

## **Title: Acceptance sampling for conformity assessment**

### **Abstract**

Metrologically sound standardised sampling schemes increase the trust and safety of products and protects EU citizens from faulty goods. This has economic benefits for the EU where conformity assessments score highly so boosting international trade. Legal metrology relies on robust conformity assessments and the MID European Directive requires the use of ISO standards 2895, 3951 and 28596 series. Currently no standardised sampling scheme exists, which fully accounts for measurement uncertainty. Therefore research is needed to develop statistical methods and to produce case study, in compliance with the guide “JCGM 106 Evaluation of measurement data - The role of measurement uncertainty in conformity assessment”.

### **Keywords**

Acceptance sampling, conformity assessment, JCGM 106, ISO 2859, ISO 3951, consumer’s risk, producer’s risk, Bayesian statistics, prior knowledge, sequential sampling

### **Background to the Metrological Challenges**

Conformity assessment (CA) determines whether a product, process, or system meets specified requirements or relevant standards and forms an important part of a quality infrastructure. Accreditation provides formal confirmation of the integrity of the conformity assessments performed. In calibration and testing the principal source of information for conformity assessment is the guide “JCGM 106 Evaluation of measurement data - The role of measurement uncertainty in conformity assessment,” (JCGM 106) and this also forms the basis for decisions in legal metrology. It covers measurement uncertainty and provides risk limitation methods for the incorrect acceptance or rejection of a product. Previous EMRP and EMPIR projects have developed best practice guidance, good practice examples and software to facilitate the uptake of JCGM 106 among calibration and testing laboratories, industrialists, and regulation authorities. However the need for conformity assessment acceptance sampling schemes remains. Sampling is frequently used in industry for statistical process control and is an integral part of legal metrology. In every case, sampling gives rise to uncertainties which must be included in measurements and assessments. Legal metrology requires rigorous sampling schemes, as although MID Modules F and F1 and the current revision to WELMEC guide 8.10, OIML G20, and OIML R 87 specify frequentist criteria that sampling plans need to fulfil. OIML R51-1 specifies sample sizes without stating criteria. It is unknown, whether the applied schemes limit the risks of (non)conformity according to JCGM 106 and which limits these are.

Acceptance sampling ensures that a defined level of quality is met and provides the route by which not all items need to be assessed and is used to verify that a large number or percent of the items conform to specifications by the inspection of only a random subset. For manufacturing companies, acceptance sampling is a crucial aspect of their quality control. ISO/TC 69 and its sub-committee SC 5 provide a series of standards for sampling schemes which provide tabulated sampling plans that are easy to apply. The ISO 2859 series is widely used to control the quality of many industrial production processes (e.g. automotive construction, aeronautics, chemistry and medical devices). In legal metrology, the EU MID Directive requires the use of ISO 2859 sampling schemes for commercially available measuring instruments. However, the standard series 2859 and 3951 have three main shortcomings. First, they ensure that the consumer’s and producer’s risk are limited for accepting, and for rejecting items. These probabilities are frequentist (long-run) risks for hypothetically repeated observations under some fixed, unknown quality levels for the measurand. This is a conceptual contrast to CA in JCGM 106, which is based on state of knowledge (or degree of belief) distributions, and risks are defined by the probability of (non)conformance given observations, or by the probability of

(non)conformance and (un)acceptable estimates for future observations. Beyond this conceptual difference, numerical differences between the criteria arise, e.g., when prior know-ledge does not coincide with presumed quality levels or with long-run averages. Second, the standard series 2859 and 3951 do not use the Bayesian approach. In contrast, sampling schemes compliant with JCGM 106 can enable the reduction of sample sizes by using prior knowledge without increasing the total sample size. Third, while standard series 3951 is restricted to Normally distributed characteristics, standard series 2859 assumes that the uncertainty contributing to the decision on each entity is negligible. Both scenarios are unsatisfactory for metrology and metrological research is required to address this issue.

Currently, there is no direct link between CA standards and acceptance sampling standards. No standards exist that use state of knowledge distributions or provide sampling schemes or sampling-based CA and are able to comply with JCGM 106. No standardised sampling scheme takes advantage of the Bayesian approach, as recognised by ISO/TC 69/SC 5 and the stated need to develop such schemes. In addition, no standardised sampling schemes exist that fully consider measurement uncertainty. ISO/TC 69/SC 5 is currently working on a technical report that will outline the statistical methodology for sampling-based CA and application scenarios for it. Ideally, the design and analysis of sampling schemes should be based on risks or utility functions and should account for prior knowledge. To this end, ISO/TC 69/SC 5 requires case study data, techniques to evaluate Bayesian properties of currently prevalent sampling plans and modelling research accounting for variable sampling and process variability in the Bayesian framework.

## Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The proposal shall focus on metrology research necessary to support standardisation in conformity assessments by providing sampling methods suitable for incorporation into standards and use in legal metrology that provide probability-based conformity statements in accordance with JCGM 106.

The specific objectives are:

1. To develop statistical methods (e.g. Bayesian approaches) and research on their application and software implementations for conformity assessment sampling schemes that are compliant with JCGM 106 with an emphasis on reducing sample sizes by consideration of prior knowledge levels and by risk- or optimised cost-based strategies. The methods developed must be built upon the technical report under development in the ISO/TC 69/SC 5 Technical report.
2. To develop case studies that demonstrate how sample sizes can be reduced based on the use of prior and other knowledge, with optimised sequential sampling plans for conformity assessment in legal metrology and industrial applications. The case studies generated must contain sampling schemes suitable for conformity assessments that are compliant with JCGM 106.
3. To contribute to the standards development work of the technical committees ISO/TC 69/SC 5, OIML TC 9/SC 2, WELMEC WG 8 and JCGM WG 1 to ensure that the outputs of the project are aligned with their needs, communicated quickly to those developing the standards and to those who will use them, and in a form that can be incorporated into the standards at the earliest opportunity.

The proposed research shall be justified by clear reference to the measurement needs within strategic documents published by the relevant Regulatory body or Standards Developing Organisation or by a letter signed by the convenor of the respective TC/WG. EURAMET encourages proposals that include representatives from industry, regulators and standardisation bodies actively participating in the projects. The proposal must name a “Chief Stakeholder”, not a member of the consortium, but a representative of the user community that will benefit from the proposed work. The “Chief Stakeholder” should write a letter of support explaining how their organisation will make use of the outcomes from the research, be consulted regularly by the consortium during the project to ensure that the planned outcomes are still relevant, and be prepared to report to EURAMET on the benefits they have gained from the project.

Proposers should establish the current state of the art and explain how their proposed research goes beyond this. In particular, proposers should outline the achievements of the EMRP project NEW04 and the EMPIR projects 17NRM05 EMUE, and 17SIP05 CASoft and how their proposal will build on these.

Proposers should note that the programme funds the activity of researchers to develop the capability, not the required infrastructure and capital equipment, which must be provided from other sources.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.0 M€ and has defined an upper limit of 1.3 M€ for this proposal.

EURAMET also expects the EU Contribution to the external funded beneficiaries to not exceed 30 % of the total EU Contribution across all selected projects in this TP.

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated partners.

## Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the 'end user' community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the "end user" community (e.g. letters of support) is also encouraged.

You should detail how your proposal's results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Facilitate improved industrial capability, or improved quality of life for European citizens in terms of personal health, protection of the environment and the climate, or energy security,
- Transfer knowledge to the legal metrology and quality assurance sector.

You should detail other impacts of your proposed JRP as specified in the document "Guide 4: Writing Joint Research Projects (JRPs)"

You should also detail how your approach to realising the objectives will further the aim of the Metrology Partnership to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically, the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work.

## Timescale

The project should be of up to 3 years duration.

## Additional information

The links provided in this section are only correct at the time of publication up until the end of the Call year.

The references below were provided by PRT submitters; proposers should therefore establish the relevance of any references.

- [1] *BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML, "JCGM 106 Evaluation of measurement data - The role of measurement uncertainty in conformity assessment," Joint Committee for Guides in Metrology, 2012.*  
[https://www.bipm.org/documents/20126/2071204/JCGM\\_106\\_2012\\_E.pdf](https://www.bipm.org/documents/20126/2071204/JCGM_106_2012_E.pdf)
- [2] *013 OIML TC9 Sequential sampling procedures for checkweighing:*  
<https://www.metpart.eu/go/need13>
- [3] *018 ISO TC69 Sampling based conformity assessment*  
<https://www.metpart.eu/go/need18>
- [4] *020 WELMEC Sampling procedures for conformity assessment*  
<https://www.metpart.eu/go/need20>
- [5] *EMN for Mathematics and statistics Strategic Research Agenda*  
<https://www.euramet.org/research-innovation/metrology-partnership/strategic-research-and-innovation-agendas>
- [6] *Orientation Paper by EMN for Mathematics and Statistics - Call 2024*  
<https://metpart.eu/normative-call-2024-s1>