

ICS 03.100.01

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.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	7
Introduction	8
Acknowledgements	9
1 Scope	11
2 Normative references	12
3 Terms and definitions	12
4 Symbols and abbreviations	19
5 Emerging risks	21
5.1 Emerging risks, innovation and engineering.....	21
5.2 Emerging risks definition.....	22
5.3 Extending and implementing the definition in ERMF	23
5.4 Scales, classes and levels of emerging risks.....	25
5.5 Maturation of emerging risks	29
6 Requirements	30
6.1 General requirements.....	30
6.2 Requirements resulting from iNTeg-Risk project.....	31
6.3 Implementation related requirements.....	32
7 ERMF – Emerging risk management framework	33
7.1 Main principles of ERMF	33
7.2 The 10 steps of ERMF	34
7.3 Comparing the iNTeg-Risk ERMF with general risk management frameworks	43
7.4 Details on implementing the ERMF.....	46
8 Concluding remarks	48
Annex A (informative) Application case for new technologies	49
A.1 Introduction	49
A.2 Specific topic and example case.....	50
A.2.1 General remarks/overview related to the specific topic	50
A.2.2 Introducing the example case - Unconventional gas.....	50
A.3 Procedure for management of emerging risks.....	51
A.3.1 Horizon screening.....	51
A.3.2 Pre-Assessment.....	52
A.3.3 Appraisal/Assessment	58
A.3.4 Continuous activities	66
A.4 Conclusions/Summary.....	67
A.5 Example – Use of new technologies for unconventional gas	67
A.5.1 Hydraulic fracturing.....	67
Annex B (informative) Emerging risks in new materials and products	72
B.1 Introduction	72
B.2 Specific topic and example case.....	73
B.2.1 General remarks/overview related to the specific topic	73
B.3 Procedure for management of emerging risks.....	73
B.3.1 Horizon screening.....	73
B.3.2 Pre-Assessment.....	74
B.3.3 Appraisal/Assessment	77
B.3.4 Continuous activities	80
B.4 Conclusions/Summary.....	81
B.5 Example - Carbon nanotubes	82

B.5.1	Introduction.....	82
B.5.2	Lack of standardized physical and chemical information	83
B.5.3	Fibrous nanomaterials emerging risk	83
Annex C	(informative) Emerging risks in new production and production networks	85
C.1	Introduction.....	85
C.2	Specific topic and example case	86
C.2.1	General remarks/overview related to the specific topic.....	86
C.2.2	Introducing the example case - Drilling in Arctic.....	86
C.3	Procedure for management of emerging risks	87
C.3.1	Horizon Screening	87
C.3.2	Pre-Assessment	88
C.3.3	Appraisal/Assessment	90
C.3.4	Continuous activities	93
C.4	Conclusions/Summary.....	94
C.5	Example – Drilling in Arctic	94
C.5.1	Introduction.....	94
C.5.2	Needs and opportunities	95
C.5.3	Status of offshore petroleum activity in the Arctic.....	96
Annex D	(informative) Emerging risk policies	98
D.1	Introduction.....	98
D.2	Specific topic and example case	99
D.2.1	General remarks/overview related to the specific topic.....	99
D.2.2	Introducing the example case - Nano-regulation	100
D.3	Process for management of emerging risks	102
D.3.1	Horizon screening	102
D.3.2	Pre-Assessment	102
D.3.3	Appraisal/Assessment	104
D.3.4	Continuous activities	106
D.4	Conclusions/Summary.....	107
Annex E	(informative) Emerging risks due to uncertainties in measurement and characterization.....	108
E.1	Introduction.....	108
E.2	Specific topic and example case	109
E.2.1	General remarks/overview related to the specific topic.....	109
E.2.2	Introducing the example case extreme storage of hazardous materials	110
E.3	Procedure for management of emerging risks	110
E.3.1	Horizon screening	110
E.3.2	Pre-Assessment	111
E.3.3	Appraisal/Assessment.....	114
E.3.4	Continuous Activities.....	117
E.4	Conclusions/Summary.....	118
E.5	Example – Extreme storage of hazardous materials	119
Annex F	(informative) Examples of factors which can influence the emerging character of a risk - the 50 iNTeg-Risk factors of emergence.....	121
F.1	Introduction.....	121
F.2	Factors using generic scale	122
F.3	Factors using specific/customized scale.....	125
Annex G	(informative) Used Tools	130
G.1	RiskEars	130
G.2	Risk Tweet.....	131
G.2.1	Activity.....	132
G.2.2	Trend.....	132
G.2.3	Criticality	132
G.3	S-RDI tool	132
G.4	Agent based modeling	133
Annex H	(informative) Sample list of emerging risks.....	134
Bibliography		139

Figures

Figure 1 — Relations among the informative Annexes and the main document	11
Figure 2 — Emergence as 3 rd dimension of emerging risks.....	24
Figure 3 — General understanding of scales, classes and levels as applied to emerging risks in this document	25
Figure 4 — Threat-opportunity based representation, combined with emerging character (emergence) of risks (threat and opportunity)	26
Figure 5 — Example of use classes of benefits, likelihood and levels of risk (opportunity)	28
Figure 6 — Maturation of emerging risk through accumulation of knowledge	29
Figure 7 — Example of three different maturation paths for emerging risks: archived or back-listed notion (C), emerging risk which have achieved stable (mature) status (B), and risks still emerging (A)	30
Figure 8 — Organization of iNTeg-Risk deliverables leading to this CEN WS document.....	34
Figure 9 — The 10 steps of the ERMF	35
Figure 10 — Main distinctive characteristics of the ERMF process	43
Figure 11 — Using ISO 31000 and IRGC frameworks as a base for creating iNTeg-Risk ERMF	45
Figure 12 — Details on the implementation of the ERMF applicable in certain contexts.....	46
Figure 13 — Example of process for management of emerging risks based on ERMF and illustration of the maturation of emerging risks	47
Figure A.1 — Registration of warning/notion in iNTeg-Risk RiskEars.....	51
Figure A.2 — Risk Tweet, with collected information on tweets related to fracking from Twitter service	52
Figure A.3 — Risk/benefit perception for fracking	53
Figure A.4 — Example of Step 2: NTA model for fracking in case of (Lack of acceptance in) Germany (linked to media reports).....	54
Figure A.5 — Example of Step 2: NTA model for fracking case depicting large public dissatisfaction that can be compared to current hydraulic fracturing related problem in Basque Country [21]	55
Figure A.6 — Risk Story from RiskEars (describing an emerging risk scenario) about contamination of underground water for fracking topic	56
Figure A.7 — Example of Step 4: Extract from the pre-assessment; filled pre-assessment for contamination of (surface and) underground water for unconventional gas example in form of the slider setting from an expert considering only environmental risks of technology	57
Figure A.8 — Example of Step 5: S-RDI analysis for unconventional gas topic when comparing it with other ERRAs (using single link clustering option).....	60
Figure A.9 — Example of Step 5: C-RDI analysis from DataEngine software of contamination of (surface and) underground water for unconventional gas	61

Figure A.10 — Example of Step 6: Characterization of contamination of (surface and) underground water scenario of unconventional gas.....	62
Figure A.11 — Example for five unconventional gas scenarios MCDM analysis based on 12 IRGC factors (for more information about factors please see Table F.4)	64
Figure A.12 — Graphical representation of shale gas resources in Germany overlapping with natural protected areas in Baden-Württemberg (shown red) from iNTeg-Risk RiskAtlas.....	65
Figure A.13 — Process of hydraulic fracturing [30].....	68
Figure A.14 — Projections of global mean surface temperatures for six SRES non-mitigation scenarios as presented by IPCC AR4 and the year 2000 constant concentration experiment [14]	69
Figure A.15 — River system in US (left), locations of major drilling campaigns in US (right) [36].....	69
Figure A.16 — Employment in various US industries and natural gas prices at major global market [38].....	70
Figure A.17 — Major unconventional natural gas resources in Europe [29].....	70
Figure A.18 — Map of 48 major shale gas basins in 32 countries [25].....	71
Figure B.1 — Image of asbestos fibres similar to fibrous nanomaterials.	83
Figure C.1 — Geographical location of the Arctic Sea [92].....	95
Figure G.1 — Overview of notions (RiskSparks, with notions included in watch list and copy list), ERIs, ERRAs and Super ERRAs	130
Figure G.2 — Reference to Google trends results for geomagnetic storms	131
Figure G.3 — MACD	132

Tables

Table 1 — Example of Color-code for scoring emerging risks (and opportunity)	27
Table 2 — Example of Color-code for the status in the (pre)assessment process.....	27
Table 3 — Examples of likelihood scale – 5 classes.....	27
Table 4 — Examples of negative impacts (consequences) scale – 5 classes.....	28
Table 5 — Short description of 10 steps of the ERMF	35
Table 6 — Extended description of the 10 steps of the ERMF	36
Table 7 — Profile of involvement of the stakeholders at different levels of governance for a hypothetical example of an emerging risk (the colors indicate the level of concern; concern primarily at national level)	48
Table A.1 — List of ERRAs considered in iNTeg-Risk project.....	58
Table A.2 — List of 50 iNTeg-Risk factors	63
Table F.1 — Generic scale for classes of emergence for emerging risks.....	121

Table F.2 — Examples of factors which can influence the emerging character (emergence) of emerging risks	122
Table F.3 — Examples of factors which can influence the emerging character (emergence) of emerging risks	125
Table F.4 — The 12 IRGC Factors	128
Table H.1 — Sample list of emerging risks.....	134

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 technologies¹⁾ 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 precautionous 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_emerging_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 1StopShop²⁾).

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.

Acknowledgements

The research leading to these results has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 213345.

This CEN Workshop Agreement has been coordinated and prepared by the following authors and contributors:

- 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)
- Daniel Baloš (R-Tech)
- Michal Basista (KMM-VIN)
- Derk H. Brouwer (TNO)
- Yves Dien (EDF)
- Krzysztof Dolinski (KMM-VIN)
- Carole Duval (EDF)
- Jesús M. López de Ipiña (Tecnalia)
- Hans-Theo Kuhl (AXA)
- Michael Löscher (EU-VRi)
- Roderick Martin (MERL)
- Vladimir Pilić (R-Tech)
- Ortwin Renn (University of Stuttgart)
- Reto Schneider (SwissRe)
- Jerzy Trebicki (KMM-VIN)
- Robert Wilson (MERL)
- Mures Zarea (GDF Suez)

Furthermore for the accompaniment of the development process of this CWA is also acknowledged

- 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.

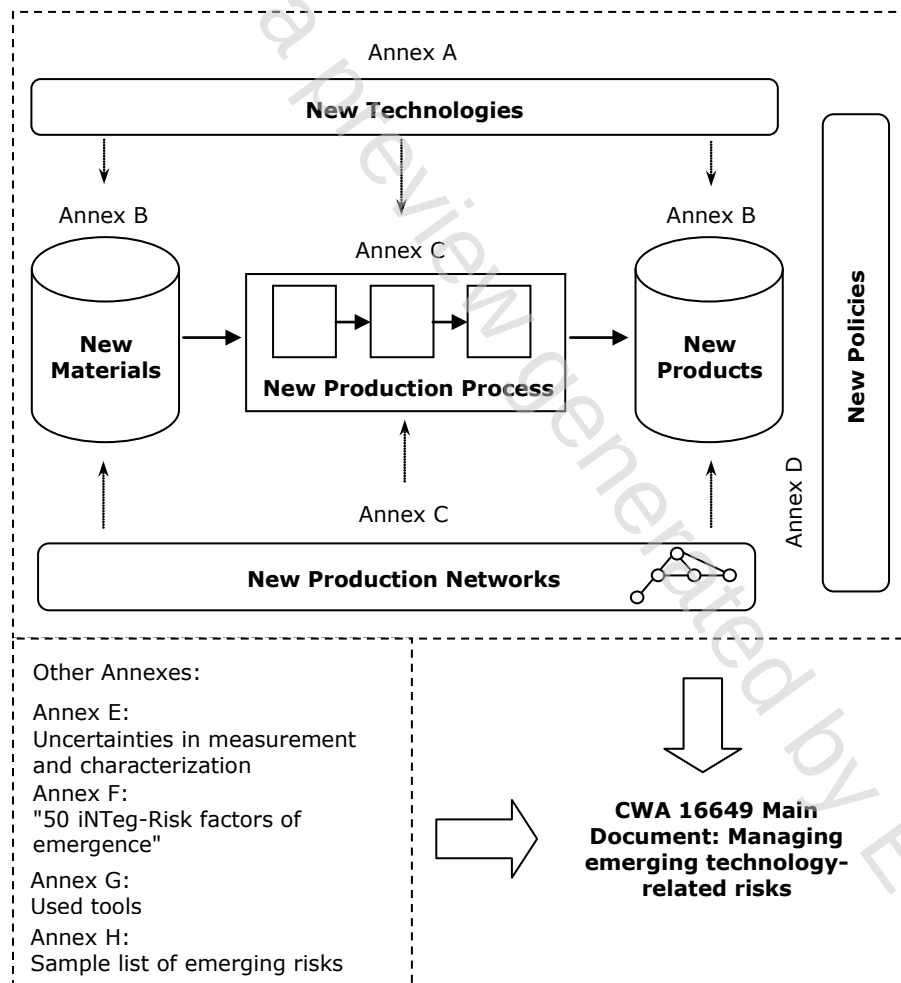


Figure 1 — Relations among the informative Annexes and the main document

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 attempt 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.