

# FINAL PUBLISHABLE REPORT

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## 1 Overview

The purpose of the 17SIP05 CASoft (2018 – 20) project was to enable the uptake of established methodologies for risk-based decision-making taking into account measurement uncertainty through the provision of dedicated software. Such software developed during this CASoft project was released and made freely available in April 2020. It allows the user to apply the methodology from JCGM106:2012, as well as from the Best Practice Guide from project EMRP JRP NEW04 ((2012 – 15) “Novel mathematical and statistical approaches to uncertainty evaluation”) for bivariate quantities. The particular need of the primary supporter was also taken into account with a specific function of the software that enables to perform simultaneously the calculation of the conformance probability for several independent measurands within a simplified framework.

## 2 Need

The project's primary supporter was Trescal, a worldwide specialist in calibration and metrology services: verification, calibration, maintenance and management of test and measurement equipment for aerospace, defence, automotive and transport industries. The primary supporter had stated that the need of all industrialists was to have control of their measurement processes with regard to their manufacturing requirements. The primary supporter had requested that software be made available for the calculation of conformance probability, customer and producer risks and acceptance intervals in order to provide reliable decisions in conformity assessments. Such software would constitute a crucial improvement for them and their clients by offering automated calculations required for the implementation of a rigorous methodology (such as that described in the Best Practice Guide “A guide to decision-making and conformity assessment” (BPG) from EMRP JRP NEW04 and in the reference document JCGM 106:2012) enabling the reduction of manufacturing costs or improving the safety of marketed products. Incorrect decisions may result in economic losses for the producer, and lead to potential lack of safety or other impact issues for the consumer. Existing guidance available in the BPG and JCGM 106:2012 provided a methodology to manage the associated risks. However, a wider implementation of that methodology was not possible due to the lack of accessible user-friendly software tools enabling users to perform the necessary calculations and to have confidence in their results. The software would constitute also an improvement regarding the software provided in JRP NEW04, which enabled only the calculation of the conformance probability in cases where two output quantities were measured.

## 3 Objectives

The overall objective of the CASoft project has been to create end-user impact from the results of EMRP JRP NEW04, in particular from the outputs of WP3 dedicated to decision-making in conformity assessment. The goal is to make the outputs of JRP NEW04 available to a large community of users (such as metrologists, industrialists and regulators).

The project has addressed the following objectives:

1. To enable the required calculations for risk-based decision-making in conformity assessment: customer/producer risks, acceptance intervals and conformance probabilities.
2. To support widespread adoption of best practice guidance in risk-based conformity assessments by increasing awareness of the software tool (in objective 1) and the BPG from JRP NEW04.

## 4 Results

**Objective 1: To enable the required calculations for risk-based decision-making in conformity assessment: customer/producer risks, acceptance intervals and conformance probabilities.**

In 2012, the Joint Committee for Guides in Metrology (JCGM) published a reference document for the calculation of the risks of incorrect decisions in conformity assessment ([link](#)). This document is denoted as JCGM106:2012. In conformity assessment, a measurement result is used to decide if an item of interest conforms to a specified requirement. The requirement typically takes the form of one or two tolerance limits that define an interval of permissible values, called a tolerance interval, of a measurable property of the item. Due to measurement uncertainty, there is a risk of incorrect decisions in conformity assessment: the acceptance of a non-conforming item as well as the risk of the rejection of a conforming item. These two risks are respectively called “consumer’s risk” and “producer’s risk”. However, such a denomination may not always be relevant. For some applications or in some areas, the terms “risk of false acceptance” and “risk of false rejection” may be preferred.

In 2015, the project EMRP JRP NEW04 generalized the methodology from JCGM106:2012 to the case of multivariate quantities of interest. This particular situation of conformity assessment deals with the case where the conformity is assessed based on two or more properties of the item. This is described in a dedicated best practice guide ([link](#)). However, both documents describe a methodology which requires complex calculations of integrals. This mathematical complexity makes it impossible for a large part of the community to uptake and to use the methodology. Two kinds of risks may need to be computed. First, the specific risk addresses the risk of an incorrect decision for an item that has already been measured: the measurement result used for conformity assessment is known. Second, the global risk addresses the risk of an incorrect decision based on future measurements: the measurement result for each item is unknown, but prior information is available about the population of items and the uncertainty associated with the future measurement result for an item is known.

It is particularly important to provide a software tool to compute the specific risk when prior information is available. In this case, the decision is made based on the posterior distribution arising from the combination of the prior and the measurement distribution according to Bayes’ theorem. This posterior distribution may be well known for specific couples of prior and measurement distributions (Gaussian/Gaussian or Gamma/Poisson for example), but otherwise can only be estimated using Monte Carlo Markov Chains (MCMC). As this is the most complicated calculation from a mathematical point of view, the project’s software includes a comprehensive tool to run the simulation of the MCMC according to a Metropolis-Hastings algorithm. The procedure is explained in the User Manual and the user has the possibility to change the parameters (length of the Markov Chain, Number of first discarded values, Autocorrelation parameter) in order to reach a suitable exploration of the probability space. Such a tool is necessary for a wider dissemination of the methods in JCGM106:2012, in the absence of any international reference document to perform such simulations.

A second motivation for the development of dedicated software is the recent revision of standard ISO17025:2017 in 2017. This standard is widely used by testing and calibration laboratories for accreditation purposes. One major modification in the standard concerns the decision rule used in cases where a conformity assessment should be performed: “...the laboratory shall document the decision rule employed, taking into account the level of risk [...] associated with the decision rule and apply the decision rule”. The project’s software aims at supporting users in this context as well as broader, societal areas such as market surveillance of diverse products and services.

The final contribution to the identification of end users’ needs was made by the primary supporter (Trescal) who was invited to the kick-off meeting and was continuously in contact with the coordinator of the project. As the primary supporter, it was important for the project to provide an answer to their problem. As a worldwide calibration laboratory, their need is also representative of the need of other similar laboratories, which was to have a guarantee for a wider dissemination of the software. As a result, the primary supporter mentioned that:

- Prior information will not be used for routine calibration operations
- A single item may be tested based on more than 100 individual measurements: all individual conformance probabilities should be made available in the same session run of the software.



In order to achieve this objective, the partners LNE, NPL and RISE contributed to write a user specification report that summarizes what the software is expected to compute and describes the mathematical methods that are coded in the software. It was particularly important to develop this document with the three partners in the project in order to obtain a document as exhaustive as possible and to maximize the probability that the needs of most end users will be taken into account by the project's software. Detailed description is given of the methods in this document which enable generation of reference data and checking that the software developed in the project correctly implements these methods. The probability distributions made available in the software are described, as well as the available combination of a prior and a measurement distribution. The specifications related to software ergonomics are also mentioned in the document (System specification, import/export functionality, graphical visualization, acceptance criteria).

The software was developed by LNE in Matlab and released as a standalone executable. This process enables the user to use the software freely, without the need to purchase a Matlab licence. The choice of the Matlab language was made because both LNE and NPL teams had experience in developing software in this language and because of the limited development time scheduled in the project. A first version of the code of the software was circulated among the consortium approximately at mid-term of the project in order to start the testing and validation phase that was led by NPL. The procedure applied by NPL consisted of the generation of reference data according to the specification report, using another software. These data were compared with the results from the project's software to check that both results were the same. Most of the generated data were consistent when they were processed using the project's software, with a maximum difference of 0.002 on the value of the risk, which was considered as acceptable.

The review by NPL as well as a presentation of the first draft to the primary supporter enabled to identify the modifications required to make before the release of the software to the public. These modifications included the correction of some bugs and improved navigability in the software, which was released in early April 2020, at the following address: <https://www.lne.fr/en/software/CASoft>

The project's software can be run using Microsoft Excel template files. The same Excel file can be used to provide the input information to the software in a first worksheet and to save the results and the corresponding risks in a second worksheet. This system was thought to save easily the input parameters of a calculation in cases where the user would like to modify one of the parameters in a future use of the software. In order to guide the end user, some of these template files were made publicly available, using examples from JCGM106:2012 (<https://zenodo.org/communities/casoftexamples/?page=1&size=20>). These data can be considered as reference data and the user can simply load the corresponding Excel file and check that the project's software provides the expected output result. This facilitates also the modification of the reference template file with the user's data to produce the corresponding results.

One last task was scheduled in the project to ensure that objective 1 can really be achieved, and that the community will benefit from having a useful tool with the project's software. A survey was jointly proposed by LNE, NPL and RISE for collecting the feedback from first end users. However, the late public release of the project's software and the COVID-19 outbreak made it difficult to wait for answers from random end users. The decision was made to contact two bodies interested in the topic of conformity assessment and to ask them to answer the survey after the download of the project's software: UKAS, the UK National Accreditation Body, and INRIM, the Italian National Metrology Institute. Both respondents from these institutes are experts of decision-making in conformity assessment, have a knowledge of the methodology and have connections with end users in their respective countries. They both confirmed the need for such a software tool for a wider implementation of the guidance proposed in JCGM106:2012.

To conclude about this objective, the project was positively impacted by a fruitful collaboration between the experts of the three NMIs for the main parts of this work:

- The definition of the methods in the user specification report
- The development of the Matlab code
- The testing and validation phase
- The impact survey targeting first end users.

The project's software also benefitted from the point of view of Trescal, the primary supporter, in the definition of the end users' need as well as for the testing and validation phase. A presentation of the draft software was made during a meeting organized between Trescal and the coordinator.



The key conclusions of the work undertaken to achieve this objective are:

- The project's software allows the user to compute either a conformance probability (leading to a specific risk), global risks (based on an acceptance interval) or an acceptance interval (based on a targeted global risk value).
- The need for a software is a real expectation of end users who do not know how to apply the methodology if they do not have the background or the time to read carefully the reference documents
- Not many users will use prior information for the calculation of a specific risk. While the guidance from JCGM106:2012 follows the general concept of the coexistence of prior knowledge and of information conveyed by the measurement itself, the project's software allows to take into account only the information arising from the measurement (no need to apply Bayes' theorem) in this case.

**Objective 2: To support widespread adoption of best practice guidance in risk-based conformity assessments by increasing awareness of the software tool (in objective 1) and the BPG from JRP NEW04.**

Different communication activities were performed during the project to support widespread adoption of best practice in conformity assessment.

A presentation at the International Metrology Congress (CIM Paris, 2019) gave a concrete example of the calculation of both the specific and the global risk with the new CASoft software. Starting from the practical definition of these two kinds of risks, LNE, with the contribution of RISE and NPL, proposed to compute the risks of an incorrect decision associated with the measurement of the thickness of a waste bag. The distinction was made between the specific risk associated with the measurement of the thickness of a particular waste bag and the global risk that estimates the expected proportion of incorrect decisions based on future measurements. The latter is very useful to the manufacturer who is able to estimate their economic losses due to conforming waste bags that would be falsely rejected. An example demonstrated that the project's software will allow to estimate the impact of a change in one of the input parameter on the global risk. If the manufacturer increases the thickness by only 2  $\mu\text{m}$ , then, the global producer's risk is decreased from 6.7% to 2.5% [1]. In this CIM 2019 presentation, we also expose the difficulty arising from the choice of the prior distribution and three candidate prior information are discussed as to know whether they should be used to assign a prior distribution or not for the computation of specific risk. The key point is that the practitioner understands that this choice has an influence on the decision-making process and that such a choice should be made based on reliable information, for the measurement considered for conformity assessment.

The presentation proposed for the European Network for Business and Industrial Statistics (ENBIS Budapest 2019) was led by RISE, with a contribution from LNE and NPL and was focused on the bivariate case. The example was the conformity assessment of a piece of wood that relies on tolerance intervals related to the width and length of the piece of wood. Only the specific risk was considered in this case and the impact of the correlation between the two components was investigated. This is a direct application of the Best Practice Guide published during JRP NEW04 project and the project's software was used to perform the calculations.

Two presentations were proposed by the project partners for the MATHMET Conference (Lisbon 2019). The first one was led by LNE, with the participation of RISE and NPL. The goal was to highlight the conceptual difference between the specific and global risk, from a mathematical point of view. The specific risk is based on a posterior distribution, while the global risk is based on a joint distribution. This is a crucial distinction to understand how to perform the calculations. However, this difference is not clearly stated in JCGM106:2012. Both the specific risk and the global risks are calculated using the project's software. Additionally, a discussion is proposed about the different solutions that can be used to control the global risks: modification of the acceptance interval, modification of the prior standard deviation or modification of the measurement standard deviation. The second presentation was led by NPL, with the participation of LNE and RISE. It summarizes the verification approach used by NPL in the validation and testing phase of the project's software. The key point is the generation of reference pairs which comprises reference data and associated reference outputs. For each pair, the project's software is applied to obtain test results used for comparison with the reference outputs. Finally, single performance measures are calculated.





An article was published in Precision Magazine ([Precision Magazine, Issue 16, June 2020](#)). This article was written free of any mathematical formulas on purpose in order to address the wider community of people involved to some extent in the process of decision-making in conformity assessment. The objective of such a paper was to increase awareness of the methodology through the explanation of the reason why measurement uncertainty leads to a risk of an incorrect decision and the announcement of the release of the project's software. NPL led the publication of this paper with a contribution from LNE and RISE. The paper was released right after the end of the project in early June 2020 and we observed the first downloads from people in the United Kingdom where Precision Magazine is mostly read. This shows the interest that many people have in this field and the need that motivated this project.

One last written contribution was made to NCSLI *Measure* magazine in order to target potential end users that are concerned with the problem of decision-making in conformity assessment. This magazine was targeted on the advice of the primary supporter of the project. An explanation of the concepts is proposed as well as an analysis of the feedback from first end users of the project's software. This publication was led by RISE, with a contribution from LNE and NPL.

Another contribution was made in May 2020 during a virtual technical day organized by the College Français de Métrologie (CFM). The project's software was presented by LNE. After the presentation, the first downloads of the software by users outside the consortium were observed.

As a conclusion, the project consortium targeted various conferences and journals in order to spread the word about the methodology for decision-making in conformity assessment as described in JCGM10:2012 and, in the same time, about the release of a software that facilitates the required calculations. The communications were adapted to the audience of the journal or the conference.

## 5 Impact

The dissemination activities undertaken during the project were targeting the primary supporter as well as the future potential users of the software. The primary supporter participated in the kick-off meeting of the project and a meeting with the project coordinator was the occasion to present the objectives of the software to be developed as well as to collect the exact need of the primary supporter. After this meeting, a gap was identified between the general scope of the software (that was thought in the first place as a direct application of the reference document JCGM106:2012) and the operational need of the primary supporter, which can be summarized as below:

- Calculation of specific risks only
- No prior knowledge
- Only Gaussian or Student's t distribution
- Any number of measured items for the same calibration operation (example of a multimeter).

The consortium thought that such need was representative of the need of similar calibration and testing laboratories. As a result, it was decided to add in the software specifications a functionality allowing the user to perform such calculations in order to maximize the probability of uptake of the software. The implementation of this simplified framework for the application of the methodology will enable Trescal to automatically produce the Microsoft Excel templates that can be directly run by CASoft in order to proceed to the calculations.

In order to increase awareness of the software in the wider scientific community, four presentations were given, each with a focus on a different practical point (bivariate case, validation procedure of the software, specific and global risk calculation). Another presentation was made in May 2020 during a online technical day organized by the College Français de Métrologie (CFM), once the software was already available online. The first downloads of the software from users outside the project team were observed.

The three publications also propose to reach different targets, with different levels of complexity. The paper published in 'Precision' was, according to the request from the editor, written without any mathematical formulas in order to reach the wider possible audience. It was accepted in April for a publication in early June, and led to first downloads from users in the United Kingdom mainly. The paper published in the proceedings of the International Metrology Congress was targeting the scientific community interested in the progress in



metrology. Many attendees are affected by the revision of standard ISO 17025 in 2017, which requires to explicit and use the decision rule in conformity assessment. Finally, a submission to NCSLI magazine in May 2020 already received a positive opinion from the reviewers and should be published after some minor modifications. It allows to reach an audience including readers outside Europe.

The main impact action is to make the software available. This was done in April 2020. CASoft software is now available at the following web link : <https://www.lne.fr/en/software/CASoft>. A total of 19 downloads was observed until June 15<sup>th</sup>.

Another impact action was to initiate a survey targeting first users of the software. To this extent, two institutes were contacted: UKAS, the UK national accreditation body, which represents the calibration and testing laboratories and INRIM, the Italian National Metrology Institute. Both recognized the interest of the software for the community, the possibility to use it to compute the risks of an incorrect decision or to validate the calculations made using another tool. They also contributed to the improvement of the software tool by mentioning some graphical bugs that will be corrected in the next couple of weeks after the end of the project.

The partners reviewed guidance documents under development by UKAS and technical discussions concerning guidance documents were published by organisations such as ASME.

In order to facilitate the use of the software, template files are provided to the end user. Some template files were made available using Zenodo website. They are accessible thanks to a dedicated webpage available at <https://zenodo.org/communities/casoftexamples/?page=1&size=20>. They refer to examples taken from JCGM106:2012 and that can be considered as reference data. When using such template with CASoft, the user will be able to validate the use of the software.

Finally, CASoft will have a future impact in project 18NET05 MATHMET. In this network project, one objective is to develop a Quality Management System (QMS) for data and software. CASoft is proposed in this project as a metrology use case to be tested against the QMS. This action will ensure to get confidence in the results produced by the software. As the project involves many other NMI, it will also participate to the dissemination of the methodology, and increase the total number of downloads.

## 6 List of publications

[1] A.Allard, N.Fischer, I.Smith, P.Harris and L.Pendrill, Risk calculations for conformity assessment in practice, 19th International Congress of Metrology (CIM2019), 2019, available online: <http://dx.doi.org/10.1051/metrology/201916001>

## 7 Contact details

n/a