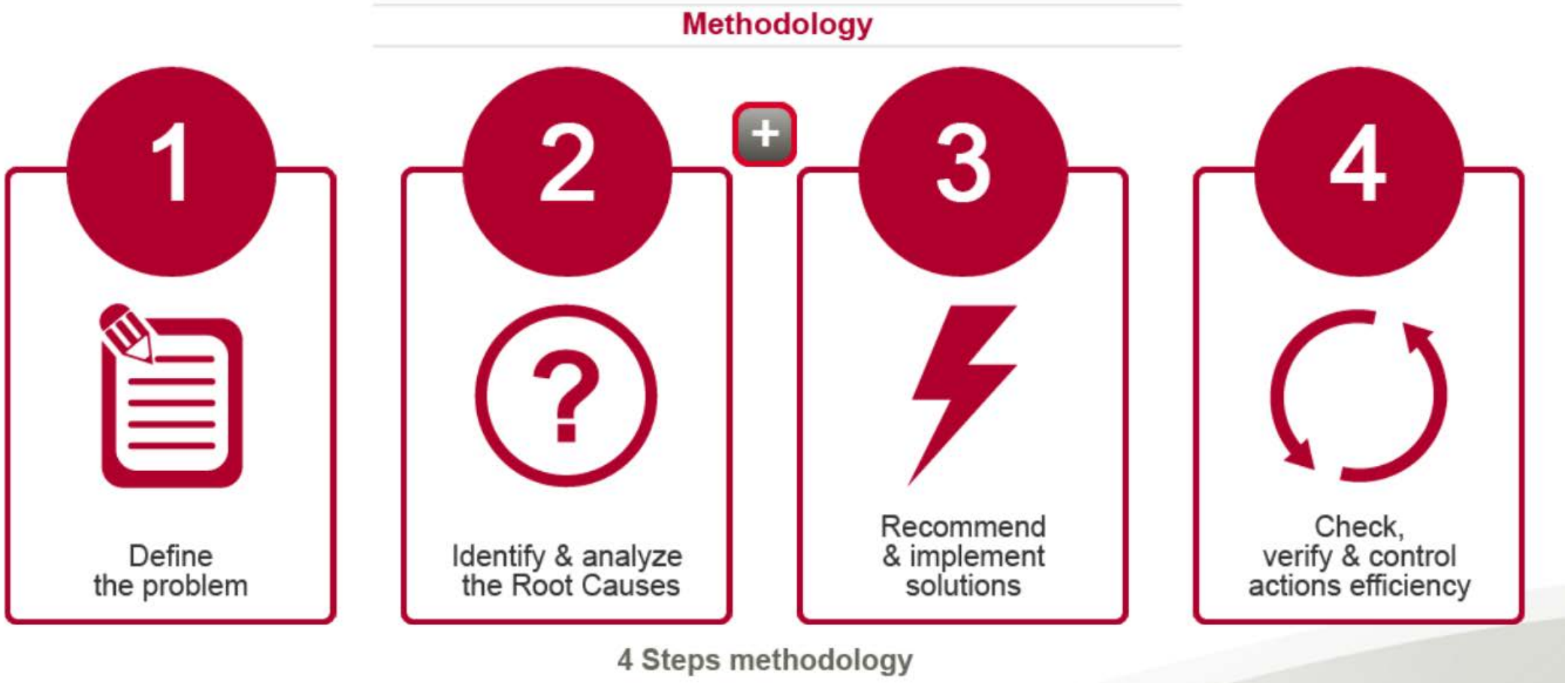
Provider feedback : workshop and best practice

- ✓ The provider also organize dedicated workshop for a restitution of main results of each program.
- ✓ This workshop is also an opportunity to exchange with other experts and improve laboratory competences.
- ✓ Participation to workshop may be considered as essential in order to get the better feedback for each program.

Note : registration in due time is required in order to participate to the workshops

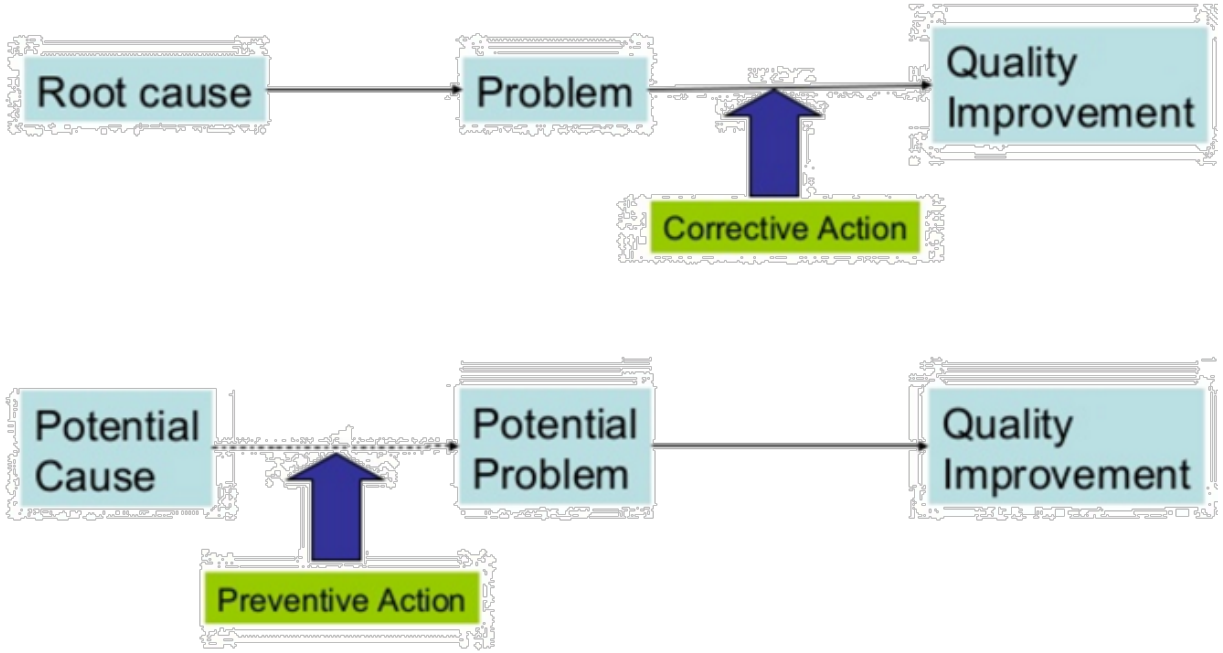
- ✓ The provider also prepare best practice papers in order to provide guidance to laboratories and ensure relevance of tests results.

Corrective and Preventive action



Corrective and Preventive action

- ✓ Corrective Action
  - The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.
- ✓ Preventive Action
  - Action taken to eliminate the cause of potential nonconformity, defect or other undesirable situation in order to prevent occurrence



Focus on Corrective actions

- ✓ It is the laboratory's responsibility to initiate corrective actions.
- ✓ The laboratory must use their own Quality System (corrective action procedure and paperwork) to complete corrective actions.
- ✓ This should include requirements to register any required action items in their internal quality management system in accordance with the requirements of ISO/IEC 17025.
- ✓ Corrective action reports must include an analysis of the true root cause and resulting actions must address the identified true root cause.
- ✓ Clearance of corrective actions shall be completed in due time (eg. 3 months from report issue date).
- ✓ The corrective action shall also includes an impact analysis on previous test performed, especially for results supporting IECEx Certificates of Conformity.

Focus on Corrective actions

- ✓ Actions should be considered closed only after all required items have been satisfied :
  - Indication that review of the results has occurred
  - Determination of root cause has been conducted
  - The selection and conduct of corrective actions has been undertaken
  - The success of corrective actions has been confirmed and
  - Preventive actions have been developed and implemented

- ✓ It is the laboratory's responsibility to ensure they maintain accurate records of the conduct of their corrective actions. As is the case with all non-conformities, these reports and information should be reviewed by the laboratory's management, internal and external assessors.

Root cause analysis

- ✓ Root Cause (s): The original event (s), action (s), and/or condition (s) generating (directly or in cascade) an actual or potential undesirable condition, situation, nonconformity or failure.

  Note : There are often several root causes for one problem

- ✓ The root cause analysis shall consider the following question :
  - What was affected ?
  - Where did the problem take place ?
  - When was the problem discovered ?
  - How much people was affected ?
  - How often has the problem occurred ?
  - What is the consequence on the quality system ?

Root cause

- ✓ Use tools when you want to conduct root cause analysis for a problem or situation.
- ✓ A simple tool for drilling down on the problem until the root cause is identified by asking « Why » 5 times or use of the fishbone diagram