OVERVIEW OF MAJOR ACCIDENT RISK MANAGEMENT ISSUES

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1. Risk management philosophy

The analytical approach developed to evaluate risk is not recognized universally. In effect, it requires those concerned with the risk to address the behavior of the source of risk in all aspects of its operation. This approach, in more or less quantitative ways, is often used to support “performance based” approaches to risk management. The more traditional approaches to the management of risk work by relying on implicit control of risk. It is this “prescriptive” method which is based on rigorously applied and maintained standards of design and operation. It is often difficult for proponents of this approach to deal explicitly with an analysis of risk. They argue that, if everything required by agreed standards and regulations appropriate for the risk generating process is done, then the risk is controlled.

The inherent integrity of plant is ensured by maintaining a system of engineering standards that takes account of lessons learned by experience. The integrity of plant which has been in operation for some time is assured through rigorous in-service inspection regimes. Standards of operation are ensured through high standards of general training and motivation of the work force.

2. The Seveso Directive

The Seveso Directive has been translated into national legislation by EU Member States. A common requirement, as specified in the directive, is the preparation by the responsible party of safety reports.

These reports must contain information that demonstrates to the competent authority that the technical means are in place for the safe operation of the installation at all times. The authority must examine the information provided.

The system set up by authorities to ensure that installations are adequately safe varies from country to country. This is evident from the criteria for safety applied. These are reflected in the content - and volume - of the safety reports.

Examples of the regulatory systems adopted in a number of Member States of the EU, including those based on the implementation of the Seveso Directive, have been placed in an order that is based on increasing reliance on analytical approaches to risk assessment and more quantified estimations of risk.

More prescriptive:	Germany Analytical approaches to risk assessment techniques have little place, either to demonstrate safety or to judge the tolerability of the risk of an establishment. More reliance is placed on adherence to engineering standards and operational procedures. Risk assessment to estimate the extent of possible consequences of an accident may be made. However the overriding character of the approach is dependence on “standards”;
	France Although authorities recognize the utility of probability as a concept in the assessment of risk, the regulations are centered on safety distances; these result from maximum effect calculations of major hazard units. More quantitative risk assessment studies can be requested by a local authority, but the basis (criteria) on which the results would be judged is not defined;
	United Kingdom The HSE adopts the position that an establishment is not required to include the results of quantitative risk assessment methods as part of a Safety Case; but to do so may make the safety arguments more convincing; the authority may ask for a quantified risk assessment to be carried out in cases where it is indispensable for arriving at informed judgement of the suitability of an installation. Criteria against which the risk results (both individual and societal) are judged have been addressed in published discussion documents. Frequently such criteria are referred to as "consultation distances", requiring that careful consideration of activities within such distances is required. The influence of valid factors other than absolute safety norms on which to base decisions is given much attention; assessments are based on the “cautious best estimate”.

	Norway If Norway were to be entered in the list above, it would fall somewhere between the UK and the Netherlands with regard to the type of approach to risk assessment used. Rather than stipulate risk criteria that set (or give guidance on) limits of acceptance of risk, the authorities require companies to declare their safety policy, which includes specifying the safety goals and objectives that hazardous installations should meet. Technical audits and assessments of the installation design and operating procedures ensure that the goals and objectives are being met.
More performance based:	Netherlands The regulatory framework adopted by the government means that the judgement of the tolerability of the external risk of an establishment is based exclusively on quantitative risk assessment approaches and on numerical risk criteria.

3. Illustrations of the use of risk assessment

3.1. Legal Context

Table 3.1 below illustrates how the differing "technical" approaches to risk assessment manifest themselves as features of the legal framework in the countries considered. Differing legal traditions and codes result in differing approaches to formulating laws and regulations.

Table 3.1. Assessment and legal influence.

Country	Is law prescriptive or goal-setting?	Do regulations relate to technical standards?	Have risk criteria been defined and specified?	Implementing authority	Is the need for quantified risk assessment recognized?
Germany	essentially prescriptive	yes	no	by Länder	no
France	contains prescriptive elements	not explicitly	yes; zoning distances	separate regional inspectorate (DRIRE)	no
Switzerland	contains strong elements of both	yes	not in regulations but in guidelines	by cantonal authorities	yes
UK	both, but bias towards goals	yes, in some areas	yes, but only in "guidance"	HSE inspectorate	yes
USA (federal law)	essentially goal-setting	yes, in some areas	specific goals and definitions without specified criteria	state and local levels, if necessary implementing reverts to EPA	no, but it can be used

Norway	goal-setting by industry	No	no	occasional Min of Lab audit	implicitly, yes; risk assessment specified as component
Netherlands	goal-setting	yes, indirectly	yes	by central inspectorate	yes

3.2. Influence of risk management on assessment

The management and control of risk can be classified into three groups; each category has different influences on the type of risk assessment method that is used. The three types of risk management and control type can be described as follows:

- setting explicit risk criteria;
- setting standards (or regulations) that control risk (implicit);
- requiring management of risk (or the management systems approach).

The first category infers that more quantitative risk assessment techniques will need to be employed to define the criteria or even level of risk that prompts action aimed at control or reduction. The second does not necessarily require the use of risk assessment, since standards and regulations have traditionally been set through a process that does not include all the components of risk assessment. However, setting standards still involves technical evaluation and therefore it is inevitable that some aspects of the risk assessment process will be employed to arrive at a well-founded standard. The third approach includes aspects of the other two, as both standards and risk criteria may be an integral part of the objectives stated for a safety management system. A management system can define its own objectives as a starting point and use highly analytical and systematic approaches to risk assessment. However, there can be a tendency for the approach to risk assessment to lack uniformity if driven solely by the needs of a management system. Complete reliance on management systems could result in some companies exercising little or no use of quantitative risk assessment.

Government Authorities

The use of risk assessment as a part of the process establishing the goals and objectives for their chemical accident programmes must take account of the need to address a broad range of circumstances. The target levels for acceptable risk are often expressed either as broad bands or values (requiring the use of more quantitative risk assessment methods) or in such a way that the relative merits of attaining a level of risk can be evaluated and understood.

The level of risk “permitted” (where specified) is usually subject to further analysis and interpretation. The integration of an analysis of the costs and benefits of the possible measures to reduce risk is a common activity in this part of the risk assessment process. A level of risk also relates to the public perceptions and acceptance of that level. The uncertainties associated with various factors in the more quantified assessment and the transparency of the process of quantification are important aspects of this type of approach. The interaction of these factors with the risk assessment process and the risk criteria that flow from it can be illustrated by examining an approach used in the United Kingdom. Three principles are adopted in the control of major hazards. These are identification (establishing the existence of a risk), reduction (reducing the possibility of a risk) and mitigation (reducing the impact of a hazard). In some areas of chemical accident prevention, preparedness and response the UK Health and Safety Executive use a principle, “As Low As Reasonably Practicable” (ALARP). It is usually applied to risks that fall below a defined level of “intolerable” risk. But account is usually taken of the different bases on which comparisons can be made.

Another approach to risk assessment, which can be exemplified by the approach taken by government authorities in Germany and France, involves less use of quantified risk assessment. Their approach to risk assessment takes into account the general principle that the zoning of land can separate a hazardous installation from potential victims of an accident. However, their approach to assessment does not rely heavily on a calculation of risk but on a thorough analysis of the standards of the construction, operation and maintenance of the installation. Various aspects of the standards related to risk are rigorously defined and used in a more deterministic way to evaluate the potential for, and the nature of, accidents that might occur. Some of the assumptions involved in this type of approach relate to the estimation of the reduction of risk obtained by the standards imposed and the effects of the separation distances required. Defining the distance between industrial activity and residential populations involves the assessment of the level of reduced risk and implicit determination of the level of risk that is undesirable.

4. Risk assessment and prevention

Chemical accident risks and associated goals or risk criteria, and the assessment methods used to derive them, cannot be considered in isolation. The impact of other related policies (e.g., general labour safety, environmental quality and health objectives) also need to be considered in the context of the risk assessment process.

4.1. How to prevent risk

Risk prevention aims to reduce one or more of the contributors to the risk of chemical accidents associated with an installation. Risk assessment methods are used to evaluate the possible impacts of different technical options to reduce the inherent risk of a process or an activity. Choice of the risk assessment method depends on the circumstances. The common principles of risk reduction are as follows:

Reducing hazard

Inherently safe design of chemical installations usually reduces the extent ("spread") of the hazard. This can be achieved by:

- reducing quantities in a single containment;
- changing conditions of a hazardous chemical (i.e. temperature/pressure);
- using a different chemical.

These are usually assessed in semi-quantitative ways, and the risk assessments of alternatives are compared against each other rather than against a fixed risk criteria.

Separating the source of hazard from possible targets

The effect of a hazard usually diminishes with distance from the source. Therefore, putting distance between source and possible targets reduces risk. This is achieved by:

- effective zoning of land;
- plant layout.

This area of prevention typically involves the use of exposure assessment techniques. These methods often rely on dispersion and/or other types of environmental exposure models, as well as considerations of the characteristics of the possible sources and types of the release. Information from the exposure assessment is then combined with information from the assessment of the hazard(s) and considerations of target populations. A possible adjunct to these type of assessments is consideration of the effects of barriers to prevent or reduce the spread of the hazardous chemical.

Improving containment

Hazards are contained by a "mechanical" (including instrumentation and control) system. The reliability of the system can be improved by:

- better mechanical design (e.g. reducing vulnerable components);
- system redundancy (e.g. parallel controllers);
- additional protection (e.g. double walls, additional control);
- interaction of process components (e.g. layout of plant).

The assessment of this type of prevention measures involves many of the same type of techniques (e.g., comparison of risk) as the other area, but differs in the technical input required for the assessment.

Table 4.1. Summary of use of risk assessment.

Country	In permitting for plant construction or operation	In land-use planning or zoning	For preparing emergency response plans	Responsibility for application of risk assessment of the chemical accidents area	Responsibility for labour safety
Germany	Länder yes	No	Yes	Länder	Separate agencies
France	submit to mairie, préfet & DRIRE yes	Maximum Credible Accident (MCA) used to establish zones	Yes	Local & DRIRE	DRIRE with Min of Lab
Switzerland	Canton special authorities yes	No	Yes	Canton	Different co-operating agencies
Norway	Company yes	Yes	Yes	Company	Several agencies
UK	Local authority & Dept. of Env. yes	Yes	Yes	Local authority	HSE main responsibility
USA	Owner & local auth. yes	Yes for local regs.	Yes	State (where active)	OSHA
Netherlands	Provincial and municipal auth. yes	Yes	Yes	Both local & central	Ministry of Social Welfare

Improving “Software”

Human error is the starting point for four out of five accidents. Improving the performance of the operator therefore offers scope for reducing risk. This can be done by:

- designing out human intervention;
- reducing human error rates (e.g., better ergonomics);
- better “design” of organizing human intervention (e.g., clearer responsibilities, better communicated instructions);
- better culture, training motivation.

4.2. Inclusion of costs and benefits considerations

Implementing risk control measures involves costs to the enterprise undertaking them. Therefore, information on cost and benefit are often included in the risk assessment process aimed at accident prevention measures. The cost case is usually handled in a fairly straightforward way. Control of risks from a process hazard usually involves a choice of the application of a well-defined technical measure. Estimating the initial (capital) and operating costs can be done with precision. Difficulty usually arises in estimating benefits. This includes the ethically and morally difficult question of deciding the "value" of human lives. In addition, there are usually a number of intangible costs that are avoided as a result of opting for a particular strategy. For example, production loss is usually a major factor in the costs of a major hazard incident. But determining the benefits of this cost reduction for a particular scenario is usually very speculative and subject to significant uncertainty.

To carry out a macro-economic assessment, indirect effects (e.g., effects on prices, employment) are estimated. These estimate can be facilitated by the use of economic models.

Some governments (notably those of the UK and US) require the presentation of cost/benefit arguments when laws and regulations are presented to the legislature. Obtaining data that is necessary for the inclusion of these factors in the risk assessment process is a major task.

Industry's ability to carry out these analytical techniques is also limited. The provision of properly authenticated data is difficult because the costing of alternatives is not straightforward. Measures to reduce risk can change plant design or operating conditions. This has effects in other parts of the process which can be beneficial. An example is the reduction of inventories of materials. The provision of total cost/benefit assessments becomes a costly activity itself. Technical solutions to reducing risk are often cost neutral.

Companies sometimes make an estimate of what it has cost to develop risk control methodology. In other cases they develop more general data on the cost of submitting plans and negotiating them with the authorities. Enterprises in Germany say that the costs of risk control are significant.

5. Comprehensive approach to management of risk adopted by UK HSE

The factors which influenced development by HSE a comprehensive approach to management of risk include:

- advancement in knowledge how people view the risk (risk perception);
- changes in the approach to regulatory environment;
- changes on the industrial scene and;
- changes in preferences, values and expectations of society.

5.1. Risk perception

How people view risks and apply value judgements is perhaps the most challenging factor to take into account when developing an approach to the regulation of risk. Recent studies show:

- The way we treat risks depends on our perception of how they relate to us and things we value. It is only fairly recently that social scientists have examined in detail what factors affect people's perception of risk. There is a wide range of factors. Particularly important for man-made hazards are 'how well the process (giving rise to the hazard) is understood, how equitably the danger is distributed and how well individuals can control their exposure and whether risk is assumed voluntarily.
- The concept of risk is strongly shaped by human minds and cultures. Though it may include the prospect of physical harm, it may include other factors as well, such as ethical and social considerations, and even the degree of trust in the ability of those creating the risk (or in the regulator) in ensuring that adequate preventive and protective measures are in place for controlling the risks.
- For many new hazards, high quality risk assessments by leaders in the field often fail to reassure people. Even using all available data and best science and technology, many risk assessments cannot be undertaken without making a number of assumptions such as the relative values of risks and benefits or even the scope of the study. Parties who do not share those assumptions may well see the outcome of the exercise as invalid, illegitimate or even not pertinent to the problem.
- The impact of a particular risk begins with the initial victims and diffuses outward to society at large. In that process, public response to the risk can be amplified or attenuated depending on how the reporting of the risk interacts with psychological, social, cultural, and institutional processes.

All these give rise to concerns which can be put into two broad categories:

- **Individual concerns** or how individuals see the risk from a particular hazard affecting them and things they value personally. This is not surprising since one of the most important questions for individuals incurring a risk is how it affects them, their family and things they value. Though they may be prepared to engage voluntarily in activities that often involve high risks, as a rule they are far less tolerant of risks imposed on them and over which they have little control, unless they consider the risks as negligible. Moreover, though they may be willing to live with a risk that they do not regard as negligible, if it secures them or society certain benefits, they would want such risks to be kept low and clearly controlled.
- **Societal concerns** or the risks or threats from hazards which impact on society and which, if realised, could have adverse repercussions for the institutions responsible for putting in place the provisions and arrangements for protecting people, e.g. Parliament or the Government of the day. Typical examples relate to nuclear power generation, railway travel, or the genetic modification of organisms. Societal concerns due to the occurrence of multiple fatalities in a single event is known as societal risk**.** Societal risk is therefore a subset of societal concerns.

Hazards giving rise to societal concerns share a number of common features. They often give rise to risks which could cause multiple fatalities; where it is difficult for people to estimate intuitively the actual threat; where exposure involves vulnerable groups, e.g. children; where the risks and benefits tend to be unevenly distributed - for example between groups of people with the result that some people bear more of the risks and others less, or through time so that less risk may be borne now and more by some future generation. Hazards that are familiar, often do not as a rule give rise to societal concerns.

5.2. Regulatory framework

Two factors determine recent changes in regulatory framework: the internalization of regulations and increasing complexity in the regulation of risk.

The regulation of risk is nowadays increasingly being undertaken at European or international level in the form of legally binding instruments on Member States - such as directives, treaties and conventions adopted in the wake of the creation of new global markets and new technologies. For some of the new risks, like those arising as a result of the release of genetically modified organisms, action will clearly have to be taken at international level to have any effect. Moreover, in other areas the technology is moving so fast that de facto international standards or practices are evolving all the time, e.g. in ensuring the safe use of computerized systems for controlling plant and machinery. Regulators, industry and pressure groups in many countries are calling for such technologies to be regulated at international level as the only effective way to prescribe appropriate standards. The internationalization of regulation requires accounting for factors such as agreements for regulatory harmonization, mutual recognition of standards and removal of barriers.

Frequent characteristic of the new hazards is that it can be very difficult to define precisely the risks they may give rise to, even when scientific knowledge is pushed to the limit. The processes that may give rise to risks are only partially understood with the result that regulatory decisions must frequently be based on limited data and considerable scientific and technological uncertainties. The control measures required by regulation should reflect the nature of the uncertainties and err on the side of health and safety.

It has become obvious that taking into account undesirable consequences should include consideration of matters such as distributional or economic equity or ethical considerations and considering the effects of policies on natural phenomena like the survival of species and the maintenance of ecosystems. The evaluation and management of hazards are evolving to include values that cannot readily be verified by traditional scientific methods.

5.3. Expectations of society

There is a growing propensity to scrutinize benefits brought about by industrial activity against potential undesirable side effects such as the risk of being maimed or killed or of environmental pollution. This is particularly true for risks:

- which could lead to catastrophic consequences;
- where the consequences may be irreversible, e.g. the release of genetically modified organisms;
- which lead to inequalities because they affect some people more than others, such as those arising from the sitting of a chemical plant or a waste disposal facility;

- which could pose a threat to future generations, such as toxic waste.

The most dramatic shift in value preferences of society has been the pressure on regulators for greater clarity and explanation of their approaches to the regulation of risk. These require:

- the targeting of action: focusing on the most serious risks or where the hazards need greater controls;
- consistency: adopting a similar approach in similar circumstances to achieve similar ends;
- proportionality: requiring action that is commensurate to the risks;
- transparency: being open on how decisions were arrived at and what their implications are; and
- accountability: making clear, for all to see, who are accountable when things go wrong.

5.4. System for reaching decisions

HSE has set up six stage iterative system for reaching decisions on how risks should be regulated and managed, namely:

Stage 1. Deciding whether the issue is primarily one for HSC/E[1].
Stage 2. Defining and characterizing the issue.
Stage 3. Examining the options available for addressing the issue, and their merits.
Stage 4. Adopting a particular course of action for addressing the issue efficiently and in good time, informed by the knowledge gained going through the six stage iterative system and by the expectation that as far as possible the course of action will be supported by stakeholders.
Stage 5. Implementing the decisions.
Stage 6. Evaluating the effectiveness of actions taken and revising the decisions and their implementation if necessary.

HSE has also set out the framework, known as the Tolerability of Risk (TOR), for reaching decisions on whether risks from an activity or process are unacceptable, tolerable or broadly acceptable and its application in practice. In this context, 'tolerable' does not mean 'acceptable'. It refers instead to a willingness by society as a whole to live with a risk so as to secure certain benefits, having the confidence that the risk is worth taking and being properly controlled. However, it does not imply that the risk will be acceptable to everyone, i.e. that everyone would agree without reservation to take the risk or have it imposed on them.

The framework makes clear that:

- both the level of individual risks and the societal concerns engendered by the activity or process must be taken into account when deciding whether a risk is unacceptable, tolerable or broadly acceptable;
- the decision-making process and criteria adopted are such that action taken is inherently precautionary;

Moreover, HSE starts from the position that, for every hazard, the law requires that:

- a suitable and sufficient risk assessment must be undertaken to determine the measures needed to ensure that risks from the hazard are adequately controlled;
- suitable controls must be in place to address all significant hazards, and that those controls, at a minimum, must achieve the standards of relevant good practice precautions, irrespective of specific risk estimates;
- where there is no relevant good practice, or the existing good practice is considered by HSE to be insufficient or inadequate, the decision as to what control measures are suitable will generally be informed by further risk assessment;
- there are some risks from certain activities, processes or practice which are not tolerable whatever the benefits, i.e. they are unacceptable. Any activity, process or practice giving rise to risks falling in that region would be ruled out unless the activity, process etc can be modified to reduce the degree of risk so that it becomes tolerable;
- as control measures are introduced, the residual risks may fall so low that additional measures to reduce them further are likely to be grossly disproportionate to the risk reduction achieved, though the control measures should still be monitored in case the risks change over time.

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[1] Health and Safety Commission / Health and Safety Executive

HSE has proposed numerical criteria for informing decisions on the tolerability of risks only for very limited categories of risk, for example, those entailing fatalities either individually or in multiple fatality accidents.

5.5. Characterizing the issue in terms of risk

The framing of the issue may point to it being one where a decision on proportionality of action requires information on the risks. In such cases, we need to characterize the risk quantitatively and qualitatively, to describe how it arises and how it impacts on those affected and society at large. Such information is needed in order to inform later consideration of options for risk reduction.

We usually undertake an assessment of the risks to achieve this. Assessing risks involves identifying the hazards associated with the risk issue, i.e. what in a particular situation could cause harm or damage, and then assessing the likelihood that harm will actually be experienced by a specified population and what the consequences would be.

A risk assessment essentially is used as a tool to inform our decisions by assisting in understanding of the nature and degree of risk and for extrapolating, from available data, experience of harm, or for representing a large amount of scientific information and judgement as an estimate of the risks. The policy process then couples the scientifically-based judgements about risks with policy considerations about the approach to their control. The latter (sometimes separately described as risk evaluation) includes such considerations as the relative weightings to be attached to likelihood and consequence, and the way that public perceptions of the risk should be taken into account.

For example, the risk assessment may show that the risks are such that individuals may not be unduly concerned because of the familiarity of the risks etc and/or that the expectation of harm to any one individual is low. Nevertheless, the activity giving rise to the risks may need to be regulated further because of the numbers of people individually affected, and other possible detriments.

The proper characterization of the risk is important to the effective application of the preferred risk control hierarchy promoted by the EU. The hierarchy actually covers controls on hazards as well as the resulting risks. At the top of the hierarchy, and consistent with the general duty to secure health and safety, is the consideration of measures or alternatives that will avoid the hazard in the first place. This might involve substitution or the adoption of processes that conform with principles aimed at ensuring that a design is inherently safer. Lower down the hierarchy is the consideration of measures that will reduce the risks, given that there are no viable alternatives to accepting the hazard.

Inherently safer design

Adoption of the principles of inherently safer design is particularly important where the consequences of plant or system failure are high. HSE will press for the incorporation of inherently safer design features, where these are possible, to reduce the reliance on engineered safety systems or operational procedures, to control risk.

For example, the concept of 'defense in depth', redundancy, diversity and segregation, the provision of multiple barriers and other good practices, as set out in safety assessment principles for nuclear plant, are fundamental to ensuring safety. These apply against a requirement to: firstly, avoid the hazard and maintain safe conditions through inherent and, where appropriate, passive design features; and, secondly to minimize the sensitivity of the plant to potential faults as far as can be reasonably be achieved, by ensuring the plant response to a fault is as near the top of a hierarchy of: (i) produces no operational response or a move to a safer condition; (ii) passive or engineered safeguards, continuously available, make the plant safe; (iii) active engineered safeguards, brought into service in response to the fault, render the plant safe.

Handling uncertainty

The process of assessing risks needs to take account of the possibility of uncertainty. For example the science underpinning the assessment may be complex, ambiguous or incomplete and/or the necessary data may not be available.

We must first distinguish between uncertainty and ignorance. The latter refers to a lack of awareness of factors influencing the issue. This is a well-recognized weakness in risk assessment - that the identification of hazards may be incomplete. The measures needed to counteract ignorance are a wide engagement of different disciplines and communities of interest in the characterization of the issue.

Uncertainty itself is a state of knowledge in which, although the factors influencing the issue are identified, the likelihood of any adverse effects or the effects themselves cannot be precisely described. Uncertainty has many manifestations and they affect the approach to its handling. In summary:

- ***Knowledge uncertainty*** - This arises when knowledge is represented by data based on sparse statistics or subject to random errors in experiments. There are established techniques for representing this kind of uncertainty, for example confidence limits. The effect on a risk assessment is estimated by sensitivity analysis. This provides information relating to the importance of different sources of uncertainty which can then be used to prioritize further research and action, which is the only feasible way to address the uncertainty, though in some cases research may not be technically possible or cost-effective.
- ***Modelling uncertainty*** - This concerns the validity of the way chosen to represent in mathematical terms, or in an analogue fashion, the process giving rise to the risks. An example is the growth of a crack in the wall of a pressure vessel. The model would postulate the way the growth rate is affected by factors such as the material properties and the stress history to which the vessel is exposed in service. The model will provide prediction of failure in terms of time and the nature of the failure. It will inform intervention strategies such as the material specification, in-service monitoring and mitigation measures. All these factors may be modelled in many ways with the assumptions for each one open to question. The rigor of the peer review process and openness to alternative hypotheses are the main safeguards. However, the most intractable problems arise when it is not practical or physically possible to subject the alternative hypotheses to rigorous testing. In such cases, the exercise of expert judgement is paramount and confidence depends on the procedures adopted for selection of the experts and the management of bias (or appearance of bias).
- ***Limited predictability or unpredictability*** - There are limits to the predictability of phenomena when the outcomes are very sensitive to the assumed initial conditions. Systems that begin in the same nominal state do not end up in the same final state. Any inaccuracy in determining the actual initial state will limit our ability to predict the future and in some cases the system behavior will become unpredictable.

Precaution and uncertainty

Risk assessment and risk management procedures have a number of safeguards to ensure that our approach is inherently precautionary and in line with the precautionary principle. Included though not defined in the EC Treaty the precautionary principle has been defined, for example, by the United Nations Conference on the Environment and Development (UNCED) in 1992 as: ‘where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent degradation’.

The precautionary principle describes the philosophy that should be adopted for addressing hazards subject to high scientific uncertainty, and rules out lack of scientific certainty as a reason for not taking preventive action. Although originally formulated in the context of environmental protection, particularly in connection with 'global' environmental issues (e.g. climate change, ozone depletion), the precautionary principle has been applied more widely.

The HSE policy is that the precautionary principle should be invoked where:

- there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that serious harm might occur, even if the likelihood of harm is remote; and
- the scientific information gathered at this stage of consequences and likelihood reveals such uncertainty that it is impossible to evaluate the conjectured outcomes with sufficient confidence to move to the next stages of the risk assessment process.

Though the precautionary principle is invoked for hazards where, because of the uncertainty involved, it is not possible to apply the conventional techniques of risk assessment to assess the risks involved whatever the circumstances, it is possible in practice, to use such techniques for operationalizing the principle. Uncertainty is overcome by constructing credible scenarios on how the hazards could be realized and thereby making assumptions about consequences and likelihood. The credible scenarios can range from a 'most likely' worst case to a 'worst case possible' depending on the degree of uncertainty. Though such risk assessments made on scenarios are inevitably narrower in scope than a full blown risk assessment, this may not be a serious limitation if the scenarios are carefully chosen to reflect what could happen in reality.

5.6. Quantitative risk assessment

In some sectors of industry the quantitative risk assessment (QRA) is used as part of the consideration of the safety of plant and operations. QRA is a powerful tool in showing the relationship between different subsystems and the dependencies within the overall system. QRA is frequently used to estimate the risk from plant, as designed and operated. However, care needs to be taken to avoid numerous pitfalls that can trap the unwary. For example, in estimating the likelihood of an event by looking back at historical accident or incident data, care needs to be taken in selecting:

- the accident/incident sample - too small a sample or too narrow a scope can mislead; too wide a scope may result in the inclusion of accidents/incidents that developed differently from the event in question;
- the time period - too short a period may lead to the omission of representative accidents/incidents; too long a period may again result in the inclusion of accidents/incidents that developed differently from the event in question. Whatever time period is chosen, the assumption of a constant relationship between accident/incidents and time needs to be questioned in the light of changes in technology and in public expectations;
- the statistical method - historical accident/incident data may not include the cause, and selective use of data and/or choice of model can result in numerical figures that do not properly reflect actual history.

The process of undertaking a QRA can lead to a better understanding of the important features contributing to risk and weaknesses in the systems as well as allowing a numerical estimate of the residual risk to be derived. The quality of the modelling and the data will affect the robustness of the numerical estimate, and the uncertainties in it must always be borne in mind when using the estimate in risk management decisions. The use of numerical estimates of risk by themselves can, for several reasons including those above, be misleading and lead to decisions which do not meet adequate levels of safety. In general, qualitative learning and numerical risk estimates from QRA should be combined with other information from engineering and operational analyses in making an overall decision.

In addition to invoking the precautionary principle as above there are many other ways in which our approach is inherently precautionary. For example:

- do not take 'absence of evidence of risk' as 'evidence of absence of risk', although they recognize that persistent absence of evidence of risk, notwithstanding appropriate and thorough efforts to find it, may be indicative;
- require that the effects of the assumptions made to cover gaps in knowledge be tested through recognized methods, e.g. sensitivity analysis;
- build safety factors into the assessment process where appropriate, e.g. in assessing toxic substances, safety factors are used depending on the quality of data, severity of effect, and whether data from animals or *in vitro* experiments are being extrapolated to humans;
- attach more weight to consequences where a hazard has attributes which makes it likely that it will give rise to societal concerns, such as the potential to affect future generations or the potential for severe detriment, e.g. a major explosion in a built-up area;
- make use of comparative risk assessment for novel hazards that bear a similarity with existing hazards, requiring a stringent control regime for reducing risks to tolerable levels.

All the above show that assessing risks is far from being a straightforward exercise. At times the risk assessment will be a simple process based on observation and judgement, while at the other extreme it can also require the use of complex techniques such as quantified risk assessment.

5.7. Examining the options available and their merits

In looking at options, it would be particularly interested in examining:

- **possible good practice** for addressing the hazards identified, and evaluating whether it is relevant and sufficient. If specific good practice is not available we would also examine the merits of good practice that applies in comparable circumstances if we believe that this is directly transferable or can be suitably modified to address the hazard;
- **possible constraints attached to a particular option;** for example whether the option is technically feasible; or whether there are legal constraints on its adoption. The general principle is that the option adopted will improve or at least maintain standards of health, safety and welfare;
- **any adverse consequences associated with a particular option.** Very often adopting an option for

reducing one particular risk of concern may create or increase another type of risk. For example: banning a particular solvent may increase the use of a more hazardous one; reducing airborne concentration of substances in the workplace by exhaust ventilation may increase risk in the community or vice versa.

5.8. Cost benefit analysis

Sometimes there is a need to carry out formal analyses of costs and risk reduction to help with judgements on the benefits of each option and the costs involved in reducing the risks. These analyses may be of varying sophistication and complexity, and might in some cases include a cost benefit analysis (CBA). CBA is often a useful tool for judging the balance between the benefits of each option and the costs incurred in implementing it. CBA aims to express all relevant costs and benefits in a common currency, usually money. This in principle requires the explicit valuation of the benefit of reducing the risk. However, such a valuation may not always be possible or practicable - in these circumstances we rely on qualitative estimates. And, in any case, we apply common sense when reviewing the results. Moreover, explicit valuations may not always be necessary because:

- most safety provision for day to day hazards is in terms of the adoption of good practice or the voluntary pursuit of best practice, taking advantage of technological advances; and
- it may be possible to compare the difference in costs from switching from one option to another against the gains so achieved in terms of avoidance of harm.

It should be noted, that cost-benefit analysis is only one of a number of factors that are taken into account in deciding whether to pursue any particular course of action.

5.9. Criteria for reaching decisions

The criteria used by regulators in the health, safety and environmental field, in general, can be classified according to three 'pure' criteria. They are:

- an **equity-based** criterion, which starts with the premise that all individuals have unconditional rights to certain levels of protection. This leads to standards, applicable to all, held to be usually acceptable in normal life, or which refer to some other premise held to establish an expectation of protection. In practice, this often converts into fixing a limit to represent the maximum level of risk above which no individual can be exposed. If the risk estimate derived from the risk assessment is above the limit and further control measures cannot be introduced to reduce the risk, the risk is held to be unacceptable whatever the benefits;
- a **utility-based** criterion which applies to the comparison between the incremental benefits of the measures to prevent the risk of injury or detriment, and the cost of the measures. In other words, the utility-based criterion compares in monetary terms the relevant benefits (e.g. statistical lives saved, life-years extended) obtained by the adoption of a particular risk prevention measure with the net cost of introducing it, and requires that a particular balance be struck between the two. This balance can be deliberately skewed towards benefits by ensuring that there is gross disproportion between the costs and the benefits;
- a **technology-based** criterion which essentially reflects the idea that a satisfactory level of risk prevention is attained when 'state of the art' control measures (technological, managerial, organizational) are employed to control risks whatever the circumstances.

The criteria that HSE has adopted in the form of a framework, known as the tolerability of risk (TOR), accommodate all three criteria.

The framework is illustrated in Fig 5.1. The triangle represents increasing level of 'risk' for a particular hazardous activity (measured by the individual risk and societal concerns it engenders) as we move from the bottom of the triangle towards the top. The dark zone at the top represents an unacceptable region. For practical purposes, a particular risk falling into that region is regarded as unacceptable whatever the level of benefits associated with the activity. Any activity or practice giving rise to risks falling in that region would, as a matter of principle, be ruled out unless the activity or practice can be modified to reduce the degree of risk so that it falls in one of the regions below, or there are exceptional reasons for the activity or practice to be retained.

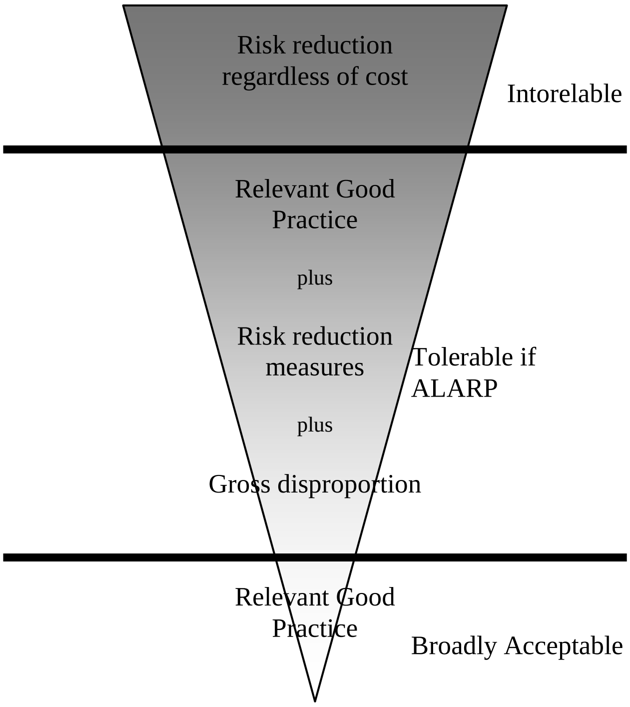

Figure 5.1. General HSE framework for the tolerability of risk.

The light zone at the bottom, on the other hand, represents a broadly acceptable region. Risks falling into this region are generally regarded as insignificant and adequately controlled. We, as regulators, would not usually require further action to reduce risks unless reasonably practicable measures are available. The levels of risk characterizing this region are comparable to those that people regard as insignificant or trivial in their daily lives. They are typical of the risk from activities that are inherently not very hazardous or from hazardous activities that can be, and are, readily controlled to produce very low risks. Nonetheless, we would take into account that duty holders must reduce risks wherever it is reasonably practicable to do so or where the law so requires it.

The zone between the unacceptable and broadly acceptable regions is the tolerable region. Risks in that region are typical of the risks from activities that people are prepared to tolerate in order to secure benefits, in the expectation that:

- the nature and level of the risks are properly assessed and the results used properly to determine control measures. The assessment of the risks needs to be based on the best available scientific evidence and, where evidence is lacking, on the best available scientific advice;
- the residual risks are not unduly high and kept as low as reasonably practicable; and
- the risks are periodically reviewed to ensure that they still meet the ALARP criteria, for example, by ascertaining whether further or new control measures need to be introduced to take into account changes over time, such as new knowledge about the risk or the availability of new techniques for reducing or eliminating risks.

Applying the generalized TOR framework

The framework is aimed at ensuring that the approach for addressing hazards is inherently precautionary and leads to control regimes that improve or at least maintain standards, while retaining the principles of proportionality, consistency, etc.

Thus when we apply the framework to policy formulation, regulatory development and enforcement activities, one should to:

- take into account that societal concerns are often absent for a wide range of hazards, for example, this is often the case for those hazards that are familiar or where the risks they give rise to are generally accepted as being well controlled. Hazards giving rise to societal concerns have a number of well known features and such concerns are often absent for many routinely encountered occupational hazards. This means that when determining where the hazard falls on the TOR triangle one can, as a general rule, for most occupational hazards, focus on the individual risks (generally assessed in relation to a hypothetical person using conventional risk assessment techniques;

- decide, from the information gathered in going through the decision-making process, how precautionary our approach will be when determining where the individual risk and societal concerns i.e. on the TOR geometry;
- concentrate on ensuring that duty holders must have in place suitable controls to address all significant hazards arising from their undertakings;
- start with the expectation that those controls should, as a minimum, implement authoritative good practice precautions (or achieve similar standards of prevention/ protection), irrespective of specific risk estimates.

In this context:

- a hazard is regarded as significant unless past experience, or going through the decision making process described earlier, shows the risk from it to be extremely low or negligible when compared to the background level of risk to which people are exposed, and the hazard does not give rise to societal concerns;
- as authoritative sources of relevant good practice are considered, those enshrined in prescriptive legislation, Approved Codes of Practice and guidance produced by Government. One can also consider including as other sources of good practice, standards produced by Standards-making organizations (e.g. BS, CEN, CENELEC, ISO, IEC, ICRP) and guidance agreed by a body representing an industrial or occupational sector (e.g. trade federation, professional institution, sports governing body). Such considerations should take into account that HSE is a repository of information concerning good engineering, managerial and organizational practice, and would also include an assessment of the extent to which these sources had gained general acceptance within the safety movement.

The next stage is to distil from the information gathered at Stages 2 (characterizing the problem) and 3 (examining options and their merits) on individual risks and societal concerns and decide whether adoption of authoritative good practice precautions is an adequate response to the hazards. The experience suggests that in most cases adopting good practice ensures that the risks are effectively controlled.

There will be, however, cases where existing good practice was not identified as an option at Stage 3. This will be particularly true for hazards that are new or not well studied, or where the circumstances in which people interface with the hazard are untypical or exceptional. In these circumstances there is need to examine whether any of the other options identified at Stages 2 and 3 would reduce the risks to the degree HSE considers appropriate. If one is found it would advocate its adoption. However, there may be occasions when one may find that no option is available for reducing the risks to a tolerable level. This will be the case for risks from activities:

- that are so high and their control inherently so difficult that it is not possible to find reasonable control measures that one could feel confident would work in practice; or
- where it is not possible to allay the societal concerns about the risk. For example, though experts may regard available control measures as adequate for controlling a particular risk, that view may not be shared by society as a whole, either because the majority of people believe that the measures will not always be observed or that they have doubts that the risks should be entertained at all.

5.10. Tolerability limits

The TOR framework just described can in principle be applied to all hazards. When determining reasonably practicable measures for any particular hazard, whether the option chosen to control the risk is good enough or not depends in part on where the boundaries are set between the unacceptable, tolerable or broadly acceptable regions in Figure 5.1. As will be clear from earlier discussions, the choice will be the outcome of much deliberation and negotiation in the course of policy development, reflecting the value preferences of stakeholders and the practicability of possible solutions.

Tolerability limits for risks entailing fatalities

In practice the actual fatality rate for workers in even the most hazardous industries is normally well below the upper limit of a risk of death to any individual 10^{-3} per annum for workers and 10^{-4} per annum for the public who have a risk imposed on them 'in the wider interest of society.

Similarly the actual risk of death per annum for the public from work activities is usually very much lower than 10^4. For example, during the period 1994/5-1998/9 the annual risk of death to the public from the use of gas (fire, explosion or carbon monoxide poisoning), averaged over the entire population of Great Britain, was 1 in 1 510 000 - in other words below the limit of what is often regarded as broadly acceptable.

As a result what is unacceptable, tolerable or broadly acceptable in specific circumstances is often spelled out or implied in legislation, Approved Code of Practice (ACOP), guidance, etc or reflected in what constitutes good practice i.e. there is no need to set explicit TOR boundaries. However, HSE on the basis of its experience accumulated over the years in engaging its stakeholders subscribes as a matter of policy to the following indicative criteria, as to where these boundaries lie, for risks in a limited category, namely those entailing the risk of individual or multiple deaths.

Boundary between the 'broadly acceptable' and 'tolerable' regions for risk entailing fatalities

HSE believes that an individual risk 10^{-6} per annum for both workers and the public corresponds to a very low level of risk and should be used as a guideline for the boundary between the broadly acceptable and tolerable regions. Risks of various kinds which contribute to a background level of risk - typically a risk of death of one in a hundred per year averaged over a lifetime. A residual risk 10^{-6} per year is extremely small when compared to this background level of risk. Indeed many activities which people are prepared to accept in their daily lives for the benefits they bring, for example, using gas and electricity, or engaging in air travel, entail or exceed such levels of residual risk.

Boundary between the 'tolerable' and 'unacceptable' regions for risk entailing fatalities

The HSE does not have, for this boundary, a criterion for individual risk as widely applicable as the one mentioned above for the boundary between the broadly acceptable and tolerable regions. This is because risks may be unacceptable on grounds of a high level of risk to an exposed individual or because of the repercussions of an activity or event on wider society. Indeed, it would be quite unusual for high levels of individual risk not to engender societal concerns, on equity grounds. The converse is not, however, true - society can be seized by hazards that pose, on average, quite low levels of risk to any individual but could impact unfairly on vulnerable groups, such as the young or the elderly or particularly susceptible individuals. Furthermore, exposure to an activity may result in a low level of average risk to any one individual but the totality of such risks across the affected population would not be acceptable as judged by the socio-political response to a particular event such as a railway disaster. Nevertheless, in the HSE document on the tolerability of risks in nuclear power stations, it is suggested that an individual risk of death of one in a thousand per annum should on its own represent the dividing line between what could be just tolerable for any substantial category of workers for any large part of a working life, and what is unacceptable for any but fairly exceptional groups. For members of the public who have a risk imposed on them 'in the wider interest of society' this limit is judged to be an order of magnitude lower - at 10^{-4} per annum.

However, hazards that give rise to such levels of individual risks also give rise to societal concerns and the latter often play a far greater role in deciding whether a risk is unacceptable or not. Secondly, these limits were derived for activities most difficult to control and reflect agreements reached at international level. In practice most industries in the UK do much better than that.

Risks giving rise to societal concerns

Developing criteria on tolerability of risks for hazards giving rise to societal concerns is difficult. Hazards giving rise to such concerns often involve a wide range of events with a range of possible outcomes. The summing or integration of such risks, or their mutual comparison, may call for the attribution of weighting factors for which, at present, no generally agreed values exist as, for example, the death of a child as opposed to an elderly person, dying from a dreaded cause, e.g. cancer, or the fear of affecting future generations in an irreversible way.

Nevertheless, HSE has adopted the criteria below (some of which are currently under review) for addressing societal concerns arising when there is a risk of multiple fatalities occurring in one single event. These were developed through the use of so-called FN-curves (obtained by plotting the frequency at which such events might kill N or more people, against N). The technique provides a useful means of comparing the impact profiles of man-made accidents with the equivalent profiles for natural disasters with which society has to live. The criteria are based on an examination of the levels of risk that society was prepared to tolerate from a major accident affecting the population surrounding the industrial installations at Canvey Island on the Thames. These criteria are, however, directly applicable only to risks from major industrial installations and may not be valid for very different types of risk such as flooding from a burst dam or crushing from crowds in sports stadia.

Thus, where societal concerns arise because of the risk of multiple fatalities occurring in one event from a single major industrial activity, HSE proposes the following basic criterion for the limit of tolerability, particularly for accidents where there is some choice whether to accept the hazard or not, e.g. the risk of such an event happening from a major chemical site or complex continuing to operate next to a housing estate. In such circumstances, HSE proposes that the risk of an accident causing the death of 50 people or more in a single event should be regarded as intolerable if the frequency is estimated to be more than one in five thousand per annum.

A different situation arises altogether when giving advice to planning authorities in connection with proposed developments in the vicinity of major hazard chemical plants. Since the developments have not yet received planning permission, not allowing them because of the putative societal risks to which would-be occupants would have been exposed by living next to a chemical plant, is relatively inexpensive when compared to the costs entailed in requiring existing developments with similar risks to introduce remedial measures. HSE's criteria for advising against a development because of the societal risks that it may engender are based in the first instance on the level of individual risk per year calculated for a hypothetical person receiving a dangerous dose, or worse, together with certain characteristics of the development.

Thus in the case of most housing developments, for example, HSE advises against granting planning permission for any significant development where individual risk of death for the hypothetical person is more than 10 in a million per year, and does not advise against granting planning permission on safety grounds for developments where such individual risk is less than 1 in a million per year. (Somewhat different criteria are applied to sensitive developments where those exposed to the risk are more vulnerable, e.g. schools, hospitals or old people's homes, or to industrial or leisure developments, reflecting the different characteristics of the hypothetical person used to assess individual risk).

Cases of proposed housing development where the individual risk of death per annum is between 1 and 10 in a million per year are scrutinized more closely, taking into account a more detailed assessment of the individual risk, the area of the development, the number of people involved, their vulnerability and how long they are exposed to the risk. Further information is available on the risk criteria presently applied by HSE in land use planning, including the criteria applied for different categories of development, for developments in the vicinity of major chemical plants, and for development of new plants.

6. UK HSE Guidance on ‘as low as reasonably practicable’ (ALARP) decisions

The HSE has produced a suite of guidance documents concerning ALARP. These are designed to give high level principles which separate parts of HSE can then use to promulgate sector specific advice. The documents are:

- Reducing Risk, Protecting People(R2P2);
- Principles and guidelines to assist HSE in its judgements that duty-holders have reduced risk as low as reasonably practicable;
- Assessing compliance with the law in individual cases and the use of good; and
- ALARP in Design - Policy and Guidance.

The HSE discussion document "Reducing Risks, Protecting People - HSE's decision making process" (R2P2) sets out, in more detail, HSE’s approach to making decisions about SFAIRP and ALARP. It is a further development of ideas previously promulgated in HSE’s Tolerability of Risks from Nuclear Power Stations (TOR) document (1992) which defined three regions of risk, delineated by an unacceptable region and a broadly acceptable region; the region in between defining a region of tolerable risk, but only when those risks are ALARP.

R2P2 makes some important statements of principles:

Principle 1

> "HSE starts with the expectation that suitable controls must be in place to address all significant hazards and that those controls, as a minimum, must implement authoritative good practice irrespective of situation based risk estimates".

Principle 2

> "The zone between the unacceptable and broadly acceptable regions is the tolerable region. Risks in that region are typical of the risks from activities that people are prepared to tolerate in order to secure benefits in the expectation that the nature and level of the risks are properly assessed and the results used properly to determine control measures; the residual risks are not unduly high and kept as low as reasonably practicable (the ALARP principle); and the risks are periodically reviewed to ensure that they still meet the ALARP criteria, for example, by ascertaining whether further or new controls need to be introduced to take into account changes over time, such as new knowledge about the risk or the availability of new techniques for reducing or eliminating risks."

Principle 3

> "Both the level of individual risks and the societal concerns engendered by the activity or process must be taken into account when deciding whether a risk is acceptable, tolerable or broadly acceptable and hazards that give rise to …. individual risks also give rise to societal concerns and the latter often play a far greater role in deciding whether risk is unacceptable or not". For high hazard sites, societal risks/concerns are normally much more relevant than individual risks, but individual risk must still be addressed. Although R2P2 gives clear guidance on individual risk criteria, it gives only limited guidance on criterion values for societal risks (50 fatalities at less than 1 in 5000 per annum, point on the boundary between the ALARP band and intolerable band).

ALARP guidance specific to the regulations implementing the Seveso II Directive is provided in:

- SHAG 190 (Appendix 4);
- L111 (Regulation 4);
- The Safety Report Assessment Manual (SRAM) (Part 2, Chapter 3); and
- The Safety Report Assessment Guides (SRAGS).

6.1. ALARP demonstration requirements

The assessor will need to focus on these measures to be satisfied they do represent good practice etc. HSE will regard relevant good practice to have met the AMN requirement when:

- the societal risks can be shown (subject to uncertainty) to be broadly acceptable, e.g. by use of an approximate risk integral (ARI) or other societal risk methodology; and
- no group, or individual, is subject to relatively high individual risks that are not ALARP.

The HSE regard good practice as being subject to the process of continuous improvement and will encourage industry to keep it up-to-date as technology advances and societal concern about MAHs (Major Accident Hazards) varies.

Having been satisfied that the measures in place represent relevant good practice, the residual risks will be in one of the following category bands:

Intolerable risk

Clearly, if the risk is in this region (whether for individual or societal risk) then ALARP cannot be demonstrated and action must be taken to reduce the risk irrespective of cost.

"Tolerable if ALARP" Risk

If the risks fall in this region then a case specific ALARP demonstration is required. The extent of the demonstration should be proportionate to the level of risk.

Broadly acceptable risk

If the risk has been shown to be in this region, then the ALARP demonstration may be based on adherence to codes, standards and established good practice. However, these must be shown to be up-to-date and relevant to the operations in question. This is shown diagrammatically in Figure 5.1.

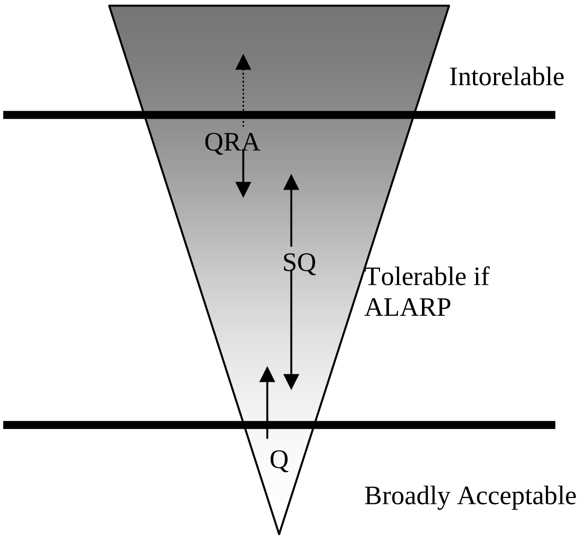

Figure 6.1. Types of risk assessment.

The definitions of Q, SQ, QRA, etc. are based upon definitions of types of risk assessments set down in HSG 190 and developed further in the Generic SRAG (with intermediate levels where appropriate), but in essence the type of risk assessment which is appropriate in a demonstration will vary gradually in depth and level of quantification from qualitative (Q) at one end to full quantified risk assessment (QRA) at the other.

6.2. Risk Reduction Measures (RRMs) database

In order to assist Assessors in determining if Operators have considered all the relevant RRMs, a database is being developed by HSL/Amey Vectra which draws together unstructured, paper based lists of measures which have been considered within HSE in the past, together with measures discussed in the open literature or research reports written for HSE.

6.3. Guidance on gross disproportion

All RRMs will involve a cost to the Operator. Equally, an RRM is intended to reduce risk from an operation and this reduction will bring about a benefit (reduction in lives saved, etc.) which can be expressed in monetary terms. The ratio of the costs to the benefits can be described as a "proportion factor" (PF). It should also be noted, however, that the benefits might also include the avoidance of such thing as environmental cleanup costs, increased insurance premiums, loss of asset value, the costs of increased regulatory interference, etc.

If this PF is greater than some defined value, then the costs can be said to be grossly disproportionate to the benefits and the RRM would not be "reasonably practicable".

It is assumed that, within the "tolerable if ALARP" region, the minimum value of PF will be 1 since values below 1 imply a bias against safety. It is further assumed that the value of PF will increase in some way as risk increases. That is to say, the operator would be expected to pay more to reduce risk by a given amount if the initial level of risk is close to the intolerable limit than if the risk were just above the broadly acceptable limit. In the intolerable region, RRMs must be implemented almost regardless of cost, implying an very high, or infinite PF (though it is recognized that CBAs and gross disproportion are not applicable in this region).

The difficulty lies in defining the upper limit of PF and the way PF increases with risk. An upper value for PF of 10 has been suggested but the way PF changes with risk is still unclear. However, the basic principle is shown in Fig. 6.2.

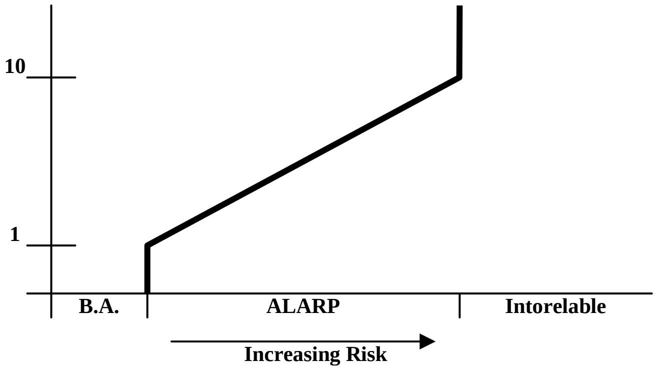

Figure 6.2. Change of proportion factor with risk.

Within the Broadly Acceptable region, providing DH's comply with relevant good practice, additional RRMs are assumed to be not reasonably practicable implying a PF of zero. However, if there are obvious and cheap measures that could be taken they should at least be considered.

Case specific ALARP demonstrations should only be based on the societal risk from a site and not the societal concerns.

HID believe that there may be a number of site specific issues which should be taken into account by the assessment team. These include the presence of hospitals or significant numbers of children or the elderly. Here, difficulties in organizing and evacuating these groups means there is an additional risk factor to be taken into account. Also, due to factors such as physiology, state of health, etc., people in these groups may also be more vulnerable to the effects of the hazard. The assessment team may decide that the presence of these groups calls for an increase in the societal risk based gross disproportion factor (i.e. an increase in PF).

6.4. Guidance on lines of defense analysis

Arguments that risks have been reduced ALARP based upon `strength in depth` concepts such as Layers of Protection (LOPA) or `Lines of Defense` may be used by companies in making demonstrations that all measures necessary have been taken. Some research is being undertaken with Vectra/HSL with a view to guidance.

6.5. Demonstration frameworks

Flowsheet approach

HSE choose not to be prescriptive on how demonstrations that all necessary measures have been taken should be made, but one way of approaching this is set down in the attached flow sheet at Figure 6.3. This method assumes that the risks are not intolerable.

Stepwise approach

Alternatively, it has been found that some Duty Holders have used the following stepwise approach. This approach assumes that the risks have been shown to be in the "tolerable if ALARP" region and that a case specific ALARP demonstration is required:

1. Identify controlled substances, their inventories and locations. Show the local environment including on and offsite populations that may be affected and other hazardous installations (including those at designated domino effect sites) that might be affected by major accidents or be initiators of a major accident. Show that the required measures are, at least, to current authoritative good practice.
2. Identify all major accidents and develop a qualitative view on the significance of each one. In the light of the view on the significance of all the identified major accidents, choose a representative subset for detailed consideration.
3. Refine the prediction of the hazard range and its likelihood, for each event in the chosen representative subset.
4. Refine the prediction of the consequences, for each event in the chosen subset, including estimates of the number of fatalities, major and minor injuries to man and damage to the environment, and develop a view on the extent of lesser harms such as major and minor injuries to persons.

5. Show the consequences and the likelihood, for each event in the chosen subset, on a suitable matrix or fN plot (with suitable error bands).
6. Divide the area of the matrix (or plot) into 3 bands (broadly acceptable risk, tolerable if ALARP, intolerable risk) and calibrate these bands against criteria. Suitable numerical criteria for individual risk are set down in R2P2.
7. For intolerable risks immediate action should be taken to reduce risks. For those events in the broadly acceptable region a comparison with relevant standards should be appropriate. For those events in the TIFALARP region look at the major accidents in a particular consequence band and select the ones with the highest frequencies.
8. For these, determine what additional risk reduction measures, beyond relevant good practice standards, (software as well as hardware) may be implemented.
9. Implement these measures unless a reasoned argument is presented showing the costs to implement this scheme are grossly disproportionate. Arguments based upon `strength in depth` concepts such as Layers of Protection (LOPA) or `Lines of Defence` may be used when these have been developed sufficiently. Where the risks have been assessed as high, the use of formal cost benefit analysis may be required to test the cost-benefit balance for the prospective remedial measures.
10. Revisit step 7 for lesser consequences and continue until proportional demonstrations are made.

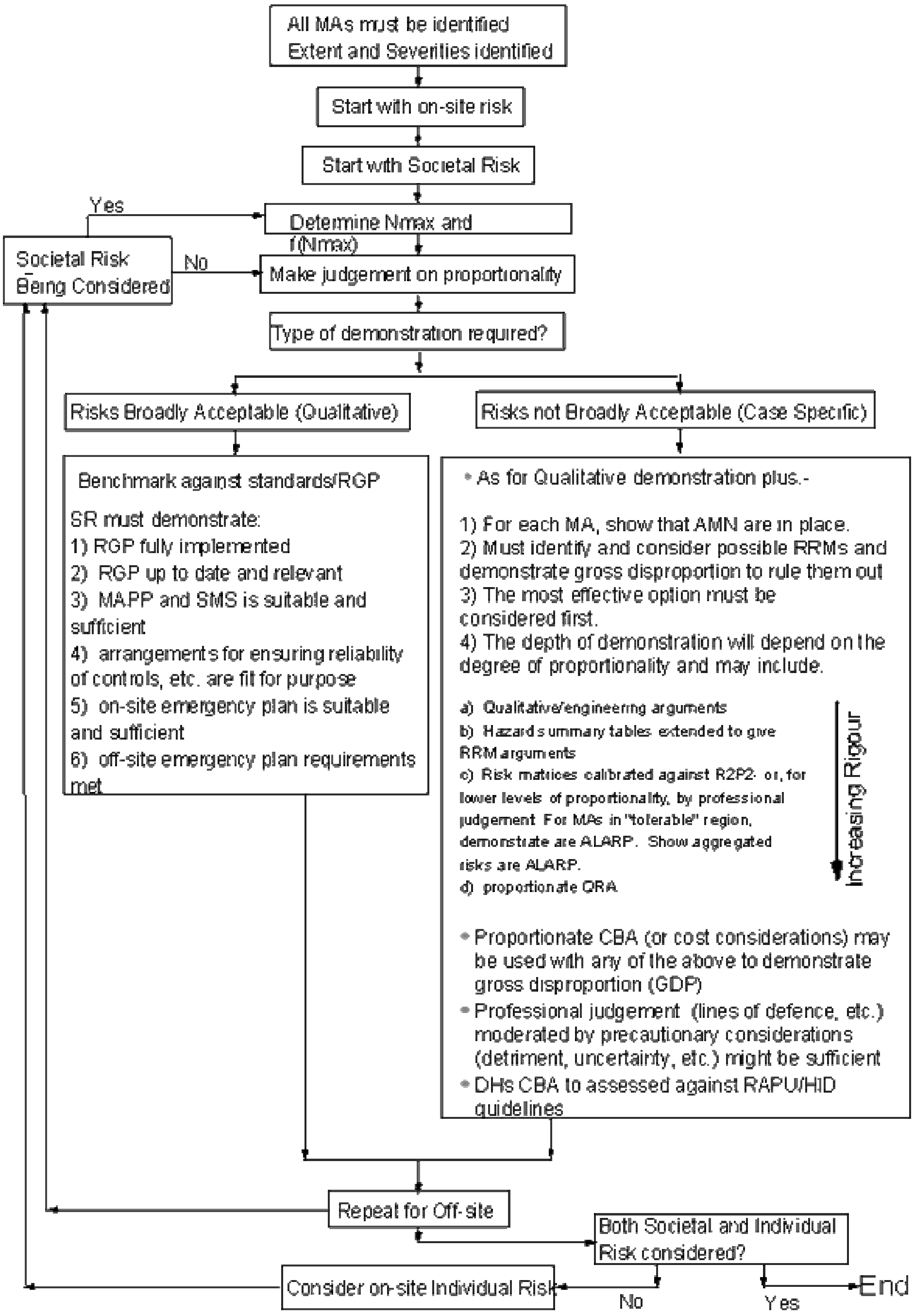

Figure 6.3. ALARP demonstration flow sheet.

6.6. Guidance on proportion factors

Work by RAPU and ESAU

The starting point for VPF was taken to be the DETR figure of approx. These were 2 x DETR for deaths from cancer and 3 x DETR for some aspects of railway safety. It is HID OPU4's contention that the values of 2 and 3 represent proportion factors (PF) similar to those described in Section 8F earlier.

The paper also examined the implied ratios of CPF to VPF in a number of CBAs (and RIAs) carried out prior to the implementation of a number of sets of regulations.

DNV Offshore Guidance

The document "A Guide to Quantitative Risk Assessment for Offshore Installations" prepared by DNV includes some guidance on gross disproportion and the value of statistical fatalities.

Section 25.8.3 of that document states:

> "The necessary degree of disproportion is generally considered to be low near the negligible criterion, rising to in effect infinity at the maximum tolerable criterion"; and
> "In the UK NRPB (1986) criteria, factors of between 1 and 15 are used, depending on the individual risk"

Section 25.8.5 of that document gives a number of examples of expenditure on RRMs and concludes that there is general agreement that the PF should range between 1 and 10.

7. Risk acceptance criteria on the level of industrial installations

7.1. Risk acceptance criteria for quantitative analyses

This type of Risk Acceptance Criteria (RAC) is most commonly used in relation to overall risk studies in the conceptual design, in engineering phases and in the operations phase.

Requirements stipulated in standards, specifications, procedures, etc. which are necessary to achieve acceptable safety, should not be interpreted as RAC. However, such requirements will be important premises in relation to the risk analysis in order to achieve an acceptable level of risk.

The RAC may be subdivided in categories according i.e. to the purpose and the level of detail of the analysis:

- Quantitative RAC for quantitative studies.
- Risk matrixes and the ALARP principle.
- Risk comparison criteria.

Some examples of decision support contexts into which risk analysis may play a role can illustrate the choice of RAC:

- In relation to decisions regarding the overall operations of an installation, the total risk potential has to be considered. The RAC that are relevant will usually be quantitative (for example FAR values) or semi-quantitative (such as risk matrix).
- One overall risk value is preferable for instance for the comparison of two alternative field development concepts, with respect to risk for personnel. PLL may in these circumstances be suitable, as this criterion also allows for different manning levels for the options being considered.
- Risk analysis or safety evaluation is often performed as one of the inputs for design development within an engineering project. Changes to the design will usually imply changes to the risk picture. The RAC should be formulated in such a way that these changes may be registered. Use of criteria related to impairment of safety functions will enable calculation of how the impairment frequency is changed according to design changes (e.g. in connection with relocation of equipment).

7.2.Relevant aspects in relation to choice of risk acceptance criteria (RAC)

The use of the RAC will always influence strongly the selection of the type of criteria. Quite often conflicting interests are involved. On one hand the RAC may be needed as basis for decisions on risk reducing measures both in engineering and operational phases. On the other, the criteria should enable comparison of the risk level with other types of risk.

The table 7.1 illustrates some of the important aspects in choosing RAC and how these may be in.

Table 7.1. Some of the important aspects in choosing RAC.

Aspect	Advantages and disadvantages of particular criteria
Suitability for decision support	Risk acceptance criteria that are simple to use in a decision-making process are often precise and associated with particular features of an installation or an activity. Such RAC are suitable for measuring the effect of risk reducing actions and other changes to design or operations.
Adaptability to communication • Easy to understand for non-experts. • Comparison of risk with other activities.	Adaptability to communication implies how the risk acceptance is interpreted and understood among all involved parties: Those that are exposed to the risk, the management of the company, authorities, the public, etc. A message may be transmitted easily if the RAC are easy to understand. On the other hand, acceptance criteria which appear easy to understand may represent an oversimplification if the decision problem is very complicated or difficult to understand. Risk acceptance criteria that are easy to understand may be ambiguous due to a low level of precision. Risk acceptance criteria that express a societal dimension will often enable comparison with other activities in the society. Such RAC are often related to parameters that belong far out in the event sequence (such as fatalities).
Unambiguity • Precision • System limits • Averaging	Unambiguous RAC are often precisely defined with respect to calculation of risk and to the applicable system limits. They are usually not subject to extensive averaging and will therefore rarely be misunderstood.
Concept independence	Risk acceptance criteria that are concept independent will not favour one particular concept solution but be neutral in relation to such a choice.
Uncertainty	Risk parameters that are far out in the event sequence will often involve the highest degree of uncertainty. Estimates will have to be made for each element in the event sequence, implying the most extensive computational uncertainty for the last elements. On the other hand, these risk parameters express the highest level of detail and will therefore often give the best basis for decisions.

The parameters most commonly used as RAC are discussed in the following subclauses in relation to the quality parameters outlined in the table above. First of all some of these quality criteria are discussed a more detail.

7.3. Popular risk measures

Fatal Accident Rate (FAR)

The FAR value expresses the number of fatalities per 100 million exposed hours for a defined group of personnel. The FAR is often used as a risk parameter. Several variants are used, mainly reflecting how the averaging of the risk level is done.

The FAR value for an entire installation is not very suitable for decision support with respect to reflection of the effect of risk reducing measures. This is due to the averaging over all exposed personnel, which means that limited effects usually will disappear almost entirely. (Area FAR is more suitable in this context).

FAR for an entire installation will favour a concept with high manning level in a low risk area, thereby implying that the risk level may be high in some smaller areas without necessarily showing an effect on the FAR for an entire installation.

FAR for a group with unformed risk exposure

The Group-FAR is the expected number of fatalities per 100 million exposed hours for the group in question. More suitable than FAR for an entire installation, because the group FAR averages over a smaller number of positions.

FAR for a physically bounded area

The area-FAR is the expected number of fatalities per 100 million exposed hours in a physically bounded area. Better suited for decision support than PLL, f-N curves, IR, FAR for an entire installation and group FAR due to its focusing on one specific area on the installation.

Individual Risk (IR)

IR is the probability that a specific individual (for example the most exposed individual in the population should suffer a fatal accident during the period over which the averaging is carried out (usually a 12 month period). It is often difficult in practice to calculate the risk level for a specific individual and the calculations are therefore often carried out for an 'average individual'. IR will then be proportional to the group FAR. For a single individual (average individual) it is relatively well suited for decisions relating to actions that may affect such an individual, because the effects will be explicitly reflected. It is relatively simple to comprehend for non-experts and relatively easy to compare with risk for other activities as long as the risk level is expressed for a single individual. Like the other risk parameters relating to personnel IR will be associated with relatively high uncertainty as the entire accident sequence needs to be quantified.

Loss of Main Safety Function (LMSF)

The frequency of loss of the main safety functions is the frequency of AEs that lead to impairment of the main safety functions. Typical main safety functions are escape ways, evacuation means, the main support structure and the control room function.

LMSF represents a typical design related criterion, which is well suited for decision-making on technical measures. Better than the escalation frequency criterion in the operations phase because non-technical measures may also influence the frequency of loss of main safety functions, probably with a higher uncertainty than for technical measures.

The term loss of main safety functions is relatively easy to understand for non-experts, but requires a good definition of how the main safety functions may be impaired. It is not suitable for comparison of risk with other activities.

The main safety functions and their required functionality have to be defined separately for each installation. Moreover the defined main safety functions will have to be accurately determined, in relation to which circumstances and loads that will imply loss of the function.

Risk matrixes

The arrangement of accident probability and corresponding consequence in a matrix (see Fig. 7.1) may be a suitable expression of risk in cases where many AEs are involved or where single value calculation is difficult. The matrix is separated into three regions as follows:

- Unacceptable risk.
- Acceptable risk.

A region between acceptable and unacceptable risk, where evaluations have to be carried out in order to determine whether further risk reduction is required or whether more detailed studies should be done first of all.

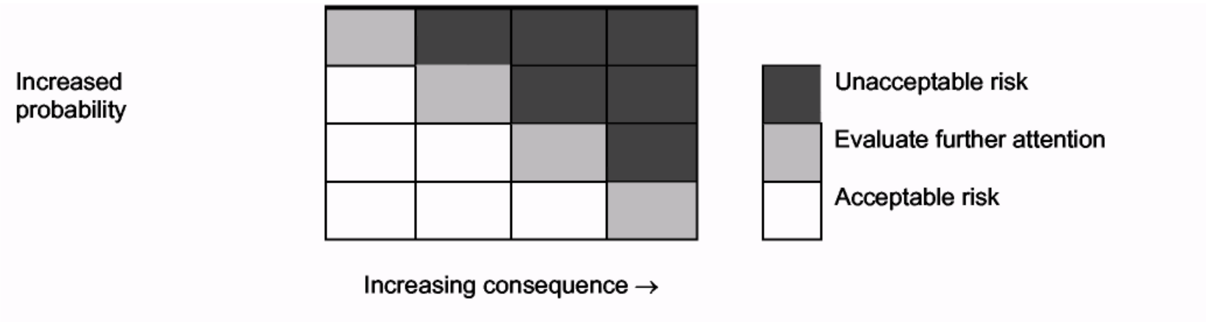

Figure 7.1. Risk matrix.

The limit of acceptability is set by defining the regions in the matrix which represent unacceptable and acceptable risk. The risk matrix may be used for qualitative as well as quantitative studies. If probability is classified in broad categories such as 'rare' and 'frequent' and consequences in 'small', 'medium' and 'catastrophic', the results from a qualitative study may be shown in the risk matrix. The definition of the categories is particularly important in case of qualitative use.

The categories and the boxes in the risk matrix may be replaced by continues variables, implying a full quantification. An illustration of this is shown in Fig. 7.2.

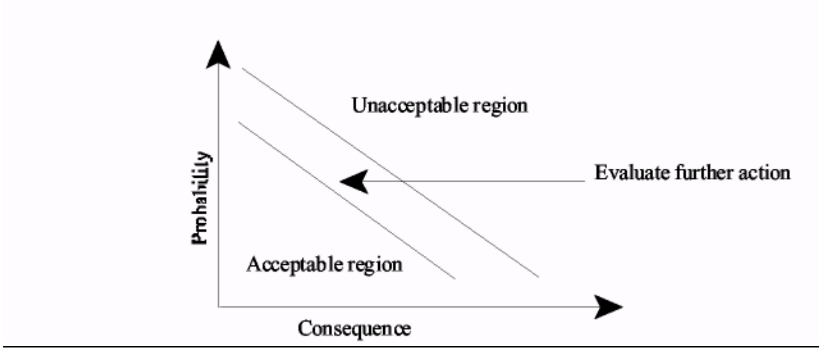

Figure 7.2. Risk matrix like presentation with continuous variables.

The upper tolerability limit (Figures 7.1 and 7.2) is almost always defined, whereas the lower limit is individual to each individual risk reducing measure, depending on when the cost of implementing each measure becomes unreasonably disproportional to the risk reducing effect.

f-N Curves

The f-N curve (f = frequency, N = number, i.e. measurement of consequence) expresses the acceptable risk level according to a curve where the frequency is dependent on the extent of consequences (such as number of fatalities per accident). The acceptance limit may be adjusted according to the resource, which is exposed. The f-N curve used as an acceptance limit may reflect risk aversion to major accidents (with multiple fatalities), if the product of f and N is decreasing with increasing N. The calculation of values for the f-N curve is cumulative, i.e. a particular frequency relates to 'N or more' fatalities. Figure 7.3 presents an illustration.

The f-N curve may be used in relation to risk acceptance for personnel, environment and assets.

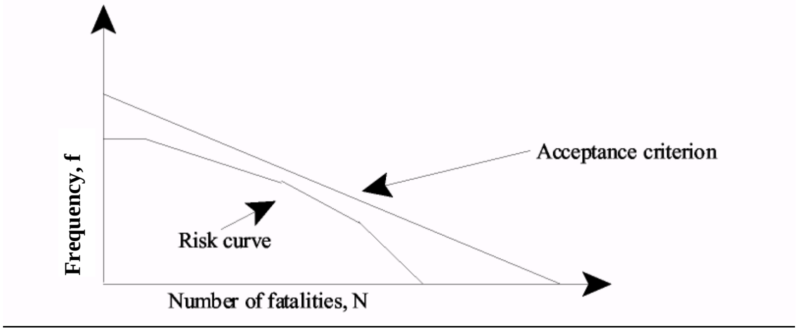

Figure 7.3. f-N curve.

ALARP - principle

The ALARP (see Figure 5.1) principle is sometimes in the industry used as the only acceptance principle and sometimes in addition to other RAC.

The use of the ALARP principle may be interpreted as satisfying a requirement to keep the risk level 'as low as possible', provided that the ALARP evaluations are extensively documented. The risk level should be reduced as far as possible in the interval between acceptable and unacceptable risk. The common way to determine what is possible is to use cost-benefit evaluations as basis for decision on whether to implement certain risk reducing measures.

The upper tolerability limit (see Fig. 5.1) is almost always defined, whereas the lower tolerability limit is sometimes defined and is in other cases left undefined. The lower limit is individual to each individual risk reducing measure, depending on when the cost of implementing each measure becomes unreasonably disproportional to the risk reducing effect.

The ALARP principle used for risk acceptance is applicable to risk to personnel, environment and assets.

Comparision criteria

This type of criteria is suitable in more limited studies which aim at comparing certain concepts or solutions for a particular purpose with established or accepted practice.

The formulation of the acceptance criterion in this context may be that the new solution should not represent any increase in risk in relation to current practice.

Examples of comparison criteria are:

- Alternative design (or use of new technology) for fire water system should be at least as safe as conventional technology.
- The risk level for the environment should not be higher compared to existing solution.
- Alternative solution should be at least as cost effective as the established practice.

This type of RAC is also suitable for risk to personnel, environment and assets.

7.4. Other aspects

Establishment of an acceptable level

The level of precision in the formulation of the RAC will depend on the need for input to decision-making. Risk analyses will be carried out on different levels of detail and in different lifecycle phases, for limited specific decisions and for complete installations. The acceptance criteria must be suited for covering such a variation. Risk acceptance criteria will have to be used in a consistent way for all activities within an operating company.

The RAC should be at a level where there is a reasonable balance between ambitions as to continuous improvement, defined safety objectives and technology improvements on one hand and what is realistic to achieve on the other.

Safety objectives

The safety objectives should as far as possible be expressed in a way which allows verification of fulfillment through an ALARP evaluation. Long and short term safety objectives form the basis for further development of the safety level and the tightening of the RAC as an element of the continuous improvement process and the Health Environment and Safety management.

Updating of RAC

It is required that the RAC be updated according to the development of the activity as a whole, in order that these criteria remain an effective means to achieve the overall safety objectives. Whenever the safety objectives are changed, it must be considered if the RAC should also be judged. It may also be necessary to update the RAC according to the development in analysis methodology, data bases and technology. The RAC will therefore change over time and through the different lifecycle phases.

If the safety objectives are reached, this may represent a significant reduction of the risk in the activity and may therefore call for revision of the RAC. Such a revision may imply that AEs that initially were not classified as dimensioning, may be re-classified at a later stage as being dimensioning for the activity in question.

Prioritizing of risk reducing measures

The overall principles for prioritizing risk reducing measures imply that reducing probability of accidents should be favored over reduction of consequence whenever this is technically, operationally and economically feasible.

This implies that the choice of technical, operational and organizational risk reducing measures should be given the following priorities:

a) Probability reducing measures, in the following order of priority:
    - Measures which reduce the probability for a hazardous situation to occur.
    - Measures which reduce the probability for a hazardous situation to develop into an AE.

b) Consequence reducing measures, in the following order of priority:
    - Measures related to the design of the installation, to load bearing structures and passive fire protection.
    - Measures related to safety and support systems, and active fire protection.
    - Measures related to contingency equipment and contingency organization.

7.5. Use of risk acceptance criteria (RAC) in lifecycle phases

The petroleum activity may be divided into different lifecycle phases. The use of RAC and risk analyses will naturally vary according to which phase of the activity is being considered. The approach to evaluation of an entire platform is, for example, quite different from the approach to evaluation of a single operation.

7.6. Conceptual design and engineering phases

Use of risk analysis and associated RAC is an important tool for establishing design criteria and making related decisions during the design process. It is important to establish design criteria as early as possible in these phases. The following three main elements in this process. Should be identified:

- Technical requirements and specifications (i.e. product specifications, economic premises and requirements, technical specifications, operational premises).
- Environmental loads and assumptions regarding external environment as well as working environment (i.e. loads related to wind, waves, earth cracks, lighting, rust, erosion, etc.).
- Accidental loads and safety requirements (i.e. RAC in relation to personnel, environment and assets, loads, functional requirements related to safety and emergency preparedness including vulnerability and reliability).

Feasibility studies and concept evaluation

The concept evaluation phase requires that quantitative RAC have been established. Coarse risk assessments are often performed during the feasibility study phase in relation to technical and economic potentials and limitations. Detailed QRA are usually not expected during the feasibility studies, but at least a qualitative assessment of safety aspects should be part of the feasibility studies.

Relatively detailed QRA is thereafter required in relation to quantitative RAC for personnel, environment and assets. These studies will consider the alternative concepts and conclude on their potential to meet the RAC. Critical aspects (operationally or technically) should be identified to the extent possible in order to estimate necessary cost in relation to meeting the RAC or to have realistic basis of comparison.

The RAC to be used should apply for the installations in normal operation. The uncertainties arising from assumptions about operational conditions as well as from calculations and experience data will have to be considered in relation to the RAC.

Generally through the engineering process and in particular during the definition of design requirements, detailed risk analysis may be used in order to determine the ability to meet the design. The results of the detailed studies should be used during the decision process in the engineering phases and will finally be integrated into the detailed updating of the conceptual risk analysis, often called a TRA. It is recommended to carry out such a detailed risk analysis for personnel, environment and assets as part of the detailed engineering phase in order that this analysis may be used actively in the decision-making process in this phase.

This means that the de-composition of the safety and emergency preparedness requirements down to area system and component level has to be carried out during the engineering phases. Comparison with RAC should still be used in order to ensure that measures are adopted in those areas where they are most efficient. ALARP evaluations should also be used during this decision-making process.

7.7. Operations phase

Normal operation

Regular activities which are required in order to operate an installation are all considered as normal operation. This will usually include maintenance and inspection and the implied activity level.

The risk level in the operations phase is usually a function of the design and the technical, operational and organizational premises that were established for the operation. The same applies to the RAC against which the risk results were measured.

The design of the installation will normally limit the extent to which risk reduction in the operations phase may be achieved, even though a program for continuous risk reduction is required. Such limitations will usually not exist to the same extent for the design of new installations. Risk acceptance criteria for new installations may therefore not automatically be valid for existing installations.

Risk during modification work

Modifications are usually carried out while the installation is in normal operation and will therefore imply an increase of the activity level on or around the installation during a period which may be short or somewhat longer. Risk analysis should be used in order to ensure that the modification work does not in itself imply an unacceptable risk level.

8. Glossary

Risk Criteria

Risk criteria. Risk criteria is a general term which refers to standards which represent a view, usually that of a regulator, of how much risk is acceptable/tolerable. They fall into at least two categories:

(a) comparative or equity-based, where the standard is what is held to be usually acceptable in normal life, or refers to some other premise held to establish an expectation of protection;

(b) cost/benefit based where some direct comparison is made between a value placed on the risk of injury or detriment, and the cost and risk-reducing effort of preventative measures. This form of criterion may relate the comparison not to the overall benefits and costs, which may be very difficult to establish, but to the benefits and costs of an increment of risk reduction.

The theory of tolerability combines equitable and cost and benefit based criteria. The ALARP criterion is cost and benefit based.

A third type of criterion is sometimes referred to as (c) "technology based". This essentially reflects the idea that a satisfactory level of risk prevention is attained when relevant best, or good, practice, or "state of the art" technology is employed. Such approaches are not strictly risk criteria but regulatory norms, though they are often in practice combined with cost and benefit based criteria as in the principle of reasonable practicability, or of "best practicable means", now little used.

Negligible, Acceptable, Tolerable and Unacceptable Risk

These terms refer to levels or ranges of estimated risk which are presumed to call, or not to call, for further measures of control. For some hazards, notably the hazardous properties of chemicals, there are serious gaps in the data on which reliable numerical estimates of risk can be based. In these circumstances expert judgement is often applied to produce a consensual view as to acceptable and tolerable risk.

General risk standards used by regulators, such as those discussed below, refer to risks to statistical or hypothetical persons, though they are usually derived from actual experience.

Negligible Risk. Negligible risk refers to a level of risk, usually presumed to be below 1 in a million per annum and perhaps much lower, of seriously adverse consequences occurring, where no thought is given to their likelihood in the conduct of normal life, though precaution (as against lightning) may have been taken as a prudential measure and will almost certainly be taken in case of peril.

Acceptable Risk. Acceptable or "broadly acceptable" risk is normally taken to be a risk, perhaps in the region of 1 in a million of a seriously adverse occurrence, where the conduct of life is not affected provided that we are in fact satisfied that reasonable precautions are in place. The risk is in other words noticed and kept in mind but not much further examined unless peril supervenes. The term "broadly acceptable" is used as denoting that the risk, though definite, assimilates to the "background level" of risks we accept as part of daily life.

Tolerable Risk. "Tolerable Risk" refers to the range of risk levels which is deliberately run on a regular basis for a benefit. The strict definition is "a range of risk that we do not regard as negligible or as something we might ignore, but rather as something we need to keep under review and reduce it still further if and as we can". For a risk to be "acceptable" on the other hand means that for purposes of life or work we are prepared to take it pretty well as it is.

Unacceptable Risk. "Unacceptable Risk" is a risk which is beyond the unacceptable region of tolerability. and unless there are special reasons a risk regulator will demand control to bring the risk below this level, or will refuse the activity. The main special reasons for a regulator accepting risks above the tolerability level refer to risks that are evident, and knowingly borne by relatively small groups of people; and to risks taken in times of a safety emergency or for the security of society and the State. In general, risks which are voluntarily borne for purposes of personal pleasure or benefit are beyond the scope of regulation.

The levels of risk considered "tolerable" or "unacceptable" for any democratic society are subject to the democratic process and could vary according to the overall benefit which society as a whole might see from the running of any particular risk. The HSE document " The Tolerability of Risk from Nuclear Power Stations (ISBN 0 11 886368 1) proposed levels which UK regulators would apply, in the absence of any contrary judgement by society, to event-based risks whose probabilities can be ascertained. Society reaches such decisions - not always in an ordered fashion - through its democratic and judicial processes[2].

Individual Risk. Individual risk is the risk of some specified event or agent harming a statistical for a hypothetical) person assumed to have representative characteristics. That does not mean that he need be an "average person", though a particular pattern of behaviour will be assumed for him. He may be the person who is most exposed to the hazard e.g. a person assumed to be camping long term at the perimeter *fence* of a hazardous plant, *in* which case the chance of death or serious injury (in case e.g. of a major explosion) could be numerically equivalent to the chance of the explosion itself In other cases, e.g. that of a toxic release, the probability of serious injury to any representative individual is likely to be at least an order of magnitude lower than the chance of the release, because of the influence of such factors as wind direction.

Calculation of the risk to a representative individual enables "aiming off for others and gives some basis for judgement in answering questions such as "What is the degree of risk to me and my family from an accident at X plant". It can enable verification whether the plant meets some specified risk criterion. Such criteria can also be expressed in terms of the chances of injury to critical groups, and calculations can be made for that purpose. "Individual risk" is not the same thing as risk to some identifiable person.

Societal Risk. This is the risk of widespread or large scale detriment from the realization of a defined hazard, the implication being that the consequence would be on such a scale as to provoke a socio/political response, and/or that the risk (i.e., the chance combined with the consequence) provokes public discussion and is effectively regulated by society as a whole through its political processes and regulatory mechanisms. Such large risks are typically unevenly distributed, as are their attendant benefits. Thus the construction of a dam represents a risk to those close by and a benefit to those further off, or a process may harm some future generation more than the present one. The distribution and balancing of such major costs and benefits is a classic function of Government, subject to public discussion and debate.

Major societal hazards can include danger from flooding, chemical complexes or nuclear plant. It is legitimate to include in this category any risk which could affect large populations of people or cause widespread damage to the environment, even though as will generally be the case, individual risk may be at relatively low levels and the risk of the event itself remote.

Societal risk is a complex and difficult concept, and some doubt its utility. Others think that this area requires elucidation more than any other, involving as it does or should major questions of public

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[2] For a discussion of this point, see the Report of the Hinkley Point Inquiry, Vol 4, pp 1059-1065
ISBN 0 11 412955 X

investment, e.g. in alternative sources of energy. The main difficulty in valuing a societal risk is the non-comparability of some of the elements that could in principle be included. The assessment of particular societal risk would at least involve the study of ranges of events each with a range of possible outcomes, the risks attaching to each needing to be isolated and compared. The summing or integration of such risks, or their mutual comparison, may call for the attribution of weighting factors for which at present no generally agreed values exist, as e.g. between the assumed cost to society of an immediate death as against a delayed death; or of major injuries or other harms as against deaths. In these circumstances the levels of uncertainty in the calculation remain very large. The attempt to structure and weigh the risks, as with all forms of risk assessment, is nevertheless an advance on crude assumptions that tend otherwise to remain unexamined:- as e.g. that a delayed death has the same value or "cost" as an immediate death.

Risk Aversion. Risk aversion is a presumed general tendency to wish to avoid or reduce or reduce certain risks more than others and hence a willingness to pay more for this than in the case of familiar or less "dreaded" risks. A risk aversion factor is an allowance made for such presumed aversion when putting a valuation on the benefit of risk reduction.

Risk Aversion Factor. A risk aversion factor is an allowance made for such presumed aversion when putting a valuation on the benefit of risk reduction. It has for example sometimes been assumed that there is a general aversion to death from cancer as opposed to other causes, or to forms of risk over which an individual has less or no control or which are unfamiliar.

Cost and Benefit Analysis. It is usual to attempt a cost and benefit analysis before embarking on any extensive investment in health safety and environmental provision, such as a new regulation. The Health and Safety at Work etc Act 1974 embodies the principle of "***reasonable practicability***" which legally implies a computation in which the "quantum of risk" is weighed against the "sacrifice (whether in money, time or trouble)" involved in averting the risk. If however it is shown that there is a gross disproportion between the risk and the sacrifice, the legal duty to take action is discharged. In layman's terms, the provision regarding "***gross disproportion***" implies at the least a need, if the risk is significant and having regard to the extent of any uncertainty, to err on the side of safety in the computation of safety costs and benefits. Since the main outcome of realised risk is death or personal injury, such computations require a financial value to be placed on the prevention of death, personal injury, pain, grief and suffering. The same requirement is implicit in the "***ALARP" principle*** which requires, where it is applied, that risks be driven down as low as reasonably practicable. The ALARP principle may be taken for all practical purposes as indistinguishable from "***ALARA***" (so far as is reasonably achievable, which still applies in radiation protection) and from the injunction "so far as is reasonably practicable" ("***SFAIRP***"). All these injunctions are taken for purposes of regulation to mean that the cost of each incremental opportunity should be set against the presumed benefit in terms of the avoidance of injury.

Such implicit costing are rarely made in relation to day to day hazards, since most safety provision is in terms of the adoption of standard good practice or the voluntary pursuit of best practice, taking advantage of technological advance. (It is in this sense that the principle of "reasonable practicability" can be held to be in part "technology based"). In the case however of major investments in safety measures, new regulations, and sometimes in determining action following formal risk assessment, computation of this kind is a normal procedure. For certain hazards which are regulated through a safety case regime, an explicit demonstration of ALARP may be expected in the safety case, though not necessarily a full cost benefit analysis.

Value of Life. Value of life is a financial value put on the loss created by the death of a statistical individual for the purpose of conducting cost/benefit analysis, where it assists in valuing the benefits of safety provision. It is not to be confused with the value society or the courts might put on the life of a real person or the compensation appropriate to its loss. Technically it can be defined as "the average value of reducing marginal risk of death at around the 1 in 10.000 per annum risk level, expressed as an expectation value".

There is currently no overall consensus on the value of a statistical life; a wide range of values has been proposed. In the UK, it is conventional to adopt a value of £750,000 per presumed death. The values in current use are based on the aversion of individuals to risk as calculated from their expressed or implied willingness to pay to secure marginal reductions in risks. In cases where the risk to society is large, though small to any one individual, and where therefore risks are often hard to estimate, a multiplier may be applied to the value of life which inter alia stands as a proxy for the additional losses or damage involved in large accidents, where these cannot be directly estimated. Other reasons sometimes deployed for applying a multiplier are

1) to take account of a presumed public aversion to particular risks, or

2) to take account of forms of inequity in the distribution of risk or harm.

There is no current consensus on values for multipliers.

Precautionary Principle. The "precautionary principle" is used principally in the control Precautionary of environmental risks to express the proposition that where the analytical basis for assessment or risk is weak, the lack of full scientific certainty should not be used as a reason for postponing cost effective measures particularly where there are threats of serious or irreversible damage. Its application to environmental policy in the UK derives from a statement by the Government as follows:

"where there are significant risks of damage to the environment the Government will be prepared to take precautionary action to limit the use of potentially dangerous materials or the spread of potentially dangerous pollutants, even where scientific knowledge *is not* conclusive, *if* the likely balance of *costs and* benefits justifies it."[3]

Vorsorgeprinzip. The German concept known as the "Vorsorgeprinzip" similarly represents an idea of acting to reduce risk in advance of a *complete* scientific understanding, by extension of evidence and in the exercise of reasonable foresight. The idea of reasonable predictability includes certain elements of the Vorsorgeprinzip; since in practice it is a combination of seriousness and uncertainty attaching to some risks which justifies the application of the concept of "gross disproportion" in determining what control measures might reasonably cost. The idea of the "foreseeability" of harmful consequences has always been regarded as an essential element in determining whether further measures of control are "reasonably practicable". Similar principles apply to ALARP.

However, none of these ideas can be held to justify the taking of expensive precautionary measures where scientific or practical justification for the existence of a hazard or the extent of a risk is nebulous or lacking. It is a principle of health and safety regulation that action should always be based on an ascertainment of hazard and be proportionate to the apparent extent of risk taking into account the cost of remedial measures.

BATNEEC. "Best available techniques not entailing excessive cost" is a risk criterion applied in environmental regulation and which combines a demand for "best practice" with a concept of reasonable economy that falls short of an estimation of cost and benefit. This appears to differ in principle, though not necessarily very far in practice, from "reasonable practicability", and is probably classifiable as a modified technology-based criterion. In its application, BATNEEC does not depend on a view that there can be only one form of relevant "best practice"; the technology referred to must be generally accessible; and the term is held to apply indifferently to plant, processes and managerial systems. Economic considerations can be applied where the cost of applying best available techniques would be "excessive in relation to the nature of the industry and to the environmental protection to be achieved".

Risk Control And Risk Management

Risk Priorities. The outcome of a risk assessment is usually an identification and prioritization of those risks which matter most, with a view to their reduction where this is reasonably practicable and to the introduction of a scheme of risk management measures tailored to the priori ties.

Another outcome may be a classification of the risks into predetermined categories each of which has a specified set of control measures allocated to it. This is fairly general in the field of situational risks, and is often applied where risks e.g. from chemicals or genetically modified organisms are inherent in their availability on the market. Such predetermined "control packages", which for example include controls over packaging labelling and carriage, will often extend to the degrees and types of precaution to be taken by those who handle them, to modes of containment and to relevant hazard Information and warnings to users.

Risk Comparison. A third outcome of a risk assessment may simply be a comparison of the risks for any of several purposes:-

(a) to balance the risks, so as to optimize their reduction and control. Thus for example, it would be no use having a very strong room with a weak lock on the door;- the risks of entry and loss relate mainly to the weak feature. To optimize control measures within a given level of expenditure it would be better to have weaker walls and a stronger lock. Such "balancing" outcomes are common and very useful in

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[3] Sustainable Development. The UK Strategy. HMSO 1994 ISBN 0-10-124262-X

designing an engineering complex such as the operating envelope of a nuclear plant.

(b) to enable "best risk options" to be considered. When for example chemicals are banned or subjected to strong and expensive control measures, it may be important to ensure that the probable substitute is in fact less risky. This is another form of risk optimization, i.e. of efficient risk control.

(c) to decide the priority in which particular harmful agents need to be tackled.

Risk Management. In all these cases the ultimate object is the management of the Risk risk. Risk management involves applying a set of measures relevant to a particular set of significant risks and intended to restrict and maintain risks within tolerable limits at proportionate cost, a definition which most obviously fits the case where a set of measures has to be tailor-made and prioritized, but is of more general application. The set may include measures developed to reduce risks, to mitigate consequences or to review or monitor risky situations and the outcomes of measures taken. Equally, risk management measures may be aimed primarily at optimising or balancing the risks, ultimately with an aim to net reduction and more efficient control.

Risk Control. Risk control is a term sometimes used in parts of industry, generally those concerned with major hazards, as a synonym for risk management, and there exist professional risk controllers or loss controllers whose function is to manage particular sets of risks. The term however in its more general application refers to the overall activity of identifying and limiting or managing risk of any sort, including the practice of risk assessment during plant design. and to activities involved in the management of risks of many different kinds, or to the activities of the professions of risk and loss control or those of risk regulators. So applied, the term includes a concept of achieving evenness in the distribution of risks (often therefore of equity) and of proportionality to risk in allocating expenditures (i.e., considerations of priority, cost and benefit). It will be noted that the fact that a risk is under control does not imply that there is now no such risk.

Residual Risk. Residual risk is the risk that remains after effective measures of risk reduction have been taken. No activity is risk free; even the banning of a hazardous substance may result only in its substitution by another agent that may be riskier. Residual risk is however usually taken to be the remainder of the risk when any given risk has been reduced.

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