PERFORMANCE EVALUATION CRITERIA

Confirmatory and screening analyses:

In confirmatory analysis, the compounds are separated by chromatographic techniques (GC, HPLC, UPLC, LC...); afterwards they are detected by MS, FLD, DAD, etc...
In screening analysis, participants use techniques as ELISA, RIA, lateral flow, microbiological assay, etc...

The Assigned Value x_{pt}:

The Assigned Value x_{pt}, is the value attributed to a particular property of proficiency test items (definition from ISO13528:2016).
In the routine, the results from the confirmatory analysis (chromatographic techniques) are considered a reference; they are used with legal purpose (as regulatory requirement).
Instead, screening methods have the purpose to analyze in a short time a wide quantity of samples; in case of "positive" results, the data will be verified through the use of chromatographic techniques.
Because of above described, the Assigned Value x_{pt} derives just from participants' quantitative results obtained with confirmatory analysis. The screening results are compared to the Assigned Value x_{pt} obtained from the confirmatory data.
The procedure for determining the Assigned Value x_{pt} is described below.
After excluding results that are identified as invalid the data population was checked for normality and for the presence of outliers by applying appropriate statistics and visual presentations. For both spiked and incurred test materials, x_{pt} represents the value of concentration obtained from Algorithm A (ISO 13528:2016) or from the median.
The chosen value is reported in the Final Report.
In case of "blank" test materials, the threshold above which the analyte should not be present is based on the capability of participants to determine the analyte. The statistical "mode" is chosen as the estimator.
Sometimes very low concentrations are quantified. When it occurs, the concentration value is assigned only if proper statistics are applicable.
The value is not assigned when $p < 8$, where "p" is the number of data after invalid results rejection. In case of $8 \leq p < 15$ the uncertainty attributable to Assigned Value is not negligible.

z-score and σ_{pt} (standard deviation for proficiency assessment):

For quantitative data (confirmatory and screening), the participant's result is converted into a z-score according to the equation:

$$z\text{-score} = (x_i - x_{pt}) / \sigma_{pt}$$

where:
x_i is the analyte concentration value reported by the laboratory;
x_{pt} is the assigned value (obtained with confirmatory methods);
σ_{pt} is the standard deviation for proficiency assessment calculated from $b * x_{pt}$.

b = %RSD / 100, (RSD = Relative Standard Deviation) the %RSD value comes from the Horwitz equation (Horwitz, W., 1988, Pure Appl. Chem. 60, 855-864)

$$(1-0.5 \log X_{pt})\ \%RSD = 2$$

where x_{pt} is expressed as a dimensionless concentration.

σ_{pt} is related to the concentration of the analyte: it comes from Horwitz equation (unless otherwise specified); in case of contamination less than 10 ppb the Thompson equation modified Horwitz equation (Thompson, M., 2000, Analyst 125, 385-386).

In particular circumstance σ_{pt} is chosen from Proficiency Test provider's (PTp) experience, derived from previous rounds. The adopted criteria is reported in the Final report.
The laboratory performance evaluation is established taking into account the following criteria for z-score:
when $|z| \leq 2$ acceptable (satisfactory)
when $2 < |z| \leq 3$ warning signal (questionable)
when $|z| > 3$ action signal (unsatisfactory)

Screening assessment
Participants who use screening methods, have to provide qualitative answer (detected/not detected). If they are able, they have to indicate in addition "less than..." or "greater than...".
The results are classified as "satisfactory" in the following cases:
The laboratory detects the analyte or the group of analytes that are effectively present in the test material.
The laboratory does not detect the analyte or the group of analytes that are not effectively present in the sample.
The results are classified as "unsatisfactory" in the following case:
The laboratory does not detect the analyte or the group of analytes that is/are effectively present in the sample, but according to the method specifications the analyte/analytes is/are detectable. It means that a false negative has been reported.
The results are classified as "questionable" in the following case:
The laboratory detects an analyte or a group of analytes that were not effectively present in the sample. It means that false positive has been detected. The false positive results are not considered unsuitable, because routine screening positive results should be confirmed by chromatographic methods.
The results are classified as "congruent" in the following case:
The laboratory does not detect the analyte that is effectively present, because his method does not allow it. This is an information concerning the capability of the method. The participant should take in consideration if his method has the appropriate capability in respect his requirement.
The results are not classified, therefore "not applicable" in the following case:
The laboratory detects the analyte or a group of analytes that were not effectively present in the sample, but the level detected is lower than declared value. In this case it is not possible to evaluate its results.
The laboratory does not detect the analyte that is effectively present, but his capability corresponds exactly to the assigne value.

Because of the different country legislations, the regulatory limits are not considered in the results evaluation.

Example of evaluation.

TEST MATERIAL CONTAMINATION	RESULT (PROVIDED BY PARTICIPANT)	EVALUATION	Z-SCORE
Contamined material (the analyte is present above or below the regulatory limit) Assigned Value X_{pt} = 6 ppb (from confirmatory methods)	detected	satisfactory	not provided
	detected = 5 ppb or detected = 7 ppb	satisfactory	provided
	detected > 5 ppb or detected > 7 ppb	satisfactory	not provided
	not detected	unsatisfactory	not provided
	not detected < 5 ppb	unsatisfactory	not provided
	not detected < 7 ppb	congruent	not provided
	not detected < 6 ppb	not applicable	not provided
Blank material Value < 6 ppb (from confirmatory methods)	not detected	satisfactory	not provided
	not detected < 7ppb or not detected < 5ppb	satisfactory	not provided
	detected	questionable	not provided
	detected > 5 ppb or detected > 7ppb	questionable	not provided
	detected =6ppb or detected = 7ppb	questionable	not provided
	detected = 5 ppb	not applicable	not provided