June 22, 2011 (Wednesday) 55th EOQ Congress

CONCURRENT SESSIONS **Wednesday 8:30 – 12:30**
KEMPINSKI HOTEL CORVINUS **Erzsébet tér 7-8, Budapest V.**

REGINA BALLROOM I. **Wednesday 8:30 – 10:30**

17.1. STANDARDIZATION AND THE NEW ISO 9004

Session Chair: ***Kari Jussila****, BIT Research Center, Aalto University of Science, Finland*

9.25 Standardization of Management Systems for Nanotechnologies
Vilya Versan and Vladimir Galeev, Russian Research Institute for Certification, Russia

Versan, Vilya (Russia)

He was born in 1938. He graduated at the Moscow Power Engineering Institute and took a Dr. degree in Economics. He worked in the electrotechnical and radiotechnical industry. Since 1991 Versan heads the Russian Research Institute for Certification. Versan has gained considerable experience in certification and quality management. He is author of more than 130 scientific works and publications.

Galeev, Vladimir (Russia)

He was born in 1950. He graduated at the Moscow Aviation Institute and took a Ph.D. degree in Economics. V.I. Galeev has gained considerable experience in quality management. He is author of more than 85 scientific works and publications. At present V. Galeev is Head of the Management Systems Departament at the Russian Research Institute for Certification. He participates in ISO/TC (Technical Committee) 176 actively. He also heads the Secretariat of the Council for Russian Quality Award.

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VNIIS

Vilya Versan
Vladimir Galeev

Russian Research Institute for Certification, Russia

STANDARDIZATION OF MANAGEMENT SYSTEMS FOR NANOTECHNOLOGIES

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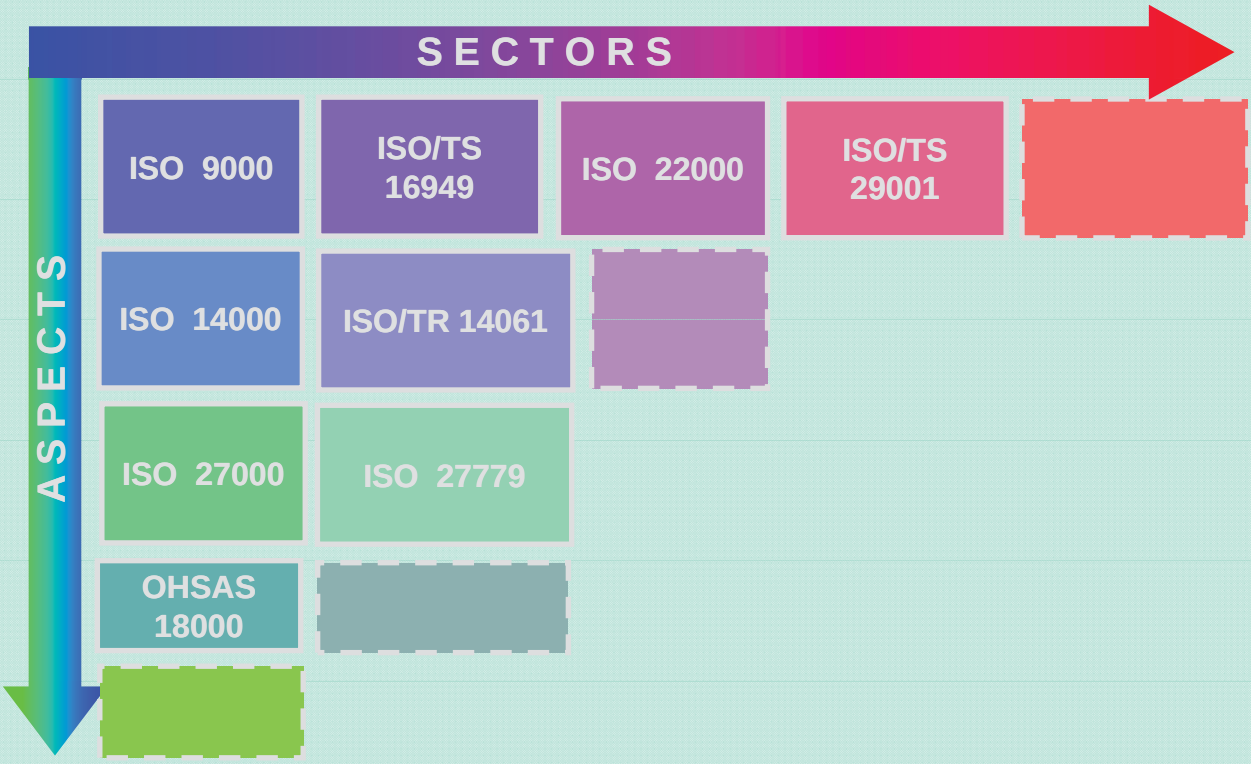
MSS DEVELOPMENT



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Nanoindustry as a sector dealing with highly innovative technologies and products and hence higher risks also needs «sector» standards

In Russia are developed a dedicated national program aimed at establishing nanoindustrial infrastructure. As part of that program VNIIS developed quality, environmental, occupational health and safety management system standards for nanoindustrial companies

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Coupled with the original text of ISO 9001, ISO 14001 and OHSAS 18001, extra requirements have constituted the content of the following three standards:

GOST R «*Quality management systems for nanoproduct producing companies. Requirements*»

GOST R «*Environmental management systems for nanoproduct producing companies. Requirements*»

GOST R «*Occupational health and safety management systems for nanoproduct producing companies. Requirements*»

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EXAMPLES OF SPECIFIC RISKS ASSOCIATED WITH NANOMATERIALS-BASED PRODUCTION

HYPERSENSITIVITY OF NANOMATERIALS TO WORK ENVIRONMENT

DIFFICULTIES OF MONITORING AND MEASURING PARAMETERS OF NANOMATERIALS AND CONSEQUENTLY IDENTIFYING NONCONFORMITIES

BIOLOGICAL HAZARDS ASSOCIATED WITH SOME NANOMATERIALS (EXTRA PERMEABILITY AND SUPERHIGH CHEMICAL REACTIVITY)

IMMATURITY OF STANDARDIZATION IN NANOTECHNOLOGIES

NEED FOR AN INTERDISCIPLINARY APPROACH TO DEVELOPMENT AND IMPLEMENTATION OF NANOTECHNOLOGIES IN THE ABSENCE OF ADEQUATELY SKILLED PROFESSIONALS

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IMPACT OF MAJOR SPECIFIC PROPERTIES OF NANOMATERIALS AND NANOPRODUCTS ON COMPANY PROCESSES IN NANOINDUSTRY (Example)

Properties of nanomaterials and nanoproducts	Company processes in nanoindustry			
	Purchasing	Storage	Production	Use (operation)
Higher sensitivity to environmental effects	+	+	+	
Extra permeability		+	+	
Difficulty of measuring characteristics	+		+	+
Poor knowledge of and lack of information about properties of nanomaterials and nanoproducts				+

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Most extra requirements for quality management systems pertain to clauses (ISO 9001):

- 6.4 *Work environment*;
- 7.1 *Planning of product realization*;
- 7.4.1 *Purchasing process*;
- 7.5.1 *Control of production and service provision*;
- 7.5.5 *Preservation of product*;
- 7.6 *Control of monitoring and measuring equipment*;
- 8.2.2 *Internal audit*;
- 8.2.4 *Monitoring and measurement of product*

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ISO 9001

6.4 Work environment
The organization shall …

6.4.1 The organization shall determine environment factors have influence on nanoproduct realization and take control of this factors taking in account corresponding risks

If contact between personnel and nanoproduct or work environment could adversely affect the quality of the nanoproduct organization shall establish documented requirements for health, cleanliness, clothing and access control of personnel

6.4.2 Cleanliness of premises

The organization shall maintain its premises in state of order and cleanliness consistent with the nanoproduct realization processes

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ISO 9001

7.1 Planning of product realization
The organization shall …

7.1.1 In planning nanoproduct realization the organization shall analyse and take into consideration possible changes nanomaterials in the course of time

7.1.2 The organization shall establish necessary analyse, verification and validation activities for nanomaterials used at different stages of nanoproduct realization

7.1.3 The organization shall use a multidisciplinary approach for planning of nanoproduct realization

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In environmental and occupational health and safety management system standards, extra requirements have been mainly added to clauses (ISO 14001; OHSAS 18001):

- **4.3.1 *Environmental aspects* (*Identification of hazards*);**
- **4.4.3 *Communication*;**
- **4.4.7 *Emergency preparedness and response*;**
- **4.5.1 *Monitoring and measurement*;**
- **4.5.5 *Internal audit***

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ISO 14001

4.4.3 Communication
With regard to its environmental aspects …

4.4.3.1 The organization shall establish, implement and maintain a procedure to obtain and analyse information of nanomaterials and nanoproducts properties related to environmental aspects

4.4.3.2 The organization shall communicate externally about environmental aspects related to nanotechnology and nanoproduct

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OHSAS 18001

4.4.2 Competence, training and awareness
The organization shall …

4.4.2.1 The organization shall establish, implement and maintain a procedure to ensure and evaluate personnel awareness of hazards related to nanoproduction

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29 organizations participated in operational testing of standards

According to participants opinion, implementation of additional requirement:

- leads to risks reduction;
- allowes to decrease losses;
- demands additional knowledge of personal;
- requires little resources

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AREA OF APPLICATION OF NATIONAL MSS FOR NANOPRODACTION

- MS improvement in nanoindustry companies
- Investment projects evaluation
- Supplier assesment
- MS certification