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Validation model for coordinate measuring methods based on the concept of statistical consistency control

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ABSTRACT

Accredited laboratories are required to perform measurements in accordance with the highest standards of quality and reliability. The pursuit of this is associated with considerable effort and commitment on the part of each laboratory that wants to find recognition in the measurement services market. Undoubtedly, the laboratory needs to possess outstanding technical capability, participate in proficiency testing and inter-laboratory comparisons, and follow reliable and validated calibration methods. This paper presents a validation procedure using the specially developed universal algorithm which offers specific, step-by-step validation of coordinate measurement methods. The paper first discusses the selection of validation methods, and then proceeds to discuss the choice of a sophisticated multi-feature check and calibration measurements performed in chosen laboratory. The final part of this publication is devoted to the development of a validation model used for verifying measurement methods.

1. Introduction

In order to demonstrate the reliability and precision of measurements, calibration laboratories tend to increasingly seek out assistance of accredited laboratories. A certificate of accreditation granted by national accreditation centers verifies the compliance of laboratory management systems with the ISO 17025:2005 standard, as well as measurement proficiency and technical capability of its personnel. In order to verify the technical capability of the staff, the abovementioned standard requires laboratory personnel to participate in proficiency tests (Delčev et al., 2013), interlaboratory comparisons (Delčev et al., 2016), and to carry out calibrations using reliable, validated methods. This forces the technical staff of accredited laboratories to implement reliable validation methods, which may not always be straightforward or familiar to the users. Moreover, the issue of validation methods is bound to be extremely important for each laboratory, regardless of its specific field of activity.

By and large, knowledge of validation processes with regards to measurement methods is based on general familiarity with the current standard (ISO/IEC 17025:2005) (especially Section 5.4 of this standard). Most auditors of laboratory management systems do not explore the area of measurement method validation. Instead, it is only assessed on the grounds of their compliance with the current standards. However, most laboratories use methods that are only partially developed on the basis of standards and still consider them as properly validated.

Effective methods of evaluation of the measurements accuracy have already been developed, as exemplified by the series of standards ISO 15530, but so far, there has not been a mention of a universal validation model for methods that are not based on normative documents.

On the one hand, validation of measuring methods is a difficult procedure to plan and implement. On the other hand, however, it is an interesting subject for debate that is rarely discussed by the scientific community. Furthermore, the implementation of reliable validation methods may also have economic significance for laboratories, as it may attract new industry partners.

Laboratories holding accreditation issued in accordance with ISO/IEC 17025:2005 should prefer the current measuring methods defined by the well-known international standards. However, most high-end laboratories, as part of their internal development, seek further improvement of their measurement methods and strive to adapt them to changing needs of the market. This type of activity requires verifying the correctness of the revised measurement method in relation to a standardized method, so as to obtain reliable and unambiguous results. Questions regarding the selection of appropriate validation parameters, techniques and criteria for

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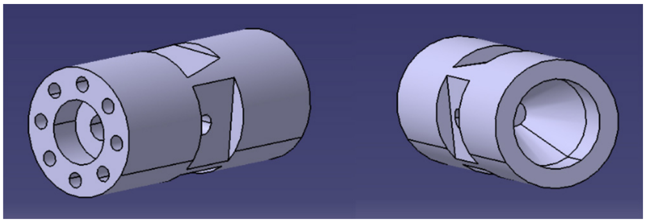

Fig. 1. Multi-feature check.

acceptance of the revised methodology remain mostly unexplored. Length measurements using the coordinate technique necessitate the validation of both standardized and non-standardized methods. Therefore, an adequate validation procedure has been developed and verified through a vast number of measurements. The most challenging aspect in the validation process of measurement methods is the development or adaptation of a validation model, that is, a mathematical model used to test out a validated method.

Validation of a measuring method is necessary to:

- Confirm the reliability of measurement results.
- Adapt a method for new purposes and applications.
- Further improve a method.

All of the above tasks are inherent to the development and application of measurement and calibration methods in coordinate metrology. It is one of the fastest growing areas of metrology with vast applications in the field of manufacturing engineering. According to Weckenmann et al. (2007), Sommer et al. (2007), Sładek and Gawlik (2007), Mailhe et al. (2008), and Sładek and Gąska (2012), there is an urgent need to develop, especially in the area of coordinate metrology, not only new measurement methods together with the necessary assessment of their accuracy, but, above all, a suitable validation model. Such a model would constitute the evaluation criterion for measuring methods at a calibration laboratory, as well as industrial laboratories that oversee manufacturing processes.

2. Validation process of coordinate measuring methods

This chapter presents a short description of the validated measurement methods (including the method used as reference). In addition, the applied instrumentation and measuring strategies are also discussed along with the mathematical validation model of coordinate measurement methods.

2.1. Selection of reference and validated methods

Validation of measuring methods, as the process of confirming that the chosen method used to perform a particular type of measurement is suitable for its intended purpose, ensures reliability and consistency of measurements. Hence, it is of utmost importance both for the scientific community, as well as the production engineering industry.

The current ISO/IEC 17025:2005 standard states that laboratories should apply the current measurement methods described in the well-known international standards. However, the necessary development and implementation of individual and specific methods should be carried out as a result of a planned validation process. There is plenty of factors that affect the proper organization of the validation process, such as the involvement of professional laboratory staff with extensive knowledge and practical measuring skills, as well as adequate resources provided by the top-level management of a given laboratory which, first and foremost, consists of acquiring suitable measuring machines together with the necessary software and effective communication. Any non-standard measuring methods should be properly validated and agreed upon in advance with the potential client.

According to ISO/IEC 17025:2005, validation of measurement methods should be carried out in relation to the following types of methods:

- Non-standard-methods designed or developed in the laboratory.
- Standard methods used outside the scope of their intended application (expanded or modified).

Methods based on the international standards have been already validated during their development, including the accuracy assessment of their results.

Based on that, this paper divides methods into validated and non-validated ones.

The following non-validated methods were selected for validation:

- Multiple measurement method—method based on the non-calibrated object, and referred to in this paper as the multi-position method; and
- Virtual CMM method—developed by the laboratory personnel.

The only validated method used in this research, which has been selected as reference method (reference for comparisons with other methods, as presented in the following sections of the paper) involves the use of calibrated workpieces (hereinafter referred to as the substitution method). The substitution method is based on the international standard ISO 15530-3:2011, and hence, it is considered here as a validated method.

2.1.1. Multi-position method

The multi-position method is based on repeated measurements of anon-calibrated object in different orientations. The measurement value with its corresponding uncertainty is obtained as a result of measurements performed in different orientations using a variety of measuring point arrangements in the CMM space. Uncertainties analyzed in this method are primarily related to the impact of CMM repeatability and its geometric errors (Osawa et al., 2005; Sato et al., 2010). Measurement uncertainty associated with thermal influences is also taken into account. In the case of certain measuring tasks (for example, distance or position measurements), the uncertainty analysis is further expanded to account for influences originating from: measurement of distance, radial correction of the measuring tip and the length standard calibration uncertainty. The Formula used for uncertainty calculation is given as (1):

$$U = k \times \sqrt{u_{\mathrm{rep}}^2 + u_{\mathrm{geo}}^2 + u_{\mathrm{corrL}}^2 + u_{\mathrm{D}}^2 + u_{\mathrm{temp}}^2} \quad (1)$$

where U—expanded uncertainty of measurement; k—coverage factor; u_{rep}—standard uncertainty contribution originating from CMM repeatability; u_{geo}—standard uncertainty contribution related to the geometric errors of the CMM; u_{corrL}—standard uncertainty of the correction applied to the average measurement result on the basis of the average distance proportional error of length measurement; u_{D}—uncertainty related to measurement of diameter; u_{temp}—uncertainty related to thermal influences.

2.1.2. Substitution method

The substitution method consists of measuring a calibrated object that is similar, in a defined way, to the measured workpiece. Measurements of both objects using this method are to be conducted under the same or very similar environmental conditions and utilize the same measuring strategy and tools. The essence of this method rests in the fact that measurements of the calibrated