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NUCLEAR ENERGY AGENCY
COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES

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Organising Committee for the 1995 CNRA Special Issue Meeting

REGULATORY APPROACHES TO PSA

Report on the Survey of National Practices

27706

Or. Eng.

COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international committee made up primarily of senior nuclear regulators. It was set up in 1989 as a forum for the exchange of information and experience among regulatory organisations and for the review of developments which could affect regulatory requirements.

The Committee is responsible for the programme of the NEA, concerning the regulation, licensing and inspection of nuclear installations. The Committee reviews developments which could affect regulatory requirements with the objective of providing members with an understanding of the motivation for new regulatory requirements under consideration and an opportunity to offer suggestions that might improve them or avoid disparities among Member Countries. In particular, the Committee reviews current practices and operating experience.

The Committee focuses primarily on power reactors and other nuclear installations currently being built and operated. It also may consider the regulatory implications of new designs of power reactors and other types of nuclear installations.

In implementing its programme, CNRA establishes co-operative mechanisms with NEA's Committee on the Safety of Nuclear Installations (CSNI), responsible for co-ordinating the activities of the Agency concerning the technical aspects of design, construction and operation of nuclear installations insofar as they affect the safety of such installations. It also co-operates with NEA's Committee on Radiation Protection and Public Health (CRPPH) and NEA's Radioactive Waste Management Committee (RWMC) on matters of common interest.

FOREWORD

This report is intended to provide a summary of the current regulatory environment within the Organisation for Economic Co-operation and Development (OECD) Member countries regarding probabilistic safety assessment (or analysis) (PSA) in nuclear power plants. The information contained in this report is obtained from fifteen responses to an OECD Committee on Nuclear Regulatory Activities (CNRA) questionnaire. The fifteen nations who responded to the questionnaire are: Belgium, Canada, Finland, France, Germany, Italy, Japan, Republic of Korea, Mexico, the Netherlands, Spain, Sweden, Switzerland, the United Kingdom, and the United States. The information provided in the responses to the questionnaire does not necessarily provide a complete characterisation of the regulatory requirements in effect in each Member country related to probabilistic safety analysis issues in nuclear power plants.

The CNRA questionnaire and the final report were authored by Mr. J. Calvo and Dr. J. Yllera (CSN), Mr. R. Andrews (NII), Mr. M.F. Versteeg (KFD), and Mr. E.J. Butcher and Dr. J.O. Schiffgens (USNRC).

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EXECUTIVE SUMMARY

The Committee for Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency holds a yearly meeting on a Special Issue relating to regulatory matters in nuclear power plants. Since there is a considerable interest among the Member countries concerning the use of Probabilistic Safety Assessment (or Analysis) (PSA) in regard to further improvement or optimisation of current regulatory systems the topic selected for the 1995 CNRA's Special Issue Meeting was Regulatory Approaches to PSA.

Results of Questionnaire

An Organising Committee was formed to present the current status on this topic to the CNRA. This Committee decided to utilise responses to a questionnaire which was prepared to collect information on how each Member country is using or plans to use PSA within its regulatory environment. Fifteen countries responded to the questionnaire.

Responses to the questionnaire show that all respondent countries have expended significant resources on development and use of PSA, in particular for plant-specific applications. Characteristics of the nuclear industry in some countries allow these countries the option of performing PSAs for generic classes of plants. A **Level 1** PSA (the most common level of PSA quantification) models accident sequences to quantitatively relate the frequency of event initiation and the probability of failure to mitigate to yield an annual core damage frequency (CDF) and is performed by all Member countries. **Level 2** PSA essentially extends a **Level 1** analysis to assess frequency of fission product releases, Most Member countries have developed or are developing **Level 2** PSAs. A **Level 3** PSA extends the **Level 2** analysis to assess the risk to health associated with accidents which result in fission product releases. Few Member countries perform **Level 3** analysis. The most common scope for current PSAs includes accident scenarios initiated by internal plant faults while operating at full power. However, efforts are being made in many Member countries to extend this scope to assess external events/hazards and accident sequences initiated while the at low power or during plant shutdowns.

The value of PSA in safety analysis, for providing insights concerning the identification of generic and plant specific improvements in plant safety is well recognised. Similarly, PSAs are also an effective tool for risk sensitivity analysis of safety issues. Specific examples of current PSA applications are mentioned or described in most responses.

There is still need for improvement in consistency in PSA methods, as mentioned in questionnaire responses, and so, research and development efforts are being devoted in most countries to improve PSA methodology and data.. Analysis of human errors and common cause component failures are mentioned most often as examples for these aspects .

However, it is well understood that lack of consistency in some PSA methods and scarce data are not decisive flaws in application of PSA, because sensitivity and uncertainty analysis are a powerful tool to address bounding conditions for reliable decision making. Additionally, sensitivity analysis are often utilised with applications to understand their impact on safety assessments.

The responses suggest that PSA experience and practices in most countries, are already sufficiently mature enough to allow PSA to contribute to the regulatory decision making process. Accordingly, many countries are progressing towards more extensive and systematic PSA use, or even

integration of PSA, in the regulatory system. Also, research and development work to improve consistency and accuracy of, and to standardise PSA and PSA application methods are mentioned.

Increasing the use of PSA in regulatory matters leads to the added need for the regulator to be equipped with the special skills and knowledge, by which assessment and review of PSA matters can take place. Often an in-depth knowledge of plant modelling, specific assumptions or boundary conditions within the PSA will be necessary before regulatory judgement on the PSA based application can be made. This may require special training requirements, which need to be identified. This may also apply to utility personnel.

PSA applications at a general level, without careful analysis of assumptions and boundary conditions, may be misleading. In general, acceptance of PSA results and applications amongst decision makers seems to increase as detailed personal knowledge of PSA keeps increasing. In the short term, acceptance for more extensive use of PSA in regulation is strongly dependent on the level of understanding of the PSA, as mentioned in some responses. Some responses identify that a shortage of such skills from the regulator may be a short term difficulty.

The general absence of uncertainty acceptance standards for PSA is also mentioned as an area where future development may take place. These acceptance criteria could be a relative measure, that is a criteria on the ratio of risk results between a base case PSA and a sensitivity study, or an absolute measure. Numerical criteria should be seen as targets, since uncertainty analyses which, are not currently in all PSA studies, need to be included in the future in order to establish a standard treatment for acceptability procedures to be developed.

In spite of identified needs for further development, it is a fact that PSA is already being accepted as a tool for supporting regulatory decisions. The issue remains on how to make these applications more systematic and affordable throughout regulator and utility organisations. Efforts to solve this issue are mentioned by many countries and some are even delineating medium term PSA implementation planning. This can be seen as a step not only promoting PSA use, but also as a vehicle going towards incorporation of PSA formally into regulatory systems. Within PSA implementation planning, measures necessary to overcome technical and organisational difficulties of integrating PSA into the regulatory system can be done more efficiently.

It seems evident that to some extent the integration of systematic PSA applications into regulatory systems is being achieved in several countries. Currently, these countries would be in transition from purely deterministic to a mixed deterministic and probabilistic regulatory system. The framework for a future system including an appropriate and fair balance between deterministic and probabilistic regulatory rules is worthy of further extensive discussion by national and international parties.

Results of CNRA Discussions

A sub-group of the Organising Committee was formed to make a formal presentation of the results of this work to the CNRA at the Special Issue Meeting. The five presentations outlined the various topics discussed in the report which were derived from the questionnaire. Following the presentation CNRA members were furnished with 2 sets of questions or elements, formulated by the sub-group for starting discussion on the issue.

The preliminary aim of the presentations was to identify and compare the differing practices and attitudes toward PSA prevalent in the Member countries. Notwithstanding this objective, based on the discussions held, it is possible to identify some consensus views on the current status of PSA and the direction of future PSA development and usage as follows:

PSA is now widely applied throughout the nuclear community. Experience suggests that PSA insights applied in the design stages of a plant is more cost effective than application to existing plants. Nevertheless, the application of PSA to existing plants has led to many significant modifications and improvements that can better risk estimates by one or more orders of magnitude.

For those countries that require a PSA as part of the larger periodic safety review, the cost of the PSA is generally small and the added safety insights are considered to fully justify the expense of undertaking a thorough PSA study.

The definition of numerical quantitative acceptance criteria for individual countries has yet to receive widespread approval. All countries agree that it is the systematic usage of PSA that leads directly to safety insights and plant improvements. The use of quantitative safety goals is of secondary importance, but do assist in providing a justifiable and robust framework for decision making and in justifying regulatory actions to the public.

Despite considerable advances in PSA methodology in recent years, there still exists a number of areas where further development is seen as necessary to reduce the limitations of the techniques. Such areas include:

a) Human Factors modelling (particularly cognitive errors)
b) Safety culture and management factors.

It is recommended that PWG5 consider evaluating the relative priority of addressing such issues and recommend how a programme of work to reduce such limitations could be formed.

Whereas it is agreed that one of the most significant benefits of a PSA is the knowledge gained (e.g., plant design, significance of safety issues, etc.), regulators are concerned that plant operators may not be taking full advantage of the insights into plant safety that the PSA offers. The plant safety insights gained from PSA could be integrated into the plant training programmes with greater effect. In a similar manner, the regulatory bodies themselves could improve the effectiveness of site inspectors by ensuring that they have an understanding of the important conclusions derived from the PSA.

1. INTRODUCTION

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international committee made up primarily of senior nuclear regulators.

Each year the Committee holds a Special Issue meeting focusing on the regulatory aspects of current important issues regarding licensing of nuclear installations. Via these meetings the Committee reviews developments which could affect regulatory requirements with the objective of providing members with an understanding of the motivation for new regulatory requirements under consideration and an opportunity to offer suggestions that might improve them or avoid disparities among Member Countries. The Committee focuses primarily on power reactors and other nuclear installations currently being built and operated. It also may consider the regulatory implications of new designs of power reactors and other types of nuclear installations.

Following selection of a topic, CNRA members nominate participants to an Organising Committee which puts together the format and arrangements for the special issue meeting. Following presentation of the report by this group, CNRA members hold a general discussion on the topic and formulate, if feasible future activities and actions to be taken.

Some of the topics the Committee discussed at during the last few years, include: regulatory approaches to severe accident issues, regulatory approaches to dealing with the safety case for ageing plants, and regulatory requirements and experience related to Steam Generators.

The topic selected for the 1995 CNRA Special Issue Meeting is Regulatory Approaches to PSA.

2. OBJECTIVES

This report has been prepared by a subgroup of the CNRA's 1995 Special Issue Organising Committee and reviewed and commented by the other Committee members. Its objective was to summarise the work results of the organising committee, for presentation to the CNRA at the special issue meeting on Regulatory Approaches to PSA.

The first draft of this report was the basis for discussions at that meeting, after presentations by its authors. The intention of the report is to present to the CNRA the current situation of PSA issues in Member countries, extracting some basic conclusions and decomposing the issues into the more detailed points discussed at the meeting. The organising committee believes that these points are the basic elements to be analysed and discussed when dealing with the issue of how and why PSA should be used at present and in the future, in the nuclear safety regulatory arena.

The main sections (Chapter 4 through 8) of this report are devoted to summarising the responses to the questionnaire which was prepared to obtain information on current and planned PSA activities in CNRA member countries. These chapters contain more specific details within this report, which can be analysed further by looking at the complete set of responses to the Questionnaire.

In the final section (Chapter 9), some conclusions from the summaries are extracted. Specific questions were offered to CNRA for their discussion at their 1995 Special Issue Meeting. Results of these discussions are presented in the Executive Summary of this report.

3. WORKING PROCESS

Following selection of the topic at the CNRA's 1994 Special Issue Meeting, the Chairman and Secretariat started the activities to outline a working plan for the organising committee and to solicit nominations for the committee from CNRA's member countries.

The working plan proposed by the Chairman was based on the concept of a questionnaire to be prepared and discussed within the organising committee, responded to by CNRA Member countries and summarised and reported to the CNRA members at the Special Issue Meeting.

A draft questionnaire was prepared by the Chairman and analysed, commented on and revised by the Organising Committee at its first meeting in Paris, on 6 October 1994. After that meeting, a final version of the questionnaire was completed and distributed to all CNRA Member countries in November. The Questionnaire is contained in the Appendix 1 of this report.

To accommodate comments from all participants in the organising committee, the final questionnaire was divided into two parts. The first part allows each country to describe the general regulatory system within which PSA programmes are being developed. It provides understanding on how PSA fits into the regulatory environment in each country's specific circumstances.

The questionnaire's second part is devoted to obtaining more detailed information about the role that PSA is playing, or is being planned to play, in each country's nuclear safety regulations. In order to achieve this, the second part was subdivided into four groups of questions: the PSA Programme in individual countries, the role of national regulatory bodies in production and uses of PSA, case examples of real and current experiences in each country about PSA applications with some regulatory implication, and planning for future uses of PSA in nuclear safety regulation.

This questionnaire was responded to by fifteen CNRA Member countries, as follows: Belgium, Canada, Finland, France, Germany, Italy, Japan, Republic of Korea, Mexico, The Netherlands, Spain, Sweden, Switzerland, United Kingdom, and the United States.

In February 1995, all the fifteen responses were received. According to an organising committee decision at its first meeting, a subgroup was formed to summarise and extract conclusions from responses to the five groups of questions. Participants from the Netherlands, Spain, United Kingdom and United States were in charge of this effort.

Draft summaries were available for discussion at the second organising committee meeting, which took place in Engelberg, Switzerland, on 6 - 7 April 1995. Comments from the other members were received and final draft versions prepared later in April, for final comments by organising committee members in May. These summaries constitute the main section of the report, with overall concluding remarks being provided in the final section.

Preliminary conclusions were also discussed at the second organising committee meeting, along with preliminary versions of the questions for CNRA discussion, which are presented in final version as Appendix 2. The draft of this report was distributed in May to the organising committee members and the final draft version was sent at the beginning of June to CNRA members for preparation in advance of the Special Issue Meeting on 19 - 20 June.

4. BACKGROUND AND REGULATORY ENVIRONMENT

4.1 Introduction

The political and historical development of each nation contributing to this report has led to a number of different regulatory regimes, with various bodies charged with differing responsibilities. It would be inappropriate for this report to attempt to summarise the differing development of these bodies. The general regulatory framework for each nation is ably indicated by the national contributions contained in Reference 1. In order to avoid inaccurate representation of the responsibility of any individual body, the generic term Regulatory Authority (RA) is used in this report to represent those bodies charged by the nations government to regulate nuclear safety on their behalf.

The central purpose of this Section is to convey and summarise the various high level attitudes of RAs towards the use of PSA in each country. Such attitudes are a function of many variables including the size of the national Nuclear Power Plant (NPP) programme, the dependency upon design in foreign countries, the national public expression of concern at the risks from NPPs and the many other social and economic factors.

Specifically this Section addresses the following questions:

a) Are PSAs undertaken for NPPs in each country? If so, are they volunteered by the operating Utility or required by the RA?
b) Who carries out the PSAs? Are they performed by the Utility or the RA?
c) What is the purpose of carrying out PSAs as seen by the RA? What objectives are set for these studies?
d) How are plant judgements made on the basis of PSA?
e) What PSA review process is followed by the RA?
f) What are the perceived strengths and limitations of PSAs as seen by the RA?

Each question is addressed only at the high level. Chapters 5 thru 8 examine in some further detail the actual scope and issues associated with planned and future PSA studies.

4.2 Are PSAs undertaken for NPPs in each country? If so, then are they volunteered by the operating Utility or required by the RA?

Every country has a significant PSA programme or undertaking for their reactor plant. Chapters 5 through 8 discuss further the specific nature of these programmes and the depth of levels of PSA produced.

A PSA may be produced:

(i) as a result of a mandatory requirement from the RA
(ii) as a result from a request from the RA
or
(iii) may be volunteered by the Utility as a means of fulfilling a more general requirement.

In many countries, it is a requirement by the RA that the Periodic Safety Review (PSR) for each station be supported by a plant specific PSA. This practice is followed (for example) by Belgium, Korea,

Netherlands, Spain, Sweden, Switzerland and the UK. Furthermore, RAs in these countries would require a full PSA as part of the design substantiation for any new reactor plant.

In Japan, there is no formal regulatory requirement for a PSA. However, the Nuclear Safety Commission has given strong encouragement for a **Level 2**- PSA = [**Level 1** PSA plus containment performance evaluation - see Chapter 5 for definition of **Level 1]** to be undertaken and the RA has requested that all plants provide such studies. The aim of the study has been to better understand the plant characteristics and to assist in the development of severe accident management measures.

In France, generic plant PSAs have been performed, by agreement with the RA, but there is no regulatory requirement for the PSA to be used as part of the design process. PSA is expected to be used 'a posteriori to confirm that adequate plant provisions have been made.

In Germany, the Licensing of plant is based on deterministic considerations with some requirement for reliability system evaluation. However, as part of the Periodic Safety review all 21 plants will have **Level 1**$^{+}$ PSAs undertaken; but formally the PSR is not a RA requirement.

In Finland, PSA is a regulatory requirement. The RA issued YVL Guide 2.8 on PSA which set forth the requirement for licensing NPPs and gives the Licensees guidance on the scope and procedures for PSA.

In the United States, the Nuclear Regulatory Commission (NRC) has no specific requirement for Licensees to undertake PRA other than the 10 CFR 52 requirement that a PRA be performed to support the licensing review of advanced light water reactors. However, the IPE programme has led to most plant now having a plant specific PSA. Also the Maintenance Rule (10 CFR-50.66) requires that risk be considered in establishing the maintenance programmes and this, in practice, has also led many utilities to updating and enhancing their plant specific PSA. The NRC has recently published a final policy statement, on the use of PSA Methods in Nuclear Regulatory Activities.

The NRC proposes that:

(a) The use of [1]Probabilistic Risk Assessment (PRA) technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defence-in-depth philosophy.

(b) PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is of course understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

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1 The terms PSA and PRA used in this document denote the same meaning only a difference in terminology utilised in the different Member countries.

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

(d) The NRC's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgements on the need for proposing and backfitting new generic requirements on NPP licensees.

The Mexican RA requires that all plants be initially licensed under the extant rules and regulations of the country of origin of the plant. In practice, this leads to the Mexican plant being required to meet requirements similar to those in the USA.

In Canada, PSAs are performed by the operating utility as a means of satisfying high level requirements. The RA identifies certain system reliability targets and requires a demonstration that these are met.

In Italy before the nuclear moratorium, the implementation of a **Level 1** PSA was a requirement for Design Certification in connection with Quantitative Safety goals. For future plants, no quantitative safety goals have been set, but a **Level 3** PSA is considered useful to support decisions in the design development.

4.3 Who carries out the PSAs? Are they performed by the Utility or the RA?

In each country, the RA is an independent body from the operating utility. Responsibility for safety ultimately rests with the operating utility rather than the RA.

In most countries the PSAs are undertaken by the plant vendor or architect-engineer or other private consulting company.

In Belgium, the PSAs are performed by Tractebel, the architect-engineer, on behalf of the utility. Consultants from abroad were involved in all projects.

In France, the generic PSAs for the two main series of PWRs have been carried out by IPSN (Technical support to the Safety Authorities DSIN) or by the utility EDF (1300Mw. series), in each case with the participation of the constructor Framatome.

In Canada, the PSAs are performed by the operating utilities: Ontario Hydro, New Brunswick Power and Hydro Quebec. The PSAs are produced by the utility staff. For new plants, the designer, AECL has performed a **Level 1** conceptual PSA on CANDU 3 and is currently performing a **Level 1** on CANDU 9 to support the design integration. Also, AECL has recently completed final detailed **Level 1** PSA for Wolsong 2, 3 & 4.

In Finland, the RA has specifically required that NPP PSAs be largely produced using plant personnel and not by the use of contractors. This decision was taken to ensure that a solid information and understanding basis exists to support the development of a Living PSA approach.

In Germany, PSA activities have been performed by GRS and the reactor vendor. **Level 1$^+$** PSA required for periodic safety review or other regulatory purposes, are performed by the operating utilities, involving plant staff, usually supported by the vendor or by consultants.

In Italy, all PSAs have been carried out at the request of the RA (ENA/DISP). The Italian Generating Board, ENEL has participated, often with leading responsibilities, in all PSA studies, generally in conjunction with the plant supplier. Work has been done in offices of the plant supplier in the UK and Italy. Experts from the RA have contributed to the production of some of the PSA studies.

In Korea, the PSAs are produced by the operating utility with consultancy assistance. The RA (see Section II) has been involved on one occasion in the IAEA IPERs of their own plant.

The PSAs for reactors in the Netherlands are performed by contractors (SAIC, PL & G, KEMA (L**evel 2**) and Seimens/NUS) on behalf of the Licensees, partly in the Netherlands and partly abroad. Plant staff are also involved in the work.
In Mexico, the operating Utility is responsible for providing the reactor PSAs. Both Mexican NPPs are fundamentally of similar design and the RA accepts that a single reactor PSA is suitable to cover both plants.

In Japan, the utility, with the assistance of vendors, volunteers the PSA as part of the in-house safety management requested by the RA. The operating utilities undertake the PSA studies and have been directly responsible for the development of a number of PSA computer codes on which the analysis is based. The RA (MITI) has sponsored several generic PSA studies on typical Japanese BWR and PWR plant to use as reference in the IPE review process.

In Spain, the Utilities are responsible for the PSA studies, and are the Project leaders. The work is carried out in the Utility headquarters offices by licensee personnel and consultants. Site personnel are also required to be assigned to the PSA project, to enhance communication between the PSA team and plant operations.

In Sweden, PSA studies have been performed as a requirement of the RA, as part of the ASAR-80 programme. Licensees carry out the work, normally at headquarters with the assistance of consultants, the Licensee being the project leader.

PSAs for the UK reactors are carried out in the UK by the Licensee or by a consultant on behalf of, and with the support of, the Licensee.

In Switzerland, the plant PSAs are produced for the operating utility, using lead consultants from abroad, supported by utility staff and national companies as subcontractors.

In the USA, PSAs are typically managed by the operating utility but largely performed by private USA consultants. The NRC has however sponsored an early PSA study (WASH 1400) as well as recent PSAs such as documented in NUREG 1150.

4.4 What is the purpose of carrying out PSAs? What objectives are set by the RA for these studies?

In all cases where PSAs are performed, the prime objective of PSA is seen as a complementary assessment tool to a deterministic safety evaluation.

Primarily, and historically, PSA is a quantitative tool that is used in a relative rather than an absolute manner. There is generally a common objective of PSA studies that encompasses:

(a) The identification of accident sequences that may contribute significantly to core damage.
(b) The identification of accident sequences that may contribute to early containment failure and/or significant release.
(c) The identification of components or plant systems whose unavailability or failure may lead to a significant influence on the likelihood of core damage etc.
(d) The identification of functional, spatial or human induced dependencies within the plant configuration that may contribute significantly to or influence the likelihood of core damage etc.
(e) The identification of operating, test, maintenance and emergency procedures that may contribute significantly to or influence the likelihood of core damage etc.
(f) The ranking of the relative importance of plant systems, components and procedures.
(g) An input to the overall decision making process on the adequacy of plant safety and decisions on plant updates and backfits.

Japan and the USA, in particular, cite the importance of PSA to the definition of severe accident management procedures.

4.5 How are plant judgements made on the basis of the PSA?

The objectives identified in the preceding section are all qualitative in nature. Over and above such objectives, all countries are aware of the international safety goals for consequences, such as core damage, or defined quantities of radioactive release, or fatality to workers and/or the public at large. Thus each RA will generally make some comparison between their own numerical reactor results and such criteria, but such comparison, as there may be, is not generally a mandatory part of the decision making process.

In contrast, the UK, Netherlands and (to a lesser extent) the USA, Canada and Switzerland, have their own numerical safety goals defined by the RA.

Safety goals may vary from a target or limit on core damage frequency (for example) to a system level reliability target. In the USA, the NRC has specifically identified that the safety goals are to beused in a generic sense and not to make specific plant licensing decisions.

The adoption by such countries of quantitative safety goals influences the perceived limitations on the use of PSA as well as the benefits (see 4.7 and also below).

All countries identify that either sensitivity or uncertainty analyses (or both) are to be carried out as part of the PSA. Japan (for example) uses both sensitivity and uncertainty studies for the **Level 1** analyses, but only sensitivity studies for **Level 2**. The UK RA does not require any uncertainty analysis, only sensitivity studies.

Without doubt, every PSA practitioner or assessor would demand some form of sensitivity or uncertainty analysis to support a PSA. However, here an interesting question arises, namely how should the acceptability of a sensitivity/uncertainty study be judged in the absence of a numerical target or criteria?

Those few countries that have numerical safety goals might seem best placed to define sensitivity acceptance criteria. With the exception of Switzerland (that prescribes a limit on core damage frequency at the 95% confidence level), no acceptance criteria for sensitivity/uncertainty studies exist.

For countries without numerical safety goals, there is similar absence of qualitative acceptance criteria. [Although the Mexican Utility has generated a PSA procedure that includes acceptance criteria for

sensitivity studies]. Acceptance criteria for sensitivity/uncertainty studies may be an area for future research and analysis. Some research in the UK is in progress.

Apart from the assessment against quantitative safety goals, each RA is required to make some judgement on the adequacy of the plant but only, taking into account the PSA to the extent identified in its Regulatory framework.

Section 4.6 below discusses the PSA procedures that have been produced by nations to assist in this PSA production and RA assessment process. Mostly however, these guides relate to the scope and methodology expected within a PSA study and not to any acceptance criteria set by the RA.

This is not unexpected. Although most national RAs require a PSA to be performed, all acknowledge that the results from the study are only one part of the input to the decision making process. Firstly the results (i.e. the relative importance of components and systems) must be seen as consistent with engineering judgement (even though the deterministic analysis may not have identified an explicit concern with a component or feature of the design). Once the PSA has brought particular plant features to the attention of the RA then a more thorough engineering assessment would take place. The decision on whether to accept the plant design as adequate is then taken largely on these engineering grounds.

Cost - Benefit Analysis

The numerical results of NPP PSA studies may be used as part of the decision making process, when backfits to existing plants, or design improvements to future plant, are being considered.

Several countries provide guidance on the money that it is worth spending on the plant to avoid a specified dose to a member of the public This approach is a basic cost benefit analysis (CBA). More detailed CBA methods exist which take account of the societal costs of accidents but their use is generally limited and the RA does not accept such CBA as the prime or sole means of deciding on plant acceptability. In the UK for example, the RA is prepared to consider arguments from Licensees containing CBAbut this is as part of an ALARP (as low as reasonably practicable) argument.

Perhaps the central reasoning behind RA reluctance to accept the wider use of CBA is the same as the reluctance to accept numerical safety goals as part of the licensing framework. Most countries feel that the uncertainty associated with PSA is too great to allow purely numerical results to determine the need or otherwise of plant modifications. Even in countries where numerical criteria are part of the licensing framework, there is still an unease about taking the numerical results too literally. Over and above this issue, is the concern that the costs of the safety modification can be determined in a variety of ways (e.g. should loss of operating utility profit be counted? How should the residual life of the station be reflected, if at all, in the argument?)

One further concern may also be expressed, namely that all RAs agree with the objective that PSA be performed on a best estimate basis. However, all agree that in many instances, the definition of best estimate is difficult to agree or to deduce without additional analytical or experimental expenditure). Thus, all PSAs contain an element of the unknown. It would therefore be difficult to implement a CBA approach to results that might enforce the expenditure of significant resource and money on an issue that, in reality may not warrant such expenditure.

4.6 What review process is followed by the RA in the assessment of the PSA?

The process followed by each country in reviewing and assessing the PSA produced by the operating utility varies. Many factors influence the approach followed by the RA, such as the resource available, the confidence in the utility and the existence of agreed procedures that the utility should follow.

Some countries use the Peer Review process offered by (for example) IAEA. Some countries undertake a complete requantification of the PSA using their own resource or contractors. In some countries, the computer codes used by the operator are supplied by the RA.

Some RAs give the utility guidance for PSA production in a number of ways. These include reference to formal or informal national PSA procedures/guides or reference to overseas procedures such as earlier guidelines developed by the NRC, or via formal and informal discussion with the Licensee/Utility.

In France no guidelines or PSA procedures are given by the RA. However there is co-operation between IPSN and EDF in the 900 and 1300 MW PSAs leading to broad consensus on methodology and application.

In Spain, the PSA procedures are evolving with the completion of each PSA study. The exact procedures are agreed with the Utility before the commencement of the study.

The Mexican utility has produced their own procedures that include acceptance rules for the PSA inclusive of sensitivity considerations.

In Germany and Canada, guidance for producing PSAs is being written by the RA.

In Finland, the RA has produced guidance (YVL 2.8) on the use of PSA in the licensing and operation of NPP. However no RA review guides exist at present. In the past, PSA procedures guides from the USA have been used in a generic manner.

In the UK high level guidance is given in the Safety Assessment Principles.

The definition of PSA production procedures is supplemented in only a few countries by the existence of specific procedures to be followed by the regulatory review. Switzerland has produced such a guide. Germany, the USA and the UK also have procedures in preparation or planned. The nature of each procedure is clearly a reflection of the regulatory framework in each country and dependent upon the understanding of the review procedures that are exercised by the utility.

Further summary information on review procedures is given in Chapter 5.

4.7 What are the perceived strengths and limitations of PSAs as seen by the RA?

<u>Strengths</u>

PSA is seen by all countries to provide a level of plant insight that cannot be provided by the deterministic approach. PSA seeks to address all types of accident sequences from those of common occurrence to those well beyond (in terms of consequence) the range that would be addressed by the design basis/deterministic analysis. PSA provides a relative weighting of the defences provided against accidental releases, which cannot be provided by other means.

Many PSAs for operating plants have now been performed throughout the world. For many plants an existing deterministic safety justification was already extant. Notwithstanding this, virtually all PSAs have led either directly or indirectly to a number of plant (procedural or hardware) improvements. It is often much argued whether PSA or engineering judgement was responsible for a particular safety improvement. In reality it is often a mixture of the two.

In an attempt to demonstrate the important influence that PSA has had upon safety plant design and mode of operation, PWG5 (Task 17) has attempted to draw together examples of PSA based safety improvements from plant in a number of OECD countries. The reader is best referred to this documentation (Reference 4.8.2) for further information.

PSA, as a tool, has many strengths, but care must be taken over its usage. Once a numerical result has been obtained, there is a danger that it may be perceived to represent a more exact estimate of the risk than it is actually intended to represent. PSA by its nature, is a tool containing, or perhaps better stated, expressing uncertainty in many factors that, can of itself, give insights into plant behaviour.

Decision making based on PSA therefore needs to recognise this uncertainty and to decide what weight to place on the quantitative results in the decision making process.

Areas where the PSA embodies, or can express, uncertainty in plant behaviour or performance include:

(a) Component reliability; due to the inherent statistical nature of the data base; or due to the absence of recorded failures when reliance rests solely, or predominantly, upon engineering judgement (e.g. failure rate of a primary coolant pipe)
(b) Containment phenomenon; due to the engineering judgement on the likelihood of containment events
(c) Hazard analysis; due to the uncertainty in the severity or frequency of external hazard curves (such as seismic)

The representation of these uncertainties can be regarded as a strength of PSA or can be regarded as a limitation if not properly recognised and accounted.

Limitations

A limitation of a tool is only a weakness if it is not recognised and properly accounted. Limitations of PSA noted by countries include the following:

(a) difficulty in ensuring completeness of sequence identification;
(b) construction errors may not be represented;
(c) management and safety culture issues are not represented;
(d) quality of data (e.g. plant reliability);
(e) engineering judgements are difficult to quantify;
(f) human errors, particularly cognitive human errors, are difficult to quantify;
(g) common mode/cause failures are difficult to quantify.

The lack of high quality data may lead the PSA to err on the side of conservatism. Ideally data should have well established means and some recognised uncertainty band or distribution of uncertainty. The intent is, and should be, to keep best estimates realistic so as to avoid the many problems associated with either

over conservatism or over-optimism. The inclusion of an uncertainty analysis in the PSA is a valuable aid in interpretation of results.

In Italy, the main limitation of PSA studies is seen to be that there is a public aversion for safety demonstration based on probabilistic statements or criteria. According to public opinion, undesired events should be made impossible by design; regardless of the inescapable fact that any low probability event may occur at some time, no matter how low the probability of that event. After a national referendum in 1988, the Italian government decided on a moratorium period, recommending that Italian industry to consider more passive nuclear reactor designs.

4.8 References

4.8.1 - National Response to questionnaire

4.8.2 - Report from Task 17 of PWG5. Mme. Lanore (IPSN) To be completed

5. ROLE OF PSA IN SAFETY REGULATION - PSA PROGRAMMES

5.1 What is the scope of the analysis?

The scope of the analysis can be focused on the following aspects:

1. PSA level, basically:

   Level 1: Core damage frequency determination and assessment of the most dominant scenarios leading to core damage.
   Level 2: Containment vulnerability and radionuclide release determination.
   Level 3: Health consequence determination.

Other intermediate levels are defined in some countries, e.g. **Level 1^+ or 2-**, meaning that some kind of containment performance analysis is carried out, but no radionuclide source term estimates are obtained.

2. Events analysed:

   - Only internal events
   - Internal and external events

3. Operating conditions:

   - Full power
   - Full power and other modes like: shutdown, start-up, refuelling, etc.

Furthermore, combinations of these aspects can be explored, like for instance if the external events are considered only at power or during shutdown conditions too.

In general, it can be said that the scope of PSA programmes has progressively increased in many countries from **Level 1** up to **Level 3** PSA; **Level 1** is common to all the countries, while the most frequent ongoing efforts aim to **Level 2** or similar (USA, UK, Canada, Switzerland, Finland, Sweden, Spain, Korea,

Japan, etc.). **Level 3** PSAs have been performed only in a few countries and not always for all the plants (UK, USA, Netherlands).

External event analysis was not considered at the beginning of PSA programmes in many countries, but nowadays is accomplished in most of them. It must be taken into account however, that concerns about some of these events, like earthquakes, are highly plant site specific. The most frequent external events analysed are fires, floods, and earthquakes. Recently, external events (fires and floods) during shutdown conditions are being analysed in some countries.

Low power and shutdown power operation PSA has been only recently analysed and is not a regulatory requirement in many countries. A few countries have performed or are performing this kind of analysis for all the plants, but it seems, that PSAs will include this subject in the near future in many countries. An important aspect within this type of analysis is to agree which are the possible non full power states of the plant that should be considered in the analysis.

5.2 Are PSAs provided for individual plants or are studies provided for a generic or specific class of plants and the results applied generically?

Practices in different countries can be classified as follows:

- 1st approach: Individual PSAs

A PSA is developed for each individual plant. Also included under this approach is the case of a plant with multiple twin units, where the PSA is developed for one unit and an applicability study of the PSA is made for the others. This approach is the most commonly used and, of course, the best in order to get good safety insights of the plant and to develop future applications, but it is in turn the mostexpensive (USA, UK, Canada, Sweden, Spain, Switzerland, Finland, Belgium, Netherlands, etc.)

- 2nd approach

A PSA is developed for a specific type of plant and its results are extended to each individual plant of that type. Some countries with a very high degree of standardisation in design and operation can take advantage of this approach (France). The development of a PSA programme by this approach saves a lot of effort at the country level compared with the previous approach.

- 3rd approach: Hybrid PSAs

This approach includes PSAs for individual plants, in which some parts of the study are plant specific and others (often involving the analysis of more advanced issues) like the **Level 2** analysis or the low power/shutdown conditions analysis, are generic (Japan). This approach may require future revisions of generic parts to become specific when methodologies are more experienced.

It must also be said that some countries have developed generic pioneer studies based on some specific plant designs followed later by a PSA for individual plants (Germany). Finally, some countries have only a few plants with different designs that the question is not really meaningful (Mexico).

5.3 What system does exist to collect and analyse reliability data at both plant and national level?

Reliability data to support PSAs are acquired in so many different ways among the countries asked, that is not easy to state what are the general practices in this area.

It can be said, however, that very few countries (Sweden) could perform a PSA based on a national data bank because, either such a bank does not exist, the bank is still under development, or it can provide only some type of the reliability data necessary, e.g. initiating event frequencies. It also happens in some cases that a country provides operating experience to a national data bank of another country.

Initiating event experience can be normally retrieved from a national bank with ease, since almost every country has regulations that require the Utilities to report these kinds of events. Regulatory reporting of component failures or inoperabilities is usually limited to some specific equipment, and therefore, acquisition of that type of information at national level usually requires substantially more effort. In PSAs that are not based on reliability data retrieved from a national bank, one of the following approaches is normally used:

1) Extended use of generic data.

Operating experience of the specific plant is almost never reflected at all in component failure data and initiating events frequencies. Testing and maintenance unavailabilities however, are mainly plant specific. Use of generic data is always necessary when the PSA is applied to new plant designs.

2) Extended use of plant experience in the acquisition of reliability data (USA, Switzerland, Spain).

As much information as possible is retrieved from plant experience, e.g. component failures on demands, operating hours, plant events, etc. through different methods: analysis of maintenance records, event reports, logbooks, etc. In the ideal case all this information is compiled in a well structured data bank, suitable for easy retrieval of reliability data and for supporting a national data bank. Inmany cases however, such a bank does not exist and the information analysis is just done for a certain period of time established in the PSA.

Normally, the specific plant experience is not suitable to provide all the reliabilitydata necessary for a PSA. In these cases, data from other sources, generic data, is used or a Bayesian update of generic data with plant specific information is performed. Generic data could be retrieved from a national data bank, if available.

3) Other possible intermediate approaches.

5.4 Are PSA studies provided on the understanding that an updated study will be necessary? If so at what interval and what is the extent of the required update?

It is normally understood that PSAs must be updated periodically to prevent them from becoming obsolete, due to important changes in design and operation of the plant in the course of the time. However, frequency and extent of updates differ between countries attempting to use the living PSA concept to countries where updates are not foreseen, because the performance of a PSA is not required by the nuclear authority. Updates can be used also to increase the scope of the PSA or incorporate new state of the art methodologies. The answers given to this question can fit into one (or more) of the following possibilities:

1. PSA has become part of the safety case and is therefore a part of plant documentation. Updates are necessary to reflect plant modifications. The frequency of PSA updates can be established by one or more of the following criteria:

a) According to the frequency of periodic safety reviews, 10 years for instance (UK, Netherlands).
b) Whenever significant plant changes occur (UK, Finland).
c) Frequency is agreed between the Regulator and the Utility but no fixed frequency exists.
d) A Living PSA concept is pursued with some nominal updating period (Finland, Switzerland).

2. PSA is a regulatory requirement but still is not connected with the licensing process. Updates will be made on regulatory demand with a certain frequency. Criteria a) and c) from point 1. could be used for instance (Spain).

3. PSA is not required but is accepted when utilised in combination with other engineering analyses as a means of satisfying regulatory requirements (USA - Maintenance Rule), or PSA is encouraged by authorities but not required and periodic updating is recommended, but its frequency is not established. Some of the previously indicated criteria could be applicable (Japan).

4. Updates are not required yet (France).

It is also expected in many countries that the Utilities will try to update periodically the PSAs whenever it might be necessary without waiting a long time for a regulatory requirement, that could need many important changes all at once.

5.5 What PSA research programmes are underway or planned?

A wide variety of Research & Development programmes have been identified in the answers to this question. A classification of the more significant research topics has been made and is given below.

Level 1 PSA

- Low power and shut-down risk analysis
- LOCA frequency analysis
- Dependent failures analysis
- Improvement of methods and data bases for common cause failure analysis
- Benchmark exercises on common cause failure analysis, human errors and accident sequence quantification
- Development of automatic fault tree modelling tools
- External events
- Development of fire risk codes and methodologies
- Development of codes and methodologies for seismic analysis: analysis of seismic hazards and seismic response, development of fragility data base, etc.

Level 2 PSA

- Severe accident methodology modelling
- Development of computer codes
- Experimental studies of H_2 deflagration/detonation phenomena and other related processes
- Experimental investigations of radionuclide resuspension during a severe accident.

- Analyses of in-vessel and ex-vessel steam explosions.
- Analyses of aerosol behaviour and retention capacity of filters.
- Analyses of containment performance related to severe accidents
- Analyses of reactor lower head failure phenomenology

Level 3 PSA

- Development and improvement of codes to predct radionuclide transport, dose distributions and health effects on the population

Human reliability

- Development of data bases
- Quantification of human actions over long timescales
- Comparison of different HRA methodologies.
- Development of human operator models
- Improvement of human reliability analysis methodologies
- Man-machine interface research
- Use of artificial intelligence as operational aid.
- Development of codes for human reliability analysis

Reliability data

- Development of data bases for component failure rates and operational events

PSA applications

- Analysis of technical specifications and allowable outage times.
- Accident precursor sequence analysis

Others

- Validation of PSA techniques
- Guidance development
- Criteria for acceptance of sensitivity studies
- Development of PSA quantification tools.
- Development of computer programmes to support living PSA activities.
- Development of dynamic accident sequence analysis methods.
- Advanced reactor passive system reliability analysis

6. ROLE OF PSA IN SAFETY REGULATION - REGULATORY AUTHORITY'S ROLE

6.1 What is the degree of regulatory involvement in the production of the PSAs ?

The degree of regulatory involvement in the performance of the PSA in some countries (USA, Switzerland) is not the same for all the PSAs that have been produced. It could be classified into the three following fundamental categories:

1. The Regulator participates actively in the performance of PSA or at least some PSA tasks (France, USA, Mexico, Italy).

   a) The PSA is developed by the Regulator alone or together with the Utility. The involvement of an institution or engineering firm in name of the Regulator or the Utility is also possible. Participation of the Regulator in project management or task leadership would fall also in this category.

   b) The Regulator also reviews PSAs. Normally the review is made by people not actively involved in the PSA performance. In the USA, for example, the regulator has sponsored and participated in the performance of plant-specific PSAs, particularly during the early years in development of PSA application to NPPs. The regulator in the USA, however, does not participate in the performance of licensee PSAs (which may be used by the licensee to support requests for license amendment requests or meet other regulatory requirements).

2. The Regulator reviews the PSA but is not involved in the development of PSA tasks. This is by far the most frequent case. The degree of involvement of the Regulator in the review of PSAs can be very different. The following principal cases are given:

   a) The Regulator sets up the scope and requirements of the PSA and discusses in an early stage topics and the methodologies to be used by the Utility. Regulator guidance is provided in some cases (Further review will take place later on usually).

   b) The Regulator reviews the PSA after completion. Reviews can be carried out in several ways, but this is a subject to deal with in question 6.4. The PSA must be updated taking into account the regulatory comments within some time interval (Switzerland, Japan).

   c) Case a) and case b) together (Finland).

   d) The regulator sits as an observer in the production meetings of the PSA and can be consulted or give its opinion about particular issues (Canada).

   e) The Regulator meets with Licensees to discuss the scope and progress of the PSA and issues arising during the course of the work. Licensees will be told if the regulator considers that any approach is unlikely to be satisfactory (UK).

   f) On top of the regulatory involvement described in cases a) and b), the Regulator acts as supervisor during the whole development of the PSA, doing more or less intensive follow-up activities. Thus, the Regulator knows at any time the PSA state of development. Draft reports of important PSA tasks are reviewed during the PSA progress. Therefore, many comments of the Regulator can be discussed early and taken into account in the final PSA report (Switzerland, Spain, Belgium).

   g) In the USA, the regulator does not routinely review all PSAs. Reviews are only performed in the context of a specific regulatory application of the results of the PSA.

3. The Regulator is neither involved in the development nor in a formal review of the PSAs. This lack of involvement occurs in countries where the performance of PSAs is not a regulatory requirement.

It can be concluded that, with the exception of the USA, a general practice is to have some intermediate reviews or discussions during the production of the PSA based for instance on draft reports of single PSA tasks, rather than just a complete review after the whole PSA package is handed up to the Regulator.

6.2 Is there any formal approval of the PSA by the Regulator required on completion of the PSA or at stages during the production of the PSA?

In countries where the PSA is voluntarily performed, no approval may be needed, depending on the later use of the PSA. If applications are developed that interact with plant licence, then an approval should be obtained.

When the PSA is performed following a regulatory requirement, a formal approval after completion of the project may or may not be needed. Although a formal approval may not exist, a kind of implicit acceptance of the study may exist. The incorporation of the comments stated by the Regulator could be regarded in some cases as an implicit approval. There may also be levels of approval or limited acceptance, for example, in connection with particular applications.

Formal approvals at intermediate development stages of the PSA are not needed in any country.

The different types of treatment given to this topic are summarised below:

1. Approval after considering all the Regulatory comments in the final report. Some comments or open issues that would need a more detailed analysis can be left for the next update (Spain).

2. Extensive Peer Reviews (IAEA, IPERs-programme) and some detailed regulatory reviews enabled the regulatory authorities to communicate the results to the parliament and to accept the results of the PSA to be used for supporting license renewal. Although , a direct regulatory approval of the PSA was not given, communication of the results to the parliament implied regulatory acceptance (Netherlands).

3. The Regulator is actively involved in the PSA development and the approval is easily obtained after fulfilment (France, Mexico).

4. The Regulator gives approval to an action requested by the Licensee on the basis (partly) of an adequate PSA but does not approve the total PSA package (UK).

5. PSAs are being performed in the framework of the periodic safety reviews and since for subjects treated in these reviews a formal approval has to be given, an approval of PSAs is also required (Belgium).

6. The PSA must include formal comments of the Regulator, but no formal approval is given since a Living PSA concept is adopted and therefore the PSA is always open to comments if significant changes have taken place in the boundary conditions of the PSA (Finland).

7. An approval is needed since PSA is a part of the Safety Analysis Report (Korea).

8. Acceptance of the PSA after a detailed review as a basis for decision-making can be regarded as a formal approval by the regulator (Switzerland).

6.3 What are the objectives of the regulatory review?

The objectives of a regulatory review are highly dependent on scope, purpose of the PSA and uses that will be made of it in the future. The level of detail of the regulatory review also (see next question) depends on these objectives.

The first and basic focus of attention during a PSA review is to be aware that the Licensee has performed a PSA according to the requirements of the Regulator, an that the methodologies applied and the analysis of the different tasks are adequate. Furthermore, most of the countries agree that a more detailed review of the PSA can provide a more thorough understanding of plant features, potential severe accident vulnerabilities and unique operating characteristics modelled by PSA. The different objectives in this sense given as responses could be summarised as follows:

- Understanding the general validity of PSA models, assumptions, analytical methods, data and numerical results.
- Understanding the range of uncertainties in core damage frequencies, containment performance, and radiological releases.
- Assessing applicability of PSA models as tools to assist plant operation and effective regulation.
- Development of the basis for a living PSA model.
- Obtaining a deeper knowledge of plant safety, identifying its major weaknesses, comparing the various contributions to the risk, and checking that plant's design is well balanced and vulnerabilities are not masked in the PSA.
- Comparing the risk estimates with some reasonable specific limits.

Fulfilment of the objectives listed above through a PSA review may not be necessary if the Regulator itself has participated in the development of the PSA.

6.4 To what level of detail does the Regulator assess the PSA and what, if any, review guidance has been developed by the Regulator?

In can be said in general that when a detailed review is performed, it is focused principally on the most important PSA subjects. However, the way the reviews are carried out differ from one country to another. Sometimes the Regulator has received assistance from other national or international institutions. A classification intended to highlight different types of observed review processes is presented hereafter:

- Continuous and interactive detailed review from the early stages of development up to the end (Switzerland, Spain, Belgium).
- Detailed review of the PSA at a few development stages of the project and after completion (Netherlands).
- Detailed PSA review when a finished PSA is submitted to the Regulator (Sweden, Finland, Italy).
- The Regulator develops a PSA for typical plant designs. Individual PSAs developed by the Utilities are compared with the corresponding typical PSA developed by the Regulator to check whether the differences of design from the typical one have been adequately reflected in the PSA (Japan).
- The level of detail depends upon a number of factors such as the consequences of the events under consideration and the depth of any independent peer review performed on behalf of the Licensee (UK).
- The level of review depends on scope and purpose of the PSA. For the case of an individual plant examination (IPE) PSA (in the USA, generally a **Level 2** PSA), a very limited high level review is

made, aimed at determining whether the methodology employed by the Licensee is capable of identifying vulnerabilities to severe accidents.
- Evaluation focused on reproducing the PSA results with different types of codes. Special attention is paid to the results of accident sequences and importance analysis (Mexico).
- The Regulator participates actively in the PSA development. It is assumed that a deep degree of knowledge is achieved and therefore an additional detailed review is not necessary (France).

With respect to the 2nd part of the question, i.e., the development of review guidance by the Regulator, the following answers have been given:

- No specific review guidance exists or is referred to. Intention of whether to develop national guidance or utilising guidance developed by others is not stated.
- No specific national review guidance. International review guides could be at least partially used (Korea).
- No specific national review guidance have been developed, but participation in the development of international review guides exist (Spain).
- The convenience of national review guidance is acknowledged. Review guides are under development or are foreseen in the future (Germany, Canada, Korea)
- Specific review guides have been developed (Switzerland, UK), or general procedures and methodology guidelines have been developed that are frequently used in PSA evaluations (USA).

It seems that the general trend and the ideal case is to have national guidance for this topic. Review guides are still scarce however, but are being developed in several countries.

6.5 Are plant and procedure improvements resulting from PSA studies mostly identified by the Utility or the Regulator? How are such modifications approved?

In almost all countries both the Utility and the Regulator can identify improvements to plant or procedures, but that usually they are identified by the Utility. Since PSA are mostly developed by the Licensees, possible design weaknesses are usually first identified by them. On the other hand, it is normally the Licensee who has to analyse possible improvements and decide which of them will be submitted to the Regulator if necessary, while the Regulator's task is to approve or refuse them. Therefore, the Regulator will usually identify weaknesses and the need for improvements rather than the improvements themselves.

The Regulator has a bigger chance of identifying plant weaknesses when he makes a detailed review or is involved in the development of the PSA. However, most of the answers given to this part of the question can be summarised as follows: Almost all of the interesting improvements in plant and procedures are identified and analysed by the Licensee during the development of the PSA, or afterwards if PSA is used to assess the potential safety benefits that further improvements might produce.

The Regulator can also identify some needs for improvement during the review process not considered before by the Licensee. The Licensee will analyse and discuss these improvements with the Regulator and could be forced to submit modifications to the Regulator in some cases, e.g. a violation of deterministic design criteria was discovered.

Planned improvements may be included in the PSA models being developed, be left for a next update, or be considered once they have been implemented.

It was pointed out in single cases that:

- Most of the proposals for procedures changes were made by the Regulator (Finland).
- No formal obligation of the Utility exists to identify the reason for plant or procedure improvements (Germany).

The way these improvements or planned changes, motivated by PSA results, are approved by the Regulators is different from one country to another depending on their specific regulations, but it general, it can be said that the process is the same as for any other changes not motivated by the performance of a PSA. In all cases requiring regulator approval, however, the regulator must be convinced that the change is an improvement, which may require a high level of confidence in the PSA as it applies to the analysis of the proposed change (e.g., changes in maintenance and testing schedules based on risk-ranking). Although summarised above, the process used by regulators to reach an acceptable level of confidence in PSA results varies from country-to-country, and in some cases from application-to-application, most if not all countries consider PSA, together with engineering judgement, a complement to deterministic analysis. At least some countries expect to use PSA to modify deterministic criteria, where appropriate (e.g., to decrease conservatism associated with some deterministic analysis). The key point of this question is to what extent and how probabilistic arguments are considered for the approval of these changes, and what would happen in case that probabilistic and deterministic criteria were in conflict, but such issues will not be considered here, since they are discussed in other parts of the questionnaire.

Although different countries have different regulatory procedures, general policy around this topic could be summarised as follows:

- Sometimes modifications have been discussed in detail and agreed between the Licensee and the Regulator's reviewers, before they are submitted to the Regulatory Agency following standard procedures as any other modifications.
- Any kind of changes in plant procedures or any documents related to the license must be communicated to the Regulator.
- Approval process depends upon the safety significance of the modification proposed.
- Proposed modifications are considered by all relevant disciplines and not confined to PSA
- Some changes may not need approval in some countries if they are considered as not safety related.

6.6 How are PSA findings accepted within the national regulatory environment?

It can be concluded from the responses given to this question that acceptance of probabilistic methods is not the same in every country but acceptance is steadily increasing world-wide. Regulators have realised through their reviews that PSA is a powerful tool that can provide important or even unique insights into plant safety and has a strong application potential.

In the best case, the PSA has become an important part of the nuclear regulatory process and therefore PSA findings are accepted as part of the regulatory decision-making process. The Regulator is aware of the strengths and limitations of both deterministic and probabilistic approaches and tries to make a real integrated use of these complementing methodologies. Development of guides for the use of PSA methods in regulatory activities is under study in some countries.

Some countries consider that PSA is well accepted in the regulatory environment as long as its uses are in agreement with deterministic methods. This is normally the case in identifying improvements to correct design weaknesses. When an application is made however, that tries to limit the application of some

deterministic criteria, acceptance of probabilistic criteria becomes more difficult. Regulatory staff members who are mainly familiar with the deterministic approach can have their own ideas about the influence of some design features and if they are not familiar with the PSA or probabilistic techniques, not enough confidence can be given to the application. In that case, some of the arguments used to undermine PSA findings can be incompleteness and uncertainties of data, models and results. Regulatory acceptance in the USA is highly dependent on the demonstrated quality of the PSA and the integration of probabilistic insights with more traditional engineering analyses.

Other countries consider PSA findings just as an auxiliary tool that would have no influence on regulation if they are not in agreement with traditional procedures.

7. ROLE OF PSA IN SAFETY REGULATION - CURRENT PSA APPLICATIONS

7.1 Introduction

Review of PSA experience in member countries indicates a growing usage. Although, in some cases, the concept of living PSA is still being developed with the ultimate field of application still somewhat undefined. In most countries this development is proceeding as a co-operative effort between the utilities, the regulatory body and (if applicable) the supporting vendors. It is evident that the support andinitiatives of the utility to enter a PSA programme is essential for its success. Therefore, it is worthwhile to note that in a few cases, PSA involvement was primarily driven by a utility desire to use the technology to guide a safety management programme. Either as an internal commitment only, or as a means of supporting regulatory interactions to manage plant safety enhancement programmes.

But, also it can be recognised that the establishment of a regulatory commitment provides momentum and stamina to further development and establishment of a living PSA programme. According to reference 7.8.6, "The most successful programmes appear to be those where during the development phase the regulators accepted PSA insights as a means of (re)evaluating the implementation of deterministic requirements for existing plants and could accept relaxation or exemption if necessary."

This reference include a list of **"Benefits Recognised by Users"** is included. There is striking resemblance between this list and the list of current PSA-applications as discussed below. To place the observed current uses of PSA in a broader perspective this 'benefits' list, which is mainly the viewpoint from industry, is repeated here.

Benefits on Plant Design and Design Process

* Identification of plant vulnerabilities.
* Resolution of plant vulnerabilities.
* Design optimisation through system engineering perspectives on how to address multiple safety concerns without introducing new concerns (integration capability)
* Identification of design alternatives.

Benefits to Plant Operations

* Improvement of Procedures and Technical Specifications
* Improvements in operator performance through EOP improvements and enhanced training.
* Improved equipment availability through optimised test and maintenance intervals.

* Justifications for continued operation.

Improved Communications with Regulators

* Exemption from ineffective regulatory requirements.
* Replacement of required modifications with more effective modifications.
* Support of regulatory interaction.
* Improved ability to deal with the technical aspects of regulatory requirements.
* Enhanced credibility with regulators.

Improved internal Decision Process.

* Basis for prioritisation of plant modifications.
* Elimination of ineffective design changes.
* Operational strategies.
* Assessment of ageing effects.

However, despite these recognised benefits some negative influences, limiting the implementation of living PSA programmes, were also mentioned. One of the identified limiting factors has also handicapped the necessary appreciation of PSA by some of the regulatory bodies.

"Credibility in the technology has been undermined by the frequently stated and legitimate concern of PSA technologist with the limitations of PSA and with absolute accuracy of the bottom line estimates. This has eroded credibility in this technology even in those applications, typical of living PSA, where the impact of such limitations is less important and can more easily be obviated."

Despite these negative factors, a growing application of PSAs and PSA techniques could be observed in the last few years, which in its turn has caused this lack of credibility to be transformed into a more healthy assessment of strengths as well as weaknesses. This will mitigate misinterpretation, or even misuse of PSA results.

7.2 Synopsis of current PSA Applications in OECD/NEA Member countries

The PSA uses dealt with in the questionnaire and associated responses can be grouped in various consistent and logical areas. For the benefit of readability the following grouping has been chosen:

* Use of PSAs for identification of weaknesses, backfitting and design
* Use of PSAs to support plant operation
* Use of PSAs to support regulation
* Use of PSAs for off-site risk management.
* Use of PSAs for other applications, e.g., prioritisation of R&D.

It is evident that some uses belong to more than one group. Especially, this is the case when a particular use of the PSA is beneficial for both plant operation and regulation. Examples are the use of PSA for the analysis of probabilistic safety indicators, or the use of PSAs to support decision-making during emergencies. If the objectives of a specific use of the PSA, as indicated by the question, vary amongst the various countries, then that particular use is repeated under the appropriate grouping headings.

From the responses on the questionnaire, the following results could be derived:

7.3 Use of PSAs for identification of weaknesses, backfitting and design

1. **Identification and comparison of alternative design and procedures (backfitting).** In almost all countries this PSA application was found to be the most commonly used. Identification and comparison of weaknesses in design and operation, and the effect of consequential fixes (backfitting programmes) was seen as one of the most important applications of PSA. In the USA, a lot of effort has been put into reviews of PSA studies of advanced evolutionary reactor designs (e.g., ABWR, CE System 80+, etc.) and, along with Italy, into the reviews of PSA studies for passive and simplified reactor designs, (e.g., AP600, and SBWR). In Japan PSA is used in the design process of the ECCS for ABWR. Also in Sweden mini-PSAs, simplified PSA of Forsmark-3, are used in the design process for the next generation of ABB Atom's BWR.

2. **Incident analysis or generic precursor studies.** Only a few countries gave a positive answer regarding the current regulatory use of PSAs for incident analysis or having a programme on precursor studies. Only in the USA is an Accident Sequence Precursor (ASP) programme is in progress. In Germany ASP studies are conducted as part of the evaluation of incidents or events observed in plant operation on a case by case basis. In Finland a programme has been developed to analyse Licensee Event Reports (LERs) provided by one utility with the help of the living PSA-code of that particular plant. In Spain a programme is under development to use PSAs for incident analysis. In the UK some developmental research is in progress.

3. **Accident Management Planning; Improvement, Optimisation of Emergency Procedures. Derivation of Accident Management Measures.** In most of the member countries, PSA insights and outcomes have been used to review and improve the existing Emergency Operating Procedures (EOPs) and to implement technical measures to cope in a better way with severe accidents. For example, in Switzerland the addition of the containment filtered venting system led to special Accident Management procedures for mitigating the containment overpressure failure, and/or to mitigate the H_2 problem. Another example is that in Germany, in the case of a BWR, credit can be taken for the high flexibility in the use of various injection systems for core cooling. In case of Station Blackout, fire fighting systems, drinking water supply and a mobile pump can feed into the reactor pressure vessel (RPV). EOPs ensure an activation in a relative short time. In Japan **Level 2**- PSAs (level 1 PSA plus containment performance evaluation) have been conducted for all NPPs for internal events during full power operation in order to determine the characteristics of the plants under severe accident conditions and to determine the essential severe accident measures. In the Netherlands, strategies and measures are being developed for physical protection of the Drywell bottom of a BWR to cope in a better way with drywell shell melt-through scenarios. This effort was the result of both **Level-2** and **Level-3** PSA insights. In Belgium Catalytic Hydrogen Recombiners for Severe Accident Scenarios will be installed in all the plants. This decision was based on the **Level 2**- PSA results. In the USA, PSA is widely used as a tool in the development of Accident Management planning/strategies. An example is the development of a possible A.M. measure to cool the in-vessel debris by cooling the vessel externally via flooding of the drywell (BWR) or the reactor cavity (PWR). This development involved the use of influence diagrams / decision trees to choose between flooding and do nothing (flooding influences the probability of ex-vessel steam explosions, and consequently containment failure). **Level 2** results played an important role in those influence diagrams.

4. **Other.** In France PSAs are used in the design process of a future plant. Also in Italy PSA activities are centred around future reactor designs. See discussion under "Identification and comparison of alternative design and procedures".

7.4 Use of PSAs to support plant operation

1. **Exemptions, specific improvements, or general optimisation of limiting conditions of operation. (Review and/or optimisation of Technical Specification).** In the majority of countries this typical PSA application was used. Optimisation of test- and maintenance intervals, relaxation of Technical Specifications (TS) were the most commonly mentioned applications. For the other countries this application was seen as a 'certain' future application of PSA. In Sweden, as a Nordic joint project, several case studies were carried out to review and optimise TS. These studies included analyses of:

* Plant shut-down requirements at multiple failures in redundant safety systems.
* Modified rules for preventive maintenance in a highly redundant, RHR-system at power operation.
* Modified surveillance test intervals and test procedures of highly redundant systems of diesel generators and Motor Operated Valves.

A more detailed description of this project can be found in references 7.8.8 and 7.8.10. In the USA PSAs have been used for evaluating the risk impacts of relaxed TS requirements for Allowed Outage Time (AOT) and Surveillance Test Interval (STI). and a handbook (NUREG/CR-6141) for performing risk based analyses of TS has been prepared. In the UK PSA is used to support and to define Technical Specifications.

2. **Evaluation or improvement of operator training programmes.** In about half of the responding countries PSA insights were used to evaluate and/or to improve the operator training programme. The most important accident sequences of the PSA were used to improve the training on the simulator (e.g., In Switzerland the training programme for the Mühleberg NPP crew was intensified regarding ATWS sequences) and to improve the Emergency Operating Procedures. In Sweden, the PSA was used to improve or to extend the Emergency Operating Procedures (EOPs) (e.g., for backflushing of strainers in the ECC system after pipe break LOCA, or feed and bleed measures in PWR). In the USA, PSA has been used informally as input for operator training evaluations, e.g., to evaluate the ability of control room operators to exercise the EOPs, and the effectiveness of the EOPs. In Japan training was strengthened for the potential important accident sequences. In the UK, the symptom based emergency response Guidelines have been developed in parallel with the evolving PSAs.

3. **Ageing analysis.** In only a few countries is ageing analysis (trending) forms a formal and integral part of the plant-specific data-collection efforts. In Finland, the Loviisa data collection and processing system contains a special trend analysis tool, which is able to analyse reliability growth or ageing of specific components. The changes in component reliability are automatically taken into considerations in the periodic Loviisa PSA updates. In the USA several NRC sponsored projects were undertaken within the Nuclear Plant Ageing Research Program (NPAR), with the main emphasis on "Risk-based management of ageing effects".

4. **Analysis of probabilistic safety indicators.** In some countries PSAs are used to analyse or to develop probabilistic safety indicators. In the Netherlands in one of the NPPs a Risk Monitor is being tested (outside the control room!; Risk follow-up) with a possible objective to derive indicators and reference points based on the combination of the outage-time (including estimated repair time) of safety graded equipment and the consequential core damage frequency. Also in Sweden, as part of the ongoing

Nordic research project), methods for risk follow-up and risk control (on-line risk monitoring) are developed and tested. In the USA, a system of off-line risk based performance indicators is under study. In the UK some plant have on-line or off-line risk monitors that can provide indications of safety.

5. **Support during emergencies or emergency planning.** In Finland, PSA calculations (importance measures) played a role in the recovery actions being taken during a fire incident at the TVO plant [fire damaged the 6,6 kV circuit breakers].

6. **Other.** In several countries Reliability Centred Maintenance is initiated as a procedure (Mexico and The Netherlands). Also maintenance planning and optimisation is mentioned in a few occasions (Spain and UK).

7.5 Use of PSAs to support regulation

1. **Prioritisation of inspection tasks.** In several countries PSA results were used to prioritise inspection tasks. In several other countries this was foreseen as a future application. It might be concluded that this application is rather new and only being used on an ad hoc basis, and that there is up till now little experience. In Mexico it is seen as one of the most important PSA applications for the regulatory body. In the USA, the use of risk-based information for inspection purposes started in the early 1980's with the development of plant risk inspection guides (RIGs). These RIGs, developed from the plant specific PSA, provided the necessary risk-based ranking of systems, components and operator actions. Also, for those plants not having a plant-specific PSA, generic risk-based guidance was developed (NUREG/CR-5637 and NUREG/CR-5692), including the method to make plant specific adjustments.

2. **Periodic Safety reviews.** In most countries, PSA plays a role in the Periodic Safety Review (PSR). For example, in Switzerland for the older plants, these periodic safety reviews are also required as part of the operating license renewal process. The PSRs are based on an updated Safety Evaluation Report, an updated plant-specific PSA, a report showing that the quantitative safety requirements are met (Total Core Damage Frequency less than 1E-4 per reactor year at the 95th percentile level) and a detailed review of plant-specific experience. PSAs are therefore an important part of PSRs, to demonstrate that plant safety is adequate, and that plant risk is acceptably low. In Sweden the next round of plant specific PSAs is undertaken, a project called ASAR-90.

3. **Support during emergencies or emergency planning.** In the USA, a prototype BWR Functional Incident Response Tree (FIRST) methodology was developed to assist the reactor safety teams (within the NRC response organisation) in their determination of potential accident outcomes. The prototype system used a generic event tree format. After initial testing during emergency exercises, the complexity of the system was found to be incompatible with the compressed times associated with decision-making during an emergency and the project was terminated.

4. **Quality Assurance (QA) Programme Optimisation.** Only one of the replying countries (USA) provided a positive answer to this question. In the USA, plant-specific, graded QA programmes are being developed which include (a) a process that will establish the plant-specific risk significance of SSCs in a reasonable and consistent manner, (b) an effective root cause and corrective action programme, (c) QA controls whose extent and nature reflect the safety function and significance of SCCs, and ensure safety margins while minimising unnecessary economic burdens, and (d) a feed-back mechanism for reassessing SSC risk significance and controls as new information becomes

available. The last item reflects the dynamic nature of risk and is an essential feature of graded QA programmes.

5. **Changes to regulations and guidance or general regulatory effectiveness evaluation.** In only a few countries do PSAs impact, or are likely to impact regulation. In the USA. the NRC issued Regulatory Analysis Guidelines (NUREG/BR-0058) which involve the use of PSA methods to screen and to prioritise safety issues for particular classes (or types) of NPPs. This process also includes cost-benefit considerations [references 7.8.4 and 7.8.5]. See further the discussion under prioritisation of research and development activities.

   In institutionalising the Regulatory Improvement Program and adopting a performance-based regulatory approach, the NRC has formulated a performance oriented framework for revisions to its regulations. As a first step to the regulatory improvement program, NRC initiated studies for regulations that appear to be "**Marginal to Safety"**. For example, the NRC is determining how risk insights can be incorporated into its fire protection, containment leakage testing and quality assurance regulations.

6. **PSA as a tool for decision analysis; cost/benefit analysis.** In only two countries PSAs are used in a formal decision analysis. In Finland, two pilot studies were initiated to investigate the usefulness of a formal decision analytic approach for real case safety decisions. The decision analysis was carried out in several sessions in which decision-makers, technical experts as well as experts in decision analysis participated. A multi-attribute value function was applied as a decision model so that attributes had to be defined to quantify the levels of achievements of the objectives. The attributes included both indicators related to the level of operational safety of the plant such as core damage frequency given by PSA, and indicators related to the safety culture, i.e., how well the chosen option fits in the regulatory policy. In the USA, cost-benefit analysis has been applied by utilities to optimise backfitting strategies and by the NRC as an integral part of Regulatory Analysis. 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 prioritisation parameter above a certain value are automatically given a "high" priority. Issues with all prioritisation parameters below a certain level are automatically given a "drop" priority. For values between these limits, the value/impact ratio (currently 1000 $/ person-rem) is used in conjunction with prioritisation parameters to assign a priority level.

7. **Other.** In the USA steps are being taken to improve PSA skills and training at NRC. Specific actions include expanding and improving the formal technical training curriculum at its Technical Training Center and recruiting outside the agency to add staff with critical PSA skills.

   In Japan initiating event frequencies are used to exempt some Postulated Initiating Events (PIEs), such as multi-failure of the process systems and aircraft crash to the reactor from further deterministic safety evaluations.

7.6 Use of PSAs for off-site risk management

1. **Safety Objectives or Safety Goals.** It is now widely recognised that PSAs 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). Most OECD/NEA member countries use 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

recognised. 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).

See reference 7.8.7 for further details.

2. **Support during emergencies or emergency planning.** In a few countries, Netherlands and Switzerland, PSA methods and outcomes have been used for regulatory decision-making to define and/or to modify the so-called Reference source term, which is the basis of the off-site emergency planning procedures.

7.7 Use of PSAs for other applications, e.g., Prioritisation of R&D

Prioritisation of research and development activities. In some countries PSA programmes had a clear interaction with the ongoing research programmes. A clear example is France, where the PSA of the shut-down modes had led to research activities concerned with boron-dilution incidents. Another example is the current development of a fire risk code in Switzerland. Some countries considered their first experiences with PSA techniques, the learning process, also as PSA development. In Sweden after the first round of plant specific PSAs, a comprehensive research project called SUPER-ASAR, was undertaken by the regulatory body, aimed at establishing 'recommended' resolutions of critical issues identified in the various PSAs. E.g., treatment of common cause failures, human dependencies, and assumptions of reliability data, were quantified in scoping studies. In the USA, the use of PSAs to screen and prioritise generic safety issues has been a high-level decision-making tool in the last few years. It is the backbone of the Regulatory Analysis Programme [references 7.8.4 and 7.8.5]. Underlying motivations of this process are originating from the Backfit Rule (10 CFR 50.109) and the policy statement on "Safety Goals for Operation of Nuclear Power Plants". In Japan Level 2 PSA outcomes are used to identify and prioritise important areas of severe accident research.

7.8 References

7.8.1 U.S.-NRC; *A Review of NRC Staff Uses of Probabilistic Risk Assessment*, NUREG-1489, March 1994.

7.8.2 U.S.-NRC; *Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, Final Policy Statement*, Federal Registry Volume 60, No. 158 August 16, 1995, 42622.

7.8.3 U.S.-NRC; *Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment (PRA)*, SECY-94-219, August 1994.

7.8.4 U.S.-NRC; *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission*, NUREG/-BR-0058, Rev. 2, August 1993.

7.8.5 US-NRC, *Regulatory Analysis Technical Evaluation Handbook*, Draft Report, NUREG/BR-0184, August 1993.

7.8.6 OECD/NEA, *Living Probabilistic Safety Assessment for Nuclear Power Plant Management,* A report by a Group of experts of the NEA Committee on the Safety of Nuclear Installations, February 1991.

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7.8.8 IAEA, Working Material on *Use of PSA in the Regulatory Process*, A report of the Specialist's Meeting organised by the IAEA and held in Vienna, 26-29 April 1993, IAEA-J4-SP-803.2.

7.8.9 IAEA, Working Material on *Use of PSA in the Regulatory Process*, A report of the Technical Committee Meeting organised by the IAEA and held in Vienna, 5-8 December 1994, IAEA-J4-TC-803.3.

7.8.10 IAEA, *Risk based optimisation of Technical Specifications for Operation of Nuclear Power Plants*, IAEA-TECDOC-729, December 1993.

8. ROLE OF PSA IN SAFETY REGULATION - FUTURE PSA APPLICATIONS

8.1 Introduction

This question was intended to allow each country to identify and discuss the regulatory applications of PSA it has under consideration or development

The question, presented in the form of a request for information on future regulatory applications, is both general and open-ended. This section of the report summarises the responses with regard to future regulatory applications of PSA anticipated by the contributing countries. It is intended to distinguish the mere continuation of current activities from new activities or current activities that are undergoing or are about to undergo significant modification.

The responses of the contributing countries vary in considerably in scope and detail, depending on the size and history of each country's nuclear power plant (NPP) program. Consequently, many of the particulars presented in the summary are from those countries with large, well-developed NPP programs. The responses to this question presented below are organised into the following summary, categories: (1) PSA Development and Use in Regulatory Decision-Making; (2) Risk-based Configuration Management; (3) Importance and Prioritisation; (4) Severe Accident Issues; (5) New Plants and Advanced NPP Designs; (6) Operational Events and Development of PSAs for RA Use; (7) Current NPP Design and Operation; and (8) PSA Effects on Regulations. These categories are somewhat arbitrary in that some applications in some categories could logically have been placed in other categories as well. The specific applications and associated activities related to each category were further grouped into subcategories of application. Listed with each category and each subcategory are the countries which are actively considering or developing

associated methods of application of PSA or related activity, as well as those countries which anticipate making significant changes to their current application practices within the near future. Also shown are countries that already utilise PSA for specific applications with the sub-category and do not anticipate making significant changes to their associated practices in the near future. Naturally, in the presentations that follow, some applications are discussed in more detail than others.

CATEGORIES OF FUTURE PSA APPLICATION		COUNTRIES WITH APPLICATIONS
8.2	**PSA Methods and Standards Development for Use in Regulatory Decision-Making**	Spain, Canada, Germany, Korea, Switzerland, UK, Japan, USA, Finland, Netherlands
	PSA Standards and Criteria	Spain, Korea, UK, USA, Canada, Netherlands*
	RA Prepared Guidance for Performing PSAs	Canada, Germany, Korea, USA, UK*, Netherlands*, Finland*
	Development of Safety Goals	Korea, Canada, UK*, USA*, Netherlands*, Germany, Finland*
	Regulatory Analysis (Cost/Benefit Backfitting)	Spain, Switzerland, Canada, UK, Netherlands, USA*
	Development of Seismic PSA Technology	UK, Japan, USA, Germany, Switzerland*
	Level 2/Level 3 Enhancements	Japan, USA, UK*, Germany, Finland
	HRA Enhancements	Germany, UK, Japan, USA, Finland, Netherlands, Spain, Switzerland*, Canada
	PSA Based Safety Indicators	Spain, Finland, Switzerland

* The asterisk indicates that the country already uses PSA for specific applications within the subcategories and that the country does not anticipate making significant changes to its associated practices within the near future.

Experts in many countries recognise that there are areas in current PSA methodology and application practices where improvements can be made to increase confidence in the analysis results. In general, these areas are associated with practical limitations in current methods, models and data used in PSAs. Programs are contemplated or underway to improve the understanding and modelling of the complex phenomena associated with the analysis. Many nuclear regulatory authorities (RAs) have indicated that programs are being initiated in their respective countries to improve the PSA in such areas as human reliability analysis, analysis of common-cause failure, evaluation of seismic hazards, and **Level 2/Level 3** methodology. Human performance issues associated with errors of commission and with organisation and management impact are examples of current PSA limitations. Although it is recognised that variations in application practices and methodology, and the unavailability of plant-specific reliability data, are likely to affect estimates of risks, the PSA framework is itself a powerful tool for logically and systematically evaluating the sensitivity and importance to risk of these and other factors and for evaluating the associated uncertainties.

It should be noted, however, that while advances in PSA methodology and applications practices are being made, following properly prepared guidance can assure that less well developed areas are treated the same way in all studies so that advances in methodology and application practices can be incorporated, as

they become available, in an orderly updating procedure. In addition, as indicated above, the sensitivity of results to uncertainties associated with assumptions can generally be estimated. Various countries are vigorously applying PSA in safety regulation and have developed or are in the process of developing safety goals, regulatory analysis (i.e., cost/benefit analyses) guidance, guidance for performing PSAs, and PSA acceptance criteria. In the UK, for example, the RA is researching the definition of acceptance criteria for sensitivity studies.

PSA is in a state of transition from its use as an exploratory tool, mostly for gaining insights into plant vulnerabilities, to its use in a much wider range of regulatory and utility risk management applications. Comprehensive implementation of PSA in a wider regulatory arena requires (a) more rigorous standards for performing PSA (assuring state-of-the-art PSA analyses of quality and precision commensurate with the needs of specific regulatory applications), (b) a process for achieving consistency in interpretation of PSA results and implications (at the same time establishing a reasonable basis for public expectations), and (c) a high level of confidence throughout the nuclear community (vendors, licensees, and regulators) in the methodology and its application (including confidence in the data incorporated in plant-specific analyses).

With regard to PSA in regulatory decision-making, there are at least two classes or levels of PSA application; one is insights oriented and the other is decision oriented. The USA Individual Plant Examination (IPE) program provides examples of the former. IPE PSAs were performed with little formal guidance concerning methodology since the IPE program had the somewhat narrow objective of helping licensees better understand their plants and severe accident vulnerabilities. The latter, however, has to do with licensing and regulation, and requires a more rigorous adherence to agreed-upon practices in order to allow for ready interpretation of summary indicators of risk (e.g., core damage frequency [CDF]) without having to make allowances for the impact of unagreed-upon and unquantified assumptions, model variations, and data interpretations.

The current state-of-the-art in PSA is such that most RAs have found it prudent not to rely on PSA alone in making regulatory decisions. There is a general consensus that PSA is more effective when combined with more traditional engineering analyses for decision making.

Most countries have initiated or are initiating PSA programs directed toward systematically introducing PSA into their regulatory activities. Some RAs are examining specific applications to identify special PSA modelling and data requirements, some are developing probabilistic safety criteria and/or safety goals, and some are developing PSA safety indicators. Several RAs are in the process of developing cost/benefit guidelines for backfitting. In addition, other RAs are considering or are in the process of developing a comprehensive methodology for seismic risk analysis, which will likely including seismic hazard evaluation methods, seismic response analysis codes for structures, systems, and components (SSCs), a suitable fragility database, and appropriate computer codes.

CATEGORIES OF FUTURE PSA APPLICATION		COUNTRIES WITH APPLICATIONS
8.3	**Risk-based Configuration Management**	Mexico, Netherlands, Finland, Switzerland, UK, USA
	During Normal Operation (most with Real-Time Risk Monitoring)	Mexico, Netherlands, Finland, Switzerland, UK, USA
	During Low Power/Shutdown Mode Operation	Finland, Switzerland, UK, USA, Netherlands

Various experts have concluded that throughout plant life, risk is controlled most effectively when both configuration specific and integrated cumulative risk levels are evaluated in "real-time" and controlled by appropriate configuration and activity management. In this light, configuration management involves managing component, train, and system unavailability during all modes of operation so as to keep the overall plant risk, within acceptable limits. Several RAs have initiated programs to develop risk-monitoring methodologies, that is, risk-based configuration management systems. For example, in the UK, Heysham 2 has real-time monitoring capabilities and the RA encourages further development of risk-based configuration management but has no specific, formal regulatory requirement at this time (It should be noted that, although Sizewell B will have a capability to perform similar calculations to Heysham 2, these will be performed off-line and the computation time is expected to be longer). The objective of a risk-based configuration management system is to use PSA concepts and methods to avoid potential high-risk configurations by monitoring the plant and making appropriate adjustments for planned and unplanned activities. This involves timely identification of the risk-significant failures of components, trains, and systems; determination of real-time risk profiles of the plant as changes occur (or are anticipated); and the rescheduling of maintenance and testing in such a way as to minimise the configuration specific and cumulative risk to plant safety. In the future, configuration management is expected to be an area in which the application of PSA to nuclear power plant operation will likely make a significant impact on safety.

CATEGORIES OF FUTURE PSA APPLICATIONS		**COUNTRIES WITH APPLICATIONS**
8.4	**Importance and Prioritisation**	Mexico, Canada, Netherlands, Spain, Finland, Korea, France, Switzerland, USA, UK, Germany, Belgium
	MOV Testing	USA
	IST Scheduling and Customised Inspections and Test Programmes	Mexico, Netherlands, Finland, Switzerland, USA, UK*, Korea, Spain, Germany*
	Graded QA	USA, Spain
	Maintenance	Canada, Spain, France, UK, Switzerland, USA, Netherlands
	Technical Specifications	Netherlands, Spain, Finland, Switzerland, Korea, USA, UK Belgium

* The asterisk indicates that the country already uses PSA for specific applications within the subcategory and that the country does not anticipate making significant changes to its associated practices within the near future.

Numerous licensee activities subject to regulatory approval can benefit from the application of PSA methodology to properly focus the attention of licensees and the regulator on those aspects that have the largest safety impact. Examples of these activities include (a) verification of the capability of safety-related motor-operated-valves (MOVs) to perform their design-basis safety functions, (b) scheduling of in-service testing (IST) and the establishment of more effective and efficient (train or system) customised testing and inspection programs, (c) development of graded quality assurance (QA) processes, (d) development of a maintenance program and compliance with associated regulations, and (e) execution of programs directed toward either the improvement of current (deterministic-based) technical specifications (TS) through the

incorporation of reliability- and risk-based methods or the development of new risk-based configuration management type TS.

(a) In the USA, guidance is being developed to use plant-specific PSAs to identify the most safety-significant MOVs and prioritise testing.

(b) In some countries, for example, Finland, Mexico, Netherlands, Spain, Korea, USA, and Switzerland, RAs intend to develop general risk-based in-service test and inspection practices (some with associated guidance for licensees and methods for verification of effectiveness) that (1) help focus attention on tests and inspections that are most needed and (2) provide a framework for allocating test and inspection resources in a cost-effective manner. The insights and experience of RA inspectors are recognised as key elements in development of risk-based inspection plans.

(c) In the USA, plant-specific, graded QA programs are being developed which include (1) a process that will establish the plant-specific risk significance of SSCs in a reasonable and consistent manner; (2) an effective root cause and corrective action program; (3) QA controls whose extent and nature reflect the safety function and significance of SCCs, and ensure safety margins while minimising unnecessary economic burdens; and (4) a feed-back mechanism for reassessing SSC risk significance and QA controls as new information becomes available. The last item reflects the dynamic nature of risk and is an essential feature of graded QA programs. Spain also plans to use PSA to optimise QA programs.

(d) In many countries the RA believes that the effectiveness of maintenance must be assessed on an ongoing basis and in a manner that provides reasonable assurance that key SSCs remain capable of performing their intended function throughout plant life. In some countries, future, comprehensive plant maintenance programs will include the use of PSA to categorise SSCs according to risk significance.

(e) In many countries regulators are encouraging the use of PSA in streamlining plant-specific TS. In general these efforts involve the calculation of risk associated with changes in allowed outage times (AOTs), limited conditions for operation (LCOs), and the simultaneous entering of LCOs of separate safety systems. This measure is expected to produce an improvement in NPP safety through the use of improved TS bases, a reduction in action statement induced plant transients, and make more efficient use of regulator and industry resources.

CATEGORIES OF FUTURE PSA APPLICATIONS		COUNTRIES WITH APPLICATIONS
8.5	**Severe Accident Issues**	Canada, Spain, USA, UK, Belgium, Germany, Japan, Netherlands, Switzerland, France, Finland
	Accident Management	Spain, USA, Netherlands*, Belgium*, Germany*, Japan*, Switzerland*, UK
	Operator Training and Licensing	Canada, Spain, USA, UK*, Japan*, Finland*
	Simulators	Canada, Finland*
	Emergency Planning	Netherlands*, USA
	Containment Leakage Requirements.	USA
	Fire Protection	USA, France, UK*, Germany, Spain, Switzerland*, Netherlands*, Finland*

* The asterisk indicates that the country already uses PSA for specific applications within the subcategory and that the country does not anticipate making significant changes to its associated practices within the near future.

In many countries, PSA is already satisfactorily incorporated in established accident management programs. In the USA, accident management is being implemented as part of a voluntary industry initiative. A key product of the RA/industry accident management activity is vendor-specific severe accident management guidelines. To confirm the adequacy of licensee implementation, work is underway to develop generic and plant-specific risk insights to serve as a basis for assessing completeness of utility accident management program elements (e.g., severe accident training) and to support regulatory audits of licensee accident management programs at selected plants. This work involves performing an assessment of accident management information contained in IPE databases in order to identify insights and information regarding accident management strategies and capabilities that should be included in the utility accident management program. Spain and UK also plan to use PSA to develop plant-specific accident management strategies.

In Canada, Spain, and USA, work is being initiated to incorporate PSA insights into planned revisions to guidance for operator licensing related activities. This is expected to include operator monitoring, the evaluation of insights from plant-specific PSAs (internal and external events - particularly HRA portions), and the incorporation of possible enhancements based on operating experience and industry feedback.

CATEGORIES OF FUTURE PSA APPLICATIONS		COUNTRIES WITH APPLICATIONS
8.6	**New Plants and Advanced NPP Designs**	Italy, Germany, France, USA, UK, Netherlands, Canada, Japan
	Design Review (and Certification)	USA, Canada, Italy, Germany, France, UK, Japan
	Licensing	USA, Netherlands, Canada, Finland

As part of the standard design approval process, applicants in some countries require submittal of a design-specific PSA for RA review. In general, the RA's assessment includes the traditional evaluation of events that could lead to core damage and off-site consequences, as well as an evaluation of what the PSA

reveals about the design. Review of PSA evaluations of plant design is typically not governed by explicit formal criteria to the same extent as deterministic evaluations.

In all countries, the RA plans to begin or continue to use PSA to supplement deterministic analyses in developing and reinforcing defence-in-depth strategies for their next generation of NPPs. PSA is expected to be used to support the choice of design options, including those involving redundancy and diversity of safety systems. For example, PSA is expected to play a prominent role in the design phase of the common French-German development of a "next generation" PWR.

CATEGORIES OF FUTURE PSA APPLICATIONS		COUNTRIES WITH APPLICATIONS
8.7	**Operational Events Assessments and Development of PSAs for RA Use**	Spain, Netherlands, France, Belgium, Sweden, Switzerland, USA, Germany, Finland
	Events Assessment (ASP)	Spain, France, Belgium, Sweden, Finland* Switzerland, USA, Netherlands, Germany*
	Generic Issues	USA, Spain

* The asterisk indicates that the country already uses PSA for specific applications within the subcategory and that the country does not anticipate making significant changes to its associated practices within the near future.

Several countries (e.g., Sweden, and USA) are beginning or continuing to develop RA capabilities to perform simplified PSAs. The Netherlands is evaluating the option to have in-house capability to perform PSAs. In general, these efforts are intended to (a) improve models and develop guidance for conducting risk assessments of reactor events while at power, (b) develop models and guidance applicable to events that may occur during low power and shutdown conditions, (c) develop models and guidance for conducting risk assessments of event sequences initiated by external as well as internal events, and (d) develop methods for extending these analyses beyond CDF to include release and public consequence results.

Current efforts in the USA are focused on an Accident Sequence Precursor (ASP) Improvements Program. Plant-specific ASP models are being modified to incorporate insights from the IPEs for their respective plants. These models have been loaded into the integrated reliability and risk analysis system (IRRAS) code to facilitate their use. Other countries (e.g., UK) encourage the exploration of the safety benefits of ASP analyses by licensees.

Other applications of simplified PSA models and methods in general areas of risk prioritisation (e.g., generic issue prioritisation) and event evaluation are being considered and explored. The ASP methodology is a simple tool for use in risk-based screening of various issues in the regulatory environment, with the understanding that the risk significant issues that are not screened out will be subjected to more rigorous analyses. In this regard, work in the areas of developing containment event trees and simplified source terms has been recently initiated in the USA.

CATEGORIES OF FUTURE PSA APPLICATIONS		COUNTRIES WITH APPLICATIONS
8.8	**Current NPP Design and Operation**	Canada, Netherlands, France, Sweden, Finland, Spain, Switzerland, UK, USA, Japan, Belgium, Germany, Korea
	Operating Procedures	Germany*, Netherlands, Canada, Finland*, Spain*, Switzerland, USA, Japan*, Belgium*, UK*
	Design Modifications/Improvements	Japan*, Canada, France, USA*, UK*, Spain*, Finland*, Germany*, Belgium*, Netherlands
	Periodic Safety Reviews	Spain, Sweden, UK*, Belgium*, Germany*, Netherlands, Japan*, Korea, Switzerland, Finland

* The asterisk indicates that the country already uses PSA for specific applications within the subcategory and that the country does not anticipate making significant changes to its associated practices within the near future.

Perhaps the most extensive use of PSA in nuclear regulatory activities has been in the assessment of NPP design and operation. For example, Japan has recently completed an extensive individual plant examination (IPE) program, using PSA to explore operating plants for previously unrecognised or underestimated severe accident vulnerabilities, and the USA is near completion of its IPE program. Other countries are in the process of developing or implementing such a program. PSA developed for these examinations are being used to improve operating procedures and make design modifications. Also, in other countries that have no formal IPE program, for example UK and Germany, there are requirements for all NPPs to have a PSA. RAs in many countries have incorporated or are incorporating PSA in their Periodic Safety Review programs.

CATEGORIES OF FUTURE PSA APPLICATIONS		COUNTRIES WITH APPLICATIONS
8.9	**PSA Effects on Regulations**	Spain, Korea, USA, Netherlands, Canada, Switzerland, Finland
	Regulatory Effectiveness	USA, Netherlands, Canada, Switzerland
	Changes in Regulations/Policy	Spain, Korea, USA, Netherlands, Canada, Switzerland*, Finland
	Data Requirements	Spain*, Korea, USA, UK

* The asterisk indicates that the country already uses PSA for specific applications within the subcategory and that the country does not anticipate making significant changes to its associated practices within the near future.

In most countries, nuclear regulations are based on deterministic analyses. Consequently, RAs going through the process of comprehensive implementation of PSA methods in nuclear regulatory activities expect to be confronted with the challenge of making appropriate modifications to regulations.

The RA in some countries are developing guidance for evaluating changes in risk as a result of operating history, including cumulative changes to plant design, changes to TS and associated licensing bases, and other changes to plant operation. The guidance developed will then be applied to evaluation of the effectiveness of major safety issue resolution efforts and resulting regulations for reducing risk to public health and safety.

Because of the importance of reliability and availability data of appropriate quality in performing plant-specific PSAs, in some countries the RA has initiated programs or new regulations for establishing nuclear databases. These programs or regulations typically require identification of a generic-to-reactor-type list of risk-significant systems and a process for identifying plant-specific, risk-significant systems and components for which reliability and availability data are necessary, together with specification of needed human reliability data.

9. CONCLUSIONS

The main conclusions that can be drawn from the preceding text are as follows:

PSA s are generally performed by the operating utility at the direct request of, or with strong encouragement from the RA. RA s recognise that PSA can provide systematic insights into plant safety, based on the ranking of the relative importance of plant features, that cannot be gained from a traditional deterministic analysis.

PSA contains, and has the potential to reflect a number of uncertainties in plant behaviour and performance. There is no regulatory consensus on the definition of quantitative safety goals. Few examples of quantitative acceptance criteria for uncertainty/sensitivity analysis exist.

All regulators believe that PSA is of most value when it reflects the best estimate (e.g., realistic) of plant risk.

There is common agreement that PSA provides only one input to the decision making process. Cost benefit techniques can introduce a further element of uncertainty into the numerical process and this leads many RAs to view its use and development with caution.

Intensity of PSA activities is increasing world-wide. The average actual trends are to develop individual PSAs of **Level 2** or similar, including the more significant external events. Analysis of non-full power operation is still not widespread. Advantage of high degree of standardisation in design is taken in particular cases to develop generic PSAs.

Scarcity of specific reliability data to cover all needs of PSA performance is acknowledged. Efforts are being made at both national and plant specific level to collect reliability data. National data banks are only operable in a few countries. While information on initiating events is close to complete in many countries and easy to retrieve, information on equipment failures, operating hours, demands, maintenance outages, etc. is more sparse and difficult to obtain. Bayesian update of generic data is frequently required.

It is generally understood that PSA must be periodically updated to cope with changes in design and operation. Extent and frequency of updates depend on the role that PSA plays in the regulatory framework in every country.

A lot of research is being done in different areas of knowledge to improve PSA studies or develop applications. The principal areas of research include **Level 2** phenomenology, human reliability, analysis of external events, dependent failures, acquisition of reliability data and development of computational tools. Further research in such areas such as human errors, safety culture, common cause failures or component dependent failures, shutdown and low-power operation, etc., can help establish more standardised methodology in performing PSAs. Nevertheless, in spite of these difficulties, PSA development has improved significantly enough , that at this time, in many issues, and even to some extent in some of the areas mentioned above, regulators and utilities alike, are able to utilise the methodology to assist in establishing the relative safety significance.

PSAs are generally produced by the utilities. Regulatory involvement is normally limited to review practices and acceptance of PSA applications. Formal or some kind of implicit regulatory approval must be obtained generally when PSAs follow a mandatory requirement, normally after including comments made during the review process.

Regulatory review is aimed to verify that PSA is performed according to any regulatory requirements that may exist, that proper use of adequate methodologies has been made, that major plant weaknesses, risk contributors, and other insights are correct, and that the overall analyses is suitable for the specific application.

The regulatory review is focused mainly on the more important topics of the PSA and the degree of detail is always in accordance with the uses that will be made of the PSA. Often, review processes take place at several intermediate stages of PSA development, so that an important consensus between Licensee and Regulator already exists when the final report is submitted to the Regulator. National review guides have been developed only in a few countries.

Specific improvements to plant or procedures derived from the PSA are more frequently identified by the Licensee than by the Regulator. The approval of such improvements follows standard procedures established by any kind of modifications and are considered under the perspective of any other relevant technical branch.

Acceptance of PSA insights and applications in regulation is increasing world-wide. It is generally recognised that deterministic and probabilistic approaches can, and should, complement each other. Implementation of PSA techniques in regulation is growing in some countries, but still quite limited in the average.

It is now widely recognised that PSAs 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 uses PSC in one way or another in their assessment of nuclear power plant safety. Although, in most countries this use is still very limited and applied on an ad hoc basis. The nuclear regulatory requirements in most of the surveyed member countries are deterministic, aided to limited extent by probabilistic risk insights. Only in a few countries PSC play a more dominant role in the decision-making process.

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 most countries the regulatory body itself doesn't carry out PSAs. Only in a few countries does the regulatory body have real hands-on experience with PSA modelling. The reasoning behind this might be multiform. It might be an approach to get an optimal knowledge of the PSA, or to increase the confidence in the assessed insights and outcomes and, thereby, to increase the use in decision-making.

The responses of the contributing countries vary in scope and detail considerably, depending on the size and history of each country's nuclear power plant (NPP) program. The regulatory applications of PSA discussed in the responses to the question on future PSA applications were organised into the following categories for summary: (1) PSA Development and Use in Regulatory Decision-Making; (2) Risk-based Configuration Management; (3) Importance and Prioritisation; (4) Severe Accident Issues; (5) New Plants and Advanced NPP Designs; (6) Operational Events and Development of PSA for RA Use; (7) Current NPP Design and Operation; and (8) PSA Effects on Regulations.

Many nuclear regulatory authorities (RAs) have indicated that programs are being initiated in their respective countries to improve the PSA in such areas as human reliability analysis, analysis of common-cause failure, evaluation of seismic hazards, and **Level 2/Level 3** methodology. Human performance issues associated with errors of commission and with organisation and management impact are examples of current PSA limitations. Although it is recognised that variations in application practices and methodology and the availability of plant-specific data are likely to affect estimates of risks, the PSA framework is itself a powerful tool for logically and systematically evaluating the sensitivity and importance of many factors to risk and the associated uncertainty. Various countries are vigorously applying PSA in safety regulation and have developed or are in the process of developing safety goals, regulatory analysis (i.e., cost/benefit analyses) guidance, and guidance for performing PSAs.

Various experts have concluded that throughout plant life, risk is controlled most effectively when both operational configuration specific and cumulative risk levels are evaluated in "real-time" and controlled by appropriate configuration and activity management. Several countries have developed risk-monitoring methodologies, that is, risk-based configuration management systems, and others are in the process of developing or plan to develop such systems. Real-time operational configuration risk management involves timely identification of the risk-significant failures of components, trains, and systems; determination of real-time risk profiles of the plant as changes occur (or are anticipated); and the rescheduling of maintenance and testing in such a way as to minimise the configuration specific and cumulative risk to plant safety.

Numerous licensee activities subject to regulator approval can benefit from the application of PSA methodology to properly focus the attention of licensees and the regulator on those aspects that have the largest safety impact. Examples of these activities include (a) verification of the capability of safety-related motor-operated-valves (MOVs) to perform their design-basis safety functions, (b) scheduling of in-service testing (IST), as well as the establishment of more effective and efficient (train or system) customised testing and inspection programs, (c) development of graded quality assurance (QA) processes, (d) development of a maintenance program and compliance with associated regulations, and (e) execution of programs directed at either the improvement of current (deterministic-based) technical specifications (TS) through the incorporation of reliability- and risk-based methods or the development of new risk-based configuration management TS. Many countries have initiated or are initiating PSA programs directed toward systematically introducing PSA into these and other regulatory activities.

Virtually all countries have used or are in the process of using or plan to use PSA in the assessment of current NPP design and operation, and many RAs have incorporated or are incorporating PSA in Periodic Safety Review (PSR) or Individual Plant Examination (IPE) programs. In these countries, the RA plans to use PSA to supplement deterministic analyses in developing and reinforcing defence-in-depth strategies for their next generation of NPPs. The RAs in various countries are developing guidance for evaluating changes in risk as a result of cumulative changes to plant design, changes to TS and associated licensing bases, and other changes to plant operation and operating history. Several countries have programs for developing RA capabilities to perform simplified PSAs.

Because of the importance of reliability and availability data of appropriate quality in performing plant-specific PSAs, in some countries the RA has initiated or proposed programmes or new regulations for establishing nuclear databases. These programs or regulations typically require identification of a generic-to-reactor-type list of risk-significant systems and a process for identifying plant-specific, risk-significant systems and components for which data are necessary.

Tremendous efforts have been made in both OECD Member countries and Non-Member countries in the production, review and other various facets of PSA. With over 200 PSAs now completed and billions of dollars spent, it is essential that one of the main areas to be concentrated on, be how best to utilise them. In advancing this issue, one of the principal areas of emphasis needs to be on training and educating those who can best profit by this knowledge (e.g., operators, maintenance personnel, inspectors, etc.). In order to take full advantage of the insights PSA gives it is necessary that people not only have the knowledge of how to operate the plant, but, to also have a good understanding on a relative basis of what is important (e.g., systems, components, etc.) to maintaining a safe plant.

In any case, the technical and organisational difficulties can be surmounted, but strong effort is required both by managerial and operational staffs, industry and regulatory groups, and the experts in PSA themselves, to enable regulatory systems to evolve from a purely deterministic methodology to one that encompasses a well balanced deterministic and probabilistic approach, and perhaps subsequently into a risk-based regulation environment. This evolutionary concept for regulatory use of PSA seems to be one that may be adopted in many countries in the future. The timing and speed of these changes, naturally, will be guided by the specific circumstances and cultures of each country.

In addition to these general conclusions, the Organising Committee reached a consensus, based on discussions during its meetings and on the Responses to the Questionnaire, about how to decompose different aspects of the main issue into a set of questions proposed for discussion by the CNRA members at their 1995 Special Issue Meeting. Those questions, offered to the CNRA as guidance for discussion, are included as Appendix 2 to this report.

APPENDIX 1

QUESTIONNAIRE

'95 CNRA SPECIAL ISSUE MEETING

REGULATORY APPROACHES TO PSA

This questionnaire has been structured to gather together information from the different Member countries on their usage of Probabilistic Safety Analysis (PSA) within a Regulatory environment. In this regard, it is important to describe the reasoning behind performing PSAs, the current national programme, real case examples of the application of PSAs, and the direction and trends for future use of PSA, recognising the difficulties that such a direction may pose. The questionnaire is divided into 2 basic sections, with a total of five general questions, namely:

Regulatory Environment

Background and regulatory environment.

Role of Probabilistic Safety Analysis in Safety Regulation

General description of national PSA programmes
Regulatory Authority's role.
Current PSA applications.
Future PSA applications.

The questionnaire is primarily directed towards power reactor applications of PSA. However, other regulatory applications of PSA (i.e., medical uses of nuclear material and Fuel Cycle facilities) may also be addressed for individual questions, where applicable.

I. BACKGROUND AND REGULATORY ENVIRONMENT

The purpose of this question is to establish the general background on the regulatory use of PSA from each of the Member countries, in nuclear installations. In particular, it is intended to identify how PSA fits into that environment so that answers to more specific PSA questions can be put into the correct context.

QUESTION

Please describe the general background of how regulation of nuclear installations is applied in your country and the basic position on the regulatory application of PSA.

Your response should identify and discuss the following points:

- ◊ The legislation and framework of national regulatory systems.
- ◊ The extent to which the Regulator prescribes the approach to overall safety justification and the role played by PSA in relation to that justification.
- ◊ The use made by the Regulatory Authority of PSA.
- ◊ Where the regulator requires a PSA to be performed, the objective of the study should be discussed (identifying limitations in the other approaches that the PSA is judged to surmount).
- ◊ Any PSA related guidance or procedures that exist.
- ◊ Whether the scope and interpretation of PSAs differ for old and new plants?
- ◊ Whether the PSA is performed on a best estimate or a conservative basis?
- ◊ Whether sensitivity studies and/or uncertainty studies are performed and how the Regulator interprets and uses the output from such studies.
- ◊ Where quantitative safety goals or criteria exist this should be identified but the actual targets, etc., need not be given. Discuss if preconditions are established and the underlying rationale.
- ◊ Where PSA is volunteered from the utility, the background to the objectives of the study should be discussed. What use of the PSA is made by the regulator (in the absence of any PSA requirements)?
- ◊ Limitations perceived by the Regulatory Authority on using PSAs.
- ◊ What review process is followed (or required) for PSA assessment (either by the Regulatory Authority or the Utility)?
- ◊ Whether the Utility uses the same criteria and judgement process as the Regulator?
- ◊ The Regulatory attitude to the use of PSA in cost/benefit analysis?
- ◊ What proportion of plants have already had PSA undertaken? What is the intention to provide PSAs for all plants?

II. ROLE OF PROBABILISTIC SAFETY ANALYSIS IN SAFETY REGULATION

1.0 PSA PROGRAMMES

The purpose of this question is to obtain general information about national programmes for PSA applications. More detailed information about specific applications is requested in questions II.3 and II.4.

QUESTIONS

(a) What is the scope of the analysis (Level 1, 2, 3, internal hazards, external hazards, shutdown/low power modes, etc.)?

(b) Are PSAs provided for individual plants or are studies provided for a generic or specific class of plants and the results applied generically?

(c) What systems exist to collect and analyse reliability data at both plant and national level?

(d) Are PSA studies provided on the understanding that an updated study will be necessary? If so, at what intervals and what is the extent of the required update?

(e) What PSA research programmes are underway or planned?

NOTE: PSAs may be produced for a number of plants, both operational and in design. The questions listed above, may therefore need to be answered for individual plants or collectively.

II. ROLE OF PROBABILISTIC SAFETY ANALYSIS IN SAFETY REGULATION

2.0 REGULATORY AUTHORITY'S ROLE

This group of questions is intended to collect information on the role of regulators in connection with the preparation and utilisation of PSAs. Since PSAs are used as a tool in regulatory applications, conditions may exist on how regulators review or interact with the development of PSAs.

QUESTIONS

(a) What is the degree of regulatory involvement in the production of the PSAs?

(b) Is there any formal approval of the PSA by the regulator required on completion of the PSA or at stages during the production of the PSA?

(c) What are the objectives of the regulatory review?

(d) To what level of detail does the regulator assess the PSA and what, if any, review guidance has been developed by the regulator?

(e) Are plant and procedure improvements resulting PSA studies mostly identified by the utility or the regulator? How are such modifications approved?

(f) How are PSA findings accepted within the national regulator environment?

II. ROLE OF PROBABILISTIC SAFETY ANALYSIS IN SAFETY REGULATION

3.0 CURRENT PSA APPLICATIONS

Many applications are usually mentioned for PSAs. The purpose of this question is to describe some cases where real experience with regulatory application of PSA has been derived. It is also intended to find out whether PSA expertise is confined to a single group (strictly concerned with PSA) or whether it has been to some extent developed throughout the organisation. This would include the basic reasoning (e.g., causes for applying PSA,....) specific process (e.g., acceptance criteria,....) and possible generalisations applied in each case.

QUESTION

Please describe real cases of PSA applications related to nuclear safety regulation that have been experienced so far. The description should include basic reasoning and specific process for typical PSA applications like (but not limited to) the following:

- ◊ Identification and comparison of alternative design and procedures.
- ◊ Exemptions, specific improvements, or general optimisation of limiting conditions for operation.
- ◊ Prioritisation of inspection tasks.
- ◊ Incident analysis or generic precursor studies.
- ◊ Evaluation or improvement of operator training programmes.
- ◊ Accident management planning.
- ◊ Support during emergencies or for emergency planning.
- ◊ Prioritisation of research and development activities.
- ◊ Quality Assurance programme optimisation.
- ◊ Changes to regulations and guidance or general regulatory effectiveness evaluation.
- ◊ Analysis of probabilistic safety indicators.
- ◊ PSA as a tool for decision analysis.
- ◊ Ageing analysis.
- ◊ Safety objectives or safety goals.
- ◊ Periodic Safety Reviews.
- ◊ Others.

II. ROLE OF PROBABILISTIC SAFETY ANALYSIS IN SAFETY REGULATION

4.0 FUTURE PSA APPLICATIONS

Many regulatory systems in the Member countries are primarily deterministic in nature. However, there have been significant advances in the state of the art in recent years, concerning PSA. The following question relates to future application and directions for PSA applications.

QUESTION

Please identify any future regulatory applications of PSA either actively under development or being considered for future development (e.g., inspection planning, optimisation of testing and maintenance schedule, PSA based performance indicators, and periodic safety reviews).

Your response should include descriptions pertaining to the following issues for each application identified:

- ◊ Objective (e.g., risk reduction and/or resource saving).
- ◊ Special modelling or data requirements (e.g., external events modelling, plant specific data, on-line models, etc.)
- ◊ Regulatory changes required for implementation (e.g., revisions to laws or regulations, regulatory guidance, codification of acceptance criteria, etc.)
- ◊ Implementation schedule.
- ◊ Other special considerations (e.g., training for both regulator and utility staff).

APPENDIX 2

PROPOSED QUESTIONS FOR CNRA DISCUSSION

- CAN APPLICATION OF PSA INSIGHTS SUBSTANTIALLY CONTRIBUTE TO THE SAFETY IMPROVEMENT OF NUCLEAR POWER PLANTS?

- CAN PSA BE EFFICIENTLY USED TO INCORPORATE OPERATIONAL EXPERIENCE AND ADVANCES IN RESEARCH AND TECHNOLOGY INTO PLANT SAFETY IMPROVEMENTS AND VERIFICATION OF IMPROVED SAFETY PERFORMANCE?

- ARE ACCEPTANCE CRITERIA FOR QUANTITATIVE PSA RESULTS OR FOR UNCERTAINTY AND SENSITIVITY ANALYSIS ESSENTIAL OR NECESSARY FOR PRACTICAL APPLICATIONS OF PSA?

- WHAT ARE THE RELATIVE MERITS OF THE DETERMINISTIC AND PROBABILISTIC APPROACHES IN REGULATION? HOW SHOULD THE PROBABILISTIC APPROACH COMPLEMENT THE TRADITIONAL DETERMINISTIC APPROACH?

- IS THE USE OF PSA METHODS AND INSIGHTS A NECESSARY CONTRIBUTION TO THE FURTHER IMPROVEMENT OF REGULATIONS AND REGULATORY PRACTICES?

FUTURE (TOTAL?) RISK BASED REGULATIONS? SHOULD CNRA/CSNI DEVELOP A COMMON UNDERSTANDING OF THE USE OF PSA IN THE REGULATORY FRAMEWORK? IS THE DEVELOPMENT OF RISK BASED REGULATIONS AN APPROPRIATE LONG TERM OBJECTIVE FOR THE APPLICATION OF PSA?