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COMMITTEE ON THE SAFETY OF NUCLEAR INSTALLATIONS

PREPARED BY TASK FORCE N° 4
PRINCIPAL WORKING GROUP N° 5

THE USE OF QUANTITATIVE SAFETY GUIDELINES IN MEMBER COUNTRIES

JULY 1994

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NEA

The Use of Quantitative Safety Guidelines in Member Countries

Addendum to CSNI Report N° 177 Consideration of Quantitative Safety Guidelines in Member Countries

Prepared by Task Force N° 4
Principal Working Group N° 5
NEA Committee on the Safety of Nuclear Installations (CSNI)

July 1994

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COMMITTEE ON THE SAFETY OF NUCLEAR INSTALLATIONS

The Committee on the Safety of Nuclear Installations (CSNI) of the OECD Nuclear Energy Agency (NEA), is an international committee made up of senior scientists and engineers. It was set up in 1973 to develop and coordinate the activities of the Nuclear Energy Agency concerning the technical aspects of the design, construction and operation of nuclear installations insofar as they affect the safety of such installations. The Committee's purpose is to foster international cooperation in nuclear safety among the OECD Member countries.

The CSNI constitutes a forum for the exchange of technical information and for collaboration between organizations which can contribute, from their respective backgrounds in research, development, engineering or regulation, to these activities and to the definition of its programme of work. It also reviews the state of knowledge on selected topics of nuclear safety technology and safety assessment, including operating experience. It initiates and conducts programmes identified by these reviews and assessments in order to overcome discrepancies, develop improvements and reach international consensus on technical issues of common interest. It promotes the coordination of work in different Member Countries including the establishment of cooperative research projects and results to participating organizations. Full use is also made of traditional methods of cooperation, such as information exchanges, establishment of working groups, and organization of conferences and specialist meetings.

The greater part of the CSNI's current programme of work is concerned with safety technology of water reactors. The principal areas covered are operating experience and the human factor, reactor coolant system behaviour, various aspects of reactor component integrity, the phenomenology of radioactive releases in reactor accidents and their confinement, containment performance, risk assessment, and severe accidents. The Committee also studies the safety of the nuclear fuel cycle, conducts periodic surveys of the reactor safety research programmes and operates an international mechanism for exchanging reports on safety related nuclear power plant accidents.

In implementing its programme, the CSNI establishes cooperative mechanisms with NEA's Committee of Nuclear Regulatory Activities (CNRA), responsible for the activities of the Agency concerning the regulation, licensing and inspection of nuclear installations with regards to safety. It also cooperates with NEA's Committee on Radiation Protection and Public Health and NEA's Radioactive Waste Management Committee on matters of common interest.

FOREWORD

Since issuing of the CSNI Report No. 177 "Consideration of Quantitative Safety Guidelines in Member Countries" in October 1990, in only three OECD member countries new major developments took place regarding probabilistic safety criteria/objectives (PSC). On the other hand, these three countries were the only three countries with explicit PSC on the public health level. Therefore, a separate document was chosen to describe these level-3 PSC in these three countries, instead of updating CSNI Report No. 177.

The only comments received sofar on CSNI Report 177 were all addessing the tables in this document. Therefore, the revised tables are included in this document, and can serve as a quick overview of the PSC as applied in OECD member states.

CONSIDERATION OF PROBABILISTIC SAFETY OBJECTIVES IN OECD/NEA MEMBER COUNTRIES; SHORT OVERVIEW & UPDATE.

REVISION 1

by
Magiel F. Versteeg and Robert M. Andrews

A report of task 4
(The Use of Quantitative Safety Guidelines in Member Countries)
of Principal Working Group N° 5 (Risk Assessment)

Committee on the Safety of Nuclear Installations (CSNI)
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INTRODUCTION

It is now widely recognized that PSA's produce numbers that can be used as a yardstick to assist safety decisions. As a consequence, significant effort has been devoted to the development of probabilistic safety criteria (PSC). Almost every member country of the Nuclear Energy Agency (NEA) of the OECD uses PSC in one way or another in their assessment of nuclear power plant safety.

These PSC include dose limits for normal occupational exposure and accidents, involving implicit or explicit frequency considerations and criteria on the loss of core integrity. A large variety of different PSC can be recognized in these OECD member countries. The choice of the PSC, their applicability, and whether or not these PSC are used in a formal or legal manner is dependent on the political and regulatory environment. In some countries PSC are used in a formal way, in other countries they are not. Probabilistic criteria may be used in the design process or/and in the regulatory process.

The various PSC can be grouped into a number of distinct categories according to the level of consequence as follows:

- PSC relating to a particular safety system/ function (level-0 PSC),
- PSC relating to the loss of integrity of the reactor-core (level-1 PSC),
- PSC relating to the magnitude of a large radioactive release (level-2 PSC),
- PSC relating to public health effects (level-3 PSC).

The PSC related to public health risks can be divided into:

- PSC referring to early or late mortality,
- PSC referring to received dose.
- PSC related to the exposure of workers to radiation from either normal plant operation or accident conditions[1].

[1]) Workers risk is outside the remit of this paper and is not therefore discussed further.

Tables 2 to 6 summarise the various PSC applied to the assessment of nuclear power plant in the OECD member countries. To directly compare these criteria is fraught with difficulties as boundary conditions and definitions can be different.

TYPES OF PSC

The PSC considered in the OECD/NEA member countries can be grouped and identified as follows:

a) System level (Level-0) PSC - Criteria for important safety systems or functions are usually defined in terms of a limit or objective on the unreliability or unavailability per demand. Established PSC of this type refer to systems such as the Emergency Core Cooling System (ECCS), containment safeguard systems or the reactor shut-down function. Table 2 provides a summary of the PSC used by the member countries.

b) Level-1 - Loss of core integrity criteria are usually defined in terms of the probability per year for core degradation. This is mostly understood as severe damage of the fuel and its cladding or as a total melt down of the fuel and consequent breach of the primary circuit boundary. These criteria are often referred to as Core Damage Frequency (CDF). Table 3 summarises the PSC in member countries.

c) Level-2 - Limits related to the release of radioactive substances appear as PSC in two distinct forms. One takes the form of limits of the frequency for the release of a defined amount of radioactive inventory (source term), while the other sets a limit or objective for the frequency of a large (but further undefined) release. See table 4. In one case (USA) a conditional containment failure probability in combination with a CDF is used as safety goal decision criterion. Although, it is not the CDF sec that is applied but the estimated reduction in CDF in case the safety issue under consideration would be resolved. Associated with this safety goal decision criterion, a cost factor of US$ 1000,-/ person-rem has to be used as the dollar conversion factor for all off-site consequences in the evaluation of the values and impacts associated with a proposed regulatory action

d) Level-3. - Criteria are specified either in mortality terms or in a surrogate form of a dose frequency relationship. A common variant of this latter approach is the limit on dose for specified plant conditions where the frequency of these conditions has an implicit probability. Such plant conditions are anticipated operational transients, and design basis accidents etc. See table 5.

Mortality PSC may relate either to individual risk or societal risk. Societal risks are based on a defined number (or numbers) of deaths. (See table 3). Another approach is a limit value for the collective dose for operational occurrences and design basis accidents (See table 6 regarding status in Canada).

SOME REMARKS ON PROBABILISTIC SAFETY CRITERIA ON THE PUBLIC HEALTH LEVEL

In only 3 countries (The Netherlands, the U.K. and the USA) level-3 PSC in terms of mortality risk have explicitly been formulated. In the UK, the HSE's paper on the Tolerability of Risk [reference 4] proposes limits and objectives on the individual risk of death to both the public (and workers). The implementation of these proposals into the NII's Safety Assessment Principles [reference 3] is generally based on surrogate dose frequency relationships, hence mortality criteria do not appear explicitly in the Regulators approach. The concept of tolerable risk levels in the UK is also applicable to other large industrial plant. In The Netherlands a similar approach has taken place, although different sets of criteria have emerged and some concepts have been abandoned recently. In the Netherlands these PSC on the public health level are applied as well to other potential hazardous industries and activities. In table 5. a quick overview is given of these level-3 PSC in these countries, while in the following text a more elaborate discussion is given.

NETHERLANDS

In the Netherlands, PSC on the public health level have been developed in the mid-eighties in order to have a yardstick in safety decision-making involving the risk impact of mainly new hazardous industries [References 1 and 2]. Although primarily developed for chemical industries and transport activities, these PSC were later declared applicable to both new and existing nuclear power plants. Until the end of 1993 these PSC differentiated between three possible risk related situations:

- normal risk, where permissible activities lie,
- elevated risk, where reduction is required according the ALARA/ALARP principle, and
- excessive risk, where the risks are unacceptable.

This differentiation and the two objectives of limiting the mortality risks of the individual citizen and preventing disasters which could affect larger segments of the population formed the basis of the definition of the probabilistic safety criteria and objectives. Regarding the latter it must be said that the terms 'objective' and 'de minimis value' were used indifferently.

For each radioactive material or other hazardous source or activity the upper bound of acceptable individual risk was chosen to be 10^{-6}/year. An individual risk of 10^{-8}/year was considered as a de minimis value or objective. In the area between these values the ALARA/ALARP (As Low As Reasonable Achievable/Practicable) principle would be applied. For all radioactive material or other hazardous sources or activities combined, an individual risk limit of 10^{-5}/year was chosen.

For the criterion and de minimis level or objective two CCDFs (Complementary Cumulative Distribution Functions) were chosen, forming two straight lines on a log-log scale of the F-N plot. The criterion was given by $10^{-3}/N^2$/year for $\geq$ N prompt fatalities and the lower level by $10^{-5}/N^2$/year for $\geq$N prompt fatalities.

The definitions of individual and societal risk in the existing literature vary considerably. For the purpose of the Dutch risk management policy regarding major accidents, the following definitions for individual risk and societal risk were chosen:

- Individual risk is defined as the expected frequency of death (both early and late) due to a hazard of a hypothetical unprotected person at any given fixed location beyond the perimeter of the installation concerned, and being there 24 hours/day for the whole year.
- Societal (group) risk is defined as the expected frequency of N or more prompt fatalities beyond the perimeter of the installation concerned due to a hazard at that installation.

Due to discussions in the Dutch parliament it was felt necessary to abandon the concept of de minimis value or objective for both individual risk and societal risk. The main reason was the recognition that risk perception and the acceptability of some risks by the general public had to be included in the question: " How safe is safe enough?". This meant that the desirable risk reduction, via the ALARA/ALARP principle, could differ from one hazardous activity to another. Therefore, one de minimis value or objective was no longer a useable concept.

On the other hand, it is believed that next generations[2] NPPs can meet the 'old' de minimis values. Therefore, as input for further policy-making on the nuclear energy option[3], a governmental issue paper [Reference 7] was send to parliament in which these 'old' de minimis values were even mentioned as a requirement to meet for future NPPs. It is evident that the perceived risks of NPPs by the general public were of major influence in selecting these low numbers as criteria for future plants.

In October 1992, an El-Al Boeing 747 crashed in a large apartment building in one of the suburbs of Amsterdam. More than 50 people were killed instantaneously. This disaster caused the Dutch government to ask for a probabilistic risk assessment of all the flying activities related to the Dutch major International Airport Schiphol. This risk assessment was also necessary in the decision-making concerning the future growth of the airport. The results showed that the area were the aforesaid 'elevated' risks lie was about 50 km x 50 km. The calculated societal risk was orders of magnitude higher than was assumed to be unacceptable for stationary installations (ca. 4. 10^{-3}/year for $\geq$ 10 prompt fatalities and 1.10^{-4}/y for $\geq$ 100 prompt fatalities mainly due to the high degree of urbanization around the airport and the large number of flying activities).

At the same moment PSAs of the transportation of dangerous materials via inland waterways as well as shunting activities on the shunting yards of the railways were finished. For shunting-yards societal risk was the bottleneck in various decision-making processes regarding new urban developments, and for transportation individual risk caused some problems.

Therefore, the risk management policy of the Dutch government is getting a more pragmatic character. At this very moment for 4 different risk sources 4 different sets of PSC are established c.q. under development:

1. Stationary Chemical Industries,
2. Nuclear Power Plants,
3. Transport of dangerous materials, and
4. an ad hoc risk management policy for the International Airport Schiphol.

1. stationary chemical industries (established):

* The criterion for individual risk is 1. 10^{-6}/year (unchanged).
* No de minimis value for individual risk is set forth.
* The criterion for societal risk is no longer a sharp criterion, but just a trade-off in a multi-criteria cost-benefit considerations in safety related decision-making. In other words, not fulfilling means the requirement to apply the ALARP concept.
* This 'criterion' is $10^{-3}/N^2$/year for$\geq$N prompt fatalities (unchanged).
* No de minimis level for societal risk is set forth.

[2]) With next generations or future NPPs is meant reactor designs of the 2nd or 3rd generation, like SBWR, AP 600, MHTGR or PRISM.

[3]) After Chernobyl the Dutch government posponed its decision to expand the nuclear energy options. Further decision-making is still waiting.

2. nuclear power plants (established):

* The criterion for individual risk is 1. 10^{-6}/year (unchanged).
* A tentative individual risk criterion of 10^{-8}/year for future NPPs[4], if any.
* The criterion for societal risk is $10^{-3}/N^2$/year for $\geq N$ prompt fatalities (unchanged).
* A tentative societal risk criterion of $10^{-5}/N^2$/year for future NPPs[3], if any.
* No de minimis values for individual and societal risk are set forth.

3. transport (under development):

* Most likely, the criterion for individual risk will be 10^{-6}/year.
* No de minimis value for individual risk is set forth.
* Most likely, the criterium for societal risk will be $10^{-1}/N^2$/km/year.
* No de minimis value for societal risk is set forth.

4. ad hoc PSC for Schiphol Airport:

* Stand-still principle within 10^{-6}/year individual iso-risk contour; risk is not allowed to increase; no extra housing developments and no additional potential hazardous industries within this 10^{-6}/year individual iso-risk contour.
* Pulling down some existing housing (a few tens) within 10^{-5}/year individual iso-risk contours (only from those parts within the 10^{-5}/year contour with the highest risk).
* Societal risk is considered to be low enough for continuation of Schiphol Airport, provided the above mentioned boundary conditions (previous two*) are fulfilled.

It has been recognized, that in case of very severe NPP accidents a societal risk criterion described by a Complementary Cumulative Distribution Function (CCDF) of the number of prompt fatalities might not be adequate enough to solely being used as a yardstick for societal disruption. Due to discussions in the parliament, additional level-3 PSC are being developed to judge the potential contamination of large areas of land in case of severe nuclear reactor accidents.

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[4]) Normal operation, operational occurrences and incidents (design basis) are excluded from this policy.

UNITED KINGDOM

In the aftermath of the Sizewell-B Public Inquiry the U.K. Health & Safety Executive published in 1988 a discussion paper on the "Tolerability of Risk from Nuclear Power Stations". In 1992 this paper was revised [reference 3] and published more or less together with the NII Safety Assessment Principles [reference 4] which implemented the proposal in the HSE 'Tolerability of Risk' paper in the form of more specific assessment guidance.

The general approach to regulation set down in the Tolerability of Risk paper, in which ALARP plays a central role, can be summarised as follows:

- For any activity the level of risk may be so great that the activity cannot be allowed to continue. The upper limit (Tolerable level) marks the boundary between risks which are just tolerable and those that are intolerable.
- Even when the level of risk is tolerable, it must be reduced to a level which is as low as reasonable practicable (ALARP).
- A point may be reached (Broadly Acceptable Level) at which the risk is, or has been made, so small that no further safety precautions are necessary.

In respect to individual risks from both normal operation and accident conditions, the HSE states in its Tolerability of Risk paper, regarding the two levels of risks:

> **'We propose to maintain our existing position that a risk of 1 in 10,000 per annum to any member of the public is the maximum that should be tolerated from any large industrial plant in any industry with, of course, the ALARP principle applying to ensure that the risk from most plant is in fact lower or much lower. But, in accordance with Barnes' findings, we propose to adopt a risk of 1 in 100,000 per annum as the benchmark for new nuclear power plants in the UK, recognising that this is, in the case of a new station, broadly achievable and measurable.**
>
> **Having considered what might be regarded as levels of risk that are just tolerable or can be used as benchmarks we must now consider what might be a broad acceptable risk to an individual dying from some particular cause, i.e, what is the level of risk below which, so long as precautions are maintained, it would not be reasonable to consider further improvements to standards if these involved a cost. This level might be taken to be 1 in a million (1 in 10^6) per annum bearing in mind the very small addition this would involve to the ordinary risks of life.'**

The HSE paper also discusses societal risks and suggests limits on the risk to workers.

The NII Safety Assessment Principles provide guidance in terms of level-1 and level-2 PSC. The judgement has been made that these criteria are reasonably consistent surrogates for the principles and targets set forth in the Tolerability of Risk paper.

In the Safety Assessment Principles, the concept of a ,Tolerable' level of Risk has been translated into a <u>Basic Safety Limit</u> (BSL) for normal operation and, separately, for accident conditions. A new plant must satisfy these BSL guidelines to be considered for licensing. Having satisfied the BSL, the ALARP principle comes into play to drive the risks lower.

The ALARP process necessitates decisions by operators and designers on a case-by-case basis. However, there comes a point at which the risks may be so low that NII considers further risk reduction measures not necessary. Each BSL is therefore complemented by a Basic Safety Objective (BSO). The BSO defines the point beyond which the assessors need not seek further safety improvements from the licensee in satisfying ALARP. The NII Safety Assessment principles provide the following guidance in terms of BSL's and BSO's.

- The total predicted frequency of a degraded core should be less than:

BSL	**BSO**
10^{-4} per year	10^{-5} per year

The total predicted frequency of accidents on the plant with the potential to give a release to the environment of more than:

10,000 TBq of Iodine 131, or
200 TBq of Caesium 137, or
quantities of any other isotope or mixture of isotopes which could lead to similar consequences to either of these should be less than:

BSL	**BSO**
10^{-5} per year	10^{-7} per year

Note: This criterion is based on the belief that large scale releases that present risks to society as well as individuals need to be controlled.

The total predicted frequencies of accidents on the plant, which would give doses to a person outside the site, would be assessed against the following criteria:

Maximum effective dose , mSv	Total predicted frequency, per year	
	BSL	BSO
0.1 - 1	1	10^{-2}
1 - 10	10^{-1}	10^{-3}
10 - 100	10^{-2}	10^{-4}
100 - 1000	10^{-3}	10^{-5}
> 1000	10^{-4}	10^{-6}

Note: This set of criteria is broadly consistent with the individual risk of death proposals in the Tolerability of Risk paper, and is also based on the belief that societal risks from smaller scale need to be controlled.

United States

In August 1986 the U.S. Nuclear Regulatory Commission issued a policy statement promulgating safety goals for the operation of nuclear power plant [reference 10]. These safety goals were specified with respect to prompt mortality risk and delayed cancer mortality risk. The quantitative safety goals were formulated as follows:

> **"The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from accidents to which members of the U.S. population are generally exposed"**

> **"The risk to the population in the area near a nuclear power plant of cancer fatalities that mighr result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes."**

In applying the objective for individual risk of prompt fatality, the Commission has defined the vicinity as the area within 1 mile of the nuclear power plant site boundary. In applying the objective for cancer fatalities as a guideline for individuals in the area near the plant, the Commission has defined the population within 10 miles of the plant site as the appropriate basis of calculation.

In the USA these defined PSC (see table 5 for an overview) are not as an objective that an individual NPP should strive to meet, but as decision-making tool for the NRC [references 5 and 6] to justify their generic backfitting initiatives. The objective is to add strength to the regulatory decision-making process for new requirements that are considered and justified as safety enhancements to <u>more than one</u> nuclear power reactor. It is only applicable to regulatory initiatives considered to be <u>generic</u> safety enhancement backfits as defined in the backfit rule (10 CFR 50.109). Specifically, application of this philosophy will minimize the number of occasions that resources are spent on conducting extensive regulatory analyses that later determine a proposed action is not justified because the incremental safety benefits would not substantially improve the existing level of plant safety. To achieve this goal two types of PSA uses are suggested [refence 8]. First a screening of the issues, and secondly a more detailed analysis of specific uses like issue resolution.

Issue screening and prioritization

With regard to the screening process it is suggested that:

> **"In the interest of the efficient use of resources, prioritization analyses should make use of <u>existing</u> work to the maximum possible extent. In most cases this will mean using an existing PRA, or more than one existing PRA if more than oneis needed to cover the spectrum of affected plants."**

> **"Therefore, modern PRAs, particularly the NUREG-1150 PRAs when appropriate, should be used as bases for generic issue prioritization. The existing population of plants should be devided into classes consistent with available representative PRAs, with these classes used consistently throughout the agency."**

A screening and prioritization might be performed in which the number of affected plants play a role [references 8 and 9]. See table 1[a] for an overview of the criteria.

The final product of a PRA-based screening is the assignment of a qualitative priority ("high", "medium", "low", or "drop") to the issue. Currently, issues with a priortization parameter above a certain value are automatically given a "high" priority. Issues with all prioritization parameters below a certain level are automatically given a "drop" priority. For values between these limits, the value/impact ratio is used in conjunction with the prioritization parameters to assign a priority level as shown in Table 1[a].

These screening criteria were approved by the Commission in early 1993 for preliminary screening and prioritization purposes.

The essential PRA elements used in this program are the calculation of consequences and risk to the public (in terms of person-rem averted) in addition to core damage frequency and the calculation of point estimates with sensitivity studies on key variables. These sensitivity studies are intended to ensure that the overall ranking given to an issue is not sensitive to key uncertaintiesassumptions made in the analysis. A formal uncertainty analysis is currently not considered necessary for these studies. The NUREG-1150 studies are regarded as valuable references for input.

Table 1[a]. Generic issue priority assignments (from reference 9).

Impact/Value ($ / Person-Rem)						
> 1000	DROP	DROP	LOW	MEDIUM	HIGH	
< 1000	DROP	LOW	MEDIUM	HIGH	HIGH	
	$< 10^{-7}$	$10^{-7} - 10^{-6}$	$10^{-6} - 10^{-5}$	$10^{-5} - 10^{-4}$	$> 10^{-4}$	Δ CDF/year
	$< 3.10^{-6}$	3.10^{-6}-3.10^{-5}	3.10^{-5}-3.10^{-4}	3.10^{-4}-3.10^{-3}	$> 3.10^{-3}$	total[4] Δ CDF/year
	$< 10^{1}$	$10^{1} - 10^{2}$	$10^{2} - 10^{3}$	$10^{3} - 10^{4}$	$> 10^{4}$	Δ person rem/reactor
	$< 3.10^{2}$	$3.10^{2} - 3.10^{3}$	$3.10^{3} - 3.10^{4}$	$3.10^{4} - 3.10^{5}$	$> 3.10^{5}$	total[3] Δ person rem

Issue resolution

The resolution of generic issues must make use of decision criteria, since the end result is a choice of one of a spectrum of potential fixes, including the option of no action. Currently, the decission criteria are applied in two phases. The first phase consists of a decision on whether the potential net improvement in the health and safety of the public is sufficient to justify regulatory action. The Safety Goal Objectives discussed in the Regulatory Analysis Guidelines (reference 5) are proposed to provide guidance in this area as shown in table 1[b]. The second phase consists of evaluating the cost effectiveness of the proposed action against a standard (currently $1000/person-rem). However, before approval by the

[4]) total means summed over all affected reactors.

Commission this table might have to change due to the already approved decision criteria from table 1[a].

By defining a clear level of incremental safety (see table 1[b].) for nuclear power plants, the safety goal evaluation to be included in the regulatory analysis provides the staff with direction in deciding whether no further backfits are warranted.

The essential elements of PSAs to be used for these purposes include [reference 8]:

- An assessment of the core damage frequency impact associated with the issue,
- Calculation of the consequences and risk to the public (in terms of person-rem averted) in addition to core damage frequency,
- An uncertainty analysis that permits the calculation of mean values for comparisons with decision criteria (which are in terms of mean values), so as not to overlook or dismiss potentially risk-significant issues prematurely,
- Applicability to the set of affected plants (meaning that more than one PRA may be needed to cover the entire spectrum of plants under consideration), and
- Integration of related issues under study to avoid piecemeal evaluation of issues.

Table 1[b]. Proposed US Safety Goal Decision Criteria for nuclear power plant issue resolution.

		Estimated conditional containment failure probability	
		10^{-2} - 10^{-1}	10^{-1} - 1
Estimated reduction in CDF	> 10^{-4}/y	Value-impact assessment necessary	Value-impact assessment necessary
	10^{-4}/y - 10^{-5}/y	Judgement of Division Director of NRC	Value-impact assessment necessary
	< 10^{-5}/y	Terminate further analysis	Judgement of Division Director of NRC

On the other hand, a level of "Adequate Protection" as a kind of minimum safety level for each individual plant has to be assumed. Determination of this level is a case-by-case finding evaluating a plant and site combination considering the body of regulations. This level of "adequate Protection" must be assured without regard to cost and, thus, whithout invoking the procedures required by the backfit rule. The Safety Goals, on the other hand, provide a definition of "how safe is safe enough" that should be seen as a guidance on how far to go when proposing safety enhancements, including those to be considered under the backfit rule. Thus, if the safety goals are satisfied with proper consideration of the uncertainties involved, no additional requirements are justifiable for implementation, even if cost beneficial. See figure 1 for a conceptual illustration of this process.

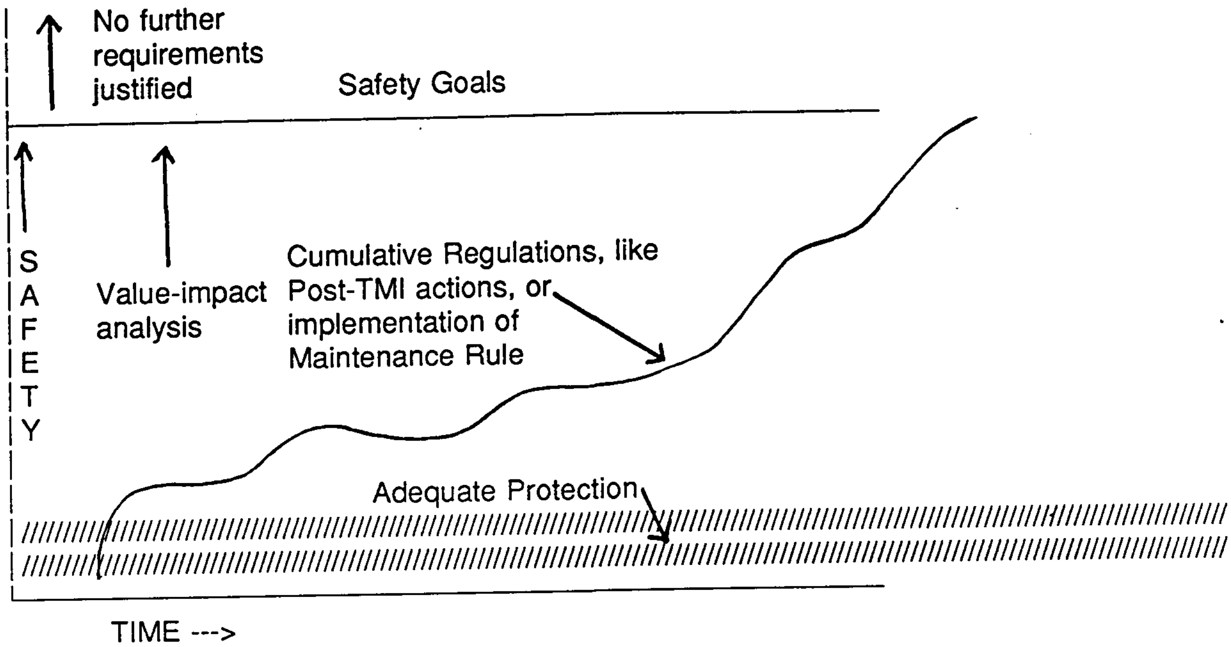

Figure 1. Conceptual illustration of use of Safety Goals

In justifying a proposed backfit under the backfit rule, the burden is on the staff to make a positive showing that a generic safety problem actually exists and that the proposed backfit will both address the problem effectively and provide a substantial safety improvement in a cost beneficial manner. The process in achieving this objective is depicted in figure 2.

In performing steps C and D, a PRA, representing that particular class of plants, should be relied upon to quantify the risk reduction and corresponding values of the proposed action. However, it is recognized that not all regulatory actions are amenable to a quantitative risk assessment, and certain evaluations may be based directly on engineering or regulatory judgement or qualitative analysis.

Although, there is a subsidiary goal for core damage mean frequency (CDF) of 10^{-4}/y, a factor of 1.10^{-5}/y as the minimal reduction of the CDF was selected as a safety goal decision criterion (figure 1). This was done to give the requirement that the proposed backfit should "substantial" improve the safety a better footing, and to provide some assurance that the PRA and data limitations and uncertainties, as well as the variability among plants, will not eliminate issues warranting regulatory attention.

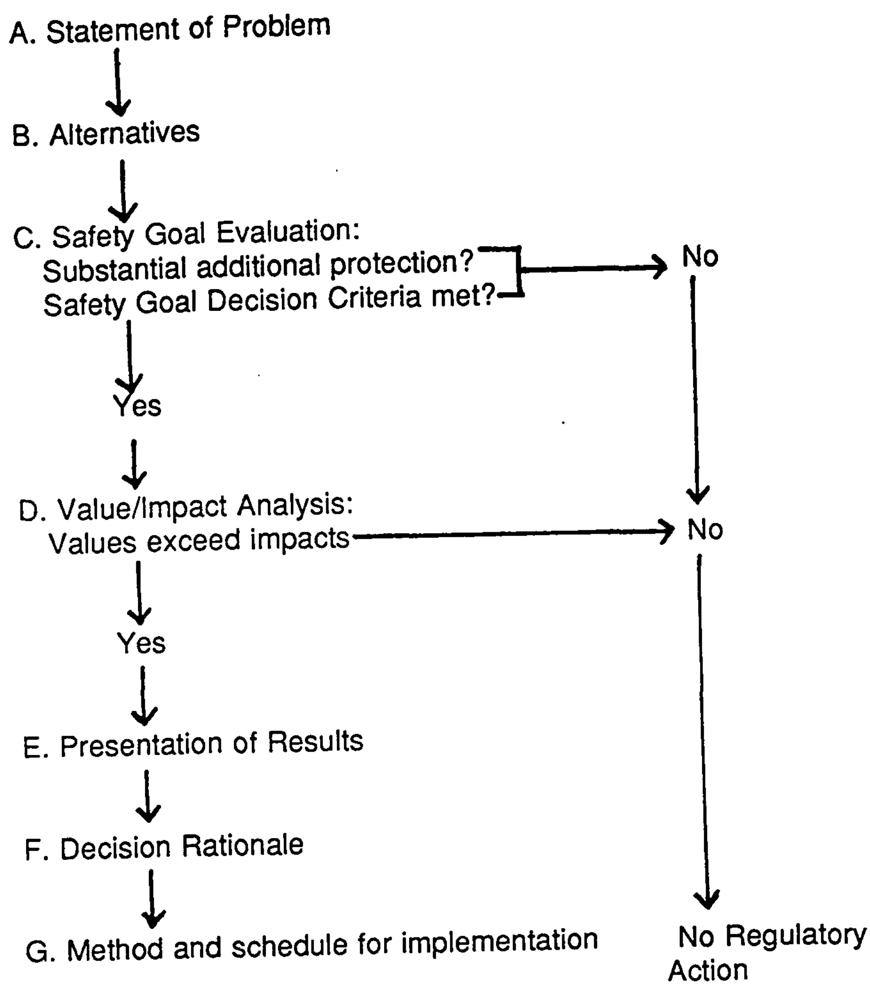

Figure 2. Regulatory Analysis for Reactor Safety Enhancements.

Also the US nuclear industry has formulated PSC for the next generation of LWRs, the ALWR. They formulated:

- a 'challenging, quantitative requirement (core damage frequency [CDF] < 10^{-5} per reactor year) in order to provide investment protection for the Plant Owner.'
- a 'challenging, quantitative requirement on mitigation (whole body dose less than 0.25 Sv at the site boundary [about 0.5 miles from the reactor] for accident sequences with cumulative frequency greater than 10^{-6} per year)'.... 'This 10^{-6}, 0.25 Sv requirement provides considerable margin to the NRC safety goal.'

SOME OBSERVATIONS

In general, the nuclear regulatory requirements in most of the surveyed member countries are deterministic, aided to limited extent by probabilistic ones. The most commonly used probabilistic requirements/rules refer to cut-off values for the consideration of initiating events especially of external origin and to the categorization of plant states for design considerations.

With regard to specific PSC, in general the frequency values set for them by different countries fall into a relatively narrow range, however the similarity may be more apparent than real due to possible differences in definitions, PSA scope, models and data bases used and calculational procedures employed.

The rationale given for the selection of uniform numerical values of PSC was very general, qualitative and based on a judgement of what is considered a tolerable or negligible risk. The UK risk values are justified, to some extend, by public consultation and a comparison of risks estimated for a number of large industrial complexes.

Because of the large uncertainties in PSA results, particularly if they refer to risks at the public health level, many countries found it advisable to define PSC as targets and not as acceptance criteria. In two countries, the Netherlands and the U.K., limit values are formulated regarding mortality risks. In the U.K. and the USA are respectively de minimis values and objectives formulated regarding mortality risks. In the Netherlands the concept of a de minimis value has been abandoned. In both the Netherlands and the U.K. these higher level PSC are also used for regulating other activities and/or industries as well.

In the Netherlands the 'old' de minimis values for individual and societal risk will be used as criteria for future NPPs.

In the USA the PSC for individual mortality risk refers to an average individual in the vicinity of the plant, whilst the Netherlands and the U.K. refer to the most exposed person.

In the Netherlands and the U.K. the level-3 PSC are 'plant oriented', that means the individual plant is scrutinized. In the USA the PSC are 'regulatory body oriented', that means that generic insights scrutinize and prioritize the areas of regulatory attention.

In the Netherlands and the U.K. the level-3 PSC are plant specific, whilst in the USA the PSC are more generic; applicable to a whole class of plants.

The Dutch and U.K. PSC refer to 'best estimate' calculations of the risk, whereas the US PSC refer more to the 'real' risk, bearing in mind the differences in the risk profile and safety culture among plants, and the inherent 'weaknesses' of PSAs, like incompleteness.

A too stringent application of PSC, without the consideration of other than safety issues, might be counterproductive.

PSC are often of a political nature, and therefore often vaguely phrased. In order to show compliance with PSC, both PSA and PSC should be consistent in the definition of terms, boundary conditions, assumptions being made, etc. See further Reference 2 for a further discussion on the necessary compatibility between PSC and the associated PSAs to be used for showing compliance with these PSC.

Table 2. Probabilistic Safety Objectives/ Criteria on the Safety System/ Function Level (Level - 0 PSC).

Country	Canada	Finland [4]	USA
Safety Function/ System failure probability PSC (Level - 0 PSC)	[/demand]	[/demand]	[/demand]
Reactivity control Shut down 1 (control rod) Shut down 2 (liquid poison)	 < 10-3 < 10-3	< 10-5	
Core Cooling Capacity at power		< 10-4	
Emergency Core Cooling Systems	< 10-3		
Containment Isolation System	< 10-3	<5.10-3	
Containment Heat Removal System	< 10-3		
Containment Spray System	< 10-3		
Auxiliary Feedwater Supply		< 10-4	< 10-4
Rapid depressurization e.g. ADS		< 10-4	

Table 3. Probabilistic Safety Objectives/ Criteria on the Core Integrity Level (Level - 1 PSC).

Country	Italy	Spain[5]	Netherl.[6]	UK[7]	USA[8]
Core damage/ melt frequency PSC (Level - 1 PSC)	[/year]	[/year]	[/year]	[/year]	[/year]
New[9] Nuclear Power Plants formal informal			<10^{-5}	$<10^{-4}$ BSL/ $<10^{-5}$ BSO	
Existing Nuclear Power Plants formal informal	$<10^{-5}$	$< 10^{-4}$	$<10^{-4}$	$<10^{-4}$ BSL/ $<10^{-5}$ BSO	$< 10^{-4}$

4) Compliance with 90-th percentile has to be shown.

5) Informally, core melt frequencies larger than 10^{-4}/ year require a more detailed analysis and/ or some design and operational modifications.

6) Regulatory statement.

7) These criteria are specified specifically with new plant in mind are also used as guidance in the assessment of older stations.

8) Semi-official policy statement US-NRC.

9) For The Netherlands and the UK, the headings new and existing nuclear power plants has in this case the same meaning as the objective and limit value of the PSC.

Table 4. Probabilistic Safety Objectives/ Criteria on the Large Release/ Source Term Level (Level - 2 PSC).

Country	Finland	France	Italy	Neth.	Swe-den	UK	USA
Large Release (Frequency)/ Source Term (Frequency) PSC. (Level - 2 PSC)	Limit on Magnitude of Source Term [% core inventory] or Limit on frequency of certain source terms [year-1 for x % core inventory]						
Unacceptable consequences and Source Terms.	>0.1% of core invent. excl. iodines and N.G.				>0.1% of core invent. excl. iodine and N.G.		
Frequencies of Large Releases or unacceptable consequences.		<10-6/y for unaccept. conseq.	<5% of core melt freq. if Source Term contains >0.1% iodine and Cs.	<10-6/y for large release = dose equi-val. of .5 Sv to the most expose d person		<10-5/y limit for Source Term of 104 TBq I_{131} , or 200 TBq Cs_{137}, or equival. <10-7/y objective for idem source term	<10-6/y

Table 5. Probabilistic Safety Objectives/ Criteria on the Public Health Level (Level - 3 PSC).

	Netherlands	United Kingdom	USA[10]
Individual Risk *Prompt fatalities* *Late fatalities*	- 10^{-6}/y limit value. - 10^{-8}/y[11] limit value for future NPPs. - No minimis value. - Both early and late fatalities. - Applicable to all hazardous industries and transport routes.	The regulatory guidance on individual risk is based on dose frequency targets, see table 6. However these limits are defined with due cognizance of the TOR paper in which an upper limit of individual risk of 10^{-4}/y, and an objective of 10^{-6}/y are proposed. The TOR also suggests that new plant should be able to achieve a level of individual risk at or below 10^{-5}/y.	The risk to the average individual in the vicinity of the plant within a radius of 10 miles should not exceed 0.1% of the sum of prompt fatality risks due to other causes. ($<5.10^{-7}$/y) = Objective.
Societal Risk *Prompt fatalities* *Late fatalities*	- a criterion for current NPPs charact. by a CCDF: $10^{-3}/N^2$/y for ≥ N early fatalities. - a criterion for future NPPs characterized by: $10^{-5}/N^2$/year for ≥ N early fatalities - No de minimis value. - Only applicable to nuclear industries as a criterion. For other hazardous industries just one factor in a decision-making proces based on multi-criteria cost-benefit considerations. - For transport routes probably a CCDF characterized by: $10^{-1}/N^2$/km/year for ≥ N early fatalities.	Societal risks are covered by both the dose frequency targets of table 6 and the large release level-2 PSC on table 4.The source term for large release is reasonably consistent with 100 cancer deaths.	The risk to population near the plant should not exceed 0.1% of the sum of cancer fatality risks resulting from all other causes. ($<2.10^{-6}$/y) = Objective.

10) Whilst in the UK and in The Netherlands the level-3 PSC are associated with individual plants, in the US all the PSC are associated with a whole class of a particular NPP-type in order to justify regulatory initiatives for generic safety enhancement backfits as defined in the backfit rule (10 CFR 50.109).

11) Only for beyond design accidents.

Table 6. Frequency-dose design objectives for accidental conditions including design basis accidents.

Country	Frequency range of occurrence (yr^{-1})	Dose limit (whole body) (mSv/event)	Remarks
Belgium	category 1 category 2 category 3	0.5 5 ≤20	implicit frequency definition category 1: Loss of Offsite Power category 2: e.g., Small LOCA, Steam Generator Tube Rupture, Uncontrolled Rod Assembly Withdrawal, Rupture of Gaseous or Liquid Waste Tank. category 3: e.g., Large LOCA, Steam Line Break Accident, Rupture of Feedwater Line Outside Containment.
Canada	3.10^{-1} - 3.10^{-4} $<3.10^{-4}$ ----------------------------- $> 10^{-2}$ 10^{-2} - 10^{-3} 10^{-3} - 10^{-4} 10^{-4} - 10^{-5} $< 10^{-5}$	5 250 -------------------- 0.5 5 30 100 250	In place since 1972. 3.10^{-1} - 3.10^{-4} applies to single failures (process systems). For this frequency band also maximum total population dose limits are formulated: 100 man-Sv/y whole body dose. For the design base area $<3.10^{-4}$ a population dose limit of 10^{4} man-Sv/year applies. -- Under trial use since 1980
Finland	1) Design Basis Accidents 2) Severe Accidents	1) 5 2) Controlled by release limit	1) Implicit frequency definition 2) The targets are reached if: major part of severe accid. releases <100 TBq Cs-137 (ca. 0.1% core invent.) or equival., No acute health effects to the public in the surrounding of the plant. Filtered containment venting systems installed.
France	10^{-2} - 10^{-4} 10^{-4} - 10^{-6}	5 150	Only used as guideline values
FRG	Design Basis Accidents	50	Implicit frequency definition
Italy	$> 10^{-3}$ 10^{-3} - 10^{-4} $< 10^{-4}$	5 100 100	guideline values additional as target/ trend: 5 mSv/event for all DBAs.
Japan	Design Basis Accidents Siting Evaluation Accidents	5 250	Implicit frequency definition
Spain	as USA	as USA	
Sweden	Severe Accidents		Controlled by level - 2 PSC; implicit frequency definition
Switzerl.	1 - 10^{-2} 10^{-2} - 10^{-4} 10^{-4} - 10^{-6}	0.2 1 100	
Netherl.	10^{-1} - 10^{-2} 10^{-2} - 10^{-4} 10^{-4} - 10^{-6}	0.4 4 40	These limits are based on a dose-risk conversion factor of 2.5 10^{-2}/Sv, and therefore a risk limit of 10^{-6}/y [e.g., 2.5 10^{-2}*4 10^{-3}* 10^{-2}]
U.K.	Limit / Objective -------- / ---------- 10^{0} / 10^{-2} 10^{-1} / 10^{-3} 10^{-2} / 10^{-4} 10^{-3} / 10^{-5} 10^{-4} / 10^{-6}	 0,1-1 1-10 10-100 100-1000 >1000	This criterion is based on the belief that large scale releases that present risks to society as well as individuals need to be controlled.
USA	Design Basis Accidents	250	

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