Risk-based approaches are a feature of the modern quality management system. A method of optimization of product quality inspection plan by the risk of non-conformity slippage is proposed. The method is based on a risk ranking matrix, criteria of the failure mode and effects analysis (FMEA), block classification of inspection plans, approaches to non-conformity prediction, and probability multiplication theorem for independent events.

The risk of non-conformity slippage was defined as a criterion of inspection plan optimization. The proposed method allows determining the acceptability of the risk, with 100 % quality inspection, in case of abandoning the inspection operation, the possibility of applying sampling and minimum sampling volumes necessary to ensure an acceptable risk level. Relationships were derived to determine the minimum required number of inspected units out of 1,000, with an acceptable risk level in product quality inspection. The initial data for the calculation are the main characteristics of the inspection plan: the probability of the object conformity with the requirements for the controlled quality characteristic, the probability of not detecting non-conformity with the provided inspection method, the rate of non-conformity slippage, which ensures an acceptable risk level. The formula allows calculating the minimum sampling volume that provides an acceptable level of non-conformity slippage risk during the implementation of the product quality inspection plan (QIP).

The proposed method was tested on the inspection plan for welds of air tanks of the railway car braking system. It is possible to abandon the original 100 % inspection plan and apply sampling, which provides an acceptable level of non-conformity slippage risk. This allows reducing the volume and costs of inspection by 18 %

Keywords: quality inspection planning, non-conformity risk, probability rank, FMEA, quality management

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DEVELOPMENT OF A METHOD FOR OPTIMIZING A PRODUCT QUALITY INSPECTION PLAN BY THE RISK OF NON-CONFORMITY SLIPPAGE

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1. Introduction

Modern quality management systems rest on risk-based thinking and approaches that involve the integration of risk management activities into all processes of the quality management system in the organization. Traditional quality inspection processes are no exception and have a significant impact on the risks of poor product quality. Excessive inspection plans lead to unreasonably high quality costs, and insufficient inspection plans increase the possibility of non-conformity slippage and associated risks. Therefore, studies aimed at optimizing inspection plans by the level of non-conformity slippage risk are relevant. The task of optimizing inspection plans is often set for Six Sigma teams to improve quality inspection processes.

2. Literature review and problem statement

Numerous studies have shown that due to the variability of product quality indicators, there are no absolutely effective methods to prevent non-conformities [1–4]. The inability to prevent non-conformities leads to the need to identify non-conformities using product quality inspection methods. Quality inspection processes are a "filter" designed to reliably identify and transfer nonconforming products for subsequent management. In one-off production, with automated control methods, for especially critical products in batch production, at low unit costs, each item is checked (100 % control). Studies of the reliability of product quality inspection [5, 6] show that there are no ideal methods to guarantee the detection of non-conformities. Therefore, even inspection of each item is not a guarantee of the absence of non-conformities in the output.

Product quality inspection is a forced quality assurance measure, so in practice, they strive to reduce the amount of control. The vast majority of studies are aimed at determining the scope of sampling, ensuring the optimization of control costs [7–10]. For non-essential products, 100 % inspection is replaced with 10 % inspection (100 out of 1,000 production units are checked). Such an inspection plan allows you to reject identified non-conforming units, significantly reduce inspection costs and have an idea of the product quality level. Obviously, with such an inspection plan, the level of product non-conformity can be significantly higher than with 100 % inspection.

Studies [11, 12] are devoted to statistical acceptance inspection plans, focused on the acceptance of batches of products with a given AQL – acceptable quality limit. These inspection plans are also not ideal. There is a probability of accepting batches with an actual quality level significantly lower than AQL – consumer risk, and the probability of rejecting a batch with an actual quality level higher than AQL – supplier risk. Non-zero consumer risk suggests that with statistical sampling, the level of non-conformities in the accepted batches of products may exceed the AQL value set in the inspection plan.

Thus, the application of product quality sampling always carries the risk of non-conformity slippage. With 100 % inspection, slippage of non-conformities is also possible, since there are no absolutely reliable methods for detecting them. Therefore, non-conformity slippage may occur with any inspection plan, despite the detection measures adopted by the inspection plan [13].

The possibility of non-conformity slippage in spite of product quality inspection measures leads to uncertainty in the compliance of the production unit with the requirements. This uncertainty can be expressed quantitatively as the product quality level – the number of non-conforming items per 1,000 units. In these conditions, it is important to predict the probability of producing high-quality products.

In [14, 15], the foundations of calculation methods have been developed, which allow predicting the probability of producing high-quality products and the number of residual non-conformities according to the given flowcharts of the production process. With respect to the product quality characteristic, all production operations can be divided into actively forming, actively transforming the characteristic, passive with respect to the characteristic and inspection operations. The separation criterion is the effect of the operation on the controlled quality characteristic [14]. These works can be taken as a methodological basis for predicting the possible number of non-conforming production units released under the inspection plan. However, risks are determined not only by the probability, but also by the consequences of slippage of non-conforming units in products.

Non-conformity slippage can lead to undesirable consequences, both at subsequent production stages, and when the product is used by the consumer. Thus, there are risks of non-conformity slippage during the implementation of the adopted inspection plan. In [16–20], system-wide approaches to risk control in quality management were studied. The paper [16] examines the role of risks in supply chains. Special attention is paid to the risks of an integrated management system based on international standards ISO 9001, ISO 14001, ISO 22000, ISO 28000. Features of risk management in project management were studied in [17]. The main difference between the current version of the international standard ISO 9001:2015 and the previous ones is the requirement to implement risk-based approaches to quality management. Features of the implementation of risk-based management systems were studied in [18]. The work [19] investigates the relationship between the TQM methodology and standardized ISO 9001:2015 approaches to risk-based quality management. System-wide approaches to risk control in a quality management system lay the foundation, but risk-based control methods need to be refined. Risk assessment methods based on data on the likelihood and consequences of an event are numerous and well known [21, 22]. Among these methods, a special place is occupied by the failure mode and effects analysis (FMEA) [23–30]. In [23, 24], approaches to quantifying the failure severity and occurrence were defined. Peculiarities of applying the risk priority number (RPN) were studied in [25–27]. Features of ensuring consumer orientation in the failure mode and effects analysis (FMEA) were studied in [28–30]. Optimization of inspection plans based on the level of non-conformity slippage risk requires investigation of the applicability of the indicated quality control methods.

The known application of risk-based approaches to the optimization of inspection plans is mainly aimed at inspection plans for potentially hazardous operating facilities (RIP) [31–35]. In [31, 32], the influence of the uncertainty of variables on inspection plans of operating facilities was investigated. Possibilities of optimizing inspection intervals of operating facilities were defined in [33–35]. In the above works, inspection plans of operating facilities were investigated. However, the approaches applied and the results obtained can be useful for optimizing production inspection plans. The problem is the lack of methods for sample size calculation, which provides an acceptable level of non-conformity slippage risk in the implementation of the quality inspection plan (QIP). Analysis and classification of known quality inspection plans, development of calculation models for determining the non-conformity slippage rate, analysis of the resulting models will provide the tools necessary for risk-based optimization of product quality inspection plans [36].

3. The aim and objectives of the study

The aim of the study is to develop a method for optimizing a product quality inspection plan based on the criterion of non-conformity slippage risk acceptability. This will make it possible to reduce inspection costs by minimizing sample sizes while ensuring an acceptable level of non-conformity slippage risk.

To achieve the aim, the following objectives were set:

– to determine basic quality inspection plans;

– to derive a calculation formula for determining the non-conformity slippage rate in the implementation of the inspection plan;

– to justify the conditions for acceptability of non-conformity slippage risk;

– to test the method of inspection plan optimization.

4. Methodological framework for determining the non-conformity slippage rate and assessing associated risks

Determination of non-conformity slippage rate was based on the analysis of the inspection plan as a chain of independent actively forming and control operations using the approaches [14, 15]. The probability multiplication theorem for independent events was used.

The non-conformity slippage risk was assessed by the risk ranking matrix method [21], using ranking criteria adopted in the failure mode and effects analysis (FMEA) [23, 24].

5. Optimization of the product quality inspection plan by the criterion of non-conformity slippage risk acceptability

5. 1. Basic quality inspection plans

Planning of risk management activities for non-conformity with the quality requirements for products and services

applies to all processes of the quality management system, including quality control processes. The procedure for optimizing the inspection plan proposed in this paper is actually an option for meeting the requirements of the international standard ISO 9001:2015 in terms of processing risks associated with quality control processes.

In relation to the quality inspection plan, risk management (optimization) activities should include:

– determination of the situation – determining the specified requirements for the inspection object, determining the inspection plan;

– identification, analysis and assessment of risk – determining the probability of non-conformity slippage, assessing the risk of non-conformity slippage, assessing the risk acceptability;

– impact on the risk – making a decision on the acceptability or revision of the analyzed inspection plan.

Thus, the optimization of the inspection plan can be carried out in accordance with the proposed algorithm (Fig. 1).

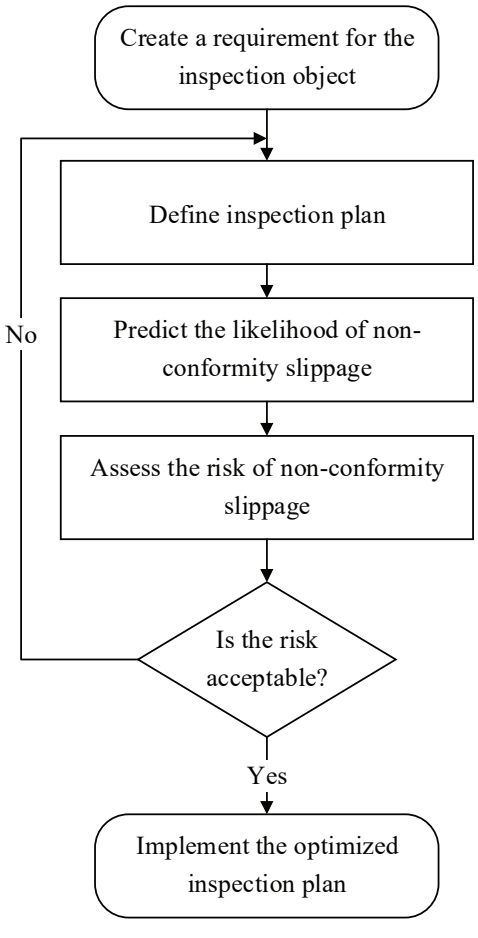

Fig. 1. Algorithm of inspection plan optimization by risk level

Optimization of the inspection plan by risk level requires the definition of standard quality inspection plans.

The object of the inspection is the products to be manufactured. The inspection plan defines the procedure for confirming the compliance of products with the established requirements. The requirements are set by the organization before assuming obligations to supply products to the consumer. The requirements are established in relation to product characteristics, based on the expected and stated needs and expectations of customers, the requirements of the organization and interested parties. The characteristic of the product, for which the requirements are established, becomes a product quality characteristic. Each quality characteristic must be associated with an inspection plan to determine the value of this characteristic for the product unit. Depending on the set value of the quality characteristic, a decision is made on the conformity of the inspection object with the requirements for this characteristic.

Preventing non-conformity is preferable to identifying it. However, it is not always possible to prevent non-conformities. Therefore, the development, optimization and implementation of quality inspection plans is a mandatory component of operational management and planning in an organization's quality management system.

Product quality inspection should be performed as close as possible to the source of non-conformities. Non-conformity of the quality characteristic usually occurs when performing an operation that forms this characteristic – actively forming operation in relation to the quality characteristic. For example, the conformity of this paper with grammar requirements is formed at the time of writing. Inspection operations should follow actively forming operations as closely as possible (automatic text checking on the computer is enabled). The inspection plan establishes a method for determining the value of the quality characteristic (inspection, verification method). The inspection method can determine the quantitative values of the controlled characteristic or detect non-conformity with the requirement (template control).

The actively forming operation together with the following inspection operation forms a block of operations of the quality inspection plan. Using the Microsoft Visio graphics editor, a logical diagram was developed, the element of which is shown in Fig. 2 by the block of operations of the quality inspection plan.

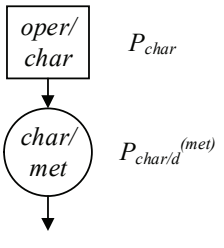

Fig. 2. Block of inspection plan operations for the product quality characteristic

The rectangle indicates the operation that actively forms a controlled characteristic. The circle indicates an inspection operation for this characteristic.

Each actively forming operation is objectively characterized by the probability P_{char} of forming the required value of the controlled quality characteristic (probability of conformity). The probability of conformity of the characteristic with the requirements is formed by all quality assurance measures according to the controlled characteristic and is an indicator of the effectiveness of such measures. The P_{char} value can be found in production as a given actual target quality level by the controlled characteristic, or as a proportion of the corresponding product by the controlled characteristic (SPC).

The inspection operation for the characteristic is objectively characterized by the probability of undetected non-conformity $P_{char/d}^{(met)}$. The probability of undetected non-conformity is an indicator of the effectiveness of the inspection operation for the characteristic and can be determined by measurement system analysis (MSA) methods.

Each quality characteristic of the object corresponds to its own inspection plan. For example, external inspection can simultaneously detect non-conformities in several quality characteristics with the same actively forming operation. In this case, the P_{char} and $P_{char/d}^{(met)}$ values for each quality characteristic of the inspection object are usually different.

Based on the analysis results, three basic options of the quality inspection plan can be considered.

First option. Single-block plan for 100 % inspection of a production batch of volume N with a non-zero inspection operation (Fig. 3). This plan provides for the verification of conformity of all N product units with quality requirements using an inspection method with a probability of undetected non-conformity other than one.

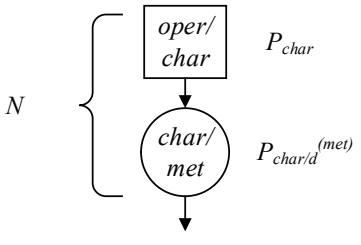

Fig. 3. Diagram of single-block non-zero product quality inspection plan

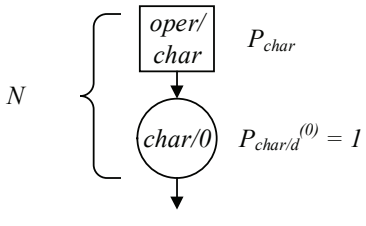

Fig. 4. Diagram of single-block zero product quality inspection plan

Second option. Single-block inspection plan for a production batch of volume N with a zero inspection operation (Fig. 4). A zero inspection operation has a probability of undetected non-conformity of one, which is equivalent to the absence of inspection operation (zero inspection operation). Such a plan leads to the slippage of all non-conformities that appeared during the actively forming operation.

Third option. Two-block inspection plan for a production batch of volume N. The plan provides for non-zero and zero inspection operations. The inspection plan contains N_1 blocks with a non-zero inspection operation and N_2 blocks with a zero inspection operation. In fact, this inspection plan checks only part of N_1 products from a batch of N units. If the number of units to be checked is set to N_1, the number of units produced without checking can be found:

$$N_2 = N - N_1. \quad (1)$$

The diagram of the two-block quality inspection plan is shown in Fig. 5.

The plan diagram can be used to determine the non-conformity slippage rate in the implementation of this plan.

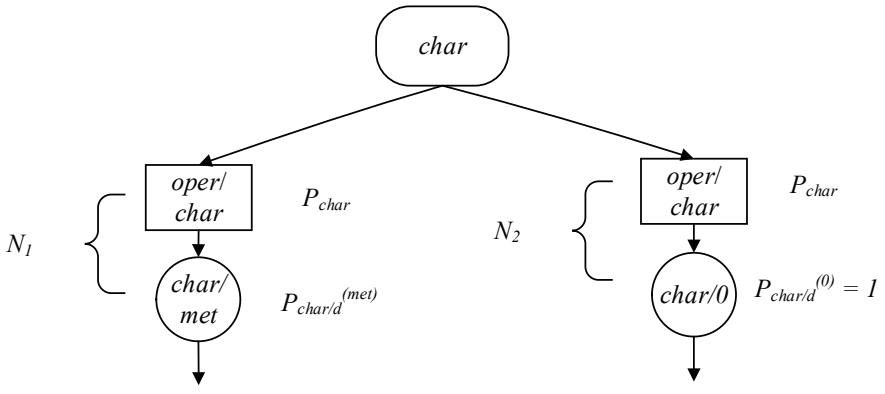

Fig. 5. Diagram of two-block product quality inspection plan

5. 2. Determination of the non-conformity slippage rate during inspection plan implementation

Non-conformity slippage in the block of inspection plan operations is the result of two simultaneous events. The first event is that during the actively forming operation, a non-conformity appeared in the controlled quality characteristic, despite all the measures taken to prevent it. The second event is that the applied inspection method failed to detect a non-conformity.

If we denote the probability of the object's conformity with the requirements for the controlled quality characteristic by P_{char}, the probability of the object's non-conformity by this characteristic is defined as $(1–P_{char})$. Thus, non-conformity slippage through the block of inspection plan operations (Fig. 2) is possible with the simultaneous occurrence of two events with probabilities:

– for the controlled quality characteristic, there will be a non-conformity – with a probability $(1–P_{char})$;

– the non-conformity will not be detected by the provided inspection method – with a probability $P_{char/d}^{(met)}$.

Since the occurrence and non-detection of non-conformity by the provided inspection method are independent events, the probability of non-conformity slippage through the block of inspection plan operations can be determined by the probability multiplication theorem:

$$P_{nc/char} = \left(1 - P_{char}\right) \times P_{char/d}^{(met)}. \quad (2)$$

For the first option – a single-block plan for 100 % inspection of a production batch of volume N with a non-zero inspection operation (Fig. 3), the number of quality non-conformities that slipped through during the implementation of the inspection plan:

$$d_{nc/char} = N \times \left(1 - P_{char}\right) \times P_{char/d}^{(met)}. \quad (3)$$

For the second option – a single-block inspection plan for a production batch of volume N with a zero inspection operation (Fig. 4), the number of slipped quality non-conformities:

$$d_{nc/char} = N \times \left(1 - P_{char}\right) \times P_{char/d}^{(0)} =$$
$$= N \times \left(1 - P_{char}\right) \times 1 = N \times \left(1 - P_{char}\right). \quad (4)$$

The third option – a two-block inspection plan for a production batch of volume N with non-zero and zero inspection operations (Fig. 5). The number of quality non-conformities that slipped through during the implementation of the inspection plan:

$$d_{nc/char} = N_1 \times (1 - P_{char}) \times P_{char/d}^{(met)} + N_2 \times (1 - P_{char}) \times 1. \quad (5)$$

The calculated value of the non-conformity rate ($d_{nc/char}$) determines the possibility of consequences caused by the quality non-conformity slippage in the considered inspection plan.

5. 3. Conditions for acceptability of the non-conformity slippage risk

The risk of non-conformity slippage is determined by a combination of the consequences and the probability of non-conformity slippage.

To determine the risk level, the risk rating matrix recommended by the international standard IEC 31010:2019 is widely used [21].

The matrix uses a five-level consequence ranking. The rank is indicated by a letter of the Latin alphabet in the range from a to e. The rank value is assigned by the expert evaluation method. Criteria may differ for different product categories, but modern approaches adopted in the failure mode and effects analysis (FMEA) methodology can be taken as a basis [23]. According to the FMEA method, a 10-point scale of consequences (severity) designated by *S* was adopted. Table 1 shows the criteria for assigning a consequence rank.

Table 1

Consequence ranking

Consequence rank	FMEA (*S*) – Severity, point	Consequences
a	10	Non-conformity slippage is a potential threat to human life and health without warning
	9	Non-conformity slippage is a potential threat to human life and health with warning
b	8	Products are not functional. Loss of main function
c	7	Products are functional with reduced efficiency
	6	Products are functional, but some functions are not available
	5	Products are functional, but some functions are limited
d	4	Products are fully functional, but there are problems with appearance, aesthetics (noticed by more than 75 % of consumers)
	3	Products are fully functional, but there are problems with appearance, aesthetics (noticed by more than 50 % of consumers)
e	2	Products are fully functional, but there are problems with appearance, aesthetics (noticed by more than 25 % of consumers)
	1	No noticeable consequences

The risk ranking matrix adopts a five-level probability rank of non-conformity slippage. The rank is indicated by Arabic numerals in the range from 1 to 5. It can be determined depending on the value of the non-conformity rate according to Table 2. The table is based on the O criteria – Occurrence (events) adopted during the failure mode and effects analysis (FMEA) on a 10-point scale [24]. The value of the non-conformity rate for the considered inspection plan can be determined by formula (3). The non-conformity rate per 1,000 units is often used.

Table 2

Probability ranking

Probability rank	FMEA (*O*) – Occurrence (probability), point	Non-conformity rate
1	1	Less than 0.01 per 1,000
	2	0.1 per 1,000
2	3	0.5 per 1,000
	4	1 per 1,000
3	5	2 per 1,000
	6	5 per 1,000
4	7	10 per 1,000
	8	20 per 1,000
5	9	50 per 1,000
	10	More than 100 per 1,000

The risk level (rank) is determined by the risk ranking matrix as the value in the cell at the intersection of the consequence rank row and the probability rank column (Table 3). For example, if the consequence rank is *b* (Table 1), with the probability rank of 4 (Table 2), the corresponding risk rank is II (Table 3).

Table 3

Risk ranking matrix [21]

Consequence rank	*a*	III	III	II	I	I
	b	IV	III	III	II	I
	c	V	IV	III	II	I
	d	V	V	IV	III	II
	e	V	V	IV	III	II
Risk ranks		1	2	3	4	5
		Probability rank				

The risk rank can range from I to V – denoted by Roman numerals:

– risk rank I. Risk level is unacceptable. A set of measures is required to reduce the probability of occurrence, the probability of non-detection, and compensation of the consequences in the event of non-conformity slippage. Red area of the table;

– risk rank II. Risk level requires an immediate response. A set of measures is required to reduce the probability of occurrence, the probability of non-detection. Red area of the table;

– risk rank III. Risk level requires systematic reduction activities. Systematic activities are required to reduce the risk level, both by reducing the probability of occurrence and the probability of non-detection. Yellow area of the table;

– risk rank IV. Risk level is acceptable. No revision of the inspection plan is required. Green area of the table;

– risk rank V. Minimum risk level possible. No revision of the inspection plan is required. Green area of the table.

Thus, the red area of the table corresponds to an unacceptable level of non-conformity slippage risk. Production with such inspection plans is not possible. The yellow area is an area of risk reduction activities through revision of inspection plans, which can accompany production under existing inspection plans. The green area is a "comfort area". The risk level is acceptable and no reduction is required. However, every opportunity should be used to effectively reduce the level of risk.

From Table 3, it follows that if non-conformity slippage can be a threat to human life and health (Consequence rating – *a*), then the green area of the table – the "comfort area" is unattainable. For all other values of the Consequence rank (*b*–*e*), the criterion for the effectiveness of the development and revision of the inspection plan can be staying in the green area of the risk ranking matrix. This provides an acceptable level of non-conformity slippage risk for the inspection plan under consideration.

Joint analysis of Tables 1–3 determined $d_{nc/char}^{\max}$ – non-conformity slippage rate, which provides an acceptable risk level for a given consequence rank (Table 4).

Table 4

Conditions for acceptability of the non-conformity slippage risk

Consequence rank	*b*	*C*	*d*	*e*
Probability rank	1	2 or less	3 or less	3 or less
Acceptable non-conformity rate $\left(d_{nc/char}^{\max}\right)$	0.1 per 1,000 or less	1 per 1,000 or less	5 per 1,000 or less	5 per 1,000 or less

From Table 4, it follows that if non-conformity slippage does not affect product functionality (Consequence rank – *d*, *e*), the inspection plan must ensure a non-conformity rate of no more than 5 per 1,000 to obtain an acceptable risk level. If non-conformity slippage leads to the limitation or loss of some functions, but the product remains generally functional (Consequence rank – *c*), the inspection plan must ensure a non-conformity rate of no more than 1 per 1,000 to obtain an acceptable risk level. If non-conformity slippage leads to the loss of product functionality without threatening human health and life (Consequence rank – *b*), the inspection plan must ensure a non-conformity rate of no more than 0.1 per 1,000. If non-conformity slippage threatens human life and health (Consequence rank – *a*), an acceptable risk level cannot be ensured only through the inspection plan or technological measures. In this case, design solutions are needed that eliminate threats of non-conformity slippage to human life and health and provide the Consequence rank – *b*–*d* or *e*.

Based on the need to calculate the volume of a batch of 1,000 units, we take N=1,000. By a joint solution of equations (1) and (5), from the condition $d_{nc/char} = d_{nc/char}^{\max}$, the equation-condition for an acceptable level of non-conformity slippage risk was derived:

$$d_{nc/char}^{\max} = N_1 \times \left(1 - P_{char}\right) \times P_{char/d}^{(met)} + \\ + \left(1{,}000 - N_1\right) \times \left(1 - P_{char}\right) \times 1, \quad (6)$$

$$d_{nc/char}^{\max} = N_1 \times \left(1 - P_{char}\right) \times \left(P_{char/d}^{(met)} - 1\right) + \\ + 1{,}000 \times \left(1 - P_{char}\right). \quad (7)$$

Consider the option of single-block zero inspection plan (see Fig. 4). For this option, N_1=0, then

$$P_{char} = 1 - d_{nc/char}^{\max} / 1{,}000. \quad (8)$$

Table 5 shows the results of calculations of acceptable non-conformity rate $d_{nc/char}^{\max}$ (Table 4). If the quality level of the actively forming operation is not lower than the levels characteristic of acceptable non-conformity slippage rates, there is no need for non-zero inspection operations.

Table 5

Quality level of the actively forming operation, which does not require non-zero inspection operations

Consequence rank	b	c	d	e
Acceptable non-conformity rate $\left(d_{nc/char}^{\max}\right)$	0.1 per 1,000 or less	1 per 1,000 or less	5 per 1,000 or less	5 per 1,000 or less
Conformity probability P_{char}	0.9999 or more	0.999 or more	0.995 or more	0.995 or more

Consider the option of single-block non-zero inspection plan (Fig. 3). For this option, N_1=1,000, then

$$d_{nc/char}^{\max} = 1{,}000 \times \left(1 - P_{char}\right) \times P_{char/d}^{(met)}, \quad (9)$$

$$P_{char} = 1 - d_{nc/char}^{\max} / \left(1{,}000 \times P_{char/d}^{(met)}\right). \quad (10)$$

Formula (10) allows, for a given inspection plan having a probability of undetected non-conformity ($P_{char/d}$), calculating the minimum required value of P_{char}, providing an acceptable non-conformity rate $\left(d_{nc/char}^{\max}\right)$. Fig. 6 shows the results of calculating inspection plans, which cannot provide an acceptable level of non-conformity slippage risk (even with single-block 100 % inspection). A nomogram for identifying inspection plans that do not provide an acceptable risk level was built using Microsoft Excel software. Coordinate system:

– horizontally – the probability of undetected non-conformity with the adopted method ($P_{char/d}$);

– vertically – the probability of conformity after an actively forming operation (P_{char}).

Areas of failure to ensure an acceptable risk level are shaded:

– for Consequence rank (*b*) – in blue ($d_{nc/char}^{\max} = 0.1$ per 1000);

– for Consequence rank (*c*) – in brown ($d_{nc/char}^{\max} = 1.0$ per 1000);

– for Consequence rank (*d*, *e*) – in blue ($d_{nc/char}^{\max} = 5.0$ per 1000).

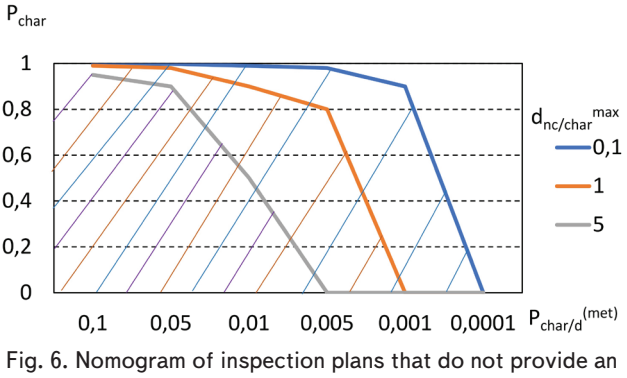

Fig. 6. Nomogram of inspection plans that do not provide an acceptable risk level

If for the inspection plan under consideration the point having coordinates ($P_{char/d}$; P_{char}) is in the shaded area (Fig. 6), such an inspection plan does not provide an acceptable risk level. For an inspection plan that specifies the coordinates of the point outside the shaded area (Fig. 6), it is possible to find the minimum number of units out of a thousand required for inspection $N_1^{\min}$. This value provides an acceptable value of $d_{nc/char}^{\max}$, therefore, an acceptable risk level for the two-block inspection plan (Fig. 5):

$$N_1^{\min}=\begin{bmatrix} d_{nc/char}^{\max}- \\ -1{,}000\times\left(1-P_{char}\right)\end{bmatrix}\Bigg/\begin{bmatrix}\left(1-P_{char}\right)\times \\ \times\left(P_{char/d}^{(met)}-1\right)\end{bmatrix}. \quad (11)$$

Domain of equation (11):

$$d_{nc/char}^{\max}\le 1{,}000\times\left(1-P_{char}\right), \quad (12)$$

which confirms the earlier conclusions about the advisability of using non-zero inspection plans (8), Table 5.

The practical application of the presented method of inspection plan optimization was tested on the example of the inspection plan for air tank weld porosity.

5. 4. Testing of the method of inspection plan optimization

The P7-78 air tank manufactured by PJSC Dniprovahonmash (Ukraine) is an element of the braking system of a railway freight car. The main function of the tank is to create a reserve of compressed air. Tank volume ensures piston movement in the working cylinder at the moment of braking. This provides the time for the locomotive air compressor to raise the air pressure in the braking system to the operating level.

An additional function of the tank is to allow the locomotive air compressor to be switched off for a period of time when no braking is performed on the move. It should be borne in mind that the locomotive air compressor, brake cylinders and air tanks of all train cars create a single pneumatic system. Therefore, shortcomings in the operation of the braking system element of one car are compensated by the operation of the braking system elements of other train cars.

Tightness is an important characteristic of the P7-78 air tank. The main reason for loss of tightness can be the appearance of pores in the metal of tank welds. Based on this, optimization of the inspection plan is shown on the example of the inspection plan for P7-78 air tank weld porosity.

5. 4. 1. Determination of specified requirements for air tank weld porosity

Requirements for butt welds (BW) with a thickness of 2.5 mm (t2.5) are set by the tank designer according to the ISO 5817-C assessment group. The designer took into account the load patterns of the air tank during operation.

The international standard ISO 5817 establishes the following requirement for tank weld porosity according to assessment group C: surface pores are not allowed, single internal pores with a diameter not exceeding 0.75 mm are allowed, the maximum permissible relative total area of internal uniformly distributed pores – 1.5 %, the maximum permissible relative total area of pores in clusters – 8 %, in pore chains – 4 %.

5. 4. 2. Initial inspection plan for air tank weld porosity

Welding is an actively forming operation according to the weld porosity characteristic. The production target quality level for air tank weld porosity calculated by the SPC method is 0.9952. Thus, the probability of conformity of the air tank weld with the porosity requirement is P_{pores}=0.9952.

The initial inspection plan for weld porosity assumes 100 % non-destructive testing of welds for conformity with porosity requirements by the radiographic method. According to available reference data, the probability of undetected pores in t2.5 butt welds by the radiographic method is $P_{pores/d}^{(Rad)}=0.02$ [5, 14].

The diagram of the initial inspection plan for the scope of N welds is shown in Fig. 7.

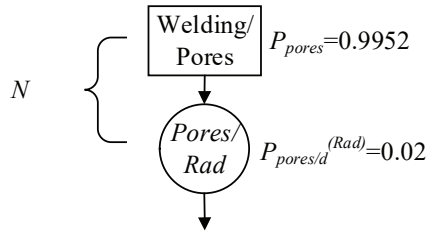

Fig. 7. Initial diagram of single-block non-zero inspection plan for weld porosity

The next step is to determine the consequence rank of weld porosity non-conformity slippage.

5. 4. 3. Determination of the consequence rank of weld porosity non-conformity slippage

The P7-78 welded air tank is a component of the braking system of a freight car, which, in turn, is a component of the train's braking system. The tank is not directly related to the main function of the braking system, that is, it does not directly participate in creating the friction force, but is used to "unload" the locomotive compressor. Excess of permissible porosity leads to a decrease in the density of the tank's circumferential weld, does not affect the performance of the train braking system as a whole, but may lead to the need for air tank replacement.

The above description fully meets the criteria for assigning S=5 for the significance rank of possible consequences of unacceptable weld porosity or the consequence rank – c (Table 1).

5. 4. 4. Optimization of the weld porosity inspection plan

All calculations were made using Microsoft Excel software.

For the consequence rank c, the quality level of the actively forming welding operation P_{pores}=0.9952 (the probability of conformity) is lower than the value of 0.999, starting from which nonzero inspection operations are not required (Table 5). Consequently, the inspection plan should include inspection operations that ensure a non-conformity rate $\left(d_{nc/char}^{\max}\right)$ of 1 per 1,000 or less. Let's determine the possibility of using the two-block inspection plan.

According to formula (10), for the probability of undetected non-conformity $P_{char/d}^{(met)}=P_{pores/d}^{(Rad)}=0.02$, the minimum required value of P_{char}, providing an acceptable non-conformity rate $d_{nc/char}^{\max}=1$, is P_{char}=0.95. Thus, the quality level of the actively forming welding operation P_{pores}=0.9952 is significantly higher than the minimum required value of P_{char}=0.95. On the nomogram (Fig. 6), the point with coordinates (0.02; 0.9952) is outside (above) the brown shaded zone for $d_{nc/char}^{\max}=1$ per thousand. Therefore, the two-block inspection plan for air tank porosity can be applied. According to formula (11), the minimum number of welds of a thousand required for inspection $\left(N_1^{\min}\right)$:

$$N_1^{\min}=\begin{bmatrix}1-1{,}000\times \\ \times\left(1-0.995\right)\end{bmatrix}\Bigg/\begin{bmatrix}\left(1-0.995\right)\times \\ \times\left(0.02-1\right)\end{bmatrix}=816. \quad (13)$$

Thus, the original inspection plan for 1,000 welds out of 1,000 can be replaced with an inspection plan for 816 out of 1,000 welds (82 % of welds are inspected). This is possible, unless otherwise required by regulatory documents, customers and other interested parties.

Such inspection plan (Fig. 8) provides an acceptable level of air tank weld porosity slippage risk and allows reducing the number of welds to be inspected by 18 %.

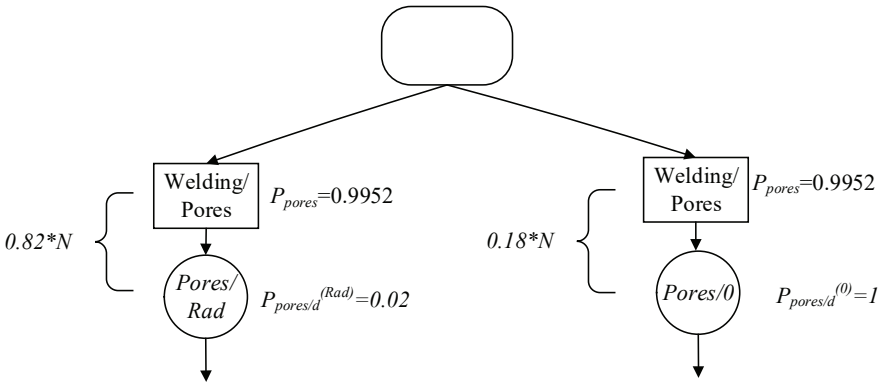

Fig. 8. Optimized diagram of two-block inspection plan for weld porosity

The possibility of using the developed method to optimize the production inspection plan is shown. In this case, the original inspection plan is redundant. Experience of practical application of the method indicates that redundancy of the inspection plan is a common situation.

6. Discussion of the results of developing a method of product quality inspection plan optimization by the risk of non-conformity slippage

Three basic options of the quality inspection plan were defined. The first option is a single-block plan for 100 % inspection of a production batch of volume N with a non-zero inspection operation (Fig. 3). It includes an actively forming operation for the quality characteristic and an inspection operation performed after the actively forming one. This option of the inspection plan is used for relatively simple and low-cost inspection operations, automatic control. The second option is a single-block inspection plan for a production batch of volume N with a zero inspection operation (Fig. 4). With this option, all non-conformities introduced by the actively forming operation slip into the manufactured product. This is the least costly option. It is used to control products of special processes. The third option is a two-block inspection plan for a production batch of volume N (Fig. 5). This is an option of product sampling. At the same time, a batch of products is divided into a controlled and an uncontrolled part. The first option of the inspection plan is applied to the controlled part and the second to the uncontrolled part. The third option is a compilation of the first two. The proposed classification simplifies the calculation of the non-conformity slippage rate for the inspection plan.

Using the probability multiplication theorem for independent events, the calculation formulas for the non-conformity slippage rate in the implementation of three basic options of the inspection plan (3)–(5) were derived. The calculated non-conformity slippage rate ($d_{nc/char}$) is determined by the volume of the product batch (N), the probability of conformity (P_{char}) and the probability of non-detection by the inspection operation $\left(P_{char/d}^{(met)}\right)$. Calculation formulas establish relationships between the main characteristics of the inspection plan and provide initial data for assessing the risk of non-conformity slippage.

Using the risk ranking matrix (Table 3), non-conformity slippage rates were determined to provide an acceptable risk level of the inspection plan (Table 4). In this case, the consequence rank of non-conformity slippage and the probability rank of slippage are initial data characterizing the inspection plan. The non-conformity slippage rate, providing an acceptable risk level $\left(d_{nc/char}^{\max}\right)$, can also be attributed to the main characteristics of the inspection plan. Acceptable non-conformity rate is used as an indicator when selecting and optimizing an inspection plan.

The quality level of the actively forming operation (P_{char}) was determined, which does not require inspection operations (Table 5). If the probability of conformity is high enough, there is no need for inspection operation to detect non-conformity. In fact, at this quality level, a single-block inspection plan for a production batch of volume N with a zero inspection operation can be implemented (Fig. 4). At the same time, the risk of non-conformity slippage will remain at an acceptable level. Abandoning the inspection operation with an acceptable risk level can significantly reduce inspection costs.

Based on the main characteristics of the inspection plan ($P_{char/d}$; P_{char}; $d_{nc/char}^{\max}$), using (10), a nomogram was constructed (Fig. 6), reflecting the objective division of product quality inspection plans into two groups. The first group includes plans that can potentially provide an acceptable risk level of non-conformity slippage (unshaded nomogram area). For this group, two-block inspection plans can be applied (Fig. 5). The remaining inspection plans (shaded nomogram area) form the second group of plans that do not provide an acceptable level of non-conformity slippage risk even when checking each product unit (Fig. 3). The use of such quality inspection plans is unacceptable. Thus, using the nomogram, it is possible to determine inspection plans for which the basic option of the two-block inspection plan can be implemented (Fig. 5).

The formula (11) was derived to calculate the minimum number of units out of a thousand required for quality inspection and ensuring an acceptable risk level $\left(N_1^{\min}\right)$. The initial data for the calculation are the main characteristics of the inspection plan ($P_{char/d}$; P_{char}; $d_{nc/char}^{\max}$). The formula allows calculating the minimum sampling volume that provides an acceptable risk level of non-conformity slippage during the implementation of the product quality inspection plan (QIP).

The optimization method was tested for the inspection plan of P7-78 air tank welds. The possibility to reduce the scope of inspection by 18 %, providing an acceptable level of non-conformity slippage risk is shown. The lack of a method for determining the number of production batch units to be checked that provides an acceptable level of non-conformity slippage risk leads to the assignment of inspection plans with an excessive number of checked units. This entails additional and unjustified costs for quality control.

The main advantage of the presented study and method, compared to the known ones, is that the criterion for inspection plan optimization is the risk of non-conformity slippage. The proposed method allows determining the acceptability of risk with 100 % quality inspection, in case of abandoning the inspection operation, the possibility of applying

sampling and the minimum sampling volumes necessary to ensure an acceptable risk level.

The closest methodological analogue is the AQL planning method – statistical sampling. This method ensures the acceptance of batches of products with a non-conformity level not exceeding the specified one. However, the possible consequences of non-conformity slippage and associated risks were not taken into account in determining statistical sampling plans.

This study is limited to inspection plans for one quality characteristic with one non-conformity detection method. Meanwhile, the use of combined non-conformity detection methods is known.

This limitation can be eliminated by adopting the failure mode and effects analysis (FMEA) method with the 1,000-point scale of the risk priority number (RPN) as the basic risk analysis method.

The development of this study may consist in the application of statistical laws to determine the probability of non-conformity with the requirements for a controlled quality characteristic. At the same time, due to the variety of quality characteristics, the main expected difficulty is the definition of a statistical law adequately describing the variability of the controlled quality characteristic.

7. Conclusions

1. The method of inspection plan optimization according to the risk of slippage of non-conformity of the controlled quality characteristic was proposed and tested. The method is based on the methods of the risk ranking matrix, failure mode and effects analysis (FMEA), determination of the non-conformity slippage rate in the adopted inspection plan.

2. Inspection plans (technological measures) can provide an acceptable risk level, provided that non-conformity slippage does not threaten human life and health (the consequence rank *b*, *c*, *d* or *e*). For these ranks, non-conformity slippage rates were determined to provide an acceptable risk level:

– 0.1 per 1,000 or less – for the consequence rank – *b*;

– 1 per 1,000 or less – for the consequence rank – *c*;

– 5 per 1,000 or less – for the consequence rank – *d*, *e*.

With the consequence rank of non-conformity slippage – *a*, design decisions are required to reduce the consequence rank to levels *b*, *c*, *d* or *e*.

3. The formula for calculating the minimum number of units out of a thousand required for inspection was derived. The calculated number of tested units provides an acceptable level of non-conformity slippage risk.

4. It is shown that using the proposed method of inspection plan optimization, the volumes of the tested products can be significantly revised, providing an acceptable level of non-conformity slippage risk.

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