

## **Business Plan for the CEN Workshop**

**on**

### **General Framework and Guidelines for Early Recognition, Monitoring and Integrated Management of Emerging, New Technology Related Risks (CEN WS/iNTeg-Risk or CEN WS 67)**

**(approved during the Kick-Off Meeting on 2011-11-04)**

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## List of Acronyms

CCMC	CEN/CENELEC Management Centre
CWA	CEN Workshop Agreement
ERMF	Emerging Risk Management Framework
ERRA	Emerging Risk Representative industrial Application
ETPIS	European Technology Platform on Industrial Safety
EU-OSHA	European Agency for Safety and Health at Work
FP7	Seventh Framework Program of the European Commission
GDP	Gross domestic product
IRGC	International Risk Governance Council
NaTech	Natural Hazard Triggering a Technological Disaster
OECD	Organisation for Economic Co-operation and Development
ENISA	European Network and Information Security Agency

## 1 Status of the Business Plan

Business Plan approved at the Kick-off meeting of the Workshop.

## 2 Background to the Workshop

### 2.1 Market and legal environment

Lack of acceptance can kill even the best and the most advanced technology. Consequently, if the EU goal is to be the leading knowledge-based society worldwide it has to ensure that the technologies and products made in the EU, on which the leadership is based, are accepted by stakeholders in industry and society. This acceptance can be reached only if the stakeholders are convinced that possible or perceived emerging risks related to these technologies can be managed in a safe, responsible and transparent way. The term emerging risks refers to **new and/or increasing** risks, as defined by EU-OSHA (2005, 2010), OECD (2003 - Emerging risks in the 21<sup>st</sup> century; An OECD international futures project, <http://www.oecd.org>) and ETPIS (European Technology Platform Industrial Safety – [www.industrialsafety-tp.org](http://www.industrialsafety-tp.org)).

The emerging risks addressed are related to industrial safety that concern installations, production systems, buildings, transport systems and safety related structural components. They deal with:

- Environmental safety, i.e. the prevention of major accidents with off-site consequences and the protection of the environment and the society
- Occupational health and safety of the workers in industry

In particular, in societies as risk-averse as Europe's, lack of confidence in the ability of industry and authorities to identify and manage emerging risks may prolong time to market or prevent success of new technologies. If technology is targeted by both EU "market policy" and the national "safety policies", possible conflict of policies may arise, and it is often worsened due to the **lack of commonly accepted approaches to management of emerging risks** (different approaches, fragmentation over countries, branches, sectors etc.). The EU therefore urgently needs a unified, consensual, validated and operational framework that comprises principles, guidelines and tools for managing emerging risks, readily available to all stakeholders.

The framework should

- demonstrate that potential and actual emerging risks are well understood and properly managed.
- accelerate time-to-market of EU technology, and hence, boost its competitiveness, by providing a common template for a more efficient and well-understood approach to identifying and dealing with emerging risks.

The European Commission has also clearly recognized the above needs. In its risk assessment bodies and committees it deals with emerging risks in different domains and it has included them explicitly also in the FP7 (NMP-2007-3.1-3 Integrated risk management in industrial systems)<sup>1</sup>.

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<sup>1</sup> Refer to [http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7CallSummaryPage&call\\_id=18](http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7CallSummaryPage&call_id=18)

## 2.2 Relation to iNTeg-Risk project

It is the basic assumption of project consortium of iNTeg-Risk that the new industrial safety policy can induce measurable change, in the similar ways as it has been shown in other areas. This expected change defines the main practical goals of iNTeg-Risk project and consequently the purpose of the CWA to be developed:

- 1) **Prevention of accidents and diseases due to emerging risks:** In macroeconomic terms the cost of accidents at work and occupational diseases in EU-15<sup>2</sup> ranges from 2.6 % to 3.8 % of GDP<sup>3</sup>. Expanding this estimation to the EU-27 GDP (2006), an optimistic burden to European (EU-27) society would be situated in 300 B€/year. Taking into account the share of emerging risks (26 %) <sup>4</sup>, over a quarter of this budget, 75 B€ /year, as well as approx. 1.8 million accidents and approx 1,200 fatalities can be attributed to emerging risks (one accident every 5 seconds and one fatality every two hours).
- 2) **Reduction of time to market:** It should be reduced by 10% by the end of the project and by 20% by 2015. The realization of the first goal will be verified by the specific market study within iNTeg-Risk, the second goal will be matter of a separate project.
- 3) **Improving understanding and reaction times in case of major accidents by 20%:** Although major accidents are not a big contributor to the overall statistics of accidents<sup>5</sup>, they may have a major impact on industry and society. One major accident<sup>6</sup>, which can be attributed to or connected with an emerging risk can disturb or even stop the development of the corresponding new technology for years.
- 4) **Contributing to the realisation of the vision of ETPIS** in the area of emerging risks: By ensuring that the iNTeg-Risk paradigm/framework for emerging risks management is widely adopted by the European industry.

Assuring the **sustainability of iNTeg-Risk results** in the post project phase: By expanding the already existing European organizational and legal structure by the end of the project.

Over 70 partners in FP7 “flagship-project” iNTeg-Risk, as well as many others stakeholders involved in the project indirectly (i.e. through the European Technology Platforms, other collaborative projects, etc.), have recognized this need and, therefore, support the research on these topics. There is a broad consensus that the European integrated approach to manage the emerging risks related to new technologies is needed and that there should be an effort to **ensure that safety, security, environmental friendliness and social responsibility, as the trade-mark of the advanced EU technologies and products, are promoted as the global competitive advantage of the EU economy.**

The Emerging Risk Management Framework (ERMF) of the iNTeg-Risk project takes into account previous research e.g. from the project Shape-Risk (FP6)<sup>7</sup> and the International Risk Governance

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<sup>2</sup> Eurostat, Work and health in the EU, A statistical portrait, Data 1994–2002 (2004), ISBN 92-894-7006-2

<sup>3</sup> The cost of poor working conditions. European Foundation for Improvement of Living and Working Conditions.

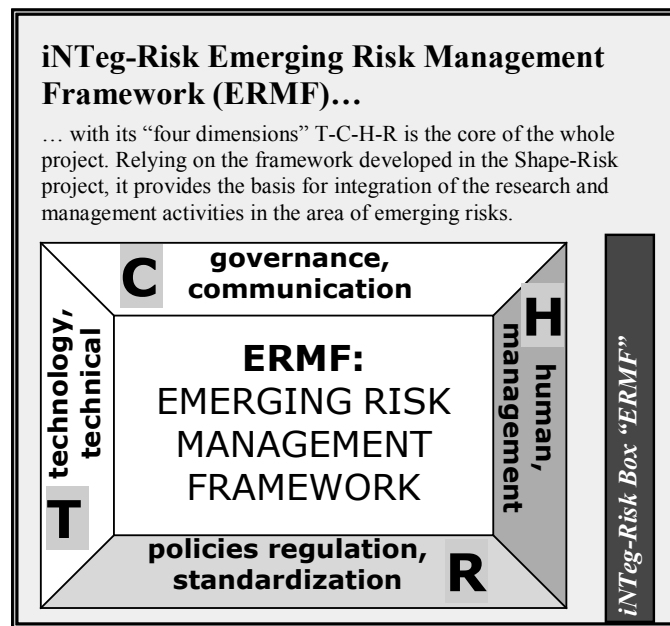
<sup>4</sup> Emerging Technologies and Ethical Issues in Engineering, THE NATL. ACADEMIES PRESS, Washington, D.C., October, 2003

<sup>5</sup> Major accident reporting system; European Commission, Joint Research Centre, Ispra <http://mahbsrv.jrc.it>

<sup>6</sup> E.g. of the size of the major accident which occurred at Toulouse 2001 which killed 30 and injured over 2,200 people and incurred damage to 27,000 homes, 1,300 companies and economic cost which exceeded 1.5 billion €.

<sup>7</sup> Refer to <http://mahb.jrc.it/index.php?id=517>

Council (IRGC). The cornerstones of this integrative framework are the four dimensions T (Technology, technical), C (Governance, communication), H (Human, management) and R (policies regulation, standardization) as given in the figure below. Applying the ERMF, these dimensions have to be integrated when performing Risk Management according the different phases of IRGC (Pre-Assessment, Risk Appraisal, Tolerability & Acceptability Judgment, Management and Communication).



**Figure 1: Emerging Risk Management Framework**

In addition, the iNTeg-Risk project identifies specific emerging risks and is developing solutions to enter into the unifying framework, concept of Emerging Risk Representative industrial Applications (ERRAs). Emerging Risks Representative (industrial) Applications are significant examples of applications related to industrial safety (emerging risks). The approach is based on finding the solutions for single ERRAs and, by capitalizing on these solutions and generalizing them, build the common European approach to emerging risk. The Integration will take place on the level of ERRAs grouped around the emerging risks related to:

- A **new technologies** (e.g. carbon capture and sequestration, unmanned aerial surveillance, liquid natural gas regasification, underground hubs)
- B **new materials and products** (e.g. nanotechnology, storage of hazardous materials, advanced engineering materials, composite materials)
- C **new production technologies and production networks** (e.g. remote operation in environmentally sensitive areas, challenges to safety posed by outsourcing, on-line monitoring of emerging risks in conventional industrial plants), and
- D **new global / EU / local emerging risk related policies** (e.g. regional interaction nature-technology (NaTech), implementation of European safety legislation on SMEs, impact of hazardous substances on public health and relations with REACH and GHS).

The solutions will be generalized and used for the framework, which will be validated in a second application cycle. Overall solutions will be made available to the users in the form of the iNTeg-Risk "One-Stop Shop" for EU solutions addressing emerging risks. The solution will include issues of

early recognition and monitoring of emerging risks, communication, governance, pre-standardization, education & training, dissemination, as well as new tools such as Safetypedia, Atlas of Emerging Risks, Reference Library, etc. the iNTeg-Risk project deliverables related to the Emerging Risk Management Framework (ERMF) and the ERRAs grouped around the emerging risks related to new materials, technologies and products, new production processes and management, complex industrial systems and networks and emerging risk policies may be used as a basis and/or referred to in the CWA. In addition, several selected documents will be used as the “backbone” for the CWA to be developed. In addition, the existing legal environment related to (risk) management standards and directives<sup>8</sup> in relation with the topics of this workshop will be taken into account.

**Table 1: Comparison of ERMF to other risk management frameworks, standards and other reference documents**

Framework	IRGC	ISO 31000	ENISA (EU)	iNTeg-Risk (ERMF)
Includes analysis of deficiencies	+++		+	+ (ref to IRGC)
Governance oriented	+++	+	+	++
Management oriented	+	+++	++	++
Application oriented	+	++	++	+++
Standardization oriented	?	+++	++	++(+)
Certification oriented	?	not so far	not	in parts
Specific for ER	++	+	++	+++
Supported by lower-level documents	(+)	++	++	+++
Supported by specific tools	+	not	partly	yes
Reference to regulation	n/a	partly	partly	yes

### 2.3 Existing frameworks and standards

Previous activities and work of other groups worldwide have already produced a basic set of standards which will be taken into account and complemented by the CWAs within the scope of this workshop. Some relevant standards<sup>9</sup> are listed below.

- ISO 14001 (2004) – Environmental management<sup>10</sup>

<sup>8</sup> e.g. Registration, Evaluation and Authorisation of Chemicals (REACH directive), Restriction of Hazardous Substances Directive (RoHS directive), Infrastructure for Spatial Information in the European Community directive (INSPIRE directive), Seveso II Directive, etc.

<sup>9</sup> The list of relevant standards is not exhaustive and can be extended by different standards also relevant for the proposed CWAs. The list contains the most relevant standards identified by workshop proposers.

- ISO 14044 (2006) Environmental management - Life cycle assessment - Requirements and guidelines<sup>11</sup>
- ISO 26000 (2010) Social Responsibility<sup>12</sup>
- ISO 27000 series on Information technology<sup>13</sup>
- ISO 31000 (2009) Risk management - Principles and guidelines<sup>14</sup>
- ISO/IEC 31010 Risk management - Risk assessment techniques<sup>15</sup>
- ISO Guide 73 (2009) Risk management – Vocabulary<sup>16</sup>

NOTE: In addition, the CWA proposing a management system related standard will take carefully into account ISO Guide 72. A respective questionnaire answered on preliminary basis is given in Annex A of this business plan.

### 3 Workshop proposers and Workshop participants

The following organizations as partners of iNTeg-Risk project have agreed to support the present Workshop proposal.

**Table 2: Workshop proposers**

Company	Contact person
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<sup>10</sup> ISO 14001:2004 (2004): Environmental management systems - Requirements with guidance for use, ISO International Standardization Organization

<sup>11</sup> ISO 14044:2006 (2006): Environmental management - Life cycle assessment - Requirements and guidelines, ISO International Standardization Organization

<sup>12</sup> ISO 26000:2010 (2010): Guidance for social responsibility, ISO International Standardization Organization

<sup>13</sup> e.g. ISO 27000: 2009 (2009): Information technology - Security techniques - Information security management systems - Overview and vocabulary, ISO International Standardization Organization

<sup>14</sup> ISO 31000:2009 (2009): Risk management - Principles and guidelines, ISO International Standardization Organization

<sup>15</sup> ISO/IEC 31010:2009 (2009): Risk management - Risk assessment techniques, ISO International Standardization Organization

<sup>16</sup> ISO Guide 73:2009 (2009): Risk management - Vocabulary, ISO International Standardization Organization

Other interested stakeholders are welcome to register for participation in accordance with the CEN/CENELEC Rules for Workshops. Key stakeholders have been already identified and contacted by iNTeg-Risk partners, and invited to be involved.

Some of the stakeholders of the CWA are:

- Risk Engineers and Risk Managers from private and governmental organizations
- European Agency for Safety and Health at Work (EU-OSHA)
- European Technology Platform on Industrial Safety (ETPIS)

This list is not exhaustive, and other stakeholders will be invited to participate.

#### **4 Workshop scope and objectives**

The goal of this CEN workshop is to summarize and exploit the results of iNTeg-Risk project with respect to the Emerging Risks Management Framework and the ERRAs grouped around the emerging risks related topics. For this purpose the CWA will consist of a general document and five supporting documents (appendixes).

The need for these documents is underlined by the background information provided in 2.1 and 2.2 of this Business Plan. In addition, the comparison of the Emerging Risk Management Framework with other risk management frameworks, standards and other reference documents in table 1, like the one proposed by International Risk Governance Council (IRGC)<sup>17</sup>, ISO 31000 proposing principles and guidelines for risk management and the framework developed by the European Network and Information Security Agency (ENISA)<sup>18</sup>, clearly shows the deficits of other frameworks and the (potential) benefits of the ERMF.<sup>19</sup>

The main objectives of this iNTeg-Risk Workshop thus are:

- using the results of the FP7 project iNTeg-Risk on management of emerging risks to and transposing them into a standard by extracting relevant information from major project deliverables.
- development of a CWA consisting of a general Guideline for the Emerging Risk Management Framework (ERMF) supported by five appendixes derived from ERRAs findings and methods and tools developed related to the iNTeg-Risk findings, as applied in the solution packages:
  - Emerging Risks in New Technologies,
  - Emerging Risks in New Materials and Products,
  - Emerging Risks in New Production and Production Networks,
  - Emerging Risk Policies,
  - Emerging Risks due to uncertainties in measurement and characterization.

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<sup>17</sup> IRGC (2009). International Risk Governance Council (2008), An introduction to the IRGC Risk Governance Framework, International Risk Governance Council (IRGC), Geneva. [http://www.irgc.org/IMG/pdf/An\\_introduction\\_to\\_the\\_IRGC\\_Risk\\_Governance\\_Framework.pdf](http://www.irgc.org/IMG/pdf/An_introduction_to_the_IRGC_Risk_Governance_Framework.pdf)

<sup>18</sup> ENISA (2010). ENISA EFR Framework Introductory Manual, European Network and Information Security Agency, Heraklion. Available at: <http://www.enisa.europa.eu/>

<sup>19</sup> The frameworks, standards and other reference documents may not be fully comparable, because of some differences in scopes.



- referencing to other iNTeg-Risk results and other useful recognized sources as well as further recommendations.
- include further details (optional) including e.g. Key Performance Indicators (KPIs) for Emerging Risks, Life Cycle Assessment (LCA) for Emerging Risk related New Technologies, Unified Modeling Language (UML) for Emerging Risks, Capability Maturity Model Integration (CMMI) for Emerging Risks related processes, Solvency II for Emerging Risks.

## **5 Workshop programme**

### **5.1 General**

As laid out in chapter 4, six documents will be developed. In addition to the main document, five appendixes will be developed. Out of these five, four will be derived from the topics of groups of ERRAs (A-D). The iNTeg-Risk case studies called Emerging Risk Representative industrial Applications (ERRAs) are grouped in (A) Emerging Risks in New Technologies, (B) Emerging Risks in new materials and products, (C) Emerging Risks in new production-technologies & production networks and (D) Emerging Risks in related policies. In addition, there will be a fifth document on the Emerging Risk Management Framework and one on Emerging Risks due to uncertainties in measurement and characterization.

The language of the workshop as well as all the documents will be in English.

### **5.2 Workshop deliverables**

#### **5.2.1 General Emerging Risk Management Framework Guideline (main document)**

A new framework for management of Emerging Risks will be defined within the scope of this CWA. The aim of this Emerging Risk Management Framework (ERMF) is to form a common EU approach for managing emerging industrial risks in the next 5-15 years. The framework will be composed of a series of principles on how to manage risks in an integrated manner and how to deal specifically with emerging risks in an ever-changing environment. The principles of the Emerging Risk Management Framework (ERMF) are based on the results of iNTeg-Risk project in terms of methods and tools which are combined with inputs of earlier projects such as Shape-Risk<sup>20</sup>. These principles cover the whole life-cycle of an industrial activity, including the responsibilities of proprietors. In this context, dedicated aspects taken from International Risk Governance Council (IRGC<sup>21</sup>) like pre-assessment, risk-appraisal, tolerability and acceptability, as well as risk management and communication are taken into account.

The principles of ERMF can be applied using the methods and tools developed in iNTeg-Risk that are summarized in this section. The application is illustrated in the subsequent sections.

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<sup>20</sup> Breedveld, L., Micheletti, C., Bolvin, C. (2007). Shape-Risk Synthesis Document WP 7 - Priority 3: Nano-technologies and nano-sciences, knowledge-based multifunctional materials, and new production processes and devices - "NMP"., Synthesis Document, Apr 2007

<sup>21</sup> IRGC (2009). International Risk Governance Council (2008), An introduction to the IRGC Risk Governance Framework, International Risk Governance Council (IRGC), Geneva.  
[http://www.irgc.org/IMG/pdf/An\\_introduction\\_to\\_the\\_IRGC\\_Risk\\_Governance\\_Framework.pdf](http://www.irgc.org/IMG/pdf/An_introduction_to_the_IRGC_Risk_Governance_Framework.pdf)

### **5.2.2 Emerging Risks in New Technologies (appendix)**

The CWA will suggest common and integrated reference solutions for the management of emerging risks related to the development and the intensification of new and advanced technologies. The CWA should include methods for integrated analysis of the problems and reference solutions for Emerging Risks in New Technologies and provide a set of specific model tools and solutions for integrated risk management.

### **5.2.3 Emerging Risks in New Materials and Products (appendix)**

The CWA will suggest common/agreed solutions for dealing with emerging risks in the area of new products and materials. The CWA should include methods for integrated analysis of the problems and reference solutions for Emerging Risks in New Materials and Products and provide a set of specific model tools and solutions for integrated risk management.

### **5.2.4 Emerging Risks in New Production and Production Networks (appendix)**

The CWA will suggest innovative solutions, reference documents, methods and tools for the handling of emerging risks within the area of new production technologies and production networks. The CWA should include methods for integrated analysis of the problems and reference solutions for Emerging Risks in New Production and Production Networks and provide a set of specific model tools and solutions for integrated risk management.

### **5.2.5 Emerging Risk Policies (appendix)**

The CWA will suggest innovative solutions, reference documents, methods and tools for the handling of emerging risks within the area of policies and decision-making. The CWA should include methods for integrated analysis of the problems and reference solutions for Emerging Risk Policies and provide a set of specific model tools and solutions for integrated risk management.

### **5.2.6 Emerging Risks due to uncertainties in measurement and characterization (appendix)**

Based on the results of iNTeg-Risk project, which will be analyzed to identify areas developed within the project that are related to uncertainties in measurement and characterization, this CWA will suggest reference solutions for integrated risk management of Emerging Risks due to uncertainties in measurement and characterization.

### 5.3 Workshop schedule

The CWAs will be elaborated according to the following preliminary programme shown in Table 3.

**Table 3: Workshop deliverables for CWA within iNTeg-Risk Workshop**

No	Activity	Description	Date	Responsibility
1	Workshop Kick-off meeting	Approval of business plan, appointment of secretariat and chairperson	2011-11-04	Secretariat, CCMC, Chairperson
2	First draft of CWAs	Preparation of first draft CWAs	December 2011 to May 2012	Editors, Chairperson
3	Workshop comment phase	Distribution of first draft CWAs to workshop participants for internal enquiry, collection of comments	June 2012 to August 2012	Secretariat, Workshop Participants
4	Workshop plenary meeting	Review of received comments, approval of revised draft CWAs <sup>22</sup>	September 2012	Chairperson, Workshop Participants
5	Public comment phase (60 days)	Publication of revised draft CWAs on CEN website for external enquiry, collection of comments	December 2012 to February 2013	Secretariat, CCMC
6	Comments resolution meeting / Formal adoption of CWAs	Review of public comments, approval of final draft CWAs by consensus of workshop participants	March 2013	Workshop Participants, Chairperson
7	Publication of CWAs	Submission of the agreed CWAs to CCMC, final editing and circulation of CWAs to CEN Members	To be defined	Secretariat, CCMC

## 6 Workshop structure

### 6.1 CEN Workshop Chairperson

The Workshop proposers have nominated a chairperson. The Chairperson was approved at the Kick-off meeting. His responsibilities include:

- chairing the CEN Workshop (kick off and plenary) meetings,
- representing the CEN Workshop in outside meetings in cooperation with CCMC and with the Workshop Secretariat regarding strategic directions, problems arising, external relationships, etc.
- monitoring progress of the CWAs,
- ensuring the liaison with relevant CEN/TCs.

<sup>22</sup> NOTE: The results of the application, verification and validation sub-project (SP3) will be included on continuous basis.

## **6.2 CEN Workshop Co-Chairs**

Two Co-Chairs were appointed at the Kick-off meeting. The Co-Chairs will support and assist in all responsibilities outlined for the chair. In the absence of the chair, at least one of the Co-Chairs will represent the CEN Workshop at outside meetings in cooperation with CCMC and will interface with CCMC regarding strategic directions, problems arising, external relationships, etc.

## **6.3 CEN Workshop Secretariat**

The Workshop Secretariat is providing the formal link to the CEN system. The following main activities will be carried out by the Workshop Secretariat:

- organizing WS plenary meetings,
- producing WS and project meeting reports and action lists,
- administrative contact point for WS projects (if any, for now there are no projects planned),
- managing WS membership lists,
- managing WS document registers,
- follow-up of action lists,
- if the Workshop works mainly by electronic means, assist Chairperson in monitoring and follow-up of electronic discussions,
- administer liaison with relevant CEN/TCs, if any.

The German CEN member DIN was approved as Secretariat at the Kick-off meeting.

## **7 Resource requirements**

### **7.1 Costs of CEN Workshop Secretariat**

The administrative costs of CEN Workshop Secretariat and other logistical support will be covered by iNTeg-Risk project through its FP7 funding.

The copyright of the CWAs will be with CEN.

### **7.2 The participation (registration) fee**

The registration and participation at this CEN Workshop is free of charge; each participant shall bear his/her own cost for travel and subsistence.

## **8 Related activities, liaisons, etc.**

It will be necessary to ensure liaison with a number of individual projects and associations listed below. The liaison does not imply participation in the consensus rights and/or any sort of partnership.

- International Risk Governance Council (IRGC);  
<http://www.irgc.org/>
- European Technology Platform on Industrial Safety (ETPIS);  
<http://www.industrialsafety-tp.org/>
- European Agency for Safety and Health at Work (EU-OSHA);  
<http://osha.europa.eu/en/front-page>

- IRIS; FP7 project to increase industrial safety and to reduce impact on human health and environment;  
<http://www.vce.at/iris/index.html>
- Steinbeis University Berlin (SHB);  
[http://www.steinbeis-hochschule.de/en/home.html?no\\_cache=1](http://www.steinbeis-hochschule.de/en/home.html?no_cache=1)
- University of Stuttgart (ZIRN), the "Interdisciplinary Research Unit on Risk Governance and Sustainable Technology Development" is part of IZKT, the "International Center for Cultural and Technological Studies" of Stuttgart University;  
<http://www.zirn-info.de/index-e.htm>
- Society for Risk Analysis Europe (SRA-E), The Society encourages those interested in all aspects of risk analysis to communicate, collaborate and develop new methodologies for risk analysis and risk management;  
<http://www.sraeurope.org/>

Liaison will also be ensured with the following ISO and CEN Technical Committees:

- ISO/TC 262 Project Committee: Risk Management
- CEN/TC 352 Nanotechnologies,
- ISO/TC 229 Nanotechnologies
- CEN/TC 391 Societal and Citizen Security
- ISO/TC 223 Societal Security
- ISO/TC 21 Equipment for fire protection and fire fighting,
- ISO/TC 67 as well as CEN/TC 12 Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries
- CEN Workshop 63 – Structural Condition for Integrated Lifetime Assessment for Plants, Structures and Components

## **9 Contact points**

### **9.1 Chairman**

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### **9.6 Editors**

Editors are proposed below for the CWA main document and five appendixes, the editors will be responsible for correcting errors in syntax (spelling, punctuation and grammar) and proofreading, with notes or observations on the technical content, the document structure and clarity based on the shape and condition of the main editor's writing.

#### **Part 1: General Emerging Risk Management Framework**

- Jovanovic, Aleksandar; European Virtual Institute for Integrated Risk Management (Main editor)
- Debray, Bruno; Institut National de l'Environnement Industriel et des Risques
- Kokejl, Roswitha; University of Stuttgart (ZIRN)
- Löscher, Michael; European Virtual Institute for Integrated Risk Management

**Part 2: Emerging Risks in New Technologies**

- Jovanovic, Aleksandar; European Virtual Institute for Integrated Risk Management (Main editor)
- Baloš, Daniel; Steinbeis Advanced Risk Technologies GmbH
- Kokejl, Roswitha; University of Stuttgart (ZIRN)
- Löscher, Michael; European Virtual Institute for Integrated Risk Management

**Part 3: Emerging Risks in New Materials and Products**

- Dolinski, Krzysztof; Institute of Fundamental Technological Research, Polish Academy of Science (Main editor)
- Basista, Michal; Institute of Fundamental Technological Research, Polish Academy of Science
- Jovanovic, Aleksandar; European Virtual Institute for Integrated Risk Management
- Kokejl, Roswitha; University of Stuttgart (ZIRN)
- Löscher, Michael; European Virtual Institute for Integrated Risk Management
- Trebicki Jerzy; Institute of Fundamental Technological Research, Polish Academy of Science

**Part 4: Emerging Risks in New Production and Production Networks**

- Øien, Knut; SINTEF, Technology and Society (Main editor)
- Jovanovic, Aleksandar; European Virtual Institute for Integrated Risk Management
- Kokejl, Roswitha; University of Stuttgart (ZIRN)
- Kviseth Tinmannsvik, Ranveig; SINTEF Technology and Society
- Löscher, Michael; European Virtual Institute for Integrated Risk Management

**Part 5: Emerging Risk Policies**

- Jovanovic, Aleksandar; European Virtual Institute for Integrated Risk Management (Main editor)
- Baloš, Daniel; Steinbeis Advanced Risk Technologies GmbH
- Kokejl, Roswitha; University of Stuttgart (ZIRN)
- Löscher, Michael; European Virtual Institute for Integrated Risk Management

**Part 6: Emerging risks due to uncertainties in measurement and characterization**

- Martin, Roderick; Materials Engineering Research Laboratory Ltd (Main editor)
- Wilson, Robert; Materials Engineering Research Laboratory Ltd
- Baloš, Daniel; Steinbeis Advanced Risk Technologies GmbH

## **Annex A**

### **Justification criteria for development of management system standards (MSS) according to ISO Guide 72**

#### **A.1 General**

The following list of questions to be addressed in the justification study is not exhaustive. Additional information not covered by the questions should be provided if it is relevant to the case.

The answers to the questions listed under A.2.3 to A.2.8 should be differentiated according to those parties that may be affected by the proposed MSS if the answers differ significantly.

#### **A. 2 Questions**

##### **A. 2.1 Basic information on the MSS proposal**

What is the proposed purpose and scope of the MSS?

*The European Commission mandated the representatives of the iNTeg-Risk project to develop an Emerging Risks Management Framework as well as Emerging Risk Representative industrial Applications. The results of the iNTeg-Risk project will be summarized and disseminated in form of a series of CWA.*

- a) Would the proposed MSS work item result in an International Standard (IS), an ISO/(IEC) Guide, a Technical Specification (TS), a Technical Report (TR), a Publicly Available Specification (PAS), or an International Workshop Agreement (IWA)?

*No, the result will be a series of CWA.*

- b) Does the proposed purpose or scope include product (including service) specifications, product test methods, product performance levels, or other forms of guidance or requirements directly related to products produced or provided by the implementing organization?

*No.*

- c) Is there one or more existing ISO technical committee or non-ISO organization that could logically have responsibility for the proposed MSS? If so, identify.

*According to the scope of ISO/TC 262 Project committee: Risk management, this could logically have responsibility for the proposed MSS. Other responsible technical committees could be for instance ISO/TC 21 Equipment for fire protection and fire fighting, ISO/TC 67 as well as CEN/TC 12 Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries, ISO/TC 207 Environmental management, ISO/TC 229 as well as CEN/TC 352 Nanotechnologies, CEN/TC 391 Societal and Citizen Security*

- d) Have relevant reference materials been identified, such as existing guidelines or established practices?

*Yes. Please refer to section 2.2 and 2.3 of this Business Plan.*

- e) Are there technical experts available to support the standardization work? Are the technical experts direct representatives of the affected parties from the different geographical regions?

*Technical experts are available to support the development of the CWA. The CWA being produced on European level affect parties from this geographical region. Participation in the workshop is open to any interested party worldwide.*



- f) What efforts are anticipated as being necessary to develop the document in terms of experts needed and number/duration of meetings?

*Respective information is given in chapter 5 and chapter 9 of this Business Plan.*

- g) What is the anticipated completion date?

*Estimated completion date is lays in the second half of 2013.*

### **A.2.2 Affected parties**

- a) Have all the affected parties been identified? For example:

- 1) Organizations (of various types and sizes): the decision-makers within an organization who approve work to implement and achieve conformance to the MSS;
- 2) Customers/end-users, i.e. individuals or parties that pay for or use a product (including service) from an organization;
- 3) Supplier organizations, e.g. producer, distributor, retailer or vendor of a product, or a provider of a service or information;
- 4) A MSS service provider, e.g. MSS certification bodies, accreditation bodies or consultants;
- 5) regulatory bodies;
- 6) non-governmental organizations.

*The project has evaluated the list of potential stakeholders and affected parties, which are for example decision makers, regulatory bodies, the European Commission etc.*

- b) Is the MSS intended to be a guidance document, contractual specification or regulatory specification for an organization?

*The CWA is intended to be a guidance document.*

### **A.2.3 Need for an MSS**

- a) What is the need? Does the need exist at a local, national, regional or global level? Does the need apply to developing countries? Does it apply to developed countries? What is the added value of having an ISO document (e.g. facilitating communication between organizations in different countries)?

*The project iNTeg-Risk has identified a lack of regulation and standardization in its specific field of research, which is due to the nature of New Technologies and its related Emerging Risks. The CWA to be produced within the scope of this CEN Workshop will be the first starting point to cover these gaps on European level.*

- b) Does the need exist for a number of sectors and is thus generic? If so, which ones? Does the need exist for small, medium or large organizations?

*The CWA is covering the need of various sectors and all types of organizations, especially organizations with limited resources (e. g. SMEs).*

- c) Is the need important? Will the need continue? If yes, will the target date of completion for the proposed MSS satisfy this need? Are viable alternatives identified?

*The need is important and increasing. The CWA being produced should be considered as first step and may need to be adjusted according to changed needs which are to be expected in this field.*

- d) Describe how the need and importance were determined. List the affected parties consulted and the major geographical or economical regions in which they are located.

*The need and the importance were identified in preparation of iNTeg-Risk project and were verified during the project basically for Europe.*

- e) Is there known or expected support for the proposed MSS? List those bodies that have indicated support. Is there known or expected opposition to the proposed MSS? List those bodies that have indicated opposition.

*The CWA will be supported by project partners, EU-VRi and the European Commission. The proposers of the CEN workshop having initiated the workshop are listed in chapter 3 of this business plan.*

#### **A.2.4 Sector-specific MSS proposals**

- a) Is the MSS for a single specific sector?

*The MSS deals with Emerging Risk on an horizontal level.*

- b) Will the MSS reference or incorporate an existing, non-industry-specific ISO MSS (e.g. from the ISO 9000 series of quality management standards)? If yes, will the development of the MSS conform to the ISO/IEC Sector Policy (see 6.8.2 of ISO/IEC Directives, Part 2, 2001), and any other relevant policy and guidance procedures (e.g. those that may be made available by a relevant ISO technical committee)?

*Yes, the CWA will be conforming to the ISO/IEC Sector Policy if applicable and the CWAs will reference or incorporate the standards given in 2.3*

- c) What steps have been taken to remove or minimize the need for particular sector-specific deviations from a generic MSS?

*There is no need for removal or minimizing the need for sector specific deviations as the CWA will not be sector specific.*

#### **A.2.5 Value of an MSS**

##### **A.2.5.1 Value to an organization implementing the MSS**

- a) What are the expected benefits and costs to organizations, differentiated for small, medium and large organizations if applicable?

*Benefits for all types of organizations applying the CWA are given in chapter 2 of this business plan.*

- b) Describe how the benefits and the costs were determined. Provide available information on geographic or economic focus, industry sector and size of the organization. Provide information on the sources consulted and their basis (e.g. proven practices), premises, assumptions and conditions (e.g. speculative or theoretical), and other pertinent information.

*A description is given in chapter 2 of this business plan.*

- c) Will the MSS allow an organization competitively to add to, differentiate or encourage innovation of its management system beyond the standard?

*Yes.*

- d) If the intended use is for contractual or regulatory purposes, what are the potential methods to demonstrate conformance (e.g. first party, second party or third party)? Does the MSS enable organizations to be flexible in choosing the method of demonstrating conformance, and to accommodate for changes in its operations, management, physical locations and equipment?

*Yes, organizations applying a CWA of this CEN Workshop will be flexible in choosing the method of demonstrating conformance, and to accommodate for changes in its operations, management, physical locations and equipment.*

- e) If third-party registration/certification is a potential option, what are the anticipated benefits and costs to the organization? Will the MSS facilitate joint audits with other management system standards or promote parallel assessments?

*The CWAs are not suited for joint audits or certification.*

#### **A.2.5.2 Value to other affected parties**

- a) What are the expected benefits and costs to other affected parties (including developing countries)?

*Same benefits as outlined in A.2.5.1.*

- b) Describe how the benefits and the costs were determined. Provide any information regarding the affected parties indicated.

*See A.2.5.1.*

- c) What will be the expected value to society?

*By means of the CWAs to be developed a common template for a more efficient and well-understood approach to identify and deal with emerging risks will be provided. This will ensure that the technologies and products made in the EU are accepted by stakeholders in industry and society. This acceptance can be reached only if the stakeholders, affected parties, and society are convinced that possible or perceived emerging risks related to these technologies can be managed in safe, responsible and transparent way. Hence, the goal of the CWAs is to demonstrate that actual and potential emerging risks are well understood and properly managed.*

#### **A.2.6 Risk of trade barriers**

- a) How would the MSS facilitate or impact global trade? Could the MSS create or prevent a technical barrier to trade?

*The proposed framework has no relevance concerning technical trade barriers.*

- b) Could the MSS create or prevent a technical barrier to trade for small, medium or large organizations?

*No.*

- c) Could the MSS create or prevent a technical barrier to trade for developing or developed countries?

*No.*

- d) If the proposed MSS is intended to be used in government regulations, is it likely to add to, duplicate, replace, enhance or support existing governmental regulations?

*The CWA may be consulted too enable smooth adding, enhancement and support of governmental regulations.*

#### **A.2.7 Risk of incompatibility, redundancy and proliferation**

- a) Is there potential overlap or conflict with other existing or planned ISO or non-ISO international standards, or those at the national or regional level? Are there other public or private actions, guidance, requirements and regulations that seek to address the identified need, such as technical papers, proven practices, academic or professional studies, or any other body of knowledge?

*With respect to existing or planned standards, no standards have been identified, either on regional, or on national or international level, which are potentially overlapping or in conflict with the planned CEN Workshop Agreement as described in this Business Plan.*

*The focus of this to be developed agreement is on integrated emerging risk management and therefore to be considered as complementary to ISO 31000, which is dealing with risk management from a general perspective, not covering specific types of risks (e.g. emerging risks). In order to avoid overlap and reinforce synergetic work with ISO Technical Committee 262 in charge of the development of the ISO 31004 for implementation of the ISO 31000 Risk Management standard, the coordinator of iNTeg-Risk project and nominated chair of the workshop established a formal liaison with TC 262 in September 2011.*

*With respect to other public or private actions, guidance, requirements and regulations, the main action that has been identified is the work of EU-OSHA in the field of emerging risks, which is focused on occupational health and safety (see <http://osha.europa.eu/en/riskobservatory/index.html>). iNTeg-Risk coordinator and nominated chair of this workshop has established contact to the Risk Observatory of EU-OSHA (Mr. Eusebio Rial Gonzales) and information exchange is taking place to avoid any overlap or conflict and to develop synergetic work. In case the workshop will identify any other relevant action during the work on the CWA, the chair will establish contact to action leaders/leading organizations to ensure alignment of work and integration of approaches where possible.*

- b) Is the MSS or the related conformity assessment activities (e.g. audits, certifications) likely to add to, replace all or parts of, harmonize and simplify, duplicate or repeat, conflict with, or detract from the existing activities identified above? What steps are being considered to ensure compatibility, resolve conflict or avoid duplication?

*No.*

- c) Is the proposed MSS likely to promote or stem proliferation of MSSs at the national or regional level, or by industry sectors?

*Yes, as it is a CWA developed in collaboration on European and national level. The Emerging Risk Management Framework might promote and establish the systematic management with Emerging Risks. The European Commission has recognized this need. In its risk assessment bodies and committees its deals with emerging risks in different domains and it has included them explicitly also in the FP7.*

#### **A.2.8 Other risk factors**

Have any other risks been identified (e.g. timeliness or unintended consequences to a specific business)?

*No.*