



BSI Standards Publication

Risk management

Risk assessment techniques

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National foreword

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English version

**Risk management -
Risk assessment techniques
(IEC/ISO 31010:2009)**

Gestion des risques -
Techniques d'évaluation des risques
(CEI/ISO 31010:2009)

Risikomanagement -
Verfahren zur Risikobeurteilung
(IEC/ISO 31010:2009)

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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Management Centre: Avenue Marnix 17, B - 1000 Brussels

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Foreword

The text of document 56/1329/FDIS, future edition 1 of IEC/ISO 31010, prepared by IEC TC 56, Dependability, together with the ISO TMB “Risk management” working group, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 31010 on 2010-05-01.

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Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC/ISO 31010:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60300-3-11	NOTE Harmonized as EN 60300-3-11.
IEC 61078	NOTE Harmonized as EN 61078.
IEC 61165	NOTE Harmonized as EN 61165.
IEC 61508 series	NOTE Harmonized in EN 61508 series (not modified)
IEC 61511 series	NOTE Harmonized in EN 61511 series (not modified)
IEC 61649	NOTE Harmonized as EN 61649.
ISO 22000	NOTE Harmonized as EN ISO 22000.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO/IEC Guide 73	-	Risk management - Vocabulary - Guidelines for use in standards	-	-
ISO 31000	-	Risk management - Principles and guidelines	-	-

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INTRODUCTION

Organizations of all types and sizes face a range of risks that may affect the achievement of their objectives.

These objectives may relate to a range of the organization's activities, from strategic initiatives to its operations, processes and projects, and be reflected in terms of societal, environmental, technological, safety and security outcomes, commercial, financial and economic measures, as well as social, cultural, political and reputation impacts.

All activities of an organization involve risks that should be managed. The risk management process aids decision making by taking account of uncertainty and the possibility of future events or circumstances (intended or unintended) and their effects on agreed objectives.

Risk management includes the application of logical and systematic methods for

- communicating and consulting throughout this process;
- establishing the context for identifying, analysing, evaluating, treating risk associated with any activity, process, function or product;
- monitoring and reviewing risks;
- reporting and recording the results appropriately.

Risk assessment is that part of risk management which provides a structured process that identifies how objectives may be affected, and analyses the risk in term of consequences and their probabilities before deciding on whether further treatment is required.

Risk assessment attempts to answer the following fundamental questions:

- what can happen and why (by risk identification)?
- what are the consequences?
- what is the probability of their future occurrence?
- are there any factors that mitigate the consequence of the risk or that reduce the probability of the risk?

Is the level of risk tolerable or acceptable and does it require further treatment? This standard is intended to reflect current good practices in selection and utilization of risk assessment techniques, and does not refer to new or evolving concepts which have not reached a satisfactory level of professional consensus.

This standard is general in nature, so that it may give guidance across many industries and types of system. There may be more specific standards in existence within these industries that establish preferred methodologies and levels of assessment for particular applications. If these standards are in harmony with this standard, the specific standards will generally be sufficient.

RISK MANAGEMENT – RISK ASSESSMENT TECHNIQUES

1 Scope

This International Standard is a supporting standard for ISO 31000 and provides guidance on selection and application of systematic techniques for risk assessment.

Risk assessment carried out in accordance with this standard contributes to other risk management activities.

The application of a range of techniques is introduced, with specific references to other international standards where the concept and application of techniques are described in greater detail.

This standard is not intended for certification, regulatory or contractual use.

This standard does not provide specific criteria for identifying the need for risk analysis, nor does it specify the type of risk analysis method that is required for a particular application.

This standard does not refer to all techniques, and omission of a technique from this standard does not mean it is not valid. The fact that a method is applicable to a particular circumstance does not mean that the method should necessarily be applied.

NOTE This standard does not deal specifically with safety. It is a generic risk management standard and any references to safety are purely of an informative nature. Guidance on the introduction of safety aspects into IEC standards is laid down in ISO/IEC Guide 51.

2 Normative references

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

ISO/IEC Guide 73, *Risk management – Vocabulary – Guidelines for use in standards*

ISO 31000, *Risk management – Principles and guidelines*

3 Terms and definitions

For the purposes of this document, the terms and definitions of ISO/IEC Guide 73 apply.

4 Risk assessment concepts

4.1 Purpose and benefits

The purpose of risk assessment is to provide evidence-based information and analysis to make informed decisions on how to treat particular risks and how to select between options.

Some of the principal benefits of performing risk assessment include:

- understanding the risk and its potential impact upon objectives;

- providing information for decision makers;
- contributing to the understanding of risks, in order to assist in selection of treatment options;
- identifying the important contributors to risks and weak links in systems and organizations;
- comparing of risks in alternative systems, technologies or approaches;
- communicating risks and uncertainties;
- assisting with establishing priorities;
- contributing towards incident prevention based upon post-incident investigation;
- selecting different forms of risk treatment;
- meeting regulatory requirements;
- providing information that will help evaluate whether the risk should be accepted when compared with pre-defined criteria;
- assessing risks for end-of-life disposal.

4.2 Risk assessment and the risk management framework

This standard assumes that the risk assessment is performed within the framework and process of risk management described in ISO 31000.

A risk management framework provides the policies, procedures and organizational arrangements that will embed risk management throughout the organization at all levels.

As part of this framework, the organization should have a policy or strategy for deciding when and how risks should be assessed.

In particular, those carrying out risk assessments should be clear about

- the context and objectives of the organization,
- the extent and type of risks that are tolerable, and how unacceptable risks are to be treated,
- how risk assessment integrates into organizational processes,
- methods and techniques to be used for risk assessment, and their contribution to the risk management process,
- accountability, responsibility and authority for performing risk assessment,
- resources available to carry out risk assessment,
- how the risk assessment will be reported and reviewed.

4.3 Risk assessment and the risk management process

4.3.1 General

Risk assessment comprises the core elements of the risk management process which are defined in ISO 31000 and contain the following elements:

- communication and consultation;
- establishing the context;
- risk assessment (comprising risk identification, risk analysis and risk evaluation);
- risk treatment;
- monitoring and review.

Risk assessment is not a stand-alone activity and should be fully integrated into the other components in the risk management process.

4.3.2 Communication and consultation

Successful risk assessment is dependent on effective communication and consultation with stakeholders.

Involving stakeholders in the risk management process will assist in

- developing a communication plan,
- defining the context appropriately,
- ensuring that the interests of stakeholders are understood and considered,
- bringing together different areas of expertise for identifying and analysing risk,
- ensuring that different views are appropriately considered in evaluating risks,
- ensuring that risks are adequately identified,
- securing endorsement and support for a treatment plan.

Stakeholders should contribute to the interfacing of the risk assessment process with other management disciplines, including change management, project and programme management, and also financial management.

4.3.3 Establishing the context

Establishing the context defines the basic parameters for managing risk and sets the scope and criteria for the rest of the process. Establishing the context includes considering internal and external parameters relevant to the organization as a whole, as well as the background to the particular risks being assessed.

In establishing the context, the risk assessment objectives, risk criteria, and risk assessment programme are determined and agreed.

For a specific risk assessment, establishing the context should include the definition of the external, internal and risk management context and classification of risk criteria:

- a) Establishing the external context involves familiarization with the environment in which the organization and the system operates including :
 - cultural, political, legal, regulatory, financial, economic and competitive environment factors, whether international, national, regional or local;
 - key drivers and trends having impact on the objectives of the organization; and
 - perceptions and values of external stakeholders.
- b) Establishing the internal context involves understanding
 - capabilities of the organization in terms of resources and knowledge,
 - information flows and decision-making processes,
 - internal stakeholders,
 - objectives and the strategies that are in place to achieve them,
 - perceptions, values and culture,
 - policies and processes,
 - standards and reference models adopted by the organization, and
 - structures (e.g. governance, roles and accountabilities).
- c) Establishing the context of the risk management process includes
 - defining accountabilities and responsibilities,
 - defining the extent of the risk management activities to be carried out, including specific inclusions and exclusions,

- defining the extent of the project, process, function or activity in terms of time and location,
- defining the relationships between a particular project or activity and other projects or activities of the organization,
- defining the risk assessment methodologies,
- defining the risk criteria,
- defining how risk management performance is evaluated,
- identifying and specifying the decisions and actions that have to be made, and
- identifying scoping or framing studies needed, their extent, objectives and the resources required for such studies.

d) Defining risk criteria involves deciding

- the nature and types of consequences to be included and how they will be measured,
- the way in which probabilities are to be expressed,
- how a level of risk will be determined,
- the criteria by which it will be decided when a risk needs treatment,
- the criteria for deciding when a risk is acceptable and/or tolerable,
- whether and how combinations of risks will be taken into account.

Criteria can be based on sources such as

- agreed process objectives,
- criteria identified in specifications,
- general data sources,
- generally accepted industry criteria such as safety integrity levels,
- organizational risk appetite,
- legal and other requirements for specific equipment or applications.

4.3.4 Risk assessment

Risk assessment is the overall process of risk identification, risk analysis and risk evaluation.

Risks can be assessed at an organizational level, at a departmental level, for projects, individual activities or specific risks. Different tools and techniques may be appropriate in different contexts.

Risk assessment provides an understanding of risks, their causes, consequences and their probabilities. This provides input to decisions about:

- whether an activity should be undertaken;
- how to maximize opportunities;
- whether risks need to be treated;
- choosing between options with different risks;
- prioritizing risk treatment options;
- the most appropriate selection of risk treatment strategies that will bring adverse risks to a tolerable level.

4.3.5 Risk treatment

Having completed a risk assessment, risk treatment involves selecting and agreeing to one or more relevant options for changing the probability of occurrence, the effect of risks, or both, and implementing these options.

This is followed by a cyclical process of reassessing the new level of risk, with a view to determining its tolerability against the criteria previously set, in order to decide whether further treatment is required.

4.3.6 Monitoring and review

As part of the risk management process, risks and controls should be monitored and reviewed on a regular basis to verify that

- assumptions about risks remain valid;
- assumptions on which the risk assessment is based, including the external and internal context, remain valid;
- expected results are being achieved;
- results of risk assessment are in line with actual experience;
- risk assessment techniques are being properly applied;
- risk treatments are effective.

Accountability for monitoring and performing reviews should be established.

5 Risk assessment process

5.1 Overview

Risk assessment provides decision-makers and responsible parties with an improved understanding of risks that could affect achievement of objectives, and the adequacy and effectiveness of controls already in place. This provides a basis for decisions about the most appropriate approach to be used to treat the risks. The output of risk assessment is an input to the decision-making processes of the organization.

Risk assessment is the overall process of risk identification, risk analysis and risk evaluation (see Figure 1). The manner in which this process is applied is dependent not only on the context of the risk management process but also on the methods and techniques used to carry out the risk assessment.

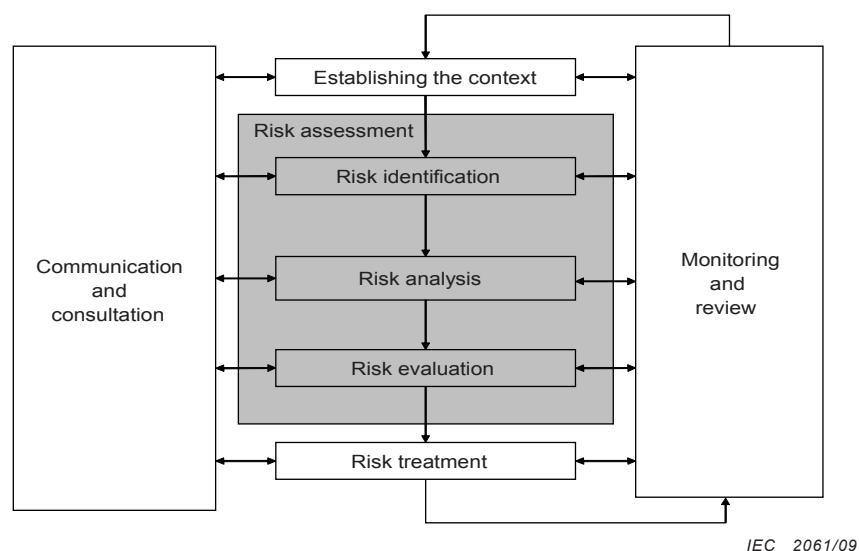


Figure 1 – Contribution of risk assessment to the risk management process

Risk assessment may require a multidisciplinary approach since risks may cover a wide range of causes and consequences.

5.2 Risk identification

Risk identification is the process of finding, recognizing and recording risks.

The purpose of risk identification is to identify what might happen or what situations might exist that might affect the achievement of the objectives of the system or organization. Once a risk is identified, the organization should identify any existing controls such as design features, people, processes and systems.

The risk identification process includes identifying the causes and source of the risk (hazard in the context of physical harm), events, situations or circumstances which could have a material impact upon objectives and the nature of that impact

Risk identification methods can include:

- evidence based methods, examples of which are check-lists and reviews of historical data;
- systematic team approaches where a team of experts follow a systematic process to identify risks by means of a structured set of prompts or questions;
- inductive reasoning techniques such as HAZOP.

Various supporting techniques can be used to improve accuracy and completeness in risk identification, including brainstorming, and Delphi methodology.

Irrespective of the actual techniques employed, it is important that due recognition is given to human and organizational factors when identifying risk. Hence, deviations of human and organizational factors from the expected should be included in the risk identification process as well as "hardware" or "software" events.

5.3 Risk analysis

5.3.1 General

Risk analysis is about developing an understanding of the risk. It provides an input to risk assessment and to decisions about whether risks need to be treated and about the most appropriate treatment strategies and methods.

Risk analysis consists of determining the consequences and their probabilities for identified risk events, taking into account the presence (or not) and the effectiveness of any existing controls. The consequences and their probabilities are then combined to determine a level of risk.

Risk analysis involves consideration of the causes and sources of risk, their consequences and the probability that those consequences can occur. Factors that affect consequences and probability should be identified. An event can have multiple consequences and can affect multiple objectives. Existing risk controls and their effectiveness should be taken into account. Various methods for these analyses are described in Annex B. More than one technique may be required for complex applications.

Risk analysis normally includes an estimation of the range of potential consequences that might arise from an event, situation or circumstance, and their associated probabilities, in order to measure the level of risk. However in some instances, such as where the consequences are likely to be insignificant, or the probability is expected to be extremely low, a single parameter estimate may be sufficient for a decision to be made

In some circumstances, a consequence can occur as a result of a range of different events or conditions, or where the specific event is not identified. In this case, the focus of risk assessment is on analysing the importance and vulnerability of components of the system with a view to defining treatments which relate to levels of protection or recovery strategies.

Methods used in analysing risks can be qualitative, semi-quantitative or quantitative. The degree of detail required will depend upon the particular application, the availability of reliable data and the decision-making needs of the organization. Some methods and the degree of detail of the analysis may be prescribed by legislation.

Qualitative assessment defines consequence, probability and level of risk by significance levels such as “high”, “medium” and “low”, may combine consequence and probability, and evaluates the resultant level of risk against qualitative criteria.

Semi-quantitative methods use numerical rating scales for consequence and probability and combine them to produce a level of risk using a formula. Scales may be linear or logarithmic, or have some other relationship; formulae used can also vary.

Quantitative analysis estimates practical values for consequences and their probabilities, and produces values of the level of risk in specific units defined when developing the context. Full quantitative analysis may not always be possible or desirable due to insufficient information about the system or activity being analysed, lack of data, influence of human factors, etc. or because the effort of quantitative analysis is not warranted or required. In such circumstances, a comparative semi-quantitative or qualitative ranking of risks by specialists, knowledgeable in their respective field, may still be effective.

In cases where the analysis is qualitative, there should be a clear explanation of all the terms employed and the basis for all criteria should be recorded.

Even where full quantification has been carried out, it needs to be recognized that the levels of risk calculated are estimates. Care should be taken to ensure that they are not attributed a level of accuracy and precision inconsistent with the accuracy of the data and methods employed.

Levels of risk should be expressed in the most suitable terms for that type of risk and in a form that aids risk evaluation. In some instances, the magnitude of a risk can be expressed as a probability distribution over a range of consequences.

5.3.2 Controls assessment

The level of risk will depend on the adequacy and effectiveness of existing controls. Questions to be addressed include:

- what are the existing controls for a particular risk?
- are those controls capable of adequately treating the risk so that it is controlled to a level that is tolerable?
- in practice, are the controls operating in the manner intended and can they be demonstrated to be effective when required?

These questions can only be answered with confidence if there are proper documentation and assurance processes in place.

The level of effectiveness for a particular control, or suite of related controls, may be expressed qualitatively, semi-quantitatively or quantitatively. In most cases, a high level of accuracy is not warranted. However, it may be valuable to express and record a measure of risk control effectiveness so that judgments can be made on whether effort is best expended in improving a control or providing a different risk treatment.

5.3.3 Consequence analysis

Consequence analysis determines the nature and type of impact which could occur assuming that a particular event situation or circumstance has occurred. An event may have a range of impacts of different magnitudes, and affect a range of different objectives and different stakeholders. The types of consequence to be analysed and the stakeholders affected will have been decided when the context was established.

Consequence analysis can vary from a simple description of outcomes to detailed quantitative modelling or vulnerability analysis.

Impacts may have a low consequence but high probability, or a high consequence and low probability, or some intermediate outcome. In some cases, it is appropriate to focus on risks with potentially very large outcomes, as these are often of greatest concern to managers. In other cases, it may be important to analyse both high and low consequence risks separately. For example, a frequent but low-impact (or chronic) problem may have large cumulative or long-term effects. In addition, the treatment actions for dealing with these two distinct kinds of risks are often quite different, so it is useful to analyse them separately.

Consequence analysis can involve:

- taking into consideration existing controls to treat the consequences, together with all relevant contributory factors that have an effect on the consequences;
- relating the consequences of the risk to the original objectives;
- considering both immediate consequences and those that may arise after a certain time has elapsed, if this is consistent with the scope of the assessment;
- considering secondary consequences, such as those impacting upon associated systems, activities, equipment or organizations.

5.3.4 Likelihood analysis and probability estimation

Three general approaches are commonly employed to estimate probability; they may be used individually or jointly:

- a) The use of relevant historical data to identify events or situations which have occurred in the past and hence be able to extrapolate the probability of their occurrence in the future. The data used should be relevant to the type of system, facility, organization or activity being considered and also to the operational standards of the organization involved. If historically there is a very low frequency of occurrence, then any estimate of probability will be very uncertain. This applies especially for zero occurrences, when one cannot assume the event, situation or circumstance will not occur in the future.
- b) Probability forecasts using predictive techniques such as fault tree analysis and event tree analysis (see Annex B). When historical data are unavailable or inadequate, it is necessary to derive probability by analysis of the system, activity, equipment or organization and its associated failure or success states. Numerical data for equipment, humans, organizations and systems from operational experience, or published data sources are then combined to produce an estimate of the probability of the top event. When using predictive techniques, it is important to ensure that due allowance has been made in the analysis for the possibility of common mode failures involving the co-incident failure of a number of different parts or components within the system arising from the same cause. Simulation techniques may be required to generate probability of equipment and structural failures due to ageing and other degradation processes, by calculating the effects of uncertainties.
- c) Expert opinion can be used in a systematic and structured process to estimate probability. Expert judgements should draw upon all relevant available information including historical, system-specific, organizational-specific, experimental, design, etc. There are a number of formal methods for eliciting expert judgement which provide an aid to the formulation of appropriate questions. The methods available include the Delphi approach, paired comparisons, category rating and absolute probability judgements.

5.3.5 Preliminary analysis

Risks may be screened in order to identify the most significant risks, or to exclude less significant or minor risks from further analysis. The purpose is to ensure that resources will be focussed on the most important risks. Care should be taken not to screen out low risks which occur frequently and have a significant cumulative effect

Screening should be based on criteria defined in the context. The preliminary analysis determines one or more of the following courses of action:

- decide to treat risks without further assessment;
- set aside insignificant risks which would not justify treatment;
- proceed with more detailed risk assessment.

The initial assumptions and results should be documented.

5.3.6 Uncertainties and sensitivities

There are often considerable uncertainties associated with the analysis of risk. An understanding of uncertainties is necessary to interpret and communicate risk analysis results effectively. The analysis of uncertainties associated with data, methods and models used to identify and analyse risk plays an important part in their application. Uncertainty analysis involves the determination of the variation or imprecision in the results, resulting from the collective variation in the parameters and assumptions used to define the results. An area closely related to uncertainty analysis is sensitivity analysis.

Sensitivity analysis involves the determination of the size and significance of the magnitude of risk to changes in individual input parameters. It is used to identify those data which need to be accurate, and those which are less sensitive and hence have less effect upon overall accuracy.

The completeness and accuracy of the risk analysis should be stated as fully as possible. Sources of uncertainty should be identified where possible and should address both data and model/method uncertainties. Parameters to which the analysis is sensitive and the degree of sensitivity should be stated.

5.4 Risk evaluation

Risk evaluation involves comparing estimated levels of risk with risk criteria defined when the context was established, in order to determine the significance of the level and type of risk.

Risk evaluation uses the understanding of risk obtained during risk analysis to make decisions about future actions. Ethical, legal, financial and other considerations, including perceptions of risk, are also inputs to the decision.

Decisions may include:

- whether a risk needs treatment;
- priorities for treatment;
- whether an activity should be undertaken;
- which of a number of paths should be followed.

The nature of the decisions that need to be made and the criteria which will be used to make those decisions were decided when establishing the context but they need to be revisited in more detail at this stage now that more is known about the particular risks identified.

The simplest framework for defining risk criteria is a single level which divides risks that need treatment from those which do not. This gives attractively simple results but does not reflect

the uncertainties involved both in estimating risks and in defining the boundary between those that need treatment and those that do not.

The decision about whether and how to treat the risk may depend on the costs and benefits of taking the risk and the costs and benefits of implementing improved controls.

A common approach is to divide risks into three bands:

- a) an upper band where the level of risk is regarded as intolerable whatever benefits the activity may bring, and risk treatment is essential whatever its cost;
- b) a middle band (or 'grey' area) where costs and benefits, are taken into account and opportunities balanced against potential consequences;
- c) a lower band where the level of risk is regarded as negligible, or so small that no risk treatment measures are needed.

The 'as low as reasonably practicable' or ALARP criteria system used in safety applications follows this approach, where, in the middle band, there is a sliding scale for low risks where costs and benefits can be directly compared, whereas for high risks the potential for harm must be reduced, until the cost of further reduction is entirely disproportionate to the safety benefit gained.

5.5 Documentation

The risk assessment process should be documented together with the results of the assessment. Risks should be expressed in understandable terms, and the units in which the level of risk is expressed should be clear.

The extent of the report will depend on the objectives and scope of the assessment. Except for very simple assessments, the documentation can include:

- objectives and scope;
- description of relevant parts of the system and their functions;
- a summary of the external and internal context of the organization and how it relates to the situation, system or circumstances being assessed;
- risk criteria applied and their justification;
- limitations, assumptions and justification of hypotheses;
- assessment methodology;
- risk identification results;
- data, assumptions and their sources and validation;
- risk analysis results and their evaluation;
- sensitivity and uncertainty analysis;
- critical assumptions and other factors which need to be monitored;
- discussion of results;
- conclusions and recommendations;
- references.

If the risk assessment supports a continuing risk management process, it should be performed and documented in such a way that it can be maintained throughout the life cycle of the system, organization, equipment or activity. The assessment should be updated as significant new information becomes available and the context changes, in accordance with the needs of the management process.

5.6 Monitoring and reviewing risk assessment

The risk assessment process will highlight context and other factors that might be expected to vary over time and which could change or invalidate the risk assessment. These factors should be specifically identified for on-going monitoring and review, so that the risk assessment can be updated when necessary.

Data to be monitored in order to refine the risk assessment should also be identified and collected.

The effectiveness of controls should also be monitored and documented in order to provide data for use in risk analysis. Accountabilities for creation and reviewing the evidence and documentation should be defined.

5.7 Application of risk assessment during life cycle phases

Many activities, projects and products can be considered to have a life cycle starting from initial concept and definition through realization to a final completion which might include decommissioning and disposal of hardware.

Risk assessment can be applied at all stages of the life cycle and is usually applied many times with different levels of detail to assist in the decisions that need to be made at each phase.

Life cycles phases have different requirements and need different techniques. For example, during the concept and definition phase, when an opportunity is identified, risk assessment may be used to decide whether to proceed or not.

Where several options are available risk assessment can be used to evaluate alternative concepts to help decide which provides the best balance of positive and negative risks.

During the design and development phase, risk assessment contributes to

- ensuring that system risks are tolerable,
- the design refinement process,
- cost effectiveness studies,
- identifying risks impacting upon subsequent life-cycle phases.

As the activity proceeds, risk assessment can be used to provide information to assist in developing procedures for normal and emergency conditions.

6 Selection of risk assessment techniques

6.1 General

This clause describes how techniques for risk assessment may be selected. The annexes list and further explain a range of tools and techniques that can be used to perform a risk assessment or to assist with the risk assessment process. It may sometimes be necessary to employ more than one method of assessment.

6.2 Selection of techniques

Risk assessment may be undertaken in varying degrees of depth and detail and using one or many methods ranging from simple to complex. The form of assessment and its output should be consistent with the risk criteria developed as part of establishing the context. Annex A illustrates the conceptual relationship between the broad categories of risk assessment techniques and the factors present in a given risk situation, and provides illustrative examples.

of how organizations can select the appropriate risk assessment techniques for a particular situation.

In general terms, suitable techniques should exhibit the following characteristics:

- it should be justifiable and appropriate to the situation or organization under consideration;
- it should provide results in a form which enhances understanding of the nature of the risk and how it can be treated;
- it should be capable of use in a manner that is traceable, repeatable and verifiable.

The reasons for the choice of techniques should be given, with regard to relevance and suitability. When integrating the results from different studies, the techniques used and outputs should be comparable.

Once the decision has been made to perform a risk assessment and the objectives and scope have been defined, the techniques should be selected, based on applicable factors such as:

- the objectives of the study. The objectives of the risk assessment will have a direct bearing on the techniques used. For example, if a comparative study between different options is being undertaken, it may be acceptable to use less detailed consequence models for parts of the system not affected by the difference;
- the needs of decision-makers. In some cases a high level of detail is needed to make a good decision, in others a more general understanding is sufficient;
- the type and range of risks being analysed;
- the potential magnitude of the consequences. The decision on the depth to which risk assessment is carried out should reflect the initial perception of consequences (although this may have to be modified once a preliminary evaluation has been completed);
- the degree of expertise, human and other resources needed. A simple method, well done, may provide better results than a more sophisticated procedure poorly done, so long as it meets the objectives and scope of the assessment. Ordinarily, the effort put into the assessment should be consistent with the potential level of risk being analysed;
- the availability of information and data. Some techniques require more information and data than others;
- the need for modification/updating of the risk assessment. The assessment may need to be modified/updated in future and some techniques are more amendable than others in this regard;
- any regulatory and contractual requirements.

Various factors influence the selection of an approach to risk assessment such as the availability of resources, the nature and degree of uncertainty in the data and information available, and the complexity of the application (see Table A.2).

6.3 Availability of resources

Resources and capabilities which may affect the choice of risk assessment techniques include:

- the skills experience capacity and capability of the risk assessment team;
- constraints on time and other resources within the organization;
- the budget available if external resources are required.

6.4 The nature and degree of uncertainty

The nature and degree of uncertainty requires an understanding of the quality, quantity and integrity of information available concerning the risk under consideration. This includes the extent to which sufficient information about the risk, its sources and causes, and its

consequences to the achievement of objectives is available. Uncertainty can stem from poor data quality or the lack of essential and reliable data. To illustrate, data collection methods may change, the way organizations use such methods may change or the organization may not have an effective collection method in place at all, for collecting data about the identified risk.

Uncertainty can also be inherent in the external and internal context of the organization. Available data do not always provide a reliable basis for the prediction of the future. For unique types of risks, historical data may not be available or there may be different interpretations of available data by different stakeholders. Those undertaking risk assessment need to understand the type and nature of the uncertainty and appreciate the implications for the reliability of the risk assessment results. These should always be communicated to decision-makers.

6.5 Complexity

Risks can be complex in themselves, as, for example, in complex systems which need to have their risks assessed across the system rather than treating each component separately and ignoring interactions. In other cases, treating a single risk can have implications elsewhere and can impact on other activities. Consequential impacts and risk dependencies need to be understood to ensure that in managing one risk, an intolerable situation is not created elsewhere. Understanding the complexity of a single risk or of a portfolio of risks of an organization is crucial for the selection of the appropriate method or techniques for risk assessment.

6.6 Application of risk assessment during life cycle phases

Many activities, projects and products can be considered to have a life cycle starting from initial concept and definition through realization to a final completion which might include decommissioning and disposal of hardware.

Risk assessment can be applied at all stages of the life cycle and is usually applied many times with different levels of detail to assist in the decisions that need to be made at each phase.

Life cycle phases have different needs and require different techniques. For example during the concept and definition phase, when an opportunity is identified, risk assessment may be used to decide whether to proceed or not.

Where several options are available, risk assessment can be used to evaluate alternative concepts to help decide which provides the best balance of risks.

During the design and development phase, risk assessment contributes to

- ensuring that system risks are tolerable,
- the design refinement process,
- cost effectiveness studies,
- identifying risks impacting upon subsequent life-cycle phases.

As the activity proceeds, risk assessment can be used to provide information to assist in developing procedures for normal and emergency conditions.

6.7 Types of risk assessment techniques

Risk assessment techniques can be classified in various ways to assist with understanding their relative strengths and weaknesses. The tables in Annex A correlate some potential techniques and their categories for illustrative purposes.

Each of the techniques is further elaborated upon in Annex B as to the nature of the assessment they provide and guidance to their applicability for certain situations.

Annex A (informative)

Comparison of risk assessment techniques

A.1 Types of technique

The first classification shows how the techniques apply to each step of the risk assessment process as follows:

- risk identification;
- risk analysis – consequence analysis;
- risk analysis – qualitative, semi-quantitative or quantitative probability estimation;
- risk analysis – assessing the effectiveness of any existing controls;
- risk analysis – estimation the level of risk;
- risk evaluation.

For each step in the risk assessment process, the application of the method is described as being either strongly applicable, applicable or not applicable (see Table A.1).

A.2 Factors influencing selection of risk assessment techniques

Next the attributes of the methods are described in terms of

- complexity of the problem and the methods needed to analyse it,
- the nature and degree of uncertainty of the risk assessment based on the amount of information available and what is required to satisfy objectives,
- the extent of resources required in terms of time and level of expertise, data needs or cost,
- whether the method can provide a quantitative output.

Examples of types of risk assessment methods available are listed in Table A.2 where each method is rated as high medium or low in terms of these attributes.

Table A.1 – Applicability of tools used for risk assessment

Tools and techniques	Risk assessment process					See Annex
	Risk Identification	Risk analysis			Risk evaluation	
		Consequence	Probability	Level of risk		
Brainstorming	SA ¹⁾	NA ²⁾	NA	NA	NA	B 01
Structured or semi-structured interviews	SA	NA	NA	NA	NA	B 02
Delphi	SA	NA	NA	NA	NA	B 03
Check-lists	SA	NA	NA	NA	NA	B 04
Primary hazard analysis	SA	NA	NA	NA	NA	B 05
Hazard and operability studies (HAZOP)	SA	SA	A ³⁾	A	A	B 06
Hazard Analysis and Critical Control Points (HACCP)	SA	SA	NA	NA	SA	B 07
Environmental risk assessment	SA	SA	SA	SA	SA	B 08
Structure « What if? » (SWIFT)	SA	SA	SA	SA	SA	B 09
Scenario analysis	SA	SA	A	A	A	B 10
Business impact analysis	A	SA	A	A	A	B 11
Root cause analysis	NA	SA	SA	SA	SA	B 12
Failure mode effect analysis	SA	SA	SA	SA	SA	B 13
Fault tree analysis	A	NA	SA	A	A	B 14
Event tree analysis	A	SA	A	A	NA	B 15
Cause and consequence analysis	A	SA	SA	A	A	B 16
Cause-and-effect analysis	SA	SA	NA	NA	NA	B 17
Layer protection analysis (LOPA)	A	SA	A	A	NA	B 18
Decision tree	NA	SA	SA	A	A	B 19
Human reliability analysis	SA	SA	SA	SA	A	B 20
Bow tie analysis	NA	A	SA	SA	A	B 21
Reliability centred maintenance	SA	SA	SA	SA	SA	B 22
Sneak circuit analysis	A	NA	NA	NA	NA	B 23
Markov analysis	A	SA	NA	NA	NA	B 24
Monte Carlo simulation	NA	NA	NA	NA	SA	B 25
Bayesian statistics and Bayes Nets	NA	SA	NA	NA	SA	B 26
FN curves	A	SA	SA	A	SA	B 27
Risk indices	A	SA	SA	A	SA	B 28
Consequence/probability matrix	SA	SA	SA	SA	A	B 29
Cost/benefit analysis	A	SA	A	A	A	B 30
Multi-criteria decision analysis (MCDA)	A	SA	A	SA	A	B 31
1) Strongly applicable.						
2) Not applicable.						
3) Applicable.						

Table A.2 – Attributes of a selection of risk assessment tools

Type of risk assessment technique	Description	Relevance of influencing factors			Can provide Quantitative output
		Resources and capability	Nature and degree of uncertainty	Complexity	
LOOK-UP METHODS					
Check-lists	A simple form of risk identification. A technique which provides a listing of typical uncertainties which need to be considered. Users refer to a previously developed list, codes or standards	Low	Low	Low	No
Preliminary hazard analysis	A simple inductive method of analysis whose objective is to identify the hazards and hazardous situations and events that can cause harm for a given activity, facility or system	Low	High	Medium	No
SUPPORTING METHODS					
Structured Interview and brainstorming	A means of collecting a broad set of ideas and evaluation, ranking them by a team. Brainstorming may be stimulated by prompts or by one-on-one and one-on-many interview techniques	Low	Low	Low	No
Delphi technique	A means of combining expert opinions that may support the source and influence identification, probability and consequence estimation and risk evaluation. It is a collaborative technique for building consensus among experts. Involving independent analysis and voting by experts	Medium	Medium	Medium	No
SWIFT Structured “what-if”)	A system for prompting a team to identify risks. Normally used within a facilitated workshop. Normally linked to a risk analysis and evaluation technique	Medium	Medium	Any	No
Human reliability analysis (HRA)	Human reliability assessment (HRA) deals with the impact of humans on system performance and can be used to evaluate human error influences on the system	Medium	Medium	Medium	Yes
SCENARIO ANALYSIS					
Root cause analysis (single loss analysis)	A single loss that has occurred is analysed in order to understand contributory causes and how the system or process can be improved to avoid such future losses. The analysis shall consider what controls were in place at the time the loss occurred and how controls might be improved	Medium	Low	Medium	No

Type of risk assessment technique	Description	Relevance of influencing factors			Can provide Quantitative output
		Resources and capability	Nature and degree of uncertainty	Complexity	
Scenario analysis	Possible future scenarios are identified through imagination or extrapolation from the present and different risks considered assuming each of these scenarios might occur. This can be done formally or informally qualitatively or quantitatively	Medium	High	Medium	No
Toxicological risk assessment	Hazards are identified and analysed and possible pathways by which a specified target might be exposed to the hazard are identified. Information on the level of exposure and the nature of harm caused by a given level of exposure are combined to give a measure of the probability that the specified harm will occur	High	High	Medium	Yes
Business impact analysis	Provides an analysis of how key disruption risks could affect an organization's operations and identifies and quantifies the capabilities that would be required to manage it	Medium	Medium	Medium	No
Fault tree analysis	A technique which starts with the undesired event (top event) and determines all the ways in which it could occur. These are displayed graphically in a logical tree diagram. Once the fault tree has been developed, consideration should be given to ways of reducing or eliminating potential causes / sources	High	High	Medium	Yes
Event tree analysis	Using inductive reasoning to translate probabilities of different initiating events into possible outcomes	Medium	Medium	Medium	Yes
Cause/consequence analysis	A combination of fault and event tree analysis that allows inclusion of time delays. Both causes and consequences of an initiating event are considered	High	Medium	High	Yes
Cause-and-effect analysis	An effect can have a number of contributory factors which may be grouped into different categories. Contributory factors are identified often through brainstorming and displayed in a tree structure or fishbone diagram	Low	Low	Medium	No

Example type of risk assessment method and technique	Description	Relevance of influencing factors				Quantitative output possible?
FUNCTION ANALYSIS						
FMEA and FMECA	FMEA (Failure Mode and Effect Analysis) is a technique which identifies failure modes and mechanisms, and their effects. There are several types of FMEA: Design (or product) FMEA which is used for components and products, System FMEA which is used for systems, Process FMEA which is used for manufacturing and assembly processes, Service FMEA and Software FMEA. FMEA may be followed by a criticality analysis which defines the significance of each failure mode, qualitatively, semi-quantitatively, or quantitatively (FMECA). The criticality analysis may be based on the probability that the failure mode will result in system failure, or the level of risk associated with the failure mode, or a risk priority number	Medium	Medium	Medium	Medium	Yes
Reliability-centred maintenance	A method to identify the policies that should be implemented to manage failures so as to efficiently and effectively achieve the required safety, availability and economy of operation for all types of equipment	Medium	Medium	Medium	Medium	Yes
Sneak analysis (Sneak circuit analysis)	A methodology for identifying design errors. A sneak condition is a latent hardware, software, or integrated condition that may cause an unwanted event to occur or may inhibit a desired event and is not caused by component failure. These conditions are characterized by their random nature and ability to escape detection during the most rigorous of standardized system tests. Sneak conditions can cause improper operation, loss of system availability, program delays, or even death or injury to personnel	Medium	Medium	Medium	Medium	No
HAZOP Hazard and operability studies	A general process of risk identification to define possible deviations from the expected or intended performance. It uses a guideword based system. The criticalities of the deviations are assessed	Medium	High	High	High	No
HACCP Hazard analysis and critical control points	A systematic, proactive, and preventive system for assuring product quality, reliability and safety of processes by measuring and monitoring specific characteristics which are required to be within defined limits	Medium	Medium	Medium	Medium	No

Example type of risk assessment method and technique	Description	Relevance of influencing factors			Quantitative output possible?
CONTROLS ASSESSMENT					
LOPA (Layers of protection analysis)	(May also be called barrier analysis). It allows controls and their effectiveness to be evaluated	Medium	Medium	Medium	Yes
Bow tie analysis	A simple diagrammatic way of describing and analysing the pathways of a risk from hazards to outcomes and reviewing controls. It can be considered to be a combination of the logic of a fault tree analysing the cause of an event (represented by the knot of a bow tie) and an event tree analysing the consequences	Medium	High	Medium	Yes
STATISTICAL METHODS					
Markov analysis	Markov analysis, sometimes called <i>State-space</i> analysis, is commonly used in the analysis of repairable complex systems that can exist in multiple states, including various degraded states	High	Low	High	Yes
Monte-Carlo analysis	Monte Carlo simulation is used to establish the aggregate variation in a system resulting from variations in the system, for a number of inputs, where each input has a defined distribution and the inputs are related to the output via defined relationships. The analysis can be used for a specific model where the interactions of the various inputs can be mathematically defined. The inputs can be based upon a variety of distribution types according to the nature of the uncertainty they are intended to represent. For risk assessment, triangular distributions or beta distributions are commonly used	High	Low	High	Yes
Bayesian analysis	A statistical procedure which utilizes prior distribution data to assess the probability of the result. Bayesian analysis depends upon the accuracy of the prior distribution to deduce an accurate result. Bayesian belief networks model cause-and-effect in a variety of domains by capturing probabilistic relationships of variable inputs to derive a result	High	Low	High	Yes

Annex B (informative)

Risk assessment techniques

B.1 Brainstorming

B.1.1 Overview

Brainstorming involves stimulating and encouraging free-flowing conversation amongst a group of knowledgeable people to identify potential failure modes and associated hazards, risks, criteria for decisions and/or options for treatment. The term “brainstorming” is often used very loosely to mean any type of group discussion. However true brainstorming involves particular techniques to try to ensure that people's imagination is triggered by the thoughts and statements of others in the group.

Effective facilitation is very important in this technique and includes stimulation of the discussion at kick-off, periodic prompting of the group into other relevant areas and capture of the issues arising from the discussion (which is usually quite lively).

B.1.2 Use

Brainstorming can be used in conjunction with other risk assessment methods described below or may stand alone as a technique to encourage imaginative thinking at any stage of the risk management process and any stage of the life cycle of a system. It may be used for high-level discussions where issues are identified, for more detailed review or at a detailed level for particular problems.

Brainstorming places a heavy emphasis on imagination. It is therefore particularly useful when identifying risks of new technology, where there is no data or where novel solutions to problems are needed.

B.1.3 Inputs

A team of people with knowledge of the organization, system, process or application being assessed.

B.1.4 Process

Brainstorming may be formal or informal. Formal brainstorming is more structured with participants prepared in advance and the session has a defined purpose and outcome with a means of evaluating ideas put forward. Informal brainstorming is less structured and often more ad-hoc.

In a formal process:

- the facilitator prepares thinking prompts and triggers appropriate to the context prior to the session;
- objectives of the session are defined and rules explained;
- the facilitator starts off a train of thought and everyone explores ideas identifying as many issues as possible. There is no discussion at this point about whether things should or should not be in a list or what is meant by particular statements because this tends to inhibit free-flowing thought. All input is accepted and none is criticized and the group moves on quickly to allow ideas to trigger lateral thinking;