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RISK MANAGEMENT

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Risk management develops as the need arises. Usually after an accident people want "authorities" to do something. On the other hand, industry wants predictable behaviour of authorities to be able to judge the soundness of their investments. This led to an adaptive process involving many decision makers embedded in legal and cultural heritage. It was indeed as struggle to determine who should be responsible and how to have risk management done by competent party (i.e. (1) industry, (2) public (3) authorities).

The basic structure of Risk Management is generally understood. The particulars of the various steps and control cycles involved such as identification, quantification, decision, reduction; the terminology and the emphasis depends on where the problem and the description originated.

In many instances some form of regulation was the end result usually after a disaster proved that the existing processes and procedures were inadequate and would remain so in absence of authority oversight i.e. regulation inadequate: LPG disasters in Spain and industrial disasters in the Netherlands led to the Dutch regulation, Flixborough essentially initiated the UK regulatory process on major hazards. The accident in Seveso, Italy, led to regulation in the European Union while the accident in Bhopal initiated the risk management program in the United States. These regulatory processes usually are the focal point for disputes between experts and stakeholders over facts, methods and the desirability of options.

The development of policy "on the fly", while new risks emerged and that consequences of choices in regulation became apparent led to a seemingly disorderly process marked by policy changes and incoherent outcomes. In the following sections some examples of the results of the processes are described, and some conclusions drawn on similarities and differences.

2.1 THE NETHERLANDS (BEN ALE)

The Dutch Prime-Minister Mr D. van Agt introduced the term "external safety" in 1979 to describe the field of policy dealing with the hazards and risks that the production, the handling, the storage and the transport of dangerous materials pose to the outside population. By using the designation "external" this field was placed adjacent to the policy associated with occupational safety termed as "internal safety".

External safety policy stems from the concern about potential disasters. It was the result of a number of disasters in the mid seventies, on the one hand, and the growing use of hazardous materials on the other. External safety thus pertains to sudden, large-scale, short duration exposures of the population to the effects of a release of these materials. These effects are mainly toxic and flammable clouds and the ensuing exposure to intoxication, heat radiation, explosion pressures and debris from explosion and fires.

2.1.1 History

In the Netherlands the concern for safety in industrial activities, both inside the establishments and in the surroundings, has a long history. As a result, many laws and regulations apply. The use of risk assessment techniques is fairly widespread in policy and regulations for such fields as design criteria for the dike system along the rivers, the introduction and use of chemicals and the transport of hazardous materials. Several attempts have been made to harmonise the techniques and the criteria over the different fields. This has proven unsuccessful to date. Especially the field of toxic chemical agents stands out both in methodology and in assessment procedures. In the field of major hazards, the methodology and the procedures are closely related to those used in engineering and in the nuclear industry. The systematic use of quantitative techniques to support the management of risks in industry and in regulation really started in the mid-seventies. It is this field which is the subject of the remainder of this paper.

The history of external safety policy is as old as the environmental laws in the Netherlands although the term was only introduced in 1979.

It all started with the explosion of a vessel holding 37000 lbs. of powder in the centre of Leiden in 1807. This accident killed 151 people, wounded 2000 and destroyed the inner city.

This led Napoleon in 1810 to issue a decree in which the following was stated: To have an industrial establishment one needed a permit. There were three classes of establishments: those who were not allowed in the city, those who were, and a class in between for which it had to be demonstrated that there was no danger for the population before it could be allowed in the city.

In 1814 this decree was transposed into a Royal Ordinance to prevent Danger, Damage and Nuisance. This terminology is used as the beginning of the low on the environment to this date.

It should be noted that even then it was decreed that objections of the neighbours should be taken into account when decisions on siting and permitting were taken, and that the objections should be put down in writing.

In 1875 the general ordinance was transformed into the “Fabriekswet” (The Law on Factories).

In 1886 a state committee concluded in its report to the government: “... regulations and laws are indispensable in the protection of the health and safety of employees; the employees do not on their own account take these sufficiently into consideration, when they design and construct their establishments”.

In 1896 the Labour Safety Law came into force. The “Factory Law” changed name to Nuisance Act. With these developments the systems of labour safety regulation and third party safety regulation became separated and developed along their own paths since.

In 1934 the Labour Safety Law was renewed. It was aimed at prevention and abatement of the danger of accidents and the promotion of health and hygiene at work. The legislation assumes that the employee has to be protected, but the health and safety of the employees and the prevention of accidents remains the responsibility of the employer.

The Labour Safety Law became the “ARBO wet” (Conditions at Work Act) in 1982. According to this Law certain categories of establishments have to issue a Labour Safety Report to the authorities.

The transport of dangerous materials is a potentially dangerous activity as well. In 1807 a barge laden with gunpowder exploded in the centre of Leiden. There were 151 people killed and more than 2000 wounded. A large part of the city was destroyed. The city-park is a witness of this accident to this day. As a reaction to this disaster, a Law on Explosives was issued in 1814, followed in 1815 by a Law on the Transportation of Gunpowder. In 1876 a law on toxic materials is adopted by parliament. This law in 1963 was transformed into the Law on Dangerous Materials, in which the transportation of all dangerous materials is regulated.

Although some risk management concepts were introduced in public policies associated with nuclear power generation, most of the development resulted from some major disasters in the chemical industry in the mid seventies [Lees]. Among these were the vapour cloud explosions in Flixborough and Beek and the release of Dioxin in Seveso. The disaster in Bhopal in 1984 [Bahwar and Trehan], where as a result of an accidental release of some 40 tons of methyl-iso-cyanate more than 3000 people were killed.

In the Netherlands these led to a growing concern about hazardous installations [Bomhof and Metz], which became apparent by the growing number of formal protests and court cases against points of sale of LPG as motor

fuel. In 1978 the Chief Inspector for the Environment issued a measure limiting the number of houses and people in offices in a circle of 150m around such road filling stations, based on a crude estimate of potential consequences.

These accidents lead to the introduction of legislation in many countries and in the European Union. The Directive on Major Hazards [European Union] or 'Post-Seveso Directive' as it is commonly referred to, obliged all members of the European Union to take the hazards of industrial activities explicitly into account, to assemble information and report to the EU. Through a number of amendments a new revised directive was issued in 1996.

The external safety policy has been developed as a reaction to large-scale accidents in which the human casualties were the most prominent effects. It is therefor not surprising that the risks for life and health of humans have attracted the most attention until now.

Nevertheless the accidents in Basel (Sandoz) and Chernobyl made clear that considerable damage can be done to the environment.

The regulation in the Netherlands was shaped by the regulation on LPG [NN 1983] and follows a risk based approach.

2.1.2 Effects or Risk

At the end of the seventies when the external safety started to develop, the general principle of environmental legislation still was as formulated by Napoleon: to prevent danger, damage and nuisance. This implied that negative effects, let alone death had to be prevented.

This led to the adoption of the maximum accident approach. In this approach the distance of an activity to the nearest off-site population should be at least the range of effects of the maximum possible accident.

This however led to very large distances. Consequently the concept of Single Population Exposure Limits entered the regulatory system. Under this concept the population could be exposed to some harm if it were only once in a persons life and not lead to death. Simultaneously the Maximum Accident inflated from the release from a small pipe to the release of the whole inventory of an establishment. Although these accidents in the beginning were thought not to be very credible, the accident in Tenerife, where two 747's collided on the runway, led to a rapid inflation of the Maximum Credible Accident.

In order to get the discussion about maximum possible accident and maximum credible accident in a more systematic framework belief was replaced by an evaluation of probability. This was already established practice in the aeronautical and the nuclear industry.

Many of the concepts needed to establish a risk based policy were laid down in the Rasmussen Report [Rasmussen] and the Canvey Island study.

The introduction of a risk based approach in environmental policy to a certain extent was a breach with the general opinion until then that no kind of pollution or risk was acceptable.

On the other hand a risk-based policy was adopted already in the early sixties regarding the height and the construction of the flood defences at the Netherlands coast. [Delta Commission]

The principle considerations in a risk-based approach are

- Risk is not zero and cannot be made zero
- Risk policy should be transparent, predictable and controllable
- Risk policy should focus on the largest risk
- Risk policy would be equitable

Risks are non-zero and cannot be made zero. Regulating risks on the basis of this principle creates the necessity to know the magnitude of risks and to limit the acceptability of these risks by setting finite, non zero standards. The systematic dealing with risks is called risk management.

Risk management in this context is divided into four phases: identification, quantification, *decision*, reduction, control.

In these the decision is not so much a phase, but a demarcation between the more analytical part of the process and the more managerial part of the process.

2.1.3 Risk management

In the risk management process as it stands to date quantification plays a central role, which is also reflected in policy documents and legislation. It has therefor been necessary to standardise to a certain extent the metrics by which risk is expressed and the methodology, which is to be used to quantify risks and to manage these.

Risk has two dimensions, which have to be determined separately:

- The extent of the consequences.
- The probability that the consequences will arrive.

It the quantification of risk in the context of the external safety policy in the Netherlands three measures of risk are used: the localised risk (LR), the societal risk (SR) and the expectation value of the number of people killed per year also called the potential loss of life (PLL).

The localised risk is defined as the probability that a person who permanently is present at a certain location in the vicinity of a hazardous activity will be killed as a consequence of an accident with that activity. Usually LR is expressed for a period of a year. It can be pictured on a map by connecting points of equal LR around a facility, the risk contours.

Societal risk is defined as the probability that in an accident more than a certain number of people are killed. Societal risk usually is represented as a graph in which the probability or frequency F is given as a function of N, the number killed. This graph is called the FN curve.

For the policy regarding the risk for the environment similar measures have been developed. In the document Premises for Risk Management, which is part of the Dutch National Environmental Policy Plan these issues are discussed extensively [NN 1988].

The calculation of risks often is not very difficult, but for a chemical installation of more that minimal size it can be time-consuming. In the COVO study [NN 1990], in which six industrial installations in the Rijnmond Area were analysed extensively, this was already established in 1979. A considerable number of systems have been developed to automate the necessary calculations. Many of these developments lead to commercially available systems. The SAFETI package, which originally was developed under contracts from the Directorate General for Environment and the Rijnmond Authority [NN 1984; Ale and Whitehouse 1984] is an example.

2.1.4 Risk calculation

Whether risks are calculated by hand of with the use of computer programs, the procedure always is similar.

From a description of the process and the associated flow diagrams and other technical material it is established which vessels and pipes are present in the installation. For each part it is determined how it can fail, how much of the contents are released and how this release takes place. Because the number of ways, by which a release can occur are endless, a choice is made of what events or scenarios can be taken to be representative for the whole gamut of releases possible in the installation. When computer programs are used to do the calculation the number of events taken into consideration usually is much larger that when the calculations are done by hand. In the former case the results usually are more accurate and better defined.

Subsequently the dispersion into the surroundings of the released chemical is determined. For a flammable material the explosive force and the heat radiation levels are calculated. For a toxic the toxic load in the surroundings. The results are combined with data on population density, weather and wind and the failure frequencies pertinent for the installation to calculate the individual risk and the societal risk.

A series of handbooks has been issued by the Committee for the Prevention of Disasters, which together form the guideline for quantified risk analysis in the Netherlands [NN 1988, NN 1990, NN 1985, Ale and Uitdehaag 1999]. Guidance can also be found in international literature [NN 1989].

With these books the methodology for the quantification of risks for hazardous installations and for the transport of dangerous materials is covered. In other area's similar standardisation has taken place. For the

calculation of airport risk the method used by NLR [Ale and Piers (a), Ale and Piers (b)] serves as the "de facto" standard in the Netherlands, although other methods are used elsewhere [Smith, Cowell]. Similarly standard methods exist in the construction of bridges and other civil engineering objects. These methods also are probabilistic in nature. [CUR]

To a certain extent expert judgement is embedded in all activities pertaining to risk analysis and assessment. Simple choices as the relevance of certain data are often a matter of judgement already. It should be borne in mind that these judgements are not necessarily objective or impartial and therefore careful scrutiny is required. Judgements as to the acceptability or tolerability of risks should not be implicit in the risk estimates nor should they cloud the opinion of the experts. If judgement rather than rigorous scientific analysis obtain a result it should be reported.

All estimates are uncertain. Some uncertainties can be assessed by systematic methods others are not. The biggest uncertainty is that analyses are based on present knowledge and that there may be a lot that is unknown. We cannot know what we don't know. In the Netherlands, when risk assessments and judgements are made quantitatively, they are based on best estimates. Several reports have been dealing with the residual overall uncertainty in the estimates, which could be larger than an order of magnitude in the frequency.

2.1.5 Risk assessment in the policy Framework

With the implementation of the SEVESO directive in the Dutch legislation it became obligatory to submit a report on the External safety. Part of this report is the quantitative risk analysis. The report also contains qualitative descriptions, which serve to give insight into the backgrounds of the safety study in the report. The External Safety Report is part of the documents to be submitted for a permit application and therefore is public.

The qualitative descriptions have to be made for the whole of the establishment. The quantitative risk analysis only has to be performed for those parts of the establishment that have been selected according to a prescribed system.

For other activities such as the transportation of dangerous materials or the operation of an airfield quantified risk assessments are demanded either by law or by authority of the decision-maker.

These assessments always serve two purposes: to find the safest way of executing the activity given the economic constraints and to find the necessary safety zoning distances and other measures in the surroundings of the activity given the residual risk.

This information subsequently is used in licensing procedures and land use planning, depending on the activity and on the applicable legislative regime.

2.1.6 Risk regulation

Several regulatory documents address the acceptability of risk and the criteria to be used to judge risks. These are formulated depending on the current state of risk quantification methodology and a cost-benefit analysis, which is either explicit or implicit in the political debate where the limits were set.

These limits have been developing gradually and are described in several documents [NN 1988,NN 1985, NN 1990]. For the preparation of these documents extensive studies have been performed into the perceptions of stakeholders, the potential predictability of these perceptions and the possible use in standard setting. The desirability of standards itself has been subject of considerations since the late 70ties.

The first explicit statement about the acceptability of risk has been made by the “interim statement on LPG points of sale” mentioned earlier. By setting a maximum number of people for the area within 150m from the LPG station a maximum was set to the acceptable size and probability of an accident, which amounted to a maximum individual risk of one in a million and a probability of a disaster killing 10 people at one in 100000. These criteria were the result of comparison with common risk values such as the risk of being killed in traffic (one in ten thousand at the time) and of considerations about the costs of remedial actions for existing stations, lost opportunity costs for the stations, if they could not expand and the costs of not being able to erect new stations close to dense population.

The argument was expanded in the policy document on LPG: The Integral Note on LPG. This document described the choices made by the government on the production, transport storage and use of LPG and the risks associated with these choices.

This document in turn led to the document “Premises for Risk Management”. In this document the principles for risk management for the whole of the environmental policy, of which external safety is a part is set out. Based on general principles on the taxonomy of risk acceptability criteria are developed. An important notion is that the field of risk is not suited for a black and white type approach. As a consequence there should be room for negotiation and deliberation embedded in any criteria set. Therefore the area of risk can be seen as divided into three areas, similar to the approach taken by Napoleon in 1810:

- A level of risk which is so large that it ahs to be deemed unacceptable regardless of the advantages that could be gained by taking the risk.
- A level of risk where reduction should be considered but which is not unacceptable per se.
- A level of risk, which is so small that it, can always be accepted.

This approach has not only be taken by the Netherlands but by almost all countries that formulated an official risk policy [Seaman & Pikaar].

The numerical values associated with the demarcation between the various areas of risk have been given in “Premises” also. These largely conform to the standards set in the LPG integral document.

For individual risk a limit of unacceptability in new situations or new developments of 10^{-6}/yr holds for establishments. The limit of acceptability is set at 10^{-8}/yr. In existing situations a sanitation limit of 10^{-5}/yr is upheld. For societal risk the limit for unacceptability is set at $f = 10^{-3}/N^2$ per year, where f is the frequency of exceeding N victims in an accident. Here the acceptability limit was set at $f = 10^{-5}/N^2$. These limits were stated as limes of policy. They did not have a base in the law and maintaining these limits was largely a matter of persistence of the local and regional authorities supported by the inspectorate.

As the implementation of these policies progressed, the effects of spatial planning became more and more clear. Especially the conflict between the desire to reduce the growth of traffic by developing office blocks near railway stations and the desire to transport hazardous materials through these stations led to a renewed debate in parliament. This led to a certain extent to a retreat from the rather strict position taken by the government earlier. In a letter to parliament [NN 2001] it was stated that the acceptability limits no longer applied and that the limit for unacceptability for societal risk should be taken to be an advise to local authorities. It was up to them to decide whether particular circumstances warrant a more lenient approach. The decision to accept a hazardous activity thus is to the discretion of the local or provincial authority, which gives a license. Civilians and interest groups can appeal against the granting of a license. This appeal has to be directed to the State Council. Although the process as described still has a strict flavour, in practice a lot of discussion and negotiation precedes the granting or refusal of a license. Risk analyses may play a role here, as these are used to optimise the layout of a proposed installation or a proposed building plan.

The revised limits were also declared applicable to the transport of dangerous goods [NN 1996]. It should be noted that in spatial planning the limit for transport will only be observed within 200m from the route.

The regulation of third party risks around airports is still under debate. It looks as though a limit for localised risk will be maintained of 10^{-5}/yr. The latest version of the proposed law on air transport has as a statement on societal risk that the risk should in 2005 not exceed the level of 1990, but the implementation of this statement is uncertain.

2.1.7 The aftermath of accidents Enschede and Volendam

At the beginning of this century two accidents revived the discussion about acceptability of risk. These were the accidents in Enschede and Volendam.

In Enschede on May 13, 2000 a fireworks storage facility exploded killing 22 people and wounding 900. About 500M€ of damage was inflicted in the city. Immediately after the accident an investigation was started into the causes of the accident. Special attention was given to the unexpected violence of the explosion. The investigative committee installed by the Government used results and advice of domestic and international institutes to obtain results.

It appeared that the firm had a long history of violating permits, that the city had legalised these violations and that inspectorates and state institutions were not aware of the hazards thus created. Especially the importance of the correct classification of the fireworks and of the storage of the correct types and quantities went unnoticed.

As a result prior to May 13 2000 most of the fireworks stored at the premises were more powerful than the labels indicated and in fact a significant part of the storage was mass-explosive contrary to the current permit.

In Volendam a fire started in a bar on New Year's eve of 2000. The overhead decoration caught fire and fell on the guests. More than 100 mostly young people were injured and 13 of them died. Most of the injured suffer long term malformation.

These two accidents gave rise to an increased awareness in the public of risk and risk policies. It also raised questions about the level of competence in the authorities to regulate these risks and supervise the implementation of regulations.

In the 4th national environmental plan [NN 2001] a renewed interest in external safety policy is declared and especially a discussion is announced about societal risk.

For this discussion there are several grounds.

Authorities are reluctant

Firstly: although external safety policy stems from the desire to limit the exposure of the population and of society to potential disasters, the part of the policy explicitly dealing with these risks proves much harder to implement than the zoning policy based on individual risk. This mainly is caused by the fact that the effects of a disaster involving toxic materials may extent considerably beyond even the 10^{-8} individual risk contour. Thus measures to reduce societal risk may involve areas at considerable distances from the source of the risk. In addition the effects of spatial planning measures on societal risk is much more difficult to assess than measures aimed at reducing exposure to individual risk. The latter only involves reference to risk contours drawn on a map. The former involves repeated calculations or reference to correspondence tables produced by RIVM. As it turns out many cities are not prepared to actually take these measures. However at the moment they are not held accountable in case of an accident. As a consequence the implicit acceptance of a risk which is higher than the advisory level is rarely, if in any case at all, discussed.

This position is enhances by the apparent reluctance of national government to discuss subjects as the development of societal risk or disaster potential resulting from the change in air traffic regulations. Here national government restricts itself to statements along lines such as "that the principle of stand still is sufficiently honoured", without actually revealing how large the disaster potential really is, and thus avoiding public debate.

Effect oriented policy may be required

Secondly: the disaster in Enschede let the old discussion relive whether there are risks society should not take at all. In the case of fireworks regulation the argument was developed that no societal benefit is seen to be gained by display fireworks and thus this activity is not worth taking any risk. Thus the zoning distance was determined to be the maximum conceivable distance at which a person could be harmed by the maximum potential accident. This brings back the old maximum accident considerations, which were abandoned 20 years ago for the very reason that there is not sufficient space to actually uphold such a policy. Nevertheless this discussion opens the question of how to measure and weigh the societal benefits of activities such as air traffic, the production of kerosene, the cooling of food, the cooling of skating rings etc.

Emergency preparedness and response underdeveloped

Thirdly there is the problem of emergency preparedness and response. At the moment there is no formal structure to take on board "after the accident" arguments when making decisions on licensing and siting. In fact, after these decisions have been taken, the resulting residual risk is as it were transferred to the emergency services "to take care of it". The question whether these services could cope in principle and in practice, given the available means, has no place in the procedure. After the Enschede en Volendam disasters this put the services in the awkward and undeserved position of having to defend perceived deficiencies in their capabilities, without them ever being in a position to ask for means to combat potential disasters of this scale.

It appears that is recommendable to incorporate considerations of emergency preparedness and response in the design, the siting and the licensing of activities. This would contribute to the survivability of those involved in an actual disaster. It would also prevent that risks are taken under the false assumption that the emergency services can cope when in fact they can not. It would finally provide a more solid base on which to build emergency response plans and equip the emergency services.

2.1.8 Conclusion

The conclusion of this story is also an outlook to the future. The safety and risk policies are under discussion. Although there are many signs of renewed interest in questions regarding risk acceptance by society, the road to a more full implementation of "premises for risk management" is long and there are many obstacles. One of the main issues to be resolved is how to decide on differing levels of risk depending on the nature of the activity and the importance or benefits of the activity for society. This issue get more and more pressing as it is discovered that the formal policy, which exits for almost 20 years is in some areas poorly implemented. This is not only because the exiting criteria for risk acceptability were ignored at licensing or siting of activities and housing. Also the inspection and supervision sometimes was sub standard to the extent that in some lines of business the majority of establishments operates in violation of the permit, the applicable standards and the law.

Major improvements are underway to repair the operational efficiency and knowledge of the inspectorate. Improvements are underway to improve the accessibility of expert advice for local authorities. But improvements in this areas will undoubtedly lead to more discoveries of situations were the standards set in "premises" are not met and were the cost of meeting them is deemed excessive.

On the other hand the pressure of society to decrease risk and create a risk free society increases simultaneously. The levels of compensation sought by victims after an accident is rising as well as the demands on the authorities to finally and fully implement the set policies.

This conflict of interests will lead in the near future to interesting and heated debates between all the stakeholders. What one would hope for is that decisions are made and implemented before the next accident hits society.

The grief that unavoidable accidents cause is enhanced by the erosion of trust that the population has in its institutions. This erosion of trust may have consequences that reach further than the field of external safety were it originated. The grief of the victims and the erosion of trust warrant decisive and quick progress in the management of technological risk, which, in a modern society, cannot be reduced to zero.

2.2 THE UK (PHIL BRIGHTON)

This section discusses the concept of risk as understood in the UK, with particular reference to the use of probabilistic safety assessment (PSA) in nuclear safety decision making. The way "risk" appears in UK fundamental legislation means that the concept cannot be limited to evaluation of numerical probabilities of physical harm. Rather the focus is on doing all that is reasonably practicable to reduce risks: this entails applying relevant good practice and then applying further safety measures until the money, time and trouble required become grossly disproportionate to the risk averted. PSA is used to inform rather than dictate such decisions.

This approach is reinforced by considering how far any practical PSA can be said to measure risk. The behaviour of complex socio-technical systems such as nuclear power stations does not meet the conditions under which probability theory can be applied in an absolutely objective statistical sense. Risk is not an intrinsic real property of such systems. Rather PSA is a synthesis of data and subjective expert judgements, dependent on the extent of detailed knowledge of the plant. There are many other aspects of engineering judgement involved in safety decisions which cannot be so captured.

These considerations raise the question whether the concept of "risk coherence", as developed in the workshop outline, is a realistic aim even within the technical context of nuclear safety decision making. The implications for wider risk communication are discussed briefly, based on recent UK experience.

2.2.1 Introduction

The introduction to this book raises many questions about the adequacy of risk information for decision-making, both at the individual and societal levels. There is a suggestion that better, more coherent, information is needed to reduce biases in the public perception of risk. "Risk" appears to be interpreted here as the quantified risk of death to an individual arising from particular individual choices or from involuntary exposures to environmental or industrial hazards.

This section, which is based on papers presented at two recent nuclear industry conferences[1], discusses a broader concept of "risk" on the basis both of general considerations on the concept of probability and of the UK experience in applying probabilistic safety assessment (PSA) in regulatory decisions.

Since 1974, the fundamental law controlling hazards from work activities in the UK has been the Health and Safety at Work (HSW) Act. Section 3 of this Act requires operators to ensure that the public is not "exposed to risks to their health and safety ... so far as is reasonably practicable" (SFAIRP). Under the UK legal system it is ultimately for the courts to rule on the interpretation of the key terms. The health and safety of workers is also covered in the Act.

This section will review how the Health & Safety Executive (HSE), as the main body responsible for enforcing this law, has developed a range of guidance on its interpretation for industrial major hazards generally and for nuclear safety in particular. It then briefly describes the use of PSA in the periodic safety reviews for the older UK power reactors. In the light of this experience, the paper identifies a number of limitations of PSA as the sole measure of "risk". The implications of this for risk communication are argued to be consistent with widespread thinking current in the UK.

2.2.2 Development of UK guidance on nuclear risk regulation

Accounts of health and safety legislation in the UK usually start with the ruling of the judge in a case in 1949 concerning the death of a coal miner when a tunnel collapsed. This ruling stated that the term "reasonably practicable" in safety legislation meant that (R2P2 2001):

> *a computation must be made in which the quantum of risk is placed in one scale and the sacrifice, whether in money, time or trouble, involved in the measures necessary to avert the risk is placed on the other; and that, if it be shown that there is a gross disproportion between them, the risk being insignificant in relation to the sacrifice, the person upon whom the duty is laid discharges the burden of proving that compliance was not reasonably practicable.*

This test remains the cornerstone of UK safety regulation including the nuclear licensing regime.

The proposals in the 1980s to introduce the pressurised water reactor (PWR) to the UK at Sizewell led to a public inquiry under planning legislation. This examined in depth the magnitude of the risks to the public, and how they were to be controlled so far as was reasonably practicable by the design process. The inquiry report called for more clarity in what levels of risk were achieved in applying the safety assessment principles (SAPs) developed several years previously by HM Nuclear Installations Inspectorate (NII, a part of HSE); also the costs of potential safety improvements should be considered more explicitly in NII's assessment. These recommendations led to issue of a discussion document on "tolerability of risk" in 1988, generally referred to as "TOR". Following public consultation, TOR was reissued (HSE 1992) along with a revised version of the SAPs (HSE 1992a).

TOR sets out a scheme in which there is a certain level of risk that is regarded as intolerable and unjustifiable in any ordinary circumstances. There is a lower level of risk below which risks are so low that the regulator need not ask operators to seek further improvement provided they are satisfied that these low risks will be attained in practice. This is termed the broadly acceptable level. Between these two levels a more detailed consideration of further measures to reduce risk is required using the test of "reasonable practicability" outlined above. Risks are then said to be as low as reasonably practicable (ALARP). This approach is termed the "ALARP principle".

TOR describes in detail the process of evaluating risk quantitatively as part of the design process for a new nuclear power plant. Both individual and societal risk is addressed. TOR includes several important qualifications relevant to risk-informed decision-making:

- judgement is an indispensable feature (para 53);

[1] IAEA international Conference on Topical issues in Nuclear Safety, Vienna, Austria, 3-6 Sept 2001;
7th IBC International Conference on Probabilistic Asssessments in the Nuclear Industry, London, UK, 26-27 Nov 2001.

- there is a rule of conservatism, and great attention is paid to the quality of the plant and its management (para 55);
- it would be wrong to claim that the risk estimates are in any way precise (para 114);
- above all, the PSA process ensures a systematic examination of the design (para 121);
- it would be wrong to take a risk figure of 1 in a million in a literal sense (para 134).

TOR also considered the application of cost-benefit analysis (CBA) to informing judgement against the ALARP principle. CBA involves balancing the cost of a potential improvement against the overall societal detriment of a reactor accident expressed in monetary terms. In principle, the detriment consists of: a) the value of lives lost adjusted for aversion to multiple fatalities; b) the costs of coping with the emergency, the loss of productive land etc; and c) the costs, if they could be estimated, of shock and disruption to social and political life. However, TOR noted that "we are far from having developed and agreed upon the accounting and valuing conventions that could enable us to perform such calculations".

The revised SAPs specify the key steps of PSA. The concept of a tolerable limit is translated into a set of numerical basic safety limits (BSLs) for various risks, such as that of a large release. A plant just meeting the BSLs would give a maximum individual risk of death offsite of the order of 10^{-5} per year. The lower basic safety objectives (BSOs) mark the point beyond which NII assessors need not seek further measures to reduce numerical risk. BSLs and BSOs are also applied to worker accident risks and to routine exposure to workers and to the public. However, the bulk of (HSE 1992a) covers the qualitative engineering principles, applying to external and internal hazards, structural integrity, safety systems, containment, ventilation etc.

2.2.3 Other developments in UK risk regulation

While the Sizewell B decision was being considered, interest in quantitative risk assessment (QRA) for other major industrial hazards was growing. QRA essentially means PSA in this context. HSE (1989) presented a comparative study of 16 cases, including Sizewell B, chemical plants, gas pipelines and flood defences, illustrating the developing experience of how QRA can aid safety decisions. Because of the different nature of the hazards and uncertainties in each application, and the various types of societal detriment, it was extremely difficult to reach conclusions about the relative riskiness of different industries. One could say more confidently that, in the cases where the decision had been to permit the activity, individual risk was below the maximum tolerable level suggested in TOR. HSE (1989) identified 41 factors, many qualitative, which contributed to the decisions. These fell into four categories: the hazard, risks and benefits; the nature of the risk assessment; broader factors important to the operators, government or regulators; and public attitudes to the activity and to the authorities. HSE (1989) concluded that these factors neither could, nor should, be ranked or weighted.

In 1999, HSE issued a further discussion document, known colloquially as R2P2. Like TOR this has now been re-issued following consultation (R2P2, 2001). The purpose of R2P2 is to explain how HSE is applying the risk management philosophy across the wide range of activities it regulates. R2P2 specifically addresses the social and political factors affecting policy decisions such as the introduction of new regulations. However, given the high level of public interest and concern about nuclear matters, much of this is applicable to operational regulatory decision-making in the field.

R2P2 gives the principles of good regulation as being: targeting of action on the most serious risks or where hazards are poorly controlled; consistency in similar circumstances; proportionality of action to the risks; transparency on how decisions are made and what their implications are; and accountability without unfair retribution when things go wrong. But the meaning of risk cannot be limited to the probability of physical harm. Ethical and social factors have to be taken into consideration. Moreover, there has been a significant court ruling in which "risk" in the HSW Act has been interpreted as the possibility of danger, or what has usually been termed "hazard" in the technical literature. The storage of highly active liquid waste at Sellafield illustrates how high potential hazard has been included explicitly in regulatory decision-making (see HSE 2000, especially para 4.19).

R2P2 also discusses how the TOR concept can be applied where risk cannot be quantified, the relevance of good engineering practice to meeting the ALARP principle, the role of QRA or PSA, and the need for a precautionary approach to deal with uncertainty. None of this implies a fundamental change to the risk management approach which has been developed by NII over many years and articulated in R2P2 and TOR and elsewhere (e.g. Vaughan 1996 and Ewing & Campbell 1994). The rest of this paper illustrates the implications of this approach for the use of PSA.

2.2.4 Application of PSA to UK power reactors

PSA was used during the design of the Sizewell B PWR and of the last two advanced gas-cooled reactors (AGRs) at Heysham and Torness. The past decade has seen the progressive application of PSA to the UK Magnox reactors and earlier AGRs. They are now all covered by a detailed and comprehensive analysis for internal plant faults, though there remain areas such as natural hazards and shutdown states where the extent to which PSA can usefully be applied has been an issue. This development has occurred under the aegis of the long term safety reviews for the Magnox reactors (HSE 2000a) and the periodic safety reviews for the AGRs (e.g. HSE 1997). It represents an application of "modern standards" in safety analysis, as PSA has become a standard procedure in the nuclear power industry world wide. Qualitative assessments of human factors issues and human reliability analysis have been integral to these PSAs.

The prime function of these has been as an additional view to the more traditional “deterministic” safety case on the adequacy of the overall configuration of the safety systems. The process of detailed fault tree and event tree analysis teases out in a disciplined fashion the interactions between front-line systems and their support services, and the logic of the success criteria from the fault studies, in finer detail than earlier safety case documents. It identifies residual weaknesses and helps achieve balance in the safety provisions. This in itself can help apply deterministic criteria more rigorously, e.g. in assessing against the single failure criterion. Incorporation of failure probabilities is needed for sorting and prioritising the enormous number of event combinations leading to failure, irrespective of any to attempt to quantify overall risk.

The quantitative criteria of the SAPs (HSE 1992a) have in practice proved effective in driving a reasonable number of improvements to plant which might not have been identified otherwise. Major improvements, such as a tertiary source of feed to the boilers, are almost always required by a systematic application of deterministic principles. The PSAs and the human factors assessments have pinpointed many minor improvements, particularly in refinement of procedures and clarification of the role of the operator in fault scenarios (HSE 1997). Further details on the application of PSA in the UK are given in Pape & Brighton (1998).

2.2.5 Limitations of PSA as a measure of risk

While R2P2 has discussed the complexity of the concept of risk in the political and legal sphere, there is also much coverage of such issues in the technical literature. A special issue of the journal *Reliability Engineering and System Safety* in 1998 revealed a vigorous debate between technical, sociological and psychological viewpoints on risks from technological systems. Okrent (1998) put forward the arguments that a rational public policy striving to allocate resources efficiently and equitably for improving health and safety can *only* be based on quantitative evaluations of risks, detriments, costs and benefits. While much of the attack on this “technocratic” approach revolves around how to take account of public perceptions of risk, Horlick-Jones (1998) has illustrated how the role of PSA is often questioned by practical engineers. He summarised evidence from the Sizewell B inquiry as follows:

> *[The design engineers] do not believe that risks can be accumulated into single numbers or that any given safety investment necessarily reduces collective risk. They look at design parameters and their implications for operator error and accident sequences.... .*

This statement would be an apt comment on difficulties NII has had with the conclusions of some of the gas-cooled reactor PSAs. In some cases, the PSA generated conclusions that seemed to conflict directly with engineering analyses carried out separately, even though against PSA assessment criteria it was adjudged a high-quality effort. The licensees have gone on to develop alternative versions of their PSAs with widely varying numerical results depending on the way engineering and human factors knowledge and judgement are built in.

To a certain extent these problems can be attributed to the rather abstract formalism of fault tree analysis and the obscurity and complexity of the masses of output generated. There is a concern that application of probabilistic concepts can undermine established good practice. It may lead to cultural barriers, or internal political conflicts, with PSA being seen as the preserve of theorists making impracticable recommendations based on an inadequate understanding of how the plant really works. Improvements in software are gradually enabling such difficulties to be overcome by making PSA more accessible to plant engineers.

Underlying these tensions, there is a more fundamental controversy. This is about the nature and use of probability theory itself. Throughout its history there has been a debate between those who would restrict application of the concept of probability to phenomena for which objective statistical information can be gathered, and the subjectivists who regard probability as the expression of a degree of belief.

The frequentist or objectivist approach of classical statistics is concerned with the properties of populations (Kendall & Stuart 1961). Given a sufficient quantity of data, the characteristics of random samples from a large population can be predicted, within a quantifiable uncertainty. Fundamentally probability theory is about the relations between subsets of a population. Standard probability distributions may be used to describe a population, and statistical tests are used to decide the goodness of fit. Such distributions may be purely empirical, eg the distribution of road accident fatalities according to age, or may come from theoretical considerations, such as the Poisson distribution for radioactive decay or the normal distribution in statistical mechanics.

This approach is applied in so-called deterministic approaches to reactor safety to describe residual deviations between validation data and physical models. Indeed the term “risk” is still used with precisely this meaning in setting temperature limits for Magnox reactors. In such cases of objective probability, if some decision is to be made, there remains one important subjective element: this is the degree of statistical confidence which is to be regarded as significant or acceptable.

On the other hand, the subjectivists (also sometimes called Bayesians) take a much more expansive view of the potential applications [Morgan et al 1990]. Subjective probabilities may be based on statistical data if available, but in their absence the subjectivist is prepared to treat expert estimates of probability on an equal footing. The same abstract mathematical tools can applied in both views. There is an extensive literature on how people, especially experts, make probability judgements [Thorn & Williams 1992]. This has led to procedures designed to detect and allow for biases and to promote a consensus amongst experts to make best use of available knowledge, eg [Budnitz & Apostolakis, 1998]. The fact remains that even with such safeguards the probability estimate may be an apt expression of the scientific community's view, but there is no guarantee that it is close to "reality". It is a statement about the beliefs of a population of experts, rather than about the physical world, in which the outcome may already be determined (eg a volcanic eruption).

In a paper frequently cited as the conceptual basis for reactor PSA, Kaplan and Garrick (1981) acknowledged the subjectivity of probability in describing a state of knowledge rather than any property of the real world; but they cite a view (attributed to ET Jaynes) that

> *[probability] is completely objective in the sense that it is independent of the personality of the user; two beings faced with the same total background of knowledge must assign the same probabilities.*

This seems unconvincing. It must be a fundamental epistemological flaw to put opinions, however expert, on the same footing as physical data. It also seems entirely contrary to common experience of human psychology. Practical engineering decisions are made in organisations of many individuals all having different knowledge and experience. Two similar professionals will make different probability judgements (if they think in those terms at all) because even if their knowledge of the problem in hand is the same they will have different experience and they *will* be influenced by personal and organisational attitudes.

The approach of Kaplan & Garrick (1981) demonstrates that the enterprise of PSA has to combine the frequentist and the subjectivist philosophies. To use PSA we must allow subjectivism. This viewpoint has also been strongly stated in the context of offshore QRA in [Aven & Porn (1998)]. We cannot claim that the results of PSA or QRA for rare major accidents are on an equal footing with frequentist risk statements such as road death statistics.

Subjectivism also arises from the very nature of complex socio-technical systems such as nuclear power plants. Each is an individual which does not behave as a random system. Most incidents are linked to organisational weaknesses and past decisions. The events of 11 September 2001 remind us that risk is also a function of conditions in the external society.

Watson (1994) has warned against regarding the risk as an inherent property of activities or systems which describes their propensity to accidents and which can be measured by PSA. Based on considerations similar to those above, he argues that risk is too complex a matter to be handled by a single all-embracing index: PSA should be seen as a tool for argument, eg between regulator and nuclear licensee (or between different departments within a licensee), rather than an objective representation of truth. In short there is no such thing as the “real risk value”.

This problem of the uniqueness of the individual and of the situation is not just a problem for rare events. It also affects the interpretation of "everyday" risks such as road deaths. It is widely stated as an apparently objective fact that the risk of dying in a road accident in the UK is about 6×10^{-5} per annum. It would be more accurate to say that the risk of death for a *randomly selected* individual is 6×10^{-5} per annum. This is no more than a simple

restatement that 3500 or so deaths occur annually in a population of 60,000,000. It tells you nothing about a specified individual (cf Kendall & Stuart). Whether one is killed in an accident in the coming year will depend on one's driving skill and behaviour and amount of travelling, as well as the traffic and weather conditions on any particular day.

Uncertainty is often raised as an issue in interpreting PSA results. "Uncertainty" is used in several ways in the literature. Often it is identified with probability or risk itself, particularly where a Bayesian approach is adopted [Budnitz & Apostolakis, 1998]. In PSA, the term has been used to refer to probability distributions of the input parameters, which may themselves be parameters of probability distributions [Kaplan & Garrick, 1981]. This can lead to discussions about how likely it is that the "real risk" exceeds an acceptance criterion [Ewing & Camplbell, 1994]. This difficulty does not arise if the concept of a real risk is abandoned as argued above. Instead, compliance with criteria has to be ensured by defining a suitable set of conventions and assumptions for the PSA to be an acceptable demonstration. In the UK this has meant a conservative approach to the PSA, obviating the need for a formal uncertainty analysis [TOR, Ewing & Campbell, 1994].

R2P2 contains an extensive discussion of uncertainty in risk assessment. As well as the quantifiable kinds of uncertainty discussed above, there may be a more fundamental lack of scientific understanding for deriving quantitative risk estimates. Effectively, it has been argued above that the effects of organisation, management and safety culture on technological risk is an area of just such uncertainty. Instead, these crucial factors are assessed qualitatively against standards and good practice established largely by experience in the industry.

2.2.6 Conclusions

This section has discussed the concept of risk in the context of UK legislation applicable to all industries, including nuclear. Numerical risk is just one of a large number of factors that may be relevant to safety decisions, whether by the industry or by the regulator. QRA or PSA can aid and sometimes challenge engineering judgement. It should not be regarded as a scientific model for predicting risk as an objective physical attribute of a nuclear plant. It should not be the sole basis for judgement in safety decision-making. When it is conducted according to consistent and conservative procedures and conventions it can be used to make comparisons with appropriate risk limits and objectives as described in TOR.

Many, if not most, NII decisions are taken without explicit reference to numerical risk criteria. Specialists within each field have knowledge and experience of what is tolerable or acceptable, whether in terms of safety analysis or practical measures. It is often difficult to relate these standards to the numerical risk criteria. Rather it is fundamentally a matter of applying engineering good practice in the nuclear context. Within a wider framework of values or fundamental objectives as described in R2P2, this can also be seen as building confidence in the competence, commitment and trustworthiness of the licensee. All these qualitative factors contribute to the overall risk assessment on which regulatory decisions are based.

This perhaps suggests that there is not such a gulf between public and technical assessments of risk as often supposed [Kirwan & Ale, 2000]. While TOR set out to explain the risks of nuclear power to the public, it seems doubtful that it has been particularly effective in this. Recent UK government guidance (eg. HSE 1998) has emphasised the importance of establishing trust and engaging in dialogue with the affected public rather than just presenting bald risk data. In a similar vein the House of Lords select committee on science and technology (HoL 2000, Chapter 4) has rejected the idea of trying to establish a universal "Richter scale" of risk.

The subjective view of numerical risk put forward here could be helpful in supporting this approach. It should not be not a function of the regulators to publish specific numerical results of PSA. They are only part of the operator's argument reflecting certain aspects of their engineering judgments. All the regulator needs to say is that it is satisfied that there are convincing qualitative and quantitative arguments that risks are tolerable and that all reasonably practicable risk-reducing measures are being taken. This is the approach adopted in recent public reports from NII (HSE 2000, HSE 1997, HSE 2000a). If there is a public demand for numerical risk estimates, then it should be primarily the responsibility of the licensees to publish their analyses and explain their judgments.

Ideally perhaps, the full details of the risk analysis should be available for public discussion and debate. From Horlick-Jones's account (Horlick-Jones 1998, §5, based on Porter 1995), American experience suggests that there could be traps to be avoided in this:

> *The American political and legal systems place great importance on openness, negotiation and on appeals to objective forms of knowledge.*

Risk analysis has emerged as an important source of such 'objectivity', hence the emphasis on 'hard' science in the regulatory process. The open politicisation of expert evidence in the American courts has led to problems of quality control prompting the expression 'junk science'.

Unable to strike bargains in private, American regulatory agencies are forced to seek refuge in objectivity, adopting formal methodologies for rationalising their every action.

This could be the downside of an excessive preoccupation with "risk coherence".

2.3 US (MICHAEL BARAM)

Risk regulation enables modern nations to promote technological progress and enjoy its benefits without incurring unacceptable harms. Over the decades, the modes of regulating risks to health, safety and the environment have evolved as agencies strive to incorporate new information and policies and achieve optimal results. (Wilpert, 2001; Stewart, 2002).

However, dissatisfaction with risk regulation is increasingly expressed. Regulated companies disparage the standards, rules and permit requirements established by agencies as being unnecessarily protective, burdensome and costly. Persons who feel threatened by use of a technology argue that the same regulations are insufficiently protective. Both types of critics support their claims by contesting the facts, assumptions and analytic methods used by the regulators.

As public officials, regulators are expected to address these criticisms. In doing so, they face several challenges. They must discern why their efforts are being discredited, misunderstood, and rejected, and how "cascades" of negative views and mistrust are so easily triggered. (Bikhchandani, Hirshleifer and Welch, 1992). And then they must carefully devise and implement appropriate measures for building credibility without trampling on fundamental rights of expression, argumentation, access to information, and participation that have become essential features of democracy (Baram, 1984). Measures which involve managing or controlling the content, flow or interpretation of risk information will be especially problematic in this regard and likely to worsen public distrust and further discredit risk regulation.

Thus, in responding to critics, regulators need to have realistic expectations about what they can accomplish to gain public trust and greater acceptance of their actions. This will require recognition that risk regulation is but one feature of a dynamic societal enterprise for managing risk, not an independent republic of experts, and that all sectors of society have entitlements to participate in the creation, interpretation and use of risk information.

2.3.1 Risk Management as an Adaptive Process

The view that managing risk is an adaptive and participatory process in a dynamic society, and that risk regulation is merely a part of this process, has been developed by Rasmussen and by Baram. (Rasmussen,1997; Baram, 1973). Their conceptual models of the process indicate how it is continuously influenced by advances in technology and analytic capabilities, changes in business organizations and commerce, new laws and policies, experience with technology (e.g. the occurrence or non-occurrence of serious harms), and variations in economic conditions and media coverage. They also implicate the less direct but significant influences that arise from changes in social and behavioural features of society such as demographics, affluence, education, lifestyle, values and aspirations.

Their models further indicate that the type and level of technological risk at any particular time is actually the outcome of multiple decisions made by numerous parties. Thus, risk management is a societal "enterprise" that encompasses disparate decisions made by legislators, courts, regulators, technical and professional organizations, corporate officers and managers, insurers and investors in technology, and the marketplace of technology consumers (i.e. purchasers and users of services and products). (Baram, 1982).

Broad sectors of the general public are also involved as "concerned bystanders", persons who express perceptions and demands regarding risk and exert influence through political, legal, economic and other channels for several reasons. Some are ideologically opposed to a technology, such as persons who adhere to religious or environmental credos and oppose any use of genetic engineering. Others fear involuntary risk from a technology, such as persons unable to discern, whether the foods they consume contain genetically-modified grain or other biotech constituents which could trigger allergenic or other harmful reactions. And there are always others who

perceive that their economic interests are challenged by an advancing technology which is not stringently regulated, such as organic food growers and retailers opposed to genetically-modified crops.

Finally, the models depict how risk-related information continuously flows through this universe of risk management, to and from regulators, other decision-makers, and concerned bystanders, through official and unofficial communication networks. Thus, risk management is influenced by the free flow of facts and opinions about technological risk and other information considered to be of relevance (such as economic, social and national security implications) from many sources including experts (e.g. risk assessors, safety managers, researchers), decision-makers (e.g. courts, regulators, corporations), and bystanders.

Although conceptual, the models offer a holistic approach for understanding the ongoing struggle to fit a technology into society, perhaps best exemplified at this time by national and global efforts to establish social controls for the rapidly advancing field of biotechnology (Baram, 2002a). Thus, the models may have value for addressing regulatory problems because they remind regulators that they are part of a larger risk management enterprise which is continuously adaptive to changes in society and sustained by the free flow of information

2.3.2 Risk Information in the Regulatory Context

Whether a risk is being addressed by a regulator, company, bystander or other party, the process of reaching a decision will involve two fundamental steps:

- First, using a chosen causal model, define and measure the risk ,estimate its incidence, and determine available methods for reducing it,
- Second, using a chosen decision-making methodology, determine the extent to which the risk is to be reduced.

Thus, the causal model and decision method essentially determine what factual information is needed and how it will be used.

a. Problems Arising from Differing Legal Mandates, Models and Methods

In the American regulatory context, the law which empowers an agency to carry out a particular regulatory program also outlines the causal model and decision method to be used. Such an enabling law must be followed by the agency, and regulatory actions which exceed the scope of the law or are inconsistent with its provisions will be challenged in court and invalidated following judicial review.(Administrative Procedure Act). Imbedded in the law are various goals and policies, as well as language indicating how Congress wants the regulator to deal with the factual issues involved (the causal model) and how the factual findings and various policy considerations should be weighed and used in making regulatory decisions (the decision method) .

Because Congress has enacted a separate law for addressing each of many types or sources of risk, and each law contains a different mandate on how to assess risk and make decisions, there are many risk regulators, and each is legally required to carry out a somewhat different approach. As a result, there is virtually no uniformity in the way risks are dealt with under this regime of separate laws for pesticides, foods and drugs, water supply, consumer products, industrial chemical products, air pollutants, water pollutants, hazardous wastes, nuclear installations, chemical and petroleum facilities, aircraft, railroads, autos, workplaces, pipelines, marine transport, and dams, for example. In only a few instances where enabling laws allow sufficient discretion have regulators agreed to adopt a common method of causal analysis or decision-making.

Compounding the disarray in which risk is dealt with are the risk regulations of 50 states. Except where federal law requires that state standards and rules be consistent with federal actions, states can proceed to deal with risk differently. Thus, in the recent decommissioning of a nuclear installation in Massachusetts, citizens concerned about the adequacy of site cleanup and residual radiological risks in the future were informed by three agencies that each had the authority and ability to protect them: the federal nuclear energy agency which had set a safety standard for maximum human exposure of 25 millirems per year above background levels, the state public health agency with its standard of 10 millirems per year above background, and the state environmental agency whose standard was lifetime exposure that would not result in more than 1 death in 100,000.

As a result, confusion and mistrust set in despite efforts by the agencies to explain their inconsistent and complex standards to the community. Eventually, the three agencies reconciled their differences, a neutral agency was brought in to evaluate the risk, and the community was given funding to hire its own experts for further independent review, bringing the matter to a somewhat acceptable conclusion (Baram,2002b).

Even though the same causal model and facts may be used by each agency in such a case, the presentation of different outcomes (e.g. standards or rules) to the public for the same risk becomes a flashpoint for mistrust. Thus, the source of that mistrust must be the dysfunctional relationship between the agencies, a matter of increasing concern in modern risk management (Fahlbruch and Wilpert, 1999), which in this case was due, in part, to the laws that required each agency to use a different decision method in addressing the same risk.

And in cases where several types of risks are posed to a community, the different causal models and decision methods used for regulating each of the risks even more readily results in a different degree of protection for each, a circumstance that is difficult to justify to the public. For example, to determine the acceptable risk level for pesticides, radiation and dams, the regulators responsible for these risks must use cost-benefit analysis. But workplace regulators must use a "technical and economic feasibility analysis", and regulators of the more common air and water pollutants discharged by industrial facilities are required to set standards based on " best available technology".

In addition to the regulators, others are at work addressing the same risks from corporate and bystander perspectives. In the corporate context, company policies and practices generally require that safety and health managers and their consultants use the causal models which have been adopted by firms and trade organizations within the same business sector, and always require that a company-oriented cost-benefit analysis be used as the decision method. However, the citizen or bystander addressing the same risk is unconstrained and usually employs a simplistic causal model and anecdotal evidence, and a highly personalized methodology for decision-making.

As a result, many disputes about a risk that arise between regulators, companies and individuals stem from differences in the types of models and methods they employ or from differences in how they actually use them. For example, even if all three parties claim to use cost-benefit analysis as their decision method, the regulator will weigh costs and benefits to the public and all its constituencies, the company will weigh the costs and benefits to the firm, and the individual will weigh personal costs and benefits, thereby producing three different versions of the level of acceptable risk.

b. Problems Arising from Use of Disputable Information

The information needed by a regulator to use a causal model and decision method can be extensive and highly diverse. Once gained and considered by the regulator, most of it will become readily available to companies and bystanders because the federal Freedom of Information Act requires that agency-held information be made available to "any person" upon request, except for information falling under a few narrow exceptions. (Baram).

In addition, federal courts have required that agencies, when officially publishing their proposed and final regulatory actions (e.g. a standard) in the Federal Register, must provide a complete summary of the factual issues, the information gained and reviewed, and the information selected and assumptions made to resolve the issues. Finally, parties who challenge a regulation in court have additional rights of access to agency-held information for litigation purposes. Thus, the American regulatory process for dealing with risk is notable for its transparency, unlike the corporate or bystander processes, since virtually all information considered and used by regulators in enacting a risk regulation can be accessed by likely adversaries such as corporations and bystanders.

The revealed information is likely to include many facts, interpretations and assumptions that can readily be disputed by experts and others. For example, in carrying out a causal analysis of the potential health risk posed by a particular product or pollutant, a regulator is likely to need information on the following matters:

- the risk source (e.g. product, facility or system), its intrinsic hazards (e.g. chemical, radiological, biological or physical), and how the source and its hazards are being managed by persons in control of the source and persons using or exposed to the source.
- the risk receptors (e.g. humans, other life forms, essential natural resources such as water supply, the ecosystem), circumstances of their exposure to the hazards (e.g. workplace, consumer, bystander), measures of their exposure (e.g. duration, intensity, uptake), receptor vulnerabilities (e.g. age, illness, genetic susceptibility), and their other exposures to the same type of hazard (e.g. multiple exposures to radiation due to natural background, x-rays, work, and lifestyle).
- the exposure pathways (e.g. air, water, soil, food chain) and their respective capacities for transmitting the hazards over time, intervening factors and synergies (e.g. meteorological conditions, interaction between different chemical hazards during transmission).

- the harmful consequences claimed (e.g. injury, illness, disease, death, contamination of resources, property damage, increased risk of disease, emotional distress) and their distribution.
- evidence of causation of harms, dose-response relationships, and mechanisms or etiology of causation based on research in diverse fields of expertise (e.g. clinical medicine and medical research, toxicology, epidemiology, biology, genetics, ecology, etc.).
- estimates of the incidence and magnitude of current and future harms under existing conditions, and the analytic methods (e.g. probabilistic risk analysis) and assumptions used.
- risk reduction options (e.g. new standard, rule, permit requirement, inspection system, guidance, moratorium, etc.), their implementation features, and assessments of their efficacies for risk reduction.

Disputes readily arise over such information (Baram, 1996). For example, in determining a human dose-response relationship for a particular chemical or pollutant exposure when no tests have been conducted on humans, as is the usual case, the relevance of data derived from animal studies used by the regulator is often called into question by corporate critics. Thus, if the regulator has relied on mouse test data, critics with hired experts will argue that " a mouse is not a man", or that data derived from testing another animal species which shows different outcomes is of greater value than mouse data, or that the regulator's extrapolations from quickly testing mice at high levels of exposure, the usual case, in order to estimate dangerous exposure levels for humans is overly conservative or otherwise erroneous.

Similar disputes arise over the quality and relevance of the epidemiological data used by regulators to statistically establish a correlation between a type of illness found among workers or community residents and an atmospheric or other pollutant identified in these exposure contexts. Corporations and courts are sceptical about retrospective epidemiological studies as being opportunistic and lacking in objectivity and professional quality, and thereby want to defer action until long-term, carefully controlled prospective studies are undertaken and produce findings. (Rosenthal, 1997). But bystanders having anecdotal information that a cluster of illnesses have occurred in such workplaces or communities usually believe that this information is sufficient and should be used to support immediate regulatory action. As a result, regulators who are precautionary about using retrospective studies and anecdotal evidence are disparaged as being pro-industry and callously unresponsive to threats to human life.

Additional information is needed to make the final risk reduction decision in the regulatory context. As noted earlier, it will depend on the mandated methodology and become publicly available. It is also highly vulnerable to disputation.

For example, cost-benefit analysis requires information on the following matters:

- identification and estimation of benefits and costs to society of reducing the risk to various levels below the current level and down to a *de minimis* level.
- quantification and monetization of these benefits and costs over time, and application of discount rate(s) to determine their present value.
- determination of the range of risk reductions for which the benefits exceed the costs (after being quantified, monetized and discounted), and then making a final risk reduction decision on "how safe is safe enough".

Although characterized as a rational decision method, the cost-benefit approach requires many subjective and controversial determinations: e.g. the scope of costs and benefits to be included, the monetization of matters which are not usually considered quantifiable such as establishing the dollar value of lives or trees saved, the discount rate to be applied (to determine the present value of future costs and benefits) and whether using different rates for costs and benefits in the same analysis is appropriate, the selection of a specific risk reduction within the eligible range, and overall, the appropriateness of using an economic analysis to make decisions about the safety and health of people and the environment which sustains society (Baram,1980) .

c. Problems Arising from Advances in Knowledge

The rapid advance of technical knowledge from the multiplicity of disciplines with relevant information derived from differing analytic approaches is beneficial over the long term, but in the short term, contributes to conflicts over risk regulation. For example, proponents of hormesis theory argue in good faith that their laboratory research indicates that, in contrast to data and assumptions from other fields of expertise commonly used by

regulators, low levels of exposure to radiation and certain chemical pollutants are actually beneficial in that they stimulate human immune response or other defense mechanisms at the cellular level. (Baram, 2001a).

At the same time, geneticists using recent data from the Human and Environmental Genome Programs argue that certain "high penetrance genes", not environmental factors, are the primary causes of many human illnesses such as certain types of cancer. Further, they claim to have also found that certain "low penetrance genes" occurring in larger sectors of the population predispose many other persons to illness when they are exposed to low doses of certain pollutants such as lead (Baram, 2001b).

Advances in other fields pose similar difficulties for regulators. For example, behavioral researchers present new hypotheses and data to regulators showing that many facility accidents arise from management system inadequacies such as insufficient attention to organizational learning from accidents and near misses, countering industry's traditional attribution of fault to human error and equipment failure (Fahlbruch and Wilpert, 1999). And economists argue that incentives and government assistance are superior means for reducing risk and should displace prescriptive rules and technical standards (Stewart, 2001).

These advances are absorbed into the societal knowledge base and become available for use by regulators and their adversaries. Thus, regulators continuously face many difficult issues. When do such findings become sufficiently established to merit recognition and use in the regulatory context for establishing causation? What are the societal implications of the new paradigms for disease etiology, accident causation, and corporate compliance behavior, and how can they be dealt with by regulators? Since the regulators are subject to judicial review in the courts, they must carefully consider such developments in enacting new regulations and reconsidering existing regulations.

2.3.3 Potentially Useful but Difficult Initiatives

Given that risk management is an adaptive process, that risk regulation is merely one of its features, and that all sectors of society have entitlements to access, create, interpret, dispute and use risk information, what can risk regulators do to make their activities more credible and acceptable? The foregoing discussion indicates several possible initiatives that seem worthy of further investigation despite some foreseeable difficulties involved in their implementation.

a. Harmonize Models and Methods

It seems advisable for regulators to convene interagency and public meetings in order to determine the extent to which uniform approaches for establishing causation and making decisions are: (1) technically suitable, (2) publicly acceptable, and (3) legally permissable under existing legislation. The positive results of this harmonization project should then be confirmed in interagency memoranda of agreement, adopted by each agency as part of its regulatory program, published, and implemented. To the extent such harmonization is obstructed by the inflexibility of existing legislation, regulators should petition law makers to amend the legislation accordingly.

In the United States, the President's office has assumed the lead role in trying to harmonize causal models and decision methods within existing legislative constraints, with most effort directed at clarifying and harmonizing approaches to the application of cost-benefit analysis for setting standards (Executive Order, 2001). In addition, several agencies with overlapping authority for regulating the same risk sector have agreed to follow certain consistent principles. Corporations and trade associations have welcomed these harmonization efforts because of the corporate efficiencies that follow, and the public has usually acquiesced. However, certain advocacy groups have disputed the proceedings and outcomes, particularly when the harmonization efforts have been instigated by industry lobbyists, the regulators have not been receptive to their viewpoints, and the outcomes are less protective.

This initiative poses some major difficulties. One is the technical issue of determining which risks are sufficiently similar and thereby suitable for being addressed by a uniform method of causal analysis. Another difficulty is that each agency has developed its own regulatory "culture" and constituency and may resist changing its practices. Probably the most significant difficulty is political in that many sectors of society are familiar with and have vested interests in existing legislation and furiously lobby against change, making Congress reluctant to amend the existing legal mandates for risk regulators.

b. Improve the Quality and Value of Risk Information

It also seems advisable for agencies to work together on improving the quality and value of the information they use in regulating risks. For example, regulators could work with professional societies in the disciplines that produce risk information to establish criteria for determining which information to include in their regulatory

deliberations, and for assigning value to the information they accept. The same criteria could also be used to screen the advances in knowledge which continuously confront regulators. This initiative would be particularly important for fields of research which have credibility problems because of their relatively permissive professional standards, such as epidemiology.

It is conceivable that criteria could thereby be established regarding the relevance of risk information to the problem being addressed, its quality (i.e. analytic validity, accuracy, replicability, acceptance by others in the same field, utility, etc.). The criteria could thereafter be published and used by agencies to screen information and assign a value to the information deemed acceptable for regulatory use. Although this initiative seems problematic, such criteria are actually used by judges in all federal courts and many state courts in the United States to determine the admissibility and value of expert testimony in trials. (Daubert, 1993, Davis, 2001). The criteria are applied and admissibility determinations made in pre-trial hearings held by the judges. In many of the cases, the expert testimony being screened is highly technical and pertains to causation and risk.

A similar approach is now being promoted by the Office of the President "for ensuring and maximizing the quality, objectivity, utility, and integrity of information" used and disseminated by federal agencies. (OMB Guidelines, 2002; BNA, 2002). According to new Guidelines, all agencies must develop and apply quality control standards to select the information they will use and disseminate for regulatory purposes, hear complaints about information quality and take appropriate corrective actions. The basic principal for an agency action "based on science" is that the agency must use "the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices". According to the main author, the highly detailed Guidelines also apply to agency contractors, and should be heeded by any outside parties such as advocacy groups and corporations that provide the government with information they hope the government will use.

Thus, precedents exist for agency self-regulation with regard to ensuring the quality and value of risk information. Difficulties are foreseeable. Agencies will be burdened with new evaluative responsibilities of a complex nature, a form of self-regulation for which they will be held publicly accountable. Persons engaged in new research areas will find new obstacles to their advancement and recognition. And those who demand more protective or precautionary regulations and usually have to rely on the newest studies and creative concepts for support will view the criteria and their applications as being unduly protective of the status quo.

Nevertheless, such an the initiative seems worthy for several reasons. It requires that agencies make explicit and predictable how they will select and value information, and provides the ground rules for openly dealing with disputes over information. It can therefore reduce widespread perception that agencies act arbitrarily, protect special interests through ad hoc determinations about information, and evade accountability on such matters. As a result, it has potential for enhancing the integrity of the regulatory process, much as a similar initiative has accomplished for the judicial process.

2.3.4 Conclusion

Dissatisfaction about risk regulation needs to be addressed and the causes need to be identified. Corrective actions then need to be taken carefully because risk regulation is imbedded in a much larger societal function of risk management, and many entitlements central to democratic systems need to be protected. To the extent that the causes of dissatisfaction implicate the information used by regulators, several initiatives may be useful. One involves harmonization of the approaches to risk regulation. Another involves agency self-regulation by use of explicit criteria for selecting and valuing risk information. Although difficulties are foreseeable, the initiatives have promise for enhancing the integrity and quality of risk regulation and seem to be worthy of further consideration.