CALCULATION OF THE PROBABILITY OF TEST OBJECT COMPLIANCE WITH THE SPECIFIED REQUIREMENTS AND NON-BINARY DECISION-MAKING RULES

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The probability of test object compliance with the specified requirements and non-binary decision is a measure of how likely the test object is to meet the criteria for acceptance or rejection based on multiple factors. It is necessary to calculate by using a valid mathematical model that takes into account the test object's characteristics, the test conditions, the test criteria, and the uncertainty of the measurements. The significance of the probability of test object compliance with the specified requirements and non-binary decision can help to evaluate the quality, reliability, and performance of the test object, as well as to support decision making in complex situations.

KEYWORDS

Probability function, binary decision, result analysis

1 INTRODUCTION

A key aspect of any conformity assessment organization's activity is the conformity decision-making process, which is based on the probability and risk factors associated with measurements and tests.

If the results of tests or studies conclude compliance with a norm, specification, standard, reference interval, etc., the laboratory must document a risk-based decision rule, considering the false-positive or false-negative decision in the area of statistical assumptions that are associated herewith with the decision-making rule [ISO 2017, ISO 2022].

Taking into account certain differences in international documents [ISO/IEC 2008, QUAM 2012, ISO/IEC 2012, JCGM 2012, EA-4/02 2022] regarding conformity decision-making, the International Organization for Accreditation has issued its document ILAC G8:09/2019, which summarizes and clarifies the requirements for decision-making by laboratories that are signatories of the ILAC-MRA mutual recognition agreement [Eurachem/Citac 2021, ILAC 2019].

Based on this, in the future we will consider the use of the requirements of ILAC G8:09/2019 in the processes of decision-making by laboratories on compliance with the established requirements, because they are free of ambiguity and in addition to a simple (binary) decision rule and a simple (binary) rule decision-making with a buffer set also guidelines for the use of a non-binary termination rule on compliance [ILAC 2019].

2 MATERIALS AND METHODS

According to the requirements of ILAC-G8:09/2019, compliance decision rules are divided into binary and non-binary rules and rules based on and not based on safe areas [ILAC 2019].

Binary compliance decision rules are based on two definitions of compliance, namely pass or fail. Regarding acceptance, the definition "passes" or "fails" is also applied. That is, the binary decision rule is used when the choice for the result is limited to two options: meets or does not meet (pass or fail / pass or fail).

Non-binary eligibility decision rules are based on more than two definitions [Khosravi 2022]. Of the non-binary rules, the most applicable are rules based on four definitions, namely: "pass", "conditional pass", "conditional fail" or "fail". Regarding acceptance, the definitions "pass", "conditionally pass", "conditionally fail" or "fail" are also used. That is, the non-binary decision rule is used when several terms can express the result: meets, conditionally meets, conditionally does not meet or does not meet (passes, conditionally passes, conditionally does not pass or does not pass / pass, conditional pass, conditional fail, fail).

Acceptance limits (AL) are used to make a decision on compliance, which are the upper or lower limit value for the permissible measured values of the quantity, which, in turn, are based on the limits of the (tolerance limit, specification limit) that establish the upper and lower limit values for the permissible values of the properties of the object of research are given [Mascenik 2014]. Correlation of the measurement result and its uncertainty with the acceptable limit determines which conclusion about conformity should be applied.

Bilateral standards usually use the nominal quantity value (nominal) as a rounded or approximate value that characterizes the value of a measuring device or measuring system, which provides a general guideline for its proper use. When testing environmental objects and in the field of security, one-sided standards are also used, which can be formulated without a nominal value in the phrases "no more" or "no less".

To make a decision, the expanded measurement uncertainty *(U)* is used: — which is obtained by multiplying the total standard uncertainty $u_c(y)$ and the coverage factor *k*: $U = ku_c(y)$. At the same time, the measurement result is expressed as $Y = y \pm U$, and is interpreted so that y is the best estimate of the value of the measured quantity Y, and from $y - U$ to $y + U$ - is the interval in which the largest fraction of the distribution of values that can be associated with Y. The similar interval is also expressed in the following way: $y - U \leq Y \leq y + U$.

To calculate the extended uncertainty of measurements according to type A, we should also need the usual statistical characteristics, such as: dispersion (variance), which is a characteristic of a random variable, which for a continuous random variable X, characterized by the distribution density $g_X(\xi)$, and is defined as $V(X) = \int_{-\infty}^{+\infty} [\xi - E(X)]^2 g_X(\xi) \mathrm{d}\xi$, the standard deviation that forms the positive square root of this variance, and also a mathematical expectation

(expectation), which is a characteristic of a random variable, which for a continuous random variable X is characterized by the density of the distribution $g_X(\xi)$ and is defined as: $E(X) = \int_{-\infty}^{+\infty} \xi g_X(\xi)\,\mathrm{d}\xi$.

To make a decision, as well as to calculate the probabilities of compliance with a non-binary rule, we will also need classical statistical parameters, such as: probability distribution (probability distribution, distribution), which characterizes the measure of the distribution probability induced by a random variable; the probability distribution function (distribution function), which sets for each value of ξ the probability that the random variable X is less than or equal to ξ: $G_X(\xi) = \Pr(X \leq \xi)$; the probability density function or PDF, which is a derivative of the distribution function, if it exists: $g_X(\xi) = \frac{\mathrm{d}G_X(\xi)}{\mathrm{d}\xi}$, as well as the normal distribution, which characterizes the probability distribution continuous random variable X, which has a probability density function of the distribution of the form $g_X(\xi)\mathrm{d}\xi = \frac{1}{\sigma\sqrt{2\pi}} e^{\left[-\frac{1}{2}\left(\frac{\xi-\mu}{\sigma}\right)^2\right]}$, for $-\infty < \xi < +\infty$; where, μ – s the mathematical expectation, σ – is the standard deviation of the quantity X. The normal distribution is also called the Gaussian distribution and is graphically displayed in the form of a bell-shaped curve, which is also called a Gaussian.

Graphically, a simple binary decision rule for a two-way normative can be illustrated as follows on a figure 1:

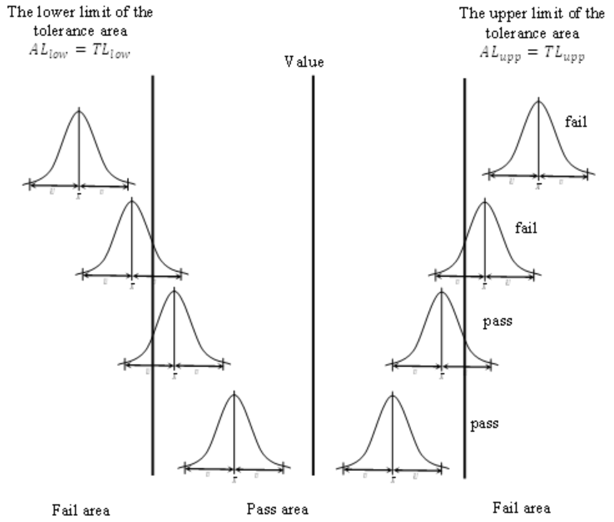

Figure 1. Simple binary decision rule for a two-way normative

In this case, the binary compliance statement for the simple acceptance rule (for the safe area w = 0) is given in the form:

- Pass — the measurement result does not exceed the limit of the tolerance field, $AL = TL$.
- Fail — the measurement result exceeds the limit of the tolerance field, $AL = TL$.

Safe areas are used to reduce the probability of making an incorrect decision about compliance. In fact, this is a protective factor built into the measurement decision-making process, which consists in narrowing the acceptance limits below the tolerance field. For this, the uncertainty of measurements is taken into account in the calculations.

Document refers to the safe area, where the width of the safe area w is the difference between the limit of the tolerance field (TL) and the acceptance limit (AL) or $w = TL - AL$. This means that if the measurement result lies within the acceptance limits, then the measurement result is considered to pass the specification [ILAC 2019].

Graphically, a binary decision rule with buffers for a two-way normative can be illustrated as follows on a figure 2:

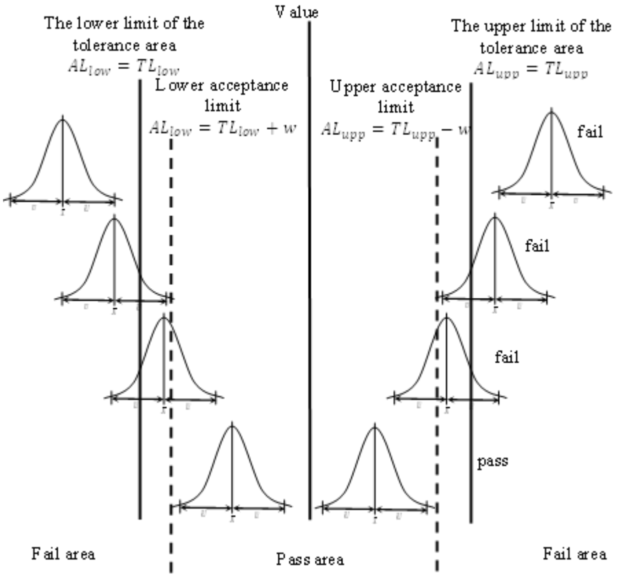

Figure 2. Binary decision rule with buffers for a two-way normative

In this case, a binary compliance statement for an acceptance rule with a safe area $w \neq 0$ is given in the form:

- Pass — acceptance is based on the safe area, the measurement result does not exceed the acceptance limit, $AL = TL - w$.
- Fail — the failure is based on the safe area, the measurement result exceeds the acceptance limit, $AL = TL - w$.

These two binary decision rules are known and standardized in the above-mentioned documents. However, there are cases when it is necessary to use a non-binary decision rule. In this case, a protective strip is also used in a certain way, but its use leads to the application of the principle of conditional compliance. This can be illustrated as follows on a figure 3:

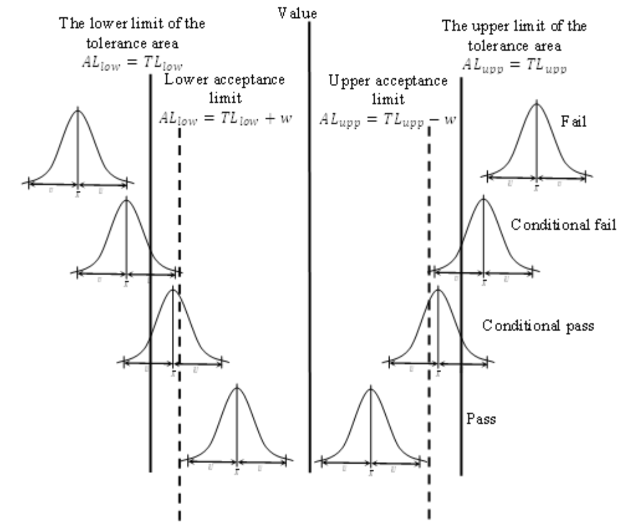

Figure 3. Non-binary decision rule

A non-binary statement of compliance for a rule with a safe area $w \neq 0$ s submitted in the form:

- Pass — the measurement result does not exceed the acceptance limit, $AL = TL - w$.
- Conditional pass — the measurement result is within the safe area and does not exceed the limit of the tolerance field, in the interval from $TL - w$ to TL.

- Conditional fail — the measurement result exceeds the limit of the tolerance field, but does not exceed the limit of the tolerance field with an added safe area, in the interval from *TL* to $TL + w$.
- Fail — the measurement result exceeds the acceptance limit and the safe area, $AL = TL + w$.

Measurement uncertainty is directly taken into account for the calculation of the width of the protective strip. ISO/IEC 17025 requires laboratories to assess measurement uncertainty and to apply a documented decision rule when claiming compliance. The approaches used can vary significantly depending on the situation, and different buffers can be applied [Modrak 2016, ISO 2017].

Often the safe area is calculated as the product of the multiplier r and the expanded measurement uncertainty U, де $w = r \cdot U$. For a binary decision rule, a measured value below the acceptance limit $AL = TL - w$ s considered as acceptable.

Despite the fact that the safe area is often set equal $w = U$, here are many cases where a multiplier *r* other than 1 is used.

The table 1 below shows examples of different buffers to achieve certain levels of specific risks based on the customer statement.

Table 1. Buffers to achieve certain levels of specific risks based on the customer statement

Decision rule	Safe area w	Specific risk
6 sigma rule	$3\ U$	<1 ppm PFA
3 sigma rule	$1{,}5\ U$	<0.16% PFA
rule ILAC-G8:09	$1\ U$	<2.5% PFA
rule ISO 14253-1	$0{,}83\ U$	<5% PFA
simple binary rule	0	<50% PFA
uncritically	$-U$	The product is rejected if the measured value is higher $AL = TL + U$ <2.5% PFR
determined by the customer	rU	The customer can himself assign an arbitration *r* for his protective strip

Where: PFA – probability of false acceptance and PFR – probability of false rejection (One-sided specification and normal distribution of results are assumed).

Specific risks include the probability that the accepted sample will turn out to be inappropriate (false-positive conclusion) or, conversely, that the rejected sample will be relevant (false-negative conclusion). This risk is based on measurements of a single sample.

Measurement uncertainty is not directly taken into account for the calculation of the width of the protective strip. If the measurement uncertainty is used as is, then the acceptance interval is limited by the tolerance part. The greater the measurement uncertainty, the smaller the acceptance interval becomes. This will lead to fewer acceptable results than if the measurement uncertainty were smaller.

To avoid reliance on the guard band among laboratories, regulatory bodies often use measurement uncertainty indirectly. This can be done in different ways, depending on the area of test or calibration. Examples of such use:

- OIML R 76-1 d. 3.7.1 requires that "... standard masses used for type evaluation or verification of an instrument (instrument) ... .. shall not have an error of more than 1/3 MPE (maximum permissible error). If they belong to class E2 or higher, then their uncertainty should not be higher than 1/3 of the MPE of the device (tolerance) [OIML 2006].
- OIML R 117-1 When conducting tests, the expanded uncertainty of determining the errors of volume or mass indicators should be below one fifth of the maximum permissible error (MPE) (tolerance) [OIML 2019].

Taking into account the risks of false acceptance and false rejection. As stated in JCGM 106:2012, "Binary decision rules aimed at reducing the consumer's risk always increase the producer's risks." This statement can be applied to any decision rule that applies buffers to improve or set a minimum risk of false acceptance. Initially, the customer, when submitting the object to a calibration or testing laboratory, can only care about the "risk of false acceptance by the consumer". However, when a laboratory returns an item as rejected, the customer will have to investigate the products their organization manufactures, as this can lead to costly product returns and recalls down the road [Dima 2010, JCGM 2012, Dyadyura 2021].

Taking into account the probability of compliance when making a decision. An object meets the specified requirements if the valid value of its *Y* property lies within the tolerance field. The knowledge about *Y* is represented by the PDF $g(\eta\eta_m)$ in such a way that a statement of correspondence is always an inference that has some probability of being true. If we denote the set of admissible (those that meet the requirement) values of *Y* by *C*, then the probability of compliance, denoted by p_c, will be:

$$p_c = \Pr(Y \in C|\eta_m) = \int g(\eta|\eta_m)\mathrm{d}\eta$$

This expression is a general rule for calculating the probability that an object meets a given requirement, based on a measurement of the corresponding property of the object. For example, if a two-sided tolerance field is given for the measured value *Y* with the lower limit T_L and the upper limit T_U, then $C = [TL, TU]$ and the probability of matching will be equal to:

$$p_c = \int_{T_L}^{T_U} g(\eta|\eta_m)\mathrm{d}\eta$$

Since an object either conforms to the requirement or it does not, the probability that it does not conform is: $\bar{p}_c = 1 - p_c$

The probability of matching depends on the level of knowledge about the measured value *Y*, which is represented and expressed using the PDF $g(\eta|\eta_m)$. In many cases it is reasonable to characterize the knowledge about Y as a normal distribution, and this probability can be calculated. If the prior distribution is normal and the measurement system (ie, the Likelihood Function) is characterized by a normal distribution, then the distribution $g(\eta|\eta_m)$ s also a normal distribution.

More generally, if the likelihood function is normally distributed and the prior information is always limited, then the posterior (available after the measurement) PDF will be approximately normal. In this case, $g(\eta|\eta_m)$ can be adequately approximated by a normal distribution with mathematical expectation (mean) and standard deviation given by the best estimate y and standard uncertainty *u*. Then the following formula can be used to determine:

$$g(\eta|\eta_m) = \frac{1}{u\sqrt{2\pi}} e^{\left[-\frac{1}{2}\left(\frac{\eta - y}{u}\right)^2\right]} =: \varphi(\eta, y, u^2)$$

Accordingly, the probability that the value of *Y* lies in the interval from *a* to *b* can be determined using the following formula:

$$\Pr(a \le Y \le b|\eta_m) = \Phi\left(\frac{b-y}{u}\right) - \Phi\left(\frac{a-y}{u}\right)$$

where $y = y(\eta_m)$ and

$$\Phi(z) = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{z} e^{\left[-\frac{t^2}{2}\right]} \mathrm{d}t,$$

which is a normal distribution function that can be as function "=NORM.DIST()" or "=NORM.DIST()".

2.1 *A single upper limit of the tolerance field.*

The figure below, taken from JCGM 106:2012, shows a normal PDF combined with a one-sided tolerance field with a single upper limit T_U. Values of the studied property *Y* that meet the requirements lie in the interval $\eta \le T_U$. The best estimate of y lies in the middle of the tolerance box, and the shaded area to the right of T_U shows the probability that the facility is out of specification (fig. 4).

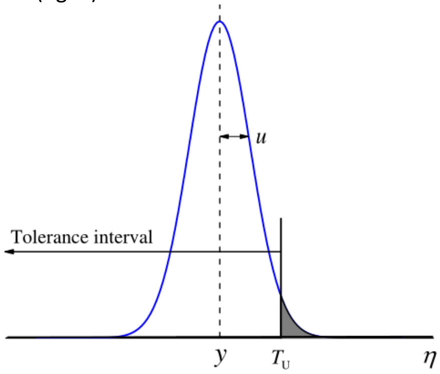

Figure 4. Single upper limit of the tolerance field

Then $a \to -\infty$, $b = T_U$, and if $\Phi(-\infty) = 0$, we obtain the probability of correspondence equal to:

$$p_c = \Phi\left(\frac{T_U - y}{u}\right)$$

The probability of matching for a single upper limit of the tolerance field can be calculated using the function "=NORM.DAP(T_U, y, u, TRUE)".

2.2 *A single lower limit of the tolerance field.*

The figure below, taken from JCGM 106:2012, shows a normal PDF combined with a one-sided tolerance field with a single lower bound T_L. Values of the studied property Y, hat meet the requirements lie in the interval $\eta \ge T_L$. The best estimate of y lies in the middle of the tolerance box, and the shaded area to the left of T_L shows the probability that the facility is out of specification (fig. 6).

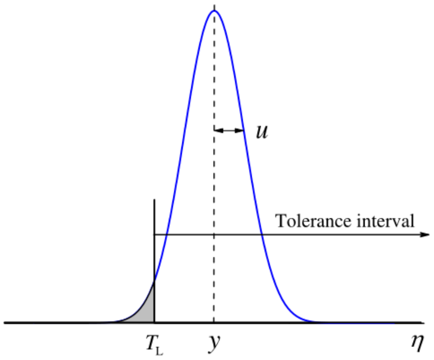

Figure 6. Single lower limit of the tolerance field

Then $a = T_L$, $b \to \infty$, and if $\Phi(+\infty) = 1$, we obtain the probability of correspondence equal to:

$$p_c = 1 - \Phi\left(\frac{T_L - y}{u}\right)$$

The probability of matching for a single upper limit of the tolerance field can be calculated using the function "=1 NORM.DIST(T_L, y, u, TRUE)".

2.3 *Two-sided tolerance fields.*

The figure below, taken from JCGM 106:2012, shows a two-sided tolerance box with boundaries T_L i T_U and a width $T = T_U - T_L$ that defines the tolerance T. As before, it is assumed that the knowledge of the measured quantity *Y* is represented by a normal PDF. The estimate y lies within the tolerance field, and there is an apparent probability fraction in the region $\eta > T_U$, located beyond the upper limit of the tolerance field (fig. 5).

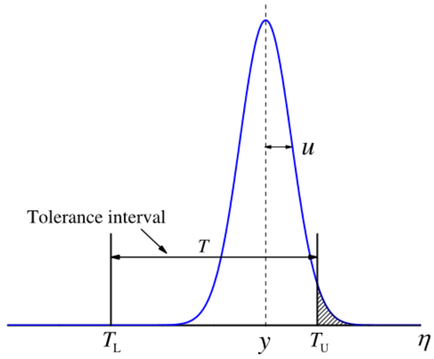

Figure 5. Two-sided tolerance fields

Then, for $a = T_L$, $b = T_U$, we get the probability of correspondence equal to:

$$p_c = \Phi\left(\frac{T_U - y}{u}\right) - \Phi\left(\frac{T_L - y}{u}\right)$$

The probability of matching for a two-sided tolerance field can be calculated using the function "=NORM.RSP(T_U, y, u,TRUE) NORM.RSP(T_L, y, u,TRUE)".

Indication of the probability of conformity in the calibration certificate, test report or medical examination results.

The probability of conformity is calculated primarily for the purpose of making a decision about conformity, and it is not necessary to indicate it in the calibration certificate. However, it is reasonable to indicate the probability of compliance when using a non-binary decision rule for compliance with a buffer strip. In this case, it is advisable to modify the non-binary statement as follows:

- Pass — the measurement result does not exceed the acceptance limit, $AL = TL - w$.
- Conditional pass — the measurement result is within the protective band and does not exceed the limit of the tolerance field, in the interval from $TL - w$ to *TL*. The probability of matching is $p_c = 0{,}74$ (74%).
- Conditional fail — the measurement result exceeds the limit of the tolerance field, but does not exceed the limit of the tolerance field with an added protective band, in the interval from *TL* to $TL + w$. The probability of matching is $p_c = 0{,}13$ (13%).
- Fail — the measurement result exceeds the acceptance limit and the protective band, $AL = TL + w$.

3 DECISION RULE

Document ILAC-G8:09/2019 proposes a specific algorithm for choosing a decision rule. When a choice of rules is available, the laboratory and customers should discuss the levels of risk associated with the probability of false acceptance and false rejection due to the chosen decision rules. There is no single decision rule capable of covering all areas of testing and calibration covered by ISO/IEC 17025. Some disciplines, industries or regulators themselves define decision rules suitable for their application and publish them in specifications, standards or regulations.

In accordance with the requirements of ISO/IEC 17025, if the Customer, in the request for calibration or testing, requires the laboratory to provide a statement of compliance with the specification or standard for calibration or testing, the laboratory conducts an assessment of the calibration object's compliance with the established requirements. Based on this assessment, the calibration or test report shall include a corresponding declaration of conformity (fig. 7).

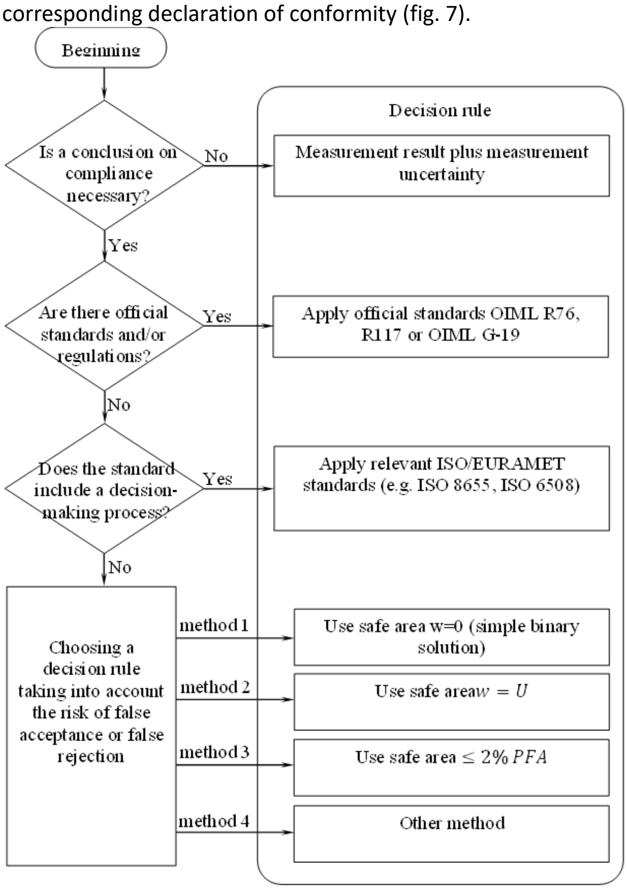

Figure 7. Decision rule

Also, the decision-making rule is agreed with the customer. By default, the customer is offered a simple binary decision rule.

Property requirements are usually provided in the form of tolerance field boundaries, which define the range of permissible values of the object's measured property or the tolerance field.

Such requirements can be, for example:

- nominal values of the physical quantity reproduced by the equipment and permissible deviations from the nominal values;
- limits of absolute or relative error of measuring equipment and other requirements.

Certain nuances in the application of the decision-making rule are its use in research at the limit of the capabilities of analytical devices in the regulation of toxicants in environmental objects and/or in food products or feed [Krenicky 2022]. The content of toxic elements (As, Cd, Cu, Fe, Hg, Pb, Zn, etc.), persistent organic pollutants (in particular, some pesticides, polychlorinated diphenyl, polychlorinated dioxins, polychlorinated dibenzofurans), mycotoxins, etc. A number of these toxicants are regulated in the form of sensitivity of the analytical method, and some, until recently, were regulated as "not allowed" even without reference to the sensitivity of the method. For certain chromatographic methods of analysis, the limit of the tolerance field can be normalized as "not more than the limit of detection" (detection) or LOD, or as "not more than the limit of quantification" or LOQ. With this normalization of the limit of the tolerance field when making a decision, it is not possible to apply a protective band and, as a result, it is impossible to use a non-binary rule and a binary rule with a protective band.

Also, uncertainties related to the principle of detection and the resolution of the chromatographic system as a whole are features of the decision-making about compliance in the chromatography of toxicants. The sensitivity of the chromatographic detector is quite rightly included in the mentioned concept of making a decision about compliance. However, not enough attention is paid to the resolution of the chromatographic system in the measurement methods. For certain pharmacopoeia methods of analysis, the resolution indicator is standardized, which characterizes the proximity of two chromatographic peaks standing next to each other, however, it does not affect the decision-making rule, but rather characterizes the quality of the chromatographic system [Pharmacopoeia 2010].

4 CONCLUSION

Relevant issues of compliance decision-making, which testing, calibration and medical laboratories make in their daily activities, are considered.

It is shown how to use spreadsheets to calculate the probability of compliance with parameters of conditional acceptance or conditional rejection when using a non-binary decision-making rule.

The peculiarities of decision-making in the analysis of micro-quantities under the conditions of the limit of detection and the limit of quantification are considered.

The peculiarities of decision-making in conditions of insufficient resolution of chromatographic systems are considered.

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