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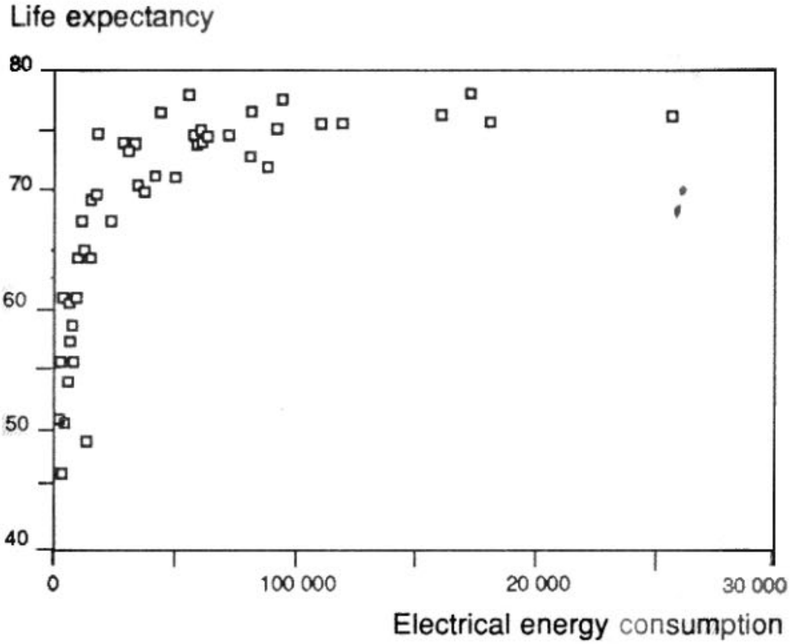

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Principles for decisions involving environmental and health risks

Final report
of a joint Nordic research project in nuclear safety

Editor
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Abstract

Decision making with respect to safety is becoming more and more complex. The risk involved must be taken into account together with numerous other factors such as the benefits, the uncertainties and the public perception.

Can the decision maker be aided by some kind of system, general rules of thumb, or broader perspective on similar decisions?

This question has been addressed in a joint Nordic project relating to nuclear power. Modern techniques for risk assessment and management have been studied, and parallels drawn to such areas as offshore safety and management of genotoxic chemicals in the environment.

The topics include synoptic vs. incrementalistic approaches to decision making, health hazards from radiation and genotoxic chemicals, value judgments in decision making, definitions of low risks, risk comparisons, and principles for decision making when risks are involved.

Key words Carcinogens, cost benefit analysis, decision making, environmental impacts, health hazards, human factors, industry, management, mutagens, nuclear power, optimisation, probabilistic estimation, radiation protection, regulations, reviews, risk assessment, safety analysis

Summary

Mankind has always been exposed to risks i.e. the possibilities of unwanted outcomes of an action or a situation. The situation has, however, improved. In the last few centuries, our expected length of life has doubled. One reason for this is the increased awareness of risks and the large efforts spent on preventing risks from diseases and other major hazards.

The most significant further reduction of risks would be attained if one could find ways of assessing the different types of risk and then reduce those that give the best value for the risk reduction money. The research project described below has by and large had this purpose. The area primarily covered refers to radiation protection and nuclear safety, but efforts have also been made towards cross-fertilisation with such areas as off-shore oil industrial safety, and regulation of genotoxic chemicals.

Synoptic and incrementalistic approaches to decision making

A *synoptic* approach towards decisions which entail risks requires
- ☐ the definition of alternative possibilities for decisions
- ☐ an analysis of the consequences of these alternatives in terms of costs, risks and benefits, and
- ☐ a decision based on the results of the analysis.

The decision making is a complex process which reflects the decision maker's set of values. To facilitate his task, various decision aiding techniques have been developed, such as cost-benefit analysis.

It is obvious that in many complex decisions, much relevant information will not be available to the decision maker at the time of decision. An alternative way of arriving at decisions in the face of uncertainties has been developed. It is called *incrementalism* and is based on an assessment of the uncertainties in the factors involved, and of the degree of consensus about the decision to be taken.

The basic rule of thumb is that small uncertainties and a high degree of consensus justify far-reaching decisions while large uncertainties and lack of consensus justify research efforts in combination with a little step or increment forward in the area subject to the decision.

Hazards from radiation and genotoxic chemicals

In our definition the hazards are the outcomes in the form of injuries following exposure to an agent. Hazard analysis means the study of the relations between exposure and hazard. Some hazards are directly noticeable following high level exposures. Delayed hazards may occur after higher or lower eposures, e g cancer and hereditary disease. These are often starting with an injury to the hereditary material, DNA. Agents that can cause such injury are called genotoxic.

The principal interest in hazard analysis within the Nordic program has concerned such agents. Ionising radiation can be genotoxic.

The present knowledge indicates that tens of chemicals can cause human cancer, hundreds animal cancer, and thousands cell DNA injury. There is an emerg-

ing international consensus that cancer initiators such as radiation and benso(a)-pyrene may cause cancer with a frequency that increases with the integrated exposure, even at low doses. It is a common hypothesis that the dose-response relationship is a linear, non-threshold one, and authorities often assume such a relationship for regulatory purposes.

It is generally difficult to establish the real hazard that follows from exposures to genotoxic agents. One consequence of a genotoxic injury to a cell may be the creation of molecular attachments (adducts) to DNA, which can serve as indicators of carcinogenic potential. This may enable extrapolation from radiation to chemical hazards. In a promising application, leukemia risks from ethylene oxide exposures have been predicted.

Value judgments and decision making

As previously mentioned, the decision making involves the application of value judgments to the results of consequence assessments. This procedure is surrounded by controversy, mainly because different individuals may follow very different values or ethics.

The word *ethics* may mean a set of values adhered to by a group and expected to govern their actions. The sets of values depend strongly on such factors as religious and cultural heritage. The discipline of ethics does not help by stating that a set of values is right or wrong in an absolute sense. Rather it puts the spotlight on the ethical dilemmas facing the decision maker:

- ☐ competing values
- ☐ conflicting obligations
- ☐ trade-off between costs and benefits in alternative outcomes.

For the resolution of such dilemmas in Western societies, there is not a fixed set of values available but an agreed process, the democratic process. This is influenced by the changing values of the population. The elected representatives of the people have the difficult task to interpret these values.

A special report concluded that for the aforementioned reasons, the discussion on ethical problems connected with nuclear energy production has to be carried out without any help from similar debates in other sectors. This holds also for the particular issue of allocation of resources to different categories of safety and health measures. The reason is that the populations involved on the whole will not accept any comparisons between threats to life.

A special study has been performed in a Swedish community to explore the willingness of home owners to take mitigating actions against radon. The results show that the willingness to take action is higher if the individuals involved are younger, have a higher income, face a cheaper countermeasure, and are exposed to higher radon levels.

What is a low risk?

Judgments on when a risk is negligible or tolerable were studied. A consensus seems to be emerging, both among countries and between the regulators of chemical and radiation risks. An annual exposure committing 0.01-0.1 persons per million inhabitants to cancer or death has been characterised as negligible.

Higher risks may lead to regulation and this is often the case at risks above the interval 1-10 cases of serious injury or death per million exposed during one year.

Economic valuation of health detriment

In the most basic cost-benefit analysis, all consequences involved in a decision are put on a common monetary scale. This means that for instance environmental and health effects are given in monetary terms. Many studies have tried to estimate the resources spent to prevent the loss of a human life. They tend to fall in the range between 1 and 10 times the value of the production time lost. In the field of nuclear safety they often exceed this range, and in the field of medical measures they often fall below the range. In the study of home owners' willingness to mitigate radon problems, the implied value was also well below the range.

An empirical study was undertaken concerning the valuation of the health risk associated with living in a home with high radon levels. The selling prices of these homes were compared with the prices of homes with less radon. The preliminary results did not indicate any dependence of house prices on their radon situation, but the error margins were large.

Methods to aid decisions involving risks

Several studies discussed factors involved in the reduction of risks, and common denominators were sought. The conclusion was that the evaluations of risks versus benefits and other factors involved in a decision can not, however, be expected to follow any given patterns. Risk comparisons can give some perspective but the public tends to handle the ethical issues involving risk in a way that is particular to each risk. Risk perception plays a large role, but is governed by many factors in a complicated interplay. These may lead to exaggertion of risks as well as indifference.

Despite these problems, simple economic valuations of health effects are still used for decision making and seem to have some impact on the decisions.

Summary in Swedish

Sammanfattning

Mänskligheten har alltid varit utsatt för risker, dvs möjligheter till oönskade utfall av ett handlande eller en situation. Läget har dock förbättrats. Vår livslängd har fördubblats under de senaste århundradena. En av anledningarna är att vi har blivit mer medvetna om olika risker och ägnat stora resurser åt att förebygga risker från sjukdomar och andra stora riskkällor.

Den största ytterligare minskningen av risk skulle vi få om vi kunde bedöma de olika slags risker som finns och minska dem som gav bäst utbyte för de insatta resurserna. Forskningsprojektet som redovisas nedan har i stora drag haft denna målsättning. Huvudsakligen har det gällt strålskydd och kärnsäkerhet, men försök har också gjorts till paralleller med sådana områden som oljeborrning och reglering av miljöfarliga kemikalier.

Synoptisk och inkrementalistisk syn på beslut

En *synoptisk* syn på beslut som berör risker förutsätter

- □ definition av alternativa beslutsmöjligheter
- □ analys av kostnad, risk och nytta i dessa alternativ
- □ beslut utgående från analysen.

Beslutet kräver att beslutsfattaren lägger sina värderingar på de faktorer som analyserats. I en metod för att underlätta beslut, kallad kostnads-nytto-analys, värderas alla faktorer i pengar.

Ofta finns inte tillräckligt underlag för beslut vid den tidpunkt när de måste fattas. Ett alternativt synsätt, *inkrementalism*, har utvecklats för beslut under osäkerhet. Det grundas på att man bedömer osäkerheterna i de faktorer som är intressanta och enigheten hos berörda aktörer.

En tumregel är att vid små osäkerheter och stor enighet kan långtgående beslut fattas, medan stor osäkerhet och splittring bör mötas med en satsning på forskning och små steg eller inkrement framåt på beslutsområdet.

Faror från strålning och kemikalier

Faror definieras här som skador efter exposition för ett agens. Faroanalys avser studiet av sambandet mellan exposition och fara. Vissa faror märks direkt efter exposition vid höga nivåer. Fördröjda faror kan förekomma både efter höga och låga nivåer. Exempel är cancer och arvsskador. De startar ofta med en skada till arvsmassan, DNA. Agens som kan ge sådana skador kallas genotoxiska.

Faroanalysen i det nordiska programmet har huvudsakligen avsett genotoxiska faror. Joniserande strålning är genotoxisk och kan orsaka cancer.

Vi vet för närvarande att tiotals kemikalier kan orsaka cancer hos människor, hundratals cancer hos djur, och tusentals skada på DNA. Inom det nordiska programmet har genotoxiska risker från strålning och kemikalier jämförts. Det börjar bli internationell enighet om att cancerinitiatorer som benso(a)pyren och strålning kan orsaka cancer med en sannolikhet som ökar med ökande dos (koncentration gånger tid). Myndigheterna antar ofta att sambandet är linjärt och inte har någon tröskel.

Den exakta storleken av faran från en exposition för genotoxiska agens är svår att uppskatta. En genotoxisk skada kan leda till påhängsmolekyler (addukter) på DNA. Dessa kan vara indikatorer på den cancerframkallande förmågan hos ifrågavarande agens. De kan möjliggöra att erfarenheter från cancerrisk från strålning kan användas för bedömning av cancerrisk från kemikalier.

I en lovande tillämpning har svenska forskare förutsagt cancerrisker hos arbetare som varit utsatta för etylenoxid.

Värderingar och beslutsfattande

I beslutsprocessen tillämpar beslutsfattaren sina värderingar på resultatet av konsekvensanalyser. Detta är omtvistat eftersom olika individer har olika värderingar.

Ordet *etik* kan betyda en uppsättning värderingar som omfattas av en grupp och väntas styra deras handlande. Värdeuppsättningarna beror starkt på sådana faktorer som religiösa och kulturella arv. Läran om etik anger inte vilka uppsättningar av värderingar som är rätt eller fel. I stället granskar den kritiskt de etiska problem som beslutsfattaren står inför:

- ☐ värderingskonflikter
- ☐ åtaganden som står i konflikt med varandra
- ☐ avvägning mellan kostnad och nytta i olika alternativ.

I västvärlden löses inte sådana problem genom att man tillämpar ett givet värdesystem utan genom att man utnyttjar den demokratiska processen. Denna påverkas av befolkningens värderingar, och dessa ändras med tiden. De valda ombuden för folket har den svåra uppgiften att tolka befolkningens värderingar.

I projektet drogs slutsatsen att diskussion om etiska frågor kring kärnenergi inte kan luta sig mot etiska avvägningar gjorda på andra områden. Detta gäller bl a avvägningen mellan förebyggande och konsekvenslindring för stora olyckor. Orsaken är att de berörda människorna i stort sett inte godtar att man jämför olika hälsofaror.

En särskild studie i en svensk kommun undersökte villigheten att åtgärda radon. Resultaten visade att villigheten att åtgärda ökade om de berörda människorna var yngre, hade högre inkomst, var utsatta för högre radonhalter eller bedömde att kostnaden var låg.

Vad är en liten risk?

Bedömningar av vad som är små risker har studerats. Internationellt börjar man bli överens både för strålning och kemikalier att en årlig exposition som leder till en riskinteckning av 0,01 till 0,1 dödsfall eller cancerfall per miljon exponerade invånare är försumbar och inte kräver myndighetsreglering.

Högre risknivåer kan föranleda reglering och så blir ofta fallet om de ligger vid 1 till 10 fall årligen per miljon exponerade.

Ekonomisk värdering av hälsorisker

I grundläggande kostnads-nytto-analys åsätts alla faktorer i ett beslut ett värde i pengar, t ex miljö- och hälsoeffekter. Många forskningsprojekt har ägnats åt frågan om hur mycket resurser som bör läggas på att förebygga ett dödsfall. Ofta ligger resultatet i intervallet 1 till 10 gånger värdet av den produktiva tid som förloras genom dödsfallet. Inom kärnenergiområdet ligger man ofta över intervallet och inom medicinområdet under. I studien av villaägare låg det värde som härletts också under intervalet.

Ett annat försök har gjorts att se hur villaägare värderar den hälsorisk som är förknippad med höga radonhalter. Försäljningapriserna på radonhus jämfördes med försäljningsvärdena på andra hus. De preliminära resultaten visade ingen inverkan av radonhalten, men osäkerheterna var stora.

Hjälpmedel för beslut som gäller risker

Flera studier har gällt om det kan finnas gemensamma nämnare för faktorer som påverkar beslut om riskminskning. Slutsatsen är att när besluten är komplicerade finns inga enkla sätt att väga risker mot nytta och andra faktorer som påverkar beslutet. Riskjämförelser kan ge en del perspektiv, men allmänheten tycks värdera riskerna på olika sätt beroende på vilken situation risken förekommer i. Riskuppfattning spelar stor roll men styrs av många faktorer i ett komplicerat samspel. Både överskattning och underskattning av risker förekommer.

Trots svårigheterna tycks beslut som rör risker dra viss nytta av de enkla ekonomiska värderingar av hälsorisker som tillämpas i en del metoder avsedda som beslutshjälpmedel.

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Preface

This is the final result of a research project which formed part of a joint Nordic research program on risk analysis and safety rationale, with reference to nuclear energy. Besides the present project, the program comprised four others relating to

- ☐ optimisation in nuclear radiation protection
- ☐ comparisons of nuclear radiation risks and others
- ☐ methods for probabilistic safety analyses and their limitations
- ☐ development and optimisation of nuclear safety regulations.

The aim of research in these areas has been to review methods for risk assessment and management with respect to nuclear safety, in order to

- ☐ give an overview of the methods available
- ☐ demonstrate to what extent these methods fit into a common framework and reflect general principles.
- ☐ provide background material for decisions, e.g. on safety regulations.

The overall purpose has been to aid decision makers by trying to find systematic approaches or rules of thumb for decisions. Nuclear safety and radiation protection were the primary areas of research, but a cross- fertilisation was intended with such areas as offshore safety and decision making with respect to toxic chemicals in the environment.

The five projects have been reported in a joint publication *Risk analysis and safety rationale* (Bengtsson 1989 d). The present report emphasises and reviews the principles discussed in the entire research progam, while the joint publication summarises method developments, practical applications etc for the five projects.

The work has been coordinated with and has drawn upon similar international work in organisations such as the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development (NEA), the International Commission on Radiological Protection (ICRP), the Commission of the European Communities (CEC) and the United Nations Scientific Committee on the Effects of Atomic Radiations (UNSCEAR). The contacts with the International Atomic Energy Agency (IAEA) in its Coordinated research programme on "Comparison of cost- effectiveness of risk reduction among different energy systems" have been particularly useful.

The work was carried out at institutions in the Nordic countries of Finland, Norway and Sweden. A reference group with one person from each country and also one from Denmark followed the work and suggested directions of research. The report was compiled by Gunnar Bengtsson.

The research fell within the program of the Nordic liaison committee for atomic energy, aided in this particular area by two research coordinators from Sweden.

The report is being distributed to scientists and to individuals working in national and regional authorities and in companies dealing with industrial risks. The main distribution is to the Nordic countries, but the report is also distributed outside of the Nordic region.

1 Structuring of decisions involving risks

1.1 Perspective on risks in the modern society

Risk is a vague term related to unwanted outcomes of an action or a situation. In this report, risk is used as a loose term and more specific terms are used when precision is necessary. The relevant outcomes are then specified, e.g. cancer, and the probability of each outcome is given.

Mankind has always been exposed to risks. In the last few centuries, the risks to human health have decreased significantly in Western societies. Our expected length of life has doubled. One reason for this is the increased awareness of risks and the large efforts spent on preventing risks. Despite the significant achievements in risk reduction, large segments of the public are very concerned over the new types of risk which have replaced the old ones.

A simplistic reaction is to demand the abolishment of new practices that entail risks. This is not tenable since all practices involve some risk. The general level of well-being would be better nursed if one could find ways of assessing the different types of risk, and then eliminating all exposures to risk for which the cost of the countermeasures is reasonable in relation to the magnitude of the risk reduction. The combined processes of risk assessment and reasonable risk reduction are the subjects of this report and jointly called optimisation of protection.

1.2 Synoptic approaches to decision making

The skeleton on which the report is based is a suggested rational scheme for decisions involving risk (Bengtsson 1989 a). This scheme, figure 1, requires the definition of alternative possibilities for decisions, analysis of consequences of the alternatives such as costs, risks, and benefits, and an evaluation of the result which leads to a decision. Such a comprehensive scheme is sometimes referred to as a synoptic approach. Synoptic means just comprehensive, or characterised by breadth of scope.

The evaluation is a complex process which reflects the values of the decision maker. The decision is often more influenced by the public perception of the risks than by the estimates of risk established from the analysis.

One way of aiding the decision is to assign monetary values to all parameters involved. The technique is called cost-benefit analysis. Even though the final analysis concerns an objective search for a minimum overall cost, the technique is not an objective one. The reason is that the assignment of monetary values

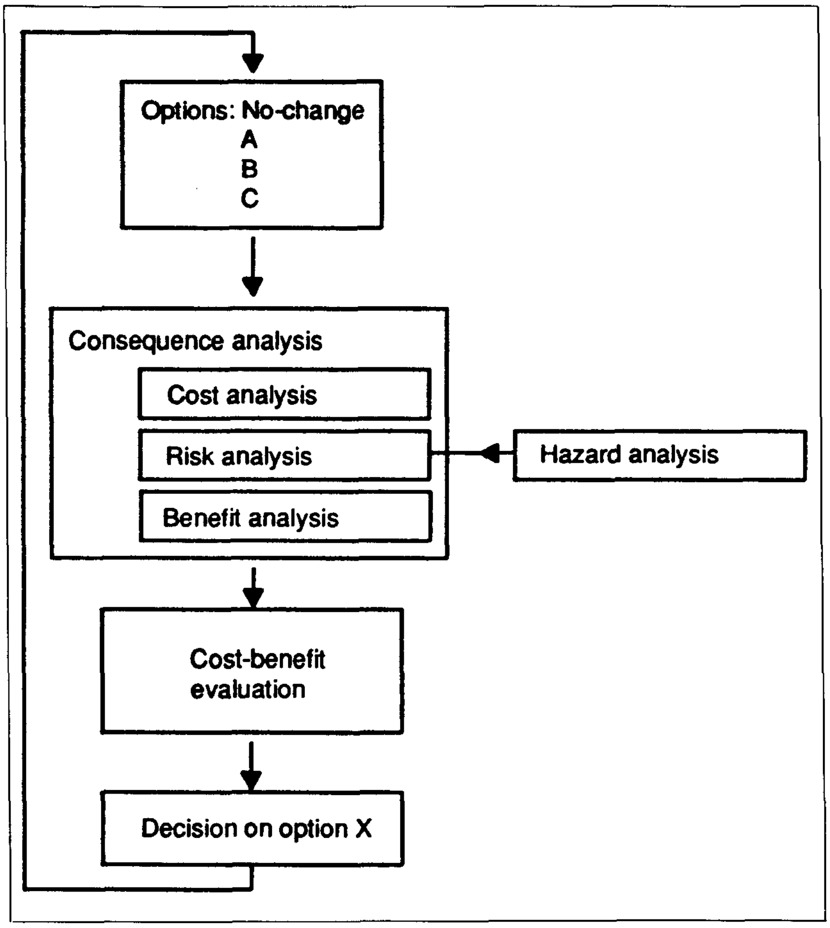

Figure 1. A synoptic schedule for risk management. The alternatives to be considered should include the no-change alternative. The hazard analysis is performed independently of whatever alternatives are considered. It pertains to the relation between exposure and injury. Results from hazard analyses can be used to calculate the risks from the alternatives considered.

to, say, health effects requires value judgments. Simpler forms of cost-benefit analysis have been used extensively in the field of nuclear radiation protection, and have been further investigated in this report.

Many other decision aiding techniques have been tried, usually involving quantification of the decision maker's values (ICRP 1989). Examples include multiattribute utility analysis and multicriteria analysis. These are fairly complex techniques which are often computer based.

1.3 Incrementalism

It is obvious that in many complex decisions, much relevant information will not be available to the decision maker at the time of decision. The scheme accounts for this problem by allowing for a reconsideration of the decision when new information has become available. In political science an alternative way of arriving at decisions in the face of uncertainties has been developed.

It is called incrementalism and is based on an assessment of the uncertainties in the factors involved, and of the degree of consensus about the decision to be taken. The basic rule is that small uncertainties and a high degree of consensus justify far-reaching decisions while large uncertainties and lack of consensus call for research efforts in combination with a little step or increment forward in the area subject to the decision.

The difference between the two methods lies mainly in the treatment of uncertainties. In the synoptic approach there is more of a belief that uncertainties can be assessed and considered in the decision, whereas in incrementalism there is an explicit recognition that the decision should be deferred as far as possible until the uncertainties have been resolved.

In this report, the synoptic approach has been chosen as the backbone of the presentation because it illustrates clearly the factors involved. A survey (Vesterhaug 1986) showed that cost-benefit analysis, a technique with a synoptic flavour, is indeed used as a guiding tool by several Nordic safety authorities. On the other hand, the management of high level radioactive waste in Finland and Sweden bears many of the marks of incrementalism, for instance the deferral of a final decision and the determined efforts devoted to research.

In a related Nordic research project, uncertainty in safety analyses and safety related decision making has been discussed (Pulkkinen and Pörn 1989).

The rest of this report is based upon the structure of figure 1 and discusses hazard and risk analysis, and evaluation for decision making.

2 Hazards from radiation and chemicals

The hazards in our definition are the outcomes in the form of injuries following exposure to an agent. Hazard analysis means the study of the relations between exposures in general and hazard, in contrast to risk analysis which pertains to the outcomes in a defined exposure situation. Some hazards are directly noticeable following high level exposures. Delayed hazards may occur after higher or lower eposures, e.g. cancer and hereditary disease.

Agents that can injure the hereditary material DNA are called genotoxic. The principal interest in hazard analysis within the Nordic program has concerned such agents. Ionising radiation can be genotoxic. Tens of chemicals can cause human cancer, hundreds animal cancer, and thousands cell DNA injury.

There are thus many similarities between hazards from radiation and chemicals. These are discussed in the following (Bengtsson 1988 c), to a large extent on the basis of a review article by Ehrenberg (1987). A version in Swedish is available (Bengtsson 1988 d).

2.1 Types of injury

Living cells are surprisingly similar whether they belong to an amoeba or a human being. Radiation causes chemical changes in the cells which may lead to injury of the chromosome material, DNA. Similar changes may also be caused by some chemicals. The cell reacts to unwanted changes by mobilising an impressive repair machinery built on enzymes, that is, organic compounds capable of accelerating chemical changes in the cells or producing such changes by catalytic action. In some cases the enzymes acting upon radiation injury may also act on injuries caused by chemicals. Although chemical injuries are extremely varied, they may thus sometimes be very similar in character to injuries caused by radiation.

An organ can not maintain its normal function if a large number of cells is injured and not fully repaired, whether the harmful agent is radiation or a chemical. If an essential organ is exposed, the entire body may be threatened. Severe injury may result from such high exposures. Prevention may be very efficient by reducing the exposure to such lower levels where only a small fraction of the cells in the organ at risk is injured. In that case no organ damage may appear.

Such a prevention may not, however, be sufficient. Even at lower exposure levels the radiation or chemical may start a process resulting in a later manifest injury. For instance, the DNA may become reprogrammed to start an unrestrained growth which manifests itself as a cancer tumor several decades after exposure. Exposure of the gonads may result in mutations that may express themselves only after generations. It is not yet known whether fetal injuries can be caused by changes in single cells, nor whether the same is a possible mechanism for lesions in arteries (atherosclerosis), premature ageing or activation of latent viruses.

The effects of low level exposures to radiation have been more studied than those from low level exposures to chemicals. In particular, many factors influencing radiation carcinogenesis in humans are known. At present, also about 30 chemicals are known human carcinogens. The list is most likely to be enlarged. More than one-half of all chemicals tested for carcinogenicity in animals turned out to be carcinogenic. At present more than 1000 chemicals are being studied. In cell studies, thousands of chemicals have caused injury to DNA. There is no complete correspondence between such genotoxicity, and carcinogenicity in animal experiments. Cancer risks from low level exposures will be dealt with in more detail later in this chapter.

Many drugs including alcohol and tobacco are known to cause fetal malformations, perinatal mortality and other injuries. Exposures to high levels of lead, mercury and ionising radiation have caused severe injury to the fetal central nervous system and even fetal mortality. Whether such injury can be caused by lower exposures is now a matter of intense research.

There is little proof of other types of late injury. Hereditary injury is suspected to be caused by ionising radiation on grounds of animal experiments, and the

Table 1. Types of biological injury from high level exposures

Type of injury	Caused by radiation	Number of known chemicals producing this effect
Human cancer	yes	tens
Animal cancer	yes	hundreds
Injury to cellular DNA	yes	thousands
Hereditary injury	yes (according to animal experiments)	(probably several)
Fetal injury	yes	tens
Mortality or organ injury in humans, animals and plants	yes	(probably almost all)

Note

There is no agreed "high level" or "low level" exposure. Often, however, exposures leading to direct organ injury or mortality (ultimate table entry) are considered as high level exposures. If the other types of injury appear in low frequency, the exposures are called low level exposures. The injuries are then difficult to verify. It is highly likely that these other types of injury may be caused by a large number of agents even though they have not been demonstrated even for high level exposures.

Regulatory action may be taken before there is scientific proof of human carcinogenicity. This explains why the Danish and Swedish occupational health authorities publish carcinogen lists with 230 and 70 chemicals, respectively.

same holds for several chemicals. Premature aging has been sought as a result of radiation exposures, with no conclusive evidence. Irradiated groups lived as long as other comparable groups, apart from the cancer mortality induced by radiation.

Table 1 gives an overview of risks from radiation and chemicals.

2.2 Strengthening and weakening the effect.

Living cells are continually bombarded by radiation and chemicals. The different agents may at higher exposure levels interact to give an effect that is more than additive. For instance, neither microwave irradiation nor galactose feeding produced cataracts in the eye lens of rats, but combined treatment did.
Different agents may also be antagonistic and give a less than additive effect when given together. In an experiment radiation doses of 7 Gy killed all mice, but administration of ginseng extract a few hours after irradiation saved four out of five.

Synergistic or antagonistic effects may also occur between two or more chemicals. The relations may be extremely complex. The carcinogenic potency of some substances (AAF and DMBA) may for instance act synergistically with another substance (PBB) if the latter is given afterhand, and antagonistically if it is given beforehand.

In the case of cancer induction, several stages are involved. As a simplification, three stages are commonly recognised:

- ☐ *initiation* by ionising radiation or a chemical.
- ☐ *promotion* by radiation or chemicals. Dioxines are considered promotors, and microwave radiation suspected of being a promotor. An initiator is usually also a promotor if it causes extensive cell death. This is the case for high doses of ionising radiation and for initiating chemicals that are toxic.
- ☐ *progression* of the tumor. This stage is not clearly distinguishable from promotion.

The whole process is extremely complex with extensive repair at the cellular level and strong defense mechanisms from the organism. Only a very small fraction of all initial DNA injury leads to a manifest tumor.

Even the risk of cancer can be weakened by certain chemicals.

Vitamin A seems to decrease the risk of lung cancer (possibly through its influence on the development of the lung epithelium). Vitamin C is believed to be a general protector against cancer (by scavenging free radicals which are produced in the cells by either radiation or chemicals). Vitamin E seems to act similarly.

The enzyme superoxidedismutase also prevents the formation of free radicals, and higher levels in blood have been correlated with decreases in mortality in mice and in human chromosome aberrations from radiation. Also chemical injury can be prevented at high levels of superoxidedismutase.

A high content of fibres in food may reduce the effect of some carcinogens, maybe since these adhere to the fibres or are more rapidly passing through the intestines. Substances (indoles) from cabbage and Brussel sprouts have been shown to inhibit chemically caused cancer. Other protectors in food are known.

In theory cancer protectors could be added to food, or food habits directed towards foods which are rich in such substances. Whether this is practically feasible and worth while is still under discussion, but research in the area seems strongly justified.

2.3. Examples of radiation hazards

Some examples of radiation risks in the environment are given in figure 2. Direct risks to humans, animals and trees result from high level exposures. At lower levels, the best present estimate of cancer risk is given, using the assumption of proportionality between cancer risk and radiation dose. All numerical values are strongly simplified and used to illustrate tendencies rather than exact figures.

High level exposures did occur in the Soviet union following the Chernobyl accident. For instance, pinetrees died within a kilometer or so from the nuclear power plant. It is not, however, sufficient to consider the most obvious direct radiation effects in the management of environmental contamination. Special organisms may be particularly sensitive, or ecological concentration processes may lead to unusually high exposures. The latter is the case in the example of reindeer in the figure. Such special cases must be identified in the case of significant contamination of the environment.

High radiation levels may also be found from radon, e. g. in Nordic homes where the maximum annual lung dose equivalents run into tens of sieverts. Lung injuries such as fibrosis can not be excluded at such high levels.

High level exposures do also occur from the ultraviolet radiation of the sun. Acute skin burns and snowblindness associated with corneitis may be the result.

But most of the radiation exposures in the environment are at lower levels there no direct injuries occur. These exposures can be represented by the contaminations resulting from the accidents at Chernobyl and Windscale, and the fallout from nuclear weapons tests. What risks may these carry?

The best established effect is the induction of cancer. Some other effects are mentioned under 2.1, but here the detailed discussion will be limited to cancer induction. The most recent review by the United Nations Scientific Committee on the Effects of Atomic Radiations (UNSCEAR 1988) lists some 400 references to recent work on radiation induced cancer, predominantly in humans. High exposure levels have been definitely associated with increased cancer incidence. Dependence on some parameters such as age, sex, dose, dose rate and spontaneous incidence is becoming known to some extent. For instance, at higher doses, the incidence often seems to be linearly related to the dose.

At lower doses and dose rates, most studies fail to establish a link between the radiation exposure and the cancer incidence. To take one example, a review of 10 studies of nuclear workers in the US and UK revealed a cancer mortality less than that of the general population. Occasional excesses were found, but deficits were found as well and stochastical fluctuations may be the likely explanation. For instance, cancer of the prostate had been recorded in four of the studies. In two of them, there seemed to be no clear dependence on radiation dose, in one study there was an increase with dose and in one a decrease.

Two major studies deal with cancer incidence from low dose rates. In both cases patients have been examined using radiations, one group of women x-rayed in Canada in relation to tuberculosis, the other group in Sweden given

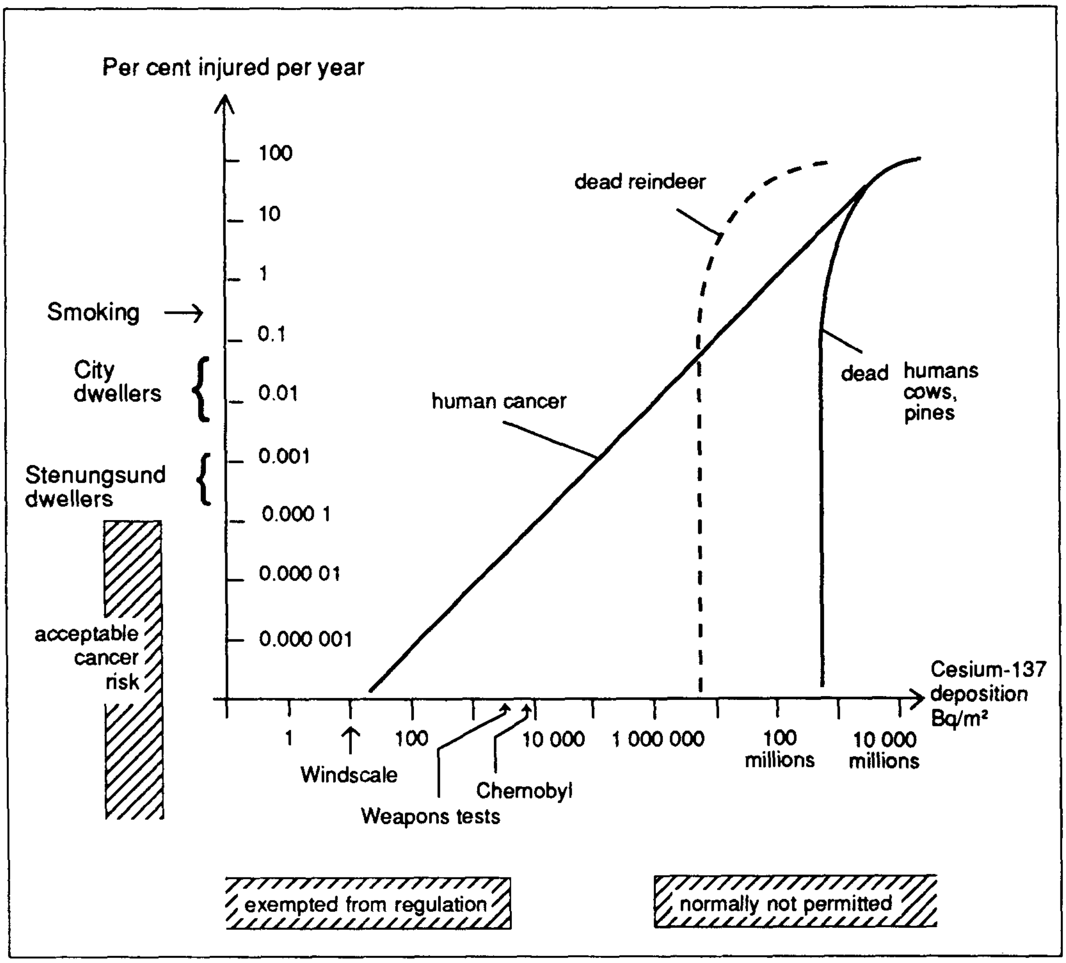

Figure 2. Examples of harmful effects of radioactive contamination and air pollution in the environment

The ordinate gives the percentage of injured individuals in exposed populations. The abscissa only pertains to radioactive contamination by cesium-137.

The injuries calculated from a radioactive contamination do not account for external irradiation but only for superficial or internal contamination, in order to provide a closer parallel to chemical exposures. Cancer from a single deposition may appear during about 50 years; the figure gives the annual mean during these 50 years.

Near the abscissa are indicated the mean contamination levels in Sweden after the accidents in Chernobyl 1986 and Windscale 1957, and after the nuclear weapons tests fallout in the sixties and seventies. The maximum contamination in Sweden after the Chernobyl accident was about 50 times the indicated mean. Also indicated are the contamination levels corresponding to radiation doses where exemption from regulation may be practised (0.01 millisievert per year) and where exposure would normally not be permitted following licensing procedures (1 millisievert per year). The corresponding cancer risks are well below one case per million exposed per year, and one case per ten thousand exposed per year, respectively.

On the ordinate are also given the cancer risks to three populations

- smokers
- city dwellers exposed to general air pollution
- Stenungsund dwellers exposed to airborne releases from heavy industry in a conglomerate in the Swedish countryside.

The ordinate also gives the acceptable risk from carcinogenic pollutants according to the Swedish environmental protection board, one case per million exposed per year. The exact significance of this acceptability is yet to be specified.

iodine- 131 for thyroid diagnosis. The results are supported by animal experiments and indicate that the cancer risk per unit radiation dose at low dose rates is one-half to one-tenth of the one at high dose rates.

The management of these cancer risks follows recommendations by the International Commission on Radiological Protection, ICRP. The cancer risk is assumed to be linearly related to the radiation dose.

One argument supporting this assumption is that environmental radiation doses are added to a lifetime dose from natural and medical exposures. Then, the relevant shape of the dose-response curve is not that prevailing at dose zero but rather the shape at about 0.1 sievert, which is likely to be more nearly linear. Another argument supporting the linear assumption is that if several contributions to the total radiation dose bring the risk into the truly linear region, then the best apportionment of the risk among the different contributions is by linearity with dose. A third, more speculative argument, is that if radiation and chemicals have similar effects, then also the chemical exposures serve to push the effect of the radiation dose towards the linearity region. Similar arguments may be applied also in considering the regulation of cancer promotors.

Under the linearity assumption, low doses of radiation are believed to cause fatal cancer in 3 – 50 cases in a population of 1000 persons exposed to one sievert of effective dose equivalent. As an average over a Western population, serious fetal injury may occur in at most one case in the same population, and future severe hereditary effects are believed to affect fewer individuals than cancer.

What is a level low enough to be exempted from regulation? There is an emerging consensus that 10 microsievert per year does not normally warrant regulation (compare 3.3). The equivalent of this level is entered in figure 2. The mean contamination level in Sweden following the Chernobyl accident was at about this level. The maximum level (50 times higher) would not under any circumstances have been permitted, had an application been filed. The figure also contains an indication of what levels would not normally be permitted when planning is possible.

The basic findings discussed above have been applied to the final disposal of low and intermediate level radioactive waste (Bengtsson 1988 a), as a case dominated by low dose rates.

2.4 Examples of chemical hazards

Table 1 (page 7) shows that many chemicals give the same type of effects as ionising radiation.

A simplified description as for radiation in figure 2 is difficult to provide since many chemicals often occur together in the environment and no common scale to quantify exposure exists. For instance, tobacco smoke contains more than one thousand identified chemicals. In a very extensive mapping of air pollution at the industrial conglomerate of Stenungsund in Sweden, only 13 chemicals or groups of chemicals could be analysed, a small fraction of those present. Attempts at describing the hazards via experiments on cells and mice had limited success.

Cancer risks

Some cancer risks from air pollution in Sweden are presented on the ordinate of figure 1 without reference to exposure levels. They can be compared with the cancer risks from Chernobyl for the average Swede. The smoker is exposed to several thousand times, the city dweller to several hundred times and the Stenungsund inhabitant to some ten times higher risk than the Chernobyl risk.

Almost all estimates of cancer risks from chemicals are very uncertain. Still they play an important role in regulation, e.g. in the US. A recent review of 128 decisions by federal authorities (Travis et al 1988) showed estimated lifetime risk levels from below one case per 100 million inhabitants and up to one cancer case for every third person exposed, the latter due to releases to the environment of arsenic from a copper smelter. Regulatory action had been taken for all cases where the lifetime risk was above 0.4 per cent and in only one case when the risk was below 0.0001 per cent.

The Swedish environmental protection board has suggested 1987 that a lifetime risk from chemical carcinogens of 0.001 per cent may be acceptable, or an annual risk of 0.0001 per cent. This can be compared with the annual cancer mortality risk of 0.00002 per cent associated with the exemption level suggested for radiation, and the 0.002 per cent "acceptable" for radiation.

Considering the different significances of the terms acceptable and exemption, the regulatory approaches for radiation and chemicals do not exhibit any gross discrepancies.

It should be noted that risk estimates, particularly for chemicals, are very uncertain and subject to intense debate. Swedish researchers have suggested (Ehrenberg 1989) that risk estimates for chemical carcinogens may draw upon the estimates made for radiation. The intermediary in common would be the so called adduct to the chromosome material DNA. Both radiation and chemicals produce such adducts. A first prediction of leukemia in workers exposed to ethylene oxide used for i.a. product sterilisation proved successful.

The cancer risks from contamination of workplaces and the environment contribute relatively little to the total cancer risks. The main contributors are smoking, food constituents, and sex related factors such as the age at childbearing for women.

Other injuries than cancer

At high exposure levels a variety of injuries is caused by chemicals as well as by radiation. There is no doubt that such exposure levels should be avoided. In the future, more attention must be paid to the effects of lower and repeated exposures that may be caused by environmental pollution. An obvious example is provided by cadmium. It is suspected that present daily intakes of cadmium in many parts of Sweden may exceed the threshold where kidney injury is caused. Higher contamination of rice by cadmium in Japan has earlier proved to injure particularly the kidneys of women above 40 years of age who had had many pregnancies.

Another suspicion concerns lead. Fetal brain injury may be linked with slightly elevated blood lead levels in the mothers, and exposure of children to lead from air pollution caused by motor traffic may have caused brain injury in children.

Fetal brain injury may also be linked with maternal consumption of fish contaminated with methyl mercury. Mothers in New Zealand had methyl mercury intakes slightly above the maximum recommended weekly intake according to the World Health Organisation. The children born may have had impaired intelligence quotient and language development.

The examples indicate a need for more attention to low level exposure to chemicals, with particular reference to sensitive groups such as children and fetuses.

2.5 Conclusions

- Many chemicals may cause cellular injury in similar ways as radiation. Chemicals may thus cause the same type of basic injury as radiation, e.g. fetal injury and cancer. It is also natural that these basic injuries at the cellular level may interact independently of what was the causing agent. Such interaction may strengthen or weaken of the effects. It is essential that assessment of the impact of environmental contaminants be based on the entire environmental pollution, not on each component separately.
- Air pollution consists of thousands of harmful chemicals and many types of radiation. The impact assessment is extremely difficult, not the least for low exposure levels. Ionising radiation has been more extensively studied than any single chemical. Methods have been suggested to assess the impact of some chemicals by analogy with radiation effects using DNA adducts as the bridge. Such methods should be further explored.
- In many cases the frequency of radiation induced cancer is proportional to the accumulated dose. Several arguments favor the general use of a linearity assumption for environmental impact assessment, and this is also implemented internationally in the case of ionising radiation. The assumption is getting international acceptance also for chemical cancer initiators. This is a promising development in spite of the enormous difficulties of quantification in the case of chemical agents.
- Cancer promotors exist at high concentrations in the normal environment, e.g. female sex hormones or metabolic products caused by smoking or the ingestion of alcohol. This may be a reason for studying further whether cancer promotor regulation should be based on an assumed linear dose-response relationship.
- In the case of hereditary and fetal injury, radiation protection is at present based on linearity assumptions. It should be discussed whether this would not be prudent also for some chemicals.
- Future work on protection against environmental chemicals should pay more attention to non-threshold types of injuries.
- Attention should also be paid to protectors against radiation as well as against chemicals. In many cases the same substances may serve both purposes. Protectors may help improve public health also in cases where prevention is recognizedly difficult, e. g. when it comes to the major health hazards associated with smoking, alcohol consumption or sun tanning.

3 Value judgments in decisions involving risks

As previously mentioned, evaluation involves the application of value judgments to the results of consequence assessments. This procedure is surrounded by controversy, mainly because value judgments may be very different between individuals.

Several factors have been studied in the Nordic project (Edsberg 1989) in order to clarify where there is room for value judgment and whether there are any general rules governing these judgments.

3.1 Ethics – critical scrutiny of value judgments

The word ethics may have two meanings. It may mean a set of values adhered to by a group and expected to govern their actions. Alternatively, it may mean the discipline which concerns itself with critical reflections over such values and norms. The sets of values depend strongly on such factors as religious and cultural heritage.

For instance, different groups may have different goals for the distribution of wealth:

- Perhaps the best known ethics was suggested by Pareto: A decision must not impair the situation for any individual. If this happens in any respect, he must in some other respect be compensated, in order that he might be considered to come out better off on the whole. According to the Pareto ethics, it is difficult to compensate future generations for the risks from nuclear waste, the benefits of nuclear power being enjoyed by the present generation.
- Another ethics was proposed by Bentham and later developed by John Stuart Mill. The goal for a decision should be to maximise the measurable collective benefit, or cardinal utility. If everybody values all benefits in the same way, and the law of diminishing returns applies, this leads to everybody having the same share of everything.
- The third ethics, suggested by Rawls, leads to similar consequences. According to this ethics, the wellbeing of a society is determined by those who are worst off. Again, if everybody values all benefits in the same way, the highest wellbeing is achieved if everybody has the same share of everything.
- Contrary to these ethical systems, another alternative is to strive for the maximum wellbeing for the individual who is best off. The solution does not imply that this individual has all resources available, since he will be better off if he is serviced by others. These must then have access to the means necessary for them to provide a maximum of services. No simple solutions appear to exist for this case.

Once the set of values is postulated, economic scientists may suggest policies which are likely to lead to fulfilment of the goals associated with the particular set. It is a common misunderstanding that there are sets of values which are right or wrong in an absolute sense.

The discipline of ethics does not provide such panaceas. Rather, it puts the spotlight on the ethical dilemmas facing the decision maker:

- ☐ competing values
- ☐ conflicting obligations
- ☐ trade-off between costs and benefits in alternative outcomes.
- ☐ uneven distribution of risks and benefits among different individuals.

A review of ethical considerations on nuclear power issues has presented the following picture (Edsberg 1989).

The evolution of ethical concepts

Ever since the old Greeks, it has been recognized that ethics is related to belonging to nature and to society, including understanding of and submission to processes like birth, life and death.

The philosopher Immanuel Kant suggested a *normative* ethics according to which there exist two types of rules. One is nature's laws, to which all creatures are subordinated, the other is the laws of ethics, which to some extent are contradictory to nature's laws, but still rule our behaviour.

Kant's categorical imperative implies that the principle on which a decision is made shall be applicable everywhere and by anyone, and also in reverse, e. g. towards the decision maker himself. Submission to this imperative implies that decisions benefit the individual and the objects of his actions, i. e. his surroundings or society. Kant also maintains that the individual who perceives himself as the most competent to contribute in a given situation should also do so in order to act ethically correct.

Later on, *consequential ethics* was suggested as an alternative to Kant's normative ehtics. John Stuart Mill proposed that the ethically correct decision is the one resulting in maximum benefit to the individuals involved. This requires a synoptic analysis which has the difficulties described in 1.2.

Societies belonging to the Western sphere of culture have adopted an ethical standard in which the individual's rights is the prime concern, and which is consequential, or at least non-normative. For the resolution of ethical dilemmas, no fixed set of values is available but an agreed process, the democratic process. This requires participation and access to knowledge. Experts having knowledge feel their obligation to make this knowledge available, in consistence with Kant's suggestions. In the Nordic countries this is witnessed by the development of codes of ethics for physicians, engineers, scientists etc.

The ethical ideals expressed in the democratic process are not stable. With changes in economy, science and education, ethical rules are challenged. An illustrative example is the development of contraceptive techniques which have had a dramatic impact on sexual ethics. It is a very difficult task for the elected representatives of the people to interpret these changing ethical values.

Ethical aspects on nuclear energy

Some of the most difficult ethical dilemmas are related to war. In Western societies, it is accepted by the majority that preparations for war should be devoted considerable resources.

In some countries, *nuclear war* is one of the accepted techniques of making warfare or deterring from war. The Nordic countries are divided on this issue. Peaceful nuclear energy is involved insofar as there may be a possibility of diversion of nuclear fuel, new or spent, which may provide weapons materials.

The spreading of nuclear technology may also facilitate the development of nuclear weapons. In accordance with Western ethics of democratic information and control, it becomes ethically correct to prevent diversion of nuclear materials and techniques to other uses than those agreed between the nations involved.

To many individuals, even the use of nuclear weapons for deterrence as accepted in the democratic process is strongly against their ethical norms. This is reflected in the Nordic countries in the emergence of professional groups against nuclear weapons, e. g. physicians, psychologists and engineers. Such individuals may be particularly motivated to prevent any possibilities that nuclear techniques be uses for weapons purposes.

Energy production influences our environment significantly. It is a relatively new insight that a degradation may have effects thousands of years from now, e. g. through the greenhouse effect of fossil fuel burning. For nuclear energy, the interest in long-term effects has been concentrated on the *long- lived nuclear waste*. A key ethical question is if we have the right to satisfy our energy needs at the expense of possibly impairing living conditions far into the future.

Again, Western democracy ethics requires an open discussion of the consequences of available alternatives, including a weighting of future problems against immediate benefits. There is one question that merits particular attention.

Should the waste be made inaccessible, in order to ensure a minimum risk of inadvertent future contact with it, or should it be made accessible for the monitoring and possible modification of the deposition techniques by future generations?

There are no obvious resolutions to such questions, as evidenced by two different Nordic answers proposed recently (Ethical aspects on nuclear waste 1988, and Disposal of high level radioactive waste 1989).

A final ethical issue deals with the possibility of a nuclear accident.

Is it acceptable to design an energy supply system which entails an albeit small risk of an accident with devastating consequences, such as the Chernobyl accident which has lead to relocation of about 100 000 persons for maybe decades? Can it be acceptable if the probability is low enough? How can the decision makers and the public be informed about the significance of such small probabilities and understand their significance?

Some consensus seems to be emerging about the tolerability of potential serious health hazards risks, as further discussed in 3.3. A related ethical issue refers to the division of resources for protection between the prevention of accidents and the mitigation of their consequences, should they occur despite the preventive measures.

Do we have the right not to put all available resources on prevention of any catastrophic accident?

Again, there are no obvious answers but the Western democracy ethics requires an open debate on the tolerability of the remaining risks of accidents and the allocation of resources for mitigation. In such a debate, again the experts have an ethical obligation to make their knowledge available as far as possible.

3.2 Economic valuation of health detriment

Several decision aiding techniques have been developed to assist the decision maker in the difficult ethical judgments he must make.

In one of these, cost-benefit analysis, all consequences involved in a decision are put on a common monetary scale. This means that for instance environmental and health effects are given in monetary terms. The theoretical basis has been reviewed by Bergman 1986. Many studies have tried to estimate the resources spent to prevent the loss of a human life. They tend to fall in the range between 1 and 10 times the value of the production time lost. In the field of nuclear safety they often exceed this range, and in the field of medical measures they often fall below the range (Bengtsson 1984).

In the mentioned theoretical study, the possibilities and limitations of cost-benefit analysis for health risk management were discussed. The report ended with the following conclusions:

- In practice, decisions involving the value of changes in risks to human health are unavoidable. Cost-benefit analysis has a sound theoretical backing in central economic theory and is a natural candiate for the generation of background material for such decisions.
- There are no economic principles that would impede the employment of cost-benefit analysis to study risk reducing measures. In particular, it is in principle possible to assess changes in health in monetary terms. The obstacles encountered are of a practical nature, mainly with respect to the difficulties of obtaining relevant data on the preferences of the individuals concerned.
- Methods to assess such preferences are available and have been tested, in particular following the new guidelines for environmental policy making in the United States.
- Empirical studies have been made on the economic valuation of reduction of risks to human health. These have given valuable insights, but the results show a considerable spread.
- Application of cost-benefit analysis should lead to the recommendation to institute a protective measure if the cost of saving a statistical life is below 3 MSEK (1 MSEK = 0,15 MUSD), and not to institute it if the cost is above 50 MSEK, subject to a number of reservations with respect to the absence of reliable data.

In addition, further research was proposed.

A pilot study (Vesterhaug 1986) indicated that optimisation of protection using monetary valuations of health detriments was likely to be employed in the off-shore oil and gas exploitation industry, and had been employed in the health care sector in the four Nordic countries of Denmark, Finland, Norway and Sweden, and in the road traffic safety sector in Norway and Sweden.

A review was made of environmental protection policies in several European countries, Japan and the United States (Bevington 1987). In general, statements of environmental policy and objectives were qualified by phrases to the effect that economic implications must be taken into account when planning pollution abatement and other protection measures, and that costs must be considered in relation to the expected benefits. Several practical difficulties were discussed in this report, e.g. the difference between business economics and national economics, and the assessment of the value of improved quality of life.

Of the countries reviewed, only the Netherlands had made full estimates of the costs of a comprehensive environmental programme, but without matching them with benefit estimations in comparable detail.

Radon mitigation

Recent international research, including a major Swedish project (Sjöberg 1987) suggests that strong reactions to risk are tied with moral indignation and the existence of credible experts who support alarm signals. Much research has been devoted to these and other factors responsible for risk reactions, with emphasis on exaggerated risk perception.

Less work has been done on indifference to risk. An earlier study on home owners indicated that about two thirds of those who were informed about potentially high radon levels in their houses were indifferent to the risk. This may be one factor behind the experience in Sweden that mitigating measures against radon are neglected by a large share of those who know they have rather high levels in their homes. To investigate the influence of economic factors, two studies were performed (Bergman 1989).

In the first of these studies, the influence on selling prices of known high radon levels in private homes was investigated. A registry at the Geological survey office of Sweden provided information on a large number of parameters influencing the selling price, e. g. lot value, age and size. Some other parameters were added. In all, the regression analysis involved 16 parameters, one of which was a high radon record (above 400 Bq/m3 of radon daughters). Some 300 houses in the Stockholm area with a radon record were studied, and 1800 randomly selected controls in the same area.

The radon houses had been granted reduced ratable values for tax purposes due to the radon. This meant a reduced annual cost by typically 0,4 kSEK (thousand Swedish crowns; 1 kSEK is about 150 USD).

No influence on the selling prices of the radon record could be found in the preliminary analysis. However, the statistical uncertainty permitted an influence corresponding to a reduction by up to several kSEK in the annual costs for those buying a radon house. The study will continue with better estimates of annual costs and radon levels.

In the second study, the willingness to mitigate a demonstrated high level of radon was investigated. The study group consisted of some 300 households in Sollentuna near Stockholm, a community where much effort had been spent by the authorities to educate the public about radon problems. All houses had a high radon level record, but less than half of them had been subject to mitigation.

The probability of mitigation was studied as a function of the radon daughter level, the household income per year, the average age of the residents, and the annual cost resulting from the mitigating measures. The results are given in table 2.

The willingness to take action is thus higher if the individuals involved are younger, have a higher income, face a cheaper countermeasure and are exposed to higher radon levels. Above all, the cost of the mitigation is a strong determinant.

One-half of the households would mitigate if the annual cost of mitigation were 3 kSEK or less, or 0.9 kSEK per person involved. This is about one order

Table 2. Probability of mitigation at average mitigation cost

Parameter		Probability of mitigation per cent
Radon daughter level	500 Bq/m^3	38
	2 000	62
	3 500	70
Household income	100 kSEK/year	37
	400	53
	700	59
Mean resident age	25 years	57
	45	46
	75	37
Mean mitigation cost	0.5 kSEK/year	97
	1	89
	3	52
	5	29
	7	18
	9	12

of magnitude less than the level of ambition advocated by the Nordic radiation protection authorities (about 20000 USD to avoid one mansievert of effective dose equivalent).

The results of both studies should be viewed with caution. None of them account for the existence of other factors influencing the willingness to mitigate against radon. Above all, many Swedish homes have a variety of problems related to health and ventilation just as radon: humidity, fungi, allergies, formaldehyde and others. Further studies are required before any firm conclusions can be drawn about the willingness to pay in relation to radon mitigation.

3.3 What is a low risk?

A literature survey was made regarding risks considered to be small. This would imply either being at the lower limit of risk levels being of concern, e. g. important enough to be regulated, or being low enough to be very generally uninteresting for regulation. There is an interval between these two risk levels, where a risk may not be directly of concern but action may be very simple and cheap, and thus implemented through regulation.

In recent discussions on regulation of risks, two aspects are usually taken into account. One concerns the risk to the individuals, often the most exposed individuals. The other reflects the total impact on society of a practice, often called societal risk or collective risk.

3.3.1 Individual risk

A first idea of what would be expected to be tolerable can be obtained by development of the ideas proposed by Lindell (1988). In Western countries in general, the life expectancy at birth has increased dramaticaly during the last century. For Sweden, for instance, the increase has been about 100 days for each year of the century. It would definitely be of concern if this development were halted, that is, if various sources of risk added up to a life shortening committment of this whole amount each year. A life shortening commitment of 10 days per year would probably be at the lower limit of concern, and 1 day would be negligible. Assuming that a fatality involves 10 000 days loss of life expectancy, probabilities of loss of life of 1/1000 and 1/10000 would be at the lower limit of concern and negligible, respectively.

This applies to all practices involving risk taken together. How many practices are of concern?

This depends strongly on how a practice is defined. We may say that we have about 10 different areas of safety, such as transport safety, safety at work, safety in consumer products, safety in the environment etc. For each of these areas we may have about 10 branches being regulated, such as road safety, air transport safety, sea safety and railway safety in the case of transport safety. For each branch we may have 10 practices, such as bus traffic, heavy road cargo and private auto transport. This leads to about 1000 practices of concern. When it comes to practices that are exempt from regulation, it is likely that they are more numerous, say 10 000.

This means that the lower risk level of concern should be about one fatality per million exposed per year, and the negligible risk level about one in a hundred million exposed per year.

Table 3. A literature survey of risk levels considered as being barely of concern or as being negligible. The data refer to annual risks or risk commitments of dying or attracting a serious disease, for a single practice. (Compare IAEA 1988 for a discussion of the definition of a practice.)

Reference	Lower limit of risk of concern	Negligible risk	Remark
	in a million exposed per year		
This paper	1	0.01	From life expectancy discussion
Royal Society 1983	1	0.1	
Swedish Energy Comm. 1978	10	1	
Health and Safety Ex. 1987	1		
IAEA 1988		0.1	Radiation
ICRP 1977	10		Radiation
Travis et al 1988	1		Radiation and chemicals
Swed. Env. Prot. Board 1987	1		Chemicals
Federal Register 1985	1		Radiation and chemicals
van Kuijen 1988	1	0.01	Radiation and chemicals
Miljöstyrelsen 1989	1		Chemicals

Comments on the data in table 3

Some qualifications may be made to the numbers presented in the table, since they are simplified and not strictly comparable. The recent policy statement by the Swedish Environmental Protection Board (1987) suggested that 1 case of cancer per million inhabitants per year would be a low risk level, or in a lifetime 10 cases per million inhabitants. In the Dutch government environmental planning program for the period 1986-1990, 0.01 cases of cancer annually per million individuals was given as a negligible cancer risk for toxic substances (van Kuijen 1988), corresponding to a lifetime risk of about 1 case per million individuals. The recent Danish report (Miljöstyrelsen 1989) claimed that a general criterion for acceptability of risk from hazardous installations would have as one component a maximum annual fatality probability of one per million for individuals in the neighbourhood.

The Swedish energy commission (1978) considered that society takes some measures to reduce risks at a level of 10 fatalities per million and year, mainly through information. At one-tenth of this level, the individual is not particularly concerned.

One study concerned the outcome of 132 past decisions by US regulatory authorities (Travis et al 1988). The hazard involved was cancer morbidity as a consequence of exposure to chemicals or radiation. In only one of the cases did the agency require regulation when the lifetime cancer risk was below 1 per million exposed individuals, thus equivalent to the Dutch level and one-tenth of the Swedish level and the international radiation exemption level.

The Danish criterion (Miljöstyrelsen 1989) refers to the most exposed neighbours. The oldest British ones (Royal Society 1983) specified that at an annual fatality risk level of 10 in a million, few people would commit their own resources to reduce the risk, and at 1 in a million even fewer. The more recent one (Health and Safety Executive 1987) refers to a level of risk which, provided there is a benefit to be gained, and proper precautions are taken, does not worry us or cause us to alter our ordinary behaviour in any way.

The United States EPA suggestion was worded as a de minimis individual lifetime risk level of 0.000 01 to 0.000 1 for small populations.

An alternative approach (van Kuijen 1988) may be to suggest that a risk of little concern would be a small fraction of the lowest fatality risk known in industrialised societies. Teenage girls are exposed to the lowest overall fatality risks, amounting to about 0.01 % per year. A small fraction of this might be one-hundredth, i.e. one in a million per year, consistent with the above mentioned lower risk level of concern.

Actually, this simplistic reasoning seems to be in line with current discussions, as evident from table 3. The table shows a number of suggestions for risk levels that are of little concern or negligible. The interpretation of the literature is not always easy, despite the simplification that all numbers are rounded to even powers of 10. For one thing, often no sharp lower limit of concern is given and then an arbitrary judgment was applied in entering the tabular data. Another difficulty lies in the definitions of the individuals concerned (compare also 3.3.3 below). The discussion may pertain to the most highly exposed individuals, a highly exposed critical group, or the average individual in a large group. The exposures may differ by orders of magnitude dependent upon how the individuals involved are defined.

Some more details are given in the comment box on page 21.

3.3.2 Collective risk: Low probability events

Society often stops requiring further action for risk reduction when the risks are diluted in time and in a large number of persons.

Examples on views with respect to the dilution in time are given in figure 3.

If there is a large dilution in time, i. e. the consequence has a low probability, the practice may pass without society demanding further risk reduction. Larger consequences may pass if the probability is lower. The most clear-cut examples emanate from Denmark and the Netherlands where very strict demands have been issued by the governments. Numerical estimates of low probabilities as used here are, however, very uncertain and should be viewed with great caution (Bengtsson 1989 d, Pulkkinen and Prn 1989, see also 3.3.4 below).

A large number of examples from other countries have been summarised by Vinck (1988). These tend to be somewhat less strict.

In the United Kingdom, the Health and Safety Executive (1987) have discussed societal risk and cite a number of examples: industrial accidents at Canvey Island, flooding over the Thames Barrier, and a major aircraft crash. The probability of these should be less than 0.001 and preferably less than 0.000 2 per year, and further risk reduction would be of concern. For nuclear accidents with a considerable uncontrolled release to the environment, a probability of 0.000 1 might be tolerable but efforts to reduce the risk further would continue.

The Health and Safety Executive (1989) have further discussed the role of quantified risk assessment. In 10 of the 16 decisions based partly on quantitative risk assessment, societal risk was taken into account in the political decision. It was concluded that too many factors are involved in assessing such risks to permit the specification of uniformly applicable limits of tolerability.

Collective risk has sometimes been expressed in non-quantitative terms. In Swedish discussions on mitigation of releases, it was decided that some rest risks needed not be included for mitigating measures, e. g. when the initiating event was an earthquake or a sudden rupture of the pressure vessel. The estimated frequencies of the exempted events are generally less than one in a million years, although there has not been any formal assignment of probabilities. This means that the individual fatality risk even for persons living close to the site is less than one in a million exposed per year.

For French oil refineries, the upper limit of acceptability for a catastrophic accident is 0.000 1 per year (Union des chambres 1985). This implies that individuals living nearby may experience a risk of 100 per million exposed per year. If similar consequences may occur in France as in other countries, i. e. hundreds of fatalities, the French criterion falls rather high up in Figure 3.

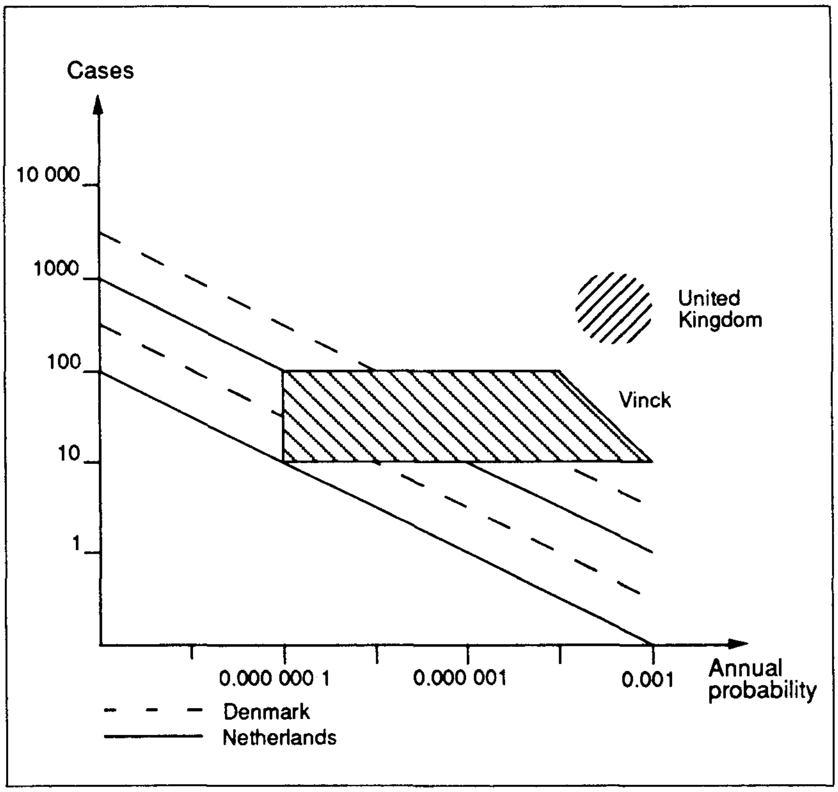

Figure 3. Consequences which are negligible or of little concern if they are sufficiently diluted in time. The ordinate gives the number of cases of serious injury or death as a result of infrequent accidents, the annual probability of which is given on the abscissa. The lower lines give the negligible consequence and the upper line the consequence of little concern for the Netherlands (van Kuijen 1988) and Denmark (Miljöstyrelsen 1989). The data from Vinck (1988) and the United Kingdom (Health and Safety Executive 1987) *are discussed in the text.*

It could be noted that the expectation value of the number of cases of seriuos injury is less than 0.01 in all cases except the United Kingdom. This is a low value in comparison with the expectation values from practices leading to regular and widespread environmental contamination, as discussed in the next section and figure 4.

3.3.3 Collective risk: Large populations

In some instances, what is a collective risk of little concern depends also on the dilution in a large population, that is, on the number of individuals concerned.

Milvy (1986) concluded that the negligible lifetime risk level seemed to be inversely proportional to the square root of the number of persons involved, being about ten in a million per year at a population size of one million persons, and about one in a million at a population size of 100 million.

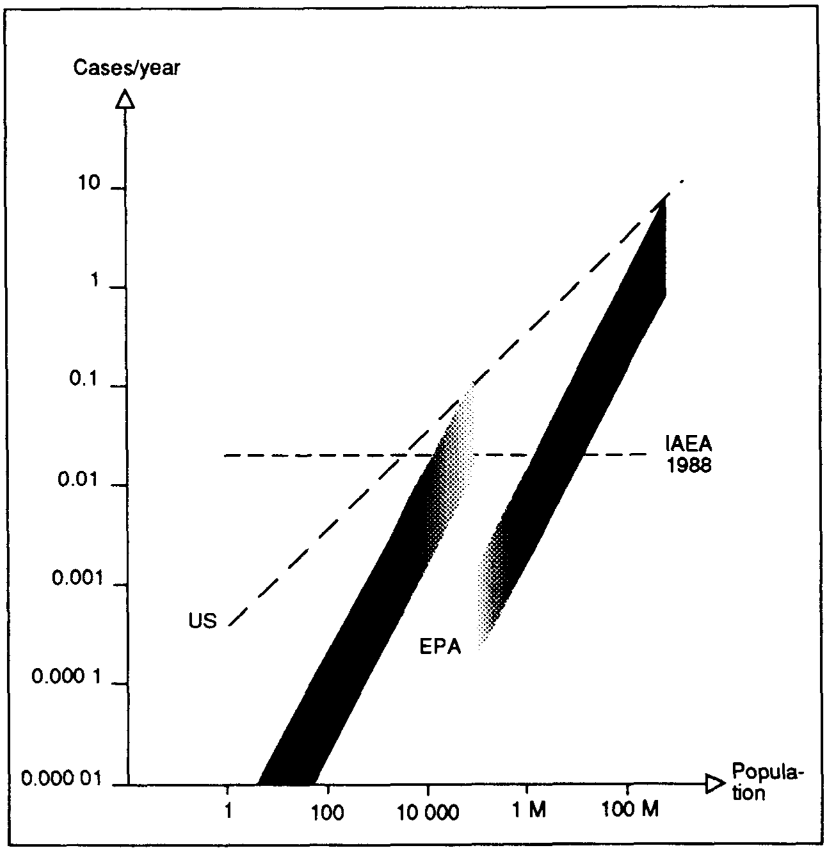

Figure 4. Influence of the population size on the negligible collective risk or the collective risk of little concern. The ordinate gives the number of cases of serious injury or fatalities per year due to a practice, as a function of the size of the populations concerned. The United States data are from Milvy 1986, and the Environmental Protection Agency data from the Federal Register 1985.

This has been expressed in figure 4 in terms of the population risk of little concern as a function of population size. The figure also refers to a proposal by the US Environmental Protection Agency (Federal Register 1985) on collective risk. The suggestion was a lifetime risk of 10 to 100 per million exposed for small populations and one hundredth of this for large populations.

This can be contrasted with the discussions on exemption by the IAEA (1988). Even for exempted levels of individual dose, further reduction of collective dose could be considered if this exceeds 1 manSv, corresponding to 100 000 persons being exposed at the dose level of individual exemption. In this case, the negligible collective risk does not depend on the size of the population involved.

3.3.4 Other expressions of risks considered to be small

A cut-off is applied in probabilistic safety analyses (PSA).

All analysts define a lower limit for the probabilities which warrant inclusion in the analysis. In nuclear power, this limit is often one in ten millions per year for contributions to the core melt frequency for sub-systems, and one in a million for larger systems. Calculated accident probabilities lower than one in a million reactor years should therefore be viewed with great caution.

3.3.5 Conclusions

The review indicates that a consensus seems to be approaching, both between countries and between radiation and chemical risk regulation. The definitions of what the levels or limits pertain to are different, but the consensus contains the following intervals:

- □ 0.01-0.1 committed cases per million persons exposed during one year is a negligible risk, and 1-10 a risk of little concern.
- □ major accidents are definitely of concern if the annual expectation value of the number of victims exceeds 0.01.

Some narrowing of the intervals might be possible with harmonised definitions for the different areas. Additional criteria for population risks are emerging.

4 Risk comparisons

4.1 A word of caution about risk comparisons

The total risk from a practice is usually multi-dimensional, involving e.g. risks to health, to the environment, to investments, to national independence or risks of anxiety coupled to health effects. Some of the dimensions can be expressed quantitatively. By describing only these, or even a selection thereof, one distorts the risk panorama. This is almost certain to create difficulties of communication with those interested in understanding and using the risk comparisons.

In addition, risks of different dimensions are perceived very differently by different individuals. The perception is influenced by such factors as the character of the negative outcome, the individual's degree of control, the number of fatalities appearing from the same source, the probability, the time of manifestation of the outcome, the uncertainty about the risks, its familiarity, the individual's knowledge, the benefits from the source, the confidence in the individuals presenting the risks, previous publicity, and equity as well as political considerations.

Successful communication about risk comparisons requires that the risks compared are as similar as possible with respect to all of these factors. Anybody attempting risk comparisons should try to emphasise in what respects there are differences between the items compared. Still, with such reservations, there is much perspective to be gained from comparisons of risks.

4.2 Comparisons of risks from radiation and genotoxic chemicals

Comparisons of radiation and chemical risks have already been referred to in Chapter 2. The risks from ionising radiation seem to be more thoroughly evaluated than those of any single chemical compound. Due to lack of data, no definite conclusions can be drawn about the relative risks from radioactive and chemical substances in the environment. There is, however, an emerging consensus on the analysis of hazards from genotoxic chemicals and radiation, and on the management of risks associated with these agents (3.3).

Risks from radiation in Sweden are discussed in 5.4. Natural sources such as radon in homes and solar ultraviolet radiation account for the largest individual and collective risks, with enviromental contamination from nuclear power or nuclear weapons lagging far behind.

4.3 Comparison of long-term risks from different energy systems

Many comparisons of risks from different energy systems have been published. In a recent one (Bento 1989), the comparisons are extended also to risks from transports, chemical risks and natural risks. Such studies are, however, not generally applicable, as has been pointed out in a study on energy risk studies (Rowe and Vinck 1988). These studies should be seen against a defined purpose.

The purpose of the present study has been to review the usefulness of certain criteria for regulating the long term health and environmental consequences of different energy systems.

The very long half-lives of some nuclides in radioactive waste raise the question of risk management over times much longer than the interval preceding the next ice age. In such a long time perspective, it is not possible to assess consequences of environmental pollution with any certainty. It has been suggested that a suitable management rule would be to make sure that the concentrations due to pollution would add only small risks in comparison with the risks from the natural levels of hazardous agents. This has been investigated for energy systems based on nuclear power, fossil fuels, and biomass (Bengtsson 1989 c).

This management philosophy has emerged from Swedish energy studies during the last decade and is based on some fundamental postulates:

- ☐ the flow of pollutants in the environment should not be large in comparison with the natural flows
- ☐ transboundary exposures are often significant, and international cooperation is therefore essential for their abatement
- ☐ pollution does not respect generation gaps and e. g. waste management must consider long time perspectives such as 10 000 years (coal ash heaps) to millions of years (high level nuclear waste)
- ☐ many pollutants, e. g. from combustion, are genotoxic and may thus cause cancer and hereditary disease.

Environmental and health risks are tolerated because without energy production, even worse harm would occur. Lack of energy in Sweden two centuries ago was associated with poverty and hardships which kept the mean life expectancy at half its present value. A reasonable amount of energy production means a healthier life on the average, even if the beneficiaries may be different from those suffering the side effects of the energy production.

This can be seen from figure 5 which shows that there is a striking correlation between the availability of electrical energy in a country and the longevity. This is consistent with the conclusion (Sagan and Afifi 1978) that energy availability and education have been the dominant contributors to increases in longevity.

While thus contributing to human wellbeing, energy production and consumption are also major contributors to global environmental pollution. This pollution threatens to have profound effects on the climate, on forests, lakes and other ecosystems, on man-made objects and on human health. It is tolerated because the availability of energy is intimately tied with a high standard of living which maintains such essentials as food supply and health care.

There is a growing realisation, however, that environmental pollution from energy production and use is approaching such levels that pollution abatement

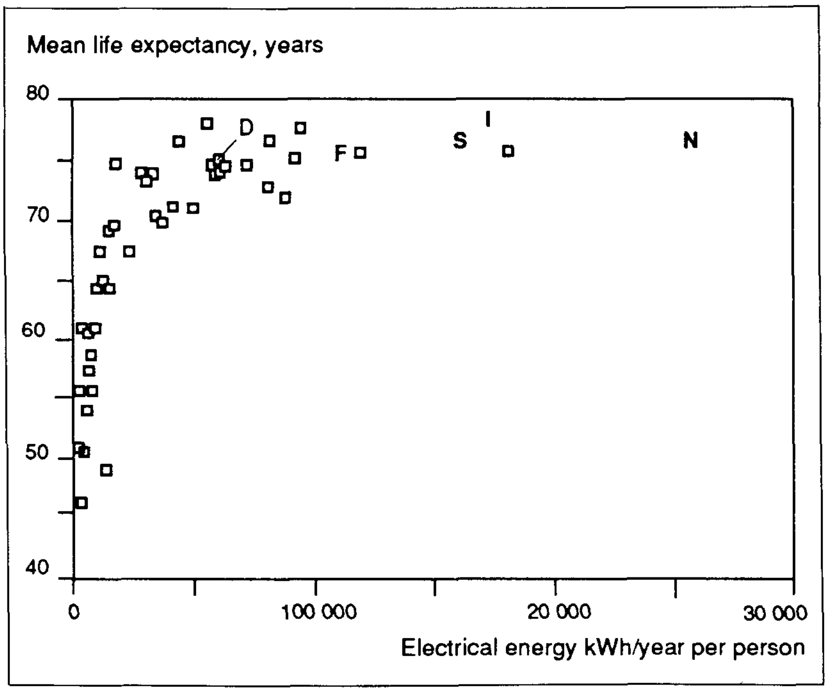

Figure 5. Energy supply and life expectancy: Relation between availability of electrical energy in kWh per inhabitant and year, and mean life expectancy at birth, taken as the average for males and females. Each point represents one country. The Nordic countries of Denmark, Finland, Sweden, Iceland and Norway are marked by their initials. Data are mainly from Statistical abstract of Sweden 1989. There is a strong correlation between electricity supply and longevity up to about 3000 kWh per inhabitant and year. Above this, every doubling of the energy availability increases the mean life expectancy by about 2 years, bur the correlation is much poorer.

must have a high priority if the standard of living is to be maintained, and that a clean environment in itself is a constituent of a high standard of living.

Many aspects of the environmental contamination are truly global, and limits to emissions must first of all be compatible with a sound global environment. This environment is likely to come out of balance if the flows of pollutants caused by mankind are large compared with the natural flows. In the paper (Bengtsson 1989 c), the "rule of the natural levels" has been applied to emissions, implying that the total emissions caused by man must at most equal the natural flows. For the purposes of calculation, it has then been arbitrarily assumed that energy production and consumption can only be permitted to contribute one-tenth of these flows.

The results show that we are already violating the rule of the natural levels on a global scale with respect to carbon dioxide emissions from fossil fuels. If the present coal consumption continues, we will also be violating them more than tenfold by emissions from coal ash heaps, in a time perspective of thousands of years.

In addition, regional and local contamination considerations may require stricter limitation. The Swedish energy situation is discussed in this context.

The Swedish energy consumption is fairly high and violates the rule of the natural levels in about the same way as the global energy use. Being part of the densely populated European region, additional restrictions should be put on the acidifying emissions from Swedish energy production and consumption if the allocation of tolerable emissions among European nations is on a per inhabitant basis. These restrictions would permit a fossil fuel consumption of roughly one-third of today's Swedish level. Carcinogenic pollutants in major Swedish cities have been estimated to cause 100-1000 cases of cancer each year, and it should be worth substantial efforts to reduce these numbers, principally by reducing traffic emissions. Nuclear power emissions are generally compatible with the rule of the natural levels, but major accidents may give local enhancements with severe environmental consequences.

These risks have promted the Swedish government to propose a change of the energy system. The Swedish parliament has also decided that nuclear power shall be phased out by the year 2010. Various measures for the implementation of these changes have been taken. Options include considerable energy conservation, and the use of various renewable energy sources.

If the changes are not to have strong consequences for the standard of living, they must be carried out over decades. In that case, the economic consequences are likely to be small in comparison with the uncertainties of economic long-term predictions in general. In calculational examples, a couple of per cent of the gross national income have been mentioned as a possible cost, but the change may even in the long run lead to an enhanced income compared with a reference alternative.

5 Risk decision principles

Several studies have been made within the Nordic project concerning principles governing decisions where risks are involved, and their practical application. Seven such studies are summarised below.

5.1 A survey of risk decision principles in the Nordic countries

The principles and practice of accounting for risks in decisions in the Nordic countries have been reviewed in a preliminary study (Vesterhaug 1986).

Wide applications where the authorities used cost-benefit analysis were found in road safety, in radiation protection and the evaluation of new technology within the health care sector. Some examples were also found in off-shore oil exploration activities and in the manufacture of explosives.

In a later development, the use of cost-benefit analyses has recently been required by both the Swedish and the US governments to be provided as an input when authorities are suggesting new regulations.

In areas where large accidents may happen, such as the nuclear power and offshore oil industries, advanced management principles are employed. These include defense in depth concepts, competence assurance, probabilistic safety assessment etc. Some aspects are developed in 5.5

In the explosives industry, reducing the probability of accidents is traditionally given less weight. The approach taken is instead to reduce the consequences, given an accident. This involves the use of large safety zones, sectioning of workplaces, partial automation, and ventilation following explosions.

5.2 Principles for regulating genotoxic chemicals

A major effort was made to promote the application of unified principles in the regulation of risks from genotoxic chemicals and radiation. Genotoxic chemicals are those which can injure the genetic material DNA of living cells. Some resultant effects such as hereditary disease and cancer may also be caused by radiation, and the similarity of effects suggests the possibility of applying unified principles for the regulation of the risks.

5.2.3 Environmental protection policies

An international symposium on the subject was held (Management of risks from genotoxic substances in the environment 1989). In the preparations for this symposium, environmental protection policies in non-nordic countries were reviewed (Bevington 1987).

The review comprised the European Economic Community, its member states France, Federal Republic of Germany, Greece, Italy, the Netherlands, Portugal and the United Kingdom, as well as Japan and the United States. The role of several international organisations was also discussed, e. g. the International Programme on chemical safety, the International Register of Potentially Toxic Chemicals, the Organisation for Economic Cooperation and Development and the International Agency for Research on Cancer. Some of the conclusions were as follows:

- Extensive guidelines for risk assessment have been issued in the United States. In several other countries, information collection is highly systematic, but the risk assessment and the issuance of guidelines is more pragmatic
- Several countries have developed systems for deciding the order of priority in which existing chemicals should be investigated. Evidence of genotoxicity moves substances high up the priority lists
- The benefits of the various chemicals and the costs of protection against their risks are often assessed, but the difficulties in the process are very great. Only the Netherlands has made full estimates of the cost of a comprehensive environmental programme, but not yet the corresponding benefit estimates.

Organisation of protection at the international, national and local levels was also discussed.

5.2.2 Symposium on risk management

The symposium (Management of risk from genotoxic substances in the environment 1989) was divided into five themes:

☐ biological aspects
☐ risk assessment
☐ risk management philosophy, legislation and practice
☐ economic aspects and cost-benefit analysis
☐ information.

A subsequent workshop discussed the prospects of unified principles for regulation. The chairman of the concluding session mentioned the following points in his summary:

> There are major differences between radiation and chemicals. In the management of chemicals you have often severe problems of identification due to the existence of thousands of genotoxic chemicals. These may also have non- genotoxic effects that are very significant but different from those of radiation, for instance causation of allergic reactions.
>
> **Status of genotoxic risk regulation**
>
> There are many areas where we know too little:
>
> - There are still large fractions of the cancer incidence that are not accounted for.
> - When causal relationships have been established they often pertain to the most easily detected types of cancer; other types are likely to be detected later on as has been the case for smoking, when lung cancer was

first detected, and radiation, where leukemias first appeared.

- In particular we fear that cancer in the offspring as a result of parental exposure will appear more commonly in the future.
- In the case of chemicals, hereditary diseases have been given far too little attention in view of the very large burden on mankind that may become manifest in coming generations.
- Also teratogenic effects for chemicals should be further pursued.

There are, however, also many areas where we know enough to act:

- Without any doubt, smoking is established as the single most important cause of cancer and effective prevention of smoking could mean more than possibly any other action to prevent cancer.
- Even qualitative indications of genotoxicity are today sufficient to prevent industry from developing a tested chemical. Thus genotoxicity testing means that in the long run many potentially genotoxic substances are stopped at a very early stage.
- At national levels, the incidence rates of some cancers are decreasing although some others are increasing. There is thus no general epidemic of cancer although at the local level quite severe effects of genotoxic substances can not be excluded.

The emerging quantitative knowledge for chemicals has also lead to the development of management approaches for chemicals similar to those for radiation: rules for exposure levels that could be exempted from regulations, exposure limits for controlled sources based on estimated risk limits, optimisations of the protective regulations to keep exposures as low as reasonably achievable. The numbers applied may be different but the consequences of these management approaches are now being evaluated in several countries such as the USA, the Netherlands and Sweden.

Potential of genotoxic risk regulation

Risk identification and assessment have made significant progress and hold potential for even mapping an individual's susceptibility to developing cancer following genotoxic exposures. The question has even been raised if such a knowledge would be desirable if it becomes attainable.

Several methods have the potential for identifying and quantifying genotoxic risks in humans, involving:

- □ adducts in human cells to DNA and to hemoglobin
- □ point mutations in the hprt-locus in lymphocytes
- □ chromosomal aberrations in lymphocytes.

Other methods can give indirect indications of human risks from genotoxic agents, e g based on short-term tests and measurements on animals, as well as structural analogies with chemicals for which hazards are known.

For analyses of non-genotoxic carcinogens and of cocarcinogens, the methodology is far less developed. However, for the latter case of potentially promoting agents, methods can be used based on:

- □ interruption of cell-cell communication, measured by metabolic cooperation in cell cultures
- □ induction of DNA synthesis and cell proliferation i. a. in hepatocytes
- □ use of transgenic mice, initiated by activated oncogenes.

Two working groups reported diverging views on the usefulness of genetic studies on the fruit fly Drosophila for extrapolation to man.

Indicator organisms can be used to monitor the effect on the environment of complex mixtures of chemicals and radiation, e. g. the plant Tradescantia (point mutations in stamen hairs), the fruit fly Drosophila (different genetic endpoints), and possibly larvae of mosquitoes (Chironomus, effect of water pollution on chromosomes in the salivary glands).

Similar approaches to management of radiation and genotoxic chemical risks have already been used to some extent and further development is desired. Because of the different conditions, the management approaches should not be the same, for instance not with the same risk limits. It is however possible and desireable to continue exploring for genotoxic chemicals a risk managment philosophy based on the no threshold, linear dose-response hypothesis. Much emphasis should be put on the source of pollution, where the responsibility for release limitation should rest.

The basis for acceptance of a practice should be an assessment of risk and costs versus benefits, not a comparison of risks. Comparison with natural exposure levels could play a role for providing perspective. The public should not only be informed about planned decisions but be actively involved in the decision making process. Optimisation of measures to limit exposures should play an important role.

In the management, similar ideas are now discussed for genotoxic chemicals and radiation with respect to exemption from regulation, both with respect to individual and collective risks that are deemed to be insignificant.

Research needs

There is still a need for *identifying the hazards* from chemicals and radiation, e. g. hereditary effects. Crossfertilisation between the fields of chemicals and radiation is possible. For instance, very early embryological injury from chemicals has been demonstrated. For radiation such injuries have been belived to be of little significance since spontaneous abortion was believed to dominate, but this assumption should be reexamined.

In the complex everyday environment, *synergism* may be very important when e. g. cancer promotors occur in high doses, i. a. due to smoking or alcohol consumption. It is not known whether synergism plays any significant role at low exposure levels.

For chemicals, there is still much need for *quantification*. Suitable quantities as measures of genotoxic harm must be developed, as well as methods for measuring these quantities.

There is a need for meaningful methods for *monitoring* the pollution of the environment with genotoxic chemicals, for instance using indicator organisms.

It may be possible to monitor the "pollution" of DNA in humans using phosphorus-32 post-labelling techniques. Representative samples from the European population might be interesting as well as from individuals occupationally exposed to genotoxic agents.

Dose-response relationships must be established, particularly for genotoxic chemicals. Under the linear no-threshold hypothesis, these can be replaced by dose/risk conversion coefficients.

The specific promising *techniques for assessment* of human hazards mentioned above should be developed.

Special attention should be paid to *less spectacular endpoints* of biological injury, for instance when it comes to hereditary effects. More should also be known about how selective processes govern the manifestation of genetic injuries.

Cost-benefit analyses could be better pursued if relevant social parameters were included when surveys are made concerning the impact of genotoxic agents.

Alternative methods to provide economic incitements for prevention and mitigations should be further studied: insurance, liabilities, taxation, subsidies, etc.

Studies in political and social sciences should explore *how opinions are formed and new decisions are actually made.*

Alternative technologies to reduce releases should be developed.

The *prevention of rare large accidents* in plants involving genotoxic chemicals should be studied more.

International cooperation and further meetings like the symposium/workshop

There is room for more international cooperation among economists on risk management.

International cooperation in risk assessment should center around concrete projects to develop and validate models for risk assessment. Such work has successfully been performed within the framework of the WHO/International Program on Chemical Safety.

Identification of chemical hazards must be based on international cooperation. For assessment of carcinogenic risks the International Agency for Research on Cancer, IARC, has an ongoing program.

Data bases could be an area for international cooperation. A case in point is data referring to hereditary side effects of chemotherapy, the assessment of which would require a large data base.

Meetings of the type referred to above could be valuable after some time when more data have been gathered. The initiative to this should come from those responsible for management of genotoxic chemicals.

5.3 Synoptic and incrementalistic decision making for genotoxic substances

Two basic approaches for decision making were described earlier in this report (1.2 and 1.3): the synoptic and the incrementalistic. In the synoptic approach, the decision maker is faced with all relevant aspects and a systematic trade-off is sought. In the incrementalistic approach, the decision maker starts from the present situation and moves on to consider how alterations may be made at the margin.

These two approaches have been used to analyse the regulation of risks from genotoxic substances (Bengtsson 1989 a).

Real-life examples showed that genotoxic risk assessment in reality plays little role for political decision makers. What counts, at least until now, are other factors such as perceived risks and the actual political situation of the decision maker.

The report concluded that there does not seem to be any clear-cut preference for the synoptic or the incrementalistic approach in the management of genotoxic risk. The synoptic approach dominates international recommendations on radiological protection but in the face of insurmountable complexities in the analysis, simplifications are introduced which resemble those which are deliberately accepted from the beginning in the incrementalistic approach. When the incrementalistic approach is accepted, as in the case of transboundary non-radioactive air pollution, it is sometimes in the hope that in due time a better approximation to a long-term synoptic goal will be realised.

A clarifying matrix has been suggested by Douglas and Wildavsky (1982). They suggest that the management of risks should to a large extent depend on the *knowledge* about the future and the consent about the most desired prospects.

Their suggested strategies are described in figure 6.

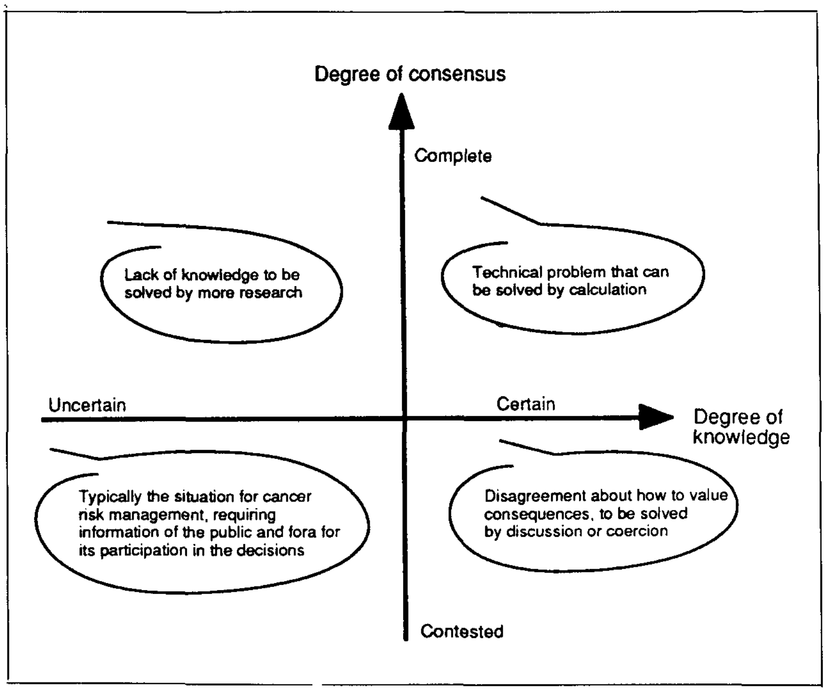

Figure 6. Management options is cases of different levels of consensus about the most desired prospects for the future and different knowledge about the future. Adapted from Douglas and Wildavsky (1982).

The synoptic approach can be applied if there is good knowledge and complete consent, conditions which may prevail for simple problems involving limited circles of decision makers. If the consent is lacking, the suggested solution is to stimulate discussions aiming at compromise solutions, or alternatively to apply coercion. If instead the knowledge is lacking, research is advocated, in combination with careful step-by-step incremental decisions which permit reorientations if necessary.

The most typical situation with respect to genotoxic risks, however, is likely to be the fourth one, where the knowledge is lacking and there are widely different views about the appropriate actions. Douglas and Wildavsky claim that only social consent keeps an issue out of contention. Risk taking and risk aversion, shared confidence and shared fears, are part of the dialogue on how best to organise social relations. Technological estimates of risk are not mirroring any objective truth, and the perceived risks will govern the decisions.

If incrementalism is to be applied to the management of genotoxic risks in this difficult situation of lacking information and lacking consent, it must be stressed that its merit is in providing processes for social interaction. This was the lesson learnt following the early work by Lindblom and Wildavsky in other contexts. In the case of genotoxic risks, it should mean continuous efforts at informing the public broadly about genotoxic risks, providing a perspective on a range of agents, and encouraging public participation in decisions concering the management of genotoxic risks.

5.4 Decisions concerning radiation risks in Sweden – a study of four cases

A study (Bengtsson 1986) considered the value judgments behind decisions involving poorly known radiation risks. The study discussed four levels of decision makers:

- ☐ the parliament, which has enacted the act on radiation protection and decided in major issues, e. g. concerning nuclear power
- ☐ the government which has interpreted the act, i. a. in some cases submitted by the radiation protection authority
- ☐ the radiation protection authority which broadly decides on the application of the act, setting minimum requirements on those who operate in such a way that they may cause irradiation of man or the environment
- ☐ the operators of activities involving radiation, who may make decisions subject to the restrictions given by the licences, e. g. aiming at more advanced radiation protection than the minimum.

Four practical Swedish cases were studied: radon in dwellings, mammography, final disposal of low and intermediate level radioactive waste, and magnetic fields from video display terminals.

The cases were discussed concerning their significance with respect to radiation injuries, the reactions from those subjected to the risks, and the decisions by those most closely responsible for acting, by the radiation protection authority, by the government and by the parliament.

The conclusions were the following.

Those who were subjected to the risks were in general poorly informed about the risks, although some of their representatives had a fairly good idea about what was debated, among these labour unions, environmental groups, and in the case om mammography, womens associations. The individual preferences with respect to these risks were strongly variable. Ideally, therefore, some kind of mapping of the individual preferences should be made as an input to those decisions which are made collectively, e. g. by the authorities.

The different levels of decision makers exhibit very interesting examples of conflicts of values. The valuation of a risk that is poorly known is not sytematically related to the level of decision maker. Those closely concerned by a risk may demand strong countermeasures, as in the case of video display terminals, or be negligent with respect to the risk, as in the case of mammography. This may be consistent with individuals being averse to risk when the costs of countermeasures are charged to others, but inclined to accept risks (risk prone) when they bear the costs themselves.

These opinions at the level of the closely concerned indviduals also reach decision makers, and here the decisions are even less clearly founded. The government delays action against radon, but pushes for actions against video display terminals, avoids decisions about mammography but demands excessive protection against radioactive waste. There is no simple interpretation of the rationale behind the decisions.

It may be a trivial remark that risks may be handled more according to the opinions of those subjected to the risks if there is an interplay between decision makers at different levels, aided by a free debate.

5.5 Possibilities of preventing radiation risks

A paper discussed the cancer risks from seven categories of exposure in Sweden and the possibilities of decreasing the risks (Bengtsson 1989 b). The exposures and risks are summarised in table 4 and the possibilities of prevention in table 5. The following conclusions were drawn with respect to the seven categories:

- Exposures to natural ionising radiations except those in buildings cannot reasonably be prevented.
- Natural radiation doses in buildings can be significantly reduced. Doses from radon can be reduced at intermediate costs in existing buildings and at low costs in new buildings. The lower doses from gamma radiation are very expensive to remedy in existing buildings but can be avoided at low cost in new buildings
- Ultraviolet exposures, mainly through outdoor sunbathing, could be strongly reduced at low cost
- Exposures in radiotherapy are very close to striking a perfect balance between the rates of curing and the rates of side effects such as cancer induction
- Medical diagnostic exposures are far from optimal and significant savings of radiation doses can be achieved at intermediate costs
- Exposures due to environmental contamination with manmade radionuclides account for few estimated cancer cases and further reduction is very expensive, or depends on political initiatives such as avoidance of nuclear weapons testing

Table 4. Exposures and risk in different categories in Sweden in the end of the 1980's.

Category of exposure	Individual dose equivalent mSv/a	Millions of Swedes exposed	Estimated cancer risk cases/a	
1. Natural radiation	0.8	8		300
□ cosmic	0.3	8		
□ elements in the body	0.4	8		
□ ground gamma radiation	0.1	8		
2. Exposures in buildings				
□ gamma radiation	0.5	8		200
□ radon	2-7	8		300-1100
3. Ultraviolet exposures	-	8		1800
4. Radiotherapy	1000	0.01		100
5. Medical examinations of patients	0.6	8		100
□ x-rays	1	4	80	
□ dental x-rays	0.02	4	3	
□ radionuclides	4	0.1	10*	
6. Man-made contamination	0.03	8		10
□ normal nuclear power	0.0001	8	0	
	(0.01**)	8	(4**)	
□ nuclear power accidents	0.01	8	4	
□ nuclear weapons testing	0.01	8	4	
7. Occupational ionising radiation	1	0.1		4
□ medical, dental, veterinary	0.2	0.04	0.4	
□ nuclear industry	5	0.003	0.6	
□ miners	10	0.005	2	
□ other industry, research	0.1	0.09	0.4	

* no cancer excess has been found in a study of the major category exposed to iodine-131

** long-term global risk commitment over the next 1000 years or so

Table 5. Possibilities of prevention of cancer risks from radiation in Sweden in the end of the 1980's (1 MSEK=1 million Swedish crowns = appr. 150 000 USD).

Category of exposure	Possible number of cancers that can be prevented (cases per year)	Cost per prevented case (MSEK/case)
1. Natural radiation	0	-
2. Exposures in buildings		
☐ gamma radiation	10	*
☐ radon daughters > 400 Bq/ m^3	30- 110	2- 7
☐ radon daughters 100-400 "	100- 500	5-20
3. Ultraviolet exposures	1000	0.01
4. Radiotherapy	0	–
5. Medical examinations of patients		
☐ x-rays	40	0.3
☐ dental x-rays	1	10
☐ radionuclides	0	–
6. Man-made contamination		
☐ normal nuclear power	0	>>3
	4**	>>3
☐ nuclear power accidents	4	>>3
☐ nuclear weapons testing	4	>>3
7. Occupational ionising radiation		
☐ miners	2	>3
☐ nuclear workers	0.6	>>3
☐ others	1	>3

* no cost estimate can be set for the replacement of existing dwellings over generations by others with restricted gamma radiation levels

** long-term global risk commitment over the nex 1000 years or so

- Occupational exposures to ionising radiations yield very few estimated cancer cases, above all due to radon in Swedish mines. Further reduction is expensive.

The article is also available in an abbreviated Swedish version (Bengtsson 1988 b).

5.6 Low probability, high consequence events: suggestions for management of the risks

A preliminary report (Wahlström 1987) discussed the problems of risk management for complex technical systems where large accidents might occur.

Such systems should be designed with multiple and independent barriers to prevent hazardous materials from influencing the environment. The operability of these barriers should be monitored. Experience on their efficiency should be collected. Operational and maintenance procedures should be implemented to ensure that the plant is maintained within its allowed operational limit. Experience on the staff efficiency should be collected. When degraded performance of systems or staff is discovered, it should be corrected. External control should be provided via the authorities.

In order to optimise the design, systematic safety analysis should be used. It is particularly important to understand human behaviour in different situations. Through feedback of operating experiences, the safety analysis can be improved. Especially interesting are incident reports, which should be collected and analysed at an international level in order to provide additional years of operational experience. The safety analysis should be understood and used by the plant management.

The use of probabilistic safety assessment has been studied in a major Nordic project (Hirschberg 1990), which has been summarised in popular form (Bengtsson 1989 d). The acceptability of accidents was discussed in 3.3.2 above.

5.7 Optimisation in nuclear safety and radiation protection related to nuclear accidents

Any exposure to ionising radiation may involve som degree of risk. The International Commission of Radiological Protedction, ICRP, therefore recommends that all radiation exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account.

This principle of optimisation has been discussed by Bengtsson and Högberg (1988) with respect to its application to the prevention and mitigation of accidents.

What is optimisation?

The protection of the general public from undue risks from accidents in nuclear power plants is based on three fundamental components:

- ☐ prevention of accidents
- ☐ mitigation of releases in case of a severe accident involving damage to the reactor core
- ☐ emergency preparedness, including both local, short term measures, such as evacuation, and regional, long term measures such as interventionlevels for radionuclides in food, etc.

Ideally, the three components should be well balanced against each other, and the total level of protection they offer against nuclear accidents should, in turn, be well balanced compared with the level of protection provided against other societal risks.

Legislation usually sets some general goals for the efforts in nuclear safety and radiation protection. Such efforts should for instance aim at reducing all exposures to a level which is as low as reasonably achievable, or lead to continuing improvements in safety. Since resources are always limited, the authorities implementing the legislation always meet the question: "How can we best meet the given goals within the limits of available resources?" The resolution of this question is basically a political undertaking, where the resources put into protection are balanced against other factors and constraints to obtain the best that can be achieved in the circumstances. This undertaking is called *optimisation of protection* in the most general sense.

The political process of optimisation can be aided by procedures such as cost /effectiveness analysis suggested by those involved in implementing protective measures. Such decision aiding techniques are a part of the optimisation procedure but their character of providing input to the decision maker rather than providing the answer should be stressed.

Comparison of approaches in Sweden and the USA

In the paper, an attempt is made to illustrate how the general process of optimisation, as defined above, has been carried out and why conclusions which deviate from simple cost/benefit criteria have been arrived at in some cases.

The principal cases discussed are taken from the Swedish program on prevention and mitigation of accidents in Swedish nuclear power plants and decisions on intervention levels following the fall-out in Sweden after the Chernobyl accident. Comparison is made with the analysis presented by the United States Nuclear Regulatory Commission in its Reactor Risk Reference Document (NUREG- 1150(Draft)). Such a comparison is interesting for the following reasons:

- Both the Swedish and the United States approach have essentially the same scientific and technical basis, i.e. plant-specific level 1 and level 2 probabilistic safety assessments (PSA's).
- In both countries, safety policies have been developed over many years with many opportunities for public discussion and comments and with important policy decisions taken at high levels.

In Sweden, the policy decisions have been taken by government and parliament on the basis of studies and recommendations of the regulatory bodies (SKI and SSI) and special expert committees. The main policy decisions were taken in 1981 (i.e. after TMI) and in February 1986. These policy decisions were confirmed after Chernobyl with some amendments, mainly concerning emergency planning with regard to accidents outside Sweden.

The concepts of quantitative safety goals and cost/effectiveness analysis used in NUREG-1150 have not been finally and formally adopted in the USA but only recommended for trial use in safety assessments.

- There are some fundamental differences between the Swedish and US approaches to optimisation and risk management.

Conclusions

The paper discusses optimisation in the prevention of accidents, in inspection, testing and maintenance, in the mitigation of releases, in countermeasures following an accident, and in the European reactions to the Chernobyl accident.

The examples show that optimisation in a simple sense, e.g. as a balance between risks and costs has not been a major factor in the Swedish policy decisions on prevention and mitigation of accidents. Many other factors must be introduced. With respect to radiation doses, there is a tendency towards more emphasis on dose limits and individual radiation doses rather than collective doses. This is natural in view of the expected reduction of the dose limits recommended by the ICRP.

The application of optimisation studies has also been limited because other factors have proved important in actual decisionmaking although they can not be measured or given a quantitative weight. If simple optimisation processes lead to results that seem to conflict with commercial or sound engineering experience, or with political judgement, they are discarded and the latter take over. Maybe one can put this in terms of the overriding importance of political and commercial survival.

Some of the difficulties in applying simple optimisation and cost- effectiveness models based on the definition of risk as (probability) x (consequence) are associated with the very large investment a nuclear power station represents and the uncertainties in the estimates of the probability of a severe accident, which destroys the plant and restricts the use of substantial land areas around it.

In fact, the investment in a plant, and even more in a multi-unit power station whose entire production capability may be lost for extended periods due to a severe accident, is so large that protection of the plant investment typically outweighs the protection of substantial surrounding land areas in most cases of simple cost-effectiveness analysis.

A large nuclear power station represents an investment in power production capability in the range of 10 billion USD. In simple monetary terms, restricted use of large land areas and health effect costed at 10 000-100 000 USD/mansievert may cause costs in the range 1-100 billion USD including costs for relocation of people living in the vicinity of the plant. Figures in the range 10 billion USD have been cited for Chernobyl, where some 100 000 people were evacuated, but no early fatalities among the public were reported.

Hence, if it is assumed that severe accidents leading to extended, total loss of production capability have about ten times higher probability than accidents also leading to large releases, then preventive efforts are more cost/effective than release mitigation measures at the same cost level. However, in a political decision-making process, it is understandable that more weight is put on nonquantifiable factors such as the substantial social problems caused by large-scale evacuation.

In Sweden, actual decisions on back-fitting measures in the same cost range (10 M USD per plant) have been taken to improve prevention of accidents in older plants as well as to improve mitigation of releases in case of accidents. Actual investment decisions to ensure continued, highly reliable power production capability run an order of magnitude higher (160 M USD investment to replace steam generators).

At production values of the order of 1 M USD per plant per day, very high collective doses would theoretically be cost/effective (e.g. at 100 000 USD/mansievert) in maintenance work to gain operating days. In reality, individual dose limitations often dominate the radiation protection efforts, e.g. due to the fact that there are a limited number of people available for some types of qualified maintenance and testing work. In Sweden, there has also been a significant impact of the tentative guideline for collective dose, 2 mansievert per year per installed GW of electric power capacity.

As to optimisation of intervention levels in food, it appears from Swedish experience that cost/effectiveness analysis based on market acceptance considerations may lead food producers to apply lower levels than justified by simple optimisation of radiation protection alone.

6 Conclusions

Many methods have been developed in the Nordic program which permit a structured analysis of decisions involving risks. Such methods may contribute to improvements in nuclear safety and radiation protection.

The evaluations of risks versus benefits and other factors involved in a decision can not, however, be expected to follow any given patterns. Risk comparisons can give some perspective but the public tends to handle the ethical issues involving risk in a way that is particular to each risk. Risk perception plays a large role, but is governed by many factors in a complicated interplay. These may lead to exaggeration of the reactions to risks as well as indifference. Despite these problems, simple economic valuations of health effects are still used for decision making and seem to have some impact on the decisions.

Generalisations are emerging when it comes to valuations of what are negligible risks and what are tolerable risks. A lively discussion is going on both with respect to various occupational hazards and concerning exposures to genotoxic substances in the environment. Continued research may help catalyze this discussion.

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Principles for decisions involving environmental and health risks

Decision making with respect to safety is becoming more and more complex. The risk involved must be taken into account together with numerous other factors such as the benefits, the uncertainties and the public perception.

Can the decision maker be aided by some kind of system, general rules of thumb, or broader perspective on similar decisions?

This question has been addressed in a joint Nordic project relating to nuclear power. Modern techniques for risk assessment and management have been studied, and parallels drawn to such areas as offshore safety and management of genotoxic chemicals in the environment.

The topics include synoptic vs. incrementalistic approaches to decision making, health hazards from radiation and genotoxic chemicals, value judgments in decision making, definitions of low risks, risk comparisons, and principles for decision making when risks are involved.

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