2016

AFRAC GUIDELINES ON THE METHOD FOR STATING TEST AND CALIBRATION RESULTS

AFRICAN ACCREDITATION COOPERATION

This document gives guidelines on the method for stating test and calibration results and compliance with specifications, and is based on ILAC-G8 2009.

Publication reference: TP003-01

Authorship

This document was prepared by the AFRAC Technical Committee.

Classification

This document is classified as an AFRAC Technical Publication.

Authorisation

Issue Number:	01
Prepared by:	AFRAC Technical Committee
Date:	15 July 2016
Approved by:	Executive Committee
Issue and application date:	5 December 2016

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Copyright

The copyright of this text is held by AFRAC and the text may not be copied for resale.

Further information

For further information about this publication, contact the AFRAC Secretariat on:

AFRAC Secretariat
Private Bag X23
Sunnyside
Pretoria
0132
South Africa
Tel: +27 12 394 3793
Email: yolandav@sanas.co.za

CONTENTS

1. PURPOSE 4
2. STATEMENT OF COMPLIANCE ACCORDING TO ISO/IEC 17025 4
3. METHOD OF STATING TEST AND CALIBRATION RESULTS AND COMPLIANCE WITH SPECIFICATION 4
4. ASSESSMENT AND REPORTING OF COMPLIANCE WITH SPECIFICATION 7
5. REFERENCES 10

APPENDIX A: AMENDMENT RECORD 11

1. PURPOSE

The purpose of this document is to provide guidelines on the method for stating Test and Calibration results and compliance with specifications. This document is based on ILAC-G8 03/2009 “Guidelines on the reporting of compliance with specification”.

2. STATEMENT OF COMPLIANCE ACCORDING TO ISO/IEC 17025

2.1. For testing laboratories, ISO/IEC 17025:2005 (clause 5.10.3.1 b) requires that “the test report shall, where necessary for the interpretation of the test results include, where relevant, a statement of compliance/non-compliance specification”.

2.2. For calibration laboratories, ISO/IEC 17025:2005 (clause 5.10.4.2) requires that “if a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met”. It is permissible to omit the measurement results and its uncertainty from the report as long as they are retained for possible future reference.

3. METHOD OF STATING TEST AND CALIBRATION RESULTS AND COMPLIANCE WITH SPECIFICATION

3.1. General Approach

3.1.1. The extent of the information given when reporting a test or calibration result and its uncertainty should be related to the requirements of the client, the specification, and the intended use of the result. The methods used to calculate the result and, where appropriate, its uncertainty should be available either in the report or in the records of the test or calibration and should include:

- sufficient documentation of the steps and calculations in the data analysis to enable a repeat of the calculation if necessary;
- all corrections and constants used in the analysis, and their sources; and
- sufficient documentation to show how the uncertainty is calculated.

3.1.2. When reporting the test or calibration result and its uncertainty, the use of excessive numbers of digits should be avoided. In most cases the uncertainty should be expressed to no more than two significant figures (although at least one more figure should be used during the stages of estimation and combination of component uncertainties in order to minimise rounding errors).

3.1.3. There are two different types of test or calibration results:

- measured numerical values; and
- non-numerical results, e.g. pass-fail outcome of a test procedure or the result of applying a go or no-go gauge.

For the first type, the results and measurement uncertainty, where appropriate, should be reported in accordance with clause 3.1.4. For the second type, the results and any factors affecting the validity of the result should be reported in accordance with clause 3.1.5.

3.1.4. Numerical results:

Where the measurement uncertainty is relevant to the validity or application of the results, when a client's instructions require so, or when the uncertainty affects compliance with a specification limit, the expanded measurement uncertainty appropriate to approximately a 95% level of confidence should be calculated. The numerical result and its expanded uncertainty should be reported in the following manner:

- Measured value 100.1 (units).
- Uncertainty of measurement ± 0.1 (units).
- Level of confidence 95%.

Notes:

- *Where appropriate, the coverage factor should also be reported.*
- *More information on reporting measurement results and uncertainty is given in Chapter 7 of the "Guide to the Expression of Uncertainty in Measurement". (See No. 4 in Reference list, page 7 below).*

The method of assessing and reporting compliance with a specification should be in accordance with section 4 below.

3.1.5. Non-numerical results

Where the method is unambiguously defined in the test or calibration criteria, test or calibration specifications, client specifications or codes of practice, and, in the absence of any client instruction to do otherwise, it can be assumed that the measurement uncertainty has already been taken into consideration in the method and the laboratory does not need to estimate it. (This may be considered as a special case of shared risk, as discussed in clauses 4.3 and 4.4 of this document.) In this case, reporting the non-numerical result alone is adequate.

Where deviations from the specified method are necessary, the laboratory should evaluate the extent to which the test validity is affected. In this case, details of the deviations from the specified method and their effects on the validity of the result should be recorded and reported.

Note: The measurement method is considered unambiguously defined if the measurement method, the measurement instruments and their accuracy, the measurement environmental conditions and any other factors affecting the result are specified.

For non-numerical results, compliance with a specification can be deduced readily from the result in most cases. For example, it may be concluded that the diameter of a hole is in compliance as it allows the insertion of the go gauge but not the no-go gauge. A statement of compliance should be included in the report.

Where the conclusion of compliance depends on both numerical and non-numerical results, a combination of the approaches discussed in clauses 3.1.4 and 3.1.5 of this document should be taken.

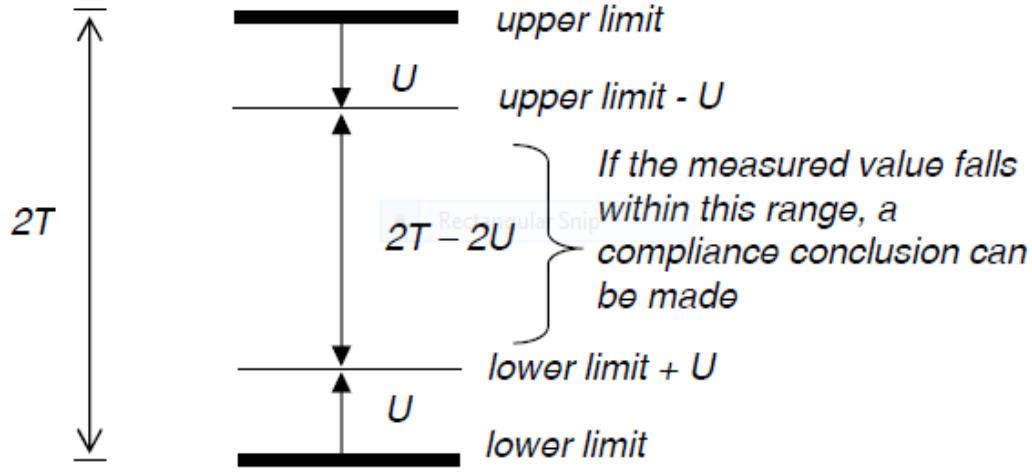
3.1.6. When a specification describes an interval with an upper and lower limit, the ratio of the uncertainty of measurement to the specified interval should be reasonably small.

Notes:

- *For an uncertainty of measurement U and a specified interval 2T,* where *T* = upper limit – lower limit/2*, the ratio U: T is a measure of the ability of the measurement method in distinguishing compliance from non-compliance.*
- *As explained in Chart 1, a conclusion of compliance can be made for any measured value falling within the range from [lower limit + U] to [upper limit - U]. If U:T is 1:3, the interval between the [lower limit + U] and the [upper limit U] will be 66.7% of the interval 2T. In such a case, if the value is measured to be within the specified interval, there will be a 66.7% probability that a conclusion of compliance* ***c****an be made. A ratio of 1:3 can thus be considered as a reference value.*

CHART 1

Ability to Distinguish Compliance from Non-compliance



U = uncertainty of measurement

$$T = \frac{\text{upper limit} - \text{lower limit}}{2}$$

Assume $U : T$ is $1 : 3$ or $U = \frac{1}{3}T$

Then $2T - 2U = 2T - 2\times\frac{1}{3}T$

$$= 2\times\frac{2}{3}T$$

or 66.7% of $2T$

- *If compliance with a specification is determined in accordance with clause 4.5 of this document, a larger U:T ratio can be tolerated. However, it should be noted that, as this ratio is an indicator of the capability of the measurement method to distinguish compliance from non-compliance, a measurement method having a U:T ratio approaching unity will be unable to confirm compliance nor non-compliance for samples having marginal properties.*

3.1.7. When the property of a batch of product or material is assessed by testing samples taken from it, details of the sampling scheme, the sampling procedure, the number of samples tested and how the reported measured value is related to the measured values obtained from individual samples (e.g. by averaging sample results) should be included in the report.

3.2. Special Cases

3.2.1. In exceptional cases, where a particular factor or factors can influence the results but where the magnitude cannot be either measured or reasonably assessed, the reported statement will need to include reference to that fact.

3.2.2. Any uncertainty that results from the test sample not being fully representative of the single unit of product should normally be identified separately in the evaluation of uncertainty.

However, there may be insufficient information to enable this to be done, in which case this should be stated in the report.

A possible remark could be:

"The test results in this report relate only to the test sample as analysed and not to the single unit of product from which the test sample was drawn."

4. ASSESSMENT AND REPORTING OF COMPLIANCE WITH SPECIFICATION

4.1 In harmony with 5.10.3.1 (c) of ISO/IEC 17025:2005, these guidelines require that, when a test is carried out to a stated specification and the client or the specification requires a statement of compliance, the report must contain a statement indicating whether the test results show compliance with that specification. There are a number of possible cases where the uncertainty has an influence on the compliance statement, and these are examined below.

4.2 The simplest case is where the specification clearly states that the test result, extended by the uncertainty at a given level of confidence, shall not fall outside or within a defined specification limit or limits. In these cases, (Case 1, 5, 6 and 10 of Appendix A below), assessment of (non) compliance would be straightforward.

4.3 More often, the specification requires a statement of compliance in the certificate or report but makes no reference to taking into account the effect of uncertainty on the assessment of compliance. In such cases it may be appropriate for the user to make a judgement of compliance, based on whether the test result is within the specified limits with no account taken of the uncertainty.

For example, if the measured result for the diameter of a rod is 0.50 mm while the specification limit is between 0.45 mm to 0.55 mm, the user may conclude that the rod meets the requirement without considering the measurement uncertainty.

This is often referred to as shared risk since the end-user takes some of the risk that the product may not meet the specification after being tested with an agreed measurement method. In this case there is an implicit assumption that the uncertainty of the agreed measurement method is acceptable and it is important that it can be evaluated when necessary. National regulations can overrule the shared risk principle and can put the uncertainty risk on one party.

4.4 An agreement between the client and the laboratory or a code of practice or a specification may state that the accuracy of the method applied is adequate and the uncertainty does not need to be considered explicitly when judging compliance. Similar considerations as for shared risk (above) apply in such circumstances.

4.5 In the absence of any criteria, test specifications, client's requirements, agreements, or codes of practice, the following approach may be taken:

a) if the specification limits are not breached by the test result, extended by half of the expanded uncertainty interval at a level of confidence of 95%, then compliance with the specification can be stated (Cases 1 and 6 of Appendix A below);
b) where an upper specification limit is exceeded by the test result, even after it has been extended downwards by half of the expanded uncertainty interval, then non-compliance with the specification can be stated (Case 5 of **Appendix A** below);
c) if a lower specification limit is breached, even when the test result is extended upwards by half of the expanded uncertainty interval, then non-compliance with the specification can be stated (Case 10 of **Appendix A** below);
d) if the measured single value, without the possibility of testing more samples from the same unit of product nor repeating the measurement, falls sufficiently close to a specification limit so that half of the expanded uncertainty interval overlaps the limit, it is not possible to

confirm compliance or non-compliance at the stated level of confidence. The result and expanded uncertainty should be reported together with a statement indicating that neither compliance nor non-compliance was demonstrated. A suitable statement to cover these situations (Cases 2,4, 7 and 9 of **Appendix A** below) would be, for example:

"The test result is above (below) the specification limit by a margin less than the measurement uncertainty; it is therefore not possible to state compliance/non-compliance based on a 95% level of confidence. However, where a confidence level of less than 95% is acceptable, a compliance/non-compliance statement may be possible".

If the law requires a decision concerning rejection or approval, case 2 and 7 of **Appendix A** below can be stated as compliance with the specification limit (with a lower calculated and reported confidence level). In Cases 4 and 9 of **Appendix A** below, non-compliance with the specification limit can be stated (with a lower calculated and reported confidence level).

If two or more samples of a single unit of product can be tested or the measurement can be repeated, replicate testing or making more repeated measurements is advisable. After estimating the average value for all test results on the same samples or results of all repeated measurements and the new uncertainty for this average value, the same judgement as described in 4.5 (a) – (d) above should be made.

Note: For 4.5(a) to (d) are based on the assumption that uncertainty distribution curve for the measured value is symmetrical above the average value. In certain cases, this may not be true, e.g. when a significant correction to a measured value is not corrected but considered as a contribution to uncertainty, or when a dominant uncertainty component known to have skew distribution is combined with other uncertainty component as though it is normally distributed. In such case, a more accurate calculation for the measured value and the measurement uncertainty may allow the making of an unambiguous conclusion.

e) If the result is exactly on the specification limit, it is not possible to state compliance or non compliance at the stated level of confidence. The result and expanded uncertainty should be reported together with a statement indicating that neither compliance nor non-compliance was demonstrated at the stated level of confidence.

A suitable statement to cover these situations (Cases 3 and 8 of **Appendix A** below) would be, for example:

"The test result is equal to the specification limit; it is therefore not possible to state either compliance or non-compliance at any level of confidence".

If the law requires a statement concerning the assessment in the form of compliance or non-compliance, regardless of the level of confidence, taking into account the provision of clause 4.3, the statement depends on the definition of the specifications:

- if the specification limit is defined as "<" or ">", and the test result is equal to the specification limit, non-compliance can be stated.
- if the specification limit is defined as "<" or ">", and the test result is equal to the specification limit, then compliance can be stated. If possible, it is also advisable to repeat the testing or measurement as explained in the last paragraph of 4.5(d) above.

APPENDIX A

Case 1

The measured result is under the upper limit, even when extended upwards by half of the uncertainty interval.

The product therefore complies with the specification.

Case 2

The measured result is below the upper limit, but by a margin less than half of the uncertainty interval; it is therefore not possible to state compliance.

However, where a confidence level of less than 95% is acceptable, a compliance statement may be possible.

Case 3

The measured result is on the limit itself; it is therefore not possible to state compliance nor non-compliance at any significant level of confidence.

However, where a decision must be made regardless of the level of confidence and the requirement is: measured result ≤ the upper limit, a compliance statement may be possible. When the requirement is : measured value < the upper limit, a non-compliance statement may be possible.

Case 4

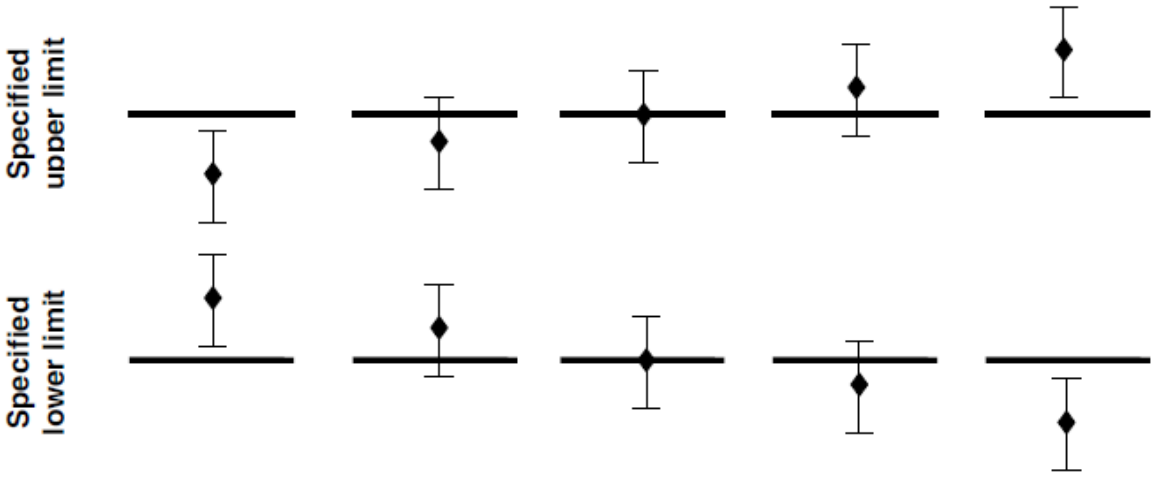
The measured result is above the upper limit, but by a margin less than half of the uncertainty interval; it is therefore not possible to state non-compliance.

However, where a confidence level of less than 95% is acceptable, a non-compliance statement may be possible.

Case 5

The measured result is beyond the upper limit, even when extended downwards by half of the uncertainty interval.

The product therefore does not comply with the specification.



Case 6

The measured result is above the lower limit, even when extended downwards by the half of the uncertainty interval.

The product therefore complies with the specification.

Case 7

The measured result is above the lower limit, but by a margin less than half of the uncertainty interval; it is therefore not possible to state compliance.

However, where a confidence level of less than 95% is acceptable, a compliance statement may be possible.

Case 8

The measured result is on the limit itself; it is therefore not possible to state compliance nor non-compliance at any significant level of confidence.

However, where a decision must be made regardless of the level of confidence and the requirement is: measured result ≥ lower limit, a compliance statement may be possible. When the requirement is: measured result > lower limit, a non-compliance statement may be possible.

Case 9

The measured result is below the lower limit, but by a margin less than half of the uncertainty interval; it is therefore not possible to state non-compliance.

However, where a confidence level of less than 95% is acceptable, a non-compliance statement may be possible.

Case 10

The measured result is beyond the lower limit, even when extended upwards by half of the uncertainty interval.

The product therefore does not comply with the specification.

♦ = measurement result with agreed method

I = uncertainty interval of agreed method

5. REFERENCES

1. LAB 12 (2000), *The Expression of Uncertainties in Testing,* UKAS, UK;

2. NF E 02-204, *Verification des tolerances des produits, Declaration de conformité,* December 1993, AFNOR, Paris, France;

3. ISO/DIS 14253 – 1: 1998 Geometrical Product Specifications (GPS) – Inspection by measurement of workpieces and measuring equipment – Part 1: Decision rules for proving conformance or noncomformance with specifications; International Organisation for Standardization, Geneva, Switzerland;

4. BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, *Guide to the Expression of Uncertainty in Measurement*. International Organisation for Standardization, Geneva, Switzerland, ISBN 92-67-10188-9, First Edition, 1993;

5. ISO 3534 Part 1, *Probability and General Statistical Terms - 1993, Statistics - Vocabulary and symbols,* International Organisation for Standardization, Geneva, Switzerland;

6. VIM, ISO (1993), *International Vocabulary of Basic and General Terms in Metrology,* International Organisation for Standardization, Geneva, Switzerland, ISBN 92-67-01075, Second Edition;

7. ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*, International Organisation for Standardization, Geneva, Switzerland; and

8. ILAC-G8:03/2009, Guideline on Assessment and Reporting of Compliance with Specification, International Laboratory Accreditation Cooperation.

APPENDIX A: AMENDMENT RECORD

Proposed by	Section	Change