Good Laboratory Practice (GLP)

for

Interlaboratory Comparison, Intralaboratory Comparison, and Proficiency Testing Follow-up

1 Introduction

1.1 Purpose

The purpose of this procedure is to provide consistent evaluation of intralaboratory comparisons, interlaboratory comparisons, and proficiency tests and may be used for Interim and Final results. For simplicity, the term proficiency test (PT) will be used in this procedure to cover all of these comparisons. This GLP provides an outline for monitoring performance by comparison with results of other laboratories that is planned and reviewed. The practice includes analyzing data from monitoring activities including proficiency testing, interlaboratory comparisons, internal surveillance, measurement assurance activities, and training or verification of training (e.g., Laboratory Auditing Program problems). The resulting analysis is used to monitor and control (where necessary), and if applicable, improve the laboratory's activities. When results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is documented on the laboratory Action Item forms with action taken as soon as possible to prevent incorrect results from being reported.

1.2 Application

The procedure is applicable for interlaboratory comparisons and proficiency tests used for method validation, competency assessment for personnel, and formal proficiency testing programs.

1.3 Prerequisites:

1.3.1 The laboratory must have the documented proficiency testing plan, analyses, and analysis reports.

1.3.2 The laboratory measurement assurance data (e.g., control charts), calibration history of standards, and uncertainty budgets must be available when integrated analysis is conducted using the data from intralaboratory comparisons, interlaboratory comparisons, and proficiency tests.

2 Methodology

2.1 Summary

This procedure provides an outline for consistent evaluation of intralaboratory comparisons, interlaboratory comparisons, and proficiency testing to comply with ISO/IEC 17025 and OWM Handbook 143, Program Handbook for laboratory recognition, including integrated evaluation with other applicable laboratory data and analyses.

2.2 Procedure

2.2.1 Assess Differences and Bias from Reference Values (Accuracy)

2.2.1.1 Evaluate Accuracy of the Laboratory Results

Evaluate the accuracy of the reported measurement results. The following statistics are often provided as a measure of accuracy or inaccuracy in PT reports: normalized error, E_n, and bias, Z value. When the normalized error is greater than the absolute value of one, the laboratory must investigate the source of this bias or inaccuracy. When the bias or Z values show an offset, it should be evaluated against additional laboratory data. When bias is greater than the laboratory reported uncertainty or the Z values exceed a value of three and the uncertainty is less than the bias value, there is cause for investigation.

2.2.1.2 Evaluate Additional Laboratory Data

Evaluate the reported measurement results, final report analysis, and statistics from the previous item against the laboratory measurement assurance data. Additional statistics might include the stability or trends for historical mean values from calibrations, the current or changing mean values from control charts, and any bias values included in uncertainty budgets.

2.2.1.3 Questions to Consider When Evaluating Differences and Bias

- What (if any) E_n failures were reported?
- Were any E_n values highlighted between 0.7 and 1?
- If E_n failures were reported, are the differences or bias correlated with data that has been observed on control charts or calibration history?
- Were any Z values between 2 and 3, or greater than 3 indicating a difference greater than the PT standard deviation?
- If a bias was present, even if all statistics were passing, are there any overriding reasons for differences from the reference values? (E.g., are there any measurement errors that need to be corrected?)
- If the laboratory includes bias in the uncertainty budgets, do the bias values need to be updated or evaluated further?

2.2.2 Assess Laboratory Uncertainties (Precision)

2.2.2.1 Questions to Consider When Evaluating Uncertainties

- Were reported uncertainties consistent with those submitted to accreditation or recognition bodies?
- Were reported uncertainties significantly higher or lower than values submitted to accreditation or recognition bodies (if so, why?)
- Are uncertainties consistent with the procedure defined in the PT plan?
- Were reported uncertainties consistent with other participant laboratories performing similar procedures?

2.2.3 Assess Uncertainties with respect to Decision Risk (Precision and Conformity Assessment)

2.2.3.1 Assess the Precision Assessment of Laboratory Results

Evaluate the reported measurement uncertainties against the required specifications, maximum permissible errors, or tolerances identified in the PT plan and for the class/tolerance specified for the PT item(s). The following statistics are often provided as a measure of precision assessment in PT reports: normalized precision, P_n.

2.2.3.2 Evaluate Additional Laboratory Data

Evaluate the reported measurement uncertainties, final report analysis, and statistics from the previous item against the laboratory uncertainty data and values submitted to the accreditation or recognition bodies as applicable. Additional uncertainties in the laboratory might include those for alternative calibration procedures or might be incomplete with respect to the Standard Operating Procedure called out in the PT Plan. If the laboratory uncertainty showed a P_n precision failure prior to participation in the PT, corrective actions should have already been identified and in process.

2.2.3.3 Questions to Consider When Evaluating Uncertainties and Decision Risk

- Do the documentary standards for this measurement include requirements for uncertainty to be evaluated with respect to decision rules?
- What are the applicable documented limits for decision rules for this PT?
- Does the laboratory include references to the applicable documentary standards on the certificate?

- Note: if tolerances or maximum permissible errors are listed on the calibration certificate(s), this is considered a conformity assessment and additional statements compliant with ISO/IEC 17025 must be listed. Are applicable statements included on the certificates?

2.2.4 Assessment of Failures Not Specific to Measurement Results

When a PT plan specifically calls out additional components for evaluation, the final report should have additional observations, comments, or notes regarding actions. Examples of observations that might be evaluated or included in a PT plan or in the PT final report:

- Certificate compliance with ISO/IEC 17025:2017;
- Completion of follow up calibration;
- Correct completion of amended certificates;
- Inclusion of uncertainty components for detailed evaluation;
- Completion of the official data sheets;
- Completion of receipt or shipping forms;
- Cleaning or adjusting standards contrary to instructions;
- Poor shipping and handling of PT standards;
- Participation by staff and laboratories who were not approved for participation;
- Laboratory Auditing Program (LAP) problem failures; and
- Undue delay of the PT.

2.2.5 Documented Analysis and Records

Document the analyses and answers to applicable questions in the PT Follow Up form (see Section 3) and appendices where needed. Identify where the records are stored as appropriate.

A 4-year history assessment is a useful summary and provides a basis for examining trends and demonstrating compliance with PT participation requirements. The laboratory may also maintain a Proficiency Testing Log to ensure ongoing participation for all staff and especially laboratory Approved Signatories.

2.2.6 Action Plans

Be sure to document all action items (whether corrective action, risk mitigation, or improvement actions) on the applicable laboratory forms.

2.2.7 Executive Summary and Impact

Write an executive summary that summarizes the PT scope, range, and results with narrative that describes the impact of success or failures from each PT.

The executive summary may be used in the laboratory management review, as a lab best practice. Include any applicable action items that require(d) management approval to dedicate resources.

3 Proficiency Testing Follow-up Form

Instructions: complete one PT Follow-up Form per PT and per laboratory (do not complete one form for each staff member unless the form is being used as part of the competency assessment for that staff member's Laboratory Auditing Program (LAP) problems). This form may be used to summarize critical PT highlights that will be used in laboratory Management Reviews.

Laboratory	
Date	
Completed By	
PT Measurement Parameter, Range, and Scope Description	
PT Identification (OWM Code) and artifact ID	
List of Participating Personnel (17025, Section 6.2) Note Approved Signatory or In Training Status	

Assessment	Results and Evidence
2.2.7 Executive Summary and Program Impact.	
PT Failure Summary.	
2.2.1 Difference, Bias, Offset Assessment.	
2.2.2 Uncertainty Analysis.	
2.2.3 Decision Rules and Conformity Assessment	
2.2.4 Non-Measurement Result Observations or Failures.	
2.2.5 Records.	
2.2.6 Analysis and Action Plan with Assigned Personnel and Deadlines.	