Standard Recommendation
S.R. CWA 16649:2013

Managing emerging technology-related risks

S.R. CWA 16649:2013

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CEN WORKSHOP AGREEMENT

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English version

Managing emerging technology-related risks

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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Foreword

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2013-05-13, the constitution of which was supported by CEN following the public call for participation made on 2011-08-30.

A list of the individuals and organizations which supported the technical consensus represented by the CEN Workshop Agreement is available to purchasers from the CEN-CENELEC Management Centre. The following organisations officially took part to the development of this CWA:

- EU-VRi - European Virtual Institute for Integrated Risk Management EEIG
- EDF – Électricité de France S.A.
- GDF Suez
- GIE AXA
- INERIS - Institut National de l'Environnement Industriel et des Risques
- KMM-VIN – European Virtual Institute on Knowledge-based Multifunctional Materials AISBL
- MERL - Materials Engineering Research Laboratory Limited
- R-Tech - Steinbeis Advanced Risk Technologies GmbH
- Stiftelsen Sintef
- Swiss Re - Swiss Reinsurance Company Ltd
- Tecnalia - Fundacion Tecnalia Research & Innovation
- TNO Research Group Q&S
- University of Stuttgart

The formal process followed by the Workshop in the development of the CEN Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of the CEN Workshop Agreement or possible conflict with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its members.

The final review/endorsement round for this CWA was started on 2012-04-22 and was successfully closed on 2013-05-13.The final text of this CWA was submitted to CEN for publication on 2013-05-16.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of The following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

Introduction

This CEN Workshop Agreement document is based on the results of the iNTeg-Risk project [1] (iNTeg-Risk: Early Recognition, Monitoring and Integrated Management of Emerging, New Technology Related Risks) and, in particular, on the deliverable D.2.1.2.1 iNTeg-Risk ERMF (Emerging Risk Management Framework) [2]. The document deals with the particular issue of emerging risk, in a more narrow sense with the emerging risks related to new technologies. The approach adopted here is complementary to the International Standard ISO 31000, Risk Management – Principles and guidelines [3], which is dealing with Risk Management in general. This CEN Workshop Agreement has been a part of the project and its preparation supported by the EU's Seventh Framework Programme for Research (FP7).

Goals

iNTeg-Risk project [1] [5], and this CEN Workshop Agreement are devoted to improving the ability of the EU industry, society and authorities to identify, monitor and manage emerging risks. The project should improve chances of market success of European innovation and new technologies[1)] developed in the EU. Its particular concern is the issue of public trust and confidence in the research efforts promoted by the EU, e.g. in the technologies and solutions - like innovations - developed within European projects. The technologies and solutions developed in these projects should be well accepted by the European society and perceived as a good and just investment of time and effort. On the other hand, mistrust or lack of confidence, lack of fairness and/or transparency of innovation can damage or even stop the innovation in a particular field.

The particular goal of this CEN Workshop Agreement is to improve management of emerging risks in the EU and promote safety, security, environmental friendliness and social responsibility as a trademark of the EU technologies. The approach proposed by the document is based mainly on the results of 17 individual applications of new technologies like nanotechnologies, hydrogen technologies, underground storage of carbon dioxide and new materials, which have been analyzed in iNTeg-Risk project ERRAs (Emerging Risk Representative industrial Applications). The solutions have been generalized and used for the framework presented here. In the project, the overall solution has been made available to the users in the form of the iNTeg-Risk 1StopShop. The shop includes tools for early recognition and monitoring of emerging risks, risk governance, education & training, as well as new tools such as Safetypedia, RiskAtlas, network of stakeholder companies and persons (ENISFER), etc. These tools are supposed to be available as a PPP-service (PPP – public-private partnership) after the end of project in May 2013.

Transparency and precaution

Transparency is required by both public bodies and general public. The transparency is a precondition for having the research and innovation perceived as balanced, fair and beneficial. However, the question if a particular innovation (e.g. a new technology – e.g. nanotechnology, new materials or new energy production technologies) is beneficial for the society often cannot be answered in a simple and straightforward way. It leads to the question "how one can be sure that the innovation related risks are acceptable", which, because of the uncertainty of these risks and their management solutions, calls for application of the precautionary principle. This principle is well rooted in Europe and in the EU policies on the highest level [6] and in a formal way [7]. But when deciding about the best balance between the advantages of a technology and possible risks different approaches are possible. There, for instance, the EU and the US have often followed different ways [8] [9], e.g. in the cases of climate change, toxic chemicals or genetically modified foods.

The emerging risks are the issue of major concern for both precautious and risk-taking stakeholders, especially for new technologies (in the case of iNTeg-Risk project, the technologies dealt with in the ERRAs).

1) Used broadly as a synonym for emerging technologies (http://en.wikipedia.org/wiki/Emerging_technologies), such as those in the list of emerging technologies proposed at http://en.wikipedia.org/wiki/List_of_emer-ging_technologies; in iNTeg-Risk seventeen such technologies are proposed as so-called ERRAs (Emerging Risk Representative Applications), see http://www.integrisk.eu-vri.eu/home.aspx?lan=230&tab=851&itm=852&pag=856

A common framework, such as the one proposed in iNTeg-Risk project, is part of the answer to the question how to reconcile the needs for innovation on one side with the needs for safety and sustainability on the other side.

The framework

The question how one can be sure that the innovation related risks are acceptable is, therefore, in the very root of the ideas which have led to iNTeg-Risk project and in the very root of the project itself. The practical answer to the question, as proposed by the project [1] consists of:

— agreed principles, in the form of iNTeg-Risk Paradigm and iNTeg-Risk Emerging Risk Management Framework (ERMF), tackled by this document;

— reference methodologies, mainly in the form of guidelines (iNTeg-Risk Guidelines) and

— tools supporting application of the above principles and methodologies in form of a software suite (iNTeg-Risk 1StopShop[2)]).

The framework is, thus, envisaged as one of the key elements of the overall iNTeg-Risk solution and it defines the practical agreed way of dealing with emerging risks and managing them. In addition, the ERMF provides the basis for the common EU recommended practices and standardized practices for dealing with emerging risks due to new technologies. The main objective of the framework is to set a transparent agreed way for management of emerging risks and to provide the basis for development of the planned pre-normative guideline documents, in particular by:

— acquiring emerging risk notions/precursors and monitoring their development;

— identifying similarities with known risks or their precursors;

— better identification of the most critical emerging risks;

— better recognition of interdependencies and relations among emerging risks;

— better knowing triggers, factors and drivers of emerging risks;

— better monitoring and optimized follow-up for the emerging risks, and

— systematic interlinking between hazards, vulnerabilities and stakeholders.

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— Aleksandar Jovanović (EU-VRi and R-Tech, Main Editor, Chairman of the CEN Workshop 67)

— Bruno Debray (INERIS, 1st Co-Chairman)

2) iNTeg-Risk 1StopShop registered as eingetragene Marke Nr. 30 2010 058 354 at Deutsches Patent- und Markenamt; Safetypedia is registered as eingetragene Marke Nr. 30 2011 018 399 at Deutsches Patent- und Markenamt;

— Knut Øien (SINTEF, 2nd Co-Chairman)

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— CEN European Committee for Standardization (CEN-CENELEC Management Centre)

— Secretariat: DIN German Institute for Standardization

The CEN Workshop Agreement is a technical agreement, developed by an open workshop structure within the framework of CEN-CENELEC and owned by CEN-CENELEC as a publication, which reflects the consensus of only the registered participants responsible for its contents. The Workshop Agreement therefore does not represent the level of consensus and transparency required for a European Standard (EN) and is not designed to support legislative requirements (e.g. the New Approach) or to meet market needs where significant health and safety issues are to be addressed. It is instead designed to offer market players a flexible and timely tool for achieving a technical agreement where there is no prevailing desire or support for a standard to be developed.

1 Scope

The present document gives guidance on steps for applying/implementing the proposed Emerging Risk Management Framework (ERMF) in industrial organizations. The document also formulates the process to follow for better management of emerging risks. In its approach it relies on the International Standard ISO 31000 which provides principles and generic guidelines on risk management.

This CEN Workshop Agreement can be used by any public, private or community enterprise, association, group or individual. Therefore, this CEN Workshop Agreement is not specific to any industry or sector, but its origin and emphasis are in the area of emerging risks related to new technologies and innovation.

The core of the document is its 10 elements/steps procedure for managing emerging risks, which should help improving the communication and alignment of different stakeholders' approaches.

This CEN Workshop Agreement can be applied throughout the life of an organization, and to a wide range of activities, including strategies and decisions, operations, processes, functions, projects, products, services and assets. It can be applied to different types of emerging risks, as a generic guideline, and it is not intended to promote uniformity of emerging risk management across different users and stakeholders. The implementation solutions for emerging risk management in each particular case will need to take into account the specificity of each of these particular cases and the specific features in each of the organizations, with specific contexts, structures, operations, processes, functions, projects, products, services, and/or assets and specific practices employed.

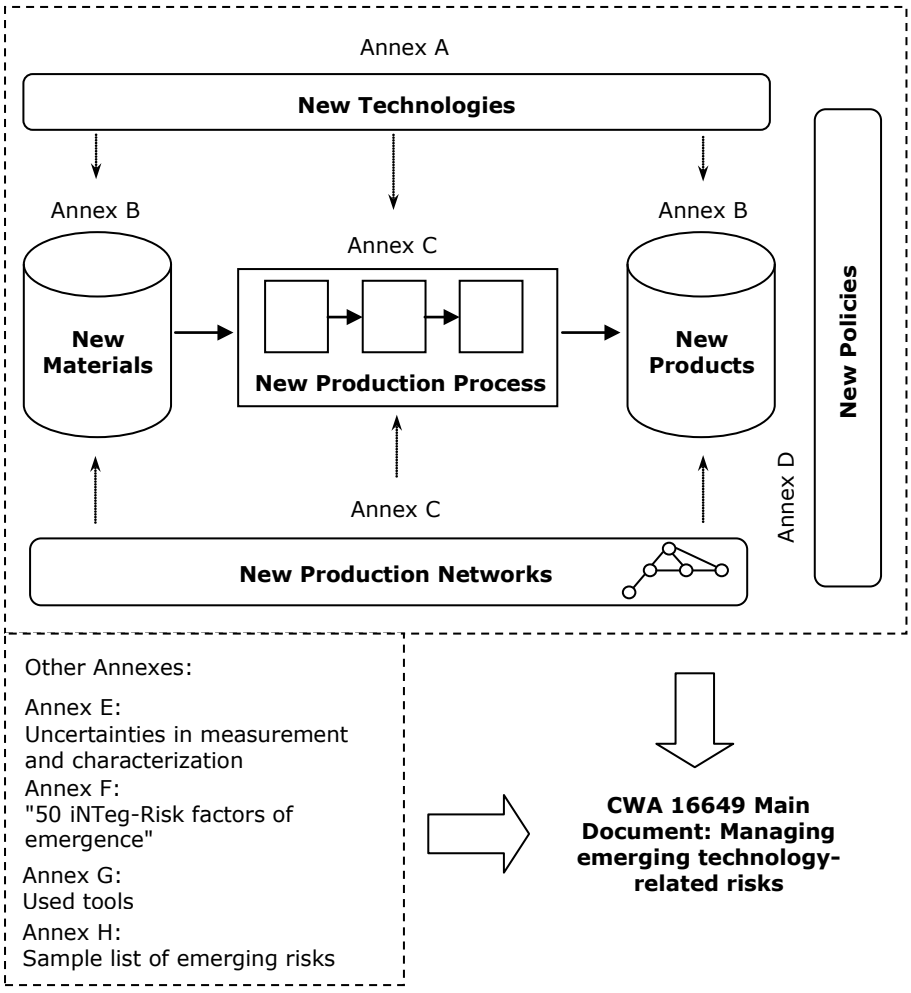

Figure 1 — Relations among the informative Annexes and the main document

It is intended that this contributes to harmonize emerging risk management processes in different countries and across organizations and types of activity and/or sectors, and does not replace the standards already available.

It is expected that this CWA enhance the realization of initiatives like European Emerging Risk Radar (E2R2) Initiative: “Matching the technology challenges of 2020” [4].

This CEN Workshop Agreement is not intended for the purpose of certification.

This CEN Workshop Agreement has a number of additional (informative) parts dealing with emerging risks related to (A) new technologies, (B) new materials, (C) new production processes and new production networks, (D) new policies, (E) uncertainties in measurements and characterization, (F) factors of emergence, (G) used tools and (H) sample list of emerging risk, as shown in Figure 1.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

N/A

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Definitions often attempts to be very precise, thus they may capture the concept in question rather narrowly. By reading several definitions for the same concept, a richer understanding of the concept may be obtained. In the definitions below, the preferred definition is stated, but in some cases alternative definitions are included as notes.

3.1
assets
items at stake, objects of importance, which are affected by the event where the value is defined by a social group (approximately equivalent concept to stakes)

3.2
communication and consultation
continual and iterative process that an organization conducts to provide, share or obtain information, and to engage in dialogue with stakeholders and others regarding the management of risk

Note 1 to entry: The information can relate to the existence, nature, form, likelihood, severity, evaluation, acceptability, treatment or other aspects of the management of risk.

Note 2 to entry: Consultation is a two-way process of informed communication between an organization and its stakeholders or others on an issue prior to making a decision or determining a direction on a particular issue. Consultation is a process which impacts on a decision through influence rather than power and an input to decision making, not joint decision making.

[SOURCE: ISO 31000:2009, definition 2.12]

3.3
consequence
combination of the intensity of the event, items affected by the event and vulnerability

Note 1 to entry: Consequences are subjective, as the affected items have symbolic or economical values that are a function of the utility that a social group draws from them. An equivalent concept is outcome. Consequences are measured by their severity.

Note 2 to entry: outcome of an event affecting objectives.