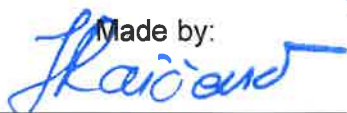
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INSTRUCTION ON COMPLIANCE WITH THE ASPECT OF DECISION RULES

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1. SUBJECT AND FIELD OF APPLICATION

The goal of the instruction is to define the decision-making rule for accredited methods in the Institut Sigurnost with defined documents and reporting method as specified in the procedure of this instruction. The use of instructions and the use of decision rules reduces the possibility of making a wrong decision about compliance when making a decision.

A decision rule that describes how measurement uncertainty will be taken into account when writing a Declaration of Conformity to the relevant regulations, standards or specifications and is written in accordance with the international manual ILAC-G8:09/2019.

2. CONNECTIONS WITH OTHER DOCUMENTS

- Procedure for nonconformance management PR. 710.01
- Procedure about the work of the laboratory PR. 721.01
- Procedure for corrective measures PR.871.01
- [1] MEST EN ISO/IEC 17025:2018(General requirements for the competence of testing laboratories and calibration laboratories - (clause 7.8.3 Specific requirements for test reports; clause 7.8.6. Reporting in relation to the declaration of conformity)
- [2] ILAC - G8:03/2009 Guidelines on the reporting of compliance with Specification;
- [3] ILAC - G8:09/2019 Guidelines on Decision Rules and Statements of Conformity;
- General business rules of the Institut Sigurnost in the domain of providing laboratory testing services (Quality Policy PO. 824.01)

3. DEFINITIONS

Decision rule: a rule that describes how measurement uncertainty is taken into account when declaring compliance with a requirement specification. [3]

Measurement uncertainty: an estimate of the appropriate measurement characterized by the range of values within which the exact value lies. It is a quantitative assessment of the limits within which the exact value of the measured quantity is found. [3]

Extended measurement uncertainty (U_k): defines the interval around the result of a measurement that can be attributed to the measured value. The reason for calculating the expanded measurement uncertainty is to achieve a high enough confidence (approximately 95%) that the true value lies within the interval of a certain result of that measurement y ($y \pm U_k$). The expanded measurement uncertainty is the product of the combined standard uncertainty and coverage factor ($k=2$). [3]

Acceptance zone: a set of characteristic values for a certain measurement process and a decision rule, which results in granting compliance when the measurement result is within that zone. [3]

Rejection zone: a set of characteristic values for a certain measurement process and decision rule, which results in giving a non-conformity when the measurement result is within that zone. [3]

Guard band (ω): magnitude size from the specification limit to the limit of the acceptance zone or rejection zone [3]

4. DECISION RULE

During testing, the laboratory takes into account the level of risk (estimated measurement uncertainty) and, depending on the obtained result, applies a decision rule. Depending on the subject of the test and the tested parameter, the Laboratory takes into account the estimated measurement uncertainty or part of it when deciding on compliance.

By comparing the test results with the associated measurement uncertainty with the limit, i.e. the interval (lower and upper limit), we distinguish 4 cases shown in the figure 1.

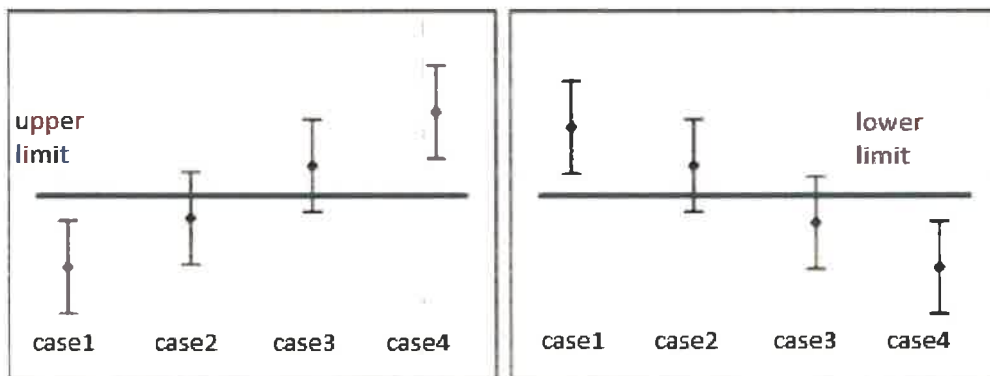


Figure 1: Compliance with the specification for upper and lower limits [2]

The declaration of conformity is given in two ways, as a binary way of deciding on conformity, where the object of examination can be in conformity or non-conformity with the relevant rules, standards or specifications, that is, a non-binary way of deciding on conformity where there are 4 possible cases of conformity.

In order to evaluate the results in cases 2 and 3 shown in Figure 1, it is necessary to apply the **Decision Rule**.

In the case of obtained limit values of test results, the laboratory assumes the level of risk and gives a result at a confidence level below 95% in relation to the limits of the calculated measurement uncertainty.

Rule 1: Rule of simple acceptance - "joint risk" ($\omega = 0$)

When the protective band is equal to zero, it is concluded that the result is acceptable when it is below the permissible limit (Figure 2).

When simply accepting, the user agrees that the "Accept / Reject" decision is based on the acceptance limits selected based on this rule. In this case, the risk of accepting measurement results outside the permitted tolerance limit is up to 50%, i.e. the risk of false rejection is up to 50% for measurement results outside the tolerance limit.

The declaration of conformity for Rule 1 is given in the attachment: Method of deciding on conformity and wording of the text of the declaration of conformity (Annex 1).

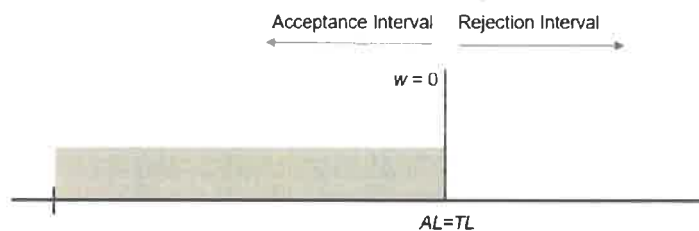


Figure 2: Rule of Simple Acceptance

Rule 2: The rule of safe rejection of test results

Using a seat belt reduces the possibility of making a wrong decision about compliance. It is actually a safety factor built into the measurement decision making process by reducing the acceptance limit below the specification / tolerance limit.

By increasing the tolerance zone with a protective belt, the rule of safe rejection of results minimizes the user's risk.

The rule of safe rejection of the results implies comparing the measurement results with the limits of the acceptance zone, which represents:

If there is a specification interval, the specification interval is increased by a buffer (Figure 3).



Figure 3: Display of acceptance and rejection zones for the normalized safe rejection interval

If there is an upper limit of the specification, the upper limit of the specification increased by a protective band (Figure 4).

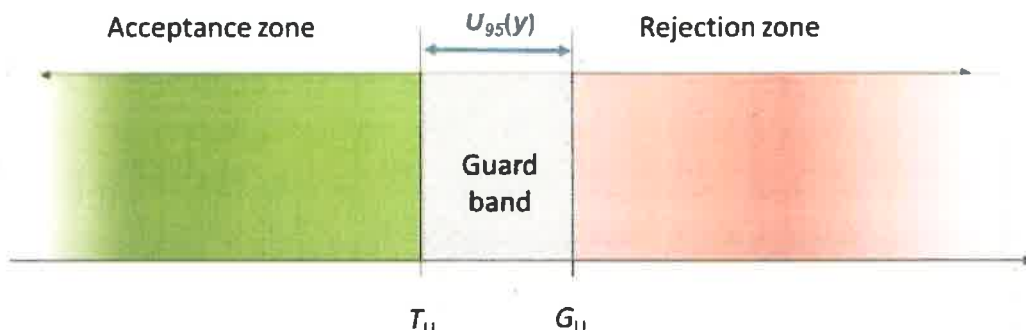


Figure 4: Display of acceptance and rejection zones for upper limit and safe rejection

In the case of the existence of a lower limit of the specification, the lower limit of the specification reduced by a protective band, where the protective band ω is equal to the expanded measurement uncertainty U_k ($\omega = U_k$). The measured value must be within the acceptance zone, otherwise the result is inconsistent.

The declaration of conformity for Rule 2 is given in the attachment: Method of deciding on conformity and wording of the text of the declaration of conformity (Annex 1).

Rule 3: Rule of Safe Acceptance of Test Results

If there is a specification interval, the specification interval is reduced by a protective belt (Figure 5).

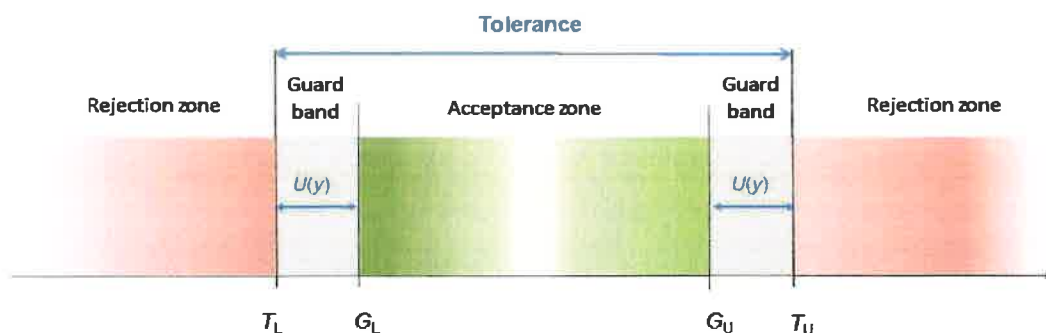


Figure 5: Display of acceptance and rejection zones for normalized interval and safe acceptance

In the case of an upper limit of the specification, the upper limit of the specification is reduced by a protective band (Figure 6).

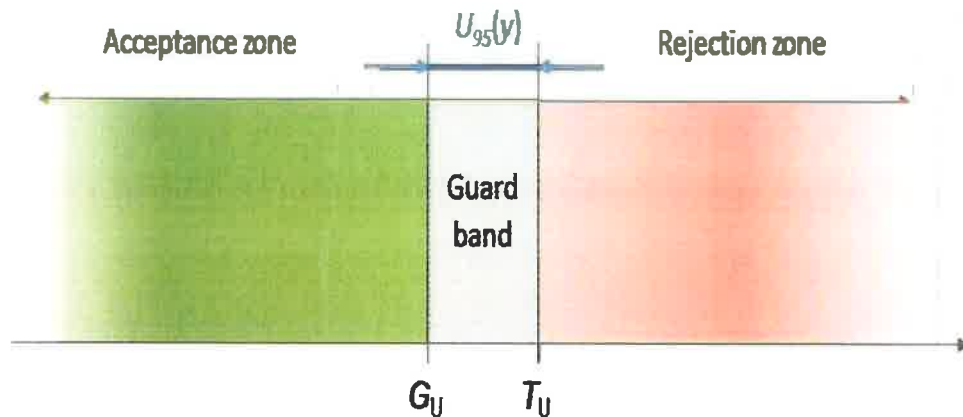


Figure 6: Display of acceptance and rejection zones for the upper limit and safe acceptance

In the case of the existence of a lower limit of the specification, the lower limit of the specification is increased by a protective band, where the protective band ω is equal to the expanded measurement uncertainty U_k ($\omega = U_k$).

The measured value must be within the acceptance zone, otherwise the result is inconsistent.

The declaration of conformity for Rule 3 is given in the attachment: Method of deciding on conformity and wording of the text of the declaration of conformity (Annex 1)

Rule 4: Rule of simple rejection - "shared risk"

The declaration of conformity for Rule 4 is given in the attachment: Method of deciding on conformity and wording of the text of the declaration of conformity (Annex 1).

The test parameters of the Laboratory of the Institute for Accredited Methods are given on the form: Decision rule for the subject of the test and tested parameters (Annex 2).

5. APPENDICES

Annex 1: Method of deciding on conformity and wording of the text of the declaration of conformity

Appendix 2: Decision rule for the subject of the test and the tested parameters

	DESCRIPTION	BINARY DECISION METHOD	NON-BINARY WAY OF DECISION-MAKING
Case1	The measurement result with measurement uncertainty is within the prescribed limit values	Based on the results of the analyzed parameters, the sample is COMPLIED with the requirements prescribed in the relevant Rulebook / Regulation or product specification	Based on the test results of the analyzed parameters, the sample is COMPLIED with the requirements prescribed in the relevant Rulebook / Regulation or product specification (NOTE: All measurement results with expanded measurement uncertainty are within the reference value limit with a 95% confidence level for the expanded measurement uncertainty.)
Case2	The measurement result is within the prescribed limits, and the measurement uncertainty interval exceeds the prescribed limit values	Based on the results of the analyzed parameters, the sample is COMPLIED with the requirements prescribed in the relevant Rulebook / Regulation or product specification	Based on the test results of the analyzed parameters, the sample is COMPLIED with the requirements prescribed in the relevant Rulebook / Regulation or product specification. (NOTE: Compliance cannot be confirmed with a confidence level of 95% for the expanded measurement uncertainty, for a certain parameter, i.e. there is a probability that the result will be found outside the limits of the reference values)
Case3	The result of the measurement is outside the prescribed limits, and the measurement uncertainty interval includes part of the limit values	Based on the results of the analyzed parameters, the sample is NOT COMPLIANT with the requirements prescribed in the relevant Rulebook / Regulation or product specification.	Based on the test results of the analyzed parameters, the sample is NOT CONFORMED with the requirements prescribed in the relevant Rulebook / Regulation or product specification. (NOTE: Non-compliance cannot be confirmed with a confidence level of 95% for the expanded measurement uncertainty, for a certain parameter, i.e. there is a probability that the result is also within the limits of the reference values)
Case4	The measurement result with measurement uncertainty is outside the prescribed limit values	Based on the results of the analyzed parameters, the sample is NOT COMPLIANT with the requirements prescribed in the relevant Rulebook / Regulation or product specification.	Based on the test results of the analyzed parameters, the sample is NOT CONFORMED with the requirements prescribed in the relevant Rulebook / Regulation or product specification. (NOTE: The measurement result with the expanded measurement uncertainty is outside the reference value limit with a confidence level of 95% for the expanded measurement uncertainty.)

On the basis of the binary / non-binary rule, Statements on conformity of the results were formed:

1. Based on the results of the test, the subject of the test is in compliance with the requirements, e.g. Rulebook on limits of exposure to electromagnetic fields (Official Gazette of Montenegro, number 6/2015) or standard...(document should be specified), i.e. measurement results with expanded measurement uncertainty are within the limits of reference values with a confidence level of 95% for expanded measurement uncertainty .
2. Based on the results of the test, the subject of the test is compliant with the requirements, e.g. Rulebook on limits of exposure to electromagnetic fields (Official Gazette of Montenegro, number 6/2015) or standard...(the document should be specified), but the conformity of the measurement results with the reference values cannot be confirmed with a confidence level of 95% for the extended measurement uncertainty, which means that there is a possibility that the result of the measurement is outside the limits of the reference values.
3. Based on the test results, the subject of the test does not comply with the requirements, e.g. Rulebook on limits of exposure to electromagnetic fields (Official Gazette of Montenegro, No. 6/2015) or standard ... (the document should be specified), but the inconsistency of the measurement results with the reference values cannot be confirmed with a confidence level of 95% for the extended measurement uncertainty, which means that there is a possibility that the result of the measurement is within the limits of the reference values.
4. Based on the test results, the subject of the test does not comply with the requirements, e.g. Rulebook on limits of exposure to electromagnetic fields (Official Gazette of Montenegro, No. 6/2015) or standard...(the document should be specified), i.e. the measurement results with extended measurement uncertainty are outside the limits of the reference values with a confidence level of 95% for the extended measurement uncertainty .

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