

# GENERAL PARTICIPATION CONDITIONS IN PROFICIENCY TESTING



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Membro degli Accordi di Mutuo Riconoscimento  
EA, IAF e ILAC

Signatory of EA, IAF and ILAC  
Mutual Recognition Agreements

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**Proficiency Testing Sector**

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## **1 Aim and importance of proficiency testing**

This document describes the conditions for participation of testing laboratories in proficiency testing schemes organized by PT Sector<sup>1</sup> in compliance with UNI CEI EN ISO/IEC 17043 standard.

Such schemes are aimed at assessing the participants' performances and at providing them a tool in order to monitor and improve the quality of analysis in testing sectors treated. As described in the UNI CEI EN ISO/IEC 17025 standard, participation in proficiency testing is an independent tool, that can provide indication about the quality of testing results.

The schemes managed by the PT Sector provide for a periodic distribution of samples to be tested; this ensures participating laboratories have a tool for assessing, with respect to other laboratories with overlapping characteristics, the accuracy and comparability of their results in time.

All schemes provided by the PT Sector PT are organized and managed in compliance with UNI CEI EN ISO/IEC 17043 standard; the statistical analysis is carried out in compliance with in international ISO 13528 and/or UNI ISO 5725-2 standards.

PT Sector is accredited as organizer of inter-laboratory assessment tests (Proficiency Testing Provider, PTP) by ACCREDIA, Ente Italiano di Accreditamento (Italian Body of Accreditation).

ACCREDIA grants this accreditation after having verified technical and management competence in the organization of proficiency testing schemes in compliance with provisions of UNI CEI EN ISO/IEC 17043 standard, of ILAC G13 and of ACCREDIA official documents; such competence is assessed periodically for the purposes of maintaining the accreditation granted. The organizers of assessment tests among laboratories accredited by ACCREDIA are considered appropriate for performing these activities supporting the accredited bodies' activities of testing, calibration, certification and inspection.

Moreover, the PT sector ensure that both technical and management requirements specified in the above mentioned standards are met not only by its staff but also by any external operators involved in such schemes, such as, for example, experts, consultants and subcontracting laboratories. By applying such standards, the PT Sector aims at promoting and maintaining the participating laboratories' trust in the organized schemes, as well as ensuring impartiality and integrity in all its technical and management activities.

The list of accredited schemes is visible on ACCREDIA website, [www.accredia.it](http://www.accredia.it) in the section concerning data banks/testing laboratories/organizations managing inter-laboratories circuits.

With regard to accredited schemes, the ACCREDIA accreditation body's logo is showed on the Participation form, on "Instructions to participants" and on the final report.

PT Sector ensures that all its proficiency testing schemes are in compliance with provisions of UNI CEI EN ISO/IEC 17043 standard, even if some of these are not accreditatet

If the report is published without the mark Accredia, PT Sector ensures that all its proficiency testing accredited schemes are in compliance with provisions of UNI CEI EN ISO/IEC 17043 standard.

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<sup>1</sup> **PT Sector:** unit in the "Laboratories office", dealing with the organization of proficiency testing, belonging to the Anti-fraud and Controls Directorate (DAEC) of the Customs and Monopolies Agency.



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## **2 Organization of schemes**

### **2.1 Coordination and review of schemes**

Every scheme is managed by a group of experts composed of a coordinator and of technical experts for the different activities foreseen, so as to manage technical functions and customer service in the best way. Experts are chosen among the PT Sector staff based upon their technical knowledge and the experience of the sector where they will have to operate. Some experts external to PT sector may be selected, in order to have all necessary skills for the effective management of a specific scheme. All expert group's members, including the scheme coordinator, are committed to respect the confidentiality of information concerning the participants (identity, results obtained, etc.).

Expert groups meet periodically, at least once a year, in order to assess the progress and the efficiency of each scheme and to provide guidelines on future developments and management of the scheme itself. Every expert group meeting is documented by written minutes.

Scheme performances are periodically reviewed and any amendments done together with all improvements needed.

### **2.2 Structure of the schemes**

The time sequence of the activities performed for each round of a scheme can be describes as follows:

- Supply, preparation and quality control (stability and homogeneity) of testing materials;
- Invitation to participants;
- Distribution of samples to participants;
- Analysis of samples and transmission of results obtained to the PT Sector;
- Statistical processing of results and issuance of the final Report;
- Scheme review;
- Subsequent Round.

### **2.3 Participation in the schemes**

The PT Sector invites the laboratories concerned by an email containing all relevant information about proficiency testing round being organized, including the period of its implementation and the tests to be carried out.

The laboratory must answer within 7 days to confirm his participation to the round.

Sending back the answer implies that the participant accepts the contents of this document.

The laboratories' participation depends upon the PT Sector's invitation, that selects participants based upon their experience (e.g. their institutional activities, accreditation, etc.) in the sector dealing with the specific proficiency testing scheme.

For every specific scheme, the laboratories concerned receive the document "Instructions to participants", detailing all necessary indications for the correct implementation of the scheme, storage of samples, any possible analytical method to be complied with and the detailed timeline of the several phases of the scheme, including the dates for the end of analysis and results to be sent to the scheme provider.

The identity of participants is only known to the PT Sector; the Head of the PT Sector is responsible for the storage and management of results obtained by participants. All information provided by a participant to the PT Sector is treated confidentially.

Participants can decide to renounce to such confidentiality within a scheme for the purposes of discussion and mutual assistance, e.g. in order to improve performances.



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In some cases, participant's results can be sent to third parties, but only if this is expressly authorized in writing by the participant itself. Such authorization is not binding if the request stems from enforcement bodies.

In order to ensure the confidentiality of information concerning results of proficiency testing, every participating laboratory will receive a reserved ID code, known only to the laboratory concerned and to the scheme organizers. Such code will remain the same for all schemes organized by the PT Sector except in case of express request by the participant or justified reasons by the PT Sector aimed at ensuring always the laboratories' confidentiality.

All laboratories participating in proficiency testing organized by the PT Sector commit themselves to maintain a professional and honest behaviour; thus, they shall not inform other participants about values obtained, in order to influence proficiency testing final result.

In order to avoid attempts of collusion, the PT Sector does not communicate to anyone the assigned values of the scheme until the Final Report is issued; sometimes it can send several differentiated samples (altered, false positives/negatives) to one or more participants in order to avoid direct comparisons of results obtained. If the PT Sector suspects that one or more participants behaved unprofessionally, decides the actions to be adopted in the specific case, involving other samples to be sent for their analysis (e.g. bait and switch samples, altered samples or surplus samples) or excluding the laboratory from the ongoing round.

The final Report is sent electronically, confidentially only to participants that have submitted their results. A certified copy of such report is published in the Agency's web site, excluding the names of the officials performing their tasks.

Every laboratory will recognize, within the Report, its own assessment through its specific ID code.

PT Sector does not issue participation certificates nor personal or company's reports; moreover PT Sector doesn't issue preliminary or interim report.

## 2.4 Test samples

### 2.4.1 Preparation of samples and quality controls

Test samples can be of different types: reference materials, samples prepared in laboratory, real samples as such or with addition of analytes being tested. In every case testing material are as similar as possible to those routinely analysed in the participating laboratories.

Test samples are subject to quality controls including homogeneity test, stability test and processing controls during all phases of preparation.

Such quality controls are subcontracted: analytical activities are placed with a subcontracting laboratory with experience in testing sector, belonging to the Customs and Monopolies Agency, possibly accredited or operating according to the UNI ISO/IEC 17025 standard. The statistical processing of data is performed by the PT Sector which is responsible for all activities subcontracted.

Details concerning type, quality, stability and homogeneity of testing materials covered by the proficiency are included in the final Report.

### 2.4.2 Unsuitable samples

If, before shipping the sample, the relevant quality controls concerning their stability and homogeneity should provide unacceptable results, the scheme could be executed late: this is properly communicated to all participants.

Sometimes, problems with samples can occur after their distribution: such cases are duly kept into account during the assessment phase of participants' results. The result of the assessment, variable on a case by case basis, could imply the publication of z scores just for informative purposes, or the provision of replacing samples. However, detailed information is included in the final Report.



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### 2.4.3 Packaging and transport

Test samples are sent to participating laboratories using a courier duly assessed and approved, in suitable packaging and under conditions allowing to ensure the integrity of products until their delivery to the laboratory. PT Sector checks if samples were received by participants using the tracking function in the courier's web site. If this on-line service is not available, PT Sector asks participants, by e-mail, for the receipt of the sample.

Sometimes samples can be hand delivered to the participating laboratories; in such case the receipt notification is provided by the "Ricevuta" ("Receipt") form filled in on receiving the sample.

Once received the samples in their laboratories, the participants shall check the content of the packaging and any accompanying documentation, and inform the PT Sector about any possible problem detected: for example, if the samples received are damaged. The PT Sector will be responsible for shipping, as soon possible, new samples.

More samples are usually available after every distribution in order to allow participant to repeat their test in case of unsatisfactory results. Such samples are stored in the PT Sector and shipped to requesting participating laboratories. Any availability and storage time for such remaining samples, compatibly with the stability examined, is defined for every single scheme and communicated to participants in the relevant reference documents (instructions to participants and/or final Report).

## 2.5 Analysis of test samples and communication of results

### 2.5.1 Analysis methods

Participants shall perform the proficiency tests using methods indicated in "Instructions to participants". If not expressly indicated, participants can use the methods they consider to be the most appropriate. In this case, methods and techniques used shall be indicated, together with other information requested, with the results sent to the PT Sector.

Unless otherwise specified, samples should be examined and treated as routine samples.

### 2.5.2 Timeframe

The time programming of all phases in the scheme, such as the shipment of samples, the period during which analysis are carried out, the final deadline for sending results and the date of issue of the Report is detailed in the invitation email and the document "Instructions to participants".

Due to the samples' stability, the time given for the analysis vary from a minimum of 10 days to a maximum of 45 days.

The time for the issue of the Report is between 30 and 40 days, depending on the number and complexity of the data to be processed.

In particular, a date can be also indicated in a date within which the beginning and/or end of analysis is recommended.

### 2.5.3 Recording and transmitting results

The results obtained during the execution of a scheme shall be recorded and sent to the PT Sector following the instructions described in the document "Instructions to participants". Generally, results are recorded into



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specific Excel forms provided by the PT Sector or in an electronic database accessible from the customs Agency' website in the [Proficiency Testing sector page](#).

Participants in proficiency testing shall send their results within the prescribed deadline. Data sent after such deadline will not enter in the statistical analysis of results; moreover, data already sent cannot be modified after the final deadline for the transmission of results.

Following the statistical analysis of experimental results, PT Sector sends the final Report to all participants. Every laboratory will recognize, within the Report, its own assessment through its specific ID code.

The PT Sector shall not disseminate the results of the assessment test until the issuance of the Report and, in any case, until all results have been received by all participants. The final Report is sent only to participants having transmitted their results.

If in the same year, the PT Sector organizes more round of a proficiency testing scheme, every Report is issued just for one round and it is identified as *Scheme n.xx/Round xx/Year/name of the Scheme*.

The PT Sector does not issue participation certificates nor personal reports or for individual companies.

### **3 Assessment of performances**

The assessments of participants' performances are discussed in every scheme's final Report, including also statistical and graphical processing of test results.

The assessment of participants' performances, in case of quantitative schemes, is based on the assigned value and on the standard deviation of proficiency testing scheme. In case of qualitative schemes, on the other hand, the participants' results are compared with expected values (ex. a value known from the beginning or the most frequent values among those provided by participants) or are assessed by sectoral experts.

#### **3.1 Determination of the assigned value**

In compliance with standard ISO 13528, PT Sector selects the approach considered as the most appropriate in order to determine the assigned value and the relevant associated uncertainty, based upon the type of scheme, the sample and the test parameter. The assigned value and the procedure implemented for its determination are detailed in the scheme's final Report.

#### **3.2 Determination of the standard deviation**

Another essential parameter for the assessment of participants' performance is the scheme standard deviation.

As scheme standard deviation the PTP shall preferentially use the standard deviation of the method, if any, used for carrying out the tests. In alternative the parameter used will be the lowest between the robust standard deviation or the standard deviation defined by perception by the PT Sector based upon data available, so as to encourage the improvement of participants' performance.

In any case, the procedures adopted by the PT Sector in order to determine such parameter are compliant with standard ISO 13528 and are detailed in the final Report.

#### **3.3 Performance indicators**

Following the statistical processing of qualitative results, carried out in compliance with standards ISO 13528 and/or UNI ISO 5725-2, the PT Sector assesses participants' performance based upon the difference among the results transmitted and assigned value, depending upon the scheme's standard deviation.



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In particular, the participants' performance is assessed using z-score or z'-score. The last one statistical parameter (z'-score) is used when the uncertainty of the assigned value is not negligible.

The interpretation of the two statistical parameters is the following:

Indicator	Value	Interpretation of the result
z-score	$ z  \leq 2$	Satisfactory
and	$2 <  z  < 3$	Questionable: generates an attention signal
z'-score	$ z  \geq 3$	Unsatisfactory: generates an intervention signal

If z-score is acceptable while z'-score is unsatisfactory, the laboratory could not have correctly assessed the uncertainty of measure of the specific test.

For qualitative assessments, the results obtained are the same as the expected values are generally considered satisfactory; if the results are not the same, the scheme coordinator, with the support of the experts, determines if the result transmitted is considered acceptable and suitable to the intended use.

If other procedures for assessing results are to be used occasionally, they shall be notified to laboratories in "Instructions to participants" and/or in the final Report.

In the presence of unusual cases for which it would not be possible to process in a significant way the results provided by participants (ex. small number of valid results, multimode distributions or unexpected instability or lack of homogeneity of samples), the Report provides specific information.

If data provided by participants are **equal to or** less than 5, data are included in the final Report without any statistical processing, thus without competence assessment in terms of z score.

The challenge partially represented by the participation in proficiency testing is the execution of a specific investigation and of the resulting corrective action, implemented due to a questionable or unsatisfactory result. The scheme coordinator can help participants concerned with their performance.

The PT Sector can also require laboratories, following unsatisfactory performance, to participate in subsequent schemes.

## 4 Communications with participants

In order to ensure the confidentiality of information, the documentation concerning the schemes, distributed electronically, together with all communications, if any, are transmitted confidentially between the PT Sector and every participating laboratory from the following e-mail address: [adm.ringtest@adm.gov.it](mailto:adm.ringtest@adm.gov.it).

The same address can be used by participants for any communication or for asking clarifications or explanations; such communications can occur also by phone, contacting the scheme coordinator or the head of PT Sector to phone numbers indicated in the reference documentation for every scheme.

Participants are encouraged to provide comments and remarks on every aspect concerning the scheme.

All records referring to the schemes (ex. results transmitted to participants, statistical processing, Report, documents and any important communication) are kept by PT Sector in its archives for minimum 5 years.





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### 4.1 Personal data

The participants, by sending the “Participation form”, expressly gives its consent to the processing of personal data, pursuant to Regulation (EU) 679/2016, for the purposes related to the provision of the service and for any subsequent obligations.

The PT sector processes this data by manual and IT means, in order to guarantee the security and confidentiality of the data (Reg.679 / 2016 art 31), it is not foreseen in any case the transfer of personal data to a third country or to an international organization (Reg. 679/2016 Article 13 paragraph 1 point f).

In relation to the processing of data, the participating laboratory may exercise its rights according to the mentioned Regulation. The period of storage of personal data is 5 years.

### 4.2 Complaints and appeals

In compliance with the quality system, the participants in the proficiency testing may complain with the PT Sector in writing by e-mail. The result of the complaint is transmitted within 15 days from receipt of complaint. Within 20 days from the issuance of the final Report, the participants can also complain about the assessment of their performance by submitting an appeal to PT Sector, signed by the head of the laboratory, indicating clearly the subject and reasons for complaint and any supporting documentation.

The laboratory is informed about the reception of the appeal and how long the procedure will take. A panel composed of people with proven experience and competence examines the appeal, and the final decision is transmitted to the complainant by ordinary mail within 40 days from the presentation of the complaint.