

TNI PT Board Acceptance Limits SOP, TNI SOP #4-001
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TNI Standard Operating Procedure



STANDARD OPERATING PROCEDURE (SOP)
Recommendation of Acceptance Limits for the Chemical, Radiochemical, and
Microbiological Components of Proficiency Tests

DOCUMENT
Calculation of Acceptance Limits for Chemical, Radiochemical, and
Microbiological Components of Proficiency Tests

SOP #4-001
Revision 3.0

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1.0 Purpose and Applicability – This SOP provides procedures for calculation of acceptance limits for the Chemical, Radiochemical, and Microbiological components of Proficiency Testing and the procedure for recommendation of those limits. These procedures apply to all proposed FOPTs and FOPTs currently in the FOPT tables.

2.0 Procedure for Recommendation of Acceptance Limits for the Chemical, Radiochemical, and Microbiological Components of Proficiency Tests

These steps are followed for all analytes by the PT Board in the statistical review of PT sample acceptance limits:

2.1. For each Field of Proficiency Testing (FoPT), approved PT Providers (PTP's) submit data on relevant studies to the PT Board, or the TNI-designated PTOB/PTPA (Proficiency Testing Oversight Board / Proficiency Test Provider Accreditor), using a standard format. Ideally, this standard format is followed for every analyte scored in the PT Study, and the submittal occurs for each PT Provider's PT study.

The submitted data from the PTP's to the PTOB/PTPA, and subsequently from the PTOB/PTPA to the PT Board, are the following for each analyte in each regular PT Study: verified Assigned Value (AV), robust participant mean (PM), robust Standard Deviation (SD), lower and upper acceptance limits, number of participant laboratories (N), and the number of participant laboratories that failed the analyte in that Study.

The PTP raw data shall only be made available to an accreditation body (AB) member of the FoPT subcommittee or the TNI PT Board. This AB member shall sufficiently mask the data so as to not identify the PTPs or the dates of the PT studies, to preserve confidentiality of the PTPs and participant laboratories. Once the data has been masked, it can be submitted to the other members of the FoPT subcommittee.

2.2. The PT Board appoints TNI members to serve on the FoPT Subcommittee, and the PT Board requests volunteers on this Subcommittee to perform statistical analyses.

2.3. The volunteer(s) calculate regression equations according to the "Calculation of Acceptance Limits" (which is part of this SOP).

2.4. The analysis results are reviewed individually by the members on the appointed Fields of Proficiency Testing (FoPT) Subcommittee, and collectively in teleconference group discussions of the Subcommittee.

2.5. The FoPT Subcommittee considers relevant reporting limits by laboratories, typical laboratory test

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method Quality Control Limits, current rates of unacceptable results (Failure Rates), acceptance limits used for chemically similar analytes in the same Fields of Proficiency Testing (FoPT's), and the acceptance limits used for the same analyte in other Fields of Proficiency Testing .

2.6. Interested PTP's may conduct trial analysis of the impact of new FoPT's and new PT acceptance limits, and submit this information to the FoPT Subcommittee for their review.

2.7. Interested PTP's may also submit alternative recommendations for FoPT PT acceptance limits, regression models, coefficients a and b , or c and d , or fixed-limit acceptance criteria for the FoPT Subcommittee to consider. These limits could, for example, be based on alternative statistical analysis. The PTP Submitter must provide sufficient justification, and any necessary data, formulas, and calculations to enable the Subcommittee to follow the analysis scheme and understand how the alternative recommendations for PT acceptance limits are derived. The Subcommittee may request review of the impact of the proposed limits by other PTPs.

2.8. The FoPT Subcommittee recommends one or more of the following actions to the TNI PT Board, for each FoPT considered:

- no change to current PT acceptance limits as posted;
- revisions to the Proficiency Testing Reporting Limit (PTRL) and applicable concentration range for proficiency testing;
- use of the revised regression equations and coefficients as calculated (usually relative to the made-to Assigned Value for the PT Study, expressed with coefficients a , b , c , and d);
- use of the robust PT Study participant mean and calculated limits for standard deviation (i.e., coefficients c and d only);
- use of fixed acceptance limits about the Assigned Value or robust participant mean;
- use of the robust participant mean and a multiple of the robust standard deviation to determine the PT acceptance limits in each individual PT Study.

2.9. After all FoPT's have been considered, the FoPT Subcommittee makes a final review of the recommendations to be presented. The Subcommittee performs a formal vote and, if approved, forwards its recommendations and the supporting data to the TNI PT Board.

2.10. The TNI PT Board shall consider the recommendations presented from the FoPT Subcommittee. If any objections or other comments have been received from PTP's or other TNI members, the PT Board shall consider the merits of those objections and comments in conjunction with the FoPT Subcommittee's recommendations.

2.11. The PT Board shall conduct a formal vote on the FoPT Subcommittee's recommendations. A Full Quorum Vote requiring a two-thirds majority is required for the proposed motion(s) or action(s) to be adopted. The voting outcomes will be:

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- to accept and approve the FoPT Subcommittee's recommendations for the PT sample acceptance limits,
- to refer the FoPT acceptance criteria back to the FoPT Subcommittee for further review, along with any available reasons or supporting documentation to justify the further review,
- to reject the recommended acceptance limits and to keep the current acceptance limits and status of the FoPT's.

The voting outcomes can apply to all FoPT recommendations as a whole, or the voting outcomes may be split so as to apply to individual FoPT's (i.e., some FoPT recommendations approved while other FoPT recommendations are referred back to the Subcommittee).

2.12. The PT Board's recommendations on FoPT PT acceptance criteria shall be submitted to the TNI NELAP Board for final concurrence and ratification.

2.13. After ratification by the NELAP Board, the revised acceptance limits shall be posted on the TNI website. Once posted, the TNI approved PTP's shall revise all PT samples to conform with the revised acceptance criteria within the timeframes specified by the PT Board. The PT board should set these timetables to be as expedient and reasonable as possible, after consultation with the approved PTP's and with Accreditation Bodies.

2.14. Once recommendations have been made and approved by the PT Board and the NELAP Board, any interested party may appeal a proposed or approved acceptance limit. This appeal should be based on the adequacy of the evaluation interval (analyte concentration ranges), problems associated with manufacturing a PT sample at the proposed concentrations, or undue penalties (possible increase in failure rates) for groups of laboratories. The appeal should not be based solely on the statistical process used to determine the limits, although the PT Board will make every attempt to address such appeals. All appeals must be supported by valid confirmatory data, and an alternative acceptance limit(s), course of action, or remedy should be suggested.

2.15. Records shall be kept of all deliberations and determinations of the PT acceptance limits and any subsequent revisions. These records should be stored at The NELAC Institute's organizational headquarters and shall be available to any interested TNI member in good standing. To be as clear and understandable as possible, the records should include, at a minimum, the following:

- The PT raw data that was used for the evaluations.
- The outlier classification and rationale for any PT data that was not used in the evaluations of the acceptance limits.
- Any departures, authorizations, and rationale for setting PT acceptance limits with procedures that

were not in accordance with the Guidelines given in this SOP.

- The conclusions of any considerations made of the new PT acceptance limits with expected laboratory method quality characteristics, applicable concentration ranges of environmental relevance, and any changes in laboratory failure rates that would have occurred if the new limits were used in place of the old PT acceptance limits.
- The resultant PT acceptance criteria that should be used.

3.0 Calculation of Acceptance Limits for Chemical and Radiochemical Components of Proficiency Tests

The underlying assumptions for these calculations are that laboratory measurements for analyte concentrations follow a normal (Gaussian) distribution. If other distributions are shown to be more applicable to the PT data, then data treatment with means and standard deviations as described in this section may not be statistically applicable.

The linear regression model was used by US EPA for determining acceptance limits prior to externalizing the PT program and is used by many environmental laboratories in calibrating test equipment. If higher-order regressions, segmented regressions, or other models are used, then acceptance criteria based on correlation coefficients and statistical outlier removals based on standard errors of the estimate may not be applicable.

Exceptions do exist for some Fields of Proficiency Testing such as pH and Ignitability, where PT acceptance limits may be set based on fixed limits and not as described below.

For those fields of proficiency testing that have acceptance limits specified in US EPA regulations, the acceptance limits used by the TNI program shall not be wider than the US EPA limits.

A. For each data set of summary results for a particular analyte (or FoPT), perform the following steps to remove obviously erroneous data (this is done any time that participant data are to be used to determine means and/or SD's, or to check the validity of fixed limits):

- 1) Display original data from lowest Assigned Value to highest Assigned Value, listing AV, PM, MR, RSD and N.
- 2) Review the data set for anomalies and PT Provider reporting errors. Remove all sets with $N < 10$. Review apparent outliers in MR and RSD in the ordered list. Flag, at a minimum, sets where the $MR < 10\%$ or the $MR > 200\%$. Also, flag data sets where the $RSD > 50\%$. If the majority of data sets contain $RSD > 50\%$, there is no need to flag these data.

NOTE: typical PTP errors and anomalies may include reporting incorrect concentration units,

significant figures, analyte names and/or incomplete data;

- i. Contact PTP's to resolve all errors and anomalies;
- ii. Record the reasons for all data set removal;
- iii. Retain all data sets that can't be justified for removal, and that do not exceed the above limits.

3) Display graphically the AV (horizontal, x axis) and MR (vertical, y axis). Look again for obvious outliers. Reconcile any errors and anomalies with the appropriate PTP, and retain all sets where the apparent problems cannot be adequately explained. Record a reason for all data sets that are removed and not considered for the subsequent data analyses.

B. If the PT acceptance limits for the analyte are to be determined assuming 100% recovery (relative to the made-to Assigned Value), then perform step 4 and skip to step 7. Effectively, $a = 1.00$ and $b = 0.00$

If the PT acceptance limits are to be set based on participant results used to calculate a consensus target value (robust mean), then it is advisable to perform the graphical analysis in step 4, then skip to step 7 and substitute the term "PM" in place of all references for "AV." Effectively, a and b are not used, and c and d are evaluated with PM ("Study Mean") as the independent variable.

Otherwise, perform the following steps to establish the relationship between AV and PM:

- 4) Display graphically the AV (horizontal, x axis) vs. PM (vertical, y axis).
- 5) Perform linear regression analysis to determine slope a , Y-intercept b , the square of the correlation coefficient R^2 (Mean), and SER (standard error of regression).
- 6) Look for nonlinearity in the plot, since that is an indication of a need for segmented regression or a higher order regression model.

C. Perform the following steps to determine the relationship between AV and SD:

- 7) Display graphically the AV (horizontal, x axis) and SD (vertical, y axis).
- 8) Perform linear regression analysis to determine slope c , Y-intercept d , the square of the correlation coefficient R^2 (Standard Deviation), and SER.
- 9) Look for nonlinearity in the plot, since that is an indication of a need for segmented regression or a higher order regression model.

NOTE: If segmented regression is indicated, either in the regression of means vs. AV's or in

the regression of SD's vs. AV's, then break one or both datasets into two or more parts at a logical point(s) and proceed separately with the linear regression analyses independently, starting at step 4.

D. Perform the following steps to consider the adequacy of the resulting regression equation:

10) If R^2 (Mean) is ≥ 0.90 and R^2 (Standard Deviation) is ≥ 0.75 and there are more than 10 data points, then the regression is acceptable, pending further Subcommittee review (go to step 12).

NOTE: The acceptance criteria for these correlation coefficients were derived from the consensus of NELAC PT Board FoPT Subcommittee participants when the PT acceptance limits were last reviewed.

11) If there is poor correlation on regressions between the PM's and the AV's, or between the SD's and the AV's, then consider a re-analysis to set the PT acceptance limits based on the use of participant means and calculated limits for SD. See the second paragraph in Section B. Alternatively, proceed with step 12.

E. Perform the following steps to confirm the suitability of the derived PT acceptance limits:

12) Calculate the PT acceptance limits over the evaluation intervals (applicable concentration ranges) using *a*, *b*, *c*, *d*. Display graphically the derived acceptance limits (y axis) along with submitted evaluation intervals (x axis).

13) Check visually for "convergence" or points at the lowest ends of the concentration range where the acceptance limits cross. If this occurs, examine the data again for a need for segmented regression or for influential data-set points (high or low) that could influence the regression in a way that causes the convergence. Display graphically AV vs. PM, AV vs. SD, and AV vs. RSD, along with the regression lines to help determine such influential points.

NOTE: "Influential points" may lie at the opposite end of the testing range from where the convergence occurs, and are best identified with analysis of the "residuals", or differences between observed and expected points, based on the proposed linear regression equation. Points are best checked for "influence" by conducting the analysis with and without the point (or points) in question and determining the effect. There are several accepted statistical procedures for this, but for the purposes of these Guidelines the initial data censoring will be to reject data points outside +/- 2.0 SER for both the PM vs. AV regression and the SD vs. AV regression.

14) Check for single points far from the body of points, to see if the points belong in the same relationship as the others. For example, if the next highest concentration point is less than 70% of the highest concentration point along the x axis, the highest concentration point exerts a

disproportionate influence on the regression results. In such a case, a reduction in the concentration range (evaluation interval) by eliminating the highest concentration point may be needed.

15) If any influential points are removed for being distantly separated, or creating “convergence,” then eliminate those points by proceeding with the analysis beginning at step 17. Document the reason(s) for any data-point removals (e.g., +/- 2 SER to eliminate data convergence at the low end, + 1 SER to achieve acceptance criteria for the square of the correlation coefficient).

16) If no PT data points are removed based on the considerations and deliberations from steps 10-14, proceed to the subsequent analyses in step 24.

F. Continuation of the analysis:

17) Remove all values farther from the line than ± 2.0 SER for the regression of PM versus AV.

18) Rerun the linear regression of PM versus AV, obtaining new values for a , b , and R^2 (mean) and SER.

19) Remove all values farther from the line than ± 2.0 SER for the regression of SD versus AV.

20) Rerun the linear regression of SD versus AV, obtaining new values for c , d , R^2 (standard deviation), and SER.

G. Repeat the performance of steps 10-14 at this point to consider the adequacy of the resulting regression equations and to confirm the suitability of the derived PT acceptance limits. If such considerations and confirmations are deemed satisfactory, then proceed to step 24. Otherwise, perform step 15 (substituting “step 21” for “step 17” in the language of step 15 this time) and then proceed to the next level of data censoring as described below:

21) Display graphically the AV (horizontal, x axis) and SD (vertical, y axis) for all datasets remaining.

22) Remove all results more than 1.0 SER above the line.

23) Rerun the linear regressions for a final time, obtaining new values for a , b , and R^2 (mean) for the regression of PM versus AV (if needed) and c , d , and R^2 (standard deviation) for the regression of SD versus AV.

NOTE: Datasets removed when determining the relationship between AV and SD are also

removed for determining the relationship between AV and PM in the final regression.

H. Repeat the performance of steps 10-14 again at this point to consider the adequacy of the resulting regression equations and to confirm the suitability of the derived PT acceptance limits. If such considerations and confirmations are deemed satisfactory, then proceed to step 24. Otherwise, if the results are unsatisfactory, then one or more of the following may need to be implemented:

- Alternate statistical analyses, regression models, data distributions, and acceptance criteria need to be used.
- The PT acceptance limits for the FoPT should be recommended based on the robust participant mean and 2 or 3 robust standard deviations in each individual PT Study.
- The FoPT should not be recommended for inclusion or continuation in the TNI PT Program.

I. Perform the following steps to test for the possible use of fixed limits.

- 24) To test whether the AV can be used as a target value, examine whether a is between 0.95 and 1.05, and whether the absolute value of b is less than 5% of the lowest AV concentration being used (i.e., the lowest point in the evaluation interval).
- 25) To test for the use of fixed evaluation intervals, examine whether the absolute value of d is less than 5% of the lowest AV being used for the equation.
- 26) If a , b , and d meet the above criteria, then consider recommending that a fixed acceptance limit of AV $\pm c \cdot 2$ or $c \cdot 3$ for the FoPT, depending on which is the appropriate multiplier for that analyte/matrix. Fixed limits should be “rounded” to logical values (for example, 12.6% could be rounded to 10%, 12%, or 15%, depending on the Subcommittee’s judgment).

NOTE: IN ALL CASES, for the PT acceptance limit recommendation to be valid for a FoPT, the number of remaining PT Study data set points used for determining the acceptance limits, after outlier removals, must be at least 10.

J. Further analyses and considerations: Verify that the proposed PT acceptance limits are consistent with test method quality characteristics for accuracy that are routinely in use at environmental testing laboratories.

- 27) Calculate the PT acceptance limits over the evaluation intervals (applicable concentration ranges) using a , b , c , d . Display graphically the derived acceptance limits (y axis) along with submitted evaluation intervals (x axis).

28) Compare the PT acceptance limits for each FoPT with method quality control (QC) limits expected in environmental laboratories for the corresponding Field of Accreditation (FoA). QC limits will likely be derived from analyses of control standards and sample matrix spikes. Ideally, the PT acceptance limits over the evaluation intervals will be 25-50% wider than the corresponding QC limits, just as interlaboratory variation is likely to be wider than intralaboratory variation.

29) PT acceptance limits narrower than laboratory QC limits should prompt re-evaluation of the proposed PT acceptance limits. Check to see if the rejection of too many PT data points could have been responsible for this occurrence.

K. Consider the number of PT studies originally considered for this evaluation relative to the number of PT studies that remained for the final determination of the acceptance limits. If over 33% of the available PT interlaboratory data sets are rejected as outliers, then the Subcommittee must consider seriously the implications of rejecting so many data sets just to make correlation coefficients and acceptance limits achieve desired criteria. Reasons for outliers of all rejected PT studies should be documented, in case reconsiderations are necessary.

If necessary reconsider the criteria in sections 3.A.2) $n < 10$ and 3.I Note to consider the contingency of a small number of PT studies.

L. For each FoPT to be revised, calculate the PTRL as the AV – 2 or 3*SD. This value is the lower PT acceptance limit when the Assigned Value is at the lowest analyte concentration in the evaluation interval. If the PT acceptance limits are based on the PM, the PTRL may be set based on one-fifth or one-tenth the lowest analyte concentration in the evaluation interval.

Consider how this PTRL relates to method Limits of Quantitation (LoQ) expected in environmental laboratories for various analytical technologies that are in routine use. With the proper sample preparation and analysis regimen, laboratories accredited for a particular FoA should be able to achieve a LoQ below the PTRL for the corresponding FoPT (which uses the same analysis technology, such as GC/MS or ICP). Re-consideration of the PT acceptance limits may be necessary if some less-sensitive common laboratory technologies cannot achieve the proposed PTRL. Some technologies that could pose difficulties in this regard are FL-AA and UV-VIS.

M. Acceptance limits relative to applicable concentration ranges: After the PT acceptance limits are plotted according to step 27 above, consider the span of the acceptance limits between the lower limit and upper limit, relative to the analyte concentration range for the evaluation interval. As an example, to illustrate the problem, if the PT acceptance limits are 50-150% of assigned value and the concentration range is narrow, e.g., 100-200 ug/L, then the resultant PT provides no suitable challenge to laboratories. The laboratory conceivably could report 150 ug/L each PT study for the analyte and never fail it. Thus, for problematic analytes where the PT acceptance limits are wide, the evaluation

interval (concentration range) should be looked at critically to verify that any outlier data did not also truncate the concentration range that could have been used for the evaluation interval.

A suitable procedure to ensure suitable challenge to the laboratories is to take the logarithm of the ratio of the highest and the lowest concentrations in the evaluation interval, and divide that by the logarithm of the ratio of the upper to lower PT acceptance limits. If the ratio is greater than two, then the PT is suitable for achieving challenge to the participants. As an example, if the PT acceptance limits are 66.6 – 133% and the evaluation interval is 20-200 ug/L, then the calculation works out as:

$$\log (200/20) / \log (133/66.6) = 1.00 / 0.301 = 3.3 \text{ (suitable challenge)}$$

For the example in the first paragraph, the ratio is actually less than 1.0 (thus, useless as a PT).

N. Even though PT sample formulation is beyond the scope of this section, the volunteers should consider the resultant evaluation intervals (concentration ranges) and groupings of analytes to determine if the PT providers will likely be able to manufacture the PT sample of appropriate quality and meet the requirements for Homogeneity and Stability. Possible concerns include ketones in the presence of amines, carboxylic acids in the presence of alcohols, and target analyte degradations into other target analytes within the PT sample.

O. As indicated with all the considerations in this section, the recommendations for PT acceptance limits may not fulfill all the desired acceptance criteria. Compromises are made to achieve as many of the desired acceptance criteria as possible, for each FoPT. The appropriate balance needs to be documented carefully, as to which criteria were achieved and which criteria could not be met, among the following:

- At least 10 valid PT studies with at least 10 participant laboratories each study.
- R^2 (Mean) is ≥ 0.90 after linear regression of PM versus AV.
- R^2 (Standard Deviation) is ≥ 0.75 after linear regression of SD versus AV or SD versus PM.
- PT acceptance limits are consistent with laboratory control limits for test method accuracy.
- PTRL is consistent with the Limit of Quantitation for the analysis technology.
- PT acceptance limits relative to the evaluation interval (concentration range) result in a PT sample that provides suitable challenge to participants.
- PT providers will be able to formulate, produce, and distribute PT samples with the recommended acceptance limits.

4.0 Calculation of Acceptance Limits for Microbiological Components of Proficiency Tests

Qualitatively, the procedures for evaluating and calculating the acceptance limits for Microbiological components in PT samples follow the same procedure as for the Chemical and Radiochemical components. The important difference is that Colony-Forming Units (CFU's) or Most Probable Numbers (MPN's), per unit volume, are first converted to base-10 logarithms, since a log-normal

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statistical distribution usually occurs for Microbiological components.

After conversion to logarithms, the PT data for Microbiology studies can be evaluated using the same procedure as for Chemical and Radiochemical components. Great care should be exercised if a made-to Assigned Value can be made and the PT acceptance limits should include the coefficients a and b , where the robust participant log-mean is correlated with the logarithm of the Assigned Value. The PT Provider procedures for Verification of Assigned Values, Homogeneity studies, and Stability studies are more critical for Microbiological components over the normal 45-day course of the PT study.

Until sufficient PT data are available for each Microbiological component, the PT acceptance limits should be based on robust participant mean, plus or minus 2 or 3 standard deviations. The standard deviations can be calculated from coefficients c and d , or be the robust participant standard deviation, after all participant Microbiological results are converted to logarithms.

5.0 Definitions/Abbreviations:

AV: Assigned Value, also known as the prepared value, or “made-to” concentration.

MR: Mean Recovery, or the relative participant mean value, either robust or calculated after outlier removal ($PM/AV*100\%$)

N: Number of participant results used to determine PM and SD within a given PT study

PM: Participant Mean (mean of participant results, either robust or after outlier removal)

RSD: Percent Relative Standard Deviation ($SD/PM*100\%$)

PTB: TNI Proficiency Testing Board

R^2 : R-square, or the square of the correlation coefficient for the regression used

SD: Standard Deviation of participant results (robust or after outlier removal)

SER: Standard Error of the Regression

a : slope of the linear regression line for PM vs. AV

b : intercept of the linear regression line for PM vs. AV

c : slope of the linear regression line for AV (or PM) vs. SD

d : intercept of the linear regression line for AV (or PM) vs. SD

6.0 References

1. M Thompson, SLR Ellison, and R Wood, "The International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories," Pure Appl. Chem. Vol. 78, #1 (2006), pp.145-196.
2. ISO 13528, "Statistical Methods for Use in Proficiency Testing by Interlaboratory Comparisons," International Organization for Standardization (2005).
3. ISO/IEC 17043: Conformity assessment - General requirements for proficiency testing (2010)

7.0 SOP Approved Changes

Prev. SOP Revision	New SOP Revision	Date of change	Description of Change
Rev 1.0	Rev 2.0	6/18/09	<ul style="list-style-type: none"> -Added the language from Rev 0.1 regarding Experimental PTs back into the SOP -Added the Note in section I from Rev. 0.1 back into the SOP - Removed language regarding +/- 3 sd from the mean in section 3.H -Reformatted SOP based on TNI SOP 1-100 guidance -Added Scope and Application
Rev 2.0	Rev 3.0	10/15/09	<ul style="list-style-type: none"> - Removed references to the terms "guidance" and "guidelines" - Deleted references to Experimental PTs - Revised Note in section 3.I to remove reference to NELAC standard. - Further clarified the masking process in paragraph 3 of section 2.1 - Added language regarding chemically similar analytes to section 2.5 - Set N<10 in section 3.A.2 - In section 6, added reference to ISO/IEC 17043 and removed reference to ILAC-G13:2007 -Added paragraph 2 to section 3.K

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