Treatment of Uncertainty in Risk Based Regulations and Standards for Risk Analysis

Abrahamsson, Marcus

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Marcus Abrahamsson

Department of Fire Safety Engineering
Lund University, Sweden

Brandteknik
Lunds tekniska högskola
Lunds universitet

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Abstract
The role of quantitative risk analysis as a foundation for decision making, regarding hazardous activities and establishments, has gained increased importance during the last decades. When performing a quantitative risk analysis, a wide range of uncertainties will inevitably be introduced during the process. The impact of these uncertainties must somehow be addressed if the analysis is to serve as a tool in the decision-making process. The objective of this report is to present a summary of how issues of uncertainty are dealt with in existing safety regulations, and in existing standards for risk analysis and management. Using this summary as a guide, various aspects of uncertainty are discussed. E.g. what role will uncertainty play in the decision-making process? Is there a need for identifying and separating different kinds of uncertainty (e.g. aleatory, or stochastic uncertainty, vs. epistemic, or knowledge based uncertainty) while creating the foundation for decision-making? Will we always be dependent on expert judgement while dealing with these issues?

The work behind this paper is the first step in a research project with the objective to produce the basis for a Swedish Standard regarding treatment of uncertainties in quantitative risk analyses. The project is to be completed by the end of the year 2001.

Brandteknik
Lunds tekniska högskola
Lunds universitet
Box 118
221 00 Lund

brand@brand.lth.se
http://www.brand.lth.se

Telefon: 046 - 222 73 60
Telefax: 046 - 222 46 12

Department of Fire Safety Engineering
Lund University
P.O. Box 118
SE-221 00 Lund
Sweden

brand@brand.lth.se
http://www.brand.lth.se/english

Telephone: +46 46 222 73 60
Fax: +46 46 222 46 12

Summary

In this report, treatment of uncertainty in various regulatory documents, e.g. policy documents and guidelines related to risk assessment is summarily presented. A summary of statements regarding treatment of uncertainty in a number of standards for risk analysis and management is also presented. This report is the first step in an attempt to create a foundation for a Swedish Standard on treatment of uncertainties in quantitative risk analysis, and the objective is to generate a platform for further research in this area.

The summary of standards displays a few basic elements of the risk analysis process that will inevitably introduce uncertainty to the results, e.g. the necessity to make assumptions about and simplifications of the system under study.

Using the summary as a guide, some fundamental aspects of uncertainty are discussed. Which parts of the risk analysis process will introduce uncertainty? What kinds of uncertainty are there? Is there a need for separating different kinds of uncertainty when performing uncertainty analysis as a part of the overall risk analysis? To what extent can we rely on expert judgement when dealing with complex systems of which we have insufficient knowledge?

The questions above will not be all the way answered in this report, and indeed some of them may well be impossible to answer “correctly”, but the report should be useful as a first introduction to the concept of uncertainty in risk analysis of complex systems.

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Introduction

The role of quantitative risk analysis as a foundation for decision making, regarding hazardous activities and establishments, has gained increased importance during the last decades. When performing a quantitative risk analysis, a wide range of uncertainties will inevitably be introduced during the process. The impact of these uncertainties must somehow be addressed if the analysis is to serve as a tool in the decision-making process.

The objective of this report is to provide a summary of how issues of uncertainty are dealt with in some selected regulations, policy documents, guidelines, and standards for risk analysis and risk management. There is no claim that this report is in any way exhaustive, but it is my belief that the documents under review here are representative of what has been published in this field so far.

The choice of standards for review is based on their applicability in a wide range of areas. More specific standards aiming at just one area, such as nuclear energy, medicine, or fire protection has intentionally been left out to narrow the scope of the report and to keep it universal. The general trend in the standards under study is that they all, to some extent, bring up the subject of uncertainty. The spirit of most of the statements could be captured as follows, "the analyst must consider any uncertainty in the results generated from used models, data and assumptions", but none of the standards offer any advise on how to treat uncertainties explicitly.

Using the summary as a guide, various aspects of uncertainty are discussed. What role will uncertainty play in the decision-making process? Is there a need for identifying and separating different kinds of uncertainty (e.g. aleatory, or stochastic uncertainty, vs. epistemic, or knowledge based uncertainty) while creating the foundation for decision-making? Will we always be dependent on expert judgement while dealing with these issues?

This report is the first step in a project regarding treatment of uncertainties in quantitative risk analysis. The objective of the project is to generate guidelines to how different kinds of uncertainty should be identified, analysed and presented within the framework of a quantitative risk analysis. The main area of the study will be large-scale accidents in technological systems such as industries, storage facilities, transport- and communication-systems etc. The project is financed by the Swedish Rescue Services Agency (Department of risk assessment), and will continue until the year 2002.

PART 1 - Risk Based Regulations and Guidelines

There is a general trend towards the use of risk based regulations in areas where complex technological systems are in use. The use of quantitative risk analysis as a foundation for rational decision-making is increasing in a number of engineering areas, e.g. aviation industry, space industry, nuclear industry, civil and marine structure industry etc, Berg & Kafka (1997).

It has been widely recognized that the process of performing QRA is connected with a wide variety of uncertainties, e.g. Morgan et al (1990), Amendola et al (1998), van Asselt (1999), and Paté-Cornell (1996). The systems often analyzed with this technique are generally complex, with potential for large-scale accidents. This, together with the fact that one often has to deal with dynamic systems with little or no statistical history regarding accidents or near accidents, makes the treatment of uncertainty a most challenging, as well as important task. As stated in Amendola et al (1998): “As QRA is used as an input in many decisions related to the control of major accident hazards and the need for accuracy in the result increases, the adequate management of these uncertainties gains increased importance”.

In a Benchmark Exercise on Major Hazard Analysis for a chemical plant, managed by the Joint Research Centre (JRC) during 1988-1990, 11 teams from different European countries performed an analysis for a reference object, an ammonia storage facility (Amendola et al (1992)). The objectives of the study were to evaluate the state of the art and to obtain estimates of the degree of uncertainty in risk studies. The result of this study showed great variability in risk estimations between the different analysis teams. These problems have also been recognised in other areas, for instance in road safety and the transportation of dangerous goods. Saccomanno et al (1991) showed that differences in estimates for accident rates, fault and release probabilities and hazard areas could result in variations in risk estimates of several orders of magnitude.

Parry (1998) also discusses the effect of uncertainty analysis and presentation on decision making. He points out that the objective of the uncertainty analysis is to ensure that the most appropriate decision has been made, consistent with state of the art, and the decisions makers’ state of knowledge. Notwithstanding this he stresses that “the absence of a standard approach to both the development of PRA models and the characterisation of uncertainty would mean that an integrated probability distribution generated by propagating probability distributions on the elements of the PRA will be subjective, and influenced by the choice of assumptions and approximations adopted by the analyst.”

These problem formulations provide roughly the background of the first phase of this project, and also the first part of this report. In this part, some guidelines or regulations regarding the assessment of risks in different areas, with somewhat different approaches, are summarily described and commented. While screening for risk based regulations and guidelines, it fairly early stood clear that not many documents provides explicit guidance on treatment of uncertainty, and that we are far from consensus on how risk assessments should be used and what the requirements on such an analysis ought to be. The list of guidelines is by no means exhaustive, and those included were chosen on the basis that they all had some specific features regarding uncertainty in the assessment, and because of the diversity regarding approach.

1.1 U.S. EPA Policy for use of Probabilistic Analysis in Risk Assessment

The U.S. Environmental Protection Agency emphasizes the importance of characterizing uncertainty[1] and variability[2] in several science and policy documents, e.g. the 1992 "EPA Risk Assessment Council (RAC) Guidance" and the 1995 "EPA Policy for Risk Characterization". In May 1997 the EPA issued a Policy statement with appurtenant guiding principles, ref /1.1/, in order to implement the recommendations in the former reports. It should be mentioned that the policy and associated guideline do not establish or affect legal rights or obligations, but merely confirms EPA's position regarding probabilistic techniques. The statement includes: "It is the policy of the U.S. Environmental Protection Agency that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be a viable statistical tool for analyzing variability and uncertainty in risk assessments."

It should be clarified though that the policy is not intended to suggest that probabilistic analysis be used in all risk assessments, but merely give guidance on when and how such an analysis should be performed to support risk management decisions. Another important issue is that the policy does not indicate that Monte Carlo analysis is the only viable probabilistic tool for uncertainty and variability analysis: "The spirit of this policy and the Conditions for Acceptance described herein are equally applicable to other methods for analyzing variability and uncertainty." ref /1.1/. Here, when discussing these issues, I will refer to techniques for uncertainty analysis in general, even when the guideline refers to Monte Carlo analysis, which is consistent with the spirit of the policy and guidelines. A characteristic of the policy is that it highlights the importance of clarity, transparency, reasonableness, and consistency in risk assessments.

In this section the Conditions for Acceptance outlined in the policy will be briefly presented. These conditions must be satisfied when submitting a probabilistic analysis to the agency to ensure high quality science regarding transparency, reproducibility, and the use of sound methods. Here only the conditions applicable to general assessments are presented, leaving out the specific conditions for and environmental and public health assessments. For a more comprehensive explanation of the conditions, see /1.1/.

1 The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section. The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.

2 The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report.

3 The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and other factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.

[1] Uncertainty due to lack of knowledge
[2] Refers to observed differences attributable to true heterogeneity or diversity in a population

4 The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.

5 Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of the distributions that indicate the location of any point estimates of interest. The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible.

6 The numerical stability of the central tendency and the higher end (i.e. tail) of the output distributions are to be presented and discussed.

7 Calculations of exposures and risks using deterministic (e.g. point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening level risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and facilitate risk communication.

It is stated in the policy and the guidelines that if these conditions (along with some situation specific conditions) are satisfied, the assessment will be regarded as scientifically sound when reviewed by the agency. The fundamental goals of the policy and the guideline is to define methods for characterizing, quantitatively, the variability and uncertainty of a risk estimate, to identify the main sources of variability and uncertainty, and their relative contribution to the overall variability and uncertainty in the results.

Another aspect of quantitative uncertainty and variability analysis, which is emphasized in the guidelines, is the importance of the process of interaction between stakeholders in the assessment. The guideline provides some basic questions that the risk assessor/manager should think through before initiating a quantitative variability and uncertainty analysis:

- Will the quantitative analysis of uncertainty and variability improve the risk assessment?
- What are the major sources of variability and uncertainty? How will variability and uncertainty be kept separate in the analysis?
- Are there time and resources to complete a complex analysis?
- Does the project warrant this level of effort?
- Will a quantitative estimate of uncertainty improve the decision? How will the regulatory decision be affected by this variability and uncertainty analysis?
- What types of skills and experience are needed to perform the analysis?
- Have the weaknesses and strengths of the methods been evaluated?
- How will the variability and uncertainty analysis be communicated to the public and decision-makers?

Questions like these might be helpful when deciding whether to undertake the challenge of a full probabilistic analysis or not. One must keep in mind that this kind of analysis is to a high degree both time- and resource consuming.

The challenge of communicating the results of an assessment to the different stakeholders is an issue that is discussed in some detail in the guidelines. The main idea is that a risk assessor always should aim at presenting quantitative results in a manner that will clearly communicate the information they contain. This since, despite the quantitative nature of an analysis, the insights that can be made from the analysis generally tend to be more qualitative in nature. The guideline provides some examples of useful (qualitative) insights that can be made on the basis of a quantitative uncertainty and variability analysis.

- An appreciation of the overall degree of variability and uncertainty and the confidence that can be placed on the analysis and its findings.
- An understanding of the key sources of uncertainty and their impact on the analysis.
- An understanding of the critical assumptions and their importance to the analysis and findings.
- An understanding of the unimportant assumptions and why they are unimportant.
- An understanding of the extent to which plausible alternative assumptions or models would affect any conclusions.
- An understanding of key scientific controversies related to the assessment and a sense of what difference they might make regarding the conclusions.

The question remains, are these insights necessary for making the decision? There might (often most certainly will) be cases when the probabilistic approach will not be necessary or even appropriate, bearing in mind the efforts involved. For example, screening calculations may show that risks are clearly below levels of concern, or the costs of remediation are so low that one might use the “better safe than sorry” principle without worrying about cost effectiveness. On the other hand, probabilistic methods may be called for in a number of other situations, e.g. when screening methods using conservative point estimates produces results above levels of concern, or when the cost of remediation is high. Ultimately, as stated in the guideline, whether or not to perform a probabilistic uncertainty and variability analysis is a matter of judgement.

1.2 Guideline for quantitative risk assessment: Instructions for a quantitative risk analysis in the Netherlands

This section is based upon an article by Uijt de Haag et al (1999). The Dutch “Guideline for quantitative risk assessment” provides the method for performing a QRA in the process industry in compliance with the regulations in the Netherlands, and specifically it provides an overview of various starting points and basic data to be used in the analysis. This approach, where the regulatory body prescribes all the important models and data to be used in an analysis, differs from most attempts to provide guidelines for quantitative risk analysis. As far as uncertainty is concerned it would not be unfair to say, that with this approach the regulatory body accepts responsibility for any uncertainties in the results of an analysis.

The background to this approach could be captured, at least to some extent, by a statement in Uijt de Haag et al (1999): “If the results of a QRA are to be used in the decision making process, they must be verifiable, reproducible and comparable. These requirements necessitate that QRA’s are made on the basis of similar starting points, models and basic data. Ideally, differences in QRA results should only arise from differences in process- and site specific information.”

In the Netherlands several guiding documents have been published, aiming mainly at the problem of comparability between assessments, e.g. the “Red book”, the “Green book”, and the “Yellow book”, (ref 1.2,1.3,1.4). The “Guideline for quantitative risk assessment” is intended to be the assembling document, making use of experiences gathered in conducting quantitative risk analyses using the former documents.

The specific feature of this guideline is that it provides not only detailed guidance on QRA calculations, but also provides default values for the inputs. As a risk assessor conducting a risk analysis you might to some extent deviate from the recommendations given in the guideline if site specific information demands it. However, any deviations should be approved by the competent authorities, and they should be clearly motivated in the QRA report.

The guideline follows in most parts the process of conducting a QRA. It starts with a method for selecting installations that contribute to the risk (based on the amount of substance, dangerous properties of the substance, process conditions etc). Then a description of default set of LOCs (Loss of Containment events), guidance on the calculation of outflow and dispersion of substances, as well as guidance on calculation of consequences is presented. Guidance on presentation of the results is also given.

As stated earlier, the guideline provides a default set of LOCs that should be included in an analysis, but it also provides the frequencies for these LOCs to be used in calculations. The different LOCs include generic LOCs (corrosion, construction errors etc), external impact LOCs, loading and unloading LOCs, and specific LOCs. The LOCs included in the guideline are related to stationary tanks and vessels, pipes, pumps, heat exchangers, pressure relief devices, warehouses, and the presence and loading/unloading of road tankers, tank wagons and ships. As an example, LOCs for atmospheric tanks and their frequencies are shown in figure 1:

Table 2. LOCs for atmospheric tanks and their frequencies, where catastrophic failure is to be modelled as an instantaneous release of the complete inventory (probability 0.5) and as a continuous release of the complete inventory in 10 minutes (probability 0.5), while a leak is to be modelled as a hole with an effective diameter of 10 mm.

Tank	Catastrophic failure*	Leak*
Single containment tank	1×10^{-5} y^{-1}	1×10^{-4} y^{-1}
Tank with protective outer shell	1×10^{-6} y^{-1} + (1×10^{-6} y^{-1})	(1×10^{-4} y^{-1})
Double containment tank	2.5×10^{-8} y^{-1} + (1×10^{-7} y^{-1})	(1×10^{-4} y^{-1})
Full containment tank	1×10^{-8} y^{-1}	-
In-ground tank	(1×10^{-8} y^{-1})	-
Mounded tank	1×10^{-8} y^{-1}	-

* Frequencies correspond to a release directly to the atmosphere and values in parentheses denote a release to an unimpaired secondary container, leading to pool evaporation only.

Fig. 1 Example of suggested LOCs in the Dutch guidelines, Uijt de Haag et al (1999)

This kind of information is available also for the other types of LOCs that are included in the guidelines. It should be mentioned that the standard values for this type of data usually are set by consensus following discussions between representatives from industry, the competent authorities and the central government of the Netherlands. Several chapters in the guidelines have an attached appendix, where a record of the reasoning leading to the specific data is presented. This is an important part of the guideline, as far as transparency is concerned. It should also be mentioned, however, that management factors related to failure frequencies are not included in the estimations at this time.

In the same manner, models to calculate outflow and dispersion following a LOC, as well as models to calculate the damage and effects following the release, is given in the guideline. The same rule applies here, a risk assessor should use these models unless he/she is has access to a model that will more successfully describe the situation at hand. In fact the guideline encourage the use of improved models, provided that the scientific performance of the model, i.e. results of validation exercises, model inter-comparison studies and/or publications, has been demonstrated to the competent authority. Future research to improve the guidelines will focus on updating the failure frequencies and the application of management factors in the models.

1.3 U.S. NRC Regulatory Guide 1.174 “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis”

The background of this regulatory guide is the following policy statement, ref. /1.6/, adopted by the NRC (Nuclear Regulatory Commission) in august 1995, regarding the expanded use of PRA as a tool in regulatory decisionmaking:

- The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

- PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state of the art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. /…/ Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

- PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on need for proposing and backfitting new generic requirements on nuclear power plant licensees.

The objective of the regulatory guide, the use of which is voluntary, is to provide general guidance on an approach determined by the NRC to be acceptable for analyzing the risk associated with plant design and operation as a consequence of proposed changes to a plant’s licensing basis, LB.

The NRC has identified a four-element approach to evaluating proposed LB changes, presented in figure 2:

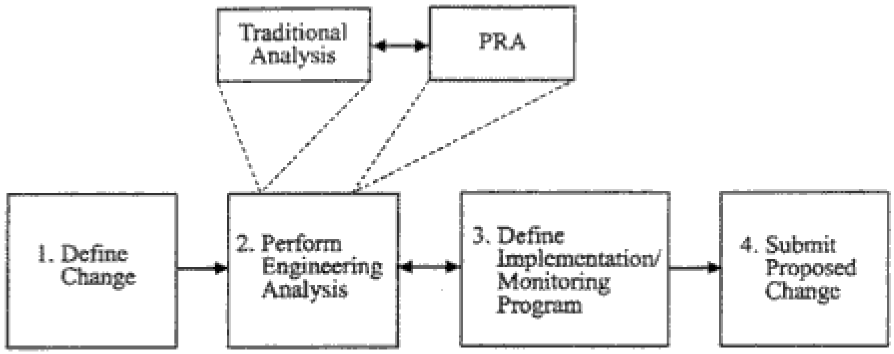

Fig. 2 Principal elements of risk-informed, plant-specific decisionmaking, ref. /1.5/.

The element of highest interest to this project is the second, performance of engineering analysis. It is this element that will be further discussed here, with focus on the probabilistic risk analysis, PRA, and uncertainties.

The main focus of this element is to evaluate the change in core damage frequency and large early release frequency, due to the proposed change, using quantitative PRA. It should be mentioned though that there might be situations where a qualitative assessment is sufficient as a basis for decisionmaking.

The guide includes a substantial, three part discussion on the use of quantitative PRA results in the decision making process. The first part deals with the scope, level of detail, and quality of the PRA, and one over-riding requirement is that the PRA should realistically reflect the actual design, construction, operational practices, and operational experience of the plant. The scope and level of detail required is to great extent situation specific. Regarding the required quality of the PRA, where quality is defined as a measure of the adequacy of the actual modeling, some approaches recommended in the guide include performance of peer review of the PRA, industry certification programs, and cross-comparison studies.

The second part of the discussion is about acceptance guidelines to be used in the decision making process. This will not be further examined here, other than that they are not intended to be overly prescriptive, but merely serve as an indication, in numerical terms, of what is considered acceptable.

The third part of the discussion is that of most interest for this project, the characterization of impact of uncertainty in the analysis. The guideline emphasizes the importance that these uncertainties be recognized and addressed in the analysis. Extensive guidance is given on how to address these kinds of uncertainty in the decision making process.

Firstly, different types of uncertainty and some methods of analysis are discussed. The two main types of uncertainty discussed are aleatory (stochastic) and epistemic (knowledge based) uncertainty. It is stated: “The aleatory uncertainty is that addressed when the events or phenomena being modeled are characterized as occurring in a "random" or "stochastic" manner, and probabilistic models are adopted to describe their occurrences. It is this aspect of uncertainty that gives PRA the probabilistic part of its name. The epistemic uncertainty is that associated with the analyst's confidence in the predictions of the PRA model itself, and it reflects the analyst's assessment of how well the PRA model represents the actual system being modeled. This has been referred to as state-of-knowledge uncertainty. In this section, it is the epistemic uncertainty that is discussed; the aleatory uncertainty is built into the structure of the PRA model itself", ref /1.5/.

Further, the guide outlines three classes of uncertainty that generally are characterized and treated in different ways, parameter uncertainty, model uncertainty, and completeness uncertainty. Completeness uncertainty could be looked upon as one aspect of model uncertainty, but due to its importance it is still discussed separately.

"Parameter uncertainties are those associated with the values of the fundamental parameters of the PRA model, such as equipment failure rates, initiating event frequencies, and human error probabilities that are used in the quantification of the accident sequence frequencies. /…/ It is straightforward and within the capability of most PRA codes to propagate the distribution representing uncertainty on the basic parameter values to generate a probability distribution on the results", ref. /1.5/.

Model uncertainty is described as follows: "In many cases, the industry's state of knowledge is incomplete, and there may be different opinions on how the models should be formulated. /…/ This gives rise to model uncertainty. In many cases, the appropriateness of the models adopted is not questioned and these models have become, de facto, the standard models to use. /…/ For some issues with well-formulated alternative models, PRAs have addressed model uncertainty by using discrete distributions over the alternative models, with the probability associated with a specific model representing the analyst's degree of belief that that model is the most appropriate. /…/ Another approach to addressing model uncertainty has been to adjust the results of a single model through the use of an adjustment factor. However it is formulated, an explicit representation of model uncertainty can be propagated through the analysis in the same way as parameter uncertainty. /…/ In interpreting the results of a PRA, it is important to develop an understanding of the impact of a specific assumption or choice of model on the predictions of the PRA. This is true even when the model uncertainty is treated probabilistically, since the probabilities, or weights, given to different models would be subjective. The impact of using alternative assumptions or models may be addressed by performing appropriate sensitivity studies, or they may be addressed using qualitative arguments, based on an understanding of the contributors to the results and how they are impacted by the change in assumptions or models. The impact of making specific modeling approximations may be explored in a similar manner", ref /1.5/.

Completeness uncertainty is not regarded as an uncertainty in itself, but a reflection of scope limitations. Completeness uncertainty is problematic, in the sense that it reflects an unanalyzed contribution to the overall uncertainty, which makes it difficult (if not impossible) to estimate its magnitude. Some ways available to handle completeness uncertainty are discussed in the guide: " The issue of completeness of scope of a PRA can be addressed for those scope items for which methods are in principle available, and therefore some understanding of the contribution to risk exists, by supplementing the analysis with additional analysis to enlarge the scope, using more restrictive acceptance guidelines, or by providing arguments that, for the application of concern, the out-of-scope contributors are not significant", ref /1.5/.

1.4 Council Directive 96/82/EG (SEVESO II)

This section is based on the document "Guidance on the preparation of a safety report to meet the requirements of Council Directive 96/82/EC (SEVESO II)", ref. /1.7/. The intention of the "SEVESO II"-directive is to prevent major accident hazards involving dangerous substances, and should one occur, limit the consequences thereof in a consistent and cost effective manner. One of the main measures in the directive to reach this goal is the requirement of a "Safety report". The guidance itself is not legislation and should not be considered mandatory.

The guidance provides no explicit information on how to treat uncertainty while performing the risk analysis that is to be included in the safety report, but the mere existence of the guideline could be looked upon as a way of handling some kind of uncertainty, e.g. uncertainty related to scope and completeness of the analysis. In this section a brief summary of the guideline will be presented, along with some comments related to the issue of uncertainty.

The guideline prescribes that the safety report should contain general information on the purpose of the establishment, main activities and production, and general statements regarding its main hazards due to relevant substances and processes. Other main features that are required are descriptions of the management and organization, location, layout of the establishment, the environment and surroundings of the establishment, dangerous substances (e.g. types and quantities), and hazardous installations and activities (e.g. processes, storage, loading/unloading). For each of these components detailed guidance on what is to be included in the report is provided.

In order to meet the directive the operator of an establishment is required to demonstrate that the major accident hazards are identified and the risks associated with the establishment are assessed. This means that the safety report should include the results of a hazard analysis and risk assessment, in terms of identification of hazard sources, relative likelihood of major accidents and their consequences. This is the part of the guidance that is of most interest to this project.

The guidance provides no specific inputs on what approach to adopt and what models to use in the risk assessment[3], and there is no specific requirement that the assessment should be quantitative. However, independent of the approach adopted, the analysis should achieve the four objectives of:

- Identification of the safety relevant sections (installations or parts of an installation);
- identification of the hazard sources;
- assessment of the consequences of potential major accidents, and
- assignment and assessment of adequacy of the prevention, control and mitigation measures.

[3] Examples of methodologies are given in the annex of the guidance

A possible procedure for conducting the hazard analysis, or risk assessment, is presented in the guidance. It is a three step procedure where step A focuses on identification of safety relevant sections, using experience from past accidents, Hazard Index methods, or other suitable methods. Step B aims at identifying those hazard sources, linked to for instance operation (human errors, technical errors etc), external events, security, or other causes related to design, construction, and safety management, which may cause a major accident in a safety relevant section. Step C, finally, focuses on prevention, control and mitigation measures, using risk principles such as ALARA (As Low As Reasonably Achievable). For these three steps, detailed information on important elements is given in the guidance. As stated earlier, the guidance provides no explicit information on how to uncertainty in the analyses.

1.5 Discussion

In many areas where risk analysis is an issue there has been a change in the past decades from strictly deterministic approaches to more probabilistic ones, see for instance Thoft-Christensen & Baker (1982), chapter 1. This development is due to the fact that there are substantial uncertainties related to the point estimates generated from a deterministic approach, uncertainties that has to be dealt with if a risk analysis is to be useful in the decision making process.

In this first part of the report a couple of different documents regarding risk assessment have been briefly presented. One can discern fundamentally different approaches when it comes to providing guidance on how to produce scientifically sound and useful risk analyses. The Dutch approach, for instance, to provide default values to all parameters and prescribe the models to be used in the assessment means that the regulatory body in a way accepts responsibility for any uncertainty involved in an assessment and the consequences they might have on the regulatory decision. This approach has strong advantages when it comes to consistency in risk related decisionmaking, since assessments using the same models and variable values will be comparable. On the other hand, it is my belief that this approach might have negative impacts on the scientific progress regarding development of new models to be used in risk assessment, as well as a risk assessor's motivation for looking up situation specific data to use in his/her analysis. As far as uncertainty is concerned, this type of deterministic approach will always suffer from substantial uncertainties and, as stated before, it seems to me that the objective of this guideline is to make it possible to make consistent decisions, and not to try to reduce uncertainty in the analyses.

The U.S. EPA policy for use of probabilistic analysis in risk assessment appropriates a somewhat different approach. It focuses more on providing conditions to be met in an assessment to ensure high quality science, regarding transparency, reproducibility, and the use of sound methods. It also recognizes the fact that there are situations where a fully probabilistic approach is not called for, and it provides guidance on how to decide whether to go through with a PRA or not. Since the main objective of this policy and guideline is to define methods for characterizing, quantitatively, the variability and uncertainty of a risk estimate, to identify the main sources of variability and uncertainty, and their relative contribution to the overall variability and uncertainty in the results, extensive guidance on probability distribution selection, presentation of the result etc is given. The strength of this approach, from a scientific point of view, is that it does not "pin down" any specific methods, but highlights the importance of transparency and of being explicit about the methods and inputs used in an assessment. From a decision-maker's point of view, though, this approach is more demanding than for instance the Dutch approach.

The U.S. NRC regulatory guide is explicit in the sense that it discusses different types of uncertainty, i.e. epistemic and aleatory uncertainty, as well as different classes of uncertainty, parameter uncertainty, model uncertainty, and completeness uncertainty. The "Seveso II"-directive and appurtenant guideline, on the other hand, does not provide any explicit guidance on treatment of uncertainty, but focuses on the scope of the analysis and therefore helps in reducing completeness uncertainty.

PART 2 – STANDARDS FOR RISK ANALYSIS AND MANAGEMENT

2.1 Standards under study

The objective of this phase of the project, i.e. the study of standards for risk analysis, is to generate some kind of understanding of how issues of uncertainty, and its impact on the result and on the use of the analysis, are dealt with in today's practice. The choice of standards for review is based on their applicability in a wide range of areas. More specific standards aiming at just one area, such as nuclear energy, medicine, or fire protection has intentionally been left out to narrow the scope of the report and to keep it universal. In this chapter, the selection of standards will be briefly presented.

2.1.1 Norwegian Standard NS 5814

The Norwegian Standard NS 5814, Requirements for risk analyses /2.1/, was prepared by the Norwegian Standardisation Association and this first edition was published in 1991. The field of application for the standard is wide with some examples of intended use listed in the introduction section as follows:

> "-a guideline for the planning, execution and use of risk analyses
> -a basis for specifying quality requirements for risk analyses
> -a basis for evaluation of completed risk analyses"

In a note in the introduction section of the standard, it is pointed out that the committee IEC/TC 56 is preparing a corresponding International Standard and that the intention is to replace the NS 5814 with a new edition when the International Standard has been published. It has not come to my knowledge that this standard has been replaced yet, though the IEC-document was published in 1995.

The IEC International Standard is one of the standards under review in this report, see section 2.1.4.

2.1.2 DS-Information DS/INF 85

This first edition of the DS-Information DS/INF 85: Risk Analyses, requirements and terminology /2.2/, was published in 1993. By the time of publishing it did not have status as a Danish Standard, but is still reviewed in this report since it provides a good description of the risk analysis process.

The main purpose of the DS/INF 85 is, as stated in the English summary: "to assure a high quality of risk analyses as they are carried out in a wide range of applications, while more detailed, descriptive guidelines might be obtained in the various areas separately."

2.1.3 European Standard EN 1050

The European Standard EN 1050:1996 /2.3/: Safety of machinery - Principles for risk assessment, was prepared by Technical Committee CEN/TC 114 “Safety of machinery”, and shall be given the status of a national standard in the countries of the European Community. The scope of the standard is to establish general principles for risk assessment related to the design and use of machinery during all the phases of the life of the machinery.

2.1.4 IEC International standard nr 60300-3-9

The IEC International standard nr 60300-3-9, Dependability management- Part 3: Application guide- Section 9: Risk analysis of technological systems /2.4/, plays a central role in this study. Many of the other standards under review here somehow connect to the IEC-document. Some of them, like the BS 8444 (section 2.1.5) and AS/NZS 3931 (section 2.1.6), have been reproduced directly from the IEC-document, and others, like NS 5814 (section 2.1.1), are referring to it in some way.

In the scope section of this standard it is stated that: “The objective of this standard is to ensure quality and consistency in the planning and execution of risk analyses and the presentation of results and conclusions.” Further it is stated:

“This section of IEC300-3 is applicable as:

> -a guideline for planning, executing and documenting of risk analyses;
> -a basis for specifying quality requirements for risk analyses (this can be particularly important when dealing with external consultants);
> -a basis for evaluating risk analyses after completion.”

The following two standards are identical with the IEC-document.

2.1.5 British Standard BS 8444

The British Standard BS 8444, Risk management, Part 3 Guide to analysis of technological systems - application guide /2.5/, published 1996, was prepared by Technical Committee DS/1, and is a reproduction of the IEC-document presented in section 2.1.4. Since the two documents are identical they will be treated as one in this report.

2.1.6 Australian/New Zealand Standard AS/NZS 3931

The Australian/New Zealand Standard AS/NZS 3931, Risk analysis of technological systems - application guide /2.6/, published 1998, was prepared by Joint Technical Committee MB/2 - Risk Management, and is a reproduction of the IEC-document presented in section 2.1.4. Since the two documents are identical they will be treated as one in this report.

2.1.7 Australian/New Zealand Standard AS/NZS 4360

This and the following standard are somewhat different from the others in the aspect that they focus on the risk management process rather than on just the execution of risk analyses.

The Australian/New Zealand Standard AS/NZS 4360, Risk Management /2.7/, was prepared by the Joint Standards Australia /Standards New Zealand Committee OB/7 on Risk Management and was published in 1995.

The objective of this standard is to provide a generic framework for identification, analysis, assessment, treatment and monitoring of risk.

2.1.8 Canadian Standard CAN/CSA-Q850

The Canadian Standard CAN/CSA-Q850-97, Risk management: Guideline for Decision-Makers /2.8/, was prepared by the CSA Technical Committee on Risk Management and published in 1997.

This guideline focuses on needs and motives of the different stakeholders in the risk management process. The definition of a stakeholder in this standard is: “individuals, groups, or organisations who are able to affect, who are affected by, or believe they may be affected by, a decision or activity.” This document bring an important issue to discussion, that of perception of risks. The following passage from the Introduction section gives a good indication on the sprit of the document:

“Risk involves three key issues:

(a) the *frequency* of the loss, that is, how often the loss may occur;
(b) the *consequences* of the loss, that is, how large the loss might be; and
(c) the *perception* of the loss, that is, how a potential risk is viewed by affected stakeholders in terms of its effect on their needs, issues, and concerns.

Because there is a need to understand how a potential loss might affect and be perceived by the various stakeholders, it is insufficient, and indeed can be quite misleading, for the decision-maker to consider risk solely in terms of probability and consequence.”

In Appendix 2 of CAN/CSA-Q850 there is an insightful description of the problem of uncertainty, although it is not a mandatory part of the guideline.

2.2 General features

In this section some general statements regarding uncertainty, reappearing in almost all reviewed standards, will be presented and discussed. Every subsection, each of which deals with one specific feature, contains a description of the statements in the standards, followed by a brief discussion. In Appendix 2 there is a comparative summary of statements on uncertainty in the standards under study.

2.2.1 Presuppositions and assumptions

All of the standards under review in some way recognises the necessity to make different kinds of assumptions, presuppositions and simplifications when performing a risk analysis, whether quantitative or not. The need for presenting/discussing these assumptions, presuppositions and simplifications is clearly stated.

The general intention with summarising all the assumptions, presuppositions and simplifications made in connection with the analysis in the result report is to ensure that validity and limitations of the risk analysis are made clear to the decision-maker. Failure to do so will possibly lead to miss-informed decisions. The decision-maker thinks he/she sees the whole picture when that just isn't the case. Most presuppositions and assumptions will originate from knowledge based (epistemic) uncertainty. Since you don't have all the information you need to describe your system you have to assume some things to be able to give at least a subjective opinion on what your system is like. More information on different kinds of uncertainty is given in chapter 3.2.

2.2.2 Procedure and methods

Describing the procedure and methods used in the execution of the risk analysis constitutes one of the major issues in the reviewed standards. Apart from just describing the procedure and methods used, several of the standards also point out the importance of stating the reasons behind the choice of methods and procedure, with regard to relevance and suitability. A majority of the standards also states that any uncertainty resulting from the procedure and methods shall be assessed in some way.

The choice of procedure and methods for the risk analysis may well be the most important phase of the analysis. Putting some effort into this task will provide a good basis for keeping uncertainties in the results of the analysis at a minimum. A key factor in selecting an appropriate 'safety technique' is the objective of the analysis. This issue is briefly discussed in Harrami et al (2000). Should there be doubt as of the relevance or suitability of the chosen procedure and methods for the specific site/situation that one want to study, alternative methods must be sought and the results generated with the different methods compared. Another aspect of the choice of methods is the availability of data, see section 2.2.3. Limited availability to hard data may to great extent govern the range of possible methods to use in the analysis.

2.2.3 Data / sources of data

The issue of available data, and the status of the sources of used data, are given a central position in statements regarding uncertainty in the standards under study. It is stated in all of them that the sources of data shall be described and documented in the analysis report. It is also stressed that any uncertainty resulting from the data used in the analysis should somehow be assessed or at least discussed. Assessing these uncertainties ranges from evaluating the relevance of the data used, to performing full uncertainty propagation through the used models, se section 2.3.4. It is also recognised in some of the standards that data that are no longer relevant to the present situation should be identified and excluded from use in the analysis.

The main concern when searching for adequate data for a risk analysis is that of data being suitable for the particular application. Even if one had access to "perfect" data regarding the systems behaviour in the past, one would have to assume that the past will repeat itself exactly in the future to be able to place complete trust in predictions based on historical data. In the ideal case, all data used in the analysis would be based on the specific circumstances that apply to the object/situation under analysis. In most cases, however, such data doesn't exist, raising the need for use of data of a generic nature or expert judgement. A lot of work has been done on eliciting-techniques for expert opinions regarding probability distributions of unknown variables, see for instance Morgan & Henrion (1990) and Paté-Cornell (1996). This will be further discussed in chapter 3.5.

The remark that data that are no longer relevant to the present situation should be identified and excluded from use in the analysis highlights a fundamental insight in all risk management work. The risk analysis is (or at least should be) an ongoing process generating a living document, where efforts are continuingly made to identify and reduce uncertainties.

2.2.4 Causal analysis

The causal analysis, where the main concern is to estimate the probability or frequency for the undesired events, is mentioned in all of the standards for risk analysis. The general opinion seems to be that the causal analysis should be based on the selected undesired events and that those possible chains of events that might lead to the undesired events should be identified and described.

As stated in IEC 300-9-3, three commonly used techniques to estimate event frequencies are:

"a) to use relevant historical data;
b) to derive event frequencies using analytical or simulation techniques;
c) to use expert judgement"

In most cases, if possible, all three techniques should be used jointly since they complement each other by having their strengths in different areas. If used jointly, they can work as independent checks on each other, which may increase confidence in the results.

However, all of these techniques are afflicted with various uncertainties. For instance, the use of historical data to estimate the frequency of upcoming events requires a substantial database to provide good representation of the activity under consideration. And, as mentioned before, even if one has got access to such a database, by using it to estimate the frequency of future events, one has to assume that history will repeat itself in the future. Most activities that are subject to risk analysis are dynamic, giving us problems regarding whether the variables that affected the events of the past actually will affect the future events. They might, but we can't be sure, and this will bring uncertainty to the results.

The use of experts to estimate frequencies of undesired events, on the other hand, will by nature bring subjective judgement into the picture. A brief discussion on expert judgement is to be found in section 3.5.

Almost all of the standards require some treatment, or at least a discussion, of the uncertainties involved with estimating frequencies of undesired events. As stated in the Canadian Standard CAN/CSA-Q850:

"What usually results from this analysis is an expected range of frequencies with some estimate of uncertainty, rather than a single number."

2.2.5 Consequence analysis

The analysis of the severity of the undesired events is a field where the uncertainties involved will be considerable, independent of whether the consequences are measured in health, environmental or economical terms. This is something that has been acknowledged in almost all of the standards on risk analysis in the study, either by stating that uncertainty in any consequence calculations due to the data and models used shall be discussed, or by just pointing out that care should be taken to ensure that the methods and models used are appropriate to the specific situation being considered.

The uncertainty connected to the consequence analysis has its origin in several sources. When performing a consequence analysis one often makes use of models of various complexity, for example gas transport-, toxicity- or dose-response models. All these models are merely approximations of the real world, which will inevitably bring uncertainty into the results of the analysis. Uncertainty generated from the models used in an analysis will be briefly discussed in section 3.1.3. Another major source of uncertainty in the consequence analysis is the data used, see sections 2.2.3 and 3.1.2.

2.2.6 Presentation of the results / conclusion

Regarding the presentation of the results and the conclusions drawn from the analysis, all of the reviewed standards to some extent require that the issues dealt with in the previous sections be clearly documented. Uncertainties in the result due to used data, models and methods shall be discussed.

It is of great importance to present in a structured manner on what basis conclusions have been drawn, and what uncertainties have been involved in the process. A comprehensive and explicit presentation will make sure that no “hidden truths” lies behind the results. It should always be possible for someone who did not participate in the execution of the analysis, or the preparation of the analysis report, to review the report and get a complete understanding of the uncertainties involved in the results which are to be used as foundation for decisions.

2.3 Specific features in some selected standards

This section will concentrate on an extract of statements that turn up only in one or two of the standards, but still provides an insightful point of interest in the matter of uncertainty. The disposition of this section will be just like the previous one. Every subsection, each of which deals with one specific feature, will contain a description of the statements in the standard, followed by a brief discussion.

2.3.1 Planning of risk analysis

The Norwegian Standard NS 5814 /2.1/ recognises the importance of "getting started". It is stated that: "The risk analysis shall be initiated early enough for the results to be available where the decisions in question are to be made". Further on it is stated: "The work will be initiated early enough for the time limits for the analysis to be reasonable. Pressures caused by time and cost considerations often result in idealized calculations and that analyses of sensitivity and uncertainty are not carried out."

These apprehensions posses substantial relevance in real life situations where matters of time limits and economic reality constitute the framework within which the work of the analyst or team of analysts is bound. When starting the analysis one should, if possible, make it clear what level of uncertainty analysis that is needed for bringing sufficient credibility to the results to be used in the decision-making process. Let's not forget that performing a "state of the art" uncertainty analysis is nearly always time- as well as money consuming. Maybe the decisions to be made using the risk analysis as a foundation doesn't require a full uncertainty analysis, e.g. when the "worst case" risk scenario generates an overall risk that is acceptable to the decision-maker. Different levels of treatment of uncertainties will be further discussed in chapter 3.3.

Naturally there are other issues, relevant for the quality of an analysis, related to the planning of a risk analysis, such as the constitution and competence of the analyst team, but these will not be further discussed here.

2.3.2 Description of subject for analysis

A couple of the standards under review, se appendix 2, recognise the necessity of making models of the system to describe reality. They also state that this will bring uncertainty into the process.

When describing the subject for analysis by making conceptual and/or mathematical models to represent it, it is inevitable to make considerable simplifications of reality. Simplifications and approximations will always introduce uncertainties into the results of an analysis. This is not an entirely bad thing, the trick is to find rational ways of treating these uncertainties so that their impact will not affect the credibility of any decisions made using the analysis, see chapter 3.1.3.

2.3.3 Sources of uncertainty

The IEC 300-3-9 International Standard /2.4/, and of course the ones reproduced from the IEC-document, states that sources of uncertainty should be identified where possible.

Knowing the sources of uncertainty in the analysis is helpful in that it will be possible treat uncertainty in a structured manner. Uncertainty may arise for fundamentally different reasons, for example there is uncertainty due to natural variability in the analysed system (stochastic uncertainty), or uncertainty may occur because we don't know enough about the system being analysed (knowledge uncertainty). The Guidelines for Chemical Process Quantitative Risk Analysis (1989) provides an exhaustive list of sources of uncertainty in analyses of chemical process industry.

Sources of uncertainty will be more thoroughly discussed in section 3.1. Different types of uncertainty, and the possible need for separation of uncertainties will be discussed in section 3.2.

2.3.4 Uncertainty propagation

The IEC 300-3-9 International Standard /2.4/ bring up the subject of uncertainty propagation: "Estimating uncertainty consists of translating uncertainty in the crucial parameters into uncertainty in the outputs of the risk model. The completeness and accuracy of the risk estimation should be stated as fully as possible".

Numerous techniques has been developed for this purpose, ranging from analytical methods, like approximation from the Taylor Series, for simple cases, to Monte Carlo and other sampling methods, when the models used get to complex for analytical methods, see for instance Granger Morgan (1990). Different techniques for uncertainty propagation will be thoroughly examined and presented in a subsequent report.

2.3.5 Sensitivity analysis

The IEC 300-3-9 International Standard /2.4/ also recognise the use of sensitivity analysis to determine which parameters influence the model output the most: "Sensitivity analysis involves the determination of the change in response of a model to changes in individual model parameters". It is also stated that the sensitivity analysis should be documented and presented in the analysis report.

Sensitivity analysis has a connection to uncertainty propagation, discussed in section 2.3.4, since it provides a method for distinguishing which parameters should be taken under consideration for uncertainty propagation. Different techniques for sensitivity analysis will be thoroughly examined and presented in a subsequent report.

2.3.6 Presentations of results and conclusions

In this section, some specific statements regarding the presentations of results will be discussed.

In the IEC-document /2.4/, it is stated that: “Uncertainty surrounding the estimates should be set out in language appropriate to the intended reader.”

This is something that should be all the time present while working with the analysis. Who is the analysis for? What decisions are to be made based the analysis? The answer to questions like these provides considerable guidance on what level of uncertainty analysis that is required, and what methods to use when performing the uncertainty analysis and presenting the results.

The Norwegian and Danish standards states that: “If possible the uncertainty shall be quantified.”

When performing a quantitative analysis, there are mainly two paths that you can walk. Either you take on the deterministic approach, presenting your results as single estimates based on e.g. a credible worst scenario. The alternative, which is becoming more and more frequent, is to perform a probabilistic analysis, resulting in a probability distribution of the risk. When performing a probabilistic risk analysis there is a variety of methods for treating and presenting uncertainty quantitatively. Different methods of doing this, along with some non-probabilistic methods, e.g. interval analysis and fuzzy arithmetic, will be presented in a subsequent report in this project.

2.4 Discussion

A general conclusion to be drawn from this study is that all the standards under review to some extent recognises and appreciates the problems of dealing with uncertainty when performing a quantitative risk analysis. Although they do not provide any substantial information on how to treat uncertainty explicitly, some insights on the phenomena itself can be drawn when studying these documents. Fig. 3 shows a schematic summary of the statements regarding uncertainty that occurred in almost all of the standards.

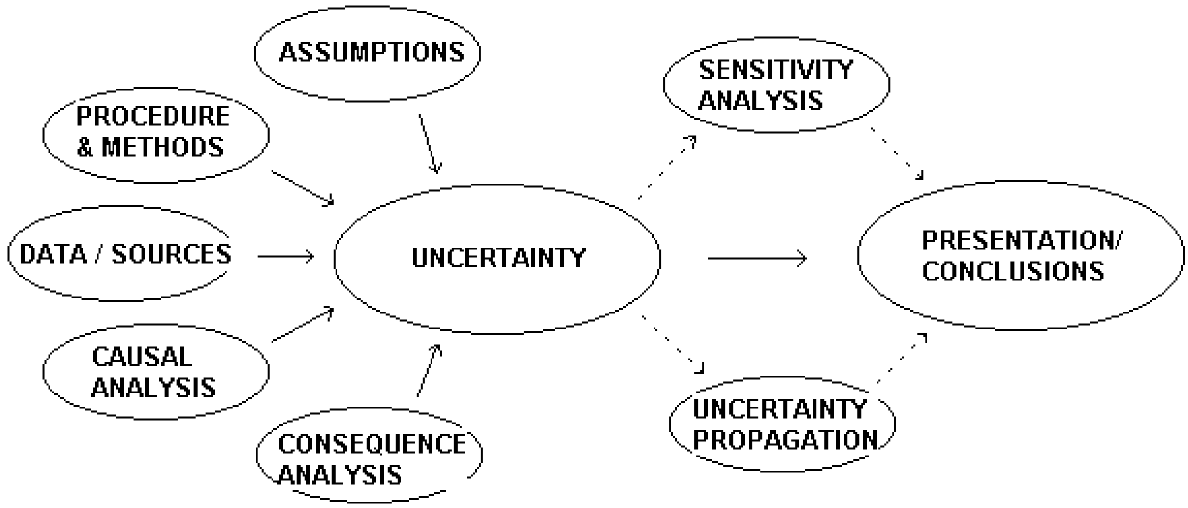

Fig. 3 Schematic summary of the statements regarding uncertainty to be found in the standards under review.

According to the standards, the different parts of the risk analysis process that generates uncertainty are the choice of procedure and methods for the analysis, any assumptions made during the process and data/sources of data used in the analysis. The causal analysis and the consequence analysis are really just the two main steps of the overall risk analysis, where the three former parts introduce uncertainty.

The two main tools for assessing uncertainty, given in the standards, are sensitivity analysis and uncertainty propagation. The sensitivity analysis, where the impact on the final result that a change in each of the different variables involved are examined, is a well established method in various areas such as engineering and economics. By finding out which parameters that are most sensitive to change, one has a good indicator on where to focus the attention when trying to reduce uncertainty. The concept of uncertainty propagation is really just a way to find out and quantify how uncertainty in the data used is transferred through the model and reflected in the results. Various methods for sensitivity analysis and uncertainty propagation will be further examined within the frames of this project and presented in a subsequent report.

The presentation phase of the analysis process is given a great deal of attention in most of the standards. The importance of thorough documentation can’t be neglected but perhaps the most important thing is to be able to present the results and the underlying assumptions etc in a way that is comprehensible for the intended reader. There is really not much use for analyses that are not completely understood by the decision-makers, no matter how sophisticated they are. The whole point of uncertainty analysis is to make sure that decisions are based on the most “accurate” knowledge available.

Even though the standards reviewed in this study provide some basic insights on the phenomena of uncertainty, there are several aspects of the matter that are not covered by these documents. In the following chapters, a couple of fundamental issues regarding uncertainty in general, such as sources of uncertainty, different types of uncertainty and the role of expert judgement, are briefly presented. Since the objective of this introductory study is to generate a platform for further studies in this area, the following discussions will not be exhaustive, but merely serve as indicators on which topics that will require specific attention within the project.

PART 3 – GENERAL DISCUSSION

3.1 Sources of uncertainty / Classes of uncertainty

3.1.1 General

To help understanding the concept of uncertainty, and to be able to treat uncertainties in a structured manner, many attempts have been made to characterise classes of uncertainty and the underlying sources of uncertainty. In this section a brief summary on classes/sources of uncertainty to be found in literature is presented.

In Parry (1998) the perhaps most traditional decomposition of classes of uncertainty is displayed. The three major groups of uncertainty from this point of view are parameter uncertainty, model uncertainty and completeness uncertainty. Parameter uncertainty, which is introduced when the parameter values for the used models are not known perfectly, is often dealt with by assigning probability distributions to the parameters, representing the analyst's state of knowledge about them. Parameters used in a model could also by subject to natural variability, which is treated the same way. Model uncertainty raises from the fact that any model, mental or mathematical, will inevitably be a simplification of the reality it is designed to represent, whereas completeness uncertainty originates from the fact that not all contributors to risk are addressed in PRA models. For example, it will not be feasible to cover all possible initiating events in a PRA. Rowe (1994) presents a conceptually different approach, where the decomposition of uncertainty into four classes is recommended. The classes of uncertainty are: temporal, i.e. uncertainty in future and past states, structural, i.e. uncertainty due to complexity, metrical, i.e. uncertainty in measurement, and translational, i.e. uncertainty in explaining uncertain results.

Knowing the sources of uncertainty involved in the analysis plays an important role in the overall treatment of uncertainty. First of all, different kinds of uncertainty call for different methods of treatment, which will be briefly discussed in section 3.2. Another aspect is the possibility for reducing uncertainty. If one knows why there are uncertainties and what kinds of uncertainties are involved, one has better chance of finding the right methods for reducing them.

3.1.2 Data/Parameter uncertainty

The data used in any kind of quantitative analysis is a potential source of considerable uncertainty. The far most common approach in quantitative risk analysis is to make use of historical data collected from the system, or a similar system, that one want to analyse. This approach is afflicted with two major sources of uncertainty. Firstly, one has to have access to a fairly extensive database in order to assume that the data really gives a reliable description of the system under investigation. Secondly, even if one has access to such a database, as already has been discussed in this report, one has to assume that the system will repeat its behaviour exactly in the future to be able to put complete trust in an analysis based on this historical data.

The first problem, that of not having extensive databases for the analysis, is often connected to activities where accidents seldom happen but where the consequences can be considerable, should one occur, e.g. nuclear industry, chemical plants and the transportation of dangerous goods. There are numerous statistical methods for dealing with these issues, and some of them will be examined and presented in a subsequent report.

The question of whether one should rely on historical data at all, given a comprehensive database, is really a matter of subjective opinion. One could look at it as the degree of belief that one have that the system will repeat itself in the future. Are there any reasons to believe that the underlying factors have changed or is the system static? Most activities involved in the risk management process are moving towards more complex and dynamic systems, inciting that this problem will not be lesser in the future. More attention to these issues will be necessary in tomorrows risk analyses.

3.1.3 The use of models

The use of models, either conceptual or mathematical, to represent reality, is the far most common approach in the risk analysis process. Since it is literally impossible to create the “perfect” model, i.e. a model that will imitate reality exactly in every detail, there will always be limitations for the use of any existing model. Being aware of this, and acting according to it by taking precaution so that the model in use is valid for the specific situation under examination, is a very important step in reducing uncertainty caused by imperfect models. Sometimes, though, there are no models that are explicitly validated for the specific situation, or at least one doesn’t know which of the accessible models to use to get the best result. In situations like these, one should make use of several parallel models to be able to compare the results and this way enhancing credibility in the results.

All use of models will introduce subjective judgement in the analysis. Which model/models that will represent reality best in the specific situation will always be a question of belief when there is no empirical data available to support any of them. Under these circumstances one often has to rely on subjective expert judgement. A short discussion on this issue is given in chapter 3.4.

3.2 Different types of uncertainty

There are two major groups of uncertainty recognised in most literature. On one hand there is the aleatory, or stochastic, uncertainty and on the other there is epistemic, or knowledge based uncertainty. These two types will be further examined in the subsections of this chapter. But couldn't uncertainty just be uncertainty regardless its origin? Is there really a need for identifying and separating these uncertainties? The answers to these questions are yes and no respectively. As stated in Winkler (1996): "At a fundamental level, uncertainty is uncertainty, yet the distinctions are related to very important practical aspects of modelling and obtaining information. Such aspects include decomposition in model building, bounding models, identification and incorporation of different types of information, probability assessment, value of information, and sensitivity analysis." There is no fundamental reason for distinguishing between different types of uncertainty, but it may well be the right thing to do in many practical applications.

The most widespread tool for quantifying uncertainties is the mathematical concept of probability. Unfortunately, the concept of probability has no univocal definition. The two main schools of thought in this field are the frequentist and the bayesian. According to Paté-Cornell (1996) the frequentist school (including classical statisticians), defines probability as a limiting frequency, which applies only if one can identify a sample of independent, identically distributed observations of the phenomenon of interest. The bayesian side, on the other hand, looks upon the concept of probability as a degree of belief. This means that not only statistical data and physical models will serve as information, but also expert opinions, which by nature will be subjective. The bayesian framework also provides methods for updating your probabilities when new data are introduced. A more exhaustive presentation of the bayesian framework will be given in a subsequent report within this project.

The type of uncertainty here referred to as aleatory, has been given many different names in literature, e.g. variability, randomness, stochastic or irreducible uncertainty. Significant for aleatory of uncertainty is that it represents randomness in nature and that it is only in the domain of this type of uncertainty that the frequentist definition of probability is valid.

As with the aleatory uncertainty described above, epistemic uncertainty has many aliases, e.g. ambiguity, knowledge-based, reducible or subjective uncertainty. What it all comes down to is that epistemic uncertainty represents lack of knowledge about fundamental phenomena. It is when dealing with this kind of uncertainty one often has to rely on experts and their subjective judgement. Different techniques for eliciting information from subjective opinions given by experts are briefly discussed in chapter 3.4.

Hofer (1996) illustrates the concept of different kinds of uncertainties with an example: "Suppose there are two dice on the table. One, call it A, is being cast continuously. The other, call it B, is covered, left untouched and it is uncertain which side is up. At any instance the number shown by B and the number that will be shown by A are uncertain, and so is their sum. For simplicity, denote these uncertain quantities by A, B and A + B. The mathematical concept of probability is used to quantify uncertainty.

There is the classical frequentistic (probability as the limit of relative frequency) and the subjective (probability as a measure of degree of belief) interpretation of probability. With both interpretations the wealth of well-established concepts and tools of probability calculus and statistics is at one's disposal. Sample evidence can be used to update degrees of belief for parameters that govern probabilities in the frequentistic interpretation. In this sense the subjectivistic interpretation is an extension of the latter. Both interpretations have their place in the example. The uncertainty of A is quantified using the frequentistic interpretation where one simply speaks of 'probability' while the subjectivistic interpretation, where one speaks of 'subjective probability' is used for B. Since B is constant, i.e. has only one true value, limits of relative frequencies don't make sense. Rather, degrees of belief are held for either of the six numbers on the die to be up. They quantify the state of knowledge for B."

In the example die A represent stochastic uncertainty, which can be treated within the frequentistic framework, and die B represent epistemic uncertainty. One way of handling a situation as that of die B is event tree analysis. This technique, along with several others will be presented in a subsequent report. Also, as will be shown within the frames of this project, different methods are available (and needed) for propagating these different kinds of uncertainty. This area will be thoroughly examined and presented further on in this project, since it appears to be a key issue when dealing with uncertainty in practical risk analysis.

3.3 Different levels of treatment of uncertainty

It has become fairly clear, that when trying to create the foundation for a standard for treatment of uncertainty, we will have to appreciate the fact that there is no method available that is useful and effective in all situations. Different levels of treatment will be required in different assessment situations.

In this section, an attempt of identifying different possible levels of treatment of uncertainty, proposed by Paté-Cornell (1996) is briefly presented. The main objective of this section is to demonstrate that there can be no single methodology to be used in every situation and assessment, but different situations call for different solutions. Paté-Cornell suggests six levels of treatment, which are briefly described below. In appendix 3, a Danish attempt to incorporate all kinds uncertainty in a quantitative analysis is summarily described. The Danish approach will be further examined in this project.

3.3.1 Level 0: Identification of hazard

Level 0 involves the identification of a potential hazard or of the different ways in which a system can fail, without attempting to assess the risk in any quantitative way. This level of analysis can be sufficient to support zero-risk policies, or to make risk management decisions when the costs are low and the decision is clear.

3.3.2 Level 1: Worst-Case

Level 1 is the “worst-case” approach. It does not involve any notion of probability. It is based on the accumulation of worst-case assumptions and yields, in theory, the maximum loss level. It is reasonable if the worst loss is sufficient to support the decision.

3.3.3 Level 2: Quasi-worst case, plausible upper bound

Level 2 involves “plausible upper bounds”. This analysis represents an attempt to obtain an evaluation of the worst possible conditions that can be “reasonably” expected when either there is some uncertainty as to what the worst case might be, or when the worst case is so unlikely that it is meaningless.

3.3.4 Level 3: ”Best estimate” central value

Level 3 relies on a “best estimate” and/or on a central value (e.g., the mean, the median or the mode) of the outcome distribution, generally through “best estimates” of the different variables. This approach is often used in applications such as cost benefit analysis.

3.3.5 Level 4: Probability and risk analysis

Level 4 relies on probabilistic risk analysis, PRA. In its simplest form, PRA can be performed to obtain a distribution of the probabilities of different system states based on the best estimates of the models and parameter values. In this form, the model involves only aleatory uncertainties. PRA also permits representation of a risk by a complete distribution of the potential losses, including both epistemic and aleatory uncertainty. Still since the effects of all uncertainties are aggregated into one risk curve, it is impossible to extract from this information the dispersion due to epistemic uncertainties about competing models and hypotheses as opposed to the dispersion due to randomness in samples.

3.3.6 Level 6: Display of risk uncertainties

Level 5 allows the display of uncertainties about fundamental hypotheses by a family of risk curves. This can be done in several ways including a statistical treatment (Bayesian inference) of existing data.

This methodology and different levels of treatment will be further examined in this project. Somehow the standard for treating uncertainty in quantitative risk analysis will have to be diverse, in order to be a useful tool in various situations.

3.4 The use of expert judgement

As mentioned in previous chapters, the use of expert judgement becomes necessary when one doesn't have a complete understanding of the underlying fundamental mechanisms. This could involve the structure of the models used as well as uncertainty regarding the quantification of the variables involved. The task of eliciting useful information based on various experts' subjective opinions is not to be taken easily. There is no universal method that applies to all situations regarding this matter. In fact, there is not one "scientifically correct" method to do it at all (Paté-Cornell 1996). The concept of encoding and aggregating expert opinions will be more thoroughly examined and presented in a subsequent report in this project. Here I will only briefly present three methods for aggregating different experts' opinions into a foundation for decision-making, presented in Paté-Cornell (1996).

The really tricky part is, of course, when the experts disagree about the problem in question, for instance the likelihood estimates regarding initial events. There are many ways to go about this, some more appropriate than others. One first thought might be to just look for some kind of common value or range that is within or at least in the vicinity of everybody's estimated confidence interval. This is clearly not a proper way to go though, since experts tend to underestimate uncertainties. It could well be that the most well informed expert displays the largest uncertainty interval, and using this method would only lead to that the choice of value or segment is driven by the narrowest uncertainty interval provided. Paté-Cornell (1996) states: "The methods that are most likely to provide a reasonable degree of objectivity are those that focus on the construction of a set of hypotheses and on the assessment of axiomatically correct probability distributions based on all scientific evidence. This requires a process that starts with gathering all available data, then assessing and aggregating relevant probabilities in an orderly and logical fashion." Its not hard to see that doing this properly will be a time- as well as money-consuming task.

The three classical ways to aggregate expert opinions described in Paté-Cornell (1996) are:

- The analytical approach, where each of the experts provides their probability distribution. Then someone (e.g. the decision-maker) creates a combined distribution, for example by equal weighting of the distributions provided by the experts or by somehow assigning different degrees of belief to the different distributions provided.

- The iterative approach (e.g. the Delphi technique), where the different assessments provided by the experts are averaged by the analyst, then sent back to the experts who are given the possibility to revise their opinion based on what the others have to say. The process is repeated until it converges, which is usually rather quickly, provided that there is one or more experts who think they know something the others don't.

- The interactive approach, where the experts generally are asked to debate and explain their assessments. The experts are given the chance to exchange information about the evidence base, on which they rely, which further helps the objectivity-process.

The methods listed above together with alternative methods available for this purpose will be further examined in this project. Some standard references in this field include Cooke (1991) and Morgan & Henrion (1990).

3.5 Conclusions to be drawn from the study

When summarising all the statements regarding uncertainty in the standards under review, it becomes clear that the concept of uncertainty is one of the central issues when performing a risk analysis, whether quantitative or not. Serving as a tool or foundation for rational decision-making, it is of great importance that the risk analysis clearly defines on what basis conclusions have been drawn and what uncertainties are connected to the results.

One could look at the uncertainty analysis as having three fundamental purposes. Firstly, it is a question of making clear to the decision-maker that we do not know everything, but decisions has to be made using what we have got. Secondly, the task is to try to define how uncertain we are. Is the uncertainty involved acceptable for meeting the decision-situations we face or is it necessary to try to reduce uncertainty in order to be able to place enough trust in the information? Consequently, the third step is to try to reduce the uncertainty involved to an acceptable level.

We have seen that uncertainty origin from several different sources and may be separated into different groups, for example stochastic or knowledge-based uncertainty. Being able to treat different kinds of uncertainty in a structured manner is a central issue when performing a high-level risk analysis.

Since most technical risk analyses deals with complex systems, of which our knowledge may be more or less imperfect, we will always to some extent be forced to use the subjective judgement of experts to be able to elicit the best available information. Different techniques for doing this are developed and will be further examined within this project.

Finally, lets conclude with the fact that a lot of work has to be done in this area to be able to make well-informed decision-making a reality. It is my hope and belief that the future work within this project will spread some light over some of the central questions regarding these matters.

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Appendices

APPENDIX 1: Summary of statements regarding uncertainty in selected standards for Risk Analysis

APPENDIX 2: Structured summary

APPENDIX 3: Background Studies on Methods for incorporating all Types of Uncertainty

APPENDIX 1: Summary of statements regarding uncertainty in selected standards for Risk Analysis

The following summary is an attempt to find out how some standards on risk analysis and management deals with uncertainty. Apart from the passages in the selected texts where the words uncertainty or sensitivity are used, subjective judgement have been used to distinguish which parts of the standards that directly or indirectly deals with the subject of uncertainty.[4]

Norsk Standard NS 5814: Krav till risikoanalyser

Norwegian Standard NS 5814: Requirements for risk analyses

3 Planning of risk analysis

3.1 Initiation

"The risk analysis shall be initiated early enough for the results to be available where the decisions in question are to be made"

Note 4: "The work will be initiated early enough for the time limits for the analysis to be reasonable. Pressures caused by time and cost considerations often result in idealized calculations and that analyses of sensitivity and uncertainty are not carried out."

4 Execution of risk analysis

4.1 Description of subject for analysis

Note 6: "It may be necessary to make simplified descriptions (models) of the subject for analysis in connection with calculations and quantitative analyses. Such simplified versions of reality will always introduce uncertainties in the results."

4.2 Presuppositions and assumptions

"All presuppositions, assumptions and simplifications made in connection with the risk analysis shall be stated"

4.3 Procedure and methods

"Any uncertainty resulting from the procedure and methods shall be discussed"

4 To keep the summary short and easy to overlook some passages in the original texts have been shortened and/or intentionally left out.

4.4 Data

“The data sources and data that are used to carry out a risk analysis shall be specified”

“Any uncertainty resulting from the data used the analysis shall be discussed. This includes evaluating:

-the relevance of the data being used
-the possibility of drawing correct conclusions on the basis of the used data
-all presuppositions made in connection with the data used
-all adjustments of the data used”

4.6 Causal analysis

“A quantitative causal analysis shall include quantification of the probability of undesired events.”

“Uncertainty in any probability calculations due to the input data and models used shall be discussed.”

4.7 Consequence analysis

“Any uncertainty in calculations/figures due to the data and models used, shall be discussed.”

4.9 Presentations of results and conclusions

“All the essential assumptions, presuppositions and simplifications that have been made shall be summarized so that validity and limitations of the risk analysis are made clear.”

“Any uncertainty in the results from the risk analysis due to input data, models and methods used shall be discussed. If possible the uncertainty shall be quantified.”

“Note 1: The assumptions upon which the analysis is based will be reconsidered when the results of the analysis are reviewed.”

“Note 2: Any uncertainty in the results of the risk analysis may be traced back to uncertainty connected with:

-descriptive models (simplifications, assumptions and presuppositions)
-procedure and methods used (suitability, relevance and limitations)
-data (relevance, accuracy, assumptions and adaptations)
-calculations (accuracy of calculations, approximations and calculation errors)
-subjective evaluations

Dansk Standard DS/INF 85: Risikoanalyse: Kvalitetskrav, teminologi
Danish Standard DS/INF 85: Risk analysis: requirements and terminology

4 Execution of risk analysis

4.1 Description of subject for analysis

"All presuppositions, assumptions and simplifications made in connection to the description of the subject for analysis, shall be stated."

"Guidance: It will often prove necessary to use simplified descriptions (models) of the subject for analysis in connection with calculations and quantitative analyses. Such simplifications of reality will always introduce uncertainty in the results."

4.2 Procedure and methods

"Any uncertainty, resulting from the procedure and methods, shall be assessed."

4.3 Sources of data

"Any uncertainty resulting from used data shall be assessed. This assessment includes:

-the relevance of the data used
-all adjustments of the data used
-the possibility of drawing correct conclusions on basis of the data used

4.5 Causal analysis

"Uncertainty in any calculations of the probability of unwanted events shall be stated"

"Guidance: Uncertainty in calculations shall be assessed in accordance with used models, methods and data."

4.6 Consequence analysis

" Uncertainty in calculations shall be stated"

"Guidance: Uncertainty in consequence calculations shall be assessed in accordance with used models, methods and data."

4.7 Documentation

"The analyzed activity is described and all presuppositions, assumptions and simplifications made are summarized. This is done to the extent that the validity of the risk analysis is made clear, and so that it is possible to see if future changes in the analyzed activity will affect the validity of the analysis."

"The <u>uncertainties</u> in the risk analysis shall be summarized. If possible, the <u>uncertainty</u> shall be quantified."

"Guidance: Any <u>uncertainty</u> in the results of the analysis may be traced back to uncertainty connected with:

-choice of scenarios
-descriptive models (simplifications, assumptions and presuppositions)
-procedure and methods used (suitability, relevance and limitations)
-data (relevance, accuracy, assumptions and adaptations)
-calculations (accuracy of calculations, approximations and calculation errors)
-subjective evaluations

European Standard EN 1050:1996, Safety of machinery – Principles for risk assessment

4 General principles

4.2 Information for risk assessment

“For quantitative analysis, data from data bases, handbooks, laboratories and manufacturers specifications may be used provided that there is confidence in the suitability of the data. Uncertainty associated with this data shall be indicated in the documentation.”

“Data based on the consensus of expert opinion derived from experience can be used to supplement qualitative data.”

9 Documentation

“For the purpose of this standard, documentation on risk assessment shall demonstrate the procedure which has been followed and the results which have been achieved. This documentation includes when relevant:

a) the machinery for which the assessment has been made (e.g. specifications, limits, intended use);

-any relevant assumptions which have been made (e.g. loads, strengths, safety factors);

c) the information on which risk assessment was based;

-the data used and the sources (e.g. accident histories, experiences gained from risk reduction applied to similar machinery);

-the uncertainty associated with the data used and its impact on the risk assessment.”

IEC International standard nr 60300-3-9, Dependability management- Part 3: Application guide- Section 9: Risk analysis of technological systems (1995)

4 Risk analysis concepts

4.1 Objective and basic concepts of risk analysis

"The results of a risk analysis can be used by a decision-maker to help judge the tolerability of risk and aid in choosing between potential risk-reduction or risk avoidance measures. From the decision-makers perspective some of the principal benefits of risk analysis include:

h) identification and communications of risk and uncertainties."

5 Risk analysis process

5.4 Risk estimation

"Risk estimation should examine the initiating events or circumstances, the sequence of events that are of concern, any mitigating features and the nature and frequency of the possible deleterious consequences of the identified hazards to produce a measure of the level of the risks being analysed. The measures could address human, property or environmental risks and should include an indication of the uncertainty associated with the estimates."

"Methods used in estimating risks are often quantitative though the degree of detail required in preparing the estimates will depend upon the particular application. Where full quantification has been carried out it needs to be recognized that the risk values calculated are estimates and 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 analytical methods employed."

5.4.1 Frequency analysis

"Frequency analysis is used to estimate the likelihood of each undesired event identified at the hazard identification stage. Three approaches are commonly employed to estimate event frequencies. They are:

a) to use relevant historical data;

b) to derive event frequencies using analytical or simulation techniques;

c) to use expert judgement.

All of these techniques may be used individually or jointly. The first two approaches are complementary; each has strengths where the other has weaknesses. Where ever possible, both should be used. In this way, they can be used as independent checks of each other, and this may serve to increase confidence in the results. When these cannot be used or are not sufficient, it may be necessary to rely on some degree of expert judgement."

5.4.3 Risk calculations

"Data used to calculate risk levels should be appropriate for the particular application. Where possible, such data should be based on the specific circumstances under analysis. Where these are not available, data of a generic nature representative of the situation should be utilized, or expert judgement sought.

Data should be collected and organized in a form, which facilitates convenient retrieval of information for input to risk analysis and traceability. Data that are no longer relevant to the current situation should be identified and excluded from use in the analysis."

5.4.4 uncertainties

"There are many uncertainties associated with the estimation of risk. An understanding of uncertainties and their causes is required to interpret risk values effectively. The analysis of uncertainties associated with data, methods and models used to identify and estimate the risks involved plays an important part in their application. Uncertainty analysis involves the determination of the variation in the parameters and assumptions used to define the model. An area closely related to uncertainty analysis is sensitivity analysis. Sensitivity analysis involves the determination of the change in response of a model to changes in individual model parameters.

Estimating uncertainty consists of translating uncertainty in the crucial model parameters into uncertainty in the outputs of the risk model. The completeness and accuracy of the risk estimation should be stated as fully as possible. Sources of uncertainty should be identified where possible. This should address both data and model uncertainties. Parameters to which the analysis is sensitive should be stated."

5.6 Documentation

"Risk estimates should be expressed in understandable terms, the strengths and limitations of different risk measures used should be explained, and the uncertainties surrounding estimates of risk should be set out in language appropriate to the intended reader."

"The extent of the report will depend on the objectives and scope of the analysis. Except for very simple analyses, the documentation should normally address the following:

k) sensitivity and uncertainty analysis."

7 Risk analysis methods

7.3.2.1 Frequency analysis

"The purpose of frequency analysis is to determine the frequency of each of the undesired events or accident scenarios identified at the hazard identification stage. Three basic approaches are commonly taken:

a) use relevant historical data;

b) predict event frequencies using techniques such as fault tree analysis and event tree analysis. Simulation techniques may be required to generate frequencies of equipment and structural failures due to ageing and other degradation processes, by calculating the effects of <u>uncertainties</u>;

c) use expert judgement.

7.3.2.2 Consequence analysis

"Consequence analysis involves estimating the impact on people, property or environment, should the undesired event occur."

"There are many methods for estimating such effects ranging from simplified analytical approaches to very complex computer models. Care should be taken to ensure that the methods are appropriate to the problem being considered."

British Standard BS 8444:1996, Risk management,
Part 3 Guide to analysis of technological systems - application guide

Reproduction of IEC International standard nr 60300-3-9, Dependability management- Part 3: Application guide- Section 9: Risk analysis of technological systems (1995)

Australian/New Zealand Standard AS/NZS 3931,
Risk analysis of technological systems – application guide

Reproduction of IEC International standard nr 60300-3-9, Dependability management-Part 3: Application guide- Section 9: Risk analysis of technological systems (1995)

Australian/New Zealand Standard AS/NZS 4360:1995 - Risk management

4 Risk management process

4.3 Risk analysis

4.3.5 Sensitivity analysis

"Since some of the estimates made in quantitative analysis are imprecise, a sensitivity analysis should be carried out to test the effect of changes in assumptions and data."

5 Documentation

5.1 General

"Each stage of the risk management process should be documented. Documentation should include assumptions, methods, data sources and results."

Canadian Standard CAN/CSA-Q850-97, Risk Management: Guideline for Decision-Makers

3 Risk Management Decision Process

3.4 Introduction to the Risk Communication Process

3.4.4 Stakeholder analysis

"The information captured through the stakeholder analysis may or may not be shared with other stakeholders, depending on such issues as the uncertainty of the information at this time and/or the need to keep it confidential at this early stage."

5 Preliminary analysis

5.3 Identifying Hazards Using Risk Scenarios

5.3.8 Other issues

"Hazard identification is uncertain in that some risk scenarios may not be identified."

6 Risk estimation

6.3 Estimating Frequency of risk scenarios

"What usually results from this analysis is an expected range of frequencies with some estimate of uncertainty, rather than a single number."

6.6 Risk Communications Considerations

"Communication between experts and laypersons can be difficult for a number of reasons. Experts and laypersons will often have vastly different levels of knowledge related to specific issues. There are often large uncertainties associated with estimating future frequencies or consequences - uncertainties that technical experts sometimes overlook or fail to acknowledge."

"The following should be undertaken as a part of the overall risk communication process:

(b) acknowledge any assumptions and uncertainties associated with the analysis."

6.7 Decisions to be made

"There are some important decisions that should be made before proceeding to the next step in the risk management decision process, risk evaluation. These decisions relate primarily to adequacy of data, the methods used for the analysis, and the uncertainties associated with the analysis.

(b) Go back

(v) Are the data used in the analyses adequate, or should better data be acquired (at what cost)? If the data are inadequate, return, and redo the analyses using more suitable data.

(vii) Is the level of uncertainty associated with the estimates considered acceptable, allowing for reasonable evaluation of the risks? If not, redo the analyses using better data or better techniques in an attempt to reduce the associated uncertainties."

6.8 Documentation Requirements

"The assumptions, results, and uncertainties associated with the various analyses are added to the risk information library, as are the revisions to the stakeholder analyses. The following matters should be documented at this step in the decision process and posted to the risk information library:

(b) description of all assumptions used in the analyses;
(d) results of all analyses, including acknowledgement of the uncertainties associated with estimates;
(e) reasons for decisions, especially those related to uncertainty and adequacy of data."

7 Risk Evaluation

7.5 Decisions to be made

"The following decisions which should be made at this step in the decision process:

(b) Go back

(i) Are the data adequate for making decisions about the acceptability of the identified risks? Do we have enough information or should we go back to previous steps to acquire better information?

7.6 Documentation Requirements

The following matters should be documented at this step in the decision process and posted to the risk information library:

(e) details related to the analysis of benefits and operational costs and all assumptions and uncertainties associated with these analyses."

8 Risk Control and Financing

8.3 Evaluating Risk Control Options in Terms of Effectiveness, Cost, and Risks

"The same methods used to estimate frequency and consequence in the risk estimation step can be applied to estimate the potential change in these parameters expected to result from the application of risk control measures: historical data, fault- and event-tree analysis, professional judgement, etc. As with other estimates, all associated assumptions and uncertainties should be acknowledged and documented."

8.8 Decisions to be made

"The following are decisions that should be made at this step in the decision process:

(b) Go back

(iv) Are the assumptions and uncertainties associated with the estimates acceptable to the stakeholders?

8.9 Documentation Requirements

The following matters should be documented at this step in the decision process and posted to the risk information library:

(d) description of uncertainties associated with the results of the analyses."

9 Action

9.4 Establishing a monitoring Process

9.4.1 Primary functions

"Monitoring is a key function of the risk management program and has four primary functions:

(d) to verify the correctness of assumptions used in the various analyses."

9.4.5 Monitoring to Verify the Correctness of Assumptions

"Assumptions are guesses about what may happen in the future and, as such, are subject to varying levels of uncertainty. It is important that all assumptions throughout the analysis be verified where possible."

"The financial and non-financial benefits of monitoring include:

(b) the accumulation of evidence to support assumptions and results of analyses."

APPENDIX 2: Structured summary

In this summary statements regarding uncertainty to be found in the various standards has been listed in the left column. If the statement, or a statement with a similar meaning, is to be found in one specific standard listed to the right, this will be marked with a *.

Statements	**Standards for Risk Analysis / Management**							
	NS 5814	DS/INF 85	IEC 60300-3-9	EN 1050	AS/NZS 3931	BS 8444: Part 3	AS/NZS 4360	CAN/CSA Q850-97
RA Concepts								
From the decision-makers perspective some of the principal benefits of risk analysis include: h) identification and communication of uncertainties			*		*	*		
Planning of RA								
Initiation of the RA early enough to guarantee time to carry out sensitivity and uncertainty analysis	*							
Execution of RA								
Risk estimation								
The measures could address human, property or environmental risks and should include an indication of the uncertainty associated with the estimates			*		*	*		
Description of subject for analysis								
Simplified versions of reality (models) will always introduce uncertainties in the results	*	*	*		*	*		
Presuppositions and assumptions								
Presuppositions, assumptions and simplifications shall be stated/discussed	*	*	*		*	*	*	*
Procedure and methods								
Uncertainty resulting from the procedure and methods shall be stated/discussed	*	*	*		*	*	*	*

Hazard identification								
Hazard identification is uncertain in that some risk scenarios may not be identified								*
Sources of uncertainty								
Sources of uncertainty should be identified where possible			*		*	*		
Data								
Any uncertainty resulting from used data shall be assessed	*	*	*	*	*	*	*	*
Sources of data								
Sources of data shall be specified	*	*	*	*	*	*	*	*
Causal analysis								
Uncertainty in any probability calculations due to the data and models used, shall be discussed	*	*	*		*	*		*
Consequence analysis								
Uncertainty in any consequence calculations due to the data and models used, shall be discussed	*	*						
There are many methods for estimating consequences. Care should be taken to ensure that the methods are appropriate to the problem being considered			*		*	*		
Uncertainty propagation								
Uncertainty in the crucial model inputs shall be translated to uncertainty in the model outputs			*		*	*		
Sensitivity analysis								
Parameters to which the analysis is sensitive shall be stated			*		*	*	*	

Presentation of results and conclusions								
All the essential assumptions, presuppositions and simplifications that have been made shall be summarized so that validity and limitations of the risk analysis are made clear	*	*	*	*	*	*	*	*
Any uncertainty in the results from the risk analysis due to input data, models and methods used shall be discussed	*	*	*	*	*	*	*	*
Uncertainty surrounding the estimates should be set out in language appropriate to the intended reader			*		*	*		
If possible the uncertainty shall be quantified	*	*						
Results from the sensitivity analysis shall be stated			*		*	*	*	

APPENDIX 3: BACKGROUND STUDIES ON METHODS FOR INCORPORATING ALL TYPES OF UNCERTAINTY

One goal of this project is to produce a summary on methods and models for incorporating other types of uncertainty than uncertainty due to input data and models. In this section a Danish effort to produce a guideline on treatment of uncertainty in QRA is summarily described.

1 Description of uncertainty in quantitative risk analysis

A substantial effort on producing a “hands on” guideline on “Description of uncertainty in Quantitative Risk Analysis in the Oil/Gas industry” started in Denmark during 1994 in a joint project with several participants, COWI, (1996a-d). The project was finished in 1996 and four reports were published, of which one was the actual guideline. Here the main features of this guideline will be briefly presented.

This guideline provides methods on how to treat uncertainty explicitly at three different levels of analysis: no description of uncertainty, rough description of uncertainty and extensive description of uncertainty. For each of these levels guidance on how to treat uncertainty and how to present the uncertainty is given. It is stressed that the uncertainty analysis, when undertaken, should be an integrated part of the overall risk analysis.

The first level of analysis is an analysis where no description of uncertainty is made. Some situations where this might be acceptable are: If you have a well-defined analysis situation and use accepted models, data and assumptions or zero risk situations, i.e. situations where the mere possibility of an unacceptable consequence makes uncertainty analysis superfluous.

The second level of analysis, where only a rough description of uncertainty is made, either quantitatively or qualitatively, might be used for the same reasons as the level 1 analysis. What’s important when performing a level 2 analysis is to be explicit about which uncertainties that have been accounted for and which that have not. Further it should be stated which sources of uncertainty that contribute most to the overall uncertainty in the results.

The level 3 analysis includes an explicit description of all the important uncertainties. In practice, it might not be feasible to cover all aspects of uncertainty in an analysis, but the minimum requirement for the level 3 analysis includes:

- A qualified quantification of all uncertainties in all of the classes of uncertainty described in the following section.
- A description of the sources of uncertainty that have the strongest influence on the result.
- Uncertainty propagation of all the important uncertain variables.
- The final uncertainty in the results is presented as an uncertainty interval by using an uncertainty factor with accompanying confidence level.

The Danish guideline provides a method for level 3 analysis, which will be presented in some detail in the following section. The description of the method will follow the steps of the guideline but for obvious reasons each step will not be extensively described.

Classification of uncertainty

The uncertainty in the results from a quantitative risk analysis is decomposed into four classes:

Class 1	Uncertainty in prevailing analysis conditions or environment; e.g. state of art, conceptualisation, and competence of analyst team
Class 2	Uncertainty due to assumptions in scenario generation
Class 3	Uncertainty in mathematical models
Class 4	Uncertainty in input data

These classes of uncertainty follow the common working process when performing a quantitative risk analysis. The analyst start in the "real world" but his actual work will only take place in the part of reality that the analyst is aware about. Next the analyst will make simplifications and assumptions within the frame of his perception of the real world, resulting in what is usually called the "mental model". Finally, some input data will be processed through some kind of mathematical model. Decomposing the overall uncertainty into the above classes will force the analyst to consider and treat conceptually different uncertainties, and thus avoiding a common mistake in uncertainty analysis. That is to treat one type of uncertainty explicitly (often uncertainty due to input data) and forgetting or ignoring other kinds of uncertainty, which may have even more influence on the overall uncertainty in the final results.

5.1.2 Best estimate / uncertainty about best estimate

When performing a quantitative risk analysis one should, under normal circumstances, present the result based on best estimates, preferably the median value. The use of conservative measures attached to assumptions and input data will often lead to compound conservatism in the results, why it should be avoided. The unknown stochastic variable, to which the median is sought, will for reasons that are beyond the scope of this paper often have the approximate shape of a logarithmic normal distribution. This method is developed with that fact as a basis.

When uncertainty in risk analysis is quantified, it must be clarified how these numbers shall be interpreted. Under normal circumstances, the uncertainty should be represented by an interval around the best estimate. For an asymmetric distribution like the lognormal, the uncertainty should be represented by an uncertainty factor. The uncertainty factor is the number, by which the median should be multiplied, respectively divided, to establish the uncertainty interval. For each of the classes of uncertainty enumerated in the previous section, an uncertainty factor corresponding to a coverage factor of 2 standard deviations and a confidence level of approx. 95% should be determined.

The contributions from each class of uncertainty to the overall uncertainty should if possible be quantified. For uncertainties originating from classes 1-3 it will often be difficult to quantify the contribution based on statistical methods. For these classes other methods must be used i.e. expert judgement. The uncertainty originating from class 4 will nearly always be possible to treat through uncertainty propagation.

For all of the four classes an uncertainty factor responding to a coverage factor of 2 and a confidence level of 95% is determined, called respectively UF1, UF2, UF3 and UF4. The total uncertainty factor, TUF, is then determined from:

$$TUF = \exp\sqrt{(\ln UF1)^2 + (\ln UF2)^2 + (\ln UF3)^2 + (\ln UF4)^2} \qquad (1)$$

This formula follows from the assumption of a lognormal distribution. The concept assumes that the different variables (classes) are independent. It is therefore important, when determining the uncertainty factor for each of these classes, that one makes sure that no part of the uncertainty is accounted for more than once.

5.1.3 Determination of uncertainty factors in the different classes

There are two alternative methods available when determining the uncertainty factors in each of the different classes. The first, simple method is based on an overall estimate for the whole class' uncertainty factor. In the second, more sophisticated method, each class of uncertainty is divided into sub classes for each of which the uncertainty factor is determined. The uncertainty factor for the whole class is generated in the same manner as the overall uncertainty factor:

$$UF = \exp(\sum_{i=1}^{n} (\ln UF_i)^2)^{1/2} \qquad (2)$$

Class 1 Uncertainty in prevailing analysis conditions or environment

Uncertainty in prevailing analysis conditions or environment could originate from the fact that in the beginning phase of the project not everything is known about the final construction of the system. Another reason could be disagreement among experts regarding how to model the system, or lack of knowledge about the fundamental physical or chemical reactions in the system. In table 1 suggestions on how to determine the uncertainty factor in this class are given. The table is not exhaustive, and the analyst should if necessary make efforts to complete it in order to cover the situation at hand as fully as possible.

	Small uncertainty 1 < UF1 < 2	Medium uncertainty 2 ≤ UF1 ≤ 10	Large uncertainty 10 < UF1
Analyst's experience and competence	Extensive. The analyst is qualified to determine the uncertainties	Reasonable. The analyst is able to give qualified estimates on most of the uncertainties involved	Little. The analyst can only give loose estimates on the uncertainties involved
Knowledge of background and conditions of the project	Extensive	Reasonable	Little
Available time and resources	Sufficient	Reasonable	Lacking
General knowledge base in the specific area	The specific area is well known. There is consensus among experts	There is some lack of clarity and disagreement among experts	There is substantial lack of clarity and disagreement among experts

Table 1 Suggestions on how to determine the uncertainty factor in class 1

When risk analysis in well-known areas by professionals with documented experience and competence, it will often be satisfactory to let UF1=2, provided that the analyst is capable of estimating the uncertainties in the other classes as well.

Class 2 Uncertainty due to assumptions

When performing a quantitative risk analysis, assumptions and simplifications will be inevitable. These assumptions will always bring uncertainty into the results, sometimes large uncertainties that could be critical to the result of the analysis. Wherever possible uncertainty due to assumptions should be quantified and treated like uncertainty in input data, see uncertainty class 4. In cases where this is not possible, table two could be used to determine the uncertainty factor in class 2.

	Small uncertainty 1 < UF2 < 2	Medium uncertainty 2 ≤ UF2 ≤ 10	Large uncertainty 10 < UF2
Description of object for analysis	Well defined		Hard to define or poorly defined
Methods and models	Well known and documented		New, unverified and poorly documented
Sources of data	Relevant and situation specific		Not directly relevant. Large adjustments has to be made
Identification of undesired events and potential hazards	Well known problems		New and unknown problems
Causal analysis	Well known problems		New and unknown problems
Consequence analysis	Well known problems		New and unknown problems

Table 2 Suggestions on how to determine the uncertainty factor in class 2

Class 3 Uncertainty in mathematical models.

Regarding models, uncertainty stemming from the following three sources should be described:

1. The relevance of the model, i.e. to what extent the used model covers the specific problem.
2. The validity of the model, i.e. how well the model represents the situation it was designed for.
3. The natural variability in the modelled phenomenon, i.e. to what extent the variables that one tries to calculate suffers from natural variability.

The relevance of the model should be described by stating what the model is designed to do, and what it really is used for in the specific case. The validity should be described by stating how the model was validated, who did it, how is it documented, and what was the result of the validation. Phenomena that are difficult to describe due to large variability should be highlighted in the analysis. The use of models with both low relevance and validity should be avoided.

Table 3 could be used as support when determining the uncertainty factor of class 3.

	Small uncertainty $1 < UF3 < 2$	Medium uncertainty $2 \leq UF3 \leq 10$	Large uncertainty $10 < UF3$
Relevance	Sufficient	Reasonable	Lacking
Validity	Sufficient	Reasonable	Lacking
Variability	Small	Medium	Large

Table 3 Suggestions on how to determine the uncertainty factor in class 3

Class 4 Uncertainty in input data

If the quality of input data is poor, and better data can not be produced, one should not perform a quantitative risk analysis. Each important uncertainty in input data should be described explicitly, whenever possible quantitatively. If quantification is not possible the reason for this should be stated, and a qualitative description estimation of the uncertainty should be made. Uncertainty in input data can be grouped in many different ways, but since there is no generally accepted way of doing this, it should be avoided unless it helps to clarify the problem or helps communication. Notwithstanding this, it is recommended that one divide uncertainty in input data into two categories as shown below:

Type A: Uncertainty determined using statistical methods.
Type B: Uncertainty determined using other methods, i.e. expert judgement.

When the uncertainty in each of the used input variables is determined, uncertainty propagation is conducted to determine the uncertainty factor of class 4. The uncertainty propagation is conducted using simulation based on Latin Hypercube Sampling, possibly combined with the response surface method. The result of uncertainty propagation will nearly always be a graphical representation of the distribution function for the output. These distributions can in most cases be approximated with the lognormal distribution, making it possible to find the uncertainty factor UF4 by interpreting the graph.

After having determined all of the uncertainty factors of the different classes the total uncertainty factor is concluded by using equation (1) described earlier in this paper.

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