IEC/ISO 31010

Edition 1.0 2009-11

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Risk management – Risk assessment techniques

Gestion des risques – Techniques d'évaluation des risques

IEC/ISO 31010:2009

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
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Gestion des risques – Techniques d'évaluation des risques

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ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX XD

ICS 03.100.01

ISBN 2-8318-1068-2

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Full document details: ISO IEC 31010-2009

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RISK MANAGEMENT – RISK ASSESSMENT TECHNIQUES

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The text of this standard is based on the following documents:

FDIS	Rapport de vote
56/1329/FDIS	56/1346/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 17 member bodies out of 18 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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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.

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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;

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- 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.

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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,

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- 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.

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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.

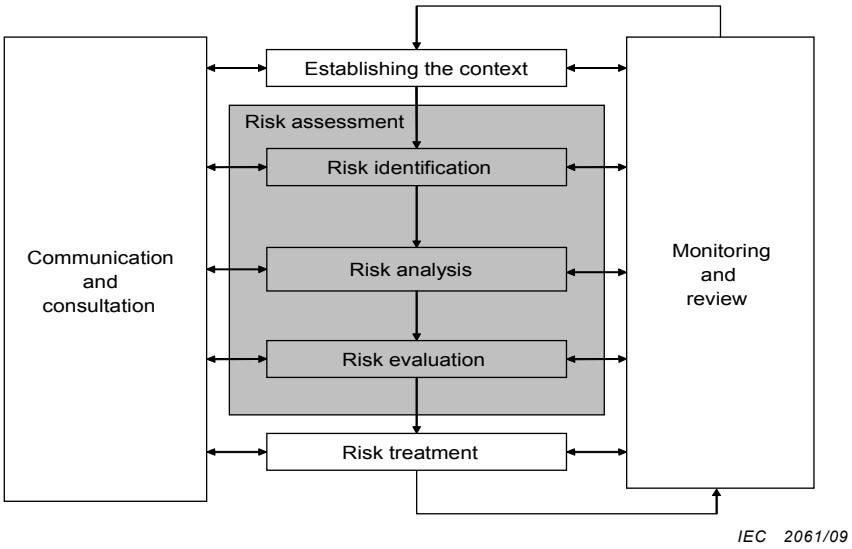

Figure 1 – Contribution of risk assessment to the risk management process

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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

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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.

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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-incidental 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.

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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

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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.

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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.

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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

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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.

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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.

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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.

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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.

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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

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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

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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-qualitatively, 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	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	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	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	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	No

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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 *State-space* 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

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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;

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- the facilitator may set people off on a new track when one direction of thought is exhausted or discussion deviates too far. The idea however, is to collect as many diverse ideas as possible for later analysis.

B.1.5 Outputs

Outputs depend on the stage of the risk management process at which it is applied, for example at the identification stage, outputs might be a list of risks and current controls.

B.1.6 Strengths and limitations

Strengths of brainstorming include:

- it encourages imagination which helps identify new risks and novel solutions;
- it involves key stakeholders and hence aids communication overall;
- it is relatively quick and easy to set up.

Limitations include:

- participants may lack the skill and knowledge to be effective contributors;
- since it is relatively unstructured, it is difficult to demonstrate that the process has been comprehensive, e.g. that all potential risks have been identified;
- there may be particular group dynamics where some people with valuable ideas stay quiet while others dominate the discussion. This can be overcome by computer brainstorming, using a chat forum or nominal group technique. Computer brainstorming can be set up to be anonymous, thus avoiding personal and political issues which may impede free flow of ideas. In nominal group technique ideas are submitted anonymously to a moderator and are then discussed by the group.

B.2 Structured or semi-structured interviews

B.2.1 Overview

In a structured interview, individual interviewees are asked a set of prepared questions from a prompting sheet which encourages the interviewee to view a situation from a different perspective and thus identify risks from that perspective. A semi-structured interview is similar, but allows more freedom for a conversation to explore issues which arise.

B.2.2 Use

Structured and semi-structured interviews are useful where it is difficult to get people together for a brainstorming session or where free-flowing discussion in a group is not appropriate for the situation or people involved. They are most often used to identify risks or to assess effectiveness of existing controls as part of risk analysis. They may be applied at any stage of a project or process. They are a means of providing stakeholder input to risk assessment.

B.2.3 Inputs

Inputs include:

- a clear definition of the objectives of the interviews;
- a list of interviewees selected from relevant stakeholders;
- a prepared set of questions.

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B.2.4 Process

A relevant question set, is created to guide the interviewer. Questions should be open-ended where possible, should be simple, in appropriate language for the interviewee and cover one issue only. Possible follow-up questions to seek clarification are also prepared.

Questions are then posed to the person being interviewed. When seeking elaboration, questions should be open-ended. Care should be taken not to “lead” the interviewee.

Responses should be considered with a degree of flexibility in order to provide the opportunity of exploring areas into which the interviewee may wish to go.

B.2.5 Outputs

The outputs are the stakeholder’s views on the issues which are the subject of the interviews.

B.2.6 Strengths and limitations

The strengths of structured interviews are as follows :

- structured interviews allow people time for considered thought about an issue;
- one-to-one communication may allow more in-depth consideration of issues;
- structured interviews enable involvement of a larger number of stakeholders than brainstorming which uses a relatively small group.

Limitations are as follows:

- it is time-consuming for the facilitator to obtain multiple opinions in this way;
- bias is tolerated and not removed through group discussion;
- the triggering of imagination which is a feature of brainstorming may not be achieved.

B.3 Delphi technique

B.3.1 Overview

The Delphi technique is a procedure to obtain a reliable consensus of opinion from a group of experts. Although the term is often now broadly used to mean any form of brainstorming, an essential feature of the Delphi technique, as originally formulated, was that experts expressed their opinions individually and anonymously while having access to the other expert’s views as the process progresses.

B.3.2 Use

The Delphi technique can be applied at any stage of the risk management process or at any phase of a system life cycle, wherever a consensus of views of experts is needed.

B.3.3 Inputs

A set of options for which consensus is needed.

B.3.4 Process

A group of experts are questioned using a semi-structured questionnaire. The experts do not meet so their opinions are independent.

The procedure is as follows:

- formation of a team to undertake and monitor the Delphi process;

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- selection of a group of experts (may be one or more panels of experts);
- development of round 1 questionnaire;
- testing the questionnaire;
- sending the questionnaire to panellists individually;
- information from the first round of responses is analysed and combined and re-circulated to panellists;
- panellists respond and the process is repeated until consensus is reached.

B.3.5 Outputs

Convergence toward consensus on the matter in hand.

B.3.6 Strengths and limitations

Strengths include:

- as views are anonymous, unpopular opinions are more likely to be expressed;
- all views have equal weight, which avoids the problem of dominating personalities;
- achieves ownership of outcomes;
- people do not need to be brought together in one place at one time.

Limitations include:

- it is labour intensive and time consuming;
- participants need to be able to express themselves clearly in writing.

B.4 Check-lists

B.4.1 Overview

Check-lists are lists of hazards, risks or control failures that have been developed usually from experience, either as a result of a previous risk assessment or as a result of past failures.

B.4.2 Use

A check-list can be used to identify hazards and risks or to assess the effectiveness of controls. They can be used at any stage of the life cycle of a product, process or system. They may be used as part of other risk assessment techniques but are most useful when applied to check that everything has been covered after a more imaginative technique that identifies new problems has been applied.

B.4.3 Inputs

Prior information and expertise on the issue, such that a relevant and preferably validated check-list can be selected or developed.

B.4.4 Process

The procedure is as follows:

- the scope of the activity is defined;
- a check-list is selected which adequately covers the scope. Check-lists need to be carefully selected for the purpose. For example a check-list of standard controls cannot be used to identify new hazards or risks;

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- the person or team using the check-list steps through each element of the process or system and reviews whether items on the check-list are present.

B.4.5 Outputs

Outputs depend on the stage of the risk management process at which they are applied. For example output may be a list of controls which are inadequate or a list of risks.

B.4.6 Strengths and limitations

Strengths of check-lists include:

- they may be used by non experts;
- when well designed, they combine wide ranging expertise into an easy to use system;
- they can help ensure common problems are not forgotten.

Limitations include:

- they tend to inhibit imagination in the identification of risks;
- they address the 'known known's', not the 'known unknown's or the 'unknown unknowns'.
- they encourage 'tick the box' type behaviour;
- they tend to be observation based, so miss problems that are not readily seen.

B.5 Preliminary hazard analysis (PHA)

B.5.1 Overview

PHA is 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.

B.5.2 Use

It is most commonly carried out early in the development of a project when there is little information on design details or operating procedures and can often be a precursor to further studies or to provide information for specification of the design of a system. It can also be useful when analysing existing systems for prioritizing hazards and risks for further analysis or where circumstances prevent a more extensive technique from being used.

B.5.3 Inputs

Inputs include:

- information on the system to be assessed;
- such details of the design of the system as are available and relevant.

B.5.4 Process

A list of hazards and generic hazardous situations and risks is formulated by considering characteristics such as:

- materials used or produced and their reactivity;
- equipment employed;
- operating environment;
- layout;
- interfaces among system components, etc.

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Qualitative analysis of consequences of an unwanted event and their probabilities may be carried out to identify risks for further assessment.

PHA should be updated during the phases of design, construction and testing in order to detect any new hazards and make corrections, if necessary. The results obtained may be presented in different ways such as tables and trees.

B.5.5 Outputs

Outputs include:

- a list of hazards and risks;
- recommendations in the form of acceptance, recommended controls, design specification or requests for more detailed assessment.

B.5.6 Strengths and limitations

Strengths include:

- that it is able to be used when there is limited information;
- it allows risks to be considered very early in the system lifecycle.

Limitations include:

- a PHA provides only preliminary information; it is not comprehensive, neither does it provide detailed information on risks and how they can best be prevented.

B.6 HAZOP

B.6.1 Overview

HAZOP is the acronym for **HA**Zard and **OP**erability study and, is a structured and systematic examination of a planned or existing product, process, procedure or system. It is a technique to identify risks to people, equipment, environment and/or organizational objectives. The study team is also expected, where possible, to provide a solution for treating the risk.

The HAZOP process is a qualitative technique based on use of guide words which question how the design intention or operating conditions might not be achieved at each step in the design, process, procedure or system. It is generally carried out by a multi-disciplinary team during a set of meetings.

HAZOP is similar to FMEA in that it identifies failure modes of a process, system or procedure their causes and consequences. It differs in that the team considers unwanted outcomes and deviations from intended outcomes and conditions and works back to possible causes and failure modes, whereas FMEA starts by identifying failure modes.

B.6.2 Use

The HAZOP technique was initially developed to analyse chemical process systems, but has been extended to other types of systems and complex operations. These include mechanical and electronic systems, procedures, and software systems, and even to organizational changes and to legal contract design and review.

The HAZOP process can deal with all forms of deviation from design intent due to deficiencies in the design, component(s), planned procedures and human actions.

It is widely used for software design review. When applied to safety critical instrument control and computer systems it may be known as CHAZOP (**C**ontrol **HA**zards and **OP**erability Analysis or computer hazard and operability analysis).

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A HAZOP study is usually undertaken at the detail design stage, when a full diagram of the intended process is available, but while design changes are still practicable. It may however, be carried out in a phased approach with different guidewords for each stage as a design develops in detail. A HAZOP study may also be carried out during operation but required changes can be costly at that stage.

B.6.3 Inputs

Essential inputs to a HAZOP study include current information about the system, the process or procedure to be reviewed and the intention and performance specifications of the design. The inputs may include: drawings, specification sheets, flow sheets, process control and logic diagrams, layout drawings, operating and maintenance procedures, and emergency response procedures. For non-hardware related HAZOP the inputs can be any document that describes functions and elements of the system or procedure under study. For example, inputs can be organizational diagrams and role descriptions, a draft contract or even a draft procedure.

B.6.4 Process

HAZOP takes the “design” and specification of the process, procedure or system being studied and reviews each part of it to discover what deviations from the intended performance can occur, what are the potential causes and what are the likely consequences of a deviation. This is achieved by systematically examining how each part of the system, process or procedure will respond to changes in key parameters by using suitable guidewords. Guidewords can be customized to a particular system, process or procedure or generic words can be used that encompass all types of deviation. Table B.1 provides examples of commonly used guidewords for technical systems. Similar guidewords such as ‘too early’, ‘too late’, ‘too much’, ‘too little’, ‘too long’, ‘too short’, ‘wrong direction’, on ‘wrong object’, ‘wrong action’ can be used to identify human error modes.

The normal steps in a HAZOP study include:

- nomination of a person with the necessary responsibility and authority to conduct the HAZOP study and to ensure that any actions arising from the study are completed;
- definition of the objectives and scope of the study;
- establishing a set of key or guidewords for the study;
- defining a HAZOP study team; this team is usually multidisciplinary and should include design and operations personnel with appropriate technical expertise to evaluate the effects of deviations from intended or current design. It is recommended that the team include persons not directly involved in the design or the system, process or procedure under review;
- collection of the required documentation.

Within a facilitated workshop with the study team:

- splitting the system, process or procedure into smaller elements or sub-systems or sub-processes or sub-elements to make the review tangible;
- agreeing the design intent for each subsystem, sub-process or sub-element and then for each item in that subsystem or element applying the guidewords one after the other to postulate possible deviations which will have undesirable outcomes;
- where an undesirable outcome is identified, agreeing the cause and consequences in each case and suggesting how they might be treated to prevent them occurring or mitigate the consequences if they do;
- documenting the discussion and agreeing specific actions to treat the risks identified.

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Table B.1 – Example of possible HAZOP guidewords

Terms	Definitions
No or not	No part of the intended result is achieved or the intended condition is absent
More (higher)	Quantitative increase in output or in the operating condition
Less (lower)	Quantitative decrease
As well as	Quantitative increase (e.g. additional material)
Part of	Quantitative decrease (e.g. only one or two components in a mixture)
Reverse /opposite	Opposite (e.g. backflow)
Other than	No part of the intention is achieved, something completely different happens (e.g. flow or wrong material)
Compatibility	Material; environment
Guide words are applied to parameters such as	
	Physical properties of a material or process
	Physical conditions such as temperature, speed
	A specified intention of a component of a system or design (e.g. information transfer)
	Operational aspects

B.6.5 Outputs

Minutes of the HAZOP meeting(s) with items for each review point recorded. This should include: the guide word used, the deviation(s), possible causes, actions to address the identified problems and person responsible for the action.

For any deviation that cannot be corrected, then the risk for the deviation should be assessed.

B.6.6 Strengths and limitations

A HAZOP analysis offers the following advantages:

- it provides the means to systematically and thoroughly examine a system, process or procedure;
- it involves a multidisciplinary team including those with real-life operational experience and those who may have to carry out treatment actions;
- it generates solutions and risk treatment actions;
- it is applicable to a wide range of systems, processes and procedures;
- it allows explicit consideration of the causes and consequences of human error;
- it creates a written record of the process which can be used to demonstrate due diligence.

The limitations include:

- a detailed analysis can be very time-consuming and therefore expensive;
- a detailed analysis requires a high level of documentation or system/process and procedure specification;
- it can focus on finding detailed solutions rather than on challenging fundamental assumptions (however, this can be mitigated by a phased approach);
- the discussion can be focused on detail issues of design, and not on wider or external issues;

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- it is constrained by the (draft) design and design intent, and the scope and objectives given to the team;
- the process relies heavily on the expertise of the designers who may find it difficult to be sufficiently objective to seek problems in their designs.

B.6.7 Reference document

IEC 61882, *Hazard and operability studies (HAZOP studies) – Application guide*

B.7 Hazard analysis and critical control points (HACCP)

B.7.1 Overview

Hazard analysis and critical control point (HACCP) provides a structure for identifying hazards and putting controls in place at all relevant parts of a process to protect against the hazards and to maintain the quality reliability and safety of a product. HACCP aims to ensure that risks are minimized by controls throughout the process rather than through inspection of the end product.

B.7.2 Use

HACCP was developed to ensure food quality for the NASA space program. It is now used by organizations operating anywhere within the food chain to control risks from physical, chemical or biological contaminants of food. It has also been extended for use in manufacture of pharmaceuticals and to medical devices. The principle of identifying things which can influence product quality, and defining points in a process where critical parameters can be monitored and hazards controlled, can be generalized to other technical systems.

B.7.3 Inputs

HACCP starts from a basic flow diagram or process diagram and information on hazards which might affect the quality, safety or reliability of the product or process output. Information on the hazards and their risks and ways in which they can be controlled is an input to HACCP.

B.7.4 Process

HACCP consists of the following seven principles:

- identifies hazards and preventive measures related to such hazards;
- determines the points in the process where the hazards can be controlled or eliminated (the critical control points or CCPs);
- establishes critical limits needed to control the hazards, i.e. each CCP should operate within specific parameters to ensure the hazard is controlled;
- monitors the critical limits for each CCP at defined intervals;
- establishes corrective actions if the process falls outside established limits;
- establishes verification procedures;
- implements record keeping and documentation procedures for each step.

B.7.5 Outputs

Documented records including a hazard analysis worksheet and a HACCP **plan**.

The hazard analysis worksheet lists for each step of the process:

- hazards which could be introduced, controlled or exacerbated at this step;

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- whether the hazards present a significant risk (based on consideration of consequence and probability from a combination of experience, data and technical literature);
- a justification for the significance;
- possible preventative measures for each hazard;
- whether monitoring or control measures can be applied at this step (i.e. is it a CCP?).

The HACCP plan delineates the procedures to be followed to assure the control of a specific design, product, process or procedure. The plan includes a list of all CCPs and for each CCP:

- the critical limits for preventative measures;
- monitoring and continuing control activities (including what, how, and when monitoring will be carried out and by whom);
- corrective actions required if deviations from critical limits are detected;
- verification and record-keeping activities.

B.7.6 Strengths and limitations

Strengths include:

- a structured process that provides documented evidence for quality control as well as identifying and reducing risks;
- a focus on the practicalities of how and where, in a process, hazards can be prevented and risks controlled;
- better risk control throughout the process rather than relying on final product inspection;
- an ability to identify hazards introduced through human actions and how these can be controlled at the point of introduction or subsequently.

Limitations include:

- HACCP requires that hazards are identified, the risks they represent defined, and their significance understood as inputs to the process. Appropriate controls also need to be defined. These are required in order to specify critical control points and control parameters during HACCP and may need to be combined with other tools to achieve this;
- taking action when control parameters exceed defined limits may miss gradual changes in control parameters which are statistically significant and hence should be actioned.

B.7.7 Reference document

ISO 22000, *Food safety management systems – Requirements for any organization in the food chain*

B.8 Toxicity assessment

B.8.1 Overview

Environmental risk assessment is used here to cover the process followed in assessing risks to plants, animals and humans as a result of exposure to a range of environmental hazards. Risk management refers to decision-making steps including risk evaluation and risk treatment.

The method involves analysing the hazard or source of harm and how it affects the target population, and the pathways by which the hazard can reach a susceptible target population. This information is then combined to give an estimate of the likely extent and nature of harm.

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B.8.2 Use

The process is used to assess risks to plants, animals and humans as a result of exposure to hazards such as chemicals, micro-organisms or other species.

Aspects of the methodology, such as pathway analysis which explore different routes by which a target might be exposed to a source of risk, can be adapted and used across a very wide range of different risk areas, outside human health and the environment, and is useful in identifying treatments to reduce risk.

B.8.3 Inputs

The method requires good data on the nature and properties of hazards, the susceptibilities of the target population (or populations) and the way in which the two interact. This data is normally based on research which may be laboratory based or epidemiological.

B.8.4 Process

The procedure is as follows:

a) Problem formulation – this includes setting the scope of the assessment by defining the range of target populations and hazard types of interest;

b) Hazard identification – this involves identifying all possible sources of harm to the target population from hazards within the scope of the study. Hazard identification normally relies on expert knowledge and a review of literature;

c) Hazard analysis – this involves understanding the nature of the hazard and how it interacts with the target. For example, in considering human exposure to chemical effects, the hazard might include acute and chronic toxicity, the potential to damage DNA, or the potential to cause cancer or birth defects. For each hazardous effect, the magnitude of the effect (the response) is compared to the amount of hazard to which the target is exposed (the dose) and, wherever possible, the mechanism by which the effect is produced is determined. The levels at which there is No Observable Effect (NOEL) and no Observable Adverse Effect (NOAEL) are noted. These are sometimes used as criteria for acceptability of the risk.

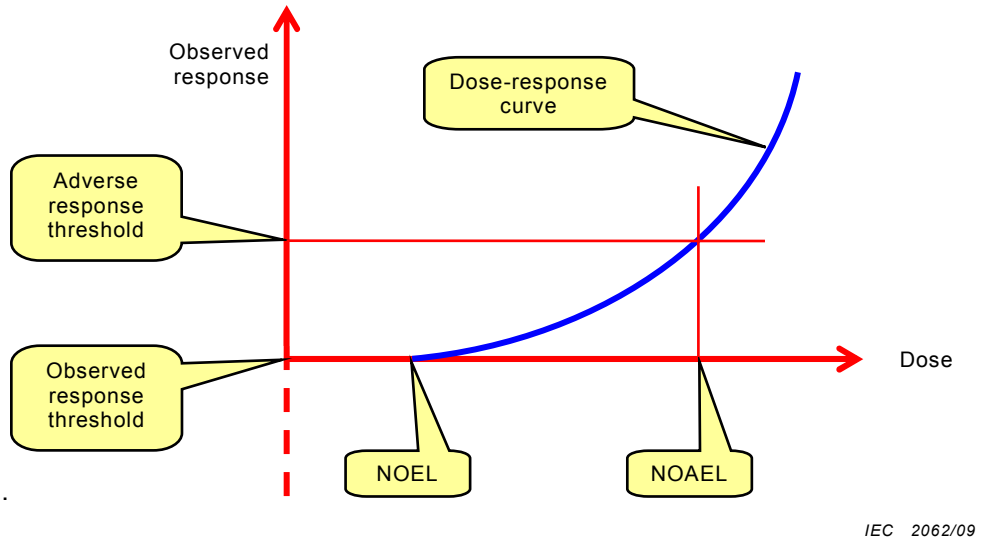

Figure B.1 – Dose-response curve

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For chemical exposure, test results are used to derive dose-response curves such as that shown schematically in Figure B.1. These are usually derived from tests on animals or from experimental systems such as cultured tissues or cells.

Effects of other hazards such as micro-organisms or introduced species may be determined from field data and epidemiological studies. The nature of the interaction of diseases or pests with the target is determined and the probability that a particular level of harm from a particular exposure to the hazard is estimated.

d) Exposure analysis – this step examines how a hazardous substance or its residues might reach a susceptible target population and in what amount. It often involves a pathway analysis which considers the different routes the hazard might take, the barriers which might prevent it from reaching the target and the factors that might influence the level of exposure. For example, in considering the risk from chemical spraying the exposure analysis would consider how much chemical was sprayed, in what way and under what conditions, whether there was any direct exposure of humans or animals, how much might be left as residue on plant life, the environmental fate of pesticides reaching the ground, whether it can accumulate in animals or whether it enters groundwater. In bio security, the pathway analysis might consider how any pests entering the country might enter the environment, become established and spread.

e) Risk characterization – in this step, the information from the hazard analysis and the exposure analysis are brought together to estimate the probabilities of particular consequences when effects from all pathways are combined. Where there are large numbers of hazards or pathways, an initial screening may be carried out and the detailed hazard and exposure analysis and risk characterization carried out on the higher risk scenarios.

B.8.5 Outputs

The output is normally an indication of the level of risk from exposure of a particular target to a particular hazard in the context concerned. The risk may be expressed quantitatively semi-quantitatively or qualitatively. For example, the risk of cancer is often expressed quantitatively as the probability, that a person will develop cancer over a specified period given a specified exposure to a contaminant. Semi-quantitative analysis may be used to derive a risk index for a particular contaminant or pest and qualitative output may be a level of risk (e.g. high, medium, low) or a description with practical data of likely effects.

B.8.6 Strengths and limitations

The strength of this analysis is that it provides a very detailed understanding of the nature of the problem and the factors which increase risk.

Pathway analysis is a useful tool, generally, for all areas of risk and permits the identification of how and where it may be possible to improve controls or introduce new ones.

It does, however, need good data which is often not available or has a high level of uncertainty associated with it. For example, dose response curves derived from exposing animals to high levels of a hazard should be extrapolated to estimate the effects of very low levels of the contaminants to humans and there are multiple models by which this is achieved. Where the target is the environment rather than humans and the hazard is not chemical, data which is directly relevant to the particular conditions of the study may be limited.

B.9 Structured “What-if” Technique (SWIFT)

B.9.1 Overview

SWIFT was originally developed as a simpler alternative to HAZOP. It is a systematic, team-based study, utilizing a set of ‘prompt’ words or phrases that is used by the facilitator within a workshop to stimulate participants to identify risks. The facilitator and team use standard ‘what-if’ type phrases in combination with the prompts to investigate how a system, plant item,

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organization or procedure will be affected by deviations from normal operations and behaviour. SWIFT is normally applied at more of a systems level with a lower level of detail than HAZOP.

B.9.2 Use

While SWIFT was originally designed for chemical and petrochemical plant hazard study, the technique is now widely applied to systems, plant items, procedures, organizations generally. In particular it is used to examine the consequences of changes and the risks thereby altered or created.

B.9.3 Inputs

The system, procedure, plant item and/or change has to be carefully defined before the study can commence. Both the external and internal contexts are established through interviews and through the study of documents, plans and drawings by the facilitator. Normally, the item, situation or system for study is split into nodes or key elements to facilitate the analysis process but this rarely occurs at the level of definition required for HAZOP.

Another key input is the expertise and experience present in the study team which should be carefully selected. All stakeholders should be represented if possible together with those with experience of similar items, systems, changes or situations.

B.9.4 Process

The general process is as follows:

a) Before the study commences, the facilitator prepares a suitable prompt list of words or phrases that may be based on a standard set or be created to enable a comprehensive review of hazards or risks.

b) At the workshop the external and internal context of the item, system, change or situation and the scope of the study are discussed and agreed.

c) The facilitator asks the participants to raise and discuss:

   – known risks and hazards;

   – previous experience and incidents;

   – known and existing controls and safeguards;

   – regulatory requirements and constraints.

d) Discussion is facilitated by creating a question using a ‘what-if’ phrase and a prompt word or subject. The ‘what-if’ phrases to be used are “what if…”, “what would happen if…”, “could someone or something…”, “has anyone or anything ever….” The intent is to stimulate the study team into exploring potential scenarios, their causes and consequences and impacts.

e) Risks are summarized and the team considers controls in place.

f) The description of the risk, its causes, consequences and expected controls are confirmed with the team and recorded.

g) The team considers whether the controls are adequate and effective and agree a statement of risk control effectiveness. If this is less than satisfactory, the team further considers risk treatment tasks and potential controls are defined.

h) During this discussion further ‘what-if’ questions are posed to identify further risks.

i) The facilitator uses the prompt list to monitor the discussion and to suggest additional issues and scenarios for the team to discuss.

j) It is normal to use a qualitative or semi-quantitative risk assessment method to rank the actions created in terms of priority. This risk assessment is normally conducted by taking into account the existing controls and their effectiveness.

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B.9.5 Outputs

Outputs include a risk register with risk-ranked actions or tasks. These tasks can then become the basis for a treatment plan.

B.9.6 Strengths and limitations

Strengths of SWIFT:

- it is widely applicable to all forms of physical plant or system, situation or circumstance, organization or activity;
- it needs minimal preparation by the team;
- it is relatively rapid and the major hazards and risks quickly become apparent within the workshop session;
- the study is 'systems orientated' and allows participants to look at the system response to deviations rather than just examining the consequences of component failure;
- it can be used to identify opportunities for improvement of processes and systems and generally can be used to identify actions that lead to and enhance their probabilities of success;
- involvement in the workshop by those who are accountable for existing controls and for further risk treatment actions, reinforces their responsibility;
- it creates a risk register and risk treatment plan with little more effort;
- while often a qualitative or semi-quantitative form of risk rating is used for risk assessment and to prioritize attention on the resulting actions, SWIFT can be used to identify risks and hazards that can be taken forward into a quantitative study.

Limitations of SWIFT:

- it needs an experienced and capable facilitator to be efficient;
- careful preparation is needed so that the workshop team's time is not wasted;
- if the workshop team does not have a wide enough experience base or if the prompt system is not comprehensive, some risks or hazards may not be identified;
- the high-level application of the technique may not reveal complex, detailed or correlated causes.

B.10 Scenario analysis

B.10.1 Overview

Scenario analysis is a name given to the development of descriptive models of how the future might turn out. It can be used to identify risks by considering possible future developments and exploring their implications. Sets of scenarios reflecting (for example) 'best case', 'worst case' and 'expected case' may be used to analyse potential consequences and their probabilities for each scenario as a form of sensitivity analysis when analysing risk.

The power of scenario analysis is illustrated by considering major shifts over the past 50 years in technology, consumer preferences, social attitudes, etc. Scenario analysis cannot predict the probabilities of such changes but can consider consequences and help organizations develop strengths and the resilience needed to adapt to foreseeable changes.

B.10.2 Use

Scenario analysis can be used to assist in making policy decisions and planning future strategies as well as to consider existing activities. It can play a part in all three components of risk assessment. For identification and analysis, sets of scenarios reflecting (for example) best case, worst case and 'expected' case may be used to identify what might happen under

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particular circumstances and analyse potential consequences and their probabilities for each scenario.

Scenario analysis may be used to anticipate how both threats and opportunities might develop and may be used for all types of risk with both short and long term time frames. With short time frames and good data, likely scenarios may be extrapolated from the present. For longer time frames or with weak data, scenario analysis becomes more imaginative and may be referred to as futures analysis.

Scenario analysis may be useful where there are strong distributional differences between positive outcomes and negative outcomes in space, time and groups in the community or an organization.

B.10.3 Inputs

The prerequisite for a scenario analysis is a team of people who between them have an understanding of the nature of relevant changes (for example possible advances in technology) and imagination to think into the future without necessarily extrapolating from the past. Access to literature and data about changes already occurring is also useful.

B.10.4 Process

The structure for scenario analysis may be informal or formal.

Having established a team and relevant communication channels, and defined the context of the problem and issues to be considered, the next step is to identify the nature of changes that might occur. This will need research into the major trends and the probable timing of changes in trends as well as imaginative thinking about the future.

Changes to be considered may include:

- external changes (such as technological changes);
- decisions that need to be made in the near future but which may have a variety of outcomes;
- stakeholder needs and how they might change;
- changes in the macro environment (regulatory, demographics, etc). Some will be inevitable and some will be uncertain.

Sometimes, a change may be due to the consequences of another risk. For example, the risk of climate change is resulting in changes in consumer demand related to food miles. This will influence which foods can be profitably exported as well as which foods can be grown locally.

The local and macro factors or trends can now be listed and ranked for (1) importance (2) uncertainty. Special attention is paid to the factors that are most important and most uncertain. Key factors or trends are mapped against each other to show areas where scenarios can be developed.

A series of scenarios is proposed with each one focussing on a plausible change in parameters.

A “story” is then written for each scenario that tells how you might move from here towards the subject scenario. The stories may include plausible details that add value to the scenarios.

The scenarios can then be used to test or evaluate the original question. The test takes into account any significant but predictable factors (e.g. use patterns), and then explores how ‘successful’ the policy (activity) would be in this new scenario, and ‘pre-tests’ outcomes by using ‘what if’ questions based on model assumptions.

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When the question or proposal has been evaluated with respect to each scenario, it may be obvious that it needs to be modified to make it more robust or less risky. It should also be possible to identify some leading indicators that show when change is occurring. Monitoring and responding to leading indicators can provide opportunity for change in planned strategies.

Since scenarios are only defined 'slices' of possible futures, it is important to make sure that account is taken of the probability of a particular outcome (scenario) occurring, i.e. to adopt a risk framework. For example, where best case, worst case and expected case scenarios are used, some attempt should be made to qualify, or express the probability of each scenario occurring.

B.10.5 Outputs

There may be no best-fit scenario but one should end with a clearer perception of the range of options and how to modify the chosen course of action as indicators move.

B.10.6 Strengths and limitations

Scenario analysis takes account of a range of possible futures which may be preferable to the traditional approach of relying on high-medium-low forecasts that assume, through the use of historical data, that future events will probably continue to follow past trends. This is important for situations where there is little current knowledge on which to base predictions or where risks are being considered in the longer term future.

This strength however has an associated weakness which is that where there is high uncertainty some of the scenarios may be unrealistic.

The main difficulties in using scenario analysis are associated with the availability of data, and the ability of the analysts and decision makers to be able to develop realistic scenarios that are amenable to probing of possible outcomes.

The dangers of using scenario analysis as a decision-making tool are that the scenarios used may not have an adequate foundation; that data may be speculative; and that unrealistic results may not be recognized as such.

B.11 Business impact analysis (BIA)

B.11.1 Overview

Business impact analysis, also known as business impact assessment, analyses how key disruption risks could affect an organization's operations and identifies and quantifies the capabilities that would be needed to manage it. Specifically, a BIA provides an agreed understanding of:

- the identification and criticality of key business processes, functions and associated resources and the key interdependencies that exist for an organization;
- how disruptive events will affect the capacity and capability of achieving critical business objectives;
- the capacity and capability needed to manage the impact of a disruption and recover the organization to agreed levels of operation.

B.11.2 Use

BIA is used to determine the criticality and recovery timeframes of processes and associated resources (people, equipment, information technology) to ensure the continued achievement of objectives. Additionally, the BIA assists in determining interdependencies and interrelationships between processes, internal and external parties and any supply chain linkages.

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B.11.3 Inputs

Inputs include:

- a team to undertake the analysis and develop a plan;
- information concerning the objectives, environment, operations and interdependencies of the organization;
- details on the activities and operations of the organization, including processes, supporting resources, relationships with other organizations, outsourced arrangements, stakeholders;
- financial and operational consequences of loss of critical processes;
- prepared questionnaire;
- list of interviewees from relevant areas of the organization and/or stakeholders that will be contacted.

B.11.4 Process

A BIA can be undertaken using questionnaires, interviews, structured workshops or combinations of all three, to obtain an understanding of the critical processes, the effects of the loss of those processes and the required recovery timeframes and supporting resources.

The key steps include:

- based on the risk and vulnerability assessment, confirmation of the key processes and outputs of the organization to determine the criticality of the processes;
- determination of the consequences of a disruption on the identified critical processes in financial and/or operational terms, over defined periods;
- identification of the interdependencies with key internal and external stakeholders. This could include mapping the nature of the interdependencies through the supply chain;
- determination of the current available resources and the essential level of resources needed to continue to operate at a minimum acceptable level following a disruption;
- identification of alternate workarounds and processes currently in use or planned to be developed. Alternate workarounds and processes may need to be developed where resources or capability are inaccessible or insufficient during the disruption;
- determination of the maximum acceptable outage time (MAO) for each process based on the identified consequences and the critical success factors for the function. The MAO represents the maximum period of time the organization can tolerate the loss of capability;
- determination of the recovery time objective(s) (RTO) for any specialized equipment or information technology. The RTO represents the time within which the organization aims to recover the specialized equipment or information technology capability;
- confirmation of the current level of preparedness of the critical processes to manage a disruption. This may include evaluating the level of redundancy within the process (e.g. spare equipment) or the existence of alternate suppliers.

B.11.5 Outputs

The outputs are as follows:

- a priority list of critical processes and associated interdependencies;
- documented financial and operational impacts from a loss of the critical processes;
- supporting resources needed for the identified critical processes;
- outage time frames for the critical process and the associated information technology recovery time frames.

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B.11.6 Strengths and limitations

Strengths of the BIA include:

- an understanding of the critical processes that provide the organization with the ability to continue to achieve their stated objectives;
- an understanding of the required resources;
- an opportunity to redefine the operational process of an organization to assist in the resilience of the organization.

Limitations include:

- lack of knowledge by the participants involved in completing questionnaires, undertaking interviews or workshops;
- group dynamics may affect the complete analysis of a critical process;
- simplistic or over-optimistic expectations of recovery requirements;
- difficulty in obtaining an adequate level of understanding of the organization's operations and activities.

B.12 Root cause analysis (RCA)

B.12.1 Overview

The analysis of a major loss to prevent its reoccurrence is commonly referred to as Root Cause Analysis (RCA), Root Cause Failure Analysis (RCFA) or loss analysis. RCA is focused on asset losses due to various types of failures while loss analysis is mainly concerned with financial or economic losses due to external factors or catastrophes. It attempts to identify the root or original causes instead of dealing only with the immediately obvious symptoms. It is recognized that corrective action may not always be entirely effective and that continuous improvement may be required. RCA is most often applied to the evaluation of a major loss but may also be used to analyse losses on a more global basis to determine where improvements can be made.

B.12.2 Use

RCA is applied in various contexts with the following broad areas of usage:

- safety-based RCA is used for accident investigations and occupational health and safety;
- failure analysis is used in technological systems related to reliability and maintenance;
- production-based RCA is applied in the field of quality control for industrial manufacturing;
- process-based RCA is focused on business processes;
- system-based RCA has developed as a combination of the previous areas to deal with complex systems with application in change management, risk management and systems analysis.

B.12.3 Inputs

The basic input to an RCA is all of the evidence gathered from the failure or loss. Data from other similar failures may also be considered in the analysis. Other inputs may be results that are carried out to test specific hypotheses.

B.12.4 Process

When the need for an RCA is identified, a group of experts is appointed to carry out the analysis and make recommendations. The type of expert will mostly be dependent on the specific expertise needed to analyse the failure.

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Even though different methods can be used to perform the analysis, the basic steps in executing an RCA are similar and include:

- forming the team;
- establishing the scope and objectives of the RCA;
- gathering data and evidence from the failure or loss;
- performing a structured analysis to determine the root cause;
- developing solutions and make recommendations;
- implementing the recommendations;
- verifying the success of the implemented recommendations.

Structured analysis techniques may consist of one of the following:

- "5 whys" technique, i.e. repeatedly asking 'why?' to peel away layers of cause and sub cause);
- failure mode and effects analysis;
- fault tree analysis;
- Fishbone or Ishikawa diagrams;
- Pareto analysis;
- root cause mapping.

The evaluation of causes often progresses from initially evident physical causes to human-related causes and finally to underlying management or fundamental causes. Causal factors have to be able to be controlled or eliminated by involved parties in order for corrective action to be effective and worthwhile.

B.12.5 Outputs

The outputs from an RCA include:

- documentation of data and evidence gathered;
- hypotheses considered;
- conclusion about the most likely root causes for the failure or loss;
- recommendations for corrective action.

B.12.6 Strengths and limitations

Strengths include:

- involvement of applicable experts working in a team environment;
- structured analysis;
- consideration of all likely hypotheses;
- documentation of results;
- need to produce final recommendations.

Limitations of an RCA:

- required experts may not be available;
- critical evidence may be destroyed in the failure or removed during clean-up;
- the team may not be allowed enough time or resources to fully evaluate the situation;
- it may not be possible to adequately implement recommendations.

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B.13 Failure modes and effects analysis (FMEA) and failure modes and effects and criticality analysis (FMECA)

B.13.1 Overview

Failure modes and effects analysis (FMEA) is a technique used to identify the ways in which components, systems or processes can fail to fulfil their design intent.

FMEA identifies:

- all potential failure modes of the various parts of a system (a failure mode is what is observed to fail or to perform incorrectly);
- the effects these failures may have on the system;
- the mechanisms of failure;
- how to avoid the failures, and/or mitigate the effects of the failures on the system.

FMECA extends an FMEA so that each fault mode identified is ranked according to its importance or criticality

This criticality analysis is usually qualitative or semi-quantitative but may be quantified using actual failure rates.

B.13.2 Use

There are several applications 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/FMECA may be applied during the design, manufacture or operation of a physical system.

To improve dependability, however, changes are usually more easily implemented at the design stage. FMEA AND FMECA may also be applied to processes and procedures. For example, it is used to identify potential for medical error in healthcare systems and failures in maintenance procedures.

FMEA/FMECA can be used to

- assist in selecting design alternatives with high dependability,
- ensure that all failure modes of systems and processes, and their effects on operational success have been considered,
- identify human error modes and effects,
- provide a basis for planning testing and maintenance of physical systems,
- improve the design of procedures and processes,
- provide qualitative or quantitative information for analysis techniques such as fault tree analysis.

FMEA and FMECA can provide input to other analyses techniques such as fault tree analysis at either a qualitative or quantitative level.

B.13.3 Inputs

FMEA and FMECA need information about the elements of the system in sufficient detail for meaningful analysis of the ways in which each element can fail. For a detailed Design FMEA the element may be at the detailed individual component level, while for higher level Systems FMEA, elements may be defined at a higher level.

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Information may include:

- drawings or a flow chart of the system being analysed and its components, or the steps of a process;
- an understanding of the function of each step of a process or component of a system;
- details of environmental and other parameters, which may affect operation;
- an understanding of the results of particular failures;
- historical information on failures including failure rate data where available.

B.13.4 Process

The FMEA process is as follows:

a) define the scope and objectives of the study;
b) assemble the team;
c) understand the system/process to be subjected to the FMECA;
d) breakdown of the system into its components or steps;
e) define the function of each step or component;
f) for every component or step listed identify:
    - how can each part conceivably fail?
    - what mechanisms might produce these modes of failure?
    - what could the effects be if the failures did occur?
    - is the failure harmless or damaging?
    - how is the failure detected?
g) identify inherent provisions in the design to compensate for the failure.

For FMECA, the study team goes on to classify each of the identified failure modes according to its criticality

There are several ways this may be done. Common methods include

- the mode criticality index,
- the level of risk,
- the risk priority number.

The model criticality is a measure of the probability that the mode being considered will result in failure of the system as a whole; it is defined as:

Failure effect probability * Mode failure rate * Operating time of the system

It is most often applied to equipment failures where each of these terms can be defined quantitatively and failure modes all have the same consequence.

The risk level is obtained by combining the consequences of a failure mode occurring with the probability of failure. It is used when consequences of different failure modes differ and can be applied to equipment systems or processes. Risk level can be expressed qualitatively, semi-quantitatively or quantitatively.

The risk priority number (RPN) is a semi-quantitative measure of criticality obtained by multiplying numbers from rating scales (usually between 1 and 10) for consequence of failure, likelihood of failure and ability to detect the problem. (A failure is given a higher priority if it is difficult to detect.) This method is used most often in quality assurance applications.

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Once failure modes and mechanisms are identified, corrective actions can be defined and implemented for the more significant failure modes.

FMEA is documented in a report that contains:

- details of the system that was analysed;
- the way the exercise was carried out;
- assumptions made in the analysis;
- sources of data;
- the results, including the completed worksheets;
- the criticality (if completed) and the methodology used to define it;
- any recommendations for further analyses, design changes or features to be incorporated in test plans, etc.

The system may be reassessed by another cycle of FMEA after the actions have been completed.

B.13.5 Outputs

The primary output of FMEA is a list of failure modes, the failure mechanisms and effects for each component or step of a system or process (which may include information on the likelihood of failure). Information is also given on the causes of failure and the consequences to the system as a whole. The output from FMECA includes a rating of importance based on the likelihood that the system will fail, the level of risk resulting from the failure mode or a combination of the level of risk and the 'detectability' of the failure mode.

FMECA can give a quantitative output if suitable failure rate data and quantitative consequences are used.

B.13.6 Strengths and limitations

The strengths of FMEA/FMECA are as follows:

- widely applicable to human, equipment and system failure modes and to hardware, software and procedures;
- identify component failure modes, their causes and their effects on the system, and present them in an easily readable format;
- avoid the need for costly equipment modifications in service by identifying problems early in the design process;
- identify single point failure modes and requirements for redundancy or safety systems;
- provide input to the development monitoring programmes by highlighting key features to be monitored.

Limitations include:

- they can only be used to identify single failure modes, not combinations of failure modes;
- unless adequately controlled and focussed, the studies can be time consuming and costly;
- they can be difficult and tedious for complex multi-layered systems.

B.13.7 Reference document

IEC 60812, *Analysis techniques for system reliability – Procedures for failure mode and effect analysis (FMEA)*

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