



PROTOCOL FOR THE OPERATION OF PROFICIENCY TESTING SCHEMES

1. GENERAL INFO: The 5th Athens Chemical Service of the General Chemical State Laboratory plans and operates Proficiency Testing schemes (PT schemes) under the trade name SCHEMA (Scheme for CHEMical Measurement Assessment) according to the International Standard ISO/IEC 17043:2010 - Conformity assessment, General requirements for proficiency testing. Based on an annual program, which is available at the [website of the General Chemical State Laboratory](#), different rounds of PT schemes are offered for a variety of substrates. Moreover, PT schemes may also be conducted by specific request; in such a case, the design of the PT scheme is tailored to customers' special requirements.

2. BRIEF DESCRIPTION: The main purpose of PT schemes is the voluntary assessment of services provided by laboratories performing measurements and calibrations. In this context, and with respect to ISO/IEC 17043:2010 requirements, the General Chemical State Laboratory (GCSL) undertakes the design, production and dispatch of homogeneous and stable samples according to a predefined schedule. Participating laboratories select the parameters to determine from the ones available, use an analytical method of their choice and are required to report their results within a predefined time frame. The PT scheme provider collects and evaluates the results, using a valid statistical procedure and issues the final report of the PT scheme, where laboratory performance is evaluated by comparing the submitted results to an assigned value (using z-scores or other performance criteria). The use of appropriate coding ensures the anonymity of the participating laboratories and the confidentiality of the results.

3. PARTICIPATION: The annual SCHEMA program is available in the Proficiency Testing webpage at the GCSL website. In the particular document, the rounds of PT schemes offered, the available substrates, as well as the parameters that may be determined are presented. The interested parties state their preferences by completing the appropriate form and returning it to the provider. One month before sample distribution, the provider verifies the registration of the participant by sending the participation form, where details and important dates for the PT scheme are indicated. Every participant receives an official notice with instructions regarding the payment of the participation fees and the dispatch cost at an account held at the Bank of Greece. The payment is due within fifteen (15) working days from the date of sample dispatch; otherwise the General Chemical State Laboratory reserves the right to withhold the final report from the participants that have not settled their accounts.

4. CONFIDENTIALITY: The personnel of the 5th Athens Chemical Service of the General Chemical State Laboratory is bound to operate under strict confidentiality by signing an appropriate statement. All information concerning the identity of the participating laboratories is confidential and pertinent data are handled only by suitably authorized personnel. Participants may elect to waive confidentiality within the proficiency testing scheme for exceptional circumstances. The information included in SCHEMA reports should not be used for purposes other than the participants' performance assessment without the previous written consent of the provider.

5. PLANNING: The planning procedure of PT schemes is an exclusive responsibility of the provider and cannot be subcontracted. The PT provider may refer to external expertise concerning the intercomparison activities by means of a steering committee of acknowledged proficiency. Whenever appropriate, the PT schemes are also supported by advisory expert groups, where internal staff and outside experts participate to enhance access to



scientific and professional expertise. Sample preparation (production and packaging) is controlled and performed either at the GCSL premises or at the premises of a subcontractor. Samples are submitted to homogeneity and stability assessment according to standard requirements (e.g. ISO 13528:2005, IUPAC IHP). Homogeneity and stability measurements may be subcontracted to other laboratories, under the supervision of the provider in order to ensure that ISO/IEC 17025:2005 requirements are met. The technical details of sample preparation are recorded by the PT provider and included in the final report of the scheme, together with the statistical analysis of homogeneity.

6. DISTRIBUTION: Sample delivery is contracted to a specialized distribution service and operated according to the predefined schedule. All participants are informed in time for the operation of the PT scheme, as well as for its exact schedule. Samples are accompanied by the following documents: an instructions note-cover letter (where details on sample handling are presented and a unique laboratory code is supplied for each participant), a form for acknowledging sample receipt, a form for submitting the results and a technical questionnaire. Participants can trace sample dispatch through a unique tracking number, and are kindly asked to inform the provider on sample receipt by completing and returning the respective form. In case sample delivery is delayed on the part of the PT provider, the participants are informed before the predefined date. In case of delivery failure or defective samples, the PT provider assumes responsibility for the dispatch of new items.

7. DETERMINATIONS - RESULTS: Participating laboratories determine the parameters they select using an analytical procedure of their choice (participants are strongly encouraged to apply official or/and validated analytical methods). They are required to submit their results, as well as to complete and return the accompanying technical questionnaire within the deadline, using the appropriate forms sent by the provider. Results submitted after the aforementioned date will not be accepted. In the same context, non-numeric results will not be taken into account for the PT scheme evaluation. Before the issue of the final report (where the assigned values are officially presented), it is possible for the participants to modify/replace values submitted in time, as long as the PT scheme provider is officially informed. Submitted results cannot be withdrawn.

8. STATISTICAL ANALYSIS - PERFORMANCE EVALUATION: After collecting the results, data are submitted to statistical analysis using valid statistical procedures according to internationally accepted standards (e.g. ISO 13528:2005, IUPAC IHP). Using appropriate statistical methodology, possible outliers within the data set are identified. Application of robust statistics allows for not excluding the outliers. The results are evaluated by comparing their deviation from the assigned value to the target value of standard deviation for the PT scheme (by means of z-scores, or other appropriate performance criteria):

$$z = \frac{(x - x_a)}{\sigma_p}$$

where x , the result reported by the participating laboratory

x_a , the assigned value (estimated as a robust consensus value from the participants' results)

σ_p , the target value of the standard deviation for proficiency assessment

As a next step, the uncertainty of the assigned value is estimated and compared to the target value for the standard deviation. In case their ratio is considered high, participant performance is evaluated using 'provisional' z-scores.

In extreme $\left(\frac{u_x}{\sigma_p}\right)^2$ ratios, (where u_x is the uncertainty of the assigned value), z-scores are not issued.



9. EVALUATION: Finally, the report of the proficiency testing scheme is issued and sent to every participant, according to schedule, provided that his account has been settled. The report is distributed by e-mail as a pdf document. A unique and confidential code is assigned to each participant in order to ensure laboratory anonymity. The final report includes the results of all participants and the evaluation of their performance for every parameter under consideration. Information is provided regarding the selection and the estimation of both the assigned value and the target value of the standard deviation for proficiency assessment of the PT scheme (application of robust statistics, etc). The final report is accompanied by an assessment questionnaire, which the participants are kindly asked to complete and return to the provider within a week. In case a participating laboratory appeals against the evaluation of its performance, the General Chemical State Laboratory, as the PT scheme provider has the responsibility to undertake a thorough investigation, reply officially, and, if deemed necessary, to follow specific corrective actions (e.g. to issue and distribute a new report).

10. MANAGEMENT: The General Chemical State Laboratory has installed and is operating a quality management system that fulfills ISO/IEC 17043:2010 requirements. The policy of the provider is aligned with the quality policy of the organization, which has been operating under the requirements of the International Standard 17025:2005 for many years. The organizational structure of the provider, as well as the procedures followed concerning the control and handling of records and documents, the choice and evaluation of suppliers and subcontractors, the conduct of thorough audits and reviews, and the implementation of the appropriate corrective, preventive and improvement actions ensure that the requirements of the International Standard 17043:2010 are fully met, the fundamental one being to provide services of high quality and to continuously improve the quality management system.