SKI Report 2005:37

Research

Experience with Regulatory Strategies in Nuclear Power Oversight

Part 1: An International Exploratory Study

Part 2: Workshop Discussions and Conclusions

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SKI

SKI Perspective

Background
The regulatory strategy used by SKI, has an impact on the licensee and therefore, indirectly, on the safety of the nuclear facilities. The regulatory policy and its implementation also has an effect on the way SKI is working and the competency needed by SKI as well as by the industry. One of SKI´s tasks is to be able to adjust the regulatory approach to current and future needs.

Little research is available on the use of overall regulatory strategies, methods and activities used by regulatory agencies in their work (to assure safety), as well as their impacts. To address this gap of knowledge, SKI has contracted two separate research projects, with two different approaches.

This report is the result of a project that concludes the experience with different regulatory strategies. The study was done at six agencies, in six countries, all working with regulatory oversight of nuclear activities. The research findings were discussed during a workshop. The conclusions from the workshop are included - as a separate section - in the report..

SKI´s Report 2003: 36,"How Agencies Inspect - A comparative Study of Inspection Policies in Eight Swedish Government Agencies", concludes the results from a project where regulatory activities at several Swedish regulatory agencies were compared.

Method
The first phase of this explorative study was to define a number of regulatory strategies, used in the oversight of nuclear activities. The next step was to develop an interview guide, and to collect information from experts from regulatory agencies, in selected countries. The interviews were carried out jointly with the related SKI-project on competency. See SKI Report 2005:04."Assuring Competency in Nuclear Power Plants: Regulatory Policy and Practice".

SKI´s purpose and goals
The goal of this project was to collect information on the use of different regulatory strategies in the oversight of nuclear power in selected countries. The goal was also to identify patterns in experts´ experiences in the use of different regulatory strategies regarding benefits and disadvantages, as well as to map specific issues and consequences. Finally SKI wanted to discuss the results and a common views on the issues in the participating countries.

In addition to increasing knowledge of regulatory issues, the aim of the work has been to contribute to a dialogue and exchange of information between agencies with similar tasks.

Results
A set of strategies have been defined and, data has been collected through interviews and analyzed. The focus of the study has been to compare strategies and their effects, rather than to compare organizations. Benefits and difficulties with regard to the different strategies have been identified, as well as issues and consequences. Important issues regarding the selection of strategies are described and documented. Finally the numbers of strategies were extended and some of the definitions of the strategies modified.

The results demonstrate the complexity in regulatory oversight. The selection of appropriate strategy, or combination of strategies, varies due to many factors – internal, as well as external. This became even more obvious during the workshop, where the participants agreed that;

- It is important to have a common understanding of regulatory strategies
- Regulators combine the strategies in different ways to achieve the regulatory goals
- Different factors such as context, national culture, legal and administrative framework, and the type of safety concern has an impact on the selection of strategy/strategies used
- The results regarding benefits, difficulties and other consequences and issues that arise from the use of the different strategies reflected the participants´ experience.

During the workshop suggestions to changes in the definitions were proposed. It was also suggested, that the term strategies should be changed to approaches to regulation. The reason for this was that several approaches are used in developing a strategy for each regulatory body.

Continued work

The result from this work has been presented within SKI, as well as externally. Conclusions from the two studies were e.g. presented at the Reactor Research conference hosted by SKI in 2004.

Suggestions for further work were discussed during the workshop, as documented in the report.

Effects on SKI´s activities

The study has increased the knowledge of different strategies, and their effects. The results have contributed to a wider and deeper understanding of the complexity of regulation, and demonstrated that more research is needed to better understand the relations between regulatory approaches and the effectiveness of these approaches.

Project information

Project coordinator at SKI; Iréne Tael
Project number; 01232

SKI-perspektiv

Bakgrund
Den tillsynsstrategi som SKI tillämpar påverkar tillståndshavarnas verksamhet och därmed, indirekt, säkerheten. Tillsynsstrategin påverkar också arbetssättet vid SKI och den kompetens som krävs vid myndigheten, såväl som i industrin. I SKI:s uppgift ingår att kunna anpassa tillsynsstrategi och tillsynsinriktning till aktuella behov och framtida förändringar.

Få studier har gjorts av myndigheters övergripande strategier, metoder och aktiviteter för att bedriva tillsynsverksamhet. Effekten av tillsyn har heller inte varit föremål för omfattande studier. För att öka kunskapen om tillsyn, har SKI beställt två forskningsprojekt, med olika inriktning.

I denna rapport redovisas resultatet av ett projekt, som studerat erfarenheterna av olika tillsynsstrategier. Studien har gjorts vid sex myndigheter, i sex länder, som arbetar med tillsyn av kärnteknisk verksamhet. Projektet avslutades med en workshop kring resultaten. Rapporten avslutas med en sammanfattning från workshopen.

I SKI-rapport 2003: 36, ”How Agencies Inspect - A comparative Study of Inspection Policies in Eight Swedish Government Agencies”, redovisas resultaten från ett projekt, som jämfört tillsynsarbetet vid ett antal myndigheter i Sverige.

Metod
I en första etapp av projektet definierades ett antal tillsynsstrategier. Därefter har myndighetsrepresentanter intervjuats med stöd av ett frågeformulär, som utvecklats inom projektet. Intervjuerna genomfördes parallellt med intervjuerna för SKI-projektet; ”Assuring Competency in Nuclear Power Plants: Regulatory Policy and Practice”. SKI-rapport 2005:04.

SKI:s syfte
Syftet med projektet var att sammanställa hur olika strategier används vid tillsynen av kärnteknisk verksamhet i ett antal länder. Syftet var också att kartlägga för- och nackdelar med de olika tillsynsstrategierna och kartlägga effekter. Slutligen ville SKI diskutera resultaten och gemensamma synsätt i de länder som deltagit i studien.

Förutom att bidra till att öka kunskapen om tillsynen, syftade arbetet till att främja dialogen och erfarenhetsutbytet mellan myndigheter med likartade uppgifter.

Resultat
Ett antal strategier har definierats, och genom intervjuer har erfarenheter av tillämpningen av strategierna samlats in och analyserats. Studiens fokus var att jämföra strategier och deras effekter på verksamheten, snarare än att jämföra organisationer. För- och nackdelarna med de olika strategierna har identifierats, liksom konsekvenser av de olika strategierna. Viktiga frågor kring valet av strategi har också kartlagts. Definitionerna för de olika strategierna har modifierats och antalet strategier utökats.

Resultaten visar på den komplexitet, som arbetet med tillsyn innebär. Valet av strategi, eller kombination av strategier, visar sig bero på många faktorer - interna, såväl som externa. Detta framkom tydligt också under den efterföljande workshopen, där deltagarna enades om att;

- Det är viktigt att definiera begrepp för tillsynen och deras innebörd,
- Myndigheter kombinerar strategier, på olika sätt, för att uppnå sina mål
- Faktorer som tillsynsområde, nationell kultur, legalt och administrativt regelverk, samt säkerhetsfrågans art påverkar vilken strategi som används.
- Resultaten i rapporten - för- och nackdelar och konsekvenser av de olika tillsynsstrategierna överensstämde med deltagarnas erfarenheter.

Under workshopen lämnades förslag till förändringar i definitionerna för de olika strategierna. Dessutom förslogs att begreppet strategier byts mot angreppssätt för tillsynen. Motiveringen var att flera angreppssätt bildar strategin för varje myndighet.

Fortsatt verksamhet
Resultaten har presenterats både internt och externt. Bland annat redovisades en sammanfattning vid SKI:s forskningskonferens 2004.

Förslag till nya projekt inom området diskuterades vid workshopen, vilket också redovisas i rapporten.

Effekt på SKI:s verksamhet
Den genomförda studien har ökat kunskapen om olika tillsynsstrategier och deras påverkan. Resultaten har bidragit till en bredare och djupare insikt om komplexiteten i tillsynen. Resultaten visar också att ytterligare forskningsinsatser krävs för att förstå sambandet mellan tillsynen och effekten av tillsynen.

Projektinformation
Projekthandläggare på SKI; Iréne Tael
Projektnummer; 01232

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Research

Experience with Regulatory Strategies in Nuclear Power Oversight

Part 1: An International Exploratory Study

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Report summary

This report presents the results of a study which explored the use of six different regulatory strategies for oversight of commercial nuclear power facilities: prescriptive, case-based, outcome-based, risk-based, process-based, and self-assessment strategies. Information was collected on experiences with the use of these different regulatory strategies from experts from nuclear regulatory agencies in Canada, Finland, Spain, Sweden, the United Kingdom and the United States. Systematic, structured open-ended interviews with expert regulators with extensive experience were used in order to understand how regulatory strategies are applied in practice.

Common patterns were identified regarding:

- Experts' perspectives on the major benefits and difficulties of using specific regulatory strategies;
- Experts' experiences with using regulatory strategies for three areas of oversight—design and modifications, quality systems, and training and qualifications;
- Expert views of the consequences of different regulatory strategies;
- Issues that emerged in the interviews regarding regulatory strategies.

Major benefits and difficulties of using specific regulatory strategies

The major benefit of a prescriptive strategy was that it is clear about requirements and expectations. The major difficulties were that it takes responsibility away from the licensee, it requires a high use of regulator resources and is rigid and difficult to change.

A case-based strategy had the key benefit of flexibility for adapting regulatory responses to unique situations, but the difficulties of being considered arbitrary, inconsistent, and unfair and requiring heavy resource use.

An outcome-based strategy had the main benefit of allowing licensees to decide the best way to operate in order to meet safety goals, but the major difficulty of identifying appropriate ways to measure safety performance.

The major benefit of a risk strategy was its use to prioritize safety issues and allocate resources. However, it was considered inappropriate to use as a stand alone strategy and a strategy that had serious methodological and data problems.

A process based strategy had a major benefit of providing in depth understanding of a licensee's performance. The main difficulties were that it was not considered effective

unless the processes were linked to outcomes, and that it was complex to define and evaluate processes.
The major benefit of a self assessment strategy was that it put responsibility for safety on the licensee, while the major difficulties were that it should not be used as a stand alone strategy and that it often does not have credibility with the general public.

Use of regulatory strategies in different functional areas of oversight

A few of the main findings regarding the experiences of using regulatory strategies for the areas of plant design and modifications, quality systems and training and qualifications included:

- Use of combinations of at least two, often three and at times four different strategies for specific examples of oversight issues

- Less reliance on a prescriptive strategy in recent years, often moving toward more use of a process-based strategy, but return to a prescriptive strategy for action and closure when necessary

- Use of a risk strategy to prioritize safety issues, activities and regulatory findings for oversight of both quality systems and plant design and modifications

- Disagreements over the incorporation of a risk strategy into regulatory decision-making for plant design and modifications and attempts to balance the use of a combination of risk and prescriptive strategies for this area of oversight

Consequences of different strategies

Regulatory strategies were viewed as affecting:

- Whether the licensee or regulator takes primary responsibility for safety
- How clear requirements and expectations are to licensees
- Significance of safety issues identified
- Expertise needed by regulators and licensees
- Resources used by regulators and licensees
- Flexibility given to licensees
- Public credibility

Issues that emerged from examples regarding regulatory strategies

- Resistance to changing regulatory strategies
- Tension concerning the use of risk analysis for regulatory decisions
- Differences in interpretations of regulatory strategy definitions
- Importance of combinations of strategies for regulatory effectiveness

Acknowledgments

We gratefully acknowledge the participation of six nuclear regulatory agencies in this study and thank the many managers and staff members who gave generously of their expertise and time to support this project. These agencies include the Canadian Nuclear Safety Commission (CNSC), Radiation and Nuclear Safety Authority, Finland (STUK), Consejo de Seguridad Nuclear, Spain (CSN), Swedish Nuclear Power Inspectorate (SKI), Health and Safety Executive, United Kingdom (HSE) and the United States Nuclear Regulatory Commission (NRC).

We also thank Irene Blom, Anne Edland, Brian Grimes and Ola Svenson for their support, insights on regulatory strategies and comments on earlier versions of this report and thank Lasse Reiman and Jose Villadoniga for enlightening discussions of issues concerning regulatory strategies during the planning stages for this study.

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1 Introduction

The Swedish Nuclear Power Inspectorate (SKI) sponsored this study to better understand the benefits and difficulties of using various regulatory strategies for oversight of commercial nuclear power safety. To date little research has been published on the use and impacts of different regulatory strategies.

A main purpose of this exploratory study is to contribute to a more systematic understanding of the experiences of nuclear regulatory staff with using different regulatory strategies. This type of information can facilitate the building of a better knowledge base of the conditions under which experts have found certain strategies to be more effective or less effective.

1.1 Background

Nuclear power regulators are responsible for finding reliable and effective strategies to assure safety. Finding effective strategies is a difficult task. Regulators, for example, need to establish a clear boundary between regulatory responsibilities for safety and industry responsibilities for safety, and maintain independent judgment as a regulator while working closely with the industry and relying on it as a major source of information about its operations and plans.

In selecting strategies regulators consider not only how a strategy may affect plant safety directly, but also possible indirect effects. Indirect effects may include such things as impacts on resources for both the regulator and the industry and effects on the safety culture of the nuclear power plant staff. Regulators also reassess and adjust strategies to respond to political, legal, economic and technological changes—as well as changes in the condition and management of nuclear installations. Regulators are under pressure to respond to these changes quickly, efficiently, and effectively.

The nature of the relationship between particular regulatory strategies and their impacts is not clear. Strategy selection may be improved with information on how regulatory strategies are used, issues regarding these strategies and the consequences of different regulatory strategies.

To begin to address the lack of systematic information on regulatory strategies SKI has supported a number of research efforts. SKI sponsored a paper that defined and discussed six regulatory strategies that are currently used in the nuclear industry—prescriptive, case-based, outcome-based, risk-based, process-based, and self-assessment (Melber and Durbin, 2001). In addition, SKI staff and contractors participated in a number of international meetings and SKI held a seminar on the use of regulatory strategies and the ways in which these strategies may affect safety (Blom, Durbin, Melber, 2001; Durbin, Melber, Blom, 2002; Grimes, 2001; Reiman, 2001).

This report, *Experience with Regulatory Strategies in Nuclear Power Oversight: An International Exploratory Study*, is on one of three related projects on regulation sponsored by the Swedish Nuclear Power Inspectorate. The studies are designed to provide insights regarding how to improve regulatory practices. The other reports are

Research on Approaches to Competency Regulation in Selected Countries (Durbin and Melber, 2004 forthcoming), and *How Agencies Inspect: A Comparative Study of Inspection Policies In Eight Swedish Government Agencies* (Lindblom et. al., 2003).

1.2 Overview of the study and organization of the report

This study collected information on experiences with the use of different regulatory strategies from experts from nuclear regulatory agencies in Canada, Finland, Spain, Sweden, the United Kingdom and the United States. The study was carried out jointly with the related project on competency regulation and oversight referenced above.

This exploratory study identified patterns in experts' experiences in the use of different regulatory strategies for specific areas or safety concerns and patterns in the issues and consequences described by interviewees related to using various strategies. The unit of analysis for the study is regulatory strategies; the study does not compare countries. Information was collected from six regulatory agencies to provide a greater breadth and depth of experiences with use of different regulatory strategies.

Chapter 2 provides an overview of the methodology used in this study. The six regulatory strategies selected are discussed and their definitions are provided in Chapter 3. Chapter 4 presents the key findings of the study. The detailed results and discussion on which the key findings are based is provided in Chapters 5 through 8. Chapter 5 discusses interviewees' perspectives on the benefits and difficulties of specific regulatory strategies. Chapters 6, 7, and 8 contain examples that illustrate key points made by interviewees about the use and effectiveness of strategies. They cover experts' experiences with using regulatory strategies for three areas of oversight. Chapter 6 provides examples in the area of design and modifications, Chapter 7 provides examples in the area of quality systems and Chapter 8 provides examples in the area of training and qualifications. Chapter 9 provides concluding remarks.

2 Methodology

The research approach for this exploratory study was to systematically collect and analyze qualitative information from nuclear regulatory experts regarding:

- Use and definitions of regulatory strategies
- Experience with using regulatory strategies for the oversight of nuclear power activities and facilities
- Perspectives on the benefits and difficulties of using different regulatory strategies

Systematic, structured open-ended interviews with expert regulators with extensive experience were used in order to better understand how regulatory strategies are applied in practice.

This research study is intended to increase available information for regulators regarding the use and value of different regulatory strategies. The study is exploratory—aimed at identifying common patterns regarding the use of regulatory strategies through the analysis of qualitative data provided by experts. The report describes a selected set of experiences with different strategies and analyzes these experiences to better understand the circumstances and types of safety issues related to the use of different strategies. Because it is exploratory in nature, the study intentionally does not test hypotheses.

Experts were interviewed from regulatory agencies in six countries (see description of sample, below), however, the study does not compare countries. The unit of analysis for the study is regulatory strategies. Information was collected from six different agencies to provide a greater breadth and depth of experiences with nuclear regulation. The focus of the research is the oversight of commercial nuclear power plants; however, some interviewees had experience with the full range of the nuclear fuel cycle—including low power research reactors, fuel fabrication plants, waste storage and transport—and provided examples of oversight in these areas. These examples were included in the report.

The research approach uses working definitions of six regulatory strategies developed in previous work on regulatory strategies (Melber and Durbin, 2001). Table 2.1 provides the list of these regulatory strategies with definitions.

The basis for this list of strategies was expert opinion on what terms for regulatory strategies are commonly used and discussed in the nuclear industry. For purposes of this study a regulatory strategy is defined as a specific approach to regulation. A strategy is more specific than an agency's regulatory mandate (the scope of its regulatory responsibility), while a strategy is more general than a regulatory process (a way the agency implements a regulatory strategy).

2.1 Data

Qualitative data were collected from structured open-ended personal interviews with experts on regulatory oversight from nuclear regulatory agencies. The interview guide is provided in Appendix A. The interview included the following areas:

- Review and brief discussion (with examples) of six strategies
  - Are the definitions clear and accurate
  - Are there additional strategies that should be included
  - Use of combinations of strategies.
- Use of regulatory strategies in three functional areas that are regulated by nuclear oversight agencies—interviewees provided examples and discussion of regulatory oversight in the following three areas:
  - Oversight of facility design and modifications
  - Oversight of quality systems
  - Oversight of training and qualifications
- General discussion of regulatory strategies most often used by agency and benefits and difficulties of using different regulatory strategies.

2.2 Sample

The sample included experts from six regulatory agencies.

2.2.1 Selection of agencies

Six agencies were selected to be included in the sample for the study. The criteria for selection were that each agency regulated a well developed commercial nuclear program, that the agency be willing to participate, and that the costs associated with the researchers visiting the site and completing in-person interviews would be reasonable.

2.2.2 Selection of interviewees

Regulatory agencies were asked to select four to six experts with experience in nuclear power plant regulation. Thirty-four individuals were interviewed about regulatory strategies in 32 separate interviews (two interviews were conducted with more than one interviewee). In addition, 14 interviewees being interviewed for a related study on competency provided examples of regulatory oversight in the area of training and qualifications and discussed benefits and difficulties of using regulatory strategies. Information from the study on competency is included in this report in the analysis of benefits and difficulties of different strategies and in the analysis of examples of the use of regulatory strategies for training and qualifications.

The interviewees are referred to as either “interviewees” or “experts” throughout the report.

2.3 Analysis

The qualitative data from interviews were summarized for each set of interview questions and analyzed to identify common patterns regarding experiences with regulatory strategies. Patterns in experiences with the use of regulatory strategies may emerge across experts as well as across agencies. Common patterns were identified regarding experts' perspectives on benefits and difficulties, consequences of regulatory strategies, definitions of strategies, and issues regarding strategies.

In some cases responses of interviewees are reported to illustrate a particular point. These responses are based on notes taken during the interviews and are generally paraphrases rather than verbatim quotes of what the interviewees said during the interview.

Table 2.1 Regulatory strategies and definitions*

*The list and definitions of strategies are not a classification scheme of strategies but a compilation of commonly used terms and their meanings.

Strategy	Description
Prescriptive	*A prescriptive strategy establishes very detailed requirements for technical solutions and conducting specific activities. Safety is assured because the regulator has established that its requirements provide for the safe conduct of these activities.*
Case based	*A case-based strategy determines the safety requirements for each licensee through individual assessment of its operation, considering the unique history of each facility. The regulator does not establish general, universal requirements that apply equally to all licensees of a particular type of facility.*
Outcome based	*An outcome-based strategy establishes specific goals or outcomes for licensees to attain but does not specify how licensees attain these goals. Licensees are free to determine how they will conduct their work activities to result in the achievement of the required safety goals.*
Risk based	*A risk-based strategy identifies areas and systems of significant potential risk—looking at risk as the combination of the consequences of a potential accident (e.g., would it be catastrophic) and the probability of an accident happening. A specific methodology and specific criteria are established for the identification of areas of greatest risk and these areas therefore receive priority for regulatory attention.*
Process/ system based	*A process-based or system-based strategy identifies specific key processes and systems that lead to safe performance and requires licensees to establish and implement these processes and systems effectively. (Examples of processes would include a way of identifying, recruiting, training and retaining competent staff and ways to develop, assess and implement changes in facilities, policies, and procedures; Examples of systems would be a quality system and the overall system of operations.)*
Self-assessment based	*Licensees develop and implement a self-assessment program to identify both good practices and problem areas needing improvement. The regulator evaluates the licensee self-assessment program, reviews the results of the licensee assessments, and selectively inspects the licensees' follow up on self-assessment results.*

3 Overview of regulatory strategies: definitions, structures, comprehensiveness, and combinations

Six regulatory strategies—prescriptive, case based, outcome based, risk based, process/system based and self-assessment based—were selected for this exploratory study (see Table 2.1). The basis for this list of strategies was expert opinion on terms for regulatory strategies that are commonly used and discussed in the nuclear industry (Melber and Durbin, 2001).

This chapter presents a brief discussion of the experts' comments about:

- The clarity and suggested changes to the definitions
- Structure of the set of six regulatory strategies
- The comprehensiveness of the set of six strategies
- The use of combinations of strategies

3.1 Clarity and suggested changes in the definitions

Thirty experts provided feedback on the definitions of regulatory strategies. Over 85% of the experts said that the working definitions were clear and accurate overall. Three experts indicated that the definitions were satisfactory; one of these commented that the definitions for prescriptive, case based and outcome based were better than for risk, process/system and self-assessment based.

Over half of the experts, across all six agencies, suggested some changes to some of the definitions to improve them, provide greater clarity, remove confusion, or broaden their meaning. In most cases these were wording changes to simplify, sharpen the definition or correct a potential for misinterpretation. (For example, there was a comment to drop the word "system" from the title and definition of process/system based and use process based only to make the definition simpler and clearer.) The specific comments on suggested wording changes for the definitions of each of the six regulatory strategies are provided in detail in Appendix B.

There were three definitions where more substantive issues of meaning were raised—risk-based, outcome-based and self-assessment strategies. These are discussed below.

3.1.1 Risk based strategy definition

The risk-based strategy definition was commented on most frequently. The two main issues discussed were:

- The difference between "risk based" and "risk informed"
- Quantitative and qualitative risk.

Nine experts from four different regulatory agencies preferred the term “risk informed” to “risk based” for the title of the risk strategy. The remaining experts did not comment on a preference for a different term than “risk based.” Those preferring risk informed saw the term as having the advantage of clearly indicating that the strategy used risk insights combined with other factors, such as deterministic analysis, defense in depth, safety margins and uncertainty. These experts thought “risk based” would be interpreted as meaning that regulatory decisions would be made only on risk analysis results. (Many other experts also emphasized that decisions should not be made using risk analysis alone, however, they did not interpret the term “risk based” as implying the exclusive use of risk analysis in making decisions.)

Five experts from two agencies made comments related to the apparent quantitative emphasis of the risk strategy definition. One key concern was incorporating qualitative risk strategies within the definition. Two experts suggested dropping the term “probability” because it implies quantitative methods and instead using broader wording that would cover both quantitative and qualitative approaches to risk analysis.

3.1.2 Outcome based strategy

Several interviewees (six from three agencies) preferred the title “performance based” for the outcome-based strategy. They thought the definition described what they would have called a performance-based approach in their agency.

3.1.3 Self assessment strategy definition

A few experts (three from three different agencies) commented that the self-assessment definition needed reworking. There appeared to be some confusion about what was included and what was excluded in this definition. Some focused on elements of self-assessment that have long been a part of regulation—such as independent safety reviews conducted internally by the plant and quality assurance audits. Others focused on the newer self-assessment programs encompassing the entire organization. For example, one expert mentioned that a working group at the Nuclear Energy Agency (NEA) of the Organization for Economic Co-operation and Development (OECD) had developed a definition for self assessment: “All the activities that the licensee performs in order to identify opportunities for improvement.”

3.2 Definitions matter

Highlighting some of the definitions where there were comments about what was included and excluded illustrates the importance of having a clear definition of a strategy. Whatever that definition is, all parties need a common understanding of what they are discussing as a starting point.

While these working definitions are only a beginning, they hopefully contribute to a dialogue of improving the clarity of stating what a strategy is and making explicit any assumptions behind a strategy label—such as whether a strategy is limited to quantitative methods.

3.3 Structure of the set of six regulatory strategies

Because the list of strategies was not intended as a classification or typology, no specific question was asked about the structure of the list of strategies. Nevertheless, five experts from three different agencies commented that the list of strategies lacked a coherent structure or typology. Only one expert commented that the list showed "a good structure." These interviewees would have liked to see a "mapping" of how the strategies relate to each other. One expert would eventually like to develop a typology and categorize the strategies along some defined parameters. A number of interviewees commented that a hierarchy of strategies should be developed since some are under others—self-assessment, for example, often was mentioned as a part of a larger strategy. Another expert indicated that different strategies were used at different levels—the whole plant, safety- related systems and components. Different strategies were also used for different purposes; one example given was a prescriptive strategy being used to set some types of requirements and a process strategy being used for inspections.

3.4 Comprehensiveness of the set of six regulatory strategies

Most of the experts agreed with the statement that the group of six strategies "represents a reasonable overview of the regulatory strategies commonly used by nuclear power regulators." Only two disagreed, one said that a performance-based strategy was not covered. This expert, unlike several others discussed above, apparently did not think the definition of outcome based captured a performance-based strategy. The remaining experts either discussed the need for a mapping of the relationships between the strategies (discussed above) or provided an example of a different additional strategy outside this set of six strategies. These strategies are presented below as part of the discussion of additional strategies mentioned by all of the interviewees.

All experts were asked if there were any strategies in addition to the six selected for the focus of this study that they had used in their agency or were aware of being used in other nuclear regulatory agencies. There were four different strategies discussed (by five experts across four agencies)—not including the performance-based strategy.

These included:

- education/promotion
- safety management
- event based
- politically based

3.4.1 Education/promotion

Two experts mentioned education or promotion, "bringing the plants along," as a strategy. Using seminars, information, knowledge and examples of good practices as ways to improve plant safety performance was presented as a positive strategy for plant regulation. While only two experts discussed this in response to the specific question on additional strategies, a number of other interviewees mentioned "coaching" and education at plants as part of the strategy they used when providing specific examples of experiences with oversight during the course of the interviews.

3.4.2 Safety management

One expert suggested that safety management be added. This approach was described as one that looks at licensee safety problem management and identifies possibilities for improvements.

3.4.3 Event based

One expert mentioned event based as an additional strategy that is used in practice. This is a reactive strategy of waiting for a problem to occur and then following up on the incident after the occurrence.

3.4.4 Politically based

Finally, one expert said that politically based was a strategy used when a government wanted something done. The regulatory agency has to do it, not because of risk or safety issues, but for political or public purposes. For example, perhaps to demonstrate that there has been careful oversight and that everything that is reasonable and practical has been done in a given situation.

3.5 Combining strategies

All interviewees across all six agencies stated that their agencies combined a number of different strategies for regulatory oversight. Interviewees mentioned using different strategies in different areas of oversight and combining more than one strategy in the oversight of one area. Many interviewees commented on the importance of being able to combine strategies and adjust strategies to the situation. The selection and use of combinations of strategies is seen throughout the examples given by interviewees in their discussions of the use of regulatory strategies for oversight of specific functional areas. These are discussed in detail in Chapters 6 (plant design and modifications), 7 (quality systems), and 8 (training and qualifications).

4 Summary and discussion of key findings: regulatory strategy use, consequences and issues

This chapter presents a summary of the key findings of this exploratory study. The summary focuses on the experiences of interviewees with the use of different regulatory strategies for oversight of nuclear safety—primarily the use of prescriptive, case based, outcome based, risk based, process based and self assessment strategies.

The summary and discussion of key findings presents:

- Experts' perspectives on the major benefits and difficulties of using specific regulatory strategies;
- Experts' experiences with using regulatory strategies for three areas of oversight—design and modifications, quality systems, and training and qualifications;
- Expert views of the consequences of different regulatory strategies;
- Issues that emerged in the interviews regarding regulatory strategies.

Detailed discussion of expert views on the benefits and difficulties of using regulatory strategies is presented in Chapter 5. Chapters 6, 7, and 8 provide examples that illustrate important points made by interviewees about the use of various regulatory strategies in three different areas of oversight—design and modifications, quality systems, and training and qualifications, respectively. Throughout this chapter specific sections of the report are referenced that present the results which are the basis for the key findings.

4.1 Summary of key benefits and difficulties of specific regulatory strategies

This summary presents experts' views on the overall benefits and difficulties of using specific regulatory strategies. It focuses on the issues that were most frequently discussed by the interviewees. In general, interviewees commented more frequently and extensively on prescriptive and risk strategies than on the other types of strategies.

4.1.1 Prescriptive strategy

Experts more frequently discussed difficulties with using a prescriptive strategy than benefits.

The major benefit interviewees identified was:

- Prescriptive strategies are clear about requirements and expectations for both industry and the regulator

  Over half of those who commented on prescriptive strategies, from all six agencies, stated that both the licensees and the regulator know clearly what is required and expected which brings stability and certainty to regulatory oversight. (Section 5.1.1)

The major difficulties interviewees identified were:

- Prescriptive strategies take responsibility for safety away from the licensee and put it on the regulator

  The most frequent comment of experts across five agencies was that the regulator becomes responsible for safety instead of the industry leading to the licensee looking to the regulator to take the initiative. This put an inappropriate burden on the regulator since most experts had a strong position that the licensee should be responsible for the safety of the plant. (Section 5.1.3)

- Prescriptive strategies require a high use of resources of the regulator

  A difficulty mentioned by several interviewees across all six agencies was the intense use of resources needed because of the detailed requirements of a prescriptive strategy. Experts commented that a high level of resources is needed for both the development of regulations and their enforcement. (Section 5.1.4)

- Prescriptive strategies are inflexible, rigid and difficult to change requirements

  Several interviewees across all six agencies expressed concern about the rigidity of prescriptive strategies. The difficulty of modifying requirements was the most frequent comment in this area—the liklihood of being ”locked in” to requirements that the agency may want to change. (Section 5.1.5)

4.1.2 Case based strategy

The major benefit of a case-based strategy identified by interviewees was its usefulness for flexibility and adapting regulatory responses to unique situations. The key difficulties that experts described with case based strategies were that they tended to be arbitrary, inconsistent, and unfair and that they require heavy resource use.

- Case based strategy allows regulators to address unique issues and be flexible

  The interviewees’ most frequent comment was that regulators should include a case-based strategy in oversight in order to allow the regulator to consider and respond to unique and specific characteristics of a licensee or an event. Experts mentioned case based strategies are particularly important when dealing with older plants and other types of non-standard facilities. (Section 5.2.1)

- Case based strategies are arbitrary, inconsistent and unfair

  The most often mentioned difficulty with case based strategies was that they can be arbitrary, inconsistent, and unfair which leads to regulatory uncertainty for licensees and for the public. (Section 5.2.6)

- Case based strategies lead to high resource use by regulators

  Case based strategies were viewed by experts as resource intense because more material must be reviewed and there are no benefits of scale since each facility is treated separately and independently. (Section 5.2.7)

4.1.3 Outcome based strategy

The most often mentioned benefit of an outcome-based strategy was that this strategy allows licensees to decide the best way to operate in order to meet safety goals. The most often mentioned difficulty was that it is very hard to identify ways to measure performance and thus to set safety goals.

- Outcome based strategies allow licensees to determine the best way to operate

  About half of the experts who made comments indicated that outcome-based strategies focus the regulator on setting high level goals for licensees rather than emphasizing detailed requirements. Several interviewees noted that this was the underlying strategy for their agency. (Section 5.3.1)

- Outcome based strategies require defining goals, outcomes, or performance indicators which is difficult

  About half of the interviewees mentioned the difficulty of finding appropriate measures for outcomes to assure safety. In large part this problem was discussed in light of the nature of the nuclear industry—because safety is so critical outcomes must reflect what may be precursors to problems or indirect indicators of problems. (Section 5.3.4)

4.1.4 Risk based strategy

The major benefit described by interviewees was the use of risk strategies to prioritize safety issues and allocate resources. The major difficulties experts' discussed were that risk strategies should not be used as stand alone strategies and that they have serious methodological and data problems.

- Risk based strategies help the regulator prioritize safety issues and allocate resources

About half of those who commented on risk strategies, across all six agencies discussed its usefulness for prioritizing safety issues and focusing resources on the most important areas for oversight. This benefit was pointed out both by experts who focused on risk strategies using quantitative methods and those who explicitly emphasized risk strategies using qualitative methods. (Section 5.4.1)

- Risk based strategies should be used only in combination with other strategies

  A frequent comment by interviewees was that a risk strategy was not appropriate to use as a sole strategy for regulatory decision-making. While a risk strategy was seen as providing a useful point of view, experts were critical of using a risk strategy alone, in particular, of excluding other types of analysis and information, such as defense in depth, robust design and deterministic analysis**.** (Section 5.4.4)

- Risk based strategies have serious methodological and data limitations

  Many experts, across all six agencies, discussed difficulties with the data available for risk analyses and with the state of the methodology and modeling of risk. One concern was the extensive infrastructure and database that quantitative risk analysis relies on that both the regulator and licensees need. A second concern was questionable data quality in general, and particularly for certain areas, such as organizational and human factors. (Section 5.4.5)

4.1.5 Process based strategy

Experts considered the major benefit of a process based strategy the in depth understanding it provided of a licensee's performance. The difficulties most frequently described were that it was not an effective strategy unless the processes were linked to outcomes and that it was complex to define and evaluate processes.

- Process based strategies provide a deep approach to understanding how things are done

  Several interviewees across five agencies discussed the deep understanding that a process strategy provides. Experts described how a process strategy helps the regulator to see the whole picture—to follow an issue from top to bottom. (Section 5.5.1)

- Process based strategies should be linked to implementation and outcomes

  The most frequent comment about process based strategies was the necessity of linking processes to both their implementation and their outcomes. Several interviewees across five agencies were concerned that the regulator might focus on means (the processes) and forget about ends (the outcomes the processes were designed to achieve). Experts indicated that looking at processes was not complete as a stand alone strategy, but a link to outputs was crucial. (Section 5.5.5)

- Process based strategies are difficult because of the complexity of defining and evaluating processes

  Experts commented on the difficulty of defining and evaluating processes—determining what is a process, defining the scope and criteria for evaluation. These interviewees focused on the complexity of this strategy, discussing the need for good knowledge of processes and for deep experience. (Section 5.5.6)

4.1.6 Self assessment strategy

The major benefit discussed was that it put responsibility for safety on the licensee, while the major difficulties mentioned were that self assessment should not be used as a stand alone strategy and that it often does not have credibility with the general public.

- A good self assessment strategy reflects licensee responsibility for safety and increases the regulator's trust in the licensee

  Almost half of the interviewees who commented on self-assessment across all six agencies, noted that a good self assessment program was an important indicator that licensees are taking ownership of and responsibility for safety. (Section 5.6.1)

- Self assessment is not a stand-alone strategy and should be used in combination with other strategies

  The most common response by experts from all six regulatory agencies, was that while self assessment was an important part of ensuring safety it was not a stand-alone strategy—not an independent strategy. Some experts saw self assessment as a component of other strategies, such as process based or outcome based. (Section 5.6.3)

- Relying on self assessment raises issues of credibility with the general public

  At least one interviewee from each agency noted that public credibility of self assessment as a strategy was a concern. Experts commented that there were public perceptions of "giving away regulation to the operator". (Section 5.6.4)

4.2 Use of regulatory strategies in different functional areas of oversight

This summary discusses some of the major findings concerning the experiences of interviewees with the use of regulatory strategies in three functional areas: oversight of safety in plant design and modifications, quality systems and training and qualifications. First the types of regulatory strategies used by interviewees are

presented. Then major findings are discussed regarding interviewees' experiences with the use of specific regulatory strategies in these three functional areas.

4.2.1 Combinations of strategies used in three areas of oversight

In all three areas it was typical for interviewees to describe the use of combinations of at least two, often three, and at times four, different strategies, for specific examples of oversight issues. However, there were distinct differences in the types of strategies used in the examples described for plant design and modifications compared to those in the examples given for both quality systems and training and qualifications. Examples for quality systems and training and qualifications used process-based strategies most often while examples for plant design and modifications were more varied, commonly using combinations of risk, prescriptive and process based strategies (as described below). Since this is an exploratory study of self-selected examples, these findings are simply suggestive of a potential pattern of difference.

In the plant design and modifications examples it was typical for a combination of two, three or four strategies to be used. Risk, prescriptive and process-based strategies were each used as one of the strategies mentioned in about half of the examples interviewees provided, with the remaining strategies each used in less than a third of the examples.

In contrast, process based was the regulatory strategy most often provided in examples for both quality systems and training and qualifications—mentioned in approximately two thirds of the examples in these areas. Process based also was dominant because it was often used as the primary strategy of a combination of strategies in examples. No other strategy was mentioned in more than a third of the examples for either quality systems or training and qualifications.

The striking difference in the regulatory strategies used for design and modifications compared to quality systems and training and qualifications is suggestive and would be of interest to follow up in future work.

4.2.2 Less reliance on a prescriptive strategy, more use of process-based strategies, but return to a prescriptive strategy for action and closure

Interviewees described a move away from the use of prescriptive strategies in general as their agencies and the industry matured. In recent years this move has often been toward more use of process-based strategies. Examples described recent use of process-based strategies in all three areas: design and modifications (Section 6.3), quality systems (Sections 7.1, 7.2, 7.3, 7.5) and training and qualifications (Section 8.1).

However, examples given in all three areas of oversight also described the use of a prescriptive strategy when licensees had not responded to the use of other regulatory strategies. Prescriptive strategies were used to get action, clarity and closure after long periods of ongoing discussion and negotiation with licensees regarding construction of

facilities (Section 6.4) and training issues (Section 8.4) and to deal with licensees with recurring and systemic problems in quality systems. (Section 7.1)

4.2.3 Use of risk strategy for prioritization of safety issues and action items

Risk strategies were used to prioritize safety issues, activities and regulatory findings for oversight of both quality systems and plant design and modifications.

In oversight of quality systems interviewees described use of a risk-based strategy to classify the safety impact of regulatory findings and to prioritize corrective action items. This risk strategy was considered effective in focusing licensees on significant safety issues rather than on correcting symptoms. (Section 7.5)

For plant design and modifications a risk strategy was commonly used to prioritize safety issues and activities. Experts described a major benefit as maintaining both regulator and licensee focus on important safety issues. (Section 6.7)

4.2.4 Incorporation of a risk strategy into regulatory oversight of plant design and modifications: tension and balance

A major issue that emerged from the examples was how agencies dealt with incorporating a risk strategy into regulatory oversight of plant design and modifications over time. Initially there was a major reliance on a prescriptive strategy in oversight of plant design and modifications, but as risk methods were developed, agencies began to incorporate a risk strategy.

Experts described tension concerning the use of a risk strategy for regulatory decision-making—both between regulators and licensees and among staff within regulatory agencies. This tension often centered on disagreement over the relative emphasis given to the use of information from risk analysis to that given to information from deterministic analysis in making decisions—use of a risk strategy was viewed as reducing the importance placed on deterministic information. There were several examples of licensee and regulator disagreements over acceptance of risk results in defining necessary actions regarding plant modifications. There were also examples of disagreements among staff within a regulatory agency over using risk versus deterministic information in decision-making about demands on licensees. (Section 6.1)

Interviewees provided numerous examples describing how agencies have incorporated the use of a risk strategy along with continued use of a prescriptive strategy for oversight of plant design and modifications. Experts indicated that there is a benefit to using a mix of both strategies, suggesting for example that one effective approach is to use a prescriptive strategy to set thresholds and then use risk-based information within established boundaries. (Section 6.2)

4.3 Consequences of different strategies

Consequences of regulatory strategies were discussed by a number of experts. Regulatory strategies were viewed as affecting:

- Whether the licensee or regulator takes primary responsibility for safety
- How clear requirements and expectations are to licensees
- Significance of safety issues identified
- Expertise needed by regulators and licensees
- Resources used by regulators and licensees
- Flexibility given to licensees
- Public credibility

Below, the comments regarding the consequences of different regulatory strategies for each of these areas are summarized.

4.3.1 Regulatory strategies affect whether the licensee or the regulator takes primary responsibility for safety

The experts interviewed often had strong opinions about the effect of different regulatory strategies on the locus of responsibility for safety—whether the regulator or the licensee took on the primary responsibility to assure safety. Experts from each of the regulatory agencies pointed out that legally the licensees have the primary responsibility for safety and that the regulator assures that this responsibility is being carried out. However, the regulatory strategy was seen by many as having an impact on how responsibility for safety was perceived.

Many interviewees stated that a prescriptive strategy removes responsibility for safety from the licensee and puts it on the regulator. (Section 5.1.3)

In contrast, self assessment strategies were often mentioned as increasing the focus on the licensee's responsibility for safety, with interviewees noting that a good self assessment program reflects licensee responsibility for safety and increases the regulator's trust in the licensee. Process based strategies also were noted as giving responsibility for safety to licensees; comments on process based strategies included that with a process based strategy "responsibility for safety and flexibility are given to licensees". Although outcome based strategies were not as clearly tied to responsibility for safety, comments about outcome based strategies included that they allow licensees to determine the best way to operate—which suggest that the licensee may take more responsibility under this type of strategy. (Sections 5.3.1, 5.5.2, 5.6.1)

4.3.2 Strategies differ in how clear requirements and expectations are to regulators and licensees

Many experts noted that a benefit of prescriptive strategies is that this type of strategy provides clear expectations to both the licensee and the regulator. This benefit also was noted when interviewees provided examples of regulatory oversight—for example, experts frequently noted when providing examples that a prescriptive strategy was easier for the licensee because there were clear requirements. In contrast to prescriptive strategies, case based strategies were frequently described as arbitrary and inconsistent. (Sections 5.1.1, 5.2.6)

Fewer experts commented directly on how clear requirements and expectations were with regard to other regulatory strategies. However, process based, outcome based and self assessment strategies were described in some of the examples of oversight as being difficult to define and scope, leading to extensive discussions and sometimes serious disagreements between regulators and licensees over what actions licensees were required to take. (Sections 5.3.4, 5.5.6, 6.4, 7.1)

4.3.3 Regulatory strategies affect the significance and timeliness of safety issues identified

Experts' comments on the consequences of different strategies for the identification of important safety issues focused primarily on the vulnerabilities of specific strategies—particularly the potential for missing a significant or emerging safety issue. There were also some comments on special strengths of some of the strategies.

Some experts viewed prescriptive strategies as likely to miss some safety significant areas and emphasize low level safety issues. This was expected because the detailed nature of this strategy was seen as leading to a focus on small, narrow issues, so there is a potential to miss a larger significant problem. (Sections 5.1.7, 6.5.2)

There was concern among several experts that a risk strategy also was vulnerable to missing some important safety areas, though for a different reason than prescriptive strategies. The limitations of quantitative risk methods due to data quality and coverage was seen as leaving this strategy vulnerable, particularly to missing emerging safety issues. On the other hand, the systematic, integrated approach of a risk strategy was mentioned by a few interviewees as a special strength of this strategy for identifying significant safety areas. Some examples described specific instances of using a risk strategy to identify areas for safety improvements or previously ignored safety issues. (Sections 5.4.2, 5.4.6, 6.2, 6.5)

Concerns about outcome based strategies centered on the difficulty of defining and measuring safety outcomes and the need to rely on precursers and indirect indicators of safety outcomes. Experts also commented that outcome strategies were unlikely to be timely in identifying safety issues. Some oversight examples illustrated late identification of problems with the use of outcome strategies. (Sections 5.3.4, 5.3.5, 8.3)

Several interviewees described process-based strategies as providing a deep understanding of issues. Some commented that this strategy focuses attention on processes related to safety and helps the regulator respond early before there are serious problems. (Sections 5.5.1, 8.1)

4.3.4 Regulatory strategies affect the expertise needed by regulators and licensees

Another consequence of regulatory strategies that was discussed was how different strategies affected the level of expertise needed by the regulator and by licensee staff. There were four strategies where interviewees noted that regulatory staff and/or licensee staff needed extensive expertise, although for somewhat different reasons. These were prescriptive, outcome, risk and process based strategies.

Prescriptive strategies were seen as needing extensive regulatory staff expertise in order to write detailed requirements for licensees. Risk strategies, particularly those using quantitative methods, were described as relying on a very high level of agency staff expertise for models, data collection and analysis, and understanding of the limitations of the assumptions and methodology. Process-based strategies were seen as needing a high level of expertise of both the regulator and the licensee to define and scope processes and evaluate them. Although not stated explicitly, it appeared that outcome strategies were viewed similarly to process strategies, because of comments on the difficulty of defining appropriate measures of outcomes and the need to link outcomes to their underlying processes. (Sections 5.1.8, 5.3.4, 5.4.5, 5.4.7, 5.5.6)

4.3.5 Regulatory strategies affect the resources used by regulators and licensees

Many interviewees noted that prescriptive strategies required high resources because the regulator had to have large numbers of technical staff to develop detailed requirements for the regulations. Case based strategies were noted as being very resource intense for the regulator by many interviewees. Reasons included that the regulator does not gain the benefits of scale and that lessons learned at one plant are not likely to be used elsewhere. (Sections 5.1.4, 5.2.7)

Outcome based strategies were noted by interviewees as being potentially resource intensive for both the regulator and the licensee since each licensee can develop a unique approach to meeting outcome goals, the regulator may potentially need to evaluate many different systems. (Section 5.3.6)

Process based strategies were described as potentially being both efficient and requiring extensive resources by the regulator, depending on the circumstances. One reason given for efficiency was that the regulator is working at a high level rather than at a detailed level. Reasons for high resource use included applying this in-depth strategy to too many areas and licensees changing processes frequently so regulators would need to conduct reviews over and over. (Sections 5.5.4, 5.5.7)

Several interviewees noted that self-assessments generally are efficient for the regulator, providing substantial information. However, one noted that if the licensee begins to perform poorly then evaluating the self-assessment can be resource intensive for the regulator. (Section 5.6.2)

4.3.6 Regulatory strategies affect flexibility and the ability to innovate

One area that clearly distinguished among the regulatory strategies was the impact on flexibility and innovation. Interviewees particularly noted the lack of flexibility and rigidity created by prescriptive regulations. (Section 5.1.5)

Many experts, on the other hand, viewed a case-based strategy as providing the flexibility needed to address unique issues. Process-based strategies also were seen as giving flexibility to licensees. Outcome based strategies were mentioned by interviewees as allowing innovation and changes to respond to new knowledge. (Sections 5.2.1, 5.3.1, 5.3.2, 5.5.2).

4.3.7 Regulatory strategies differ in their credibility with the public

A number of interviewees commented on the effects of different regulatory strategies on the credibility of the regulator with the public.

Some interviewees noted that the public was most comfortable with prescriptive strategies. Several experts commented that risk based strategies were not always credible with or accepted by the public. Experts said that it was difficult to communicate to the public what is meant by risk analysis. (Section 5.4.8)

Many interviewees indicated that the public was uncomfortable with self-assessment strategies. Several interviewees commented that the public was likely to consider a regulator as having given up regulatory authority in an area if the agency relied solely on a self-assessment strategy. (Section 5.6.4)

4.4 Issues that emerged from examples regarding regulatory strategies

Interviewees discussed a number of important issues when they described their experiences using regulatory strategies for specific areas of oversight of nuclear safety. These issues include:

- Resistance to changing regulatory strategies
- Tension concerning the use of risk information for regulatory decisions
- Different interpretations of definitions of regulatory strategies
- Importance of combinations of strategies for regulatory effectiveness

4.4.1 Resistance to changing regulatory strategies

Experts discussed difficulties in oversight regarding coming to agreement on decisions about necessary actions for licensees to undertake. Disagreements in some situations arose between the regulator and the licensee and in other situations among staff within the regulatory agency. Often these disagreements were associated with resistance to the introduction of a different regulatory strategy than had been used previously. Experts described examples of licensees pushing an agency to stay with a prescriptive strategy and not change to a different strategy (often process based) because a prescriptive strategy is more explicit about what is expected of the licensee. Interviewees discussed how a change from a prescriptive to a process-based strategy demands more of licensees—they can no longer depend on the regulator to specify what they have to do and to tell them how to fix inadequate submissions to the regulator.

There also were difficulties within regulatory agencies with the introduction of new regulatory strategies. Some of the issues were typical of the introduction of any change—learning new methods and standards for new strategies. But some of the issues were more substantive—one in particular concerned differences in judgments about the appropriate use of risk information for regulatory decisions. This issue is discussed separately below.

4.4.2 Tension concerning use of risk information for regulatory decisions

Interviewees from four of the agencies indicated there was tension among staff regarding a recent emphasis on using probabilistic risk analysis for regulatory decisions. There were some who regarded the past reliance on deterministic analysis in making decisions as the most sound way to regulate, while others saw the introduction of risk analysis as bringing a more systematic tool to bear on safety issues. One expert commented on the need for considerable education and a culture change in engineering communities for acceptance of a risk strategy.

To many, the issue is one of balance, as one interviewee indicated: the question is whether you start with deterministic analysis and use risk analysis to inform it or start with risk analysis and use deterministic analysis to inform it. Another indicated the need to take elements from both risk and deterministic analysis and combine them; this interviewee considered risk analysis more systemic but missing certain areas, such as organization and human factors.

While this middle road may characterize the position of many staff, the tension among staff concerning what some see as undue emphasis on risk analysis was described as an issue at this time at a number of agencies.

4.4.3 Different interpretations of definitions of regulatory strategies

The importance of being precise and explicit about the meaning of a regulatory strategy was highlighted repeatedly in the course of conducting this study. While the set of

working definitions provided in this study, was a helpful starting point, it became clear that definitions were interpreted differently by some interviewees. In some instances the problem was with the definition—such as a need for clearer wording. In other instances it was evident from the context of the discussion, that interviewees used some of the regulatory strategy terms in different ways because of how these terms have been used in practice at their agencies.

Some examples of these differences were discussed in Chapter 3. In particular the term "risk based" was interpreted by some as meaning that regulatory decisions would be made using only quantitative risk analysis results while others interpreted the term more broadly as using risk analysis as one factor in decision making. Self-assessment was another strategy where the definition caused some confusion and was interpreted in different ways.

The discussion of comments about accuracy, comprehensiveness and areas of confusion with the regulatory strategy definitions indicates the importance of having a clear definition of a strategy. Whatever that definition is, all parties need a common understanding of what they are discussing as a starting point. While these working definitions are only a beginning, they hopefully contribute to furthering a dialogue that will improve the clarity of stating what a strategy is and make explicit any assumptions behind a strategy label.

4.4.4 Importance of combinations of strategies for regulatory effectiveness

Many interviewees stated that particular strategies should not be used alone but should be combined with other strategies. This was emphasized for self-assessment and risk based strategies in particular, but also was recommended for case based, outcome based and process based strategies.

Although many combinations of strategies were used, there were some recommendations for specific combinations of strategies. One was the combination of process based and outcome based strategies. A process based strategy was viewed as having many benefits, but it was seen by interviewees as incomplete if not linked to outcomes, since it was necessary to know that the processes led to the desired, intended outcomes they were designed to achieve. Similarly, interviewees indicated that when using an outcome based strategy, if licensees did not achieve the goals or outcomes set by the regulator, there was no way of understanding why the outcomes had not been achieved. Experts said the processes the licensee used had to be linked to outcomes in order to track what led to problems or failure. Several interviewees suggested combining self-assessment with process and outcome based strategies, and a number of experts discussed the benefits of combining risk and prescriptive strategies for oversight of plant design and modifications.

5 Benefits and difficulties of specific strategies

This chapter presents experts' perspectives on the overall benefits and difficulties of using specific regulatory strategies. Interviewees were asked an open-ended question regarding their views on benefits and difficulties of using the regulatory strategies that were the focus of this study: prescriptive, case-based, outcome-based, risk-based, process-based and self-assessment. In addition experts discussed benefits and difficulties of specific strategies in their examples of regulatory oversight of functional areas. In general, interviewees commented more frequently and extensively on prescriptive and risk strategies than on the other types of strategies.

5.1 Prescriptive strategy

In most interviews experts discussed some of the general issues of using a prescriptive strategy when asked about overall benefits and difficulties of using the regulatory strategies that were the focus of this exploratory study. While some commented on benefits, experts more frequently focused on difficulties with using a prescriptive strategy. The major benefit from the perspective of interviewees was that a prescriptive strategy is clear about requirements and expectations for both the licensee and the regulator. The major difficulties described were that prescriptive strategies take responsibility for safety away from the licensee, lead to a high use of resources by the regulator and are inflexible and rigid.

All of the benefits and difficulties identified by the interviewees are listed; following this listing each is discussed in detail.

Interviewees identified the following benefits:

- Prescriptive strategies are clear about requirements and expectations for both the licensee and the regulator
- Prescriptive strategies are useful for specified technical areas or under certain conditions

Interviewees identified the following difficulties:

- Prescriptive strategies take responsibility for safety away from the licensee and put it on the regulator
- Prescriptive strategies lead to a high use of resources by the regulator
- Prescriptive strategies are inflexible, rigid and difficult to change requirements
- Prescriptive strategies discourage innovation
- Prescriptive strategies may miss some safety significant areas and focus on low level issues
- Regulator does not have sufficient specific knowledge to adequately develop detailed requirements for a prescriptive strategy

5.1.1 Prescriptive strategies are clear about requirements and expectations for both the licensee and the regulator

The most common benefit—mentioned by over half of those who commented on prescriptive strategies, including experts from all six regulatory agencies—was that both the licensees and the regulator know clearly what was required and expected. This was considered a major strength of this strategy. One expert explained that a prescriptive strategy brought stability and certainty.

Other comments include:

Leaves out doubt and ambiguity
Simple, clear, well understood, stable qualities
Easy to understand by all stakeholders
People know what is required
Good for industry, high certainty

The advantage of such clear expectations is important when implementing strategies. Another comment made by an expert in discussing this issue captures this perspective:

Ability to say: "Do this or consequence"

In some oversight examples experts described how they returned to a prescriptive strategy when they could not get a licensee to respond to other strategies. For instance, a combination of outcome and self-assessment strategies had not been effective in terms of licensee performance during construction of a facility. The licensee did not correct problems the regulator identified, but instead engaged in "endless" negotiations with the regulator. Finally, the regulator decided to set specific prescriptive requirements to assure the licensee would take specific corrective actions (see Section 6.4).

5.1.2 Prescriptive strategies are useful for specified technical areas or under certain conditions

A number of experts mentioned a specific area or condition where a prescriptive strategy was useful. The examples of specific areas were "maintaining barriers for defense in depth and safety margins," "hard issues, such as cracked pipes," and "security."

Specific situations considered suitable for a prescriptive approach included:

- The early phase of the industry when neither the industry nor the regulator had much knowledge or experience on how to run plants;
- When licensee lacks incentive for performing well;
- When licensees are small operators without many resources;
- When plants have similar design but different operators, to develop common standards.

5.1.3 Prescriptive strategies take responsibility for safety away from the licensee and put it on the regulator

The difficulty most often commented on, by experts in five of the agencies, was that the regulator becomes responsible for safety instead of the industry. The interviewees saw this as having a negative impact for both the licensee and the regulator. It led to the licensee looking to the regulator to take the initiative. It also put a large burden on the regulator, which was not an appropriate burden, since most experts had a strong position that the licensee should be responsible for the safety of the plant.

Examples of typical comments are:

Industry relies too much on the regulator, waits for the regulator to act

Unsound for good safety culture

Causes some de-motivation

Prescriptive means the regulator is responsible for the results

It takes responsibility away from the operator

5.1.4 Prescriptive strategies lead to a high use of resources by the regulator

Another difficulty mentioned by several interviewees across all six agencies was the intense use of resources needed for a prescriptive strategy. Because of the detailed requirements of a prescriptive strategy there is a high level of resources needed for both the development of regulations and their enforcement. A couple of comments that illustrate this common concern are:

Large burden in developing regulation and its basis

Time consuming for regulator to establish detailed requirements

5.1.5 Prescriptive strategies are inflexible, rigid and difficult to change

There also was concern among several interviewees across all six agencies about the rigidity of prescriptive strategies. The detailed nature of prescriptive requirements makes it time-consuming to change them. The difficulty of modifying the requirements was the most frequent comment in this area. One interviewee commented that while a prescriptive strategy can be useful, it "locks you in."

Similarly, another interviewee commented, "Imagine being prescriptive for software 10 years ago—we'd have to start over." His point was that establishing detailed requirements for an area where technology is likely to change leaves the regulator with requirements that are no longer appropriate. The difficulty of modifying prescriptive regulations was considered a significant problem.

One expert described an example of oversight in plant design and modifications that illustrates this point. A prescriptive regulation for earthquake requirements had to be changed soon after it took effect because the level of detail was so specific that any

minor deviation required an exemption. There were many applications for changes that took a long time and high use of regulator and industry resources. Later a new regulation was developed which was more flexible and less prescriptive to avoid this problem in the future (see Section 6.5.2).

Another difficulty mentioned was that the same rules are applied in different situations; unique circumstances are not recognized.

5.1.6 Prescriptive strategies discourage innovation

Some interviewees, from three agencies, specifically were concerned with a prescriptive strategy discouraging innovation. The detailed and directive style of prescriptive regulation "stifles innovation—may eliminate better ways of doing things" according to one expert. Another commented that it does not "give the licensee the basis for continuous improvement."

This concern about innovation appears to be partly related to (but different than) the drawback of a prescriptive strategy taking responsibility for safety away from the licensee. It may be an extension of the effect of taking this responsibility away, in the sense that some of the experts expressed concern that when the licensee does not have responsibility for safety it leads to a lack of initiative and de-motivation on the part of the licensee. It also may be related to the inflexibility of prescriptive strategies in that licensees may not be allowed to innovate when regulations are very detailed and require licensees to conduct activities in very specific ways.

5.1.7 Prescriptive strategies may miss some safety significant areas and focus on low risk issues

A number of interviewees from four agencies were concerned that the focus of prescriptive strategies is often on small, narrow issues and thus has the potential for missing significant safety concerns. A couple of these experts commented on a tendency toward conservatism in using prescriptive strategies that led to some unnecessary requirements.

Some typical comments were:

> *Can miss things if look at issues too narrowly*
>
> *Can focus on things that are not risk priorities because of long time to make changes*
>
> *Focus is very small and you may only resolve little thing and miss big problem*
>
> *Frequently oversimplified—over conservative*

5.1.8 Regulator does not have sufficient specific knowledge to adequately develop detailed requirements for a prescriptive strategy

A few interviewees across four of the agencies mentioned the difficulty of having the knowledge to adequately develop detailed requirements for prescriptive regulation. There were two dimensions to this concern. One was that the regulator does not have sufficient knowledge to be prescriptive about how to do things—the staff at the plant is more knowledgeable about how to conduct activities. A second, different kind of concern, is that there would never be sufficient knowledge to develop prescriptive requirements because it is not feasible to be able to predict all possibilities and account for all eventualities and interactions, which is implicit in detailed prescriptive requirements. As one expert said, "The unexpected is likely to occur."

5.2 Case based strategy

Experts considered the flexibility of a case based strategy for adapting regulatory responses to unique situations its major benefit. The major difficulties identified were that case based strategies are arbitrary, inconsistent, and unfair, and demand heavy resource use. Other benefits and difficulties of case based strategies were mentioned less often.

Interviewees identified the following benefits:

- Case based strategy allows regulators to address unique issues and be flexible
- Case based strategies may be more efficient for small regulators, small industries and industries with a lot of variability across facilities
- Case based strategies allow regulators to attend more to details
- Case based strategies are most useful in specific areas

Interviewees identified the following difficulties:

- Case based strategies are arbitrary, inconsistent and unfair
- Case based strategies lead to high use of resources by regulators
- Case based strategy should be combined with other strategies
- Case based strategies miss the holistic view of the industry

Each of these is discussed in more detail below.

5.2.1 Case based strategy allows regulators to address unique issues and be flexible

The most frequent comment about a benefit of a case based strategy was that it allows the regulator to consider and respond to the specific characteristics of the licensee since all plants are unique. Interviewees commented that regulators review plant specific outcomes, need to be able to change emphasis depending on the maturity and other characteristics of the licensee, and that case based strategies are particularly important when dealing with older plants and other types of non-standard facilities. Some

interviewees specifically mentioned that a case based strategy allows the regulator to be flexible and respond to the particular circumstances of the plant. Comments include:

Has to be used because every case is different; we are at different stages for different reactors, can't do it the same everywhere

We approach a site taking the history of the site into consideration; need to use history and intelligence regarding each site

A plus is that you are at least tailoring—application of technique to a particular facility

5.2.2 Case based strategies may be more efficient for small regulators, small industries and industries with a lot of variability across facilities

While this was not a common comment, it presents a different perspective on the resource impact of a case based strategy and is also consistent with comments about the need for case based strategies in facilities with unique characteristics (aging facilities, new licensees, etc.) included in responses to benefits and difficulties of using a case based strategy and in examples of regulatory oversight. Comments include:

May be efficient if you have few resources, small industry

Essential for a small organization

5.2.3 Case based strategies allow regulators to attend more to details

A few interviewees noted that using a case based strategy allowed regulators to examine licensee conditions in greater detail and to have a deep knowledge of the plant.

5.2.4 Case based strategies are most useful in specific areas

Several interviewees noted that case based strategies are more appropriate for particular areas and less appropriate for others.

Particularly important in making judgments at old plants

Not very useful for day-to-day plant modifications and operations

Wouldn't understand with regard to training which is overarching in systematic assessment of training

5.2.5 Case based strategies are arbitrary, inconsistent and unfair

The most often mentioned difficulty with case based strategies was that they can be arbitrary, inconsistent, and unfair. A corollary to this difficulty is that case based strategies lead to regulatory uncertainty for licensees and for the public. Regulatory responses cannot be predicted. Typical comments about difficulties with case based strategies include:

Doesn't insure consistency—no foundation in underlying goals makes it arbitrary and capricious

Treat licensees differently, unequal, unfair, arbitrary

Utility doesn't know what to expect, try to avoid

Drawback primarily that you treat cases unequally and unfairly
Regulator can be seen as random and unpredictable

5.2.6 Case based strategies lead to high use of resources by regulators

Another commonly raised difficulty with case based strategies was that these strategies are very resource intense and not efficient. Specific reasons for the increased use of resources and inefficiency included that more material must be reviewed, that the agency is re-learning all the time, and that there are no benefits of scale. In one example of an approach to regulatory oversight an interviewee commented that a case based approach depends on the licensee having a large technical resource and that it also means that the regulator must have its own in house expertise. Specific comments include:

Solutions do not apply to all plants; dedicate a lot of effort to solve one problem for one plant, uses lots of resources of regulator
You are re-learning all the time

5.2.7 Case based strategy should be combined with other strategies

A few interviewees commented that case based strategies should not be used alone. This also was suggested by examples of regulatory oversight, for example, two interviewees from one agency noted that a major event had occurred which highlighted the risk of the agency's previous, case based strategy.

5.2.8 Case based strategies miss the holistic view of the industry

Finally, a difficulty with case based strategies noted by interviewees was that case based strategies miss the holistic view of the industry and make comparisons across plants difficult.

5.3 Outcome based strategy

When discussing outcome based strategies interviewees seemed to respond to outcomes at two different levels. In responding to the general question about overall benefits and difficulties of outcome based strategies, most of the interviewees focused on a very high level outcome strategy (e.g., setting high level goals), while other interviewees focused on lower level outcomes related to specific work products for expected technical outcomes.

This second, more specific level was more likely to be discussed in the examples of regulatory oversight for the functional areas of plant design and modifications, quality systems and training and qualifications (see Chapters 6, 7, 8). It is important to note this difference because it may have influenced the comments on benefits and difficulties. Difficulties at one level may not be perceived at another level. For example, a comment that outcome based strategies are unacceptable because waiting

for an accident is unacceptable would relate to very high level goals but would not be as applicable to specific work outcomes at a lower level.

The most often mentioned benefit of an outcome-based strategy was that it takes the regulator out of the detail of telling licensees how to do things, and allows licensees to decide the best way to operate in order to meet safety goals. The most often mentioned difficulty with this strategy was that it is hard to identify ways to measure performance and thus to set safety goals. Other benefits and difficulties identified were focused on more specific issues regarding outcome-based strategies.

Interviewees identified the following benefits:

- Outcome based strategies allow licensees to determine best way to operate
- Outcome based strategies allow innovation and changes to respond to new knowledge
- Outcome based strategies are most useful in specific areas

Interviewees identified the following difficulties:

- Outcome based strategies require defining goals, outcomes, or performance indicators which is difficult
- Outcome based strategies do not address safety issues early enough
- Outcome based strategies lead to high use of resources by both regulators and licensees

- Outcome based strategies can be associated with regulatory uncertainty
- Outcome based strategies should be used in combination with other strategies

Each of these is discussed below.

5.3.1 Outcome based strategies allow licensees to determine best way to operate

The most common benefit, mentioned by about half of those who commented on outcome based strategies, was that these strategies take the regulator out of the business of setting detailed requirements on the licensee by setting high level goals. Several interviewees noted that this was the underlying strategy for their agency—that even the improvement notices provided to licensees stated goals, not details.

Typical comments are:

Enables regulators to specify goals and focus on mandate
Often used for establishing regulations and requirements—clear roles
Tells utility the goal to be achieved

5.3.2 Outcome based strategies allow innovation and changes to respond to new knowledge

Several of the experts noted that providing outcomes to licensees but not specifying how to achieve those outcomes allowed licensees to innovate and respond to new knowledge. Allowing flexibility with regard to how licensees addressed problems was presented as a clear advantage. This was discussed in contrast to prescriptive strategies that require licensees to use a particular approach, which may be inefficient. Comments included:

Provides freedom for licensees to solve problems—innovation and optimal solution

Must give operator freedom to act if they have responsibility

5.3.3 Outcome based strategies are most useful in specific areas

Some interviewees indicated that outcome based strategies are appropriate for certain areas of oversight. Areas mentioned included radiation protection, technical standards and maintenance. One interviewee also mentioned that it is not a good strategy for the main safety systems.

5.3.4 Outcome based strategies require defining goals, outcomes, or performance indicators which can be difficult

The difficulty mentioned most frequently, by about half of the interviewees who made comments regarding outcome based strategies, was the difficulty of finding appropriate measures for outcomes to assure safety. In large part this problem was discussed in light of the nature of the nuclear industry—because safety is so critical the regulator cannot wait until something happens.

One interviewee noted that the regulatory agency is focused on what it does not want (an accident) and that it is harder to measure what does not happen. Goals and outcomes therefore must reflect what may be precursors to problems or indirect indicators of problems. These were considered difficult to identify and potentially incomplete (measuring what can be measured rather than what is important). Another noted that it is necessary to have an indicator of the severity of a problem associated with outcome measurements.

Other interviewees mentioned that even when measures were identified there were often communication problems—it was hard to explain to the licensee exactly what was to be measured. Comments include:

Must find ways of measuring the right things; the things you monitor are indirect

Can't measure real final goals (no accidents) so must use measures that connect to goals

Trying to measure what doesn't happen leads to the use of "virtual" outcomes—probabilities

Difficult to write outcomes or criteria that are clear enough that anyone can see if they're being met

5.3.5 Outcome based strategies do not address safety issues early enough

The experts who discussed outcome based strategies identifying problems too late were most concerned about the reactive nature of outcome based strategies—waiting for an event or "outcome" before acting. This was the most clear safety concern regarding reliance on outcome based strategies. Comments included:

> *Can define 100% of where you want to be without how to get there but it is naïve to believe that you can define everything early enough*
> *Cannot apply very much, react too late*

An example of late reaction with reliance on an outcome strategy was given for oversight of training and qualifications. An interviewee described past use of an outcome strategy by relying on examination scores and plant performance as the basis for accepting that a plant had a good training system for staff. This appeared to work for some time until problems occurred when staff experience levels dropped. The regulator eventually determined that training had been inadequate for a long period but an informal pattern of on the job learning from experienced staff had temporarily filled this gap. The problem identification from the interviewee's point of view was late, although the situation was eventually corrected (see Section 8.3).

5.3.6 Outcome based strategies lead to high use of resources by both regulators and licensees

A number of the experts interviewed noted that outcome based strategies could result in each licensee developing their own approach to meeting goals. There were two different issues mentioned regarding this aspect of outcome based strategies. First, with regard to regulatory oversight this can be difficult because the staff has to review different approaches and it is hard to verify compliance. Comments on this issue include:

> *If let licensees go off and each do own thing, staff has to know each thing—easier to maintain one approach*
> *Require more guidance documents*

Second, that because it does not specify what the licensee is to do it is not efficient for industry. Comments on this issue include:

> *For small operators it can be too expensive—requires resources and high competence in operator's organization*

5.3.7 Outcome based strategies can be associated with regulatory uncertainty

Several interviewees commented that with outcome based strategies the licensee can develop an approach that is not acceptable to the regulator and that leads to issues of compliance and to re-work. Comments include:

> *Not clear to licensee what to do, not as efficient to industry*

Falls into "you propose and we dispose" mentality, redone work—"bring me a rock"

5.3.8 Outcome based strategies should be used in combination with other strategies

Several regulators commented that outcome based strategies should be used in combination with other strategies. Like other strategies, outcome based strategies were most often described as combined with other strategies as part of an overall strategy in the examples of regulatory oversight. In one example the interviewee commented that if you do not look at processes but only outcomes there are too many outcomes to check and when you find a problem in an outcome you do not know the cause. Looking at the outcome is efficient but you also need to check some processes. Another noted that if you only look at outcomes you do not get a holistic view. Comments on this topic from the question on benefits and difficulties include:

Still evolving—always view as combined
Good strategy provided regulator has sufficient and necessary controls of route (process) to outcome

5.4 Risk based strategy

Experts discussed benefits and difficulties of risk based strategies extensively, but there were more comments on the difficulties of using risk-based strategies than the benefits. The major benefit described by interviewees was the use of risk strategies to prioritize safety issues and allocate resources. The major difficulties experts discussed were that risk strategies should not be used as stand alone strategies and that they have serious methodological and data problems.

Interviewees identified the following benefits:

- Risk based strategies help the regulator prioritize safety issues and allocate resources
- Risk based strategies are a systematic, integrated way to assess safety
- Risk based strategies address uncertainty

Interviewees identified the following difficulties:

- Risk based strategies should be used only in combination with other strategies
- Risk based strategies have serious methodological and data limitations
- Risk based strategies have the potential of missing important safety areas
- Risk based strategies have the potential for misunderstanding and manipulating information rather than solving problems
- Risk based strategies have problems of credibility and acceptance both within agencies and among the public
- Risk based strategies have the potential for staff inattention to areas not identified as safety priority

Each of these is discussed in more detail below.

5.4.1 Risk based strategies help the regulator prioritize safety issues and allocate resources

The most frequently discussed benefit, mentioned by about half of those who commented on risk strategies, across all six agencies, was its usefulness for prioritizing safety issues and focusing resources on the most important areas for oversight.

One interviewee noted that this strategy helps concentrate the regulator and utility on what is important regarding risk. Others pointed out that qualitative risk assessment is good for prioritization of safety issues, emphasizing that risk assessment sometimes is assumed incorrectly to encompass only quantitative approaches.

Some stressed the use of risk analysis in planning for use of resources as well as for setting priorities.

A few typical comments are:

> *Greatest benefit, focus on important things, those which have safety risk, e.g. modifications*
>
> *Important strategy for prioritization and resource allocation*
>
> *Best instrument to help us to focus on what is important to safety*

In oversight of quality systems, interviewees described the use of a risk-based strategy to classify the safety impact of regulatory findings and to prioritize corrective action items (see Section 7.5). A risk strategy also commonly was used in oversight of plant design and modifications to prioritize modifications and safety issues for facility construction (see Section 6.7).

5.4.2 Risk based strategies are a systematic, integrated way to assess safety

Several experts from three agencies emphasized the integrated approach of risk analysis. They commented that the systematic way a risk strategy analyzes safety performance allows comparison of plants and looks at the big picture. This systematic approach was seen as making plants safer and a way to avoid missing issues, in contrast to the concerns expressed by some others (see Section 5.4.6).

Two examples of oversight of plant design and modifications illustrate this benefit. The first is the description of the introduction of the use of plant specific probabilistic safety assessments (PSA) at one agency to identify areas for safety improvements. This was initially done on a pilot basis at one plant, and when found effective in identifying new areas for safety enhancement, the regulator instituted the program industry wide (see Section 6.2). Second, an interviewee described the introduction of risk assessment as these methods were developed. The interviewee mentioned that station blackouts were not identified as an area of safety concern before the use of systematic risk assessment (see Section 6.5.1).

5.4.3. Risk based strategies address uncertainty

Two interviewees from one agency discussed the benefit of risk analysis in explicitly identifying uncertainty. One expert commented that being required to address uncertainty forces the regulator and the licensee to specify what is known and what is not known. While the interviewee saw this as a definite advantage, he thought sometimes people incorrectly concluded that there was more uncertainty in a risk-based strategy than other strategies.

5.4.4 Risk based strategies should be used only in combination with other strategies

The most frequently mentioned difficulty, commented on by interviewees from five of the agencies, was that a risk strategy was helpful only when used in combination with other strategies—it was not appropriate to use as a sole strategy for regulatory decision-making. A risk strategy was seen as useful in providing one of several different points of view.

A risk strategy was seen as a good complementary strategy, as indicated in the following comments:

Always a back-up to deterministic assessments

Good on top of everything

However, many experts were against using a risk strategy alone. In particular, experts were critical of using a risk strategy and excluding deterministic analysis and information. One expert explained, "Pure risk is dangerous to safety because PSA lacks some information, need more balance, need to use experience. Risk informed has three elements: 1) risk based 2) experience 3) deterministic. There are some qualities you want in the plant that are not supported by PSA, including robust design, transparent safety, simplicity and balanced defense in depth, balance in barriers."

Other comments include:

Useful for informing but has limitations in being used for deciding

Deterministic and defense in depth needs to augment

Must be complemented with deterministic and other factors

5.4.5 Risk based strategies have serious methodological and data limitations

Many experts, across all six agencies, also discussed difficulties with the data available for risk analyses and with the state of the methodology and modeling of risk.

One concern was the extensive infrastructure and database that quantitative risk analysis relies on. One interviewee commented that, "lacking that you are using

'engineering judgment' to supplement data." Questionable data quality was a concern of a number of experts. In particular, experts expressed concern about the lack of good data for certain areas, for example organizational and human factors and safety culture.

Some examples of comments include:

> *Can't say all operator actions have been identified and frequency and consequence are fully known, especially errors of communication and dependency in a complex system*
>
> *Focus on areas where method is well developed and can ignore others*
>
> *Need awareness of limitations or use of wrong numbers, need high commitment re quality of tool*
>
> *May not handle those things that are not quantifiable*
>
> *Not all factors that influence safety are modeled, e.g. organizational factors*

5.4.6 Risk based strategies have the potential for missing important safety areas

There was concern among several experts, from four agencies, that risk analysis may miss some important safety areas and the regulator would be unaware of this gap. The potential for the regulator to be unprepared for emerging areas was a major focus of this issue.

Concerns were largely centered on missing an important safety issue, as stated by one expert: "You don't know what you don't know." One interviewee mentioned the area of waste as an example of an area that might be missed in risk analysis. Others emphasized new phenomena, areas that have not been predicted or focused on in the analysis. For example, one interviewee commented that an accident may occur in an area that was not covered, so there is a need for long term robust solutions based on sound engineering.

5.4.7 Risk based strategies have the potential for misunderstanding and manipulating information rather than solving problems

A few regulators from four agencies commented on the problem of using the methodology to generate "desired" conclusions or the quantitative results appearing to be more accurate than they are in fact. These experts were concerned that it is easy to focus on the end results as if they are exact, forgetting the assumptions and estimates that go into generating the results, so that there is an appearance of greater precision than exists in actuality. One interviewee mentioned that the results were far from reality, for example, it is not possible to make competency into numbers.

A second, related, issue was manipulation of information. One expert referred to a tendency to "pencil whip" problems instead of fixing them: to use quantitative risk analysis to demonstrate that a particular problem is low probability "on paper" so that a licensee does not have to deal with it, rather than to physically fix a problem.

5.4.8 Risk based strategies have problems of credibility and acceptance both within agencies and among the public

Four interviewees across three agencies discussed the issue of acceptance of using risk strategies and methodologies. Credibility was a concern, particularly with the general public, but also within regulatory agencies.

For many of the reasons discussed above, such as problems with data completeness and assumptions and difficulty in communicating to the public what is meant by risk analysis, acceptance is an issue.

One expert commented on the need for considerable education and a culture change in engineering communities for acceptance of a risk strategy.

5.4.9 Risk based strategies have the potential for staff inattention to areas not identified as safety priority

Two experts from one agency were concerned about the potential problem of staff neglecting areas not considered high safety priority. They commented that all equipment is important and thought that staff might ignore equipment that was not designated "safety related." This concern is the flip side of prioritizing the most important safety issues and areas—these interviewees were focused on the potential to de-motivate staff which could lead to problems.

5.5 Process based strategy

Experts considered the major benefit of a process-based strategy the in depth understanding it provided of a licensee's performance. The difficulties most frequently described were that it was not an effective strategy unless the processes were linked to outcomes and that it was complex to define and evaluate processes.

Interviewees identified the following benefits:

- Process based strategies provide a deep approach to understanding how things are done
- Process based strategies give responsibility for safety and flexibility to the licensee
- Process based strategies are systematic and consistent
- Process based strategies are efficient in terms of resource use under certain conditions

Interviewees identified the following difficulties:

- Process based strategies should be linked to implementation and outcomes

- Process based strategies are difficult because of the complexity of defining and evaluating processes
- Process based strategies lead to high use of resources by the regulator under certain conditions

Each of these is discussed in more detail below.

5.5 Process based strategies provide a deep approach to understanding how things are done

Several interviewees across five agencies discussed the deep understanding that a process strategy provides. Experts described how a process approach helps the regulator to see the whole picture—to follow an issue from top to bottom. One interviewee commented that this strategy can be applied to many types of problems and that when implemented, licensees show how they are solving problems.

Others said that this approach allows the regulator to concentrate on processes related to safety and to react earlier, before there are serious problems.

5.5.2 Process based strategies give responsibility for safety and flexibility to the licensee

A few interviewees from three agencies mentioned that a process strategy has the benefits of putting responsibility for safety on the licensee and giving the licensee flexibility to determine how to carry out activities. A couple interviewees stressed the high sense of ownership and allowance for variability across operators, leaving the specifics to licensees.

5.5.3 Process based strategies are systematic and consistent

A few interviewees across three agencies discussed the systematic and consistent way that a process strategy assesses licensees. A number of experts commented that this strategy is consistent by using the same criteria applied across facilities. Some interviewees focused on the systematic characteristics of a process strategy that is clear, consistent, stable, well defined and provides good verification. These experts, unlike those who described the complexities of defining and evaluating processes (see Section 5.5.6), found a process strategy one where the licensee can easily understand the regulator's expectations.

5.5.4 Process based strategies are efficient in terms of use of resources under certain conditions

Several experts commented that a benefit of a process-based strategy was that it was efficient for the regulator. They discussed two specific dimensions: working at a high level of oversight and using a sampling method to evaluate licensee activities.

These interviewees referred to the benefits of occasional sampling and mentioned that the regulator saves resources by taking samples to verify licensee performance.

Others emphasized working at a high, as opposed to a low detailed level, which allows the regulator to get into a process without too much of the "nuts and bolts" and to "do more with less".

5.5.5 Process based strategies should be linked to implementation and outcomes

The most frequently mentioned difficulty of using a process based strategy, discussed by several interviewees across five of the agencies, was the necessity of linking this strategy to both the implementation and outcomes of processes. There was a concern that the regulator might focus on means—the processes—and forget about ends—the outcomes the processes were designed to achieve. Experts indicated that looking at processes was not complete as a stand alone strategy, but a link to outputs was crucial.

Some interviewees commented that oversight of implementation (e.g. knowing technical and operational factors) and looking at actual outcomes were important elements in applying this strategy. One expert commented that if a process was not appropriately set up and this was not identified, the situation could exist for a long time.

5.5.6 Process based strategies are difficult because of the complexity of defining and evaluating processes

Several experts across four agencies commented on the difficulty of defining and evaluating processes, discussing the need for good knowledge of processes and for deep experience. Some were concerned with the difficulty of determining what is a process, defining the scope and the criteria for evaluation. A few experts commented on the misunderstandings between regulators and licensees on verifying compliance, agreeing on what is a good process or a well-defined process.

These comments appear to be related to a point made in some of the examples of using a process strategy in oversight, that both the regulator and the licensee need a high level of expertise to effectively use this strategy. One expert discussed the use of a process-based strategy for periodic safety reviews by plants and said it was highly effective because the plants did an overall assessment and took initiative and responsibility. He noted that the process strategy relies on the licensee and the regulator to have many skills and significant expertise to be able to take on these initiatives and to evaluate them (see Section 6.6).

5.5.7 Process based strategies lead to high use of resources by the regulator under certain conditions

A number of interviewees commented that a process strategy could become a burden to both the licensee and the regulator. Interviewees mentioned that a high level of effort is likely under certain situations:

- When the strategy is applied to too many areas
- If licensees change processes frequently and the regulator has to review them again and again
- The need to sample frequently to make sure the plant actually follows processes

5.6 Self-assessment based strategy

Experts commented more frequently about the difficulties of using a self-assessment strategy than the benefits of this strategy. The major benefit discussed was that it put responsibility for safety on the licensee, while the major difficulties mentioned were that self assessment should not be used as a stand alone strategy and that it often does not have credibility with the general public.

Interviewees identified the following benefits:

- A good self assessment program reflects licensee responsibility for safety and increases the regulator's trust in the licensee
- Self assessment strategies typically are efficient in terms of resource use for the regulator

Interviewees identified the following difficulties:

- Self assessment is not a stand-alone strategy
- Relying on self assessment raises issues with the general public
- Self assessment requires an adequate and independent regulatory role
- Monetary and other pressures on the licensee can undermine effectiveness of self assessment
- Self assessment best used in low risk areas.

Each of these is discussed in more detail below.

5.6.1 A good self assessment program reflects licensee responsibility for safety and increases the regulator's trust in the licensee

Almost half the interviewees commenting on self-assessment strategies, across all six agencies, noted that a good self-assessment program was an important indicator that licensees are taking ownership of and responsibility for safety. Comments include that licensees have the primary responsibility for the safety of the plant—so that a self assessment program was essential:

Self-assessment is needed because the licensees have to get better and better and better
The licensees must do a lot of work on their own to improve; you could also say they do it for themselves, not just compliance
They must have responsibility and have to convince themselves and us that they are open and deserve trust

Interviewees also discussed the relationship between self assessments by the licensee and trust. Interviewees noted that the licensee's ownership and responsibility for safety, reflected by their self assessment programs, was a basis for the regulatory agency's trust in the licensee to perform safely. One interviewee noted this as a good indicator of the safety culture of the plant and a number of interviewees noted that their confidence in the licensee's self assessment program was what made them trust the licensee to perform safely. A different but congruent comment was that once the regulator had confidence in the licensee, then it was possible to rely more on the licensee's self assessment program.

5.6.2 Self-assessment strategies typically are efficient in terms of resource use for the regulator

Several interviewees from three agencies noted that regulatory reviews of self assessment were an efficient way to obtain a lot of information on plant performance. One comment was that having a strong licensee self-assessment program is required for effective regulation "unless the regulator is as large as the licensee". (However one interviewee noted that while relying on self assessments can be very efficient when the licensee is performing well, it can become resource intensive as a way to identify and respond when the licensee is performing poorly.)

5.6.3 Self assessment is not a stand-alone strategy and should be used in combination with other strategies

The most common difficulty, mentioned by interviewees from all six regulatory agencies, was that while self-assessment was a necessary part of ensuring safety at nuclear power plants it was not a stand-alone strategy. Experts from all of the regulatory agencies indicated that a self-assessment strategy was used in some way by their agency—generally self assessment was required of licensees and monitored by the regulatory agency. Typical comments include:

Self-assessment should be an underpinning philosophy but can't stand on its own
It is not an independent strategy—needs to be in combination with other strategies
Our agency is going in the direction of more self-assessment but it only works if the regulator can rely on the licensee to work properly; regulatory oversight cannot be totally based on self- assessment alone
Self-assessment is a necessary element of a good model

Other interviewees stressed that self assessment should be used in combination with specific other strategies. These interviewees specified that self-assessment was associated with one or more other strategies, most commonly with process based strategies but also outcome and risk based strategies. For example:

Key player in outcome based
Just part of process based system
If there is a good process, then there is a self assessment component. It is an extra line of defense, not used by itself
If you do outcome based and risk based right it will generate a self assessment system

5.6.4 Relying on self-assessment raises issues with the general public

At least one interviewee from each agency noted that public perceptions of self assessment as a strategy was an issue. One comment pointed out that a disadvantage of self assessment based programs was that they provided less openness to public scrutiny than regulatory oversight programs. More common comments were associated with public perceptions of "giving away regulation to the operator". Typical comments include:

Has some communication issues, can be seen as deregulation rather than a variation of regulation
If something happens, hard to explain to public, to media that regulator is only supervising self assessment

5.6.5 Self-assessment strategies require adequate and independent regulatory oversight

Several interviewees noted that self-assessment alone was not adequate and the importance of regulatory role; without regulatory oversight, they noted, plant safety deteriorates. Interviewees focused on the need for, and minimum level of, regulatory oversight—especially independent tools and methods. One interviewee cited a study done of deregulation in another industry which found that within six months of deregulation there were serious decreases in safety.

5.6.6 Self-assessment best used in low risk areas.

Four interviewees from two agencies noted that this was a strategy best used in low risk areas. Two of the interviewees commented that the regulator should still have a role in checking the results of the self-assessment. These comments were about using self-assessment as a stand-alone strategy and did not indicate that licensee self-assessments were unnecessary in high-risk areas as part of a combination of strategies.

5.6.7 Monetary and other pressures on the licensee can undermine effectiveness of self-assessment

Three interviewees from two agencies noted that self-assessment based strategies are vulnerable if the licensee is facing monetary or other pressures. This theme was also clear in examples expressing concern over the effects of economic changes on licensee programs.

6 Plant design and modifications: experience with regulatory strategies

This chapter discusses the experience of the experts interviewed with the use of regulatory strategies for oversight of plant design and modifications. After a brief summary of the combinations of strategies used for oversight, specific examples are presented to illustrate patterns in the experiences of interviewees with the use of strategies in this functional area.

These patterns include:

- Tension concerning use of a risk strategy for regulatory decisions
- Balancing use of risk strategies with prescriptive strategies
- Transition from prescriptive to process based strategies
- Use of prescriptive strategy for action and closure
- Limitations of prescriptive strategy
  - Unable to predict all possibilities leading to unexpected difficulties or gaps in requirements
- Lack of focus on most important safety issues
- High level of expertise needed for process based strategy
- Use of a risk based strategy for prioritization
- Identification of potential generic problem from situation at one plant
- Late intervention

During the interview, experts were asked to provide an example of the oversight of plant design or modifications and to "walk through" how the regulator had addressed the specific issue. After providing the example they were asked the following questions:

- *What strategy or strategies would you say was used in this example?*
- *Do you know how this strategy came to be selected?*
- *How effective do you think this strategy has been in this case?*
- *Please describe the major benefits (if any) of using this strategy.*
- *Please describe the major difficulties (if any) of using this strategy.*
- *If there were difficulties, do you think this strategy would usually result in these kinds of problems or would better implementation have solved most of them?*
- *Do you think that other strategies would work equally well for this area of oversight, or is this strategy the most appropriate given the context of your country and agency?*

Overall, the interviewees provided 36 detailed examples of the use of regulatory strategies in this functional area: 28 examples regarding modifications and 8 examples regarding plant design. (In a few instances different interviewees discussed the same example in separate interviews.)

In general the interviewees discussed examples that most often illustrated the use of risk (used in about 60% of all examples), prescriptive (used in about 50%) and process-based strategies (used in about 45% of all examples). It was less common for examples to discuss the use of outcome based (about 30% of all examples), case-based (about 30%) and self-assessment (used in less than 25% of the examples).

It was typical for a combination of two, three and sometimes four strategies to be used in oversight of plant design and modifications—and many different combinations were used in the examples. Common combinations of strategies given in the examples were 1) prescriptive, risk and process based and 2) risk, process and outcome-based. When only a single strategy was indicated as the approach used, it typically was either prescriptive or risk-based.

6.1 Tension concerning use of a risk strategy for regulatory decisions in oversight of plant design and modifications

Often there is tension concerning the use of a risk strategy for regulatory decision-making—both between regulators and licensees and among staff within regulatory agencies. This tension often centered on disagreement over the relative emphasis given to use of information from risk analysis to that given to information from deterministic analysis in making decisions.

There were several examples of licensee and regulator disagreement over acceptance of risk results in defining necessary actions regarding plant modifications. Also, there were some examples described where there was disagreement among staff within a regulatory agency over the emphasis on using risk versus deterministic information in decision making about demands on licensees. Use of a risk strategy was viewed by some as reducing the importance placed on deterministic information. Some of these examples are described below.

6.1.1 Disagreement between regulator and licensee

Three examples are described where the regulator disagreed with the licensee's requests for taking or not taking action based on risk analysis results

Example 1: During a required major safety review, plant staff identified a potential hazard related to access for maintenance testing at the bottom of the reactor. A risk analysis determined that there was a remote probability of a failure. The probabilistic risk analysis (PRA) results were not accepted by the regulator as definitive because of the high safety significance of a failure. The regulator suggested that a change be made to modify the access so that if there were a failure, even though highly unlikely, there would not be a safety significant consequence. The level of the possible consequence not the probability of the consequence occurring, was the key consideration, to reduce risk. The plant agreed to make the change, which was reviewed and checked by the agency.

Example 2: This example, similar to the first, began with the plant claiming that valve problems did not need to be addressed due to the very low frequency of needing to use the equipment. The regulator questioned this reasoning and established a dialogue with the plant staff making sure the plant would guarantee the operability of the equipment (a specific requirement—that equipment be operable in situations for which it was designed). The plant was given three days to provide evidence. At first the plant gave verbal assurance; then the agency required better assurance. It turned out that there were two different views within the utility; the plant's internal safety department questioned whether the operating side had made the right judgment. Finally, the utility realized they had weak grounds and so changed their position. The regulator did not accept low risk based on frequency of use, but applied the "operability of equipment" standard as the threshold. The difference in this example from the first one, was the internal disagreement within the utility itself as well as between the plant and the regulator.

Example 3: In the third example the regulator reviewed a plant's probabilistic safety assessment (PSA)[1] regarding fire protection and although there was agreement on almost everything, there was disagreement on some elements. The plant analysis used some rules that the agency disagreed with; certain valves did not close and although the PSA concluded this was acceptable, the agency did not think the analysis was robust enough. There continues to be ongoing discussion between the plant and the regulator regarding the analysis and the need for modifications.

6.1.2 Disagreement within a regulatory agency

A common pattern discussed by experts across four of the agencies was the tension between a recent emphasis on probabilistic risk analysis and the past reliance on deterministic analysis. Below is an example from one agency that presents in considerable detail the salience of this issue in regulatory oversight.

Example 4: There was a controversial decision within a regulatory agency to grant a plant's application for an exception from technical specifications for a specific situation that was given as an example in two different interviews. The waiver was requested to allow the plant to continue operation beyond technical specification conditions. In both

[1] PRA and PSA refer to the same methodology; different individuals use the two different terms

interviews the experts described the discussion and the decision-making within the agency as difficult and controversial. In one interview the expert said that both PSA and deterministic analyses were used and the agency evaluated the risk impact. There were differences among experts within the agency; the PSA experts considered the waiver reasonable while some subject matter experts did not. The waiver was granted and no difficulties occurred during the period of the waiver. The agency made extra inspections during the waiver period including one unannounced inspection to assure safety. According to the PSA expert this was a very effective though difficult application of the risk strategy. In future applications, this expert suggested additional specific deterministic analyses, for example, of safety margins.

In the second joint interview of two subject matter experts, they described the decision to grant the waiver as based solely on risk assessment with no consideration of deterministic information—the plant submitted a risk analysis justification only. From these experts' perspective, the permit would not have been granted on a deterministic analysis basis. In explaining why they considered the risk strategy as applied in this example as less effective they said that deterministic analysis has well defined rules while probabilistic risk assessment (PRA) depends on the probability of an occurrence—"like playing the lottery." They did not think it was clear whether the number in the analysis results represented reality. No event occurred during the short time frame of the waiver. This fact did not lead to their concluding that the decision was correct; on the contrary it led to their concern that this experience will encourage more decisions based inappropriately solely on risk analysis.

6.2 Balancing use of risk and prescriptive strategies

Several experts described the evolution over time of incorporating a risk strategy into oversight of plant design and modification. This accompanied a reduced reliance on a highly prescriptive approach that was typical of the initial early period of nuclear regulation.

Example 5: In one example that illustrates this pattern, the expert described the evolution of oversight of design for new plants. The initial approach was highly prescriptive. At that time engineering judgment was used to estimate risk and a consensus evaluation was developed. Then the agency decided on specific prescriptive requirements. In the interviewee's opinion, this led to over-conservatism in numerous judgements and therefore to excess and unnecessary requirements. The benefit was significantly large margins of safety. This strategy allowed for failures to meet specific requirements and therefore they had no adverse safety impact. Now, the agency has developed a new approach, combining prescriptive and risk strategies. The regulator uses risk if there is sufficient data to do analysis that will lead to more accurate information. The expert stressed that there is always a benefit of using a mix of both strategies, suggesting that a good approach is to use a prescriptive strategy to set thresholds and then use risk-based information within established boundaries.

Example 6: In an example described earlier (Example 2) the expert commented that having a basic prescriptive requirement—must demonstrate operability of equipment in

the situation it is designed for—was fundamental to the effectiveness of applying a risk strategy. If the regulator had not had a certain baseline in mind there could have been a different outcome. In this example the agency insisted on the plant meeting the threshold of operability in spite of low frequency of use of equipment—the interviewee said that having a basic prescriptive requirement was fundamental. This is a specific illustration of the application suggested above in Example 5—using a prescriptive strategy to set a threshold, "operability of equipment," and using a risk strategy within the boundaries of that threshold.

Example 7: In this example, from a third agency, the regulator asked each plant to conduct a plant-specific PSA to see if this activity would be useful for identifying areas for safety improvement. This program was a move away from the highly prescriptive strategy that had been the dominant approach of the agency up to that time. At one plant the PSA identified a number of design changes that would improve safety performance of some systems, for example the high-pressure injection system valves. The plant decided to make these changes (knowing that if they did not decide on their own, it was likely the agency would request that they make the change for its safety benefit). The results of using this risk strategy have been effective so that the agency requires all plants to develop and maintain a plant-specific PSA. The major benefit according to the expert is that making changes that reduce risk in any one component or system reduces the overall risk of plant operation.

6.3 Transition from prescriptive to process based strategies

Several examples were given of the effective use of prescriptive strategies during the early period of design and construction or when a new field of expertise was being introduced. At this time, the agency and the industry had limited experience and knowledge and therefore prescriptive strategies were seen as necessary. As experience and knowledge were developed, the agency moved to greater reliance on process based strategies.

Example 8: In one example, the initial period of oversight of design and construction was described as using a prescriptive strategy to address high uncertainty. Although this resulted in "over-engineering," there was not sufficient knowledge to use other approaches. The agency changed when there was more information. There was a major transition from prescriptive—approving everything—to one that was more process dependent (and combined with outcome-based). The agency became more dependent on the licensee's quality assurance (QA) process. The licensee took on responsibility for safety instead of relying on the agency (the pattern under the prescriptive strategy). Inspections focused more on monitoring the processes of the licensees.

Example 9: A second example, from a different agency, provided a similar story, but for a very different area: analysis of human factors (HF) when making plant modifications. When the interviewee began human factors work in the agency, the plants had no experience and no expertise in this area. The agency was forced to be prescriptive in requirements. The regulator was able to transition in the late 1990's

when the plants had hired staff in human factors and organization (required by the regulatory agency). Now the agency was able to move to a process based strategy, which the expert considered preferable, but not possible until the plant had proper expertise in the field of human factors. The specific example the expert discussed was the inability of plants to consider human factors issues in control room modifications because of lack of expertise. As the interviewee explained, even if the plant uses an outside company for design of the HF element, the plant needs to be able to internally review the design and assess its implementation; the plant cannot do this unless they have their own HF staff.

6.4 Use of prescriptive strategy for action and closure

There were a number of examples where experts described a prescriptive strategy as a needed and effective way to assure plant safety performance. A prescriptive strategy was used to assure proper changes were made and to avoid long periods of negotiation with the licensees over disagreements. This strategy also was used when a plant did **not** perform well and the regulator needed to provide closer oversight. Interviewees often described using a prescriptive strategy after other strategies had not been effective.

Example 10: This example concerns the construction of new facilities (not an operating nuclear plant). The licensee had done a good job with earlier construction of facilities. For new construction the regulator used a combination of outcome based (general goals) and self-assessment strategies. Criteria were set for actions and meetings with the regulator for follow-up. The regulator identified poor integration of QA into the work and the licensee revised the QA program. The regulatory staff then recognized discrepancies between the licensee's plans and safety reports and the actual work. The regulator became concerned about whether the self-assessment strategy was effective. The use of contractors and competence of operators were weak links. There were "endless discussions" with the operator of the facility. Finally the regulator had to set requirements; the expert said that the regulator must be able to go into great technical detail if needed, to go back to a prescriptive strategy. However, he did not think using a prescriptive approach from the beginning would be a good strategy.

Example 11: In an example from another agency there was a problem with a modification on a safety system. When the plant implemented the modification it interfered with the design basis of the plant. The plant had done a poor analysis. The regulator found there were several other modifications with problems. The interviewee said the plant had tried to solve the problem quickly and cheaply and the regulator needed to control and improve the situation. In response the plant did improve their analysis and improved other areas with problems. This expert concluded that a prescriptive strategy works better than other strategies because the regulator must be able to demand the appropriate standard of performance from licensees when they do not perform well on their own.

Example 12: Another example, described in one interview and referred to briefly by two others at one agency, was where a prescriptive strategy was used when one plant was performing poorly. The regulator "had to check everything" and became very

prescriptive because the regulatory staff developed a lack of trust in the licensee over time. In this example the licensee did not identify a significant hardware problem that revealed itself, and it was a symptom of a series of more systemic problems within the organization, leading to a higher level of regulator involvement and oversight.

6.5 Limitations of a prescriptive strategy

Several examples described difficulties with prescriptive strategies. Two limitations of prescriptive strategies are discussed below—the inability to predict all possibilities which leads to unexpected difficulties and potential lack of focus on the most significant safety issues.

6.5.1 Unable to predict all possibilities leading to unexpected difficulties or gaps in requirements

A number of examples described the difficulty of not being able to think of all possibilities in advance when developing prescriptive requirements, which led to future unexpected problems with regulatory oversight.

Example 13: In this example, a plant had several design and implementation failures. The plant had failed to implement the design completely and did not identify these problems during testing. Later the plant found it had mis-located cabling of some equipment, which under certain scenarios led to an unexpected potential for a common cause failure mode in an emergency safety system. This problem suggested to the regulator that there might be other undetected problems at the plant—it might be a symptom that other elements had not been correctly tested initially. It was possible to correct this problem, which the plant did. But the complexity of the design itself increased the likelihood of problems with this system. The plant also carried out an overall analysis to show that the design and testing was correct. Some other problems were found—all failures were related to this complex design. A simpler design of this feature would have been better, but this vulnerability was not recognized at the time the design was originally accepted by the regulator. Because it was a design that had been accepted elsewhere and came with an extensive set of prescriptive requirements the regulator failed to recognize the extra complexity and interconnections of the design. The interviewee commented that the designer expects to be able to predict all possible failures and interactions and that testing will be implemented perfectly. According to the interviewee prescriptive requirements assume one can identify everything in advance, but it is very hard to think of all eventualities, particularly interactions among systems and components. He concluded that a different type of strategy for reviewing the design initially would have been preferable.

Example 14: The expert discussed the original approach to plant design and construction, which was highly prescriptive (presented earlier in Example 5). The interviewee pointed out that there were some areas that no one had thought of as being

of potential concern and so no requirements had been developed for that area. An example of one such area was station blackouts. This was later identified as a safety issue when risk analysis was developed and incorporated into the agency's regulatory oversight strategy.

6.5.2 Lack of focus on most important safety issues

Several of the experts in describing the use of prescriptive strategies discussed the problem of detailed requirements that may "lock" the regulator and the plants into specifics that eventually turn out not to focus on important safety issues. At times requirements may become unnecessary or there may be an undesirable focus on compliance that is not essential to safety.

Example 15: One example was an electrical power system problem that was part of a modification. A combination of strategies was used; prescriptive was one element. The expert commented that part of the problem with prescriptive regulation is that it generally does not distinguish level of significance of issues so some inspectors may tend to look at compliance across all issues equally instead of placing emphasis on those that have the greatest safety significance.

Example 16: Another is the original prescriptive approach to plant design, which was described above in Example 5. The interviewee pointed out that the flip side of the wide safety margins of this approach was over-conservatism and the development of excess, unnecessary requirements in some areas.

Example 17: A last example concerned a prescriptive regulation that was highly detailed regarding earthquake requirements. The level of detail was so specific that any change was very difficult and created a lot of contention between the regulator and industry. There was a decision to revise the regulation fairly soon after it was issued since anything different from the rule needed an exemption. This was an example of addressing an important safety issue, but the particular application of the prescriptive strategy led to use of resources focused on correcting too great a level of detail in the regulation.

6.6 High level of expertise needed for process based strategy

Many of the experts describing the use of a process-based strategy commented on the need for a high level of competency and expertise on the part of both the regulatory and plant staff for a process-based strategy to be effective.

Example 18: One example of this was the discussion of periodic safety reviews carried out by plants described in Example 1. This was a requirement initiated by the regulatory authority when plant aging became a concern and the agency realized the need to stand back and have the plant carry out an overall assessment instead of piecemeal consideration of issues. The interviewee evaluated this process-based strategy as highly effective because the licensee takes initiative and responsibility. The

expert commented that a process-based approach requires the licensee to have skills and works well for a small regulator with limited resources. A limitation of the strategy, according to the interviewee, is that it relies on a high level of expertise within the licensee and also on a high level of expertise of the regulator. It would not work with small licensees (e.g. a utility that has only one plant) since the utility would not be able to maintain sufficient expertise. The expert was becoming concerned in general with the increased financial pressures in the industry, e.g. global competition, privatization; as the industry is split competence is eroding and there is a loss of expertise.

Example 19: An expert from a different agency described how the introduction of a process-based strategy for oversight of human factors design and implementation of modifications had to wait until licensees had internal expertise in this field, as discussed in Example 9. The specific issue was control room modifications considering human factors issues. The agency used a prescriptive strategy until licensees hired staff with expertise in organizational and human factors, because without such internal competency the regulator did not think that the plant would be able to adequately review human factors design and implementation on their own.

6.7 Using a risk based strategy for prioritization

Using a risk-based strategy to prioritize safety issues for design, construction and modifications was a common pattern mentioned explicitly by interviewees from all six agencies. It is discussed as one aspect in a number of descriptions of oversight activities presented in this chapter. One example illustrating this common application of a risk approach is presented below.

Example 20: An interviewee described how a utility prepares a preliminary safety case for a new plant design, going through a series of preparing a plan of activities, getting permission from the regulatory agency to proceed with a given set of activities, and then executing them. The expert indicated that safety commissioning must be driven by the safety case and that risk analysis was used to drive prioritization of safety issues. The interviewee said that a main benefit of prioritization is maintaining the focus on important safety issues—if the regulator does not focus on what is most important the licensee loses confidence and safety culture is undermined.

6.8 Identification of potential generic problem from situation at one plant

In a number of examples, interviewees described the use of combinations of strategies for oversight which identified problems at one plant that were then determined to be generic safety problems.

Example 21: In this example a plant was individually and independently adding electrical demand on busses, which appeared adequate when analyzed separately. It

would only be a problem if under abnormal conditions there was a need for emergency systems and full power, then the system could not handle the full electrical load. The plant had not recognized this situation. The agency used a combination of prescriptive, process and performance or outcome based strategies. The agency requires that specific processes and systems are looked at, e.g. how the licensee manages design control. The inspection procedures are fairly prescriptive. The inspector reviewed the process and it was not being done well (potential impacts were not recognized—performance or outcome based). The inspector reviewing the system identified the problem of electrical overload. There was a way to overcome this problem, and the plant did make the necessary modification once the inspector identified it. The expert commented that if the agency had relied on only an outcome based strategy the problem would not have been found until an event. Based on this plant's experience, the regulator instituted an industry-wide inspection program of electrical systems. After a few team inspections the plants were hiring consultants to find and correct problems and there were fewer inspection findings. This was an effective program since the problem was dealt with across the industry.

Example 22: An interviewee described one plant being shut down after an independent review indicated many areas were found lacking. The regulator decided to undertake a major program of requiring licensees to refurbish many of their aging units. The interviewee discussed one example in detail that was ongoing for about three years. This complex work included many design changes. A PSA was done and used to determine requirements for improvements—for example in fire protection and control areas. There were discoveries of unanticipated problems, e.g. thinning of pipes, diminished operability and difficulties with contractor work. A number of strategies were used for different decisions. The agency started with some prescriptive requirements. A risk basis was used to evaluate what was most important to require. Approvals were based on design requirements being met and completion of work. This included using process and outcome based strategies in addition to the prescriptive and risk-based approaches already mentioned. The interviewee considered this a highly effective approach, now they are sampling and getting confirmation that their assessment is accurate. The expert concluded that while the development of the combination strategy may not have been efficient due to the long time and high resources used, it is a good model for the future since the agency was assured that requirements were met and the facility will be safe and reliable.

Example 23: An interviewee described how a defect was found in a significant piece of hardware during an outage. The plant is required to conduct specific inspections during outages, including a higher level of sampling of certain equipment as the plant ages. The plant must share its findings with the regulator. The selection of the hardware to be inspected is determined using a risk-based approach—selected because of its high safety significance. The plant did an analysis regarding the impact of the defect and presented the results to the regulator. It is up to the licensee to develop their own processes to deal with the problems they discover. The interviewee considered this a very effective strategy because this process allowed the agency to get full information and understand the situation. Based on this information the regulator later looked into whether the same problem was occurring elsewhere.

6.9 Late intervention

A number of interviewees described regulatory strategies used in examples of responding to safety issues at plants at a later point than was desirable, and discussed the lessons learned from these experiences.

Example 24: Two experts in different interviews described this example of using process-based audits that had specified outcomes as the combination strategy for oversight of construction of a new facility (not a commercial power reactor). Although the regulator was involved from the early design stage in oversight, the problem was only uncovered during the commissioning of the facility. The root of the problem was an inadequate QA program; design verification did not work well and the plant got involved in construction before it should have and ran into construction difficulties because of not adhering to the QA system. There was no safety impact because the regulator discovered the problem during commissioning. However, there was a public expectation of the regulator to act earlier to prevent such a situation. So there was a sense that the regulator had not been intrusive enough in oversight. In hindsight the agency recognized that there were inspector audit findings that were signals of problems, but at the time these did not appear as significant as they did later. The facility staff learned from the experience and developed an independent quality oversight group. The interviewees also said the regulator learned—although the experience was intense, it had long term benefits. One of the interviewees commented that once a facility has a good program, the agency is able to reduce resources; the audit program is the focus, not individual issues. One important lesson learned according to this expert was for a new reactor the agency needs to be intrusive at the design phase, it is too costly to wait until later stages.

Example 25: In two different interviews experts from the same agency gave this example: an old design fault was revealed in an incident. This was an example of the use of an outcome- based strategy—reaction to an incident—to identify a problem. Several years earlier the particular piece of equipment had been reviewed and was thought to be good. It now appeared that requirements on verification of design and testing were not enough. The main problem was that testing was done on new material that was used in the equipment, but when it got old it came apart. It may have been a fault of the initial testing of the material. The expert thought they should have asked the licensee to commit to test the material in all types of conditions. The management of aging was a new area at the time. The incident was used for a complete review of all analysis at all plants—not just this issue, because the incident raised concerns about analyses in general and the need to consider different conditions, not only aging but such things as performance in accident conditions. While the response to the problem involved other strategies, the interviewee described the example primarily to illustrate what had been done incorrectly in the past and the lessons learned for future preventive, problem identification.

Example 26: A third interviewee, from a different agency, discussed the same example above (Example 25), from the perspective of how his agency used the information from that incident after a similar problem was identified in his country. The agency informed all plants of the situation that had occurred in the other country as well as in

their own country and then each plant determined if it had a similar vulnerability and needed to make changes. The agency used a combination of prescriptive, risk and process-based strategies. There are prescriptive requirements licensees must meet. A risk based strategy is used to determine the time frame licensees are given for taking action to make necessary changes—based on the degree of risk of the situation. Finally, a process-based strategy is used—licensees analyze their plant condition and determine a course of action needed to meet the prescriptive requirements. The combination of strategies was effective in dealing with the issue; there was concern among some within the agency, but not this interviewee, that it took too long a time for all of the plants to complete making the changes.

7 Quality systems: experience with regulatory strategies

This chapter discusses the experience of the experts interviewed with the use of regulatory strategies for oversight of quality systems. After a brief summary of the use of strategies for oversight in this area, examples illustrating patterns identified regarding experiences with the use of strategies in the oversight of quality systems are presented.

The patterns identified were:

- Responses to systemic and recurring problems: process based and prescriptive strategies
- Difficulty with process based strategy: lack of follow through reduces regulatory effectiveness
- Benefits of process based strategies
- Difficulties with changing strategies: using a new process based strategy
- Use of risk-based strategies to set priorities

Interviewees were asked to "walk through" an example of the oversight of quality systems. After providing the example they were asked the following questions regarding the example:

- *What strategy or strategies would you say was used in this example?*
- *Do you know how this strategy came to be selected? If yes, please describe.*
- *How effective do you think this strategy has been in this case?*
- *Please describe the major benefits (if any) of using this strategy.*
- *Please describe the major difficulties (if any) of using this strategy.*
- *If there were difficulties, do you think this strategy would usually result in these kinds of problems or would better implementation have solved most of them?*
- *Do you think that other strategies would work equally well for this area of oversight, or is this strategy the most appropriate given the context of your country and agency? Please explain.*

Twenty eight interviewees provided examples of the oversight of quality systems. In some instances the same example was discussed by more than one interviewee from the same regulatory authority or the same regulatory action was taken in response to similar events by one regulator. In these instances the information from the interviews was sometimes combined.

Almost all of the experts described combining two or more strategies for oversight of quality systems. Over seventy percent of interviewees noted the use of a process-based strategy, usually as the primary strategy, in their examples of oversight of quality systems. The other strategies were each mentioned by about 25% of interviewees as

used in oversight of quality systems. Experts described the strategies used as effective in most of the examples (over 75%); only one interviewee described an example he thought was not effective. Other interviewees did not think there was adequate information to evaluate effectiveness of the strategy in their examples.

7.1 Responses to systemic and recurring problems: process based and prescriptive regulatory strategies

A number of the examples were of regulators becoming dissatisfied with the performance of a licensee, determining that problems were systemic and recurring, concluding that the licensee was not adequately controlling the quality of work, and requiring improvements in the quality system to address these findings. Actions by regulators varied based on responses by licensees to regulatory initiatives. Three examples are discussed to illustrate this pattern. In the first example the licensee made significant improvements based on recommendations by the regulator, which had used primarily a process based strategy. The regulator influenced the licensee to make improvements and accepted the licensee's program. In the other two examples the regulatory agency engaged in discussions with one or more utilities regarding problems with quality systems but could not reach agreement and closure until they instituted a prescriptive edict.

Example 1: In this example, the regulatory agency required all licensees to have safety management systems including quality assurance. However there was a problem with one licensee's quality assurance system, especially in their ability to "close the loop" and make corrections based on the findings from their quality assurance system. More and more issues arose that should have been prevented by the quality system. The regulator's confidence in the self assessments being done by the utilities eroded and an inspection was conducted to evaluate the system in detail. The inspection uncovered a culture problem in the plant. Staff were cutting corners and not telling management about problems in the quality assurance system. The enforcement strategy in this case was the regulator using influence to promote a better quality system at the utility. This resulted in utility management actions to improve the quality system and more openness in the system for greater ease of checking by the regulator. The interviewee described the overall regulatory strategy as process based, and noted that risk and the unique qualities of this case also were considered. The interviewee thought the result was very effective in turning around the problem, developing important knowledge about the system, and initiating licensee staff response. Major benefits of the strategy noted were an ability to do more with less and to develop confidence in the system. The interviewee noted that this approach was successful in part because of a relationship of confidence and trust—without this relationship it would not have worked—and that if the licensee actions were not adequate the regulatory agency would have escalated the enforcement actions.

Example 2: In this example two interviewees from the same regulatory agency described problems in quality systems that resulted in more prescriptive requirements on licensees. Issues arose across a number of licensees. These included:

- A utility was beginning refurbishment and it was clear that the quality system was not working well. Work was not done according to procedures, there was considerable rework, the wrong components were sometimes used, and engineering work was not compatible with conditions in the field.
- A poor quality system during design and construction led to massive design and manufacturing errors. There were many quality systems findings by the licensees regarding these problems but a lot of leading indicators were ignored.

One interviewee commented that these and other instances of poor quality systems created a great deal of concern because the quality system goes to the heart of everything—if the licensee does not manage to do the work correctly it makes the regulator question their ability to operate.

The interviewees described a period of allowing licensees to voluntarily implement industry standards for quality systems. There were inadequate improvements in licensee performance with this approach. The regulatory agency became prescriptive and imposed a national management standard for licensee quality systems. The interviewees described this approach as a prescriptive strategy because the licensee was required to create a process that complies with a set standard. They said that a prescriptive strategy was selected because licensees were not complying with an industry standard that was voluntary. They thought that the strategy was successful in bringing up the standard.

Example 3: This interviewee commented that "quality system problems are harder than hardware problems to identify and address". The example describes the outcome of a special inspection conducted on the process to control the safety software in nuclear power plants. The interviewee described the approach as very practical, a combination of process based, prescriptive, and case based strategies. The regulatory agency had a safety guide for software assurance. The inspections found variation in the plants; some had good processes and some did not. In two or three plants the inspection identified a number of problems and sent the plants a letter requiring improvements. The utilities did not respond to the original letter. There was on-going discussion between the regulator and the plants over a period of years but improvements were not being made to the satisfaction of the regulator. Finally the regulator adopted a prescriptive strategy and set clear requirements for the plants. The plants have implemented the required improvements. The interviewee noted that a benefit of the ongoing discussion was that both the regulator and the utility learned from the process. The major difficulty was that the process was too long for safety—it took six years, it should have been one year. The interviewee concluded that the eventual outcome was effective but it took too long.

7.2 Difficulty with process based strategies: lack of follow through on findings reduces regulatory effectiveness

In all, six interviewees discussed cases in which involved lack of follow through on issues identified during quality system audits. In some cases it was the corrective

action programs of the licensee that were not being implemented, in other cases it was the regulator that did not follow through on the findings of quality system inspections. Quality systems may be more vulnerable to this lack of follow through than other functional areas. One reason suggested was lack of prioritization of the findings of these audits (see the discussion of the use of risk based strategies to prioritize findings, Section 7.5). Other suggested reasons were the difficulty of demonstrating problems with the quality system compared to technical issues and a historical focus on hardware rather than quality systems by utilities and licensees. Two examples are provided below.

Example 4: In this example the interviewee described the use of a new, process based quality management inspection. During this inspection a lot of information was collected about the quality system and issues were identified. However, neither the regulator nor the licensee assured action on the inspection findings. Because of the lack of follow-through on the inspection findings, problems arose which reflected badly on both the plant and the regulatory agency. The interviewee thought that this experience exposed the regulator's own cultural attitudes, which gave more weight to technical areas rather than management processes. The regulatory agency has since increased attention to quality systems and management oversight.

The interviewee's assessment was that this increased attention to processes has been an effective strategy because looking at the quality management system touches on everything the licensee does and provides greater insights than only looking at specific areas. The benefit of the experience to the regulator was that it brought home these points and improved internal communication within the agency.

Example 5: In this example the regulator did a specific inspection on the quality system of a utility prior to a large modification at a plant. A process based strategy was selected to examine how the licensee governed its own processes and to get a holistic view. The inspection focused on the licensee's own safety assessments and how they work. Many issues were identified by the licensee and by the regulator; however, the regulatory agency did not follow up to assure that the issues were addressed by the licensee. For example, problems with suppliers—poor documentation and poor assurance of qualifications of personnel—were identified by the quality system process but the licensee did not see these problems as important and the regulator focused on technical areas rather than these quality system problems. A number of problems arose that had been predicted by the quality system inspection results. Because the problems had not been resolved based on the inspection findings both the licensee and the regulator suffered. The effectiveness of the strategy to review the quality system process was diminished because of lack of follow through. The interviewee suggested that the lack of follow through might have been caused in part because of a utility and regulator tradition of looking at technical and hardware issues instead of process issues.

7.3 Benefits of process based strategies

Several interviewees provided examples that discussed benefits that resulted from the use of a process-based strategy. These benefits included:

- Getting a safe result efficiently (Example 6)
- Providing the regulator with a clear basis on which to evaluate performance. (Examples 6 and 7)

Example 6: In this example the regulatory agency has an overall requirement that licensees have adequate arrangements to deliver quality management systems. In response to the initiation of a large modification by a licensee the regulator required that the quality management systems be documented and made more transparent to the regulator. This allowed the regulator to have more confidence in the area and to reduce inspection. In developing and instituting this new system the utility received high marks on a national quality award system. This primarily process based approach was effective in getting a safe result on a huge project and getting the operations back on line quickly. The interviewee stated that a major benefit was that the licensee took responsibility and ownership. Another benefit noted was that the regulator could clearly explain the basis on which they approve the work.

Example 7: In this example the regulatory agency changed their approach to quality systems. Historically two documents—one describing the quality system for construction and another describing the quality system for operations—were required. The adequacy of the quality system according to International Atomic Energy Agency (IAEA) standards was evaluated during the review of one plant's operating license. Based on this assessment the regulator determined that the plant needed to develop a modern quality system with self assessments. It took the plant two years to complete the new quality system plan.

The main issue with the earlier quality system had been that it was two systems—one for how to conduct work and another, separate system, for quality assurance. The previous quality system only described audits and did not cover the normal way of operating. The new system defines both processes and indicators and is a single system. The interviewee said the strategy used was process based including self-assessment and outcome measures. The major benefits described were the development of a new quality system and improved operations. Although there were no clear performance problems prior to the implementation of the new quality management system, the overall system for assuring safe operation had been unclear in the past. This was improved with the new system.

7.4 Difficulties in changing strategies: using a new process based strategy

One of the questions asked about the examples was whether there were any difficulties in implementing the approach described and, if there were difficulties, whether they were inherent to the strategy or due to implementation problems. Many interviewees noted that there were difficulties in changing strategies. They discussed issues of resistance by licensees and also by regulatory staff to changing from one strategy to another. In most examples the difficulty was attributed to the response to change and noted briefly in response to the question. In the example below the interviewee

expands on this issue and describes particular difficulties with changing from a prescriptive to a process based strategy.

Example 8: In this example, the regulator required one plant to establish an integrated safety management system based on IAEA guidelines with clear policies, regulations and an assessment process. The plant had been having problems and the requirement was established as part of the license renewal. The interviewee described the strategy as process based with some prescriptive elements. Instituting the new strategy was described as difficult because it was new and different from previous, more prescriptive strategies. The major benefits of the new strategy noted by the interviewee included

- better assurance that the plant was taking safety steps in a more systematic and integrated way rather than taking a piecemeal approach and
- responsibility for safety rested more on the plant than the regulator than under a more prescriptive strategy.

Despite these benefits, the interviewee noted problems in communication between the regulator and the licensee regarding what was required. The plant was accustomed to having detailed prescriptive requirements rather than developing a system themselves. The nuclear power plant has staff with technical expertise but not expertise in developing systems. The interviewee assessed these problems as inherent in the acceptance of a process based strategy compared to a prescriptive strategy—where the "rules of the game" are clear.

7.5 Use of risk-based strategies to set priorities

In these three examples the interviewees noted the importance of using a risk based strategy to set priorities for and manage resolution of quality system findings.

Example 9: In this example the regulatory agency changed the approach to dealing with quality systems. In the past the licensee submitted documentation to the agency, regulatory staff reviewed the materials and sent the licensee their findings and corrective actions. This approach was adequate for simple issues but was problematic for complicated issues. The utility was spending a lot of time and effort in submitting the documents and responding to the findings and corrective actions. The regulatory staff was spending a lot of time reviewing documents, communicating findings and corrective actions to the utility, and then evaluating the utility's response. In some instances the utility would spend a lot of resources responding to a problem and then find that their solution was unacceptable to the regulator. The approach was mechanistic and prescriptive and created tensions between the regulator and the utility. The regulatory agency changed to a process-based approach with more collaboration between the industry and the regulator. The agency worked with the utility to classify the safety impact of regulatory findings. A risk-based strategy based on discussions among technical experts was used to prioritize findings. The goal is to improve the process used by the licensee and the plant is now encouraged to fix their processes rather than focusing on correcting symptoms. There is a collaborative effort to set priorities and decide the level of importance. The interviewee's assessment was that the change from prescriptive and mechanistic to process and risk based has been

effective. A major benefit has been that they are improving the system, not just addressing symptoms.

Example 10: In this example the interviewee discussed the institution of a new integrated management system audit. The integrated management system audit replaced auditing a management systems component during separate audits of various systems. The reason the change was made was the recognition that these management systems are not separate, but are part of an overall system. The regulatory staff from various areas worked together. This provided a more consistent message to the licensee and gave the regulator more credibility. The interviewee's assessment was that this process based program was instituted because other strategies were not working well and that this approach got regulatory staff looking at the big picture and away from looking at details. The interviewee thought the approach had been effective because the licensee has responded and fixed problems; because the licensee has had favorable trends in doses, incidents and other performance measures; because working relationships with the licensee have improved; and because the method has been more consistent and efficient in evaluating this area. A challenge encountered was in managing the findings that emerged from this approach, in particular, ranking the findings in terms of priority. A risk-based strategy was successfully used to determine the time line for fixes.

Example 11: In this example the interviewee noted that because there are basic prescriptive requirements that all plants have a quality assurance system, the industry is mature, and quality assurance programs are well established few issues emerge with failure of quality systems to identify problems. Instead, quality system problems emerge in prioritizing and fixing corrective action problems. When deficiencies are found in a licensee's response to a corrective action, a risk based strategy is used to evaluate the importance for safety. The interviewee noted that the use of risk information provides a focus on safety significance for regulatory action and that the use of a risk-based strategy for prioritizing corrective action items has been effective in assuring that the regulator pushes the licensee to focus on the important issues.

8 Training and qualifications: experience with regulatory strategies

This chapter discusses the experience of the experts interviewed with the use of regulatory strategies for oversight of training and qualifications. After a brief summary of the overall patterns identified regarding of the use of strategies in the oversight of training and qualifications, specific examples illustrating these patterns are presented.

The patterns identified were:

- Advantage of process based strategies: in depth evaluation provides insight and assurance of competency for both regulator and licensee
- Advantage of an outcome based strategy: successful change from a prescriptive to an outcome based approach for in-service testing
- Moving to process-based strategy when outcome based strategies fail to detect problems early
- Advantages of prescriptive strategies: clarity and closure

Interviewees were asked to "walk through" an example of how the regulator had addressed an issue with regard to training and qualifications. After providing the example they were asked the following:

- *What strategy or strategies would you say was used in this example?*
- *Do you know how this strategy came to be selected? If yes, please describe.*
- *How effective do you think this strategy has been in this case?*
- *Please describe the major benefits (if any) of using this strategy.*
- *Please describe the major difficulties (if any) of using this strategy.*
- *If there were difficulties, do you think this strategy would usually result in these kinds of problems or would better implementation have solved most of them?*
- *Do you think that other strategies would work equally well for this area of oversight, or is this strategy the most appropriate given the context of your country and agency? Please explain.*

Thirty-three examples of the oversight of training and qualifications were provided by interviewees. In some instances more than one individual participated in a single interview. In some instances the same example was discussed by more than one interviewee from the same regulatory authority or the same regulatory action was taken in response to similar events by one regulator. In these instances the information from the interviews was sometimes combined. As noted in the methodology section, examples of training and qualifications were provided by experts interviewed regarding regulatory strategies and also by competency experts who were interviewed as part of a study on regulation of competency. Examples from both sets of interviews were included in the analysis and are used as illustrating examples**.**

The regulatory strategy most often used in the training and qualifications examples was process based, mentioned by over 60% of the interviewees. It was usually used in

combination with other strategies. Prescriptive and outcome based strategies were mentioned in about 30% of the examples. Case-based, risk-based, and self assessment-based strategies were mentioned in very few examples.

The examples on training and qualifications provided by interviewees were analyzed for common patterns regarding the regulatory strategies used. For each pattern, one or more examples have been summarized as illustrations.

8.1 Advantages of process based strategies: in depth evaluation provides insight and assurance of competency for both regulator and licensee

A major pattern described in the examples of oversight of training and qualifications was the implementation of process based approaches. At least one interviewee from each regulatory agency provided such an example. The process-based strategy was sometimes used in regulations and sometimes used in inspection and oversight of regulations that were more prescriptive or outcome based. Interviewees often noted that the process based strategy provided important insights to both the regulator and the licensee regarding training needs and effectiveness. Many also noted that in-depth process strategies were resource intense—for both the regulator and the licensee—and were therefore used judiciously. Most of the interviewees describing these process-based strategies gave broad overviews of how the strategy was used for oversight of training and qualifications in their agency. Two examples are provided below in which a process based strategy is used to address specific issues.

Example 1: Two interviewees from one regulator described a review of training done by a plant after a new fire alarm system was installed as part of a plant modification. The licensee is required to supervise and have their own training process. The regulator does verification of the program. In this case the regulator used a process based inspection approach to evaluate the training program initiated by the licensee for a new fire alarm system. The regulator evaluated whether the plant addressed how the new system would affect staff. The inspection included reviewing training documents and interviewing staff—including the fire brigade, maintenance workers, operators, and safety engineers—to determine whether training in the new system was adequate. The inspection team found that training was only developed and provided for operators even though the change affected staff across a number of areas. While this was not a deviation from the regulatory guides, it represented a problem. The regulator followed up over a two year period to see whether the plant had collected feedback and improved the training program. Both the interviewees noted that their overall assessments of the results were positive. One interviewee described a new program by the licensee for evaluating and developing training. The licensee also instituted a program of annual reviews with staff to evaluate training needs. The other interviewee, however, noted that the plant had not yet collected feedback to evaluate the effectiveness of the program. Both stated that the approach has been a good oversight strategy and very effective as way to do an in depth evaluation. One interviewee stated that there were no difficulties in carrying out the in-depth inspections in this way, but these inspections are very resource intensive.

Example 2: In this example the interviewee described a recent review by the regulator of the technical competence of licensees as a whole. In particular, the regulator evaluated the continuing ability of licensees to act as intelligent customers when dealing with contractors. This issue was of concern to the regulator because the regulator relied on the licensees to have full competency and the licensees were experiencing changes that could affect competency, including reorganizing, privatizing, and using more contractors for jobs previously performed by employees. The licensees' systems were not transparent enough to assure the regulator of continued competence of licensee employees to act as intelligent customers, run the plant, and perform safety and engineering analyses. The strategy used to address the issue was primarily process-based in combination with other strategies. The licensees adopted systematic assessment methods for training and qualifications, including developing skills matrices, manpower models, and evaluations of the adequacy of internal expertise to cover unique skill areas. The interviewee noted that both the regulator and the licensees learned a great deal during the institution of the program. A difficulty was that because licensees selected different models of process development for competency programs the regulator had to use a high level of resources to study and understand each of the different models.

8.2 Advantage of an outcome based strategy: successful change to an outcome based approach for in-service testing

One regulator has moved from a prescriptive and process based system to an outcome based system with good results. This is a summary based on two interviewees from the same agency

Example 3: In the area of in-service inspection (non-destructive testing) the regulator had a prescriptive regulation. The rules prescribed both how to do the in-service inspections and how to qualify people to do the work. In the 1980's a problem arose in which stress fractures were not discovered until there were leaks. In-service inspections done by qualified individuals and as prescribed by the regulation had not found the cracks. The industry and the regulator worked to develop a joint solution. An outcome based program was instituted with the regulator setting criteria for qualifying personnel. Personnel were qualified to do in-service inspections by demonstrating the ability to find cracks instead of demonstrating knowledge on a test and following a prescribed procedure. Personnel could use any procedure that identified cracks or other flaws. The industry created a large facility with mock-ups of different cracks and flaws. The regulator conducts research on performance of in-service inspections and evaluates the mock-ups in the industry facility. The industry makes changes as new techniques become available, provides training and evaluates the effectiveness of training. The regulator does not qualify people, but oversees and does research.

Both interviewees said it has been an effective strategy and that evaluating actual performance of individuals doing simulated in-service inspections provided a more accurate and reliable competency than prescribing specific knowledge and specific

techniques. Difficulties discussed included high initial start-up costs, time to create the facility and mock ups and the ongoing costs of maintaining the validity of mock-ups.

8.3 Moving to process-based strategy when outcome based strategies fail to detect problems early

Two examples, from two different agencies, were discussed in which outcome-based strategies used in the past were changed to process based strategies because problems went undiscovered until they were difficult to fix. In the first case the general plant performance measures remained good for many years because of good informal training of new employees by experienced workers. The lack of an adequate training program was not identified. When the informal system broke down, many problems occurred before an adequate formal training program could be instituted and the competency of the staff improved. In the second example a problem at the plant uncovered two kinds of competency problems—lack of integration of knowledge across fields and erosion of knowledge over time. In both examples a process-based strategy has been instituted as part of a new oversight strategy for training and qualifications.

Example 4: In this example the interviewee described a past strategy that was outcome based in that it relied on (1) examination scores as the basis for determining the quality of personnel and (2) on good plant performance as the basis for accepting that training programs were adequate. Under the outcome based system the regulator reviewed event reports and reacted to events. The licensee did root cause analyses on any problems that occurred and proposed solutions. For a long time the licensee did well because they had a good staff that "passed the torch" from generation to generation. That is, the training was being done informally on-the-job. Then experience levels dropped and problems started to occur. The problems were systemic and recurring. The regulator required a full scale review and found that there was not an adequate overall system for assuring training and competence of staff. Because the individuals had been effective in doing their jobs, the use of outcome indicators failed to identify the underlying systematic problems with training. There was not a good established training program so it was a major job to establish an adequate training system. The interviewee thought it was important to look at outcomes but also to be sure there is a good underlying system. The regulator has now moved to a process based strategy requiring licensees to use a systematic approach to training (SAT).

Example 5: In this example the interviewee described incidents in the 1980's in which the core oscillated. The regulator evaluated the staff and thought there was a good fuel department and good operators. But looking at the operators separately from the fuel department they found the operators did not understand why the fuel was behaving strangely. There was a different knowledge base needed and it needed to be applied in a different way than anticipated. The licensee and the regulator determined that the fuel department must be more involved in day to day procedures. They also determined that the knowledge and competence in the fuel department had slowly lost ground over time. In the beginning everyone had basic knowledge of neutron physics but this knowledge eroded because it was not used day to day. The interviewee

explained that in this instance the regulator had waited until an event or incident—an outcome based strategy—and then made inspections and required the licensee to also investigate the event. When investigating, both the licensee and the regulator addressed whether there are other aspects that could be affected by the same problem. They both also examined whether this type of problem could be affecting other departments. Although the original focus was on the utility where the problem had occurred, similar issues were identified at other plants. Experience feedback was used and there were seminars with the industry. The regulator now uses a process-based strategy. Now the licensee is required to define needed knowledge and processes.

The interviewee thought that under the outcome based approach everything was accepted until something happened—the regulator was very reactive. Now, for the last 10 to 15 years, the regulator has been more proactive by using a process-based strategy. Although the outcome-based strategy was eventually effective for the incident, there can be many incidents that are not discovered—the strategy was not effective at preventing problems.

8.4 Advantages of prescriptive strategies

Four interviewees, from three different agencies, provided separate examples of situations where a prescriptive strategy was particularly useful in the area of training. Two of these examples are presented below. The interviewees discuss the difficulty of assuring that licensees see training as important and safety related, and the advantage of using a prescriptive-strategy in response.

Example 6: In this example the interviewee described an inspection of a quality assurance program which included a review of training. In particular, the inspection team reviewed the implementation of a new spent fuel storage facility and the training of people who participate in handling spent fuel. The training program itself was very good, but when the inspection team observed people moving fuel from the spent fuel pool to storage they identified problems. The regulator determined that one supervisor had not been trained for this activity. The plant claimed that the training was not necessary for this position. This resulted in a letter of non-conformance from the regulator. The interviewee noted that the regulatory response was clear and definitive because there was a prescriptive regulation regarding the requirements for training. The benefit of the strategy is that the next time the plant moves fuel the training will have been completed. Having a clear rule requiring the training assured that the licensee would conform even though the plant claimed the training was unnecessary.

Example 7: In this example, the regulator required nuclear power plants to change from generic simulators to plant specific simulators. The use of generic simulators for training and testing was determined by the regulator to be inappropriate because differences between the simulator and the actual plants that the operators control created confusion. International research and standards also supported physical as well as functional fidelity between the simulators and the plants. The industry resisted making the change and argued that probabilistic risk assessment supported the use of generic simulators. The regulator rejected this argument and prescribed physical as well

as functional fidelity. The industry complied because of the ability of the regulator to make it a prescriptive requirement. The prescriptive strategy has been effective, providing an easy to apply, well-defined standard.

9 Concluding remarks

This report has presented the experiences and insights of expert staff of nuclear regulatory agencies in six countries in using a variety of regulatory strategies for the oversight of nuclear power safety. As stated in the beginning of the report, a major purpose of this exploratory study is to contribute to a more systematic understanding of the use of different regulatory strategies. The potential value of helping to build such a knowledge base is:

- assistance to regulators to be more intentional and better informed in their choices of strategies
- creation of a set of working definitions of strategies to contribute to further development of clarity and explicitness in discussions of regulatory strategies
- provision of some systematic, experience-based information on the use of strategies
- identification of some of the barriers to effective use of strategies
- identification of some of the conditions for effective implementation of strategies
- improvement of the clarity of regulatory intent within a regulatory agency and between an agency and its regulated industry

The in-depth examples provided by the regulatory experts who participated in the study illustrated the complexity of regulatory oversight and the sophistication of regulators in the selection of combinations of strategies for many difficult safety areas. The selection of appropriate regulatory strategies varies by the content of the area being regulated—the functional area of oversight or the specific safety issue. Selection of regulatory strategies also varies by the context—such as the maturity of the industry, whether the regulatory agency is new or established and the extent to which there is a mandate for public involvement.

Levels of complexity and pressure are increasing rapidly—as technological change, deregulation, privatization, global economic competition, shrinking budgets and major reorganizations are more significant issues for both regulators and nuclear power owners and operators currently than they were in earlier periods.

There were some common patterns of difficulties with the use of specific regulatory strategies or issues related to experts' views of the effectiveness of certain strategies. These issues would be worthwhile discussing further and are briefly presented below.

- Tension over reliance on a risk strategy for regulatory decision-making

  Staff disagreed over the relative emphasis given to the use of information from risk analysis to that given to information from deterministic analysis in making decisions—use of a risk strategy was viewed as reducing the importance placed on deterministic information. There were some who regarded the past reliance on

deterministic analysis in making decisions as the most sound way to regulate, while others saw the introduction of risk analysis as bringing a more systematic tool to bear on safety issues.

- Identification of methods and conditions for closure and action using a process based strategy

  Process based strategies were widely used in oversight and considered to have many benefits, but a recurring difficulty in a number of examples was a long period of negotiation between the regulator and the licensee over actions to be taken.

- Appropriate regulatory strategies under new conditions of utility ownership, organization and resources

  There were concerns among several experts about the erosion of competence and loss of expertise at licensees with increased financial pressure, downsizing and reorganization, in particular with ownership and management by parent firms that are totally separate from the plant. Maintaining expertise within the regulatory agency was a lesser concern, but also an issue.

References

Blom, I., Durbin, N., and Melber, B. (2001). Strategies for regulating nuclear power plants: a regulatory agency perspective. *Proceedings of the International System Safety Society*, Hunstville, AL, September, 2001. Unionville, VA: System Safety Society

Durbin, N., Melber, B., and Blom, I., (2002). Regulatory strategies and safety culture in nuclear power installations. *Proceedings of the International Conference on Safety Culture in Nuclear Installations*, 2-6 December 2002, Rio de Janeiro, Brazil.

Durbin, N., and Melber, B. (2004, forthcoming). *Research on Approaches to Competency Regulation in Selected Countries*, SKI Report, Swedish Nuclear Power Inspectorate, Stockholm.

Grimes, B.K., (2001). "The Changing Context of U.S. Nuclear Power Regulation" Paper prepared for the Swedish Nuclear Power Inspectorate.

Lindblom, L., Clausen, J., Edvardsson, K., Hayenhielm, M., Hermansson, H., Nihlen, J., Palm, E., Ruden, C., Wikman, P., Hansson, S.O., (2003). *How Agencies Inspect: A Comparative Study of Inspection Policies in Eight Swedish Government Agencies,* SKI Report 2003:36, Swedish Nuclear Power Inspectorate, Stockholm.

Melber, B., and Durbin, N., (2001). Alternative regulatory strategies: the case of commercial nuclear power**.** In *Proceedings of the International System Safety Society*, Hunstville, AL, September, 2001. Unionville, VA: System Safety Society.

Reiman, L., (2001). Some views on candidate trends at STUK, presentation at the Swedish Nuclear Power Inspectorate, SKI Seminar, October 2001.

Appendix A: Interview guide

REGULATORY STRATEGY INTERVIEW GUIDE

Name of interviewee:
Date of interview:
Location of interview:

Use and Effects of Regulatory Strategies by Nuclear Regulators in Selected Countries

Introduction

We are working with the Swedish Nuclear Power Inspectorate (SKI) to better understand the benefits and difficulties of using specific regulatory strategies for oversight of commercial nuclear power safety. To date there has been little research on the use of alternative regulatory strategies and their impacts. This exploratory study is designed to begin to address this gap in knowledge. We hope to contribute to a more systematic understanding of the experiences of nuclear regulatory agencies with alternative strategies.

In this interview we will be asking about your experience with various regulatory strategies used by your agency. We recognize that these will be your personal experiences and will not necessarily represent either the opinions of your agency or of your colleagues.

Overview of interview: We have identified and defined six regulatory strategies that have commonly been used by regulators of nuclear power facilities. You received a letter with a list and description of these strategies earlier. (We have a copy of that list to discuss with you during the interview.) We will begin by reviewing and briefly discussing (with examples) these six strategies to ask whether you find these definitions clear and accurate, and whether there are additional strategies you think should be included. We realize that agencies may use different strategies for different areas of regulation and that they may combine strategies. Later in the interview we also will ask you about combinations of strategies your agency may use.

After the questions about the definitions of the regulatory strategies, we will ask about the use of regulatory strategies in the following key functional areas that are regulated by nuclear oversight agencies—

- **Oversight of Nuclear Power Plant Design**—this includes assurance that the technical design basis of the original plant design is not inadvertently abrogated by plant modifications or procedure changes leading, for example, to a situation in which the plant safety systems could not respond appropriately to a plant off-normal condition.
- **Oversight of Quality Systems**—This includes assurance that the systems put in place to provide quality in work performance (doing-it-right-the-first-time and quality-control), and the verification that quality work has been performed (quality assurance) are adequate in scope and properly implemented.

- **Oversight of Training and Qualifications**—Includes oversight of plant policies and practices to assure proper preparation of all staff—including experience and educational requirements, training programs, testing requirements and use of simulators.

We would like to discuss your experiences with the regulatory strategies used by your agency in each of the areas. We recognize that you may not have experience with regulation in all areas—we would like you to discuss your own experiences with each area to the extent possible. We are aware that some agencies use a combination of strategies and that different regulatory strategies may have been used in each of these areas.

In the final part of the interview we want to get your general opinion about the regulatory strategies most often used by your agency and your thoughts about the effectiveness of different regulatory strategies.

Interview questions

Regulatory strategy definitions: *(hand page with list to interviewee)*

Please look over this list of regulatory strategies and definitions. For each of the strategies listed:

1. Do you think the definition clear and accurate?
2. Are there any changes to the definition you would suggest?
3. Does this list represent a reasonable overview of the regulatory strategies often (or "commonly") used by nuclear power regulators.
4. Does your agency typically combine some of these strategies for regulating various nuclear power activities? (if yes, could you give an example?)
5. Are there any other additional strategies not covered in this list of six that your agency has used? If yes, please name and describe them. *(if not already discussed)*
6. Are there additional strategies you are aware of, though your agency has not used them? If yes, please name and describe them. *(if not already discussed)*

Experience with regulatory strategies

We would like you to tell us about the process used by your agency to regulate nuclear power plants in a number of key functional areas, as we mentioned earlier:

1. First, we want to ask you about **oversight of plant design**.

(*Hand page with description of plant design to interviewee.)*

Is the attached description clear? Are there any changes or clarifications you would add to a brief description of this area?

Please give a specific example of your experience with the strategy or strategies (now or in the past) used for some aspect of **oversight of plant design (e.g., original design or modifications**). We would like you to "walk us through" how this strategy was used in your agency in this specific example.

(If interviewee expresses concern over limited experience, reassure:
If you are familiar with only part of the regulatory process for oversight of plant design and modifications, please tell us about that part of the process that you know about.*)*

- What strategy (or strategies) comes closest to the regulatory oversight approach used in this example?
- Do you know how this strategy came to be selected? If yes, please describe.
- How effective do you think this strategy has been in this case?
- Please describe the major benefits, if any, of using this strategy for this case.
- Please describe the major difficulties, if any, of using this strategy for this case (for example, were there implementation problems? Communication problems?)
- If there were difficulties, do you think this strategy would usually result in these kinds of problems or would better implementation have solved most of them?
- Do you think that other strategies would work about equally well for this area of oversight, or, in your opinion, is this strategy the most appropriate (given the context of your country and your agency)? Please explain.

2. Second, we want to ask you about **oversight of quality systems**.
   (*Hand page with description of quality systems to interviewee.)* .

   Is the attached description clear? Are there any changes or clarifications you would add to a brief description of this area?

Now, Please describe a specific example of your experience with the strategy or strategies (now or in the past) used for some aspect of **oversight of quality systems**. We would like you to "walk us through" how this strategy was used in your agency in this specific example.

> *(If interviewee expresses concern over limited experience, reassure:*
> If you are familiar with only part of the regulatory process for oversight of quality systems , please tell us about that part of the process that you know about.*)*

- What strategy (or strategies) comes closest to the regulatory oversight approach used in this example?
- Do you know how this strategy came to be selected? If yes, please describe.
- How effective do you think this strategy has been in this case?
- Please describe the major benefits, if any, of using this strategy for this case.
- Please describe the major difficulties, if any, of using this strategy for this case (for example, were there implementation problems? Communication problems?)
- If there were difficulties, do you think this strategy would usually result in these kinds of problems or would better implementation have solved most of them?
- Do you think that other strategies would work about equally well for this area of oversight, or, in your opinion, is this strategy the most appropriate (given the context of your country and your agency)? Please explain.

3. Finally, we would like you to describe a specific example of your experience with the strategy or strategies (now or in the past) used for some aspect of **oversight of training and qualifications**. We would like you to "walk us through" how this strategy was used in your agency in this specific example.

   > *(If interviewee expresses concern over limited experience, reassure:*
   > If you are familiar with only part of the regulatory process for oversight of training and qualifications, please tell us about that part of the process that you know about.*)*

   Is the attached description of training and qualifications clear? Are there any changes or clarifications you would add to a brief description of this area?

Now, please describe one example of your experience with using a regulatory strategy or strategies (now or in the past) for training and qualifications**.** We would like you to "walk us through" how this strategy was used in your agency in this specific example.

- What strategy (or strategies) comes closest to the regulatory oversight approach used in this example?
- Do you know how this strategy came to be selected? If yes, please describe.
- How effective do you think this strategy has been in this case?
- Please describe the major benefits, if any, of using this strategy for this case.
- Please describe the major difficulties, if any, of using this strategy for this case (for example, were there implementation problems? Communication problems?)
- If there were difficulties, do you think this strategy would usually result in these kinds of problems or would better implementation have solved most of them?
- Do you think that other strategies would work about equally well for this area of oversight, or, in your opinion, is this strategy the most appropriate (given the context of your country and your agency)? Please explain.

4. What is an example of one of the most successful experiences you (or your agency) has had with using a regulatory strategy? This can be an example you have already discussed or a new example. (*Allow interviewee to use example outside his/her agency if wants to, e.g. as part of international review team etc.)*
   - Why do you think this strategy was so effective? *(Probe for both inherent characteristics of the strategy and for good implementation.)*
   - What were the specific benefits in using this strategy? *(skip if already covered)*
   - Were there any difficulties in using this strategy? If yes, please describe. *(skip if already covered)*
   - How do you think this strategy came to be used in this case? *(skip if already covered)*
   - Would this strategy be as effective in other regulated areas? If not, why?

5. What is an example of one of the least successful experiences you (or your agency) has had with using a regulatory strategy? This can be an example you have already discussed or a new example. (*Allow interviewee to use example outside his/her agency if wants to, e.g. as part of international review team etc.)*
   - Why was this strategy less effective than others? *(Probe for both inherent characteristics of the strategy and for good implementation.)*
   - What were the specific problems in using this strategy? *(skip if already covered)*
   - Were there any benefits in using this strategy? If yes, please describe them.
   - How do you think this strategy came to be used in this case? *(skip if already covered)*
   - Would this strategy be more effective in other regulated areas? If yes, why?

Overall assessment of best practices/strategies for safety regulation in nuclear power

6. Based on our discussions, we are interested in your general comments on the overall use of regulatory strategies by your agency.
   (Probe whether the agency tends to use one or two strategies as a preferred approach to oversight. Probe regarding WHY this strategy or strategies may have been selected, e.g., national policy, national culture, history of the nuclear industry, etc.)
7. Referring back to the list of strategies, *(hand list of strategies to interviewee and discuss each separately)* what do you think are some overall benefits and difficulties of the different strategies? For example, what are some common pitfalls of particular strategies, such as specific types of implementation problems?
8. Do you think that some strategies on the list are more or less effective due to the context of your country's nuclear industry? *(Provide specific examples of context, e.g., size of industry, variability of types of reactors—such as: US—70-100 reactors compared to Sweden, 12 reactors on 4 sites; US—mix of private and public, France all public; Canada all one design-CANDU reactor, versus large diversity in Germany etc.)*
   Please explain. *(Skip this question if already covered in #12 above.)*
9. Do you think that some strategies are more or less effective due to the culture of your country? Please explain. *(Skip this question if already addressed in 12, above.)*
10. Are you familiar with studies or reports on uses of regulatory strategies? *(Probe for titles, agency sources.)*
11. Do you have any other comments or questions? Is there anything you wanted us to ask about but we did not?

Thank you very much for taking the time to discuss this issue with us.

Definition/Description of Areas

Oversight of Plant Design – Includes oversight of plant modifications to verify that the technical design basis of the original plant design has not been inadvertently abrogated by plant modifications or procedure changes. Inadvertent changes to the plant design basis could lead, for example, to a situation in which the plant safety systems could not respond appropriately to a plant off-normal condition.

Oversight of Quality Systems — Includes assurance that the systems put in place to provide quality in work performance (doing-it-right-the-first-time), and the verification that quality work has been performed are adequate in scope and are properly implemented.

Oversight of Training and Qualifications—Includes oversight of plant policies and practices to assure proper preparation of all staff—including experience and educational requirements, training programs, testing requirements and use of simulators.

REGULATORY STRATEGIES AND DEFINITIONS

Strategy	Description
Prescriptive	A prescriptive strategy establishes very detailed requirements for technical solutions and conducting specific activities. Safety is assured because the regulator has established that its requirements provide for the safe conduct of these activities.
Case based	A case-based strategy determines the safety requirements for each licensee through individual assessment of its operation, considering the unique history of each facility. The regulator does not establish general, universal requirements that apply equally to all licensees of a particular type of facility.
Outcome based	An outcome-based strategy establishes specific goals or outcomes for licensees to attain but does not specify how licensees attain these goals. Licensees are free to determine how they will conduct their work activities to result in the achievement of the required safety goals.
Risk based	A risk-based strategy identifies areas and systems of significant potential risk—looking at risk as the combination of the consequences of a potential accident (e.g., would it be catastrophic) and the probability of an accident happening. A specific methodology and specific criteria are established for the identification of areas of greatest risk and these areas therefore receive priority for regulatory attention.
Process/system based	A process-based or system-based strategy identifies specific key processes and systems that lead to safe performance and requires licensees to establish and implement these processes and systems effectively. (Examples of processes would include a way of identifying, recruiting, training and retaining competent staff and ways to develop, assess and implement changes in facilities, policies, and procedures; Examples of systems would be a quality system and the overall system of operations.)
Self-assessment based	Licensees develop and implement a self-assessment program to identify both good practices and problem areas needing improvement. The regulator evaluates the licensee self-assessment program, reviews the results of the licensee assessments, and selectively inspects the licensees' follow up on self-assessment results.

Appendix B: Suggested changes to strategy definitions

Many of the interviewees made specific suggestions for ways to improve some of the definitions of the regulatory strategies. The definition for each of the six strategies is listed below followed by the specific recommendations of interviewees.

Prescriptive strategy

A prescriptive strategy establishes very detailed requirements for technical solutions and conducting specific activities. Safety is assured because the regulator has established that its requirements provide for the safe conduct of these activities.

Suggested changes

Safety is assured when the licensee meets the requirements established
Safety is assured because those regulations take into account safety margins
Safety is **hopefully** assured
The process of establishing requirements includes dialogue with experts at plants

Case based strategy

A case-based strategy determines the safety requirements for each licensee through individual assessment of its operation, considering the unique history of each facility. The regulator does not establish general, universal requirements that apply equally to all licensees of a particular type of facility.

Suggested changes

Use “facility”-based rather than “case”-based, term case has too many meanings, such as safety case, accident cases etc.
May establish general requirements but modify them for each specific plant as needed
Apply internal and external experience feedback

Outcome based strategy

An outcome-based strategy establishes specific goals or outcomes for licensees to attain but does not specify how licensees attain these goals. Licensees are free to determine how they will conduct their work activities to result in the achievement of the required safety goals.

Suggested changes

Prefer term performance based for this strategy—what is used by agency, easier for people to relate to, to understand (6 interviewees)

Meaning of safety goals unclear—is it society's, the regulator's or the licensee's safety goal?

Licensees not completely free to determine how to conduct activities, statement should be more limited, recognize licensees cannot do anything they want (2 interviewees)

Risk based strategy

A risk-based strategy identifies areas and systems of significant potential risk—looking at risk as the combination of the consequences of a potential accident (e.g., would it be catastrophic) and the probability of an accident happening. A specific methodology and specific criteria are established for the identification of areas of greatest risk and these areas therefore receive priority for regulatory attention.

Suggested changes

Risk informed better title than risk based (9 interviewees)
Change "probability of an accident happening" to "risk of undesirable outcomes"
Make definition broader, to include qualitative methods (3 interviewees)

Process/system based strategy

A process-based or system-based strategy identifies specific key processes and systems that lead to safe performance and requires licensees to establish and implement these processes and systems effectively. (Examples of processes would include a way of identifying, recruiting, training and retaining competent staff and ways to develop, assess and implement changes in facilities, policies, and procedures; Examples of systems would be a quality system and the overall system of operations.)

Suggested changes

Drop the word "system" from the title and within the definition, clearer to use simply "process-based"
Clarify it is a licensee process not a regulator process that is identified for oversight

Self-assessment based strategy

Licensees develop and implement a self-assessment program to identify both good practices and problem areas needing improvement. The regulator evaluates the licensee self-assessment program, reviews the results of the licensee assessments, and selectively inspects the licensees' follow up on self-assessment results.

Suggested changes

Need to have safety focus, missing something related specifically to specific goals or safety topics for licensee
Narrow definition, could be broader and include independent safety assessment reviews, internal audits to develop processes and activities.

SKI Report 2005:37

Research

Experience with Regulatory Strategies in Nuclear Power Oversight

Part 2: Workshop Discussions and Conclusions

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Foreword

During the planning of the research project*, "Experience with Regulatory Strategies in Nuclear Power Oversight"*, it was decided that the results of the study should be available for the participating organizations to discuss. When the report of the results was prepared, the participating regulatory agencies were invited to a workshop to discuss the findings of the report and next steps. The workshop took place in Sweden in November 2004. The following section gives an overview and conclusions of the workshop, as well as suggestions for next steps.

"- Would you tell me, please, which way I ought to go from here?
- That depends a good deal on where you want to get to, said the Cat."

Lewis Caroll,
Alice´s Adventures in Wounderland.

List of workshop particiapants

Canada
Canadian Nuclear Safety Commission (CNSC)
Mr. Ken Pereira, Executive Vice President, Operations

Finland
Radiation and Nuclear Safety Authority (STUK)
Mrs. Marja-Leena Järvinen, Deputy Director, Nuclear Reactor Regulation
Mrs Kaisa Koskinen, Development Manager, Nuclear Reactor Regulation

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Mr José I. Villadóniga, Advisor to the President
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Swedish Nuclear Power Inspectorate (SKI)
Mrs Judith Melin, Director General**,**
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Mr Christer Viktorsson, Deputy Director General
Mrs Iréne Tael, Quality Manager
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Nuclear Safety Directorate (NSD) of the Health and Safety Executive
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1 Overview of Workshop Discussions

SKI held the workshop at Johannesbergs Slott in Rimbo, Sweden on November 10th and 11th, 2004 to discuss the research report *Experience with Regulatory Strategies in Nuclear Power Oversight*. Attendees at the workshop included representatives from the six countries that participated in the study; Canada, Finland, Spain, Sweden, the United Kingdom and the United States. Overall the participants agreed that the findings in the report reflected their experiences as regulators of nuclear power installations[1]. In particular they agreed that

- It is important to have a common understanding of regulatory strategies.
- Regulators combine the six strategies in different ways to achieve regulatory goals.
- Different factors such as context, national culture, and type of safety concern influence the strategies used by regulators
- The findings in the research report regarding benefits and difficulties and consequences of different strategies reflected their experience.

Participants also agreed on changes to the terms and definitions proposed in the report.

- The six "strategies" discussed in the report should be referred to as approaches to regulation. These approaches are used alone or in combination to develop strategies for regulation.
- New definitions for 5 of the 6 approaches were created
- The addition of an influence or education approach was agreed on. A hazard approach was suggested and most participants agreed it should be added.

Many of the discussions at the workshop focused on how regulators might use information from the report. There was a general agreement that understanding of how the approaches fit into the overarching goals of regulators and the overall process of regulation is important. This resulted in the agreement that safety, efficiency/effectiveness, and public trust were primary regulatory goals. The discussants also developed a preliminary model of how regulatory approaches fit into the process of regulation.

There was also agreement on next steps for this area of research

- Map how approaches fit into the overall regulatory system
- Examine the effects of different regulatory approaches on competency needed by regulatory personnel
- Explore the effects of different approaches on licensees, especially safety culture
- Look at the effects of different approaches on public opinion and trust
- Determine the effects of different approaches on the effectiveness of regulation

Below is a summary of the key topics of discussion during the workshop.

[1] It was noted that these findings do not necessarily apply to other areas of regulation, such as waste management.

2 Overarching goals

A major topic of discussion was the need to consider regulatory approaches and strategies within the context of the overarching goals of regulators. It was noted that the consequences of approaches and strategies need to be assessed in terms of achieving the overarching goals of safety, effectiveness and public trust.

Safety

There was agreement that safety is the primary goal of the regulator. The importance of recognizing that licensees must take the primary responsibility for safety and that the regulator's role is to make certain that the licensee fulfills this responsibility was noted. Another key point about the goal of safety was that there are differences across countries in whether the mandate of the licensee and the regulator is to maintain safety or improve safety. The legal mandate of the country has an impact on this question as well as whether the regulator is ensuring, securing, overseeing, or assuring safety in nuclear power installations.

Another point of discussion on the goal of safety was the interface between security and safety. During this discussion it was pointed out that security and safety could be in conflict.

Effectiveness and efficiency

A second goal that was discussed was the regulators' responsibility to assure safety in an effective and efficient manner and within the resources available. It was noted that regulation should be balanced and proportional, realistic with regard to margin of safety, sensible, and make good use of resources. One discussant described this as striving for sustained excellence—noting the need to have a broad approach and be balanced and consistent in the goals of regulators and licensees.

Public and other stakeholder trust and accountability

There was strong agreement that this goal was dependent on first achieving the goals of safety and efficiency/effectiveness. However, it was proposed that although trust is dependent on achieving the first two goals, achieving those goals does not automatically engender trust by the public and other stakeholders. Intentional efforts are needed to communicate effectively. Transparency is critical. Opinions were expressed that public trust is less dependent on specific strategies but is more a function of the communication of the regulator to stakeholders.

3 Mapping the regulatory process

Another important discussion was about mapping the process of regulation to better place regulatory strategies within a regulatory framework. Participants agreed that the six strategies discussed in the report are actually approaches to regulation that are used selectively to create strategies[2]. The group discussed the need to place the report findings about the six approaches into a higher level framework, to depict how approaches are used in a dynamic regulatory system.

It was agreed during this discussion, that there is a need to show the dynamic and proactive nature of the interrelationships of regulatory activities. It was stated that regulatory strategy can affect licensee strategy and may have consequences (side effects) that are not intended. This is particularly important to note with regard to taking actions to produce a desired outcome and finding it has undesired effects on licensee attitudes (also see discussion of systemic thinking, below). The intent is to show that overall strategies are dynamic and proactive and that different approaches are used as appropriate. During the work it was emphasized that it is necessary to include the full range of stakeholders, to include research, planning, public information, and other aspects of regulation. Another aspect is to consider the specifics for the different areas of nuclear regulation, such as waste management, in addition to nuclear power plant operations.

Participants also discussed systemic thinking in dealing with approaches to regulation. Different levels of perspective—events, patterns, systemic structures, mental models and vision—were discussed[3]. It was agreed that regulators have increasing leverage on making change to licensees at higher levels—that is, changing the overall vision has more impact than responding to a single event.

There was discussion of the ways in which the strategies regulators use affect licensees. In some cases these affects may be intentional attempts to change the mental model of nuclear power plant operators, but the concern of the discussants was on unintentional and indirect effects of different approaches and strategies. It was stated that there could be long term and, subtle, effects on licensees that regulators may be unaware of. For example, while using a strategy to directly address a specific problem, the regulator may be sending messages of a more general nature to the licensee that could affect a licensee's approach in the future. Some of the specific consequences identified in the report (such as impacts on responsibility for safety) were mentioned. The discussion centered on being more intentional and aware of these connections and thinking through the implicit and indirect effects of regulatory approaches in a positive, proactive way. That is, regulators should not only avoid sending the wrong message, but intentionally send the right message. Additionally, the importance of recognizing the differences in the leverage that regulators can assert at different levels of perspective was noted.

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[2] The change in term from strategies to approaches was a key agreement early in the discussions. It is mentioned again under other topic areas where it is relevant, such as in the discussion of refining the definitions.

[3] From "Vision Deployment Matrix: A Framework for Large-Scale Change" in *Organizing for Learning* by Daniel H. Kim, Waltham, MA: Pegasus Communications. As presented by José Villadoniga Tallon.

4 Benefits, difficulties, and consequences of different strategies

There was a general agreement that the benefits and difficulties of the six strategies and the consequences of different strategies described in the report were accurate. Discussions expanded on the overall findings of the report, starting with a general agreement that regulation is complex and that regulators must

- consider the context within which they are regulating,
- respond to changes in industry and context, and
- use different combinations of approaches depending on the situation.

It was noted that regulators need to reassess their approaches and strategies periodically as well as continuously in response to the dynamic environment.

5 Context and driving factors

There was a general agreement that the selection and success of different approaches and strategies are part of a dynamic system and are specific to the country and to the area of oversight. It was noted that regulators use operational experience, monitoring, and information to adjust to these factors. Specific examples of changes to regulatory approach were mentioned. In the discussions of context and driving factors, four levels were distinguished. These were international, national, agency (or internal) and licensee. Some of the factors discussed with regard to each level are provided below**.**

International

- Knowledge base on certain areas is extensive across countries
- Standards and recommendations (e.g., by IAEA) selectively accepted and used by countries
- Some areas affect multiple countries and have requirements and conventions from overarching bodies such as EU and IAEA
    - Transportation (prescriptive requirements)
    - Safeguards (prescriptive requirements)
    - Radiation protections (EU) (outcome based and prescriptive requirements)
- Any serious international incident creates a response across all agencies

National

- Definitions of acceptable risk differ by country (—e.g., *as low as reasonably practical* compared to *adequate protection of health and safety)*
- Deregulation
- Economic pressures
- Cultural, political, environmental, and social
- Public's expectation

Agency or internal

- Cost and resources available to regulator
- Risk management—balancing achievement of goals relative to costs
- Nature of activity
- Trust in operator

Licensee

- Strategy of licensee
- Competency of licensee
- Trust of regulator
- History and culture of the industry

6 Providing licensees with a framework and flexibility

It was agreed that overall approaches should provide licensees with a framework and with flexibility. One participant suggested that combining an outcome approach with guidance from risk was one strategy that could meet this need because an outcome approach gives flexibility to the licensee and a risk approach gives guidance. Another strategy mentioned that combines flexibility with guidance was using a process approach with criteria (outcomes or benchmarks which could be prescriptive). It was also noted that any new and emerging areas such as new technology, organizational change and human performance require a flexible strategy. One strategy mentioned was the use of outcomes to maintain safety goals while knowledge about the new area is gained, then when more knowledge is developed the strategy or approach may be changed.

7 Comments on specific strategies and issues

Strategies

Some specific comments on the findings regarding certain strategies were made, these included:

- Discussants mentioned that certain strategies and conditions improve the effectiveness of process-based approaches. Combining process and outcome approaches and establishing good criteria were mentioned, as well as the overall stability in the licensee processes.
- The use of prescriptive strategies in response to licensee lack of action (as discussed in report) was discussed. It was noted that prescriptive response in each country may also occur in response to any major incident that happens any where in the world. This responds both to safety concern and to public confidence concerns.

Issues

There were comments on specific issues raised in the report, these included:

- A comment on the issue of conflict between deterministic and risk based analyses was that the discussion of deterministic and risk analyses in the report implied that these were essentially different in their underpinning but that both are ultimately based on risk analyses.
- In response to the issue of difficulty of defining and measuring outcomes the comment was made that the problem is that it is hard to measure safety itself, so there is a tendency to measure any lack of safety. This can lead to negative emphasis instead of positive. It was noted that trends can be used to provide positive indicators. There was a general agreement that this is difficult area.
- Another issue raised in the report that was discussed was the difficulties in establishing credibility with the public for self assessment approaches. One question raised was whether this is inherent in a self-assessment approach or whether it is a problem of communication to the public.

8 Safety Culture

The relationship of approaches and strategies to safety culture was discussed. There was general agreement that this is a difficult area because "how do you enforce or regulate a culture?" The discussion focused on the difficulty of having a good influence on safety culture. It was mentioned that Canada has developed a program that includes the envelope around human performance that includes performance assurance, QA, and training. Two distinct issues were identified as needing attention; whether safety culture can be regulated and effect of the regulator on licensee safety culture. Two types of approaches were suggested as most appropriate for evaluations of safety culture—process and self assessment.

9 Relationship of approaches to mid-level and overall regulatory strategies

There was an agreement that the six strategies defined and discussed in the report actually represent different approaches to regulation rather than different strategies. Strategies were agreed to be combinations of approaches. Participants discussed the combinations of approaches into mid-level strategies and overall strategies used by regulators. The use of different approaches and strategies at different levels—rulemaking, oversight, and enforcement—was discussed (see table below). It was noted that although agencies may have an overarching strategy, specific needs of licensees or specific conditions may require the use of different strategies for specific purposes and that combinations of approaches and strategies from each level may be seen as the overall regulatory strategy. An example given by Canada was that although the overall strategy is outcome based, a prescriptive approach was most appropriate for a very large number of small firms using radio-isotopes because these licensees needed specific clear requirements.

Unlike commercial nuclear power plants, these small entities did not have the resources to develop their own processes and independent safety assessments. It was mentioned that it would be useful to look at the consequences of approaches at each of these levels.

10 Terms and definitions

A discussion of the working definitions of the six strategies used in the report started with an agreement that it was important to have a common understanding of terms and concluded with suggestions for changes to the terms used and the definitions and for the addition of additional approaches.

There were several overall agreements regarding terms.

- Refer to these as regulatory approaches rather than regulatory strategies.
- Terms should not use "based" for any of the approaches.
- Agreements regarding specific terms
  - "case-based" should be changed to "facility";
  - "risk-based" should be changed to "risk-informed"; and
  - process/system-based should be changed to "process".

Participants agreed on new definitions for five of the six approaches; prescriptive, facility, outcome, risk informed, and process. The table below shows the agreed on changes to terms and definitions and provides a brief summary of the discussion when there was no agreement on a change.

REGULATORY APPROACHES AND REVISED DEFINITIONS	
Approach	**Description**
Prescriptive	*A prescriptive approach establishes specific requirements for conducting activities including technical solutions.*
Facility	*A facility-based approach determines the safety requirements for each licensee through individual assessment of its design and operation, considering the unique history of each facility.*
Outcome	*An outcome approach establishes specific performance goals or outcomes for licensees to attain but does not specify how they shall be obtained. Licensees determine how they will conduct their work activities.*
Risk informed	*A risk informed approach uses a specific methodology and specific criteria for the identification of areas of greatest risk and these areas therefore receive priority for regulatory attention.*

Process	*A process approach identifies specific key processes that lead to safe performance and requires licensees to establish and implement these processes effectively.*
Self-assessment approach)	There was no agreement was reached about how to include this approach. Suggestions included: • Keep as separate approach with current definition. *Licensees develop and implement a self-assessment program to identify both good practices and problem areas needing improvement. The regulator evaluates the licensee self-assessment program, reviews the results of the licensee assessments, and selectively inspects the licensees' follow up on self-assessment results.* • Change to: *A self-assessment approach requires licensees to develop and implement a program to assure safe operation*. • Replace self assessment with approach called safety management. • Drop self assessment because it is just one of many licensee processes evaluated.
Influence/education approach	The group did not develop a definition but agreed with the report's finding of education and coaching as an approach used.
Hazard approach	This was discussed as an addition but no definition was agreed upon. Some felt it was included in risk-informed but others felt the focus on hazard potential rather than risk was significantly different. A suggested definition was *A hazard approach uses a specific methodology and specific criteria for the identification of areas of greatest hazard and these areas therefore receive priority for regulatory attention*.

There was no final agreement regarding the definition of self assessment. A concern expressed about self assessment was that it could imply self regulation by the licensees. Some participants liked the definition provided in the report and noted that the second sentence makes it clear that it is not referring to self regulation but that the regulator continues to oversee the licensee's program. Others suggested that the definition be changed to *A self-assessment approach requires licensees to develop and implement a program to assure safe operation*. Other participants suggested replacing "self assessment approach" with "safety management approach". Two advantages of this term were presented: 1) safety management is a broader more inclusive term that better captures the intention and full range of activities of the approach and 2) safety management is a neutral term than self assessment, which might be perceived as meaning self-regulation. Another point of view was that self assessment is simply one of many processes covered under a process approach and should not be singled out as a separate approach with a separate definition. It was noted by some participants that self assessment is a term that is currently widely used by regulators, licensees and international bodies such as IAEA and NEA.

Two additional approaches were suggested. There was agreement with the suggestion made by some interviewees in the report that an *influence* or *education* approach should

be included. No definition was developed for this approach. Another suggestion was that a hazard approach should be included. There was less agreement about adding this approach—some argued that it is included in risk-informed while others felt the focus on hazard potential rather than risk is significantly different. A suggested definition for a hazard approach was to use the definition for risk-informed approach and replace "risk-informed" with hazard.

11 Suggestions for further work

Participants ended the workshop with a discussion of suggestions for further work. Five areas were agreed to be key next steps. These are listed below with some of the more specific related issues discussed.

- Map how approaches fit into the overall regulatory system
  - build on framework, work on refinements
  - look into other fields for ideas, leadership literature
  - situation specific and environment specific strategies
  - being more conscious of decision making regarding approaches

- Examine the effects of different regulatory approaches on competency needed by regulatory personnel
  - The impact on human resources needed by regulator—skills needed by staff
  - The impacts on regulatory personnel activities
  - Using information on regulatory strategies to train staff to be more effective in their interactions with licensees and be positive influence on safety

- Explore the effects of different approaches on licensees, especially safety culture
  - Licensee perspectives on regulatory approaches
  - Implications of different strategies and approaches on licensee safety culture
  - Effect of approaches on licensee personnel and resources
  - How regulators influence licensees

- Look at the effects of different approaches on public opinion and trust

- Determine the effects of different approaches on the effectiveness of regulation
  - Effect of approaches on regulator resources
  - Addressing how approaches affect regulatory effectiveness, based on actual impacts rather than opinions of experts. What are indicators of effectiveness? Outcomes of regulation.

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