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APPLICATION OF RISK ASSESSMENT METHODOLOGY IN THE REPUBLIC OF BELARUS

APPLICATION AND IMPROVEMENT OF RISK ASSESSMENT METHODOLOGY IN THE REPUBLIC OF BELARUS

DIRECTIONS

- when selecting technical regulation objects
- when developing and applying technical regulations
- when developing and applying standards
- when selecting forms (schemes) of product conformity attestation to technical regulation requirements
- when selecting rules and procedures of conformity attestation including market surveillance, accreditation, tests
- when carrying out state surveillance over compliance with technical regulation requirements
- when exchanging the hazardous products information

Selection of Technical Regulation Objects

Development and Application of Technical Regulations, Technical Requirements Setting in Technical Regulation

- ❑ Development of scientific basis for risk analysis and assessment of hazardous factors
- ↓
- ❑ Requirements setting in specific technical regulations and standards
 - to the products itself
 - to processes of product development, production, operation (use), storage, transportation, realization and utilization, related to product safety, or provision of services

DETERMINING FACTOR IN REQUIREMENT
SETTING AND DEVIDING OF TECHNICAL
REGULATION INTO TYPES



RISKS,
inherent to one
or another products

interference degree of the state
into the regulation of safety
requirements

Methodology development of **transformation**, interpretation of **essential** technical requirements of technical regulations through standards interrelated with technical regulation

DEVELOPMENT OF TECHNICAL REGULATION

Making-up technical requirements in technical regulation

**Main principles to be followed when
making-up requirements in technical regulations**

- determination of the level of the requirements non-conformity permissible risk
- harmonization of the requirements with the relative international documents and agreements
- definition of the form of the requirements presentation
- established requirements shall be relative to all the stages of the products life cycle and to all conditions of their use

DEVELOPMENT OF TECHNICAL REGULATION

Making-up of technical requirements in technical regulation

Carrying out of works for establishment of the technical requirements shall be accompanied by the risk analyses and aligning of each requirement with the permissible risk level

At that one shall take into account danger of possible incorrect use of the product

Risk analysis is carried out at all stages of life cycle of dangerous systems, equipment or products, including

- design
- manufacturing, mounting, performance and maintenance
- demounting, decommissioning
- utilization

**The common task of risk analysis —
justification of decisions,
concerning risk**

**Risk analysis
provides base for risk assessment,
measures for decrease of risk
and assumption of risk**

These decisions may be taken as a part of the larger process for risk management by comparison of the risk analysis results with the permissible risk criteria

DEVELOPMENT OF TECHNICAL REGULATION

Making-up technical requirements in technical regulation

IN TECHNICAL REGULATION

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graph TD; A[IN TECHNICAL REGULATION] --> B[It should be exactly determined the necessary safety level, which the manufacturer shall provide for protection of public interest]; A --> C[All the kinds of risk, protection of which is to be foreseen are established]; C --> D[It concerns safety of products, safety of personnel, customers, etc.];
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It should be exactly determined the necessary **safety level**, which the manufacturer shall provide for protection of public interest

All the kinds of risk, protection of which is to be foreseen are established

It concerns safety of products, safety of personnel, customers, etc.

In line with this it's necessary to determine clearly the requirements to products, in order the conformity attestation bodies could properly assess conformity of this products against established requirements

Selection of Technical Regulation Objects

Development and Application of Technical Regulations, Technical Requirements Setting in Technical Regulation

STAGES OF RISK ANALYSIS AND ASSESSMENT

1. Determination of **products scope**

including intended use and all types of possible predictable improper use of products

2. Carrying out the **hazard identification**, related to the technical regulation object

and arising at all stages of life cycle and under all conditions of product use, including assembling, operation, repair and utilization etc.

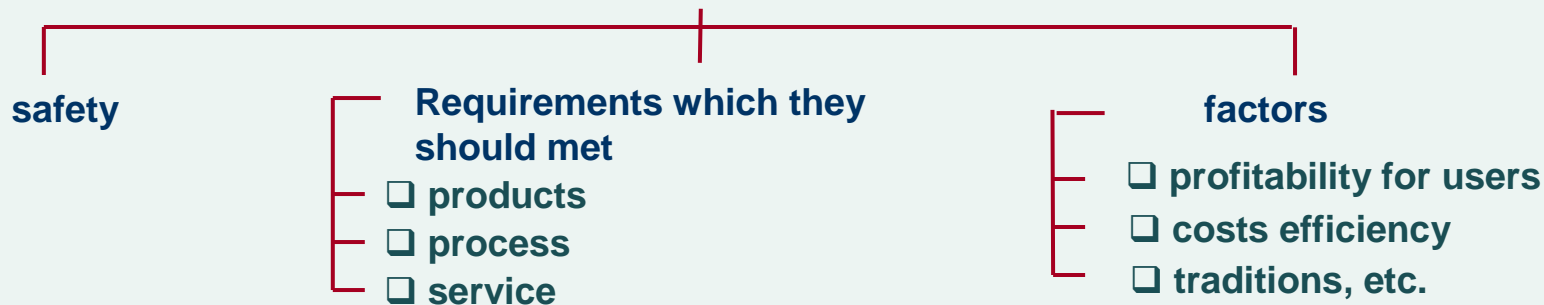
3. Determination of **risk magnitude**, arising as a result of **defined hazard**

including risk quantification

4. Comparison of risk with accepted level

5. Risk management, risk mitigation measures to the accepted level

**Permissible risk
is an optimal balance between**



Selection of Technical Regulation Objects Development and Application of Technical Regulations, Technical Requirements Setting in Technical Regulation

KEY METHODS OF TECHNICAL REQUIREMENTS PRESENTATION IN TECHNICAL REGULATIONS

- ✓ **specific technical requirements**
 - ✓ **essential technical requirements**
 - ✓ **technical requirements, presented in the form of references to specific standards**

TECHNICAL REGULATIONS

depending on the way of setting out the specific technical requirements

- **Directive technical regulations**

- for technical regulation objects, which can have **new risks arising during further stages of products life cycle**

- **Technical regulations, containing operation safety requirements**

- for technical regulation objects, which have **risks that are reduced (eliminated) at the development stage, and new risks don't arise at further stages**

IMPLEMENTATION OF TECHNICAL REGULATIONS ESSENTIAL REQUIREMENTS

INTERRELATED STANDARDS

WHERE NOT APPLIED BY MANUFACTURER OR ARE ABSENT



Conformity attestation – for compliance to **directly** essential requirements of technical regulation



Definition of decision made and **risk assessment**,
confirming the implementation of essential requirements of technical regulation

AUTHORIZED BODY

- Rendering of help to the manufacturer in **carrying out risk assessment**
- Carrying out the analysis of notes, prepared by manufacturer, containing **risk assessment**, and confirming the implementation of essential requirements of technical regulation

TECHNICAL DOCUMENTATION

- **risks**, connected with specific products under assessment, should be reflected

CONFORMITY ASSESSMENT RULES AND PROCEDURES

KEY FACTORS, INFLUENCING THE SELECTION OF FORMS (SCHEMES) OF CONFORMITY ATTESTATION

- **products complexity** simple, of medium complexity and complex
- **degree of potential hazard for products** low, medium, high
- **sensitiveness degree** of safety indicators, administered by technical regulation, to the change of production and (or) operational factors
- **risk degree** in scores
- **applicant status** manufacturer or seller

WITH RESPECT TO

- total risk from misleading conformity attestation
- damage from application of products, which have passed conformity attestation
- assessment objectivity, which is characterized by the degree of executive procedure independency (the first and the third party)

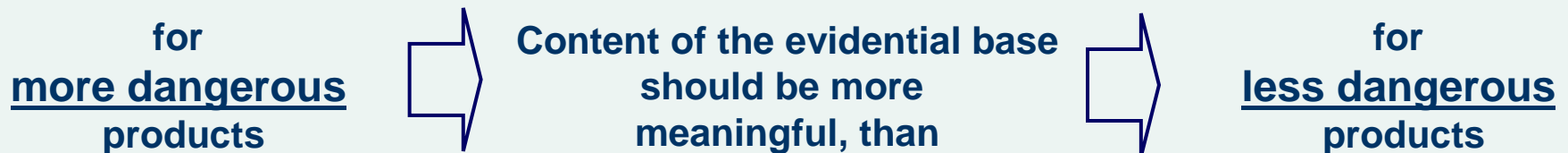
DEVELOPMENT OF TECHNICAL REGULATION

Making-up technical requirements in technical regulation

**Use of conformity declaration
does not depend on the extent of potential danger of products**

**Harm-doing risk at using the products
for human-beings and environment
is connected only with the content of evidential base**

Is provided with the relevant conformity attestation forms and schemes



**In both cases
conformity attestation procedures are completed by the manufacturer's
acceptance of declaration of conformity,
particularly after voluntary third party certification**

By this he assumes before authorities responsibility that he met all the technical regulation requirements and attested them properly

GUIDANCE DOCUMENTS



«Technical regulations development recommendations»

are based on the provisions of the Law of the Republic of Belarus «On technical regulation and standardization», the WTO Agreement on Technical Barriers to Trade, UNECE Recommendations and good technical regulation practice of APEC and EC member-states



«Methodological recommendations. Safety assessment of engineering products on the basis of risk analysis»

basic concepts, principles of risk assessment and determination, key methods of risk assessment

provisions on engineering products safety assessment, definition of hazards, associated with these products, and the strategy of safety measures selection

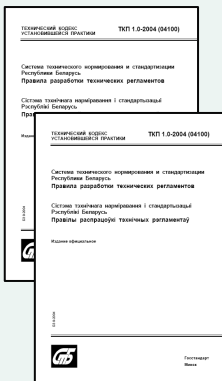
Fundamental technical codes of good practice (TCP)

TCP 1.0-2004, TCP 1.10-2007

development rules of technical regulations, and rules of their composition, presentation, preparation and maintenance

TCP Project

development and presentation rules of standards interrelated with technical regulation, rules of its drawing up and the form of the list of standards interrelated with technical regulation



SET OF STANDARDS ON RISK MANAGEMENT

Guidance STB ISO/IEC 51-2006

Safety aspects. **Guidelines for their inclusion in standards**

Guidance STB ISO/IEC 73-2005

Risk management. Terms and definitions

STB ISO 14971-2005

Medical devices. Application of **risk management** to medical devices

STB IEC 60300-3-9-2005

Dependability management
Risk analysis of technological systems

STB IEC 60300-2-2008

Dependability management.
Part 2. Dependability management recommendations

STB IEC 61078-2008

Dependability management. Analysis techniques. Reliability block diagram and Boolean methods

STB IEC 61165-2008

Dependability management. Analysis techniques. Application of markov techniques

STB IEC 61014-2008

Reliability growth programs

PROJECTS

STB IEC 62198

Project risk management. Guidance on application

STB IEC 60300-1

Dependability management.
Dependability management system

STB IEC 61025

Dependability management.
Fault tree analysis

STB IEC 61160

Design review

HAZARDOUS PRODUCTS INFORMATION EXCHANGE

Establishment of Uniform system of collection and exchange of information, about products, posing hazard to life and health

similar to the RAPEX European system



REQUIRES DEVELOPMENT OF



**The Law of the Republic of Belarus
«On products safety»**

- Operation rules of the Uniform information system
- Requirements to the provision of information about cases of products non-conformity to the safety requirements
- Requirements to the hazardous products information exchange

**The provision, establishing the
operation order of the Uniform
information system**

System structures

UNIFORM INFORMATION SYSTEM

- ❑ **Information about products**, posing hazard to life and health
- ❑ **Information about manufacturers, importers (sellers), distributors**, delivering products, posing hazard to life and health
- ❑ **Information about accounting and analysis of cases of harm causing** to man's life, health and heredity, property, and environment as a result of non-compliance with technical regulations and standards requirements

INFORMATION SOURCE

- Results of the state control (surveillance) of the state administration bodies
- Information from manufacturers
- Information from importers (sellers), distributors