BILATERAL PT SCHEMES—A FLEXIBLE TOOL WHEN RESULTS ARE NEEDED QUICKLY

Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

Al Ramsay[1], Claudia Ketteler[2]
[1]Waters, Milford, MA, USA, [2]Waters, Frechen, Germany

INTRODUCTION

When laboratories have had an unacceptable result requiring corrective action, reported results too late, when they want to develop methods, extend their scope of accreditation quickly or when they want to monitor laboratory staff performance, a flexible schedule for participation and quick reporting of PT results is often critical. Waiting for regular PT rounds and especially until the reports are issued, may take too much time to allow the laboratory to successfully meet their objective. Bilateral PT schemes accredited to ISO/IEC 17043 provide the laboratory greater flexibility to participate and obtain PT results when they need them. These schemes are widely used across the world with growing interest by laboratories and accreditation bodies.

BILATERAL PT

The term Bilateral PT is described in EA-03/04 Section 6.2.A as one possible type of proficiency testing, defined in section 4.3 as a test item with accurately determined characteristics provided by an assessor or third-party in the context of an accreditation procedure[1]. This type of PT is further described in ISO/IEC 17043. Section A.3.3 defines split-sample testing schemes as involving comparison of data generated by as few as two participants, where the participant result(s) is compared to another participant's data with a lower measurement uncertainty, considered to be the assigned value[2]. Bilateral or split-sample PT is employed in the U.S. as defined by The NELAC Institute (TNI) standard EL-V3-2009-Rev2.0 section 3.15, where this type of PT is described as a supplemental proficiency testing study where PT is conducted using a sample lot from a previously closed PT scheme. The detailed requirements for supplemental PT are described in EL-V3-2009-Rev2.0 section 8.4. To summarize these requirements:

- The PT Provider must provide a sample from a previously released, closed PT and have adequate procedures and systems in place to track all lots and assigned values provided to laboratories that may participate in supplemental PT
- The participant must not have had any previous experience with the orignial PT and the supplemental PT must have no identifying features relating to the original
- The closing date for supplemental PT is the date the participant has reported their data, but not more than 45 days after the opending date
- The PT Provider must conduct stability testing or have adequate data showing that the sample was stable for the period of the supplemental PT

PT results are then evaluated according to EL-V3-2009-Rev2.0 section 10.2 Acceptance Limit Determination, which refers PT providers to analysis/analyte-specific criteria provided in the Fields of Proficiency Testing (FoPT) tables maintained by The NELAC Institute[3]. Evaluation criteria are dependent on the analysis and/or analyte. Certain criteria are provided as a fixed percentage acceptance limit based on regulatory requirements, others are provided as regressions based on historical data collected over many years from various U.S. PT scheme providers, while evaluations for some analytes are based on analysis of participant data.

ERA
A Waters Company

00002U 2009 TNI Evaluation Final Complete Report

John Smith
QA Director
Environmental Laboratory Testing
1234 1st Street
Golden, CO 80403
(303) 431-8454

EPA ID:
ERA Customer Number: CO00099 C000001

TNI Analyte Code	Analyte	Units	Reported Value	Assigned Value	Acceptance Limits	Performance Evaluation	Method Description	Analysis Date	Z Score	Study Mean	Study Standard Deviation	Analyst Name
WP Trace Metals (cat# 500) Study Dates: 05/29/12 - 06/13/12												
1000	Aluminum	µg/L		2610	2150 - 3030	Not Reported				2580	150	
1005	Antimony	µg/L		710	502 - 853	Not Reported				700	39.9	
1010	Arsenic	µg/L		639	536 - 748	Not Reported				629	44.0	
1015	Barium	µg/L	2092	2160	1880 - 2440	Acceptable	EPA 200.7 5 1998	6/13/2012	-0.365	2140	126	
1020	Beryllium	µg/L		709	603 - 801	Not Reported				694	36.2	
1025	Boron	µg/L	1829	1840	1500 - 2140	Acceptable	EPA 200.7 5 1998	6/13/2012	-0.436	1860	84.1	
1030	Cadmium	µg/L		95.9	81.1 - 110	Not Reported				94.5	6.62	
1040	Chromium	µg/L		481	418 - 544	Not Reported				477	19.0	
1050	Cobalt	µg/L		283	248 - 318	Not Reported				296	12.1	
1055	Copper	µg/L		735	662 - 808	Not Reported				732	33.9	
1070	Iron	µg/L		2410	2140 - 2710	Not Reported				2410	102	
1075	Lead	µg/L		1320	1160 - 1470	Not Reported				1330	58.0	
1090	Manganese	µg/L		2090	1880 - 2320	Not Reported				2120	98.6	
1100	Molybdenum	µg/L		500	424 - 571	Not Reported				493	20.6	
1105	Nickel	µg/L		617	555 - 691	Not Reported				613	21.4	
1140	Selenium	µg/L		1160	923 - 1340	Not Reported				1150	78.0	
1150	Silver	µg/L		152	130 - 174	Not Reported				150	10.3	
1160	Strontium	µg/L		84.7	71.3 - 98.1	Not Reported				84.0	4.54	
1165	Thallium	µg/L		518	417 - 622	Not Reported				513	30.8	
1185	Vanadium	µg/L		1780	1560 - 1990	Not Reported				1760	73.3	

All analytes are included in ERA's A2LA accreditation. Lab Code: 1539-01

Page x of x

Figure 1. Supplemental PT Report Example

EXAMPLE BILATERAL PT– QUIK RESPONSE SCHEME

Environmental Resources Associates (ERA) began offering bilateral proficiency testing in 2000 to environmental testing laboratories accredited in the United States via the QuiK Response™ PT scheme.

The design of the QuiK Response PT scheme reflects the requirements outlined in EL-V3-2009-Rev2.0. PT samples from ERA's traditional schemes are retained following the close of each round for potential use as QuiK Response PT, and the QuiK Response scheme operates in accordance with EL-V3-2009-Rev2.0 section 8.4.

An excerpt from a PT report is provided as Figure 1 for demonstration. The data provided is actual participant data however, the excerpt has been modified to remove any identifying information regarding the participant to ensure confidentiality.

In the example report provided as Figure 1:

Reported Value
The participant's result: Barium = 2092

Assigned Value
Per TNI requirements, assigned is derived from the formulation, and is analytically verified: Barium = 2160

Acceptance Limits
U.S. TNI upper and lower limits for acceptable perfomance evaluation based on the TNI regression equation effective when the report was created.* In the example report provided:

> Acceptance limits for Barium are set at the Mean +/- 3 SD where:
> Mean = a*T + b; SD = c*T + d; where T is the assigned value
> Barium: a = 0.9986, b = -0.6148, c = 0.0433, d = 0.0448
>
> *Note: the TNI FoPT table NPW_FOPT_2011_10_03 was in effect when the report used for this example was generated, the current FoPT table in effect as of the time of this writing, NPW_FOPT_eff_070113_rev2 reflects a fixed acceptance limit of +/- 15% for Barium.

Performance Evaluation
This provides an indication to the participant that the result is acceptable or not acceptable dependent on whether the reported value is within the range of the TNI acceptance Limits for this analyte. Analytes not reported by the laboratory for the proficiency test are evaluated as not Reported. In this example, the reported value for Barium of 2092 is within the calculated acceptance limits of 1880 – 2440

Method Description
The analytical reference method details provided by the laboratory

Analysis Date
The date when the analytical procedure was performed as reported by the laboratory

z-Score, Study Mean, Study Standard Deviation
The study mean and study standard deviation are calculated purely using original study data, excluding the reported value from the QuiK Response scheme. These specifically are calculated as robust, biweight mean and robust biweight standard deviation[4]. The participant's reported value is then

$$z = (x - X) / s$$

Where:

x = Laboratory's reported value (QuiK Response PT)
X = Robust biweight mean (Original PT)
s = Robust biweight standard deviation (Original PT)

Analyst name is the name of the analyst who performed the analysis as reported by the participant.

DISCUSSION

Performance evaluation for bilateral or supplemental PT is relatively straightforward in the United States due to the prevalence of prescribed fit-for-purpose criteria. Similar fit-for-purpose criteria prescribed in other jurisdictions when applied to this type of scheme may provide an equally straightforward performance evaluation for participants. Accreditation Bodies in Canada for example use regression in performance evaluation and while differences exist to those used in the U.S., evaluation of bilateral PT data is also straightforward using the appropriate regressions.

In jurisdictions where performance evaluation is based on data reported as part of the round the issue becomes more complex since only two participants are involved, the PT Provider and the laboratory.

IUPAC/CITAC Guide: Selection and use of proficiency testing schemes for a limited number of participants-chemical analytical laboratories provides examples of performance evaluation using a metrological approach[5] that may be useful however, many of the examples of evaluation provided in the guide to not demonstrate the extreme case of only 2 participants.

SUMMARY

In the example provided, the scheme utilizes unused samples from lots used as part of previously closed larger scheme rounds with larger participation, generally N > 30. The samples are analytically verified for continued stability of the assigned value through the close of the QuiK Response PT. Procedures are in place to ensure laboratories have had no prior knowledge or experience with the lot. This allows the QuiK Response participant to complete the PT in a very comparable manner to participants in the original simultaneous scheme round.

Since the previous scheme data has already been statistically analyzed, evaluation of the single bilateral PT participant result can be completed very quickly. Performance evaluation using a z-score incorporating the participant data and data reported as part of the orignal, closed scheme round provides one possibility for estimating accpetable or unacceptable performace quickly, when other forms of PT may not be feasible.

References

1. EA-EURALAB-EURACHEM Proficiency Testing Working Group. EA-03/04 Use of Proficiency Testing as a Tool for Accreditation in Testing, April 2001.
2. ISO/IEC 17043:2010(E) Conformity assessment—General requirements for proficiency testing, February, 2010
3. The NELAC Institute. EL-V3-Rev2.0 General Requirements for Environmental Proficiency Test Providers, 2009.
4. Kafadar, Karen. "A Biweight Approach to the One-Sample Problem," Journal of the American Statistical Association, Vol. 77, No. 378, June, 1982, pp. 416-424.
5. Kuselman, I., Fajgeli, A., IUPAC/CITAC Guide: Selection and use of proficiency testing schemes for a limited number of participants-chemical analytical laboratories (IUPAC Technical Report)*, Pure Appl. Chem., Vol. 82, No. 5, pp. 1099-1135, 2010

TO DOWNLOAD A COPY OF THIS POSTER, VISIT WWW.WATERS.COM/POSTERS