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METHODS FOR MEETING REQUIREMENTS IN THE FIELD OF ENGINEERING PRODUCTS SAFETY

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Abstract

The article is devoted to the issues of compliance with the requirements in the field of engineering products safety. In particular, the technical regulations "On the safety of machinery and equipment". The purpose of the work is to develop a management system to ensure the production of safe products. The author proposes a product safety management system. The system is based on the principle of a process approach. The system can be used independently or as a part of an integrated management system. The author proposes a method for evaluating the level of improvement of the organization's processes, including those related to safety.

Keywords: engineering, system, safety, risk

I. Introduction

In modern conditions of development of technical regulation systems, the issue of integrating the requirements of technical regulations into the organization's management system is of particular relevance. The legislation of the Russian Federation on technical regulation consists of Federal law No. 184 "On technical regulation" [12] and Federal laws and other regulatory legal acts of the Russian Federation adopted in accordance with it. In accordance with Federal law No. 184, a lot of technical regulations have been adopted at present, including:

1. On the safety of high- speed rail transport.
2. On the safety of equipment for working in explosive environments.
3. On the safety of devices running on gaseous fuel.
4. On the safety of pyrotechnic compositions and products containing them.
5. On the safety of lifts.
6. On the safety of machinery and equipment.
7. On the safety of wheeled vehicles.

Technical regulations are a document adopted by an International Treaty of the Russian Federation, ratified in accordance with the legislation of the Russian Federation, or an intergovernmental agreement concluded in accordance with the legislation of the Russian Federation, or a Federal law, or a decree of the President of the Russian Federation, or a resolution of the Government of the Russian Federation and establishes mandatory requirements for the application and execution of technical regulation objects (products, including buildings, constructions and structures or processes related to product requirements for design (including survey), production, construction, installation, adjustment, operation, storage, transportation, sale and utilization) [1-28].

Technical regulations are adopted in order to [12]:

1) protect the life or health of citizens, property of individuals or legal entities, state or municipal property;

2) protect the environment, life or health of animals and plants;

3) warn of actions that mislead buyers.

Technical regulations are adopted to establish measures to ensure safety requirements. In particular, the technical regulation "On safety of machines and equipment" establishes minimum necessary requirements to safety of machines and equipment when designing, manufacturing, installing, adjusting, operating, storing, transporting, realizing and utilizing to protect the life or health of citizens, the property of individuals or legal entities, state or municipal property, environment, the life and health of animals and plants, as well as the prevention of actions misleading purchasers [12]. Article 39 of the technical regulations states that machines and (or) equipment that are put into circulation for the first time on the territory of the Russian Federation are subject to mandatory conformity assessment.

II. Methodology

The application of “the process approach" when developing, implementing and improving the effectiveness of the quality management system (or any other management system of the organization) is aimed at increasing the satisfaction of customers by meeting their requirements. Understanding and managing the interrelated processes as a system contributes to the effectiveness and efficiency of the organization in achieving the intended results. This approach allows the organization to manage the relationships and interdependencies between the system processes, so that the overall performance of the organization can be improved.

The process approach involves the systematic identification and management of processes and their interaction in such a way as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of processes and systems as a whole can be achieved by using the PDCA cycle paying special attention to risk-based thinking, aimed at using opportunities and preventing undesirable results.

The application of the process approach in the system makes it possible to:

– understand and constantly to fulfill the requirements;
– consider the process from the viewpoint of adding their values:
– achieve effective functioning of processes;
– improve processes based on evaluating data and information.

III. Results

In organizations, in addition to the traditional management system, such systems as the quality management system (for certification of the organization) and the occupational safety system (to meet the requirements in the field of occupational safety) are being implemented. In this situation, it is logical to develop a Product Safety Management System (PSMS) to meet the requirements of technical regulations, and integrate it into the organization's management system. As an analog, the standard ISO 22000:2018 can be used, which contains the requirements for the organizations involved in food production [3]. The industrial development leads to the fact that it is advisable to develop a single integrated management system at the enterprise, rather than several separate systems aimed at meeting individual, local requirements.

As a part of the creation of the PSMS, it is proposed to develop an organization standard (OS) containing the main requirements for the product safety management system. Due to the fact that quality management systems based on the application of ISO 9000 series standards have become widespread, it is proposed to structurally bring the OS closer to ISO 9001.

The standard contents of the OS "Product safety management system. The requirements".

1. Application.
2. Normative references.
3. Terms and definitions.
4. Product safety management system.
4.1. General requirements.
4.2. Documentation requirements.
5. Management responsibility.
5.1. Management responsibility.
5.2. Policy in the field of products safety.
5.3. Planning of the product safety management system.
5.3.1 Hazard identification, risk assessment and identification of management measures.
5.3.2 Legislative requirements.
5.4. Responsibility, authority, and information interchange.
5.5. Analysis on the management part.
6. Resource management.
6.1. Providing resources.
6.2. Human resources.
6.3. Infrastructure.
6.4. Production environment.
7. Planning and production of safe products.
7.1. Generalities.
7.2. Program of mandatory preliminary events.
7.3. Hazard analysis.
7.4. Risk-management.
7.5. Verification and validation.
7.6. Tracking system.
7.7. Management of non-conformities.
8. Measurement, analysis, improvement.
8.1. Generalities.
8.2. Monitoring and measurement.
8.3. Continuous improvement.

The proposed PSMS is intended to be used in conjunction with the organization's QMS. Additional documented procedures must be implemented to meet the safety requirements:

1. Risk-management.
2. Hazard analysis.
3. Evaluating the level of process improvement.

In accordance with one of the eight principles of quality management (the process approach) for the implementation of the PSMS, a register of processes was developed. This register is presented in Table 1.

Special attention should be paid to the development and verification of design and technological documentation. At the stages of design and technological preparation of production, it is recommended to use the FMEA analysis methodology or other methods for evaluating the potential risk of defects and (or) product failures that may lead to the violation of the requirements of technical regulations.

Since the requirements of technical regulations, in particular "On the safety of machinery and equipment", are applied to all stages of the product life cycle, including operation by the consumer, the issues related to the rules and technical conditions of operation of the object must be noted in the in-line documentation for the product.

Table 1: *Register of the processes of the product safety management system*

№	Name of the process
1	***Management activities in the PSMS***
1.1	Strategy, policy and objectives in the field of products safety
1.2	Planning and development of an FSMS
1.3	Allocation of responsibilities and privileges*
1.4	Analysis of the PSMS on the management part
1.5	Informing the public*
1.6	Funding the PSMS
2	***Main processes of the PSMS***
2.1	Mandatory pre- production activities
2.2	Hazard analysis
2.3	Risk-management
2.4	Checking the design documentation
2.5	Checking the technological documentation
3	***Auxiliary processes****
3.1	Human resources management
3.1.1	*Definition of the staff requirements*
3.1.2	*Staff development and training*
3.1.3	*Development of a staff social support system*
3.2	Infrastructure control
3.3	Material resources control
3.4	Production environment control
4	***Measurement, analysis, improvement****
4.1	Process monitoring, measurement and analysis
4.2	Process control
4.3	Non- conformities control
*Note. For the processes marked with *, it is possible to make changes and additions to the diagram of the existing QMS processes .*	

PSMS, like any other system, needs constant improvement. However, a number of large companies suffer significant losses, despite major improvements in their processes. This is the so-called "process paradox", which is typical for many domestic organizations [4-15]. In this regard, a three-level system for evaluating process improvement is proposed. This system can be used both for the PSMS and for the QMS of the organization as a whole.

Each level of improvement is divided into two sub-levels, depending on the degree of implementation of the requirements for the process. Each next level includes the requirements of the previous one.

Level I - Certainty. It is characterized by setting goals and objectives of the process. The activity concerning the process description is completed. Outputs, inputs, control actions and process resources are defined. It should be noted that resources alone, taken separately, do not determine the results of the activities in advance. The quality of performance depends on two components: the quality of goals and the quality of execution.

Table 2: *Criteria for evaluating the levels of improvement of the PSMS processes*

№	Criterion name	Weight

Criterion 1. Leading role of management		
1.1	Personal involvement of management in the formation and development of the mission, vision, core values, policies, main goals and objectives in the field of product safety.	0,35
1.2	Personal involvement of management in ensuring the development , implementation and continuous improvement of the product safety management system.	0,35
1.3	Personal involvement of management in providing feedback to the staff to improve their performance.	0,30
Criterion 2. Policy and strategy		
2.1	Development and improvement of policies and strategies and the degree of participation of the interested parties in these processes.	0,25
2.2	Mechanisms for collecting and analyzing comprehensive information about the effectiveness and efficiency of the company's operation when forming policies and strategies	0,25
2.3	Mechanisms for projecting policy and strategy implementation to all levels of management, structural divisions, and key processes	0,25
2.4	Mechanisms for informing the staff and consumers about the policy and strategy	0,25
Criterion 3. Process management		
3.1	Activities for the development , implementation and improvement of the SMBP	0,20
3.1.1	*Documentation control*	*equally*
3.1.2	*Records control*	
3.1.3	*Planning and building the organizational structure of the PSMS, distribution of responsibilities and priveleges*	
3.1.4	*Building, maintaining and developing a system for measuring and monitoring the PSMS processes*	
3.1.5	*Planning the processes of the PSMS*	
3.2	Main processes of the PSMS	0,60
3.2.1	*Mandatory pre- production activities*	*equally*
3.2.2	*Hazard analysis*	
3.2.3	*Risk-management*	
3.2.4	*Checking the engineering documentation*	
3.2.5	*Checking the technological documentation*	
3.3	Auxiliary processes	0,20
3.3.1	*Infrastructure and production environment control*	*equally*
3.3.2.	*Control of auxiliary processes*	
Criterion 4. Results of activity		
4.1	Mechanisms for collecting and analyzing information on the results of the PSMS activities	0,30
4.2	Financial results of the PSMS	0,35
4.3	Other non-financial results of the PSMS activities	0,35

Level II – Performance. Performance is the degree of implementation of planned activities and achievement of planned results. Based on this definition, it is necessary to allocate a criterion for rating a process to the sublevels of the performance level. The organization's processes are fully described in a formalized form.

Level II – Efficiency. Efficiency is the relationship between the result achieved and the resources used. The main activity of the organization is aimed at identifying and minimizing activities that do not add value to consumers (including internal ones). The organization should develop evaluation criteria. This is a necessary condition for the organization to "get" to sublevel 2 of level I. It is proposed to use the criteria listed in table 2 to evaluate the PSMS.

These criteria may change (new ones may be added or removed) due to the specific character of a particular product or production. Accordingly, the expert method can change the weight coefficients of the criteria. The reasons for applying certain weight coefficients must be recorded in the appropriate type of records [11, 17, 21].

The evaluation of the levels of excellence of various components of the model is based on the following six "dimensions" that correspond to the basic principles of TQM:

1. The degree of focus on consumers and other interested parties (from minimum satisfaction to full consideration of the interests of all interested parties).

2. The degree of consistency of the applied approach (from short-term episodic measures to long-term policy and strategy planning).

3. The extent to which the approach is applied across management levels, departments and processes.

4. The degree of staff involvement in the relevant processes.

5. The degree to which the process procedures are documented (from informal execution to fully documented processes).

The degree of focus is on preventing inconsistencies and continuous improving, rather than fixing problems that arise.

The PSMS self-evaluating system includes 4 criteria for evaluating the levels of process improvement (leading role of management, policy and strategy, process management, performance). Each criterion has three levels of improvement. Each level of improvement has two evaluation options, depending on the level of development. To evaluate all the subcriteria and components of the model group, special qualimetric scales are used that verbally describe three ordered "levels of excellence" or stages of development of the subcriteria and components. These three levels of excellence correspond to a 6-point numerical scale (from 1 to 6 points). This allows us to move from a qualitative evaluation of the relevant subcriteria and components (activities, works) to their quantitative evaluation. The methodology for calculating the values of the" improvement levels "of criteria is developed taking into account the "importance" of each of the indicators in the overall process.

Calculation the score in subcriteria points (for criterion 3). To do this, use the weighted average formula.

$$Q_i=\sum q_k \times b_k \quad (1)$$

where q_K is the weight of the k-th component of the i-th criterion; n is the number of components in the subcriterion; Q_i is the evaluation of the i-th subcriterion in points.To calculate the score in criteria points we use the following formula.

$$Q_m=\sum q_n \times Q_i \quad (2)$$

where q_n is the weight of the i-th subcriterion;Q_i is the evaluation of the i-th subcriterion in points;.k is the number of criterion components; Q_m is the score in points of the m-th criterion.

The calculation of the overall evaluation of the organization.

$$Q=\sum q_m \times Q_m \quad (3)$$

where q_m is the weight of the m-th criterion;Q is the overall rating in points.

To "balance" the influence of different criteria, the criteria weights (q_k) are applied. When grouping processes according to the activity (for example, human resources management processes or basic production processes), process weights (q_n) are used. When evaluating the level of improvement of the organization, the process group weights (q_m) are used. Formula 1-3 are used for calculation and the results can be presented in the form of a leaf-type diagram (Fig.1).

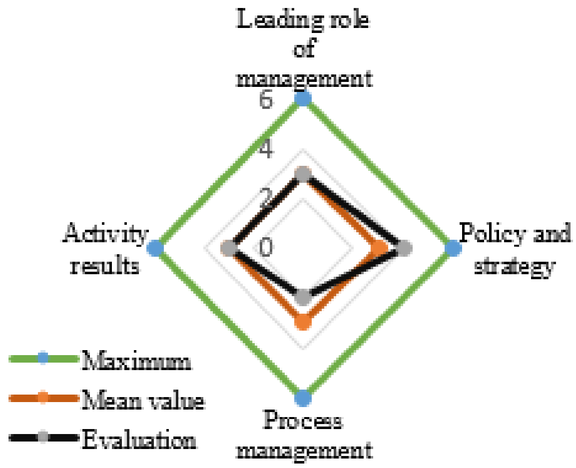

Figure 1: ***Leaf-type diagram***

IV. Discussion

The government of the Russian Federation intends to increase the amount of fines for violations of technical regulations by 20 times. The corresponding bill has been submitted to the state Duma and is being prepared by deputies for consideration. If the document is adopted, the business will receive confiscation of the goods and a fine of one million rubles for non- compliance with the mandatory requirements of technical regulations.

V. Conclusions

The compliance with the requirements of technical regulations is mandatory for all territories of the Russian Federation. However, due to the fact that they have been adopted quite recently, a unified approach to the methods of fulfilling the requirements has not yet been formed. As a result of the research, the author came to the conclusion about the high relevance of this problem. The article proposes an approach to meet the requirements of technical regulations, based on the construction of a product safety management system. The proposed system can be independent or used as a part of an integrated management system. The developed methodology for evaluating the levels of process improvement based on ISO 9000 series standards is applicable for choosing the optimal direction of development of the organization's processes, which entails obtaining strategic benefits, including material profit.

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