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Regulatory Use of Risk Information - Initial Developments at Slovenian Nuclear Safety Administration

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ABSTRACT

Similarly to other regulators worldwide, the SNSA intends to enhance the use of PSA and risk insights in its activities in order to ensure a better and more focused regulatory oversight as well as improved interface with a licensee. The main aim of the SNSA is to establish PSA as a standard tool to complement the deterministic based regulation for a variety of regulatory tasks. The PSA applications should, in particular, support the decision making process as well as the interactions with the Krško NPP. As a first step in the internal use of PSA, PSA event analysis and risk based performance indicators are being introduced. In 2004, the SNSA will start introducing risk follow up and risk informed inspections. By mid 2005 the legal basis for the use of PSA will be also established in Slovenian legislation.

1 INTRODUCTION

Regulators world-wide identified regulatory activities that could benefit from inclusion of risk information. These improved activities form the basis of the overall strategy of risk-informing the regulations.

The risk-informed approach enhances the traditional deterministic approach by:

- explicitly considering a broader range of safety challenges
- prioritising the challenges on the basis of risk significance, operating experience, and engineering judgement
- considering a broader range of counter-measures to mitigate the challenges
- explicitly identifying and quantifying uncertainties in analyses
- testing the sensitivity of the results to key assumptions.

A risk-informed regulatory approach is also used to identify insufficient conservatism and provide a basis for additional requirements or regulatory actions.

A basis for risk-informed approach is a sound PSA model. A Krško plant specific PSA model and associated software is available at the SNSA. It has been developed by the Krško NPP and its consultants [1]. PSA model was also reviewed by independent reviewers, their comments considered and model updated accordingly. Evolution of the Krško PSA model is shown by Figure 1. Through numerous reviews (IAEA, TSO-s, PHARE/RAMG) it was established that the model is of adequate quality. Today NPP Krško maintains “living” PSA, using the model for different internal applications. From time to time, the SNSA also uses the PSA information in decision-making process and in its communications and discussions with the Krško NPP. The use of PSA in the plant is followed and monitored by the SNSA however there has not been any formal approval of these applications so far.

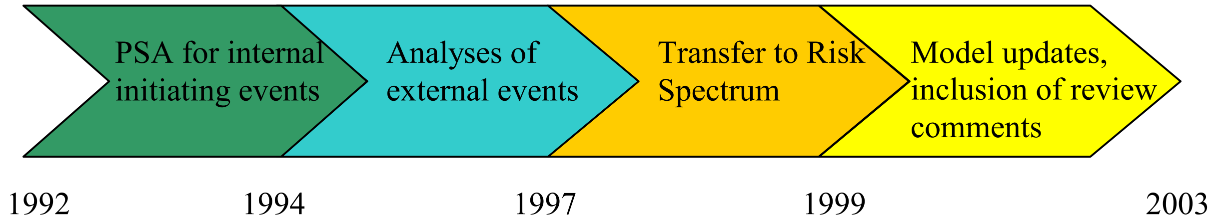

Figure 1: Evolution of the Krško PSA model

2 RISK-INFORMED REGULATORY ACTIVITIES – GENERAL CONSIDERATIONS

2.1 Risk-informed decision making

Regulatory authorities have traditionally used a deterministic approach as the basis for making decisions on safety issues. This has been done by applying high-level criteria such as the need to provide defense in depth and adequate safety margins. These have been developed into lower level requirements in order to ensure that the risk to workers and members of the public is adequately controlled. The need to meet these deterministic conservative rules and requirements for the design and operation of a nuclear facility is the basis for most of regulations, safety standards, guidance etc. that are currently used by regulatory authorities. If these rules and requirements are met, they are expected to provide a high degree of confidence that the level of risk to workers and members of the public from operation of the nuclear facility will be acceptably low. The conservative approach has provided a way of taking account of uncertainties in the performance of equipment and humans.

However, in recent years, PSAs have been produced for most of the nuclear facilities and the information provided by these PSAs are increasingly being used to complement the deterministic approach. The move has been towards an integrated approach that combines the insights provided by the deterministic approach and those from the probabilistic approach with any other requirements in making decisions on safety issues for a nuclear facility or in determining the priorities for the regulatory activities. The basic characteristics of a decision making process are shown in Table 1.

Deterministic and probabilistic approaches are both systematic approaches aimed at ensuring that the risk to workers and members to the public from the nuclear facility is adequately controlled. However, they use different assessment techniques and boundary conditions and thus have different strengths and limitations. Insights provided by the probabilistic approach complement those provided by the deterministic approach. When this integrated process is applied for making decisions about safety issues at nuclear facilities, it is referred to as Risk Informed Decision Making. When it is applied for making decisions about the way a Regulatory Authority carries out its activities, it is referred to as Risk Informed Regulation. In both cases the PSA provides only one of the inputs – the others being related to factors such as mandatory requirements, insights from deterministic analysis, insights from cost benefit analysis, etc.

The integrated decision-making process applied by regulatory authorities in making decisions about the way they carry out their regulatory activities encompasses:

- Developing, adopting and updating regulation, rules and guides,
- Issuing, amending, suspending or revoking authorisations,
- Carrying out regulatory inspections,
- Ensuring that corrective actions are taken,

– Taking enforcement actions when necessary,
– Etc.

All these activities involve judgements by the regulatory authority that can benefit from applying an integrated decision making process that explicitly takes any relevant risk information into account. Risk information can be used to prioritize the tasks within an activity, and to optimize and enhance tasks themselves. The risk concepts can be considered in a quantitative manner but there may be aspects of the operation of the installation where only a qualitative analysis is possible or where a decision is made without a need of the PSA. The need for any analysis and quality required should be judged on the importance to safety of the issue being considered. There is a great danger in spending too much time and effort on the production of the analysis rather than on practical measures affecting safety.

Table 1.: regulatory decision making process

MOST IMPORTANT INFLUENCES	TYPICAL STAGES OF REGULATORY DECISION MAKING	DECISION MAKING CRITERIA

Factors originating from various developments:
• public view on risk,
• changes in the regulatory environment and industrial scene,
• changes in the values, preferences and expectations,
Various principles:
• targeting of actions:
  • most serious risk,
  • less controlled hazards,
• consistency of actions,
• proportionality - actions commensurate to risk,
• transparency - being open on how decisions are arrived at and what are their implications.
	Issue recognition:
	• new hazards or inadequacies,
	• events and experiences,
	• new regulatory requirements (abroad),
	• public perceptions, etc.
	Issue characterisation:
	• addressing hazards,
	• safety/risk assessment,
	• uncertainties, etc.
	Available options examinations to address the merits and disadvantages:
	• research to improve knowledge,
	• review the existing good practice,
	• cost-benefits,
	• adverse consequences, etc.
	Adoption of the decision:
	• selection of the appropriate option,
	• integration of scientific, technological, economic and political factors into decision making process,
	• addressing uncertainties, assumptions, preferences, etc.
	Decision implementation:
	• constructing the regulatory tool (new decision, guidance, enforcement, etc.)
	• communication with the licensee and other stakeholders,
	• setting up priorities,
	• create the monitoring measures,
	• assuring the compliance with established principles,etc.
	Evaluation the effectiveness of actions taken:
	• achievements of intended results,
	• possible modifications,
	• lessons learned, etc.
		Types of criteria - tolerability of risk:
		• Criteria type - limits, available technology, cost-benefit,
		• Tolerability of risk:
		• Acceptability of risk,
		• Maintaining the benefits with confidence of controlling the risk,
		Some other specifics and principles of decision making:
		• Individual and societal concern taken into account,
		• Taken actions are inherently precautionary,
		• Suitable and sufficient safety assessment must be undertaken to determine measures needed for controlling the risk,
		• Controls must achieve standards of relevant good practice precautions, irrespective of specific risk estimates,
		• Relevant good practice,
		• Unacceptable risk regardless the benefits - modification necessary,
		• Residual risk monitoring regardless how low it is,
		• Numerical criteria for risk-informed decisions for some categories of risk.

A danger of concentrating too much on PSA-produced risk value is that inadequate engineering or operational procedures may be apparently justified by meeting numerical risk (PSA) criteria. It is important to get first a good design and then develop risk estimates otherwise there is a danger of justifying poor engineering and operation. Only afterwards the risk analysis should ensure that the design is balanced and there are no weaknesses. Because if numerical risk criteria are the sole criteria, the design may meet them but not be the »best« design because the PSA does not distinguish between measures which reduce the fault initiation and those which mitigate the consequence, while good engineering emphasizes early termination of fault sequences rather than mitigation of releases. It is possible, by using the intermediate risk criteria to use numerical methods to mirror some of these deterministic requirements but at the expense of a more complicated PSA.

2.2 Risk-informing the regulation

The rationale for risk-informing the regulations are expected benefits such as improved effectiveness, efficiency and realism in the regulator's decision, practice and processes, increased public confidence and reduced unnecessary burden on licensees without compromising safety.

The nature of the risk informing depends on safety philosophy which determines the policy to deal with changes in risk depending on the absolute value of the risk. One such policy is founded on the principle that »undue« risk increase is not allowed, but »insignificant« risk increase may be tolerated in some cases. If the risk is above the limit associated with adequate protection, it must be reduced regardless of the cost. If the risk is below the limit, however, the safety policy may link risk reduction to cost-benefit consideration. If the risk is substantially below the risk limit, then the safety policy may allow a slight increase in risk because of economic or other justification. Some other safety policies may not allow any increase in risk, no matter how small. These differing philosophies result in very different approaches to risk informing of the regulations.

The type and amount of risk informing also depends on the nature of the existing regulations – in particular, whether they are prescriptive or performance-based in nature. In practice, regulations often consist of a combination of prescriptive and performance-based elements. This is due to the lack of practical performance indicators for some objectives, and/or may reflect the regulator's desire to achieve its aims in a more prescriptive manner. By setting the performance goal at the highest level practical, i.e., the most aggregated level of safety significant SSC (System, Structure or Component), maximum flexibility is achieved. Since performance indicators often include risk-related data, performance-based regulations are likely to incorporate some risk elements already. Prescriptive regulations are likely to be more deterministic, while performance-based regulations are likely to be more risk informed.

In summary, extent of risk informing that is warranted for regulation in each country may depend on where the regulation falls in the prescriptive to performance-based spectrum. If a whole body of regulations has already incorporated performance-based elements to the extent practical, comparatively little additional risk informing may be called for.

The process of risk-informing the regulations needs to preserve essential factors included in the deterministic formulation of the regulations. These factors include the fundamental safety principles of defense in depth, safety margins, the ALARA or ALARP principles for radiation protection and adherence to existing safety goals. In complementing the risk information, these principles are particularly important to reduce the effects of the uncertainties that are associated with such direct challenges to plant safety as equipment unreliability, human error, severe accident phenomena, as well as the uncertainties attached to more indirect factors such as the management style and safety culture at the plant.

3 STRATEGY

Until 2002, the SNSA activity in the PSA area was limited to assuring a review of the NPP Krško PSA model, analysis and use of PSA by inviting international missions and contracting TSOs, while maintaining its own minimal level of expertise.

The legal foundations in Slovenia to use PSA in the regulatory decision-making process have been lacking. The new nuclear law, accepted in the year 2002, provides fundamentals for the inclusion of PSA in this process. The law defines ¨*Safety analysis* shall mean an analysis of the safety of a nuclear facility carried out on the basis of deterministic or probabilistic methods.″ The details of the regulatory use of probabilistic methods are still to be defined in new regulations that are expected to be issued by the middle of the year 2005.

The SNSA has launched several projects with IAEA, ENCONET and the "Jožef Stefan" Institute aiming at establishing appropriate infrastructure and transferring the know-how to enable comprehensive utilization of PSA. Within these projects:

– a basis for PSA strategy was established,
– a frame for use of PSA at the SNSA was developed,
– a basis for introduction of risk- informed inspection at the SNSA was prepared together with basic elements for such inspection,
– the combined use of deterministic and PSA-based methods to enhance the event investigation process at nuclear power plants was developed and
– quantitative criteria for temporary modifications based on PSA methodology were developed.

SNSA identified areas of specific interest in its utilisation of PSA:

– Risk informed regulatory rules and requirements
– Risk follow-up and monitoring
– Risk informed inspection
– Operational event analysis
– Review of optimisation of TS
– Review of on-line maintenance
– Assessment of modifications
– Ranking of safety issues
– Use of risk-based safety indicators
– Training of regulatory staff and managers.

The Strategy distinguishes a preparatory stage, which is mainly focused on establishing the organisational framework, and the implementation. The implementation is structured to reflect both the SNSA needs and the timing of specific PSA application. This allows for a gradual increase of knowledge and abilities to perform specific applications. Another important consideration is the continuity, which will assure that the SNSA staff devoted to PSA applications will be continuously using them rather than at intermittent time intervals. This will assure that the accumulated knowledge is actively maintained and continuously enhanced and the experience with the Krško PSA model continuously available. The Strategy is to be implemented in a stepwise fashion over a longer period (i.e. 4 years). This would both optimise/minimise the resource requirements and ease the integration of PSA application activities into the SNSA organisation.

Within the preparatory phase, two areas are considered important since they form the basis for future applications:

– Establishment of infrastructure basis for PSA applications
– Establishment of requirements for risk-informed regulatory submittal.

It should be noted that this is in addition to specific SNSA procedures which are also necessary but not essential for this phase.

A job description, qualification and training requirements for the staff (PSA staff but also others who will be using the PSA) will be developed as a part of the initial activity. Important tasks within the initial activity are also: to monitor the activities of the SNSA PSA support and its interface with other organisational units, including arrangements for using PSA in the SNSA decision-making process, to interface with the licensee on PSA application matters and to develop specific procedures that establish administrative framework for activities within the SNSA (such as organisation and QA procedures, PSA acceptance guidelines and guidelines for PSA based decision-making). A management position responsible for monitoring the PSA application activities program and co/ordination of activities within the SNSA will be also established to:

- Assure technical and timely co-ordination of the risk application activities,
- Highlight and resolve organisational problems within the SNSA,
- Monitor the resource allocation and utilisation,
- Co-ordinate human resources for implementation of specific tasks,
- Approve changes in the program implementation schedule.

The process for risk-informed regulatory review and approval of plant-specific changes will be defined. The specific aim is to establish SNSA-specific requirements for a licensee's submittal and for a review by the regulator. The requirements will specify which information needs to be provided by the licensee and which types of calculation and analyses will have to be accomplished before a request can be submitted. This will allow the SNSA to require more thorough information and to maintain consistency in various submittals.

In the frame of development and introduction of PSA in regulatory activities it is necessary to develop qualitative and quantitative criteria for risk in support of decision making. The need to establish such criteria has been heightened by the introduction of the new nuclear law and preparation of the accompanying acts. The criteria have been developed with consideration of Slovenian specifics (small regulatory body, only one NPP, Westinghouse PWR…) [1].

4 DESCRIPTION OF INITIAL DEVELOPMENTS

In 2002, the SNSA started a program to include PSA in its own work, simultaneously intensifying training of its personnel in the PSA area. At that time the SNSA was able to review the submitted PSA reports and to perform some rudimental analysis with the model. IAEA workshops and training courses were used to train SNSA personnel on use of PSA. The support provided through PHARE RAMG projects that encompassed PSA related workshops regarding event analysis, performance indicators and risk informed decision making should be also mentioned.

The initial phase of SNSA action plan for use of risk information in its work was mainly concentrated on issues related to the basis of the regulatory assessment process. The introduction of risk-informed indicators (along with other safety performance indicators) and PSA-based events analysis was also included at this phase which can be considered as almost finished. Underway is the PSA project for the year 2004 [4] with its most important goal to develop tools, procedures and SNSA personnel skills to such a level that will enable the SNSA to perform risk follow-up on a limited scale (i.e. for reviewing maintenance activities) using data and model provided by the NPP. Another equally important task is the introduction of risk-informed inspection (RII) concept to the SNSA. The implementation of this task will include two pilot inspections using RII tools and principles.

Initial activities are designed to achieve multiple objectives while preparing the SNSA for more advanced or broader applications. The initial tasks are specifically intended to:

- Gain experience in PSA applications early in the overall project,
- Address outstanding issues in relation to the Krško NPP utilisation of PSA (OLM),
- Implement useful applications to address the focus of SNSA.

The PSA-based event analysis combining the root cause analysis with the PSA approach is considered a mature application (being performed by regulators elsewhere). Although it is technically demanding, the accumulated SNSA experience is such that the use of such an analysis at SNSA is not seen to be a problem. The method proposes the combined use of the traditional qualitative root cause analysis of events with a PSA-based method called Probabilistic Precursor Event Analysis. The aim of this analysis is to provide supplementary insights to the standard root cause analysis that is predominantly qualitative. Unlike the root cause analysis that focuses on examining the causes to determine how to prevent the recurrences, the PSA-based analysis is looking at the consequences of an event to the plant, and determines the conditional risk value, which represents the level of protection remaining during and after the event. Using this approach it is also possible to perform assessment of the so-called "near misses" and quantify their potential contributions to the overall plant risk. The foundation of such a PSA application is a PSA model, verified for the use in a particular application. The model used by the SNSA was in that sense reviewed by ENCONET [3] and found to be suitable. The first draft procedure for PSA event analyses was based on ENCONET guidelines [5], while the final internal procedure [6] also incorporates our experiences gained through participation in IAEA Consultants Meeting [7]. During the introduction of the method trial PSA-based event analyses were performed on past events, while later on the method was used on analyses of past year events at NPP Krško.

Another application that is under development at the SNSA and also uses PSA related risk insights, is the use of performance indicators. That is a subject of a separate article within the same conference as this article [8].

The regulatory application chosen for the second phase of development of the use of risk information is risk follow-up. This tool is successfully used in Finland, and several regulators consider its initiation in the near future. At the SNSA, the procedure on the establishment of the monitoring needs, along with the reporting requirements for the NPP needs to be developed. Risk follow-up is called the process where operation of a plant with all operational events, plant outages and power changes, equipment outages and unavailability, etc. is placed onto the baseline PSA models to generate a timeline of risk of operation during a year. This is useful for comparison purposes, since it graphically depicts the full year of plant operation, and for public information purposes, to demonstrate how safe the plant is. The application will also place the Krško OLM process in relation to other events and deviations and potential risk evolutions. This will allow the SNSA to establish a much more accurate picture of the risk evolutions at Krško over the time, as well as instantaneous risk measures during important events. Besides gaining an insight into the level of nuclear safety at each point of operational cycle the results will also help the SNSA define areas where improvements of nuclear safety are still possible. The application is expected to be used on a trial basis and in a limited scope within one year.

Related to the above application the SNSA already acquired some knowledge on OLM review [3]. The OLM is a utility application, however a regulatory body needs to establish its own position on the matter, and be able to asses the utility application in this respect. During the last two years the Krško NPP has been performing the OLM and regularly submitting to the SNSA the risk estimates. Specific activities conducted by the regulator in relation to this application focus on the understanding of impact of various maintenance activities, evaluating the impact of the models and assumptions taken, and independently assessing their basis. On a trial basis, the selected OLM cases have been recalculated and risk impacts compared with those determined by the licensee. Specific 'what if' situations have been also evaluated to identify any safety relevant risk evolution. The SNSA will adopt a methodology and knowledge to be able to fully review this plant application within the scope of the risk follow- up.

The Risk Informed Inspection (RII) process is a highly complex task whose complete implementation will be a challenging task for the organisation and management of the SNSA [4]. The RII has been successfully implemented at the USNRC and is being implemented at the CSN. The preliminary review of regulatory inspection at the SNSA has confirmed that in many respects the inspection process is well covering a variety of aspects of plant safety but there are possibilities for improvements as far as the intensity (frequency) and the focus of specific inspection processes are concerned. A RII approach is expected to provide a basis for improved inspection that focuses on risk-significant aspects. It will also help establish a systematic structure and ensure consistency in the SNSA inspection process. PSA application will provide for a focus on safety important issues, which will then be assessed either more frequently or more thoroughly. Less important issues (or equipment) will still be inspected, but a reduction of frequency and level of detail would be desirable. The use of risk insights will be of relevance for determining safety relevance of inspection findings. The activity is to be introduced in a gradual manner, initially starting with a pilot study. Two pilot inspections using RII tools and principles are planned for this year, including the full process of evaluation of the findings. At that time it is also expected that PSA staff assignments are made, assuring that the inspectors receive the necessary risk basement support. These pilot inspections will also introduce the licensee to RII principles and activities.

5 CONCLUSIONS

The use of PSA provides many advantages that the SNSA wishes to use. The speed of the adoption of PSA in its work depends on limited financial and human resources of the SNSA. With the support of outside resources the SNSA will accelerate the introduction of the use of risk informed information (PSA) for its internal purposes, for the review of NPP Krško PSA activities and for the formal decision making. The goals are to improve the focus on present nuclear safety issues, to reduce its own workload and the regulatory burden to the licensee.

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