TOWARDS A CONCEPTUAL MODEL FOR THE PRODUCT CONFORMITY ASSESSMENT

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The conformity assessment represents an important part of product design and manufacturing. The domain is of a continuous interest, so that today we can notice a conformity assessment industry existence. The present research contributes by development of a conceptual model for the conformity concept. Concepts, entities and relations are introduced into the proposed model, and finally a case study is presented to highlights the research achievements.

Keywords: conceptual modelling, product, conformity assessment, product conformity, characteristic conformity.

1. Introduction

Conformity assessment bodies (CABs) represent a special type of an organisation, being classified as third-party for conformity assessment. They are in call to assess the conformity against specified requirements by acting independently based on an evaluation system [1, 2]. The evaluation system came in response to the standards as specified in Table 1 [3].

With reference to the Leibniz's Law of Indiscernible such that if two objects disjoint, at least one property[2] differs between the two, then one may refer to the concept of identity as a property of the object [4].

Conformity assessment consists in three functions: i) selection, ii) determination and iii) review, decision and attestation [1].

Selection, as referenced by the domain of conformity assessment, represents a set of activities focusing on reading the identity of involved objects and their associated characteristics. Achieving the identity means the sum of all information, i.e. the input information, in need for the second phase – the determination. The object, or the objects to be evaluated for conformity, can be seen as a whole or as a part of a whole. In the last case, the selection phase should consider a procedure and a plan for sampling.

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[2] The term *characteristic* is not the same as the one of *property*. *Characteristic* refers to a measurement result and it may change over time, since *property* is of a fundamental type and it is constant over time [4].

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Table 1

International standards for conformity evaluation systems

Standard	Title	CABs type
EN ISO/IEC 17020	Conformity assessment - Requirements for the operation of various types of bodies performing inspection	Inspection body; Notified body; Designated body.
EN ISO/IEC 17021-1	Conformity assessment - Requirements for bodies providing audit and certification of management systems	Certification body
EN ISO/IEC 17024	Conformity assessment - General requirements for bodies operating certification of persons	Certification body; Notified body.
EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories	Calibration laboratory; Testing laboratory; Anti-doping laboratory; Notified body.
EN ISO/IEC 17025 EN ISO 15189	Medical laboratories - Requirements for quality and competence	Medical laboratory
EN ISO/IEC 17029	Conformity assessment - General principles and requirements for validation and verification bodies	Verification body
EN ISO/IEC 17043	Conformity assessment - General requirements for the competence of proficiency testing providers	Proficiency testing provider
EN ISO/IEC 17065	Conformity assessment - Requirements for bodies certifying products, processes and services	Product/ Process/ Service certification body; Notified body.

The information to be gathered should consider the requirements of the applicable standards, specifications or designs, along with other expressed requirements or regulations [1].

The selection phase considers and establishes a specific method to test, to inspect or to calibrate the object of interest. On the other hand, here the term of object may have the meaning of a family of objects. The identity of the object, or the objects, will follow by consequence [1, 5]. Three terms are determinant in the selection phase, i.e., the sampling, the test, and the inspection.

Sampling represents the set of activities having the focus on gathering of specific materials/ information/ data in regard with the object for conformity assessment [1]. When sampling is implied into the conformity assessment, the term of “sample” replaces the term of “object” for identity of what is under testing.

The sample representativeness (the equivalence of a reflexive, symmetric and transitive relation type) should be subject of a verification against a defined specification [6].

Testing represents a set of activities to determine a set of object’s characteristics [1]. The test it is expected to run under a predefined plan, including sampling if applicable. For the selection phase, the testing is seen as the plan for testing – the test protocol or the test method [7, 8].

Inspection represents an examination of an object to assess its conformity against expressed detailed requirements. For the selection phase, the inspection is seen as the plan for inspecting – the inspection strategy [7]. As usual, inspection accounts for a set of examinations. Examination represents a set of measurements (tests) or direct observations [1]. That is to say, the concept of identity creates a certain hierarchy on the testing and inspecting.

The determination function focuses to gather a complete set of information in regard with a predetermined set of requirements fulfilment. The term of determination develops activities as testing, inspection, audit, validation, verification and peer assessment. A specific activity, or a combination of them, comes into the term of scheme, i.e., a programme (a set of rules and procedures) for conformity assessment. In general terms, the conformity assessment scheme is part of a conformity assessment system [1]. The conformity assessment over a product, being apart from conformity assessment over a specified set of characteristics, should be aware in this regard [6, 9].

The decision represents the final stage in the product conformity assessment accounting for the results of the inspections and tests performed within the determination phase [1]. The complexity of the actual task has evolved during the time so, today, conformity assessment practitioners need support in analyse the gathered data, find the significant relationships and finally to assess the conformity of the product against the specified standard, specification, etc. [2, 5]. The state of conformity/non-conformity, that is – conformity is a state to be assigned to a particular product, is a temporal entity, and can be study including as a learning path [10]. The decision on the conformity is subject of uncertainty in measurement and to an associated risk [11, 12].

The concept of uncertainty is ubiquitous [11]. With Q standing as quality, and q as quale/qualia, let $u(q)$ be the combined[3] standard uncertainty.

Then the measurement result can be expressed as an interval, say it $q \pm k \times u(q)$ [11], a formulation with the meaning that the value of a measurement can be found anywhere inside the indicated interval and a specific distribution law associated with this interval exists. The covering coefficient, k, is a value addressing the confidence interval, $2 \leq k \leq 3$. The term $k \times u(q)$ is known as extended uncertainty [11].

Assessment for the conformity means to compare a measurement result, q, against a specified or design limit, q^{d}. The comparison is a matter of probability, introducing in this respect the concept of risk-of-false-acceptance,

[3] The combined standard uncertainty is the expression of multiple uncertainties sources.

$\Upsilon_{\mathrm{A,L}} = \varphi\left(\frac{q_{x_{\mathrm{j}}}^{\mathrm{L}} - q_{x_{\mathrm{j}}}}{u\left(q_{x_{\mathrm{j}}}\right)}\right)$ as applicable against the lower limit, and respectively, $\Upsilon_{\mathrm{A,U}} = 1 - \varphi\left(\frac{q_{x_{\mathrm{j}}}^{\mathrm{U}} - q_{x_{\mathrm{j}}}}{u\left(q_{x_{\mathrm{j}}}\right)}\right)$ against the upper limit [12], where φ-function comes from cumulative standard normal distribution table [13], or it can be computed, e.g., with excel function NORM.DIST [14], accounting eq. (1) [12].

$$\varphi(z) = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{z} \left[e^{\left(-\frac{t^2}{2}\right)} \right] dt \tag{1}$$

The research focuses with a high genericity level over the domain of product assessment conformity by introducing the needed concepts and models. By the means of a conceptual modelling, the research highlights the interests on the concepts of testing versus inspection, characteristic and conformity in regard to the phases of selection, determination and decision. The risk in conformity assessment is addressed with reference to decision phase. A case study is introduced to highlight the research outcome.

2. A conceptual formulation of conformity

The goal of the determination phase stands for the particular object $O_x^{\mathrm{d}} \in O^*$, where O_x^{d} stands for the object's design/specification and O^* represents the category of engineered objects.

The eq. (2) stands for conceptual model of conformity assessment.

$$O_x^{\mathrm{t}} \sqsubseteq O_x^{\mathrm{d}} \leftrightarrow K_x^{\mathrm{t}} \sqsubseteq K_x^{\mathrm{d}} \tag{2}$$

In this respect, the product conformity assessment focuses on O_x^{t} as the physical object under test (that is, O_x^{t} is the result of the sampling phase and it may be a set of objects under test), and the sets of characteristics (K_x^{t}, K_x^{d}) are each the sum of the corresponding partitions, i.e. there is no characteristic left outside the test and decision. The relation $O_x^{\mathrm{t}} \sqsubseteq O_x^{\mathrm{d}}$ has the meaning O_x^{t} conforms to O_x^{d}. The decision over the product conformity refer to the sets of O_x^{t} and O_x^{d} standing for the condition $O_x^{\mathrm{t}} \sqsubseteq O_x^{\mathrm{d}}$ if and only if $K_x^{\mathrm{t}} \sqsubseteq K_x^{\mathrm{d}}$. The set of characteristics is made by the 2-tuple of $K = (Q,q)$ for both K_x^{t} and K_x^{d}, eq. (3).

$$\forall x \in n, 1 \leq j \leq \mathrm{p}, \left(Q_{x_{\mathrm{j}}}, q_{x_{\mathrm{j}}}\right)_x^{\mathrm{t}} \sqsubseteq \left(Q_{x_{\mathrm{j}}}, q_{x_{\mathrm{j}}}\right)_x^{\mathrm{d}} \tag{3}$$

Based on eq. (3) one may decide on the product conformity ($O_x^{\mathrm{t}} \sqsubseteq O_x^{\mathrm{d}}$) if eq. (3) stands, and respectively, on the non-conformity ($O_x^{\mathrm{t}} \not\sqsubseteq O_x^{\mathrm{d}}$) if it doesn't. A measurement result is compared with a design or a specification value disregarding the uncertainty in measurement.

Let considers a 2-tuple (Q,q), and let the design/specification be expressed in terms of lower limit, ${q_x}_{\mathrm{j}}^{\mathrm{L}}$, respectively, of upper limit, ${q_x}_{\mathrm{j}}^{\mathrm{U}}$, eq. (4).

$$\left(Q_{x_{\mathrm{j}}}, q_{x_{\mathrm{j}}} \pm u\left(q_{x_j}\right)\right)_x^{\mathrm{t}} \sqsubseteq \left(Q_{x_j}, \left(\overline{{q_x}_{\mathrm{j}}^{\mathrm{L}}, {q_x}_{\mathrm{j}}^{\mathrm{U}}}\right)\right)_x^{\mathrm{d}} \tag{4}$$

Eq. (4) is applicable for the case when the manufacturer and the buyer agree upon the risk-of-false-acceptance to be supported by both parties disregarding the risk amplitude.

A risk-based model for conformity assessment

One may observe in eq. (2) that the product conformity depends (if and only if) with the condition that the 2-tuple of (Q, q), for both testing and design instances are equivalent. Eq. (2) materializes the observation by introducing the relation of image as equivalent for conformity.

Eq. (2) depends on the limitation of Leibniz's law of Indiscernible; for this reason, the conformity formulation is transposed in risk terms as in eq. (5).

$$O_x^{\mathrm{t}} \sqsubseteq O_x^{\mathrm{d}} \leftrightarrow \begin{cases} \left(Q_{x_{\mathrm{j}}}, q_{x_{\mathrm{j}}} \pm u(q)_{x_{\mathrm{j}}}\right)_{\mathrm{x}}^{\mathrm{t}} \sqsubseteq \left(\mathrm{Q}_{\mathrm{x_j}}, \left(\overline{{q_x}_{\mathrm{j}}^{\mathrm{L}}, {q_x}_{\mathrm{j}}^{\mathrm{U}}}\right)\right)_{\mathrm{x}}^{\mathrm{d}} \\ \Upsilon_{\mathrm{A,L}} + \Upsilon_{\mathrm{A,U}} \leq \Upsilon_0 \end{cases} \tag{5}$$

Eq. (5) applies for the cases when the declaration of conformity depends with the level of false acceptance risk, resulting in final a declaration of "conform", "non-conform", or "conformity cannot be declared". The last case fires if the condition $\Upsilon_{\mathrm{A,L}} + \Upsilon_{\mathrm{A,U}} \leq \Upsilon_0$ stands not.

3. Case study

The case study considers the product "Calibration block no. 1" (Fig. 1), the product is manufactured and tested in accordance to the standard ISO 2400:2025 and its function is to be used in the standardization of ultrasonic equipment prior to examination.

The product's characteristics to be achieved and evaluated for product conformity are as follows:

a) Steel grade = S355 J0 according EN 10025-2:2019 or equivalent;

b) Shape and dimensions as in Fig. 1;

c) Machining (320 x 120 x 30 mm for rough machining prior heat treatment), heat treatment (Austenitizing/ 920°C x 30 minutes, Quenching in water + Tempering/ 650°C x 3 hrs.);

d) Non-destructive examination 100% UT/ $f \geq 10$ MHz, transducer size of 10 x 15 mm, scatter noise of 10% from screen height;

e) Surface finishing $R_a \leq 0.8$µm;

f) Ultrasonic velocity, TOF = 5920 ± 30 m/s for longitudinal waves, and 3255 ± 15 m/s for transverse waves.

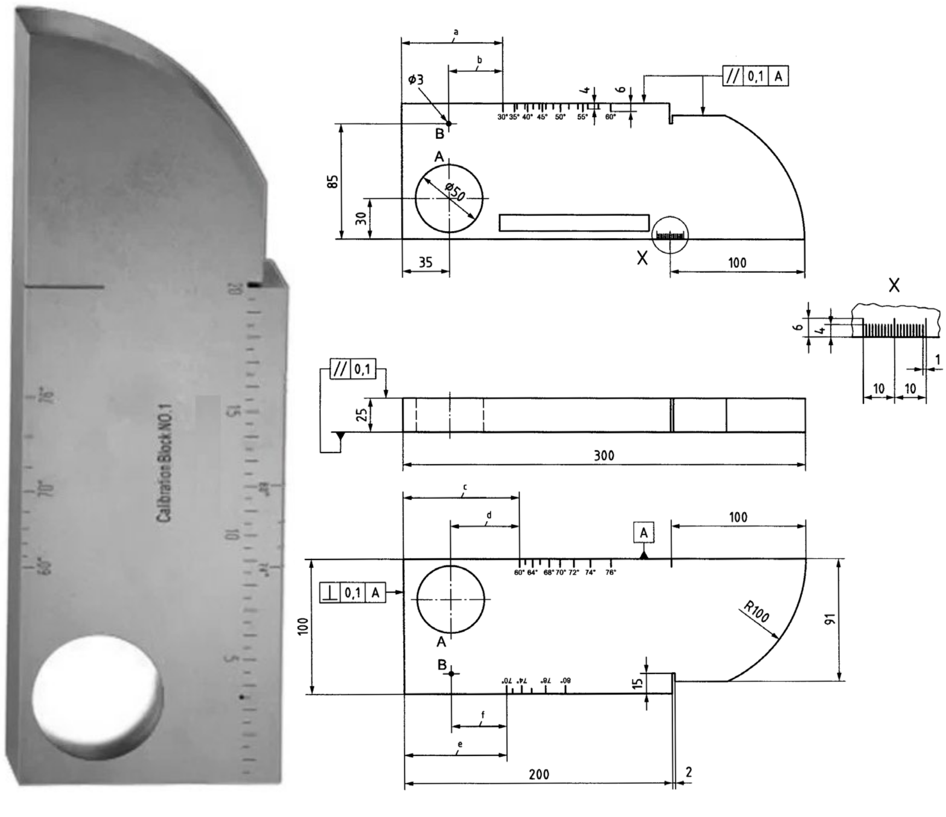

Fig. 1. Calibration block no. 1 – the 3D model [15, 16]

With the definition supplied by the applicable specification, we will refer to the design product as O^{d}, and the product to be tested as O_x^{t}.

It worth notes that there is a set of objects, $1 \leq x \leq n$, to be tested, as they resulted from the sampling phase, but the specification is unique.

The proposed conformity assessment scheme is illustrated in Table 2 with focus on selection and determination.

By consequence, the conformity assessment is based on eq. (5). The laboratory accepted risk level to be considered, $\Upsilon_0 = 0.05$.

The case study considers two characteristics of the product "Calibration block no. 1", namely the ultimate tensile strength, R_m, and the roughness, R_a. The case of R_m exemplifies the computations needed to evaluate the conformity for material grade S355 J0 according to the standard EN 10025-2:2019, and R_a for surface finishing according the standard ISO 2400:2025 (Table 2).

There is no correlation between the characteristics R_m and R_a. Also, we may extent the hypothesis of uncorrelation to all involved characteristics.

Table 2

The proposed conformity assessment scheme

Q^d	q^d	q^t
Chemical composition	EN 10025-2:2019 Conformity: S355 J0	Test certificate according EN 10204:2005, type 3.1 or 3.2
Mechanical testing	SR EN ISO 6892-1:2020 Conformity: S355 J0	
Non-destructive examination	ISO 2400:2025 Conformity: Free from internal discontinuities	
Dimensional check	ISO 2400:2025 Conformity: Specified dimensions and geometrical constraints	
Surface finishing	ISO 2400:2025 Conformity: $R_a \leq 0.8\mu m$	
Ultrasonic velocity longitudinal wave transverse wave	ISO 2400:2025 Conformity: TOF = 5920 ± 30 m/s Conformity: TOF = 3255 ± 15 m/s	
Final report on product conformity	Declaration of compliance to ISO 2400:2025	Certificate of conformity according ISO/IEC 17065:2012
	Mean value of longitudinal wave velocity	
	Mean value of transverse wave velocity	

Both the cases presented herein use test results obtained in a specialized laboratory.

For the R_m case, the results were gathered on a set of five distinct products, and for R_a, five measurements on a single product. The mean value and the associated measurement uncertainty are under consideration for both characteristics. The uncertainty computation and the laboratory accepted risk level selection are both outside of the research scope.

3.1. Evaluation for the R_m characteristic

The laboratory tests results for the ultimate tensile strength, R_m, are illustrated in Table 3. The five measurements of the R_m characteristic finally resulting in the mean value, $\overline{R_m}$, and the associated uncertainty, $u(R_m)$. Then $\overline{R_m}$ is considered as q_{x_1} parameter.

Table 3

The laboratory tests results for R_m

R_m-1	**R_m-2**	**R_m-3**	**R_m-4**	**R_m-5**	**$\overline{R_m}$**	**$u(R_m)$**
MPa						
560	559	566	563	561	561.8	3.3

According the standard EN 10025-2:2019, the following limits will be under consideration, i.e. $q_{x_1}^{\mathrm{L}} = 470$ MPa and $q_{x_1}^{\mathrm{U}} = 630$ MPa. Then the corresponding risks-of-false-acceptance are,

$$\Upsilon_{\mathrm{A,L}} = \varphi\left(\frac{q_{x_1}^{\mathrm{L}} - q_{x_1}}{u(q_{x_1})}\right) = \varphi\left(\frac{470 - 561.8}{3.3}\right) = \varphi(-27.82) =$$
$$= NORM.DIST(-27.82; 0; 1; TRUE) = 1.243 \times 10^{-170},$$

$$\Upsilon_{\mathrm{A,U}} = 1 - \varphi\left(\frac{q_{x_1}^{\mathrm{U}} - q_{x_1}}{u(q_{x_1})}\right) = 1 - \varphi\left(\frac{630 - 561.8}{3.3}\right) =$$
$$= 1 - \varphi(20.67) = 1 - NORM.DIST(20.67; 0; 1; TRUE) = 1 - 1 = 0.$$

Since $q_{x_1} \in \left(\overline{q_{x_1}^{\mathrm{L}}, q_{x_1}^{\mathrm{U}}}\right)$ and the condition $\Upsilon_{\mathrm{A,L}} + \Upsilon_{\mathrm{A,U}} \leq \Upsilon_0$ stands, then R_m result is accepted as conform to the specification EN 10025-2:2019.

3.2. Evaluation for the R_a characteristic

The laboratory tests results for roughness, R_a, are illustrated in Table 4. The five measurements results in the mean value, $\overline{R_a}$, and the associated uncertainty, $u(R_a)$. Then $\overline{R_a}$ is considered as q_{x_2} parameter.

Table 4

The laboratory tests results for R_a

R_a-1	**R_a-2**	**R_a-3**	**R_a-4**	**R_a-5**	**$\overline{R_a}$**	**$u(R_a)$**
μm						
0.70	0.73	0.71	0.72	0.74	0.72	0.05

According to the ISO 2400:2025 standard, the following limits will be under consideration, i.e. ${q_x}_2^{\mathrm{L}} = 0$ µm and ${q_x}_2^{\mathrm{U}} = 0.8$ µm. Then the corresponding risks of false acceptance are,

$$\Upsilon_{\mathrm{A,L}} = \varphi\left(\frac{{q_x}_2^{\mathrm{L}} - q_{x_2}}{u(q_{x_2})}\right) = \varphi\left(\frac{0-0.72}{0.05}\right) = \varphi(-14.4) =$$
$$= NORM.DIST(-14.4; 0; 1; TRUE) = 2.6 \times 10^{-47},$$

$$\Upsilon_{\mathrm{A,U}} = 1 - \varphi\left(\frac{{q_x}_2^{\mathrm{U}} - q_{x_2}}{u(q_{x_2})}\right) = 1 - \varphi\left(\frac{0.8-0.72}{0.05}\right) = 1 - \varphi(1.6) =$$
$$= 1 - NORM.DIST(1.6; 0; 1; TRUE) = 1 - 0.945 = 0.055.$$

Since $q_{x_2} \in \left(\overline{{q_x}_2^{\mathrm{L}}, {q_x}_2^{\mathrm{U}}}\right)$, but $\Upsilon_{\mathrm{A,L}} + \Upsilon_{\mathrm{A,U}} \leq \Upsilon_0$ doesn't stand, then R_a conformity cannot be declared in respect to ISO 2400:2025.

4. Conclusions

The research highlights some important achievements in the field of conformity assessments through conceptual modelling.

Under the hypotheses of conformity as a temporal concept which depends to the identity of the engineered objects the following outcomes applies.

The concept of conformity applies to a specified product or a family of products if and only if all the specified characteristics are part of the conformity assessment.

The conformity assessment considers the specified characteristics against the associated specified tolerance limits and the measurement uncertainty estimation.

The conformity assessment depends to the risk-of-false-acceptance such that the inverse of "conformity" may not be the "non-conformity". In such a case, "conformity cannot be declared" may be preferred depending upon the risk level. The case study exemplifies also the case of non-declared conformity.

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