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NUCLEAR ENERGY AGENCY
COMMITTEE ON THE SAFETY OF NUCLEAR INSTALLATIONS

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Special Expert Group on Human and Organisational Factors (SEGHOF)

STATE-OF-THE-ART REPORT ON SYSTEMATIC APPROACHES TO SAFETY MANAGEMENT

February 2006

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed:

- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

The original Member countries of the OECD are Austria, Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The following countries became Members subsequently through accession at the dates indicated hereafter: Japan (28th April 1964), Finland (28th January 1969), Australia (7th June 1971), New Zealand (29th May 1973), Mexico (18th May 1994), the Czech Republic (21st December 1995), Hungary (7th May 1996), Poland (22nd November 1996), Korea (12th December 1996) and the Slovak Republic (14 December 2000). The Commission of the European Communities takes part in the work of the OECD (Article 13 of the OECD Convention).

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of 28 OECD Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

COMMITTEE ON THE SAFETY OF NUCLEAR INSTALLATIONS

The NEA Committee on the Safety of Nuclear Installations (CSNI) is an international committee made up of senior scientists and engineers, with broad responsibilities for safety technology and research programmes, and representatives from regulatory authorities. It was set up in 1973 to develop and co-ordinate the activities of the NEA concerning the technical aspects of the design, construction and operation of nuclear installations insofar as they affect the safety of such installations.

The committee's purpose is to foster international co-operation in nuclear safety amongst the OECD member countries. The CSNI's main tasks are to exchange technical information and to promote collaboration between research, development, engineering and regulatory organisations; to review operating experience and the state of knowledge on selected topics of nuclear safety technology and safety assessment; to initiate and conduct programmes to overcome discrepancies, develop improvements and research consensus on technical issues; to promote the coordination of work that serve maintaining competence in the nuclear safety matters, including the establishment of joint undertakings.

The committee shall focus primarily on existing power reactors and other nuclear installations; it shall also consider the safety implications of scientific and technical developments of new reactor designs.

In implementing its programme, the CSNI establishes co-operative mechanisms with NEA's Committee on Nuclear Regulatory Activities (CNRA) responsible for the program of the Agency concerning the regulation, licensing and inspection of nuclear installations with regard to safety. It also co-operates with NEA's Committee on Radiation Protection and Public Health (CRPPH), NEA's Radioactive Waste Management Committee (RWMC) and NEA's Nuclear Science Committee (NSC) on matters of common interest.

ACKNOWLEDGEMENT

This state-of-the-art report has resulted from the work of the CSNI SEGHOF and it is fair to express thanks to all the persons who have contributed to the work. The report would not have been possible without a significant contribution from some individuals and they deserve to be mentioned separately: Mr. Yves van den Berghe (AVN), Dr. Albert Frischknecht (HSK), Mr. Benito Gil (CSN), Dr. Anibal Martin, Mrs. Helen McRobbie (CNSC), Dr. Craig Reiersen (HSE NII), Mr. Daniel Tasset (IRSN/ASN) and Dr. Kaisa Åstrand (STUK). The IAEA supported the work through Dr. Kerstin Dahlgren-Persson. The final version of the report was prepared by Dr. Pekka Pyy and Mrs. Elisabeth Mauny at the OECD Nuclear Energy Agency.

EXECUTIVE SUMMARY

There is a growing awareness of the significant contribution which human and organisational factors (HOF) make to nuclear safety. Within the HOF area, attention is increasingly focused on addressing management and organisational issues. This reflects an evolving recognition that the members of a nuclear licensee form part of a socio-technological system, and that their performance is influenced by the organisation and the culture within that organisation.

A series of events across the nuclear industry and other sectors has reinforced the appreciation of the importance of robust safety management. Also, the management and organisation of nuclear installations is impacted by a number of current challenges such as deregulation, change in institutional ownership of the industry, contractorisation and an ageing plant and workforce. It is in this context that the CSNI (Committee on Safety of Nuclear Installations) Special Experts' Group on Human and Organisational Factors (SEGHOF) was requested by the CNRA (Committee on Nuclear Regulatory Actions) to examine the role and influence of safety management in nuclear plant operations in 2000. A workshop on "systematic approaches to safety management" was held in spring 2002 and this was followed by a survey in 2003-4 of relevant practices and developments across licensees and regulators.

This report provides a brief explanation of the relationship between safety management and safety culture. It reinforces the need for nuclear licensees and regulators to take positive steps to ensure that licensees develop and sustain a robust safety management system as a part of their management systems as a whole. The report draws out the main findings of the workshop and presents the results of the survey in more detail. It seeks to identify current issues and areas warranting further consideration.

The workshop explored the development of current organisational theories and their application to nuclear plant safety management. It identified areas where future work should be considered. One of the identified key needs was to gather and share information about current practices and approaches used by different countries. The findings of the workshop are reported separately in NEA/CSNI/R(2003)14. A questionnaire-based survey was subsequently prepared to investigate licensee methods and tools and regulatory expectations in SEGHOF member countries. Respondents were also asked to highlight research developments as well as current practices. The principal findings of the survey are summarised as follows:

- There is a clear trend for regulatory bodies to develop regulatory requirements and guidelines on safety management.
- There is a move towards developing integrated management systems in which safety, quality and business management are not perceived as separate activities to be managed in different ways.
- A number of areas warranting further research and development in the area of safety management have been identified.

SEGHOF concludes that the CSNI and CNRA should consider the following future activities to further refine the nuclear community's understanding of the key aspects of effective management and organisation of nuclear plants. This should enable good practices to be drawn out and shared internationally:

- To update the CSNI/SEGHOF survey about systematic approaches to safety management at suitable intervals to provide a useful reference for workers in this area.
- To produce a short publication comparing regulatory approaches to assessment of licensee approaches to safety management (including other industries than nuclear).
- To exchange experience about regulatory oversight and licensee approaches in the area of safety culture.
- To clarify competences (including human and organizational factors) needed in the development, implementation and operation of Safety Management Systems as a part of Management Systems in general.
- To identify successful practices for dealing with identified organisational deficiencies.

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1. INTRODUCTION

Operating experience shows that a large proportion of events have human and organisational causes. For this reason, the OECD NEA CSNI (Committee on Safety of Nuclear Installations) established the Special Experts' Group on Human and Organisational Factors (SEGHOF). SEGHOF's mandate is to improve on our current understanding of, and advance, the utilisation of methodologies for human and organisational factor assessment and to address emerging safety issues, in order to maintain and improve the safety of nuclear installations in member countries. SEGHOF responds to requests from the CSNI and its other working groups, and from requests made by the NEA CNRA (Committee on Nuclear Regulatory Activities). It draws upon a wide base of experience from its members who work actively with human and organisational factors issues as nuclear regulators, licensees and researchers across the CSNI member countries.

There is growing interest in the nuclear safety field in the development and improvement of licensees' safety management systems. Accidents such as Chernobyl (Ukraine), Seveso (Italy, chemical), Challenger and Columbia (US space shuttles) have demonstrated the impact of human and organisational failures. These events made companies, public organisations and the general public aware of the impact of organisational processes on risk. Safety Management has thus been developed as a concept describing the systematic management processes through which the risks are controlled and a high level of safety is maintained in the day-to-day operations of an organisation. In 2000, the CNRA proposed that the CSNI SEGHOF should carry out work to deepen the industry's understanding of the role and influence of safety management in nuclear facility operations.

In order to address this requirement, SEGHOF organised a workshop on "Scientific Approaches to Safety Management" in 2002 [NEA/CSNI/R(2003)14]. The workshop sought to present state-of-the-art information on organisational theory and to determine which approaches may be suitable in terms of application to nuclear installations. The workshop also provided a wide forum for exchanging experiences of, and approaches to, the issue of Safety Management. Following the workshop, a survey was developed to collect information and experiences on systematic approaches to safety management used by licensees and regulators.

This report sets out the principal outcomes of the workshop and the survey of practices in member countries.

1.1 Objectives

The principal objectives of this report are as follows:

- to clarify the concept of Safety Management and its role and influence in nuclear facility operations, with respect to other concepts such as human factors, quality management and safety culture;
- to identify approaches used by utilities and regulators from different countries, and to discuss specific tools and applications related to detection, prevention, monitoring, correction and mitigation of safety related issues; and
- to identify needs for further research and development.

The report does not give an exhaustive review of different theoretical approaches and practical developmental processes in the area of safety management.

1.2 Audience and use of the report

This report will assist those responsible for developing, implementing and regulating safety management systems.

2. TOWARDS THE STUDY OF SAFETY MANAGEMENT

2.1 Contribution of Human and Organisational Factors to Nuclear Events

Plant personnel actions and the wider safety management system comprise an important line of defence in nuclear installations. There is a growing awareness of the contribution that human and organisational factors make to ensuring nuclear safety. It is clearly necessary to address these factors and to ensure that they are suitably considered and implemented in nuclear plant design and operation. As the technology and reliability of nuclear plant designs improve, the relative significance of human and organisational factors (HOF) increases. The nature of the HOF challenges may also change. Indeed, the principal causes of many recent events with significant public and economic impact have been identified as human and organisational deficiencies. These are well-documented across a range of different sectors, and include prominent events such as Challenger and Columbia (US, aerospace), Kings Cross (UK, rail), Piper Alpha (UK, offshore oil) and Chernobyl (Ukraine, nuclear).

According to a recent report (NEA, 2004), 48% of the events reported in the IRS as of 2002 identify HOF as contributors to, or root causes of, the events. Yet this category of event cause can cover a wide range of factors, extending from the classical operator "slip" or "lapse" type errors through to deep-lying organisational weaknesses. Moreover, it is arguable that most events, if analysed thoroughly enough, have their roots in organisational weakness. For example, although a maintenance error may have caused an event, asking "why" this error occurred may reveal an underlying deficiency in the arrangements for work environment, delegation, communication, training and assessment of competence, which in turn may have resulted from shortage of resources or other organisational failures. Despite the impact on safety of management and organisational factors, it is only recently that this area started to receive the level of attention that it warranted, as discussed below.

2.2 From human engineering to safety management

During the late 1970's, management effort was primarily focused on assuring efficiency in huge construction undertakings that produced the new nuclear plants. The Three Mile Island accident occurred in March 1979 and highlighted shortcomings in the relationships between the plant owner, the licensee, and the project organisation. Several actions were undertaken in response to the TMI accident. The corrective actions were mainly focused on human engineering aspects such as technological, procedural, training and man-machine interface aspects. The increase in requirements and regulations thereafter is well known, and shaped the approach taken by the nuclear industry to the introduction of the discipline of human factors for several years. However, subsequent analyses on the causes of the accident pointed out the influence of factors related to deeper underlying organisational aspects such as management structures, resources, etc. It was increasingly believed that these aspects could have a significant impact on plant safety because they set the context under which plants are designed and operated, and the way in which plant hardware is utilised, maintained and understood by plant operators. It is instructive to note that, even

in the Kemeny (1979) and Rogovin (1980) reports of the TMI accidents carried out shortly after the event, organisational weaknesses were identified as significant:

- As the evidence accumulated, it became clear that the fundamental problems are people-related problems and not equipment problems. (Kemeny, 1979)
- The responsibility of management at all levels should be integrated in a consistent way (Kemeny, 1979)
- There are structural problems in the organisations, there are deficiencies in various processes and there is a lack of communication between key individuals and groups (Kemeny, 1979)
- The principal deficiencies in commercial reactor safety today are not hardware problems, they are management problems (Rogovin, 1980).
- The kinds of changes needed to cope with these problems and attitudes are institutional, organisational, and managerial (Rogovin,1980).
- Individuals managing and operating nuclear plants constitute a relevant safety system (Rogovin,1980).

The response to the Chernobyl accident again showed how, in the early analyses after the accident, the emphasis was mainly on the reactor and plant deficiencies ("*we do not use this type of technology*" or "*this cannot happen with our technology*") while later, more measured, analysis identified organisational, cultural, managerial and institutional failings and pointed to the "*lack of an adequate Safety Culture*". The Chernobyl event was followed by the production of a seminal document on safety culture (INSAG-4, 1991). This document sought to set out the characteristics of a positive safety culture and offered nuclear operators guidance on how to foster and sustain the culture of safety within their organisations.

Although there are numerous reports, presentations and analyses on recent nuclear operational experience available to NEA members (e.g. NEA, 2004), it is instructive to consider one particular example which illustrates the emerging awareness of the significance of management and organisational factors to safety.

Following the Columbia shuttle accident, the Investigation Board issued a report (NASA, 2003) which highlights a tendency to identify the plant failure, blame the operator concerned and seek to fix the technical problem and replace or retrain the individual responsible. It concludes that this approach may foster an erroneous belief that the underlying problem has been solved. The report goes on to note that insights from High Reliability Organisations Theory (e.g. LaPorte & Consolini 1991, Reason 1990) and Normal Accident Theory (Perrow, 1984) highlight the importance of strong organisational culture and commitment to building successful safety strategies. The report also refers to weaknesses in NASA's safety culture and the negative effects of factors such as resource constraints, fluctuating priorities, schedule pressures, mischaracterisation of the Shuttle as operational rather than developmental, and the lack of an agreed and widely shared national vision.

2.3 The Concept of Safety Management

The previous discussion illustrates how the HOF focus has shifted from individual operator performance towards the performance of the organisational system which gives the context to the individuals' actions.

The IAEA (INSAG-3 1988, INSAG-12 1999) state:

> "*All safety activities, whether organisational, behavioural or equipment related, are subject to layers of overlapping provisions, so that if a failure should occur it would be compensated for or corrected without causing harm to individuals or the public at large. This idea of multiple levels of protection is the central feature of defence-in-depth…"*

Organisational processes that support safe human performance and technical performance are thus identified as potential lines of defence. As can be seen through analyses of operational feedback from nuclear installations, latent failures may seriously compromise safety. These latent failures may occur throughout the organisation. Most seriously, they also may be affect higher levels of the organisation and may remain undetected for a long time. It is therefore prudent to ensure that these important organisational lines of defence are properly specified, implemented and supported. Here, we need to consider what is generally understood by the concept of *safety management*.

Safety management is the term used for the organisational measures applied to ensure that an acceptable level of safety is maintained throughout the life of an installation. Management is responsible for recognising the safety significance of both the design of the installation and the way in which it is operated and maintained and to put in place suitable organisational processes to manage risk. This requires that the organisation is well structured with clear lines of authority and well defined responsibilities. Also, the safety policy, requirements and procedures need to be well established, understood and observed by all. All these features of control and operation need to be considered systematically, and this leads to the general definition of *Safety Management System* as offered in INSAG-13 (1999):

> *"The safety management system comprises those arrangements made by the organisation for the management of safety in order to promote a strong safety culture and achieve good safety performance."*

2.4 Elements of a safety management system

There are some general elements that should always be included in the management system for high hazard industries with the aim of ensuring safety (thus becoming Safety Management System). These elements are presented in the following figure.

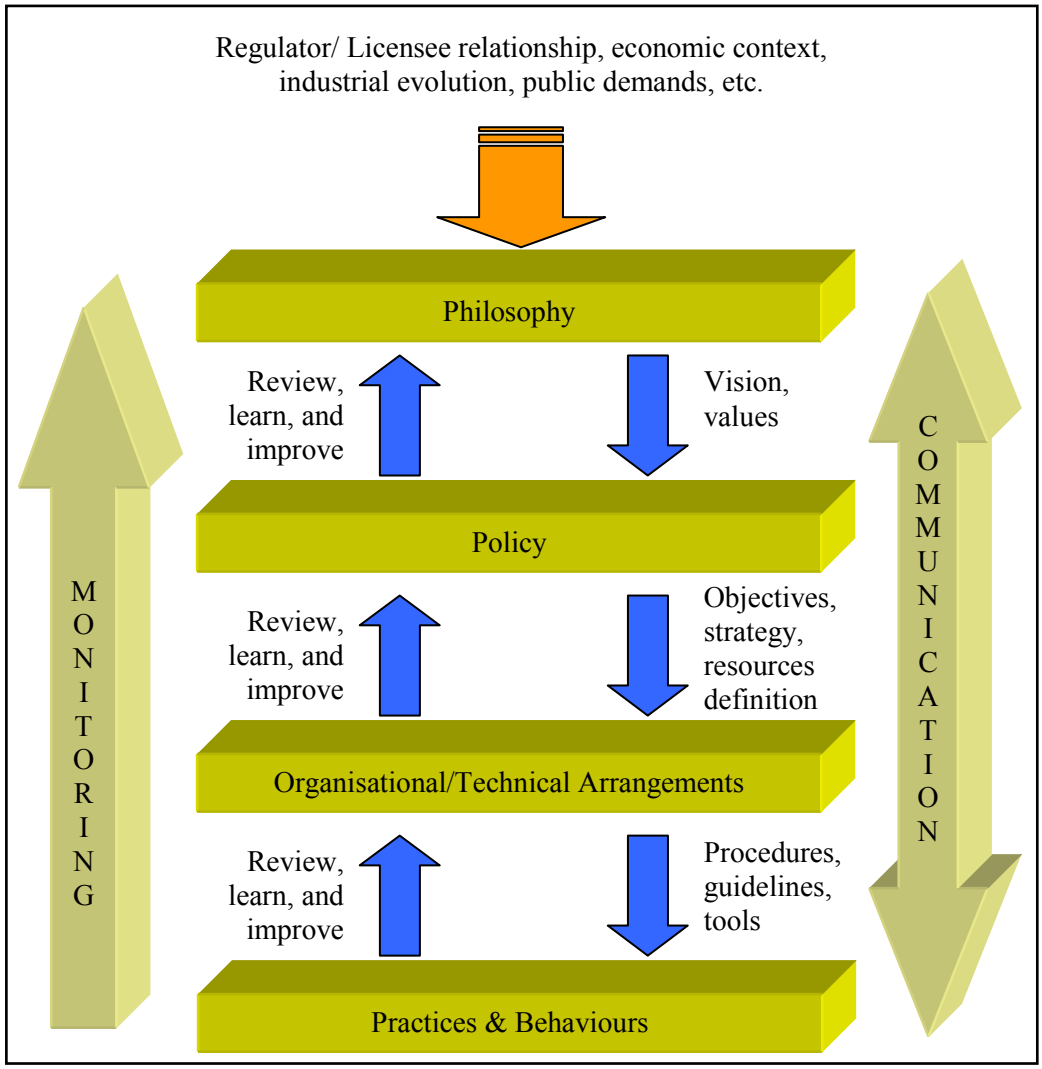


Figure 1 – Elements of a Safety Management System (based on Transport Canada's report on Introduction to Safety Management Systems (Transport Canada, 2001).

It should be recognised that the safety management system exists within an environment that includes factors such as public demands, the economic context, socio-technological trends and the regulator-licensee relationship.

The structure of a Safety Management System is based on following levels:

At the top level, a *management philosophy* establishes safety as the primary criterion in decision making. It provides commitment to continuous development and improvement of processes supporting safe operation and improvement of safety performance. Key values are stated, such as "continuous vigilance is required to avoid threats to safety" and "safety is everyone's responsibility". At this level, a "vision of the future" should be built that takes into account contextual elements such as economics,

technological evolution and public demands. This vision will also be influenced by the regulatory framework and requirements.

A s*afety policy* specifies how safety will be achieved. Objectives are clearly defined regarding responsibility, authority and accountability. Safety goals are defined and a strategy is developed for incorporating these safety goals into day-to-day operations. Resources and processes required to reach these goals are defined, including requirements for making available a sufficient number of trained and qualified staff.

The *organisational and technical arrangements* level translates the policy into practical means for staff to meet management expectations. In particular, it concerns requirements and guidelines to be followed and the identification of the means for planning, organising and executing jobs and tasks. Methods for identification and assessment of hazards, minimising risk (*risk analysis and management)* and limiting the consequences of potential events are developed at this level.

Finally work *practices and behaviours* address what really happens on the job. At this level, the implementation of the safety management system is characterised by the behaviour of staff directly responsible for safe operations in the field and those working in other areas that might impact on nuclear safety.

Two additional components are required to ensure the operation of the safety management system: a communication system and arrangements for monitoring and improving the effectiveness of the safety management system.

- **Communication:** is needed throughout and between all levels of the organisation in order to transmit and promulgate the organisation's vision, objectives, values and expectations and secure staff commitment in the field through the different levels of this model. The system should support both formal and informal communication. Behaviour of managers and participation of staff in decision-making processes are key factors for the efficiency of the communication system.

- **Monitoring:** is needed to ensure that the safety management system is being implemented effectively, and that potential improvements are identified and implemented. The monitoring arrangements should be regarded as a key part of a licensee's Review, Learn and Improve (RLI) processes which should support *organisational learning* and lead to an understanding of the strengths and weaknesses of actual work practices and behaviours. The RLI process should not only feed upwards through the organisation so that general lessons can be learned, but should also operate at a more local level *within* each element of the safety management system. It should include tools such as self-assessment and use of indicators, independent assessment, peer-reviews, field observations and inspections, and responses to regulatory reviews. For example, indicators and measures of the effectiveness of the management system, at the work practices and behaviour level, include compliance with procedures, use of prescribed methods and tools, etc. It is important to note that an essential element of the RLI process, and one which is often weak, is the "Improve" stage, and the management system should ensure that learning points are not only recognised, but also lead to tangible improvements.

This representation of a Safety Management System is strongly related to the concept of safety culture. This relationship is further developed below.

2.5 The relationship to the concept of Safety Culture

It should be recognised that the culture of the organisation will also have an impact on the management system and vice-versa. A culture manifests itself at different levels, ranging from the more visible manifestations to the invisible basic assumptions. A three-level model, consisting of "artefacts", "espoused values" and "basic assumptions" has been proposed when studying organisational culture (Schein, 1992) which can be applied to safety culture as well. The concept of safety culture refers to those shared values, beliefs and assumptions of the whole organisation, which are related to safety or which have an impact on safety behaviour, as well as to the artefacts reflecting them.

The relationship between the concepts of management system and safety culture is shown in Figure 2.

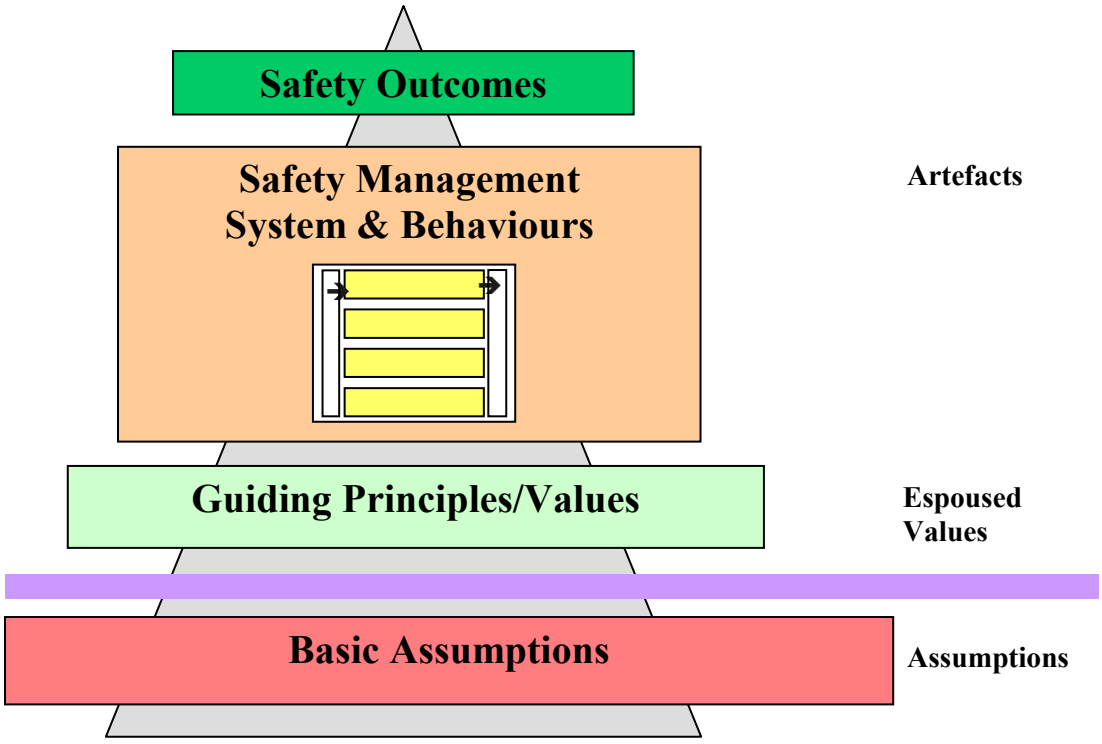


Figure 2: A Model of Safety Culture

The safety management system is located on the level of the artefacts and espoused values. The model of culture, however, shows that these visible elements are based on and reflect the organisation's basic assumptions. For instance, a basic assumption that considers safety and production to go hand in hand, would also be reflected in how the policy statements are formulated regarding these issues. A basic assumption that errors are opportunities for learning, would be reflected in a safety management system that has processes and procedures that promote open reporting of all types of deviations, including near misses. Behaviours arise from implementing the safety management system and also are influenced by, for example, the basic assumptions.

When considering how to reach the desired safety outcomes, proper attention needs to be given to both the management system and the safety culture of the organisation. Thus, to achieve this, there is a need to have a proper understanding of the relationship between the two. At the same time, it is important to understand that a special challenge lies in the fact that safety culture cannot be implemented as a "quick

fix". However, leaders can change culture by evolving new basic assumptions and communicating and acting according to them.

2.6 A Note on Licensee/Regulator relationship

Any activity on the topic of Safety Management as well as Safety Culture must rest on the principle that the licensee is responsible for the safe management of its plant and the regulator should not undermine this principle. However, a sound safety management of nuclear operations, reinforcing mutual respect and confidence, is a common interest of operators and regulators. Moreover, the regulator, especially in deregulated markets, has to be sure that the licensee has the appropriate processes in place to manage safety and the appropriate tools to self-assess its effectiveness in managing activities which may impact on safety.There is a trend for nuclear regulators to develop more formal regulatory requirements in the area of safety management and to assess licensee management systems. This is consistent with the general evolution of an awareness of safety management as a critical issue in the safe operation of nuclear facilities. Regulation in the area of management systems and safety culture, however, needs an approach that is different from that in the technical area, since it is arguable that there is no "one best way" or absolute standard in the area of organisation and culture. Moreover, the accessibility of the culture of an organisation to the regulatory body is limited as shown in figure 3, as based on the Schein's model (1992).

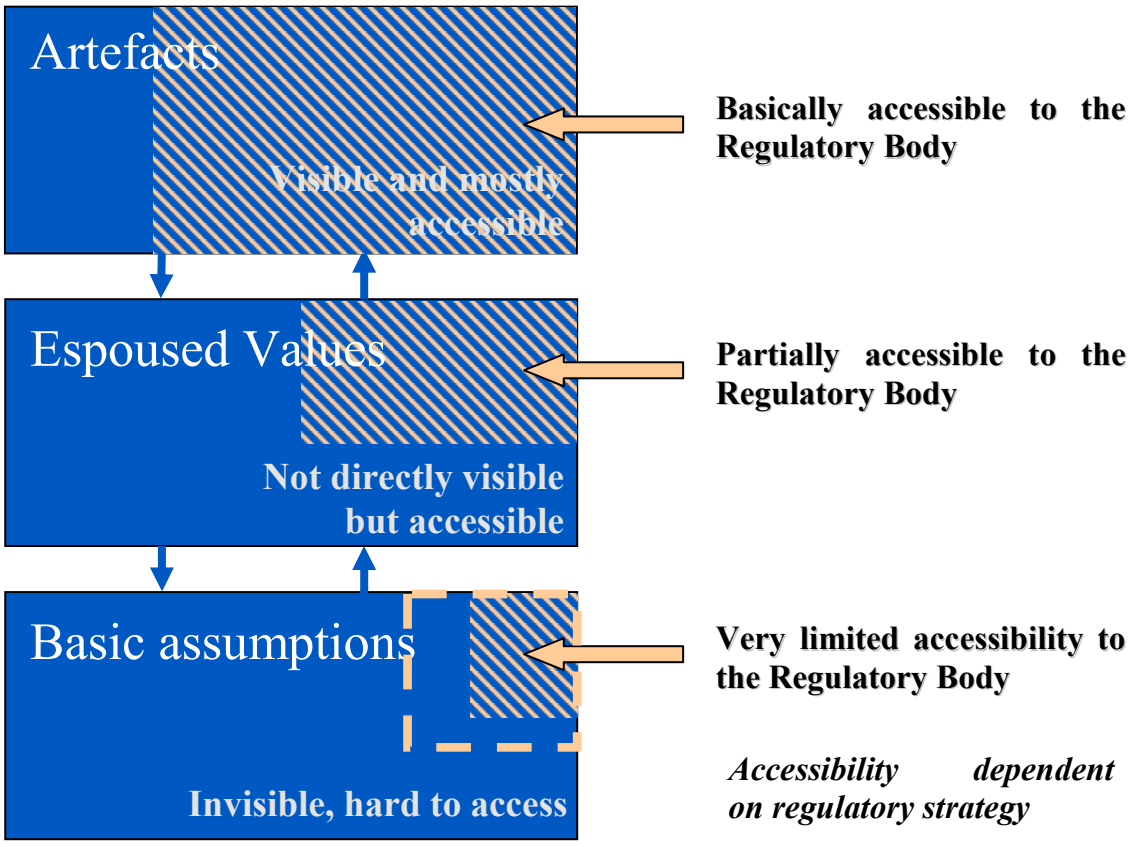


Figure 3: Regulatory oversight of safety culture and safety management.

The artefacts level, and particularly the safety management system, is basically accessible to the regulator, since it is visible. The regulatory body, for instance, can examine the operator's processes, including its documentation system, its procedures and guidelines as well as its organisational structure and gather information from plant activities and staff.

Also, the level of espoused values is at least partially accessible to the regulator, although the organisation's values are less directly visible than the artefacts. Despite its importance for understanding the organisation's culture, the basic assumptions are the least accessible elements of the culture to the regulator. However, depending on the regulatory strategy applied by the regulator, it may be possible to gain some insight into the basic assumptions of the organisation. For instance, a process-based regulatory approach, where the regulators conduct interviews with plant staff on different organisational levels and spend enough time interacting with the organisation to deepen their knowledge about how the organisation works, enables the regulator to understand a greater extent of the basic assumptions.

It has to be considered, however, that, in order to gain access to the deeper levels of the culture, appropriate competencies, such as application of interview techniques and knowledge about human and organisational factors are of significant benefit. Moreover, to some extent also, the national culture and the nature of the existing relationship between the regulator and the licensees can have an impact on the regulator's ability to maintain oversight of organisational and cultural issues.

In order to achieve an effective progress in this matter it is important that tools and methodologies are developed and applied and gain credibility by the regulatory authorities and the licensees. Consequently, it is advisable to establish at an early stage a common understanding between licensees and regulators as to the scope and bounds of regulatory interest and the approaches used to manifest that interest.

2.7 International Nuclear Activities in the Field of Safety management

2.7.1 WANO

The General Meeting of the World Association of Nuclear Operators (WANO, www.wano.org.uk) in October 2003 gathered more than three hundred top officials of the nuclear power operating companies around the world to review and share recent operational experience. The meeting provided an opportunity for some critical self-assessment, and produced a set of valuable references for Safety Management improvement. The outcomes of that meeting are summarised in (Nucleonics Week, 2003a). The meeting referred to a series of high profile events and pointed out that even licensee organisations that were considered to be top performers could suffer significant incidents owing to deficient safety organisations. The Chairman conveyed a clear and general warning about how complacency and negligence are threatening the nuclear industry and warned of the potential consequences of "loss of motivation to learn from others ... overconfidence ... (and) negligence in cultivating a safety culture due to severe pressure to reduce costs following the deregulation of the power market". He added that troubles, if ignored, "are like a terrible disease that originates within the organisation" and can, if not detected, lead to "a major accident".

Shortly after the WANO meeting, the IAEA's Director General addressed the American Nuclear Society and stated that much work was needed in the safety area to achieve uniform standards of safety and safety culture and warned against signs of deterioration of safety culture in the industry (Nucleonics Week, 2003b).

2.7.2 IAEA Standards and Safety Management

The significant efforts of IAEA in the field of safety and management of nuclear organisations can be only briefly referenced here. They include the hierarchy of Safety Standards from Safety Fundamentals, Safety Requirements and Safety Guides (http://www-pub.iaea.org/MTCD/publications/sss.asp), as well as several safety and technical reports series and technical documents (www.iaea.org).

Of particular relevance to the topic covered in this report are the draft safety standards on Management Systems (IAEA 2005a, IAEA 2005b) with requirements and guides on an integrated management system. It integrates all aspects of managing a facility or activity so that the requirements for safety, health, quality, environment, security and economics are established and implemented in a coherent manner to enable the organisation to achieve its overall objectives. It also contains requirements and guides on safety culture. It replaces the Code on Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations (IAEA, 1996). The term Management System reflects the evolution in the approach from the initial concept of 'Quality Control' (controlling the quality of products) through 'Quality Assurance' (the system to assure the quality of products) and 'Quality Management' (the system to manage quality). The "Management System" is a set of interrelated or interacting elements (system) that establishes policies and objectives and which enables those objectives to be achieved in an efficient and effective way.

Furthermore, as mentioned before, the International Safety Advisory Group (INSAG) to the IAEA has produced a series of reports on the topics of safety management and safety culture (INSAG -3, -4, -10, -12, -13, -15). The new safety standards on Management Systems (IAEA, 2001, 2002, 2005a, 2005b) support the two general aims of the safety management presented in the INSAG 13 report on Safety Management (1999).

- To focus the performance of the organisation on achieving and improving safety through the planning, control and supervision of safety related activities in normal, transient and emergency situations;
- To foster and support a strong safety culture through the development and reinforcement of good safety attitudes, values and behaviour in individuals, teams and the organisation so as to allow them to carry out their tasks safely.

2.7.3 NEA

The NEA/CSNI has identified safety management as a high level safety issue. The CSNI Special Experts Group on Human and Organisational Factors (SEGHOF) has given the lead in addressing this area. SEGHOF, in its current form and in its previous guise as the Expanded Task Force on human factors (ETF), has existed since 1989. It has a broad experience considering management and organisational factors, since it is composed by the representatives of regulatory bodies, industry and researcher organisations. Present SEGHOF work includes activities such as management and regulation of organisational change, safety management (this report), HOF in the design modification process, maintenance, human performance and future control room issues, etc.

Regulatory interest in safety management has also been recorded by the Committee on Nuclear Regulatory Activities (CNRA). In its 1998 report on Future Nuclear Regulatory Challenges (CNRA, 1998), CNRA identified key aspects related to the subject. In 2000, CNRA proposed that CSNI/SEGHOF should carry out the work described in this report. The CNRA has also contributed to discussion of the issue by issuing several reports - e.g. "The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture" (CNRA, 1999), "Nuclear Regulatory Challenges Arising from Competition in Electricity Markets" (CNRA, 2001) and the organisation of topical issue meetings.

Recently, the CNRA raised the question as to whether the relative importance of HOF has increased during the last decade (CNRA, 2004). The CSNI working groups, i.e. SEGHOF, the Working Group on Operational Experience (WGOE), and the Working Group on Risk (WGRISK) were asked to consider this matter. SEGHOF concluded that although many technical problems were resolved in the past, human factors problems remain essentially the same, although their relative importance has increased. In particular, the conclusions noted that: the perception of the importance of HOF has increased during the past 5-10 years; new challenges to the organisation of NPPs have appeared (deregulation, reorganisation, ageing workforce, perception of society); new technologies have introduced more complex environments to the work force; and awareness of and attention to safety culture & safety management has increased. WGOE reviewed the evolution of the importance of the Human Factors issue during the last twenty year period and noted that the human contribution to events has increased during this period. It was suggested that event discussions often tend to focus on HOF issues, and this might bias the observations to a certain extent. WGRISK also reviewed this issue and noted that human performance and human factors have, and remain, highly important to safety, as confirmed by events and safety studies (CNRA, 2004).

3. WORKSHOP

There has been an unprecedented progress in the field of behavioural sciences, including the study of organisation and management, for the last half century at least. The development of knowledge on management and organisational issues has provided tools to inform the management of large businesses with a high degree of complexity. The amount of research on management, leadership and organisation processes has increased and the number of publications in this area is much more than most managers would be able, or expected, to read and implement, especially as they sometimes offer conflicting advice and guidance.

The aim of organising this workshop started from the premise that the safety management of nuclear installations should benefit from an enhanced understanding of the relevant available inventory of knowledge and that a workshop could accomplish this in an efficient way. The workshop on "Scientific Approaches to Safety Management", held in Paris 8^{th} –10^{th} April 2002, (NEA/CSNI/R[2003]14), has been an initial step in the direction of developing a better understanding on the role and influence of Safety Management in nuclear facility operations. It provided the opportunity to present and discuss practical and scientific approaches to Safety Management.

3.1 Methodology

Two significant goals were set for the workshop. These included:

- to identify the present state-of-the-art on organisation theory (taking this in a wide sense as including management, organisational and behavioural sciences)
- to determine which systematic approaches in the state-of-the-art seem to be suitable in terms of application to nuclear installations.

The workshop was intended to be of interest to companies operating nuclear installations, regulatory bodies, research organisations and consultants in the field of organisation and management. Although the main theme of the workshop was nuclear safety, the presentation of experiences from other industries where safety is a prominent element was encouraged.

The focus of the workshop was on modern organisational theories and their application to the Safety Management of installations or activities. Insights were obtained by means of selected presentations and organised discussion sessions. For more information, see Workshop Proceedings, NEA/CSNI/R(2003)4.

3.2 Findings

The workshop discussed four different approaches in business and behavioural sciences including: business models, knowledge management, learning organisation and emotional intelligence. The first three approaches are generally accepted and are widely implemented by licensees and monitored by regulators. Emotional Intelligence is a fairly recent construct that is receiving attention by some organisations but can be best viewed as an area under development.

The workshop discussions brought forward comments, remarks and suggestions for research topics, both from the point of view of the regulators and the licensees. The goals, discussions and conclusions are fully documented in the Workshop proceedings, NEA/CSNI/R(2003)14. Only the main outputs are presented here.

An understanding was reached on the importance of developing pilot research programs to assess the usefulness of new management theories to nuclear safety management. NEA was regarded as an adequate forum to promote knowledge and experience in this field. Cooperation of regulators, their technical support organisations and utilities of member countries would facilitate developments in this area.

The following six areas of interest were identified for future work in the field of Safety Management:

- **Operating experience approach.**
  Continue exchanging experience with implementation of safety management systems and their integration in business management systems.

- **Indicators and diagnosis**.
  Identify methods to measure and to assess the efficiency of improvement programs on safety.

- **Intervention and remediation tools**.
  Share information on methods to assess operating experience and on intervention and remediation tools related to organisational and managerial issues.

- **In-depth research.**
  Transfer and apply existing knowledge about management science to the nuclear industry. Potential future directions of work are in the fields of emotional intelligence and knowledge management.

- **Regulatory needs**.
  Review present regulatory needs and challenges including the role and expectations of regulators with regard to safety management.

- **Experience from other industries**.
  Continue exchanging information with other industries requiring high reliability.

4. SURVEY

The workshop led to the need to continue to map the approaches to systematic safety management. Consequently, the aim of the survey was to collect information and experiences on regulatory to oversee and assess the licensee's processes and performance. Also licensee approaches were covered. This questionnaire fulfilled, at least in part, some needs in the areas of "operating experience approach" and "regulatory needs" as identified through the workshop (see section 3).

4.1 Methodology

The survey was conducted using a questionnaire. This consisted of three parts.

Part A was directed to the regulatory bodies (or technical support organisations, where it was more convenient) and covered the regulatory requirements and inspection systems in place.

Part B of the questionnaire was addressed primarily to licensees and consisted of a number of questions regarding approaches, methodologies and tools being used for in Safety management. Regulatory bodies were also asked to use this part to inform on tools they use in their own management systems. In addition, research institutes or consultants could inform about methods and tools they are developing for nuclear industry by using this part of the questionnaire.

Part C was addressed to all interested parties and aimed to define further needs for research and developmental work by collecting needs, challenges and further ideas identified by participating countries and organisations.

The questionnaire was sent to all involved parties through SEGHOF Members. The full results of the questionnaire are attached to this report (see Appendices 1-3). The findings described in the following chapters are based on the responses, which were not reviewed in detail.

4.2 Findings

4.2.1 Considerations about the responses to the Questionnaire

The survey results do not represent a comprehensive "state of the art" on regulatory requirements, methodologies and activities in the area of Safety Management. Neither do they provide a comprehensive overview of the activities of many organisations/countries across the world, within or outside NEA/SEGHOF. However, the responses of the organisations and countries that have contributed to this survey (see Appendices 2-3) might be considered as a representative sample of the current situation in this area. Given its potential value, SEGHOF might consider at a later stage to keep this information up-dated as a useful reference for member countries.

As expected, although the questionnaire tried to give a common theme for describing the situation in each country on Safety Management, there is a significant heterogeneity in the responses. In spite of that, important trends can be clearly detected. The findings described below compile the main issues and common points extracted from the responses. However, it is recommended to read the individual

responses to the questionnaire (Appendix 3) for a better understanding of the specific situation in each country.

4.2.2 Regulatory Requirements and Practices

Questions in Part A of the questionnaire covered regulatory requirements on Safety Management and the regulatory assessments of the licensee management systems. Responses from the regulatory bodies of ten countries were received.

Regulatory requirements

In the early stages of nuclear regulation, regulatory requirements in the area of Safety Management were very close to the criteria specified in documents like the US NRC Regulatory Guide 1.70 (1999). Those requirements were rather generic, concentrating on issues such as description of organisational structures, functions and responsibilities. This sort of requirement is still used in most of the regulatory frameworks.

More recently, this situation has changed or seems to be evolving in many countries, which are working on additional regulatory developments in this area. One of the observed trends during these last years is the tendency, in the vast majority of the countries, to develop some kind of regulatory requirements on safety management systems, especially on human and organisational issues within those systems. New requirements are under development (Finland, Japan, Spain, etc.) or have been recently developed (Sweden, UK, Switzerland, etc). Others have promoted this change more recently.

Regulatory bodies are trying to give a response to new and modern needs in Safety Management. This response is not different from responses to new challenges like market deregulation, safety improvement challenges in the HOF area, anticipated shutdowns or life extensions of NPPs, evolution of traditional management systems according to new working conditions. These issues have been identified in several NEA/CNRA documents (e.g. CNRA, 1998, 1999, 2000, 2001, 2001a, 2001b, 2001c) .

The historical trend perceived through the questionnaire responses, can briefly be described, in three main steps:

1) Initial detailed regulation on technical issues and very simplistic regulation on organisational aspects; basically those issues related to organisational structures, functions and responsibilities, which were compiled in current Safety Reports, and that were used in combination with compliance based regulatory strategies.
2) Movement to Quality Management and more or less explicit requirements on Safety Management Systems, in several cases integrated in licensee´s Quality Systems.
3) Focus on safety improvements through emphasis on the development of HOF issues within the licensee´s established SMS structures, trying to move one step forward in the incorporation of social science concepts such as (organisational) culture, motivation and leadership, organisational learning, etc.

This trend can be summarised as increasing regulatory scrutiny of safety management matters and a move towards a more holistic approach to regulation. The horizontal scale in Figure 4 shows the move towards integrating safety management and business management (quality, financial, process management, etc.), while the vertical scale shows that, some regulators are going deeper into staff values, beliefs and assumptions related to safety. This approach embodies a more systemic view of nuclear safety. There are some ideas, partially related to the above mentioned trend, in the existing literature (e.g. Reason 1997, Waring 1996).

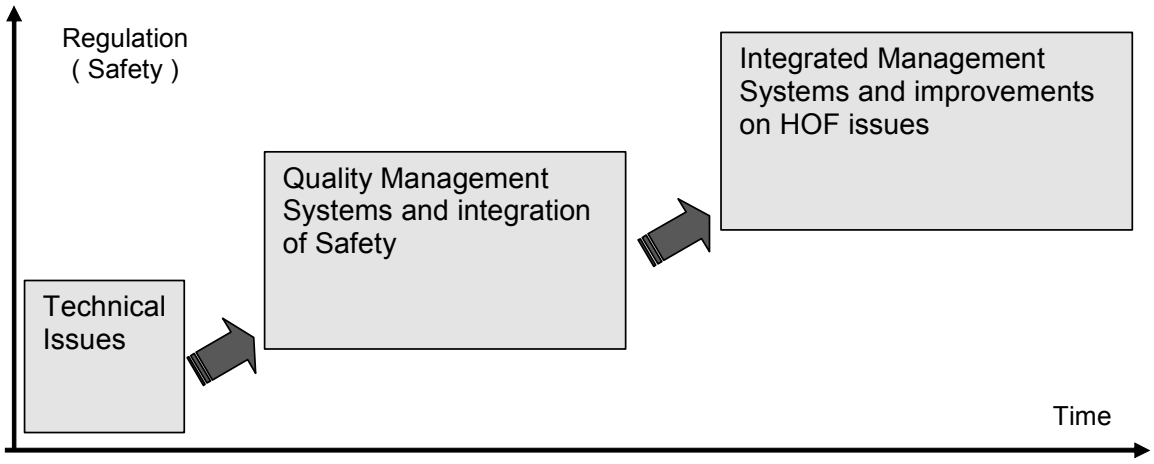


Figure 4: Progression of regulatory approaches over time

In some countries, such as Sweden, France, Switzerland, Finland, Canada or Japan, these requirements are elaborated on the basis of formal licensee´s Quality Management Systems as a starting point. In other countries like U.K, Belgium or Spain, there are specific requirements on Organisation and Management issues and even specific requirements on Safety Management Systems. In those countries the regulatory link between Quality Systems and HOF issues is not established so markedly. In spite of the heterogeneity of the responses, a concept of Safety Management System can be perceived in most of the regulations that is rather close to the concepts described in documents like (INSAG-13 1999), (Sugarman 2000).

The requirements are mainly focused on the development of different elements or components of a Safety Management System, such as processes, methods, tools, etc. Those are the artefacts or "tangible elements" that must be in place and are needed to develop sound Safety Management Systems.

In some countries there are also requirements regarding competencies needed to put the components of the SMS in place. In this respect, attention is drawn to requirements for developing MTO (Man, Technology, Organisation) assessments in certain NPP processes (e.g. design modifications) and for the need to develop an adequate level of expertise in both technical and social sciences. Some regulatory bodies have developed within their regulations specifications for all the components of a SMS (e.g. Sweden). In other countries, there is detailed specification on just some of them.

The detail of the requirements seems to be rather varied among countries, but several of the following components and processes of a SMS are often specified:

- Licensees' mission, vision and values
- Safety policies
- Safety goals and strategies
- Safety culture programs
- Organisational structures
- Responsibilities and authorities
- Qualification, competence and training
- Staffing plans
- In-house expertise and contractors use
- Communications

- Financial, cost and investment resources strategies
- Safety analyses
- Safety reports
- Safety committees
- Fitness for duty policies
- Self assessments
- Independent internal assessments
- External assessments

In addition, processes, which are important for safety and affect many parts of the licensee organisation, such as Management of design modifications, and operating experience feedback, appear to be commonly required as components of a SMS and receive particular consideration. Management of organisational change is also a very important process with an impact on safety that affects the whole organisation and which is being regulated in many countries in the context of the SMS (e.g. the UK Licence Condition 36).

An example closely related to the work of SEGHOF specialists is human factors analyses that are required in some countries for those issues involving factors at work that affect peoples´ abilities to do their job. This corresponds to the implementation of article 12 of the International Convention on Nuclear Safety within the national legislation (IAEA, 1994)

Regulatory assessments of the licensee management systems

Affirmative responses from all countries to the question as to whether licensee's SMSs are assessed by regulatory bodies, independent of the existence of written regulation, demonstrate the recognised need to assess the impact of SMS on nuclear safety.

Differences between countries appear with regard to the circumstances of such assessments. Two basic approaches were identified in the replies: performance of an assessment after an important event has happened or when degradation in the licensee performance is observed (case by case); or performance of assessments in a more systematic way on a regular basis (this latter option is followed in many countries). These different approaches depend not only on general strategy and regulatory philosophy, but also on the particular assessment practices used within each country. A combination of approaches is often used.

Different types of regulatory assessment methods can be observed. Process-based assessments performed by the regulator itself are dominant, although other methods are also put in practice, such as use of licensees' self-assessment and a simple comparison of safety management practices between utilities. Frequently a combination of several basic assessment approaches and methods used is the strategy followed by the majority of the regulatory bodies.

A large spectrum of regulatory assessment methods and activities was mentioned in the survey responses:

- Document reviews and approvals
- Field observations
- Interviews with licensees staff
- On the spot inspections
- Regular inspection programmes
- Licensee self-assessment requirements
- Independent assessment of safety management by third parties

- Performance assessments
- Assessment of the SMS after significant events
- Assessment by the regulatory bodies of the licensees organisation and management, based on detailed tools
- Development of new competencies for licensees and regulatory body staff

These activities are usually formally defined in the procedures that set out the roles and responsibilities of the regulatory body and which guide the way in which they carry out their work. As an example, the performance of periodic safety reviews as part of the licensees' SMS is explicitly required by some regulators. Safety reports, periodic (independent) safety reviews, and annually revised safety programmes might constitute an adequate framework, a set of administrative barriers within the SMS, for licensees to monitor and improve safety, especially on those issues related to Human and Organisational Factors. Some countries have already developed or are developing inspection procedures or manuals to deal with safety management issues. This is especially the case when the inspections of SMS or their components are done on a regular basis. Finally, some countries (e.g. Spain) are sponsoring R&D projects in order to develop appropriate assessment tools related to organisational issues that could be used by the licensees and/or by the regulatory body.

4.2.3 Approaches, Methodologies and Tools used in the nuclear industry

The implementation of a safety management system needs practical tools and methods. Part B of the questionnaire addressed these tools used or under development in the nuclear industry.

The 16 responses received may be classified according to the following groups:

- Use of established approaches for Management Systems:
  - Implementation of *established approaches* which are widely known and used in companies and public organisations
- Development of specific Managerial Programs and Tools:
  - Implementation of tools tailored specially for a company or plant, and used with the aim of identifying possible safety improvements
  - Continuous development programs
  - Tools and methods resulting from research

Quality Management and Safety Management

Most, if not all NPPs, have comprehensive management systems with emphasis on nuclear safety, which are compatible e.g. with ISO-9001, IAEA 50-C/SG-Q (1996) or the draft safety standards on Management Systems (IAEA 2005a, IAEA 2005b). The systems include an in-house tailored quality manual or standard and internal and external audits, which help to standardise and improve the transparency and the efficiency of the processes. Implementation of Quality Management Systems in the nuclear industry also helps to increase nuclear safety.

The quality manual and the management system are most effective when they are continuously updated and when the personnel are committed and feel ownership of the system and of safety. This can be attained through participative development of the system such as the process reported to be in use in Sweden where employees are actively involved in developing and updating of the quality manual.

The relationship between Quality Management Systems and Safety Management Systems has been a debated issue. Nowadays, there is a trend towards Integrated Management Systems, in which safety

(nuclear and occupational safety), quality, environment and business issues and requirements are handled together in one single management process.

Benchmarking

A common safety management system goal is the continuous enhancement of performance. An important way to identify ideas for development is to benchmark one's own activities and solutions not only with those of other organisations in the same industry but also across other industries and countries. The European Union LearnSafe Project (Wahlstrom et al. 2003) which has the characteristics of a developmental programme, was cited in one survey response as an example of this practice.

Peer reviews are used in several companies as a systematic tool for benchmarking assessments and identification of areas for improvement. The framework used in the peer review process, as well the knowledge and experience of the participating peers, determines the areas covered as well as the criteria used in the review. WANO and IAEA have developed their frameworks for peer reviews, which are generally accepted by the nuclear industry. Also the NEA carries out peer reviews in some cases.

The results of (WANO) peer reviews remain generally confidential and are not accessible to the regulators, whereas the IAEA OSARTS and NEA reviews are requested by the governments and their results basically are public. Such initiatives have great value, as they reflect the commitment of industry to safety enhancement. It is important that regulators encourage such initiatives and allow therefore some room for self-regulation.

Measurement techniques

Most Safety Management Systems include techniques for measuring the safety performance of the organisation, and thus the effectiveness of the management system itself. Reporting of performance measures by the line organisation (including indicator results), as well as other types of self-assessment including regular audits, follow-up of corrective action programs and management reviews, serve this function.

Whether the safety level is sufficient or unidentified safety gaps exist is an important issue which requires constant attention by organisations and their personnel in high-hazard industries. Several specific managerial tools (such as recurrent safety audits) have been developed, aiming to question current safety levels and to create better solutions for identified safety issues. For example, in Swedish companies periodic reviews have been introduced to measure safety culture and work satisfaction. The results of these reviews are used to assist in the development of specific action plans. It is important that identified issues are classified according to their safety significance and that handling of a specific issue within the action plan is in relation to its classification.

Specific processes and software tools have been developed for reporting, processing and follow-up of safety issues, whether they originate from employee perceptions or suggestions, analysis of incidents or near miss events, safety audits and regulatory inspection findings. These processes ensure safety issues are systematically recorded, and issues are usually not closed by the organisation until follow-up of the effectiveness of corrective actions is complete. This kind of personnel innovation enhances the participation in Safety Management at all levels of the organisation, and help the organisation to develop towards becoming a "learning organisation".

Safety indicators, which are used to monitor safety performance, have been developed and are used by utilities in many countries as a basis for their self-assessment. The in-house development of indicators is a good way to gain deeper insight into causal chains impacting safety. Participation in indicator development can therefore also be used as a method in training personnel.

Use of business models

The EFQM model -business excellence model developed by the European Foundation for Quality Management, http://www.efqm.org/ - is a practical tool that can be used for self-assessment of management systems and organisation performance. It helps to identify weaknesses and strengths and to improve future performance. The EFQM model is based on 9 criteria, including "enablers" (Leadership, Policy and strategy, People, Partnership and Resources, Processes) and "results" (Customer results, People results, Society results and Key Performance results).

The EFQM model can be used as well for self-assessment of licensee and regulatory body organisations, and e.g. the UK and Finnish regulatory bodies use this model. Because the model is widely used, it allows for benchmarking with other public and private organisations acting in similar conditions.

Safety Culture Development programs

In organisations working in high-hazard industries, there is a need to keep personnel continuously attentive to and aware of risks. Some nuclear organisations have special safety culture programs or campaigns with changing messages. By means of such programs, safety is continuously highlighted as a topic in the organisational conversation, even in the absence of specific events.

Some programs are more specialist-driven and aim at making improvements in organisational factors (e.g. the Organisational and Human Factors Programme in Spain) whereas others are more management-driven and aiming at safety enhancement of a wider scope (e.g. the Swiss approach SAFE). Both of these programs are under constant development and include a wide variation of different sub-goals and activities (e.g. creation of guidelines or indicators for enhancement of performance, training, workshops, posters, pocket cards reminding of safety issues etc). These types of programmes may also be used as tools to develop insights and to get new personnel to commit to safety objectives.

Research projects and results

The survey allowed reporting by member countries on some specific research initiatives related to regulatory and managerial tools or methods being developed for, and tested by, regulators or licensee organisations. Some examples mentioned in the survey are discussed below.

The CAMM (Canadian Adaptive Machine Model) is an organisation and management review method which was developed for the Canadian regulatory body. Through this method, "organisational behaviours" are measured both qualitatively and quantitatively, using a variety of techniques, including functional analysis, semi-structured interview protocols, behaviour-anchored rating scales, behavioural checklists for work observations and survey of organisational culture and safety scales. Findings have been presented against the five safety culture characteristics (originally defined by the TECDOC-1226 (IAEA, 2001). CAMM characteristics are:

- Safety is a clearly recognised value
- Accountability for safety in the organisation is clear
- Safety is integrated into all activities in the organisation
- A safety leadership process exists in the organisation
- Safety culture is learning-driven in the organisation

The method has been applied at a large number of nuclear facilities in Canada and has also been adapted for use by utilities in Spain. Guidelines for licensee self-assessment are under development in Canada.

Core-Task Analysis (CTA) is a broader methodology developed by the Finnish Technical Research Centre VTT for the analysis of complex work and organisations. Included is the "Contextual Analysis of Working Practices" (CAWP) which focuses on operator teams' ways of working in organisational contexts. By modelling the content of work demands and using behavioural markers on interpreting courses of actions inferences are made of how people work and what sense work makes for them. The method has been applied to training of operators and designing information tools in NPPs. Contextual Assessment of Organisational Culture (CAOC) is a related method that aims at assessment of organisational culture in relation to the demands set by the core task(s) of the organisation. The method has been used for analysis of maintenance culture of several NPPs. Both methods require social science expertise. The research processes are participatory and bring forward deep and comprehensive understanding of cultural matters, task demands, working practices and developmental needs of the organisation (Norros, 2004).

4.2.4 Needs and Challenges for Further Development

Based on the results of a workshop on "Scientific Approaches to Safety Management" held in Paris from April 8 to 10, 2002 (NEA/CSNI/R (2003)14: "Scientific Approaches to Safety Management) and the survey (Appendix 1), SEGHOF has identified the following areas for further development.

a) Management systems and safety - Clarifying concepts

There is a need to clarify concepts, approaches and methods, in particular regarding the relationship between Safety Management and other management systems, as well as the relationship with other concepts.

The following items have been suggested:

- To establish a common understanding of the concepts of Safety Management and Safety Management Systems and to improve the understanding of how existing processes (including organisational changes) that affect safety relate to these concepts.
- To clarify the relationship between Safety management and safety culture.
- To clarify the relationship between Safety management and other Approaches, such as influence of QA Systems, use of Business Models (e.g. EFQM model), moving towards Learning Organisations, etc.
- To describe Management Systems related to nuclear safety in a more "business language", in order to promote a better understanding and acceptance by managers in the field.

b) Promoting and increasing knowledge in the area of Safety management

Continue exchanging information about the implementation of safety management systems and their integration in business management systems. In addition, some suggestions from the survey identified the need to exchange information about the application of knowledge on specific concepts related to safety management in the nuclear industry.

- Specific efforts are needed in order to implement concepts in the nuclear industry such as learning organisation (guidelines, workshops, training, benchmarking with non nuclear organisations, etc).
- An exchange of information about the application of existing scientific knowledge on relevant concepts, such as Knowledge Management, Emotional Intelligence, Leadership and Motivation and Management Styles, etc, is required

- Sharing information on methods to assess operating experience and on intervention and remediation tools related to organisational and managerial issues is needed. An exchange of information about methods for measuring and assessing the effectiveness of improvement programs on safety is also required.

c) Human and organisational factors in Safety Management systems

There is a need to systematically address human performance and organisational issues in Safety Management Systems and to identify appropriate methods for achieving that purpose (including incorporation of human and organisational factors competences).

d) Regulation, Assessment and Improvement of Safety Management

This fourth topic concerns both regulators and licensees and relates to the strategies and methods that may be used for assessing Safety management. Needs and challenges related to evaluating and regulating safety performance were identified as following:

- To clarify the role of the regulator in the area of Safety Management and safety culture and to make regulatory expectations in these areas more explicit (e.g. performance objectives and criteria).
- To analyse the adequacy of current methods for assessing Safety Management Systems effectiveness.
- To improve methods and tools for the licensees and regulators to evaluate the performance of Safety Management, such as quantitative measurement approaches, performance indicators, inspection guides etc,
- To identify successful practices for dealing with identified organisational deficiencies.

e) Exchange of experiences across the nuclear industry and with other industries

It is recognised that Safety Management is not a concept that is exclusively used in nuclear power plants or even the nuclear industry. There is an opportunity to explore concepts and methods developed for and applied in other nuclear installation types and other high-hazard industries, both by operators and regulators. Some examples are the introduction of safety management systems in the chemical industry on the basis of the Seveso II Directive(http://europa.eu.int/comm/environment/seveso/), in Aerospace and Aviation, in the Transportation sector, etc.

The identification of successful approaches across the different industries could provide valuable information both to NPP licensees and regulators.

5. CONCLUSIONS AND VIEWS FOR FURTHER WORK

5.1 Concepts

This report provides a brief explanation of the relationship between safety management and safety culture. It reinforces the need for nuclear licensees and regulators to take positive steps to ensure that licensees develop and sustain a robust safety management system.

Within the area of human and organisational factors (HOF), attention is increasingly focused on addressing management and organisational issues. This reflects an evolving recognition that the members of the plant personnel form a socio-technological system, and that their performance is influenced by the organisation and the culture within that organization. The same principle applies to regulatory organisations.

In day-to-day operations, when Management Systems are in action, safety depends on the concrete operations, decisions and attentiveness of each member of the organisation. For them, communication and personal contacts between managers and employees as well as managers' behaviour and management styles play a key role. These issues, related to the concept of leadership, would merit further consideration in relation to nuclear safety.

5.2 Regulatory approaches

Any regulatory activity must rest on the principle that the licensee is responsible for safe operation of its plants. The regulator should, in all activities and actions, support this responsibility of the licensee. Especially with regard to areas such as safety management and safety culture, the regulator should provide some space for licensee self-regulation and encourage the licensee to develop its own solutions and tools. Notwithstanding this, it is the role of the regulator to verify that the licensee has the appropriate processes in place to support effective Safety Management and the tools to assess its effectiveness. To be able to accomplish these goals, both the regulator and the licensee need to make sure they have incorporated the needed knowledge and skills in their approaches.

There is a trend in most countries to develop regulatory requirements on Safety Management Systems and, in doing this, address managerial, organisational and human issues. Regardless of the existence of written regulations, all regulatory bodies are involved in different forms of assessment of the impact of licensees' Safety Management Systems on nuclear safety. Different regulatory strategies and approaches can be observed in these assessments. A process-based approach seems to be rather common. Frequently, a combination of several strategies (licensee self-assessment, use of prescriptive criteria, comparison of practices between utilities and risk-informed performance-based approaches, etc.) is the option selected by the regulatory bodies. As the requirements placed by regulators, and the Safety Management assessment processes that they conduct, are comparatively new and developing areas, there is clearly a need for continuing exchange of experiences.

5.3 Developments in the nuclear industry

Currently, there is a global trend towards integration of Management Systems. This means that requirements and issues related to safety, quality, environment, personnel and economy are considered in a holistic manner. How the Management System integrates these different goals is a question to be solved by each organisation, but balancing the different goals and attending to each of them appropriately in decision making is important. A *Safety* Management System that is distinguished from other management systems with separate responsibilities for safety and economic objectives is no longer considered to be a sound solution. As an example of this, the IAEA is currently developing new safety standards with requirements and guides for the development of Integrated Management Systems (IAEA 2005a,b).

The nuclear industry is actively developing Management Systems and managerial tools, with the objective of enhancing safety and efficiency. As companies and public organisations in different countries that look for better management of organisational factors are working from different cultural premises, the implemented solutions are understandably different. They include use of widely known techniques, in-house developments, with or without use of consultants, and financing of dedicated research projects. One important trend of today is outsourcing of resources. It is important that enough of the licensee's own resources and expertise are maintained to allow them to function as intelligent customers in specifying their needs, receiving services, developing activities and guidance on the integration of human and organisational factors in safety management constructs.

There is no need for a restrictive uniformity of approaches in the area of safety management. However, the industry would benefit from more exchange of information and experience in this field. Licensee organisations and regulators alike have limited experience of the impact of integrating safety management in management systems as whole, and both managers responsible for implementing solutions as well as experts in the field would benefit from continuing exchange of experience in the topic. More fora are needed for those discussions, where experts can become familiar with the present scientific knowledge and experience obtained from the application of different management solutions. Co-operative research projects, such as the European Union Project LearnSafe (Wahlstrom et al, 2003), have recently made some advances in this area.

In the CSNI SEGHOF workshop on "Scientific Approaches to Safety Management" in 2002 (NEA/CSNI/R[2003]14), four different approaches in business and behavioural sciences were discussed, including business models, knowledge management, learning organisation and emotional intelligence. The first three approaches are generally accepted and implemented by the licensees and monitored by regulators. Emotional Intelligence is a fairly recent construct that is receiving attention by some organisations but can be best viewed as an area under development.

5.4 Potential Further Work to Address Needs and Challenges

There is a general agreement that all organisations, with any type of responsibility for nuclear safety (nuclear industry, regulators and international organisations), have a role to play in developing appropriate Safety Management Systems, and that the international community should work together on this topic:

- NEA and IAEA can provide guidance to both regulators and licensees, providing good practices in the areas of Safety Management and safety culture.
- The regulators have responsibility for fostering and monitoring Safety Management through setting out clear expectations and sound strategies and approaches.
- The industry has responsibility for developing Safety Management Systems and fostering safety culture in their organisations.

Improvements to Safety Management Systems should involve both regulators and industry, with the support of research teams and international groups. Some specific suggestions were provided in the survey regarding possible ways to address the identified needs. In response to the needs and challenges described in Section 3 and 4, SEGHOF considers that the CSNI and CNRA should consider the following future activities to further refine our understanding of the key aspects of effective management and organisation of nuclear plants and to enable good practices to be drawn out and shared internationally:

- To update the CSNI/SEGHOF survey about systematic approaches to safety management at suitable intervals to provide a useful reference for workers in this area
- To produce a short publication comparing regulatory approaches to assessment of licensee safety management (including other industries than nuclear).
- To exchange experience about regulatory oversight and licensee approaches in the area of Safety Culture.
- To clarify competences (including human and organizational factors) needed in the development, implementation and operation of Safety Management Systems as a part of Management Systems in general.
- To identify successful practices for dealing with identified organisational deficiencies.

REFERENCES

CNRA. 1998. NEA Committee on Nuclear Regulatory activities. Future Nuclear Regulatory Challenges. Paris, 1998.

CNRA. 1999. NEA Committee on Nuclear Regulatory activities. The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture. Paris, 1999.

CNRA 2000. NEA Committee on Nuclear Regulatory activities. Regulatory Response Strategies for Safety Culture Problems.

CNRA. 2001. NEA Committee on Nuclear Regulatory activities. Nuclear Regulatory Challenges Arising from Competition in Electricity Markets. Paris, 2001.

CNRA.2001a. NEA Committee on Nuclear Regulatory activities. Improving nuclear regulatory effectiveness.

CNRA. 2001b. . NEA Committee on Nuclear Regulatory activities. Assuring future nuclear safety competencies.

CNRA. 2001c. . NEA Committee on Nuclear Regulatory activities, Working Group on Inspection Practices (WGIP). The Effectiveness of Licensees in Inspecting the Management of Safety.

IAEA. 1994. Convention on Nuclear Safety. IAEA, Vienna, June 1994.

IAEA. 1996. INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations Code and Safety Guides Q1-Q14, Safety Series No. 50-C/SG-Q, IAEA, Vienna (1996).

IAEA. 2001. IAEA-TECDOC-1226: "Managing change in nuclear utilities" (2001).

IAEA. 2005a. INTERNATIONAL ATOMIC ENERGY AGENCY, Management System Requirements, Safety Standards Series No. GS-R-3 (or DS338), IAEA, Vienna (in preparation).

IAEA. 2005b. INTERNATIONAL ATOMIC ENERGY AGENCY, Management System Generic Guidance, Safety Standards Series No. GS-G-3.1 (or DS339), IAEA, Vienna (in preparation)

INSAG -3. 1988. INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Basic Safety Principles for Nuclear Power Plants, 75-INSAG-3, IAEA, Vienna (1988)

INSAG-4. 1991. INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Safety Culture, Safety Series No. 75-INSAG-4, IAEA, Vienna.

INSAG-10. 1996. IAEA - INSAG-10: “Defence-in- Depth in Nuclear Safety” (1996)

INSAG -12. 1999. INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev.1, INSAG-12, IAEA, Vienna (1999).

INSAG- 13. 1999. INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Management of Operational Safety in Nuclear Power Plants, INSAG 13, IAEA, Vienna (1999)

INSAG-15. 2002. INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Key Practical Issues in Strengthening Safety Culture, INSAG-15, IAEA, Vienna (2002).

Kemeny., J.G. 1979. The Accident at Three Mile Island: The Need for Change: The Legacy of TMI. October, 1979.

NASA 2003. Columbia Accident Investigation Board, Report on the Failure of NASA's Columbia Spacecraft. (August, 2003).

NEA/CSNI/R(2003)14, Workshop Proceedings: "Scientific Approaches to Safety Management". (Paris 8-10 April 2002).

NEA 2004. Nuclear Regulatory Challenges Related to Human Performance. NEA05334, ISBN: 92-64-02089-6. , 24 pages

Norros, Leena. Acting under uncertainty. The core-task analysis in ecological study of work. 2004. 241 p. 547.

Nucleonics Week. 2003a. Vol.44, No.42. (Oct 16, 2003).

Nucleonics Week. 2003b. Vol.44, (Nov. 20, 2003).

Perrow, C. 1984. Normal Accidents. ISBN: 046505143X. Basic Books, March 1984. 386 p.

Reason, J. 1997. Managing the risks of organizational accidents. Ashgate (1997).

Reason, J. 1990. Human Error, Cambridge University Press, New York. LaPorte, T., Consolini, P.M. 1991. "Working in Practice but Not in Theory: Theoretical Challenge of High Reliability", Journal of Public Administration Research and Theory, 1:19-47.

Rogovin. M. 1980. TMI - A Report to the Commissioners and to the Public. January, 1980.

Schein, E. H. 1992. Organizational Culture and Leadership. 2nd ed. Jossey-Bass: San Francisco.

Sugarman, B. 2000. Case study; Decision making; Improvement; Innovation; Leadership; Journal For Quality And Participation, Vol. 23, No. 5, NOVEMBER 2000, pp. 33-37

Transport Canada. 2001. Guide N°TP 13739 "Introduction to Safety Management Systems" – (2001).

US NRC. 1999. Regulatory Guide 1.179 - Standard Format and Content of License Termination Plans for Nuclear Power Reactors http://www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/active/01-179/.

Wahlström, B., B. Wilpert, S. Cox, R. Solá, C. Rollenhagen, M. Ibanez, Y. Canaff, M. Friberg, O. Andersson, R. Scheuring, P. Gerdes, H. Rycraft, E. Dunge, K. Egnér: Learning organisations for nuclear safety (LearnSafe), FISA-2003, 10-12.11.2003, Luxembourg.

Waring, A. 1996. Safety Management Systems. Chapman & Hall (1996).

APPENDIX 1: THE QUESTIONNAIRE

Survey on Developments Related to Safety Management in NEA Member Countries: Systematic Approaches, Methodologies and Tools used for the Management of Safety

Introduction. – During recent years there has been rapid development of managerial knowledge and systematic approaches, methodologies and tools to aid in the management of safety.

Many of these developments may have a positive impact in nuclear safety. It is likely, however, that the use of any specific tool will be dependant to some extent on the larger social culture within which each national nuclear industry operates.

To better understand the importance and usefulness of the various nuclear safety management systems, the NEA Special Expert Group on Human and Organizational Factors (SEGHOF) is collecting information and experiences on managerial developments and systematic approaches used by organizations in nuclear industry to properly manage their licensed facilities, and regulators for assessment of utility safety levels. Examples of such tools may be the business models (as EFQM), applications of the theory of organizational learning, systematic tools used in knowledge management or different in-house developed managerial systems and tools, with which management can better follow up and ensure that the organization performs safely enough.

This document is a questionnaire to facilitate information collection and usage. SEGHOF solicits your support by answering a number of questions regarding approaches, methodologies and tools being used by your organization for the management of safety.

The descriptions and experiences obtained in the development and application of this kind of methods and tools are asked in **Part B**. This part is addressed primarily to licensees. Regulatory bodies can also use it to inform on tools they use in their own management. In addition research institutes or consultants can inform about methods and tools they are developing for nuclear industry by using this part of the questionnaire.

In addition, the regulatory requirements and inspection systems are asked in **Part A** of the questionnaire. This part is directed to the regulatory body (or technical support organisation, where it may be the more convenient), and only one answer per country is expected.

With aim to define further needs for research and developmental work, the **Part C** of the questionnaire is addressed to all interested parties and is aimed to collect all identified needs, challenges and ideas on field.

A State-of-the-Art Report (SOAR) on Systematic Approaches to Management of Safety will be written on the basis of material obtained by this questionnaire. Given the potential value of the information to be collected, SEGHOF might consider at a later stage to keep it up-dated as a useful reference for member countries on the subject.

Given the difficulties associated with establishing a set of questions that properly fit each individual case, the questionnaire has to be interpreted in a flexible manner so as to obtain the most accurate and clear description of every intended item, while keeping in mind the necessary effort to, later on, provide information on fairly uniform bases. Your anticipated assistance in completing this short questionnaire is appreciated.

It is the purpose of SEGHOF to distribute copy of this Survey, when it becomes available, to all participants.

Procedure. - The SEGHOF members of each country are asked at their discretion to fill Part A, and when appropriate Parts B and C, or to pass it to the regulatory body, and to distribute the Parts B and C of the questionnaire to licensees, utilities, consultants, research institutions, specialists and the like. They are also asked to collect responses and make them available to the Task Facilitator (Mr. Anibal Martín) and to the SEGHOF Secretariat (Mr. Pekka Pyy) by sending them in an e-mail message to the following addresses: Mr. Anibal Martín: anibalmartinm@terra.es, Mr Pekka Pyy: Pekka.PYY@oecd.org

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES. The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.
Regulatory organisation identification and contact person (e-mail-address)
Are there regulatory requirements of any sort on the utility management system?
If yes, status and content of requirements (describe here or attach documents)
Does the regulatory body assess the management system of the utility?
If yes, description of the approaches, methods and criteria used in assessment, or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.
If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES. The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development. To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.** It is easier to answer, if you read first all questions !. There are several sub-questions, part of which may be irrelevant in your case, ignore those!
Title of the approach
Scope and Purpose. For which end the approach / tool is used?
Brief description of the approach (200 words maximum)
When measurements are involved, please specify required techniques
Status (in use / published method / piloted / under development / ...)
If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?
If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?
How is it validated? Is there any qualification or checking done?
Application process
Any detail or examples?

Information system requirements?
Is it usage restricted? What kind of restrictions?
Experiences
Type of results obtained
Were results useful as expected?
How the results are exploited? E.g. how findings are used?
Benefits from the nuclear safety point of view? Safety enhancement?
Any follow-up system?
Strengths and weaknesses?
Hints for improvement. Further developmental needs for approach / tool?
Organisation, address and contact person (e-mail address)
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT To be filled for all interested.
Present needs and challenges in Safety Management / Management of Safety
What should be developed or done? For what purpose is needed?
How and who should take care?
Any further suggestions on how to apply available knowledge to Safety Management?
Contact person (name, address, e-mail address):
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

APPENDIX 2: TABLE OF RESPONSES

TABLE OF RESPONSES

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

APPENDIX 3: RESPONSES

- Appendix 3.a): Responses from Belgium
- Appendix 3.b): Responses from Canada
- Appendix 3.c): Responses from Finland
- Appendix 3.d): Responses from France
- Appendix 3.e): Responses from Japan
- Appendix 3.f): Responses from Spain
- Appendix 3.g): Responses from Sweden
- Appendix 3.h): Responses from Switzerland
- Appendix 3.i): Responses from UK
- Appendix 3.j): Responses from USA

Appendix 3.a): Responses from Belgium

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

AVN (Association Vinçotte Nuclear), Belgium
Yves Van den Berghe (yves.vandenberghe@avn.be)

2. Are there regulatory requirements of any sort on the utility management system?

Yes

- **If yes, status and content of requirements (describe here or attach documents)**

The FSAR should include:
- a description of the organisational structure of the licensee (corporate and on-site level)
- qualification and training requirements for key staff positions
- a description of the plant safety review committees (composition and role)
- a chapter on QA (details of the QA-programme should be covered by a QA-manual)

In addition there is a requirement (although not covered by regulatory rules) that the working of the organisation should further be described in organisational procedures, including a description of the transverse safety relevant processes (such as management of modifications and operating experience feedback) and the working of the safety review committees.

Please note that the content of the FSAR is directly inspired from the standard format and content as prescribed by the RG 1.70 from the USNRC, with some additional requirements and some relaxations.

3. Does the regulatory body assess the management system of the utility?

Yes

- **If yes, description of the approaches, methods and criteria used in assessment, or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.**

A performance assessment of the utility management system is systematically covered by the periodical inspections, which cover all safety related activities and domains of the nuclear plants (operations departments, maintenance departments, safety departments, fuel departments etc.).

Aspects covered during these inspections include: safety policy and related objectives and action plans, compliance and management of safety issues, organisational changes including changes of organisational procedures, training and qualification of plant staff, working of safety committees, relationship with safety authority/regulatory body, emergency planning organisation and exercises, access control and ALARA-policies, operating experience feedback, QA-programme.

In addition each organisational change (which impacts the FSAR content) has to be reviewed and approved by AVN.
For major organisational changes a specific review project is organised within AVN, for which ad hoc requirements (including documents to be presented and analysis to be performed) are defined, review methods are developed and inspection activities are organised. The definition of these methods and inspection activities depend on the scope and the potential impact of the proposed organisational change on the safety related processes and activities.
By rule, AVN requires that the licensees perform a self-assessment of the organisational change and present its results for review to AVN. Clarification of requirements as well as document review and inspection findings from the AVN side and progress of preparation, implementation and evaluation activities from the licensee side are periodically discussed with licensee representatives (management level) during this review project.

The performance of the utility management systems (including safety culture issues) is also evaluated during specific inspections, which occur after safety significant events, and during the review of related licensee event reports.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. **Present needs and challenges in Safety Management / Management of Safety**

- **What should be developed or done? For what purpose is needed?**
  Development of internationally accepted models (or standards) for safety management against which existing management systems could be assessed.
  Development of tools to evaluate the performance of safety management (specific indicators and assessment methods, …)

- **How and who should take care?**

- **Any further suggestions on how to apply available knowledge to Safety Management?**
  Knowledge on safety management is not restricted to the nuclear industry. Concepts and methods developed for and applied in other high-risk industries could be explored.

2. **Contact person (name, address, e-mail address):**
   Yves Van den Berghe (yves.vandenberghe@avn.be)
   AVN (Association Vinçotte Nuclear)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   IPMS NS: Integrated Performance Management System applied to Nuclear Safety

2. **Scope and Purpose. For which end the approach / tool is used?**
   Nuclear Safety is considered as one of the business domains in NPP that must be managed for performance assurance and improvement.
   IPMS is a management system model which is compatible with external standards (ISO, EFQM, ...) and is owned by process communities chaired by process owners.

3. **Brief description of the approach (200 words maximum)**
   The IPMS model is in-house developed performance (or quality) standard.
   Its 2 main advantages are:
   - universality: applicable at different organisational and functional levels: global company or organisational entity, total business or business domain
   - gradualism: enabling a development according to a maturity trajectory

   IPMS applies the Plan-Do-Check-Act principles and considers 5 components:
   1. Objectives: the strategic framework: deliverables, vision, improvement action programs
   2. Operational process: the chain of activities producing the deliverables
   3. Supporting activities: HRM, material resources, rules and methods, communication, documentation
   4. Evaluation of global results: performance indicators, follow up of action programs, assessments
   5. Organisational behaviour: the people factor: leading for performance, motivation for performance, organising for performance, building teams & culture

   To assure consistency the 5 components must be aligned and progressively built up.

4. When measurements are involved, please specify required techniques

Once the management system for nuclear safety described (= IPMS NS) the maturity level can be quantitatively measured by self-assessment or audit.
Bottlenecks and misfits can be identified and recommendations can be formulated for both system alignment and improvement.

5. Status (in use / published method / piloted / under development / ...)

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**

  IPMS is an internal model founded on available literature (i.e. without consultancy) and has been used since 1997 for a a lot of business domains: O&M, Health & Safety, Environment, Document management, Procurement,...
  A rough draft of IPMS NS is available and is currently used to describe the NS domain in depth, as basis for the Safety Quality Manual. The description will show a lot of parallels with the other care- systems IPMS Health & Safety and IPMS Environment, to facilitate system implementation and audit practices.
  The IPMS model is owned by the Quality community of Electrabel represented in Generation by the Process Performance Management department.

- **How is it validated? Is there any qualification or checking done?**

  IPMS NS will be fully validated by the NS process community and especially by the process owner.
  From the regulatory side, transparent compatibility with the applicable norm 10CFR50appB will be assured.

6. Application process

- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**

  IPMS is considered as the basic document for process communities owning system responsibility at global Generation level, and as input (the "what") for local NPP modi operandi (the "how").
  Process communities are assisted by the Process Performance Management department to correctly manage the system performance they are accountable for.
  The care audit programs embrace all the IPMS components every 3 years.

- **Any detail or examples?**

  A lot of IPMS descriptions in use are available; IPMS NS is currently developed forward.

- **Information system requirements?**

  No specific IT tool is required: Microsoft Office applications satisfy.

- **Is it usage restricted? What kind of restrictions?**
  The IPMS general framework is openly available a.o. for didactic purposes. A management book will be published by Electrabel in 2004, the fruit of 2 years of partnership with the Vlerick Leuven Gent School for Management in Belgium.
  Concrete IPMS descriptions appeal to a lot of company knowledge and cannot be considered for free by third parties.
  IPMS descriptions are especially destined for process communities and must be accepted by certification bodies.

7. Experiences

- **Type of results obtained**
  Some results:
  - furthers management system thinking (management mindset glue)
  - useful for quality (= performance) level assurance and improvement by audits and self assessments
  - allows basic functional mapping of management system elements

- **Were results useful as expected?**
  Yes, also sustained by top-down commitment.

- **How the results are exploited? E.g. how findings are used?**
  Management system performance constitutes foundation for operational performance, so management system appraisal leads to medium term improvement actions.

- **Benefits from the nuclear safety point of view ? Safety enhancement?**
  IPMS helps to write down and implement the NS management system
  - with the same structure as for other business domains
  - according to the PDCA approach for continuous improvement
  The performance (= maturity) level can be progressively increased: from exhaustiveness and effectiveness to adequacy and finally to efficiency, in a balanced way.

- **Any follow-up system?**
  Model stability checked:
  - no major changes in 6 years
  - academic validation (see end of point 6)

- **Strengths and weaknesses?**
  Advantages: see point 3
  Weaknesses: management system theory and applications are to a large extent "conceptual" and not very "physical", involving huge conviction and sensitisation efforts.

8. Hints for improvement. Further developmental needs for approach/tool ?
Further development and application of the IPMS methodology. Assertive willingness for sharing the IPMS approach with other companies, seeking the advantages.

9. Organisation, address and contact person (e-mail address)

Contact: Bernard Hindryckx
- Electrabel (Belgium)
- mobile: 32 478 652653
- e-mail: bernard.hindryckx@electrabel.com

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Large documentation and details are available on request.

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. Present needs and challenges in Safety Management / Management of Safety

- **What should be developed or done? For what purpose is needed?**
  Nuclear Safety deserves a management system description in a better "business language".

- **How and who should take care?**
  Watch for parallel developments of other care systems: Health & Safety and Environment, and with emerging system models for "the NS equivalent" Industrial Safety (cfr Seveso context).

- **Any further suggestions on how to apply available knowledge to Safety Management?**
  Consolidate all known elements on "what" in a promising management system model.
  Promising = all relevant issues consistently integrated, and gradual PDCA approach.

2. Contact person (name, address, e-mail address):

Contact: Bernard Hindryckx
- Electrabel (Belgium)
- mobile: 32 478 652653
- e-mail: bernard.hindryckx@electrabel.com

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Large documentation and details are available on request.

Appendix 3.b): Responses from Canada

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)
Canadian Nuclear Safety Commission, Helen McRobbie (mcrobbieh@cnsc-ccsn.gc.ca)

2. Are there regulatory requirements of any sort on the utility management system?
All of our nuclear power plants have a requirement in their licenses to establish and implement a quality assurance program that conforms to the N286 series of standards. The standards are as follows:
N286.0-92 – Overall quality assurance program requirements for NPPs
N286.1-00 – Procurement quality assurance for NPPs
N286.2-00 – Design quality assurance for NPPs
N286-3-99 – Construction quality assurance for NPPs
N286.4-M86 – Commissioning quality assurance for NPPs
N286.5-95 – Operations quality assurance for NPPs
N286.7-99 – Quality assurance of analytical, scientific and design computer programs for NPPs

- **If yes, status and content of requirements (describe here or attach documents)**

The N286 series of standards is based on the following set of principles for quality assurance:

1. The required quality and means of achieving it will be defined.
2. A policy statement will be issued committing all units of the organization to the program.
3. Organizational responsibilities will be defined and understood.
4. Personnel will be competent at the work they do.
5. Individuals will be held accountable for their work.
6. The right people will have the right information at the right time.
7. Relevant experience will be sought and used.
8. Work will be planned and controlled.
9. The right items, processes and practices will be used.
10. Work will be verified to confirm that it is correct. Those who verify work will do so independently from those who do the work.
11. Deficiencies will be identified and remedied.
12. The root cause of deficiencies will be determined and corrected.
13. Changes to accepted items, processes, and practices will be controlled.
14. The preparation and use of documents will be controlled.
15. Essential records will be maintained.
16. Periodic assessments of program effectiveness will be conducted.

As an example of the contents from one of the standards, CSA N286.5 for operations includes the following topics:

Basic Requirements
- Organization and responsibilities
- Personnel capability
- Accountability
- Communication
- Use of experience
- Work planning and control
- Control of items, processes, and practices
- Verification
- Nonconformance
- Corrective action
- Change control
- Document control
- Program assessment – management self-assessment and independent assessments

Requirements for Operating
- Operating authority
- Operating documents
    - Operating policies and principles
    - Operating procedures
    - Temporary procedures
    - Non-routine and emergency operating procedures
    - Procedure adherence
    - Procedure implementation
- Work control
- Equipment control
    - Identification and labeling of field equipment
    - Turnovers
    - Equipment and status control
- Operator surveillance
- Operator communication
- Radiological safety
- Housekeeping

Requirements for Maintenance
- Maintenance procedures
- Maintenance planning
- Corrective maintenance
- Preventive maintenance
- Calibration of system instrumentation
- Periodic inspection
- Measuring and testing equipment
- Replacement item management
    - Procurement
    - Non-identical replacement items

Requirements for Technical Support
- Plant performance monitoring
- Surveillance testing
- Non-standard tests
- Operating experience
- Design changes
- Fuel management
- Reactor physics

Requirements for Chemistry Control
- Specifications
- Monitoring
- Data evaluation
- Control of chemicals
- Chemical analysis

Requirements for Emergency Preparedness
- Emergency classification
- Emergency response organization
- Emergency plan
- Emergency facilities, equipment and resources
- Personnel protection
- Public information program
- Evaluation of emergency program effectiveness

3. Does the regulatory body assess the management system of the utility?
- The CNSC assesses the management system of the utility through evaluations and audits to ensure licensees comply with the N286 series of quality assurance standards.
- The CNSC also carries out organization and management assessments using an Organization and Management Review method developed by a consultant. The method is described in RSP-0060 which can be forwarded at your request.

- **If yes, description of the approaches, methods and criteria used in assessment, or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.**
  - The management systems of licensees are evaluated using the N286 series of standards as the criteria. The primary methods used include field observations, interviews with NPP staff, and document reviews.
  - The management systems are also assessed using the Organization and Management (O&M) Review Method developed by a consultant. The O&M method uses document reviews, interviews, behavioural anchored rating scales, a questionnaire (Organizational Culture Inventory by Human Synergistics) administered to staff throughout the organization, and observation of meetings and work processes.
  - Organizational changes are primarily evaluated using criteria from the N286 series of quality management standards.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. Title of the approach

Organisation and Management Review Method (Haber, S.B. and Barriere, M.)

2. Scope and Purpose. For which end the approach / tool is used?

The method allows the generation of a behavioral profile of the organization through those processes and management functions related to safety performance of nuclear facilities.

Up to the present the methodology has been applied at all of Canadian NPPs, 2 research facilities, a mine/mill facility, and a conversion facility. We have just finished using it for the second time at one NPP. The results from this evaluation will be compared to the previous evaluation done in 1997. In addition, we will compare results obtained from the O&M method to results obtained during routine compliance verification activities by CNSC staff.

3. Brief description of the approach (200 words maximum)

The Organization and Management Review Method is used to measure five Safety Culture characteristics within a nuclear organization. Those characteristics areas follows:

- Safety is a clearly recognized value.
- Accountability for safety in the organization is clear.
- Safety is integrated into all activities in the organization.
- A safety leadership process exists in the organization.
- Safety culture is learning-driven in the organization.

The method uses a functional model of the organization (called the Canadian Adaptive Machine Model) that is the dynamic, interactive, behavior-oriented characterization of a facility which depicts its human organization. Five organizational components identify the key organizational and management processes that relate to safety, their primary functions, key coordinating mechanisms, and the way that information flows throughout

the organization. Organizational behaviors within those components are measured both qualitatively and quantitatively. (See next section)

The behaviors include attention to safety, coordination of work, decision-making, goal/priority-setting, resource allocation, time urgency, aggressive-defensive culture style (high perfectionistic), roles and responsibilities, performance quality, management emphasis on safety, employee awareness of risk, external communication, formalization, training, organizational knowledge, constructive style, cohesion, hazard, offsite consequences, onsite consequences, organizational culture, communication (interdepartmental and intradepartmental), commitment, job satisfaction, organizational learning, problem identification and resolution, performance evaluation, personnel selection, and passive-defensive style (low avoidance).

4. When measurements are involved, please specify required techniques

The techniques used to assess the organizational behaviors identified are as follows:
Functional analysis
Semi-structured interview protocol
Behavioral anchored rating scales (BARS)
Behavioral checklists of work observations
Survey of organizational culture and safety scales

5. Status (in use / published method / piloted / under development / ...)

In use, published under CNSC Research Document, RSP-0060. Pilot conducted in 1997 at a power reactor. Technology transfer from the consultant to CNSC in-house staff expected in November 2003.

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

  This method was adapted from outside and further enhanced internally. It has been used in Canada since 1997.

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**
  Further enhancements based on internal research using consultant services. Research and data owned by CNSC.

- **How is it validated? Is there any qualification or checking done?**

  Collection tools found in the open literature. Method validated in Canada, Spain, US, at different types of facilities.

6. Application process

- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**

  The method has been carried out by a consultant and CNSC staff. Lead-time is approximately 4-6 months. Period from data analysis to final report

is approximately 3 months. Team size is approximately 6 people depending on the size of the facility. On-site data collection is from 10 days to 2 weeks. Ten evaluations were conducted in 7 years, with most of the work conducted between 1999 and 2002. Information used in the licensing process.

- **Any detail or examples?**

- **Information system requirements?**

- **Is it usage restricted? What kind of restrictions?**

  This methodology is publicly available in RSP-0060. One of the methods used, the Organizational Culture Inventory, is copyrighted by the firm Human Synergistics. The other methods are found in the open literature. Final report is proprietary.

7. Experiences

- **Type of results obtained**

  Until recently, a profile of the organization in terms of its processes, their strengths and weaknesses were described. Recommendations for improvement of specific areas that will enhance safety performance were also provided. At present, performance within the 5 safety culture characteristics will be reported, and whether their related objectives have or have not been met. Recommendations for improvement in those areas will continue to be included.

- **Were results useful as expected?**
  Most licensees found the results useful and many have implemented changes based on CNSC recommendations. CNSC staff has, in the past, found the report too detailed and difficult to operationalize. Future reports will be more user-friendly and less technical The Commission has used the results for its regulatory decisions.

- **How the results are exploited? E.g. how findings are used?**

  This information is integrated with other technical information which is then provided to the Commission members for licensing decisions.

- **Benefits from the nuclear safety point of view ? Safety enhancement?**
  Provides the utility and the CNSC with a macro ergonomic view of the organization in terms of its safety performance. The strengths of the various processes that directly influence safety performance are clearly highlighted. Areas where improvement will enhance safety performance are also clearly highlighted.

- **Any follow-up system?**
  Future guidelines for licensee self-assessments are in development. A regulatory document is planned, which will delineate regulatory expectations. Heightened monitoring by licensing staff is planned.

- **Strengths and weaknesses?**
  Strengths: This method is well-founded through extensive international research. The measurement tools are in the literature, providing robust, reliable, valid and useful means to measure behavior. The model has been validated in the Canadian nuclear industry and internationally for multiple nuclear facilities (reactor & non-reactor).
  Weaknesses: Evaluation process is labor-intensive, with a long planning cycle and data analysis period. Because of the unique skills required to perform these evaluations, staff must be appropriately trained to use this method.

8. **Hints for improvement. Further developmental needs for approach /tool ?**
   Train site inspectors to use some data collection tools for ongoing monitoring. Future reports can be streamlined to be more useful for follow-up and monitoring improvements. Integrate this method's results with other types of inspections. Test the applicability of using only the differentiating variables that must be present for ensured safety performance.

9. **Organisation, address and contact person (e-mail address)**

Garry Schwarz

Canadian Nuclear Safety Commission
Schwarzg@cnsc-ccsn.gc.ca

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here: Phillips, P.H. and Schwarz, G.S. (2002). Canadian Regulatory Perspective on Organization and Management Assessments. Paper presented at the IAEA Safety Culture Conference, Rio de Janeiro, Brazil, December, 2002.

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. Present needs and challenges in Safety Management / Management of Safety

Foster a better understanding of the implication of safety culture on performance by educating all stakeholders. Increase collaboration between the regulator and the industry to increase the commitment from both parties, and increase the buy-in from industry that safety culture is important to good safety performance.

- **What should be developed or done? For what purpose is needed?**
  - Guidelines of regulatory expectations (performance objectives and criteria) in the area of safety culture and safety management.
  - Safety Management programs developed by each licensee to meet those expectations and to perform their own assessments.
  - A standard or other prescriptive document may not attain the desired results, i.e. the achievement of a learning organization.

- **How and who should take care?**

  Both the regulator and the industry have a responsibility: the regulator for promoting, monitoring and enforcing good safety culture through clear expectations and the industry for developing a safety management program and fostering safety culture in their respective utilities.

  International groups, such as the NEA and IAEA, can provide guidance to both the regulators and licensees about safety management programs and safety culture.

- **Any further suggestions on how to apply available knowledge to Safety Management?**

2. Contact person (name, address, e-mail address):

Garry Schwarz

Canadian Nuclear Safety Commission
schwarzg@cnsc-ccsn.gc.ca

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Canadian Regulatory Perspective on Organization and Management Assessments
[Paper presented at the IAEA Safety Culture Conference, Rio de Janeiro, Brazil, December, 2002].

P.H. Phillips, G.R. Schwarz

Organization and Management Systems Division
Directorate of Assessment and Analysis
Canadian Nuclear Safety Commission
Ottawa, CANADA

Abstract. The Canadian nuclear industry is undergoing change in response to a variety of internal and external pressures on licensee organizations. Operational experience also indicates that management and human performance aspects are among the leading causes of unplanned events at licensed facilities. These observations have raised the CNSC's awareness of the importance of organization and management processes and human performance to the safety performance of a facility. The CNSC is utilizing quality management and organizational assessment approaches to address this issue. The Organization and Management Review Method has been developed to carry out organizational evaluations. The method has been applied to a number of nuclear facilities in Canada. Results have provided a more complete profile of the organizations and have thereby contributed to the oversight monitoring of licensees. Some of the data are being meta-analyzed to determine what influence culture has on the other organizational dimensions and whether there are performance indicators that can predict future safety performance. We hope that a clear profile of a "good performer" which will allow us to compare and rate facilities against a series of benchmarks or standards yet to be developed. Some of the challenges that the CNSC faces with respect to the implementation of the O&M Method are being addressed. All of the information relevant to safety performance should be taken into account when giving recommendations pertaining to licensing decisions.

1. Introduction

In recent years a number of pressures have come to bear on Canadian nuclear facilities. These pressures include the need to improve operational performance, the privatization of nuclear power plant operating organizations, deregulation of the electricity market, organization downsizing and outsourcing of selected support functions such as engineering and safety analysis services. In addition, operational experience has indicated that management and human performance aspects are among the leading causes of unplanned events at licensed facilities. These have raised the CNSC's awareness of the importance of organization and management, and human performance to the safety performance of a facility.

The CNSC is utilizing two approaches to respond to these challenges in the organization and management area. The first is quality management (QM), traditionally referred to as quality assurance. This approach focuses on establishing the adequacy of implementing formal management processes such as design, engineering change control, operating experience review and corrective action. Quality management audits demonstrate that a management structure and managed processes, which meet specified standards, are in place. For many years quality management was implemented at Canadian nuclear facilities on a voluntary basis. The new Nuclear Safety and Control Act and Regulations, and the introduction of QM requirements in facility licence conditions, have made mandatory the implementation of quality management programs at nuclear facilities. This is resulting in organization and management improvement as management and structured processes, which meet defined standards, are being put into place and implemented.

The quality management audit approach, however, is not well suited to assess organizational culture and the behavioural aspects associated with activities such as communication, organizational learning and the coordination of work. To assess those behavioural aspects, the CNSC has, since the late 1990's, developed

and implemented the Organization and Management Review Method (O&M Method), which was based on the preliminary work conducted in the US and Sweden (Haber and Barriere, 1998). It provides the user with the tools, both qualitative and quantitative, for measuring those organizational factors, including safety culture, that influence safety performance. Based on our experience to date, we believe that the O&M Method complements the quality management approach and gives the CNSC an improved understanding of the safety performance of a licensee's organization and management processes. A review of the literature that examines the importance of organizational factors and their relationship to safety culture follows.

Sorenson (2002) provides a survey of the state of the art in the study of safety culture and its link to safety performance. In his review of the empirical evidence, he notes that much work has been done to validate the notion that safety culture and other organizational factors have a strong relationship to the safety of operations. Although there has only been little direct research on the organizational factors that comprise a "good" safety culture, much literature is available that makes the indirect assumption that plants with low accident rates have a relatively good safety culture (Lee, 1998). In its extensive study of the predictors of safety performance, the Advisory Committee for the Safety of Nuclear Installations (ACSNI, 1993) has shown that the regulator's behaviour will affect the culture of the licensees, and that the most effective safety cultures will develop in less prescriptive regulatory structures. The study goes on to indicate that, along with the external impact of the regulator on the organization, the key predictive indicators of safety performance are effective communication, good organizational learning, and an organizational focus on safety.

Haber and Shurberg (2002) have shown that safety culture is a construct that can be measured. They suggest that the O&M Method can tell us about the organization's performance and will discriminate between high and low performers. High performers will demonstrate such behaviours as constructive values, a drive to perfection, a questioning attitude, effective communication, as well as a strong emphasis on safety. These behaviours are consistent with those described by ACSNI (1993).

2. Organization and Management Review Method

The O&M Method starts with a conceptual model of the organization (Haber and Barriere, 1998). The model, known as the Canadian Adaptive Machine Model, or CAMM, was developed to assist the CNSC in examining the various functional groupings or components of the organization and the ways in which information flows. The model was adapted to the Canadian nuclear industry to illustrate a typical facility that could adapt itself or reconfigure itself to off-normal situations when necessary. A nuclear organization can be configured into five components that include the Strategic Apex (to set the corporate vision, goals and policies), a Middle Line (to oversee activities related to operations, maintenance and service), a Technostructure (to standardize work processes, outputs and the skills of the operating professionals), an Operating Core (to accomplish the work of the organization) and Support Staff (to facilitate work and minimize any disruptions to the flow of work). Once the model was described, statements about the roles, responsibilities and interactions of the various components were generated, along with their coordinating mechanisms. From those statements, nineteen observable behaviours, that we refer to as dimensions, were identified that could be measured within the organization.

3. Application of the Method

Five types of data collection tools are used to measure the dimensions. First, a functional analysis of the organization's documentation such as its organization charts, procedures (especially those related to safety), and results from recent performance assessments is carried out. Based on this analysis the evaluation team chooses a subset of the dimensions to examine. Structured interviews, behavioural anchored rating scales (BARS), work observations (using Behavioural Checklists) and a paper-and-pencil

survey (an Organization Culture Survey, including safety scales) are then used at site to assess each of the identified organizational dimensions. Depending on the size of the facility and the extent of the data collection, the evaluation can take from 10 days to 2 weeks. The corporate units that have a direct working relationship with the facility are also included in the evaluation. The method has been applied to all nuclear power plants in Canada, as well as other types of facilities, such as a mine/mill facility, a conversion facility, a research reactor and a particle accelerator. A total of 9 facilities have been evaluated to date.

4. Results

The results of the O&M Method have been used by CNSC staff to obtain a more complete profile of organizations and have thereby contributed to the oversight monitoring of licensees. More specifically, results have pointed out those organizational factors and management principles and processes that are working well, and those requiring improvement. They have also verified findings from previous audits and inspections, and have provided information to assist CNSC staff in identifying areas for more focused follow-up examinations utilizing audits or inspections.

The reaction of the licensees to the method varies from those that embrace it whole-heartedly to those that remain unconvinced of its merit. Many licensees see the value of the evaluations in confirming organizational weaknesses. On the basis of the results, some licensees have developed facility improvement plans, incorporating the findings from multiple performance assessments, including the O&M evaluation. Some licensees have also expressed concern with the intrusiveness of the evaluation team on-site because of the labour-intensive nature of the data collection activities.

At present, some of the data from all of the evaluations are being meta-analyzed to determine what influence culture has on the other organizational dimensions and whether there are performance indicators that can predict future safety performance. This research is preliminary and no clear conclusion can be drawn at this time.

5. Regulatory Challenges

There are a number of challenges that the CNSC faces with respect to the implementation and reliance on the O&M Method as a regulatory inspection tool. Although the method is generally recognized by CNSC staff as providing additional information about the effectiveness of the organizational factors, management principles and processes of the facility, its role in the CNSC compliance program has yet to be established. Areas requiring attention include: the lack of criteria which define when organizational behaviours are acceptable; the use of results to monitor improvement in the facility; and the enforcement of corrective actions.

In addition, the role that the O&M Method may play in the regulatory oversight of the changes facing the Canadian nuclear industry is currently under consideration. Examples of regulatory challenges that have emerged in this area include: the adequacy of a change management process to confirm that a licensee can justify and rationalize proposed changes within the organization (with no negative impact on safety); the industry's increasing use of contractors, raising issues such as contractor training, work protection and worksite supervision; the aging of plants and the problems associated with maintaining or replacing components while complying with regulatory requirements; and the costs and difficulties that the industry faces to maintain and attract a skilled workforce while ensuring that safety is not compromised.

A number of activities are under consideration to address those challenges. Workshops and information sessions have been initiated to better assist regulatory staff in tracking licensee improvements. The production of a regulatory document which touches on those organizational areas not currently addressed in other regulatory documents or requirements may be developed. In order to do that, first the criteria for

good performance must be established before it can be determined whether all organizational factors should be included. The ACSNI has suggested that the best safety standards "can arguably only be achieved by a program which has a scope well beyond the traditional patterns of safety management functions" (1993, pg. 37). Thus, it is incumbent on the regulator to ensure that any regulatory documents encompass the scope and breadth of those issues that are intrinsic to safety but may not be evident. The CNSC will endeavour to meet that challenge.

Sorenson (2002) points out that it is important to identify performance indicators that capture the attributes of safety culture and its relationship to safety and operations, and safety regulation. It is therefore our longer term goal to develop performance indicators which can be used to flag potential problems in the licensee's organization and that will help us to predict when safety in a nuclear facility is likely to decline.

6. Future

One way that we are trying to advance the practical aspects of the O&M Method is to suggest a complementary way of integrating O&M evaluations with QM audits to embrace their similarities. Although, in some respects, some of the methods used in both approaches are not compatible with each other in terms of their data collection techniques, results from each method show both confirmatory findings and the unique information that each method contributes to build an organizational profile of the licensee's facility. QM audit information, although most effective for ensuring compliance, can provide information useful in O&M evaluations, and vice versa. From the research presently being conducted on the data, it is hoped that what will emerge will be a clear profile of a "good performer" which will allow the CNSC to compare and rate performers against a series of benchmarks or standards yet to be developed. That step will help licensing staff to better monitor those areas of their licensee facilities where improvements are needed in terms of organizational effectiveness.

7. Conclusion

Organizational change can occur over a long period of time and through informal processes, as well as through planned and managed change initiatives. It is therefore important that the regulator keep a close watch on organizational factors as part of the normal regulatory oversight activities. In today's economy with unstable markets and de-regulation of the electricity industry, it is more important than ever that a regulator make informed decisions that benefit the health, environment and safety of the public. This is the modern regulatory environment in which the regulator needs to be mindful of the challenges that the nuclear industry faces. The most comprehensive information about licensee performance is the key to making well-informed regulatory decisions. That means that all of the information relevant to the organizational factors, management principles and processes that relate to safety performance, whether it comes from specialized audits, inspections or evaluations, should be taken into account when making licensing decisions.

References

[1] ACNSI Study Group on Human factors (1993). Third Report: Organizing for Safety. Advisory Committee on the Safety of Nuclear Installations Health and Safety Executive, United Kingdom.

[2] Haber, S.B. and Barriere, M.T. (1998). Development of a regulatory organizational and management review method. Atomic Energy Control Board, Research Report RSP-0060.

[3] Haber, S.B. and Shurberg, D.A. (2002). Assessing safety culture in an organizational context IEEE7th. Human Factors Meeting, Scottsdale, AZ, 5-1 – 5-6.

[4] Lee, T. (1998). Assessment of safety culture at a nuclear reprocessing plant. Work Stress, 12(3), 217.

[5] Sorenson, J.N. (2002). Safety culture: a survey of the state-of-the-art. Reliability engineering and system safety, 76, 189-204.

Appendix 3.c): Responses from Finland

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

Kaisa Åstrand, STUK (Finland)
kaisa.astrand@stuk.fi

2. Are there regulatory requirements of any sort on the utility management system?

In the previous legislation including regulatory guides there are no requirements on the utility management system.
However, the regulatory guides concerning quality assurance (guide YVL 1.4) and organization and management (guide YVL 1.7) are under revision. In the draft versions of both guides the management system is mentioned.

- **If yes, status and content of requirements (describe here or attach documents)**

In the draft regulatory guide YVL 1.4, on quality assurance, it is required that the management system of nuclear installation ensures that all factors influencing safety are managed.
In the draft regulatory guide YVL 1.7, concerning organization, management and personnel, description of all elements of safety management system is required in the documentation of the nuclear installation.
The content of the guides can change during the further discussion on drafts!

3. Does the regulatory body assess the management system of the utility?

Yes.

- **If yes, description of the approaches, methods and criteria used in assessment,**
  or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.

The administrative rules of nuclear installations must be submitted to the regulatory body (STUK) when applying for an operating licence, and later always when there are changes in the organization, for approval. The administrative rules shall specify the duties, authority and responsibility of a nuclear facility's responsible manager, his deputy and the personnel directly required to operate the facility. Furthermore, the administrative rules shall state the competence requirements for the personnel.
The management of safety in nuclear installation is inspected in inspection A1 Safety management, belonging to the periodic inspection programme. Decription of the inspection, as included in the quality manual of STUK, is attached.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Section 122 of the Nuclear Energy Decree
guide YVL 1.1 Finnish Centre for Radiation and Nuclear Safety as the regulatory authority for the use of nuclear energy
see: http://www.stuk.fi/english/

Attachment 1: description of inspection "safety management"

A1, Safety management

Outline of the inspection

The inspection is targeted at the management operations of the nuclear power plant from a safety point of view. The inspection is aimed at studying which importance has been embedded in factors affecting to safety in the plant documentation concerning management operations, in practical implementation and in future plans. Similarly, the procedures concerning the management operations are studied in order to identify possible safety deficiencies and connections between the deficiencies identified in connection with STUK's oversight operations and, the management operations by the licensee.

The entities to be inspected / assessed

For example the following basic elements of management operations are included in the inspection:

- the principles of management operations (values, mission, vision)
- the plant's safety policy
- safety targets and goals
- the status and operation of the support groups of the management
- short and long run planning of the operations
- fulfilment, follow-up, assessment and measuring of risk-aware safety management operations
- procedures designed to maintain, reinforce and develop the safety culture among personnel
- training projects for personnel and their assessment.

The inspection also includes the assessment of management operations in practice.

The inspection criteria

The inspection criteria include for example the following:

- the requirements set in the Government decisions
- the requirements set in the operating license statements
- the requirements set in the YVL Guides
- the requirements set in the STUK decisions
- the principles set by the utility itself and the procedures applied
- "good practices " applied elsewhere.

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**

   EFQM (business excellence model developed by European Foundation for Quality Management)

2. **Scope and Purpose. For which end the approach / tool is used?**

   EFQM model is a self assessment tool. It is used to assess management system and our performance. It helps us to recognize our weaknesses and strengths and to improve our performance. EFQM model has 9 criterions: 1.Leadership, 2. Policy and strategy, 3. People, 4. Partnership and resources, 5. Processes, 6. Customer results, 7. People results, 8. Society results and 9. Key performance results. (more information is available at www.efqm.org)

3. **Brief description of the approach (200 words maximum)**

4. **When measurements are involved, please specify required techniques**

5. **Status (in use / published method / piloted / under development / ...)**

   Model is developed by EFQM, it is widely used in public sector in Finland. EFQM has been used from 2001 at STUK NRR, before that STUK used once (1996) Finnish quality award model which was based on Malcolm Balridge model.

   Model is used by many companies around Europe and it has been improved on the basis of feedback companies have given. Model is adopted by public sector in many European countries as well.

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**
- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**
- **How is it validated? Is there any qualification or checking done?**
6. Application process - EFQM is used on departmental level and each department is responsible for the usage (so managers are responsible). - The model can be used also to assess only one specific area or even function. The process we have used is common self assessment process (participants were mainly managers) but we have also use the model with all employees. - Not any special information system needs. Anyhow it cannot be denied that systematic approach to findings (areas that need to be improved) is really useful. - No restrictions
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**
- **Any detail or examples?**
- **Information system requirements?**
- **Is it usage restricted? What kind of restrictions?**
7. Experiences
- **Type of results obtained** As a result of self assessment you get a kind of list of your strengths and weaknesses (areas that should be improved). This list shall be prioritized and make decisions which improvement projects will be carry out
- **Were results useful as expected?** The usage of model helps to find out areas that need to be improved most urgently
- **How the results are exploited? E.g. how findings are used?** Prioritized results were (are) taken into account on annual plan as development / improvement projects.

- **Benefits from the nuclear safety point of view ? Safety enhancement?**

  In the first hand this is a tool to assess management system, but as a regulator we should keep safety in mind all the time and all our activities should help us to produce and promote safety (safety management) --- so it can be said that it helps. For example we made competence analysis, improvements on out processes after EFQM self assessment

- **Any follow-up system?**

  All actions shall be (and are) followed up by managers. When actions are in our annual plan they are followed as a part of reporting process

- **Strengths and weaknesses?**

  This model aims to find 'major' weaknesses but the process itself produces a huge amount of weaknesses and strengths. There is a possibility that too many improvement projects will be started and people get exhausted!

8. Hints for improvement. Further developmental needs for approach/tool ?

9. Organisation, address and contact person (e-mail address)

STUK (Finland)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   Core Task Analysis (CTA)

2. **Scope and Purpose. For which end the approach / tool is used?**
   CTA is a method for the study of complex high-reliability work that draws on work and organisational psychology. It is a holistic framework for studying working practices of individual persons, teams, and organisations from a cultural perspective.
   The CTA approach may be applied in the assessment and development of practices and organisations, in evaluation and validation of technologies, in human-centred design, and in human reliability studies including incident and accident analyses.

3. **Brief description of the approach (200 words maximum)**
   The methodology focuses on the definition of the content of work demands, on understanding the courses of action in on-going situations and the construction of shared meaning and practices in work communities. The CTA provides basis for evaluation of actions and enables inferences regarding good practices.
   The CTA approach comprehends human conduct in connection to its physical and societal circumstances, and it considers cognition as a distributed system between human actors, technological tools. Thus, CTA takes distance from the traditional information processing approach. The approach distinguishes between the actual situation-specific course of actions and the underlying habitual and cultural basis of behaviour. The habits and culture provide continuity in behaviour and the possibility for intrinsic control of behaviour. The method may reveal the dynamics of adaptive behaviour in uncertain environments. By defining habits and culture the method may identify result-critical features in practices without an identification of already explicit deviations in the outcome. Thus, CTA facilitates prediction and identification of potential risks in practices. The elaboration of the habitual and cultural regulation of behaviour promotes the development of core-task-informed (incl. Risk-informed) instruction of the personnel. It also facilitates a core-task informed design of technologies.

4. When measurements are involved, please specify required techniques
CTA requires:
Functional modeling of the work domain for the identification of intrinsic result-critical constraints. Modeling includes a detailed analysis of tools, information and other relevant resources as affordances for action. As a result, the core-task demands of the analysed work may be derived. Modeling is accomplished in a participatory manner and users, designers and domain experts are involved.
Analysis of work performance using cognitive ethnography which includes observations, video recordings, process tracing interviews, self-rating techniques, orientation interviews, and log-outs from the process.
Assessments of organisational culture for which a particular method has been developed (CAOC) may be used to complement the analysis of individuals' and teams' working practices.

5. Status (in use / published method / piloted / under development / ...)
Piloted and under development; the development and results are described in research reports and publications.

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

- The CTA is dominantly a research approach. It has been developed internally on the basis of long-range research work in various high-reliability domains (nuclear, aviation, maritime, medical, manufacturing). A CTA tool pack is under development to create more robust tools to be exploited in development work.
- CTA is used in developmental projects and in training of operators (NPP simulator training tool)
- CTA is used in evaluation and validation of artefacts (NPP, Anaesthesia)
- A complementary method for the CTA is the Contextual Assessment of Organisational Culture (CAOC); this method is used for research and organisational development;
- CAOC will be described in a separate sheet

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**
- From the methodological perspective the CTA may be qualified as an ecological approach as human conduct is considered from the point of view of the human-environment interaction. Moreover, behaviour is explained on the basis of what it is a sign of, what it means, not merely as a result of external or internal causes. Thus, it challenges the prevailing information-processing paradigm in the study of human conduct.

- CTA links with three contextually oriented approaches to the analysis of work. These are the cultural historical theory of activity (Leont'ev 1978) and its adaptation in the developmental work research approach (Engeström 1999) , the Naturalistic Decision Making approach (Zambok 1997) and the cognitive engineering approach labelled Cognitive Task Analysis (Vicente 1999).
  Owner: VTT Industrial Systems Human factors team

- **How is it validated? Is there any qualification or checking done?**

  The empirical methods used have not been validated in a test-theoretical sense. However, effort has been made to explicate the philosophical and theoretical reasoning behind the conceptual apparatus and the instruments. In implementing interviews and observations and in the analysis of the qualitative data, established quality criteria of qualitative research are systematically followed.

  Where possible and relevant statistical validation will be accomplished.

  The generalisation of results relies on the possibility of communicating the contextually relevant results that may, by analogy, be applied in other contextual domains.
  Comparative studies across domains are significant for the development of the methods and for understanding complex work in a contextually relevant way.

6. Application process

- initiates from practically relevant problems that appear to require research-informed reflection and explicit development work
- joint definition of the scope of the study
- establishing an interdisciplinary project team that has in-house participation
- workshops for modeling of the core task
- field studies with interviews, observations etc., simulator studies, analyses of incidents
- analysis of the results
- workshops for discussing the results
- suggestions for developmental measures
- continuity in co-operation for follow-up is appreciated
- reporting of results in scientific forums

- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**
- The application of the methodology is time consuming. Due to its contextual orientation the CTA also requires domain-specific knowledge. Both qualifications may appear signs of inefficiency. However, due to the contextual orientation of the methodology, and the participative and interdisciplinary nature of the resulting research process important and genuine development processes may be launched in organisations and among communities of practice.

- **Any detail or examples?**

- **Information system requirements?**

- **Is it usage restricted? What kind of restrictions?**

7. Experiences

- **Type of results obtained**
  Qualitative results, and also statistically testable results
  Explanations of observed courses of action, incidents, a accidents
  Criteria to be used in reflecting practices
  Criteria for testing and evaluation of technologies
- **Were results useful as expected?**
  Yes, but development needs are evident with regard the methods and the research process
- **How the results are exploited? E.g. how findings are used?**
  - self-reflection
  - development programs in organisations
  - as a tool in human-centred design
  - training , training tool for the instructors
- **Benefits from the nuclear safety point of view ? Safety enhancement?**
  Focuses on the underlying regulatory mechanisms of human behaviour (habits and culture). This is important because the method is used in high-reliability domains in which the possibility for negative feedback control is, and must be limited by applying defence-in-depth principles.
- **Any follow-up system?**
  Continuous critical research, feed-back is systematically collected from the enterprises, feedback from the scientific community
- **Strengths and weaknesses?**
  S: contextual orientation, participatory nature, allows development processes
  W: currently incomplete stability of the tools, need for relevant validation

8. Hints for improvement. Further developmental needs for approach /tool ?

- validation of empirical tools
- combining the qualitative and conceptual methods with quantitative tools that are theoretically compatible with the CTA

9. Organisation, address and contact person (e-mail address)

Leena Norros (leena.norros@vtt.fi
VTT (Finland)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:
The homepages of the previous and the on-going national nuclear safety programmes
FINNUS http://www.vtt.fi/pro/tutkimus/finnus/index.html
SAFIR http://www.vtt.fi/pro/tutkimus/safir/index.htm

(Klemola and Norros 1997; Klemola and & Norros 2001; Norros and Klemola in press)

(Norros and Hukki 1997; Hukki and Norros 1998; Norros and Nuutinen 1999; Norros and Nuutinen 2002; Norros submitted 2003)
(Reiman and Norros 2002; Reiman and Oedewald 2002; Reiman and Oedewald 2002)

Engeström, Y. (1999). Activity theory and individual and social transformation. Perspectives in Activity Theory. Y. Engeström, R. Miettinen and R.-L. Punamäki. Cambridge, Cambridge University Press**:** 19-38.

Hukki, K. and L. Norros (1998). "Subject-centred and systemic conceptualisation as a tool of simulator training." Le Travail Humain: 313-331.

Klemola, U.-M. and L. Norros (1997). "Analysis of the clinical behaviour of anaesthetists: recognition of uncertainty as basis for practice." Medical Education **31**: 449-456.

Klemola, U.-M. and L. & Norros (2001). "Practice-based criteria for assessment the anaesthetists' habits of action.Outline for a reflexive turn in practice." Medical Education **35**: 455-464.

Leont'ev, A. N. (1978). Activity, Consciousness, and Personality. Englewood Cliffs, Prentice Hall.

Norros, L. (submitted 2003). Acting under Uncertainty. The Core-Task Analysis in Ecological Study of Work.

Norros, L. and L. Hukki (1997). Analysis of control room operators' ways of acting in complex process control situations. The 13th Triennial Congress of the International Ergonomic Association, Tampere, Finland.

Norros, L. and U.-M. Klemola (in press). Naturalistic analysis of anaesthetists' clinical practice. How professionals make decisions. H. Montgomery, B. Brehmer and R. Lipshitz. Mahwah, New Jersey, Lawrence Erlbaum Associates.

Norros, L. and M. Nuutinen (1999). Contextual analysis of the nuclear power plant operators' utilization of a disturbance management system. 7th European Conference on Cognitive Science Approaches to Process Control, Villeneuve d'Ascq, France.

Norros, L. and M. Nuutinen (2002). The Core-Task Concept as a Tool to Analyse Working Practices. WHOLE. N. Boreham, M. Fischer and R. Samurcay.

Reiman, T. and L. Norros (2002). Regulatory Culture: Balancing the Different Demands on the Regulatory Practice in Nuclear Industry. Changing Regulation - Controlling Hazards in Society. A. R. Hale, A. Hopkins and B. Kirwan. hhh, Elsevier.

Reiman, T. and P. Oedewald (2002). The Assesment of Organisational Culture - A methodological Study. Espoo, Technical Research Centre of Finland.

Reiman, T. and P. Oedewald (2002). A new methodology for assessing and developing maintenance culture. VTT Industrial systems review**:** 48-52.

Vicente, K. J. (1999). Cognitive Work Analysis. Toward a Safe, Productive, and Healthy Computer-Based Work. Mahwah, NJ, Lawrence Erlbaum Publishers.

Zambok, C. (1997). Naturalistic decision making: Where are we now? Naturalistic Decision Making. C. Zambok and G. A. Klein. Hillsdale, NJ, Lawrence Erlbaum.

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   Contextual Assessment of Organisational Culture (CAOC)
2. **Scope and Purpose. For which end the approach / tool is used?**
   CAOC is a methodology that offers a set of methods for assessing organisational culture in complex sociotechnical systems by utilising contextual and appropriate criteria for an effective activity. The CAOC can be applied in the development of work, organisational practices and culture at the target organisation.
3. **Brief description of the approach (200 words maximum)**
   Organisational culture is considered as consisting of the practices, routines, norms and assumptions prevalent in the organisation. The aim of the studies utilising the principles of CAOC is to model the core task of the organisation and to characterise its organisational culture in order to assess how the culture supports perceiving and fulfilling the demands of the particular core task. In CAOC-based research, a conceptualisation of the target organisation's culture is made. The theoretical core task model constructed in the study acts as a point of comparison when examining the key features of culture. The result is an assessment of the strengths and weaknesses of the culture, increased understanding of the reasons for different conceptions and ways of thinking prevalent in the organisation and opening of the internal dialogue in the organisation. The aim of the CAOC-based research is thus not only to assess the given culture, but also to give the personnel new concepts and new tools for reflecting on their organisation, their jobs and on appropriate working practices. The preliminary results of the study are presented to the personnel in different occasions and interpretations of the results are discussed together with them.

4. When measurements are involved, please specify required techniques

The CAOC-Methodology consists of both qualitative and quantitative methods:

- interviews of personnel from all the levels of the organisation
- survey (CULTURE03) consisting of four measuring instruments (measure of values, own work, core task and ideal values)
- groupworking
- seminars for the whole personnel
- observation of actual work (when practically possible)

5. Status (in use / published method / piloted / under development / ...)

The methodology has been piloted in four case studies. Reports about the methodology and the results from the case studies have been published.

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

CAOC is a research methodology developed at VTT Industrial Systems. First pilot study utilising the basic principles of CAOC was conducted in 1999 at the Finnish Nuclear Regulatory Authority (see Reiman & Norros 2002). After this study considerable changes to methodology have been made (see Oedewald & Reiman in press).

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**

Methodology is based on various theories validated elsewhere, such as Weick's (1995) sense-making theory, Schein's (1985) theory of organisational culture and the cultural historical theory of activity (Leontiev, 1975), and on the work done by the psychologists at VTT (Norros & Nuutinen 2002, Reiman & Norros 2002, Reiman & Oedewald 2002, Oedewald & Reiman in press).

Owner: VTT Industrial Systems

- **How is it validated? Is there any qualification or checking done?**

One means of validation is the usefulness of the results in subsequent development work. The results have not been compared to objective performance data of the plants, but plans for that are in progress. Since the results of the study focus on the conceptions and assumptions of the personnel, the plausibility of the results as assessed by the participating organisation is also a one means of validation. This is illustrated further in e.g. Oedewald and Reiman (in press).

6. Application process

Cultural assessment made in accordance with the principles of CAOC consists of three phases:

- modelling the organisational core task (interviews, groupworking)
- characterising the culture of the organisation (interviews, survey, seminars)
- explaining the effect of the culture on the effectiveness of the organisation.

The methodology strives for conceptualising both the “objective” core task demands and the way they are understood in the culture. The aim is to determine the core task at the level of the entire organisation or its operational groups. Thus, the core task modelling focuses on the boundaries and requirements of work activity in the entire sociotechnical system.
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?** Currently the utilisation of the methodology is quite time-consuming, but the further development of the methodology aims at "lightening" the methods in order to be able to conduct the case studies more efficiently. The study usually focuses on the entire organisation or some sub-unit, such as the maintenance unit.
- **Any detail or examples?**
- **Information system requirements?** statistical software
- **Is it usage restricted? What kind of restrictions?**
7. Experiences
- **Type of results obtained** At a maintenance organisation, cultural tensions were identified. These tensions were connected e.g. to the nature of expertise and to the role of rules and instructions in daily work. The tensions complicated constructive dialogue about development needs in organisational working practices. The research brought these tensions into surface and facilitated their consideration. Also results on organisational values, development targets, experiences related to own work (meaningfulness, work stress, feedback etc.), cultural assumptions and organisational climate have been obtained.
- **Were results useful as expected?**
- **How the results are exploited? E.g. how findings are used?** The CAOC-methodology contributes to the design and redesign of work in complex sociotechnical systems. The approach strives to enhance organisations' capability to assess their current working practices and the meanings attached to them and compare these to the actual demands of their basic mission and so change unadaptive practices.
- **Benefits from the nuclear safety point of view ? Safety enhancement?** The preventive nature of cultural research is one of the main arguments favouring its use. The reflection of organisational practices and culture brings into surface many assumptions and routines that might in the long run be detrimental to safety, but are currently taken for granted and not questioned.

- **Any follow-up system?**
  - under development

- **Strengths and weaknesses?**
  S: contextual, participatory, development oriented
  W: time-consuming, currently too little statistical follow-up data

8. Hints for improvement. Further developmental needs for approach / tool ?

9. Organisation, address and contact person (e-mail address)
Teemu Reiman, teemu.reiman@vtt.fi
VTT (Finland)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Reiman, T. & Norros, L. (2002). Regulatory Culture: Balancing the Different Demands of Regulatory Practice in the Nuclear Industry. In Kirwan, B., Hale, A.R. & Hopkins, A. (eds.), Changing Regulation – Controlling Risks in Society. Oxford: Pergamon.

Reiman, T. & Oedewald, P. (2002). Contextual Assessment of Organisational Culture – methodological development in two case studies. In Kyrki-Rajamäki, R. & Puska, E-K. (eds.), FINNUS. The Finnish Research Programme on Nuclear Power Plant Safety, 1999-2002. Final Report. VTT Research Notes 2164. Helsinki: Yliopistopaino.

Oedewald, P. & Reiman, T. (In press). Core Task Modelling in Cultural Assessment – A Case Study in Nuclear Power Plant Maintenance. Cognition, Technology & Work.

References

Leontiev, A.N. (1975). *Dejatel'nost. Coznanie. Litšnost*. [Activity. Consciousness. Personality.] A Finnish Translation. Kuopio: KOY.

Norros, L. & Nuutinen, M. (2002). The concept of the core-task and the analysis of working practices. In: Borham, N., Samurcay, R. and Fischer, M. (Eds.), *Work Process Knowledge*. London: Routledge.

Schein, E. H. (1985). *Organizational Culture and Leadership*. San Francisco: Jossey-Bass.

Weick. K. E. (1995). *Sensemaking in Organizations*. Thousand Oaks, CA: Sage.

Appendix 3.d): Responses from France

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

France
Thomas.maurin@asn.minefi.gouv.fr

2. Are there regulatory requirements of any sort on the utility management system?

The Quality order of August 10, 1984 prescribes to the operator of a nuclear installation to implement a quality system appropriate for the activities concerning quality.

- **If yes, status and content of requirements (describe here or attach documents)**

  See in Annex the document Quality Order of August 10, 1984 (english translation)

3. Does the regulatory body assess the management system of the utility?

Our policy is neither making a formal assessment of utility management or organisation nor developing criteria to that effect.

- **If yes, description of the approaches, methods and criteria used in assessment,**
  or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.

Requirements contained in the Quality Order may be, and are, verified during inspections on site. These inspections are either thematic or post incident. Specific inspections regarding management of safety and also the human factors programs and actions have been done in French NPPs. They may concern for example issues such as general policy and organisation of the plant for managing safety, resources, staff, organisation and actions of safety quality departments, verification and audits made and corrective actions, etc.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. Present needs and challenges in Safety Management / Management of Safety

- **What should be developed or done? For what purpose is needed?**

There is a need for methods, tools, that may be used for evaluating management of safety. It is difficult to measure what is a good management and what is not, there is a need for criteria.

Some data may come from operationnal experience feedback. For example, IRSN developed a model called Recuperare, which is built on the French HRA principles and developed for operating feedback analysis. This model focuses on the recovery process during events.

This model has been used for the Dampierre analysis on the organisational point of view in 2000. The results were significants. For example, faults in recovery mechanisms were more numerous in Dampierre plant compared to the other French ones. The same observation has been done for the “cumulative” events.

The results outlined several problems :

- management of the crew
- communication in the crew itself,
- communication between different crews.

This analysis concluded that Dampierre crews had difficulties to manage events.

This method is based on incidents analysis. But there are a lot of other aspects to consider out of incidents only. For example, some topics could be developped, such as

- definition of what is management of safety (relation with INSAG 13), how to improve it, what are signs of degradation, etc.
- safety culture and management of safety
- role of human factors program and actions in management of safety (role of human factors specialists in actions such as risk analysis, self-diagnosis and evaluation, safety vs. performance)
- interaction between management of safety and management of quality (total quality, etc.)
- role of regulator in management of safety, requirements, inspection, etc.

- **How and who should take care?**

- **Any further suggestions on how to apply available knowledge to Safety Management?**

2. Contact person (name, address, e-mail address):

France
Thomas.maurin@asn.minefi.gouv.fr

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Order of August 10, 1984 Concerning Basic Nuclear Installation design, construction and operation quality

OFFICIAL GAZETTE OF THE FRENCH REPUBLIC
SPECIAL ISSUE
September 22, 1984, page 8652

Order of August 10, 1984 Concerning Basic Nuclear Installation design, construction and operation quality

The Minister for Industrial Redeployment and Foreign Trade,

- in view of Decree 63-1228 of December 11, 1963 concerning nuclear installations, amended by decree 73-405 of March 27, 1973, and notably Article 10a,
- in view of Decree 93-278 of March 13, 1973 amended, concerning in particular the setting up of a Central Service for the Safety of Nuclear Installations,
- in view of the opinion expressed by the Interministerial Commission for Basic Nuclear Installations during its session of July 2, 1984,

on a proposal from the General Director for Industry, adopts:

CHAPTER I - General provisions

Article 1

The operator of a Basic Nuclear Installation shall ensure that quality standards befitting the importance of their safety related functions, within the meaning of the above-mentioned decree of March 13, 1973, be defined, obtained and maintained for the following elements:

- structures, components and equipment,
- assemblies which combine them,
- installation operating conditions.

For this purpose, the operator shall ensure that a system is set up to define the requisite quality level of the aforesaid elements, to obtain and maintain the level required, to check that the level is consistently achieved and to analyse and correct any possible deviations.

This system involves a monitored set of planned, systematic actions, based on written procedures and giving rise to filed records.

It must be so devised as to confirm that the quality level of the above elements has been obtained and maintained.

It is set up at the design stage and extends throughout all the subsequent stages of existence of the Basic Nuclear Installation.

Article 2

2.1 Taking into account the specificity of this Basic Nuclear Installation, the operator shall identify the activities performed by himself or by service companies employed and which influence the quality of the safety related elements referred to in Article 1.

Such activities are referred to as "quality related activities" in the present Order.

2.2 The provisions of Articles 6 to 10-1, 11-2, 12, 13-1, 13-3, 14 and 15-1 of the present Order apply to quality related activities. Measures enabling compliance with these provisions are defined and implemented by the operator or the service companies he employs.

Article 3

For the purpose of implementation of the present Order, any person covered by Article 1 of the aforementioned decree of December 11, 1963 or any natural or legal person having submitted a basic nuclear installation authorisation application shall be referred to as "operator".

For the purpose of implementation of the present Order, the holders of contracts with the operator himself or with other providers of services shall be referred to as "service companies", in all cases where the contract concerns the provision of goods or services, constituting one or several quality related activities.

CHAPTER II - Overall liability of the operator

Article 4

Being responsible for the safety of the installation, the operator shall thereby be responsible for implementation of the provisions of the present Order concerning quality-related activities.

As regards quality related activities carried out by service companies, the operator shall ensure that the relevant contracts fully inform the said service companies of all provisions enabling implementation of the present Order.

The operator organises or has organised by all service companies supervision such as to ensure compliance of the latter with the provisions thus notified. He shall notably ensure that the goods or services provided are duly inspected with a view to checking their conformity to the stated requirements.

Article 5

The operator shall constitute and keep updated a dossier summarising the measures and means provided for implementation of the present Order, describing in particular the service company surveillance principles adopted. The operator shall forward this dossier to the Central Service for the Safety of Nuclear Installations, together with subsequent up-datings, save as otherwise stipulated in the transient provisions of Article 17 of the present Order. In the case of a Basic Nuclear Installation to be authorized, this dossier shall be forwarded with the authorisation decree application.

The operator shall hold or have held at the disposal of the Head of the Central Service for the Safety of Nuclear Installations and of the Basic Nuclear Installation inspectors thereof all elements testifying to compliance with the present Order.

The operator shall be in a position to report implementation of the provisions of the present Order to the Head of the Central Service for the Safety of Nuclear Installations, notably as regards the identification of quality related activities. Upon request, he shall provide the Head of this department with full information and justifications in this respect. Depending upon the results obtained, the Minister for Industrial Redeployment and Foreign Trade may require the operator to adopt all measures deemed necessary for implementation of the present Order.

CHAPTER III - General principles

Article 6

The basic requirements for obtaining and maintaining the quality level designated in Article 1 must be defined for each quality related activity, taking into account its safety role. These requirements shall be referred to as "defined requirements" in the present Order.

Article 7

The human and technical resources together with the organisational provisions implemented for the performance of a quality related activity must be adapted to this activity and enable compliance with the defined requirements.

In particular, only adequately skilled staff may be assigned to quality related tasks. Appraisal of the competence of such staff shall notably be based on their training and experience.

Quality related activities for which staff require prior qualification or accreditation or for which the technical means involved must be qualified, shall be identified, taking into account their nature and their safety related importance.

Organisational provisions must be such as to enable identification, for each quality related activity, of the specific assignments and obligations of staff or organisations concerned and the links between them.

Article 8

Organisational provisions shall be so defined and implemented as to provide for technical inspections adapted to each quality related activity. These provisions must be such a to ensure:

- that each quality related activity has been carried out in accordance with the defined requirements,
- that the result obtained corresponds to the defined quality level,
- that appropriate corrective and preventive actions with respect to possible non-conformances and incidents, as listed in Article 12 of the present Order, have been defined and implemented.

Staff responsible for technical inspection tasks in the framework of quality related activities must differ from the staff assigned to perform such activities.

Article 9

Organisational provisions shall be defined and implemented for verification of the satisfactory implementation of Articles 6, 7 and 8 of the present Order.

Staff and organisations responsible for verification tasks must:

- have reached an adequate technical level,
- be independent of those responsible for performing the quality related activities,
- report directly to a person having supervisory functions with regard to the performance of quality related activities.

They shall periodically assess the efficiency and adequacy of the provisions made pursuant to the present Order, notably on the basis of appropriate surveys and, as and when required, of programmed sampling checks. These assessments shall cover both the organisational arrangements made and the technical aspects of the quality-related activity considered.

These organisational arrangements include provisions whereby lessons can be learned from any abnormal situations observed and remedial actions implemented accordingly.

CHAPTER IV - Documents concerning quality related activities

Article 10

10-1. For each quality related activity, the following documents shall be drawn up and, as required, kept updated and used:

a) Prior to initiation of this activity, description of the general provisions made pursuant to the present Order. The corresponding document may cover several quality-related activities,

b) Preliminary description of defined requirements, performance and inspection conditions and the conditions under which non-conformances or incidents are to be processed,
c) Records of the performance of the activity, providing adequate information for characterisation of the related performance and inspection conditions, together with the results obtained,
d) Programme of verification measures, including surveys, as provided for in Article 9,
e) Documents certifying that the verification measures have been carried out, showing the results obtained and reporting periodic survey data,
f) Documents certifying the supervision carried out in compliance with Article 4 on all service companies and reporting any observations.

10-2. The operator shall prepare a recapitulative document constituting an overall assessment of the quality level achieved prior to start-up of the installation. Subsequently he periodically prepares a statement on the quality level obtained and maintained for the safety related equipment referred to in Article 1.

Article 11

11-1. The operator shall make or have made all necessary provisions to ensure that all quality appraisal documents, including those describing the installation itself:

- be filed for an appropriate period of time,
- be protected,
- be preserved under satisfactory conditions,
- be readily accessible.

11-2. All provisions made for the filing of documents concerning a quality related activity shall be the subject of a continually updated written account.

CHAPTER V - Non-conformances and incidents

Article 12

Any deviation with respect to a requirement defined for the performance or result of a quality related activity, any situation liable to be prejudicial to the quality level defined or any situation justifying, from the safety standpoint, corrective actions, shall be referred to, depending on circumstances, as "non-conformances" or "incidents" in the present Order.

The action of correcting a non-conformance or incident is considered as a quality related activity.

An inventory of non-conformances or incidents is kept updated.

Article 13

13-1. Non-conformances or incidents which have severe safety implications must be identified. These non-conformances or incidents shall be referred to as "significant non-conformances or incidents" in the present Order.

For this purpose, a procedure shall enable, for each quality related activity, taking into account insofar as possible established criteria, determination of the incidents or non-conformances to be considered significant. The posts occupied by those responsible for this identification shall be indicated.

13-2. The operator shall report significant non-conformances or incidents to the Central Service for the Safety of Nuclear Installations as soon as possible. He shall make appropriate provisions in this respect with regard to his service companies.

The report shall describe measures already taken or envisaged to limit extension of the non-conformance or incident and, if need be, mitigate the consequences. If the installation is operating, the report shall indicate the provisions made or envisaged to continue or resume operation under satisfactory safety conditions.

13-3. Significant non-conformances or incidents shall be subjected to thorough analysis:

- to accurately determine their causes and their direct or potential safety consequences,
- to derive useful lessons for the quality related activity affected and, where appropriate, for other quality related activities.

A dossier is prepared and kept updated for each significant non-conformance or incident, containing notably the elements of this analysis.

13-4. The operator periodically provides the Head of the Central Service for the Safety of Nuclear Installations with information on the stage reached in this dossier.

CHAPTER VI - Special provisions

Article 14

Work resulting from thought and discussion and leading to the drafting of one or several technical documents necessary for the carrying out of a quality related activity shall be referred to as a "study" in the present Order.

A study is a quality-related activity.

Irrespective of the implementation of other provisions of the present Order, studies are covered by the following measures:

14-1. In the case of a study, the document referred to in Article 10-1 comprises notably rules devised to ensure:

- the definition and consultation of the persons and organisations concerned,
- the taking into account of observations made,
- the adoption of successive revisions of documents pertaining to the study considered.

These rules must also provide a means of ensuring that the various organisations or persons concerned by a study are informed of other studies or documents, such as design bases, codes, standards or regulatory provisions, which could be useful for the study considered.

14-2. Apart from justified exceptions, each study must be audited pursuant to Article 8. The nature of this verification will depend on the safety-related importance of the study considered. The verification will take place in the course of examinations carried out by persons who did not participate directly in the performance of the study in question.

14-3. Apart from justified exceptions, the persons and organisations responsible for verification tasks pursuant to Article 9 shall be informed of the stage reached in the studies concerned. The corresponding documents shall be placed at their disposal.

14-4. Critical examinations focused on the overall design or on large subsets of the installation are performed to check the overall consistency of the related studies.

Article 15

15-1. The provision of the present Order must have been applied to activities which were initiated prior to filing of the Basic Nuclear Installation authorisation application and which, when the said application is filed, are identified as quality related activities.

15-2. The operator forwards to the Central Service for the Safety of Nuclear Installations, in connection with his Basic Nuclear Installation authorisation application, a statement concerning initiation of these quality related activities and the provisions made accordingly to ensure implementation of the present Order.

Article 16

The research and development or training activities carried out in a Basic Nuclear Installation specialised therein are not subjected to the provisions of Article 2-2 and Articles 4 to 15. However, whatever the case considered, the operator must be in a position to report to the Head of the Central Service for the Safety of Nuclear Installations all provisions made pursuant to Article 1.

CHAPTER VII - Implementation procedures

Article 17

By way of transitional provisions, any operator or any person acquiring this capacity within a period of one year, starting form the date of publication of the present Order in the Official Gazette of the French Republic, shall have a maximum period of one year after the date of the aforementioned publication to present the dossier provided for in Article 5 and comply with the provisions of the present Order, save as otherwise provided in the measures below.

For construction and operating activities already under way or for those to be initiated within a period of one year, starting from the above-mentioned date of publication, the operator may request the Minister for Industrial Redeployment and Foreign Trade (Central Service for the Safety of Nuclear Installations), ten months at the latest after the above-mentioned date of publication, an extension of the one year period and, in this case, shall propose the envisaged schedule and the conditions under which would be set up the provisions enabling implementation of the present Order. Upon receipt of this request with the associated proposals, the Minister for Industrial Redeployment and Foreign Trade may extend the time limit, under conditions he determines, provided the extended period, starting from the above-mentioned date of publication, does not exceed three years, subject to the provisions of Article 18 below.

Article 18

Waivers with respect to the provisions of the present Order are granted by the Minister for Industrial Redeployment and Foreign Trade, under conditions he determines.

Article 19

The Head of the Central Service for the Safety of Nuclear Installations shall be responsible for implementation of the present Order, which will be published in the Official Gazette of the French Republic.

Done in Paris, August 10, 1984

Appendix 3.e): Responses from Japan

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

NUPEC, Japan
makino@nupec.or.jp sakaue@nupec.or.jp

Are there regulatory requirements of any sort on the utility management system?**Yes**

- **If yes, status and content of requirements (describe here or attach documents)**
  (1) Law for the Regulations of Nuclear Source Material,Nuclear Fuel Material and Reactors
  (2) Safety Preservation Rules
  (3) Quality Assurance for safety operation of nuclear power plant (JEAC4111-2003) (will be published in near future)

2. Does the regulatory body assess the management system of the utility?

Yes

- **If yes, description of the approaches, methods and criteria used in assessment, or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.**

(1) In licensing the establishment of a nuclear installation, the competent minister confirms that the applicant possesses the technical ability and financial position sound enough to establish reactors, and possesses such technical ability as to operate them competently.

(2) Safety Preservation Rules ;
At the operation of a nuclear installation, in addition to regulations focusing on the integrity of structural aspects, evaluation is also performed concerning managerial aspects of the license holder such as the organization, reporting system, operational procedure, equipment maintenance, surveillance, radiation dosage control for personnel, radioactive waste management, radioactive gaseous and liquid waste release management, radiation monitoring and safety education for personnel. These aspects are comprehensively documented in the “Safety Preservation Rules”, which shall be approved by the regulatory body on the basis of the Reactor Regulation Law.
By the Amendment of the Reactor Regulation Low, The Nuclear Safety Inspection System was established and the Nuclear Safety Inspectors are stationed at each nuclear installation who confirm the observance of Safety Preservation Rules.

(3) New regulation for assessing the management based upon QA will be instituted.

-

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

(3) Not yet. JEAC-4111-2003 will be published in near future.

Appendix 3.f): Responses from Spain

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

- Consejo de Seguridad Nuclear (Spanish Nuclear Safety Council, CSN)).
- Benito Gil Montes (PSA and Human Factors Division)
- e-mail: bgm@csn.es

2. Are there regulatory requirements of any sort on the utility management system?

Yes.

(1) Since they came into operation, all the Spanish NPPs are required to present to the CSN prior approval any change in the structures or functions of their organisations.

(2) Since December 1995, the CSN Safety Guide 1.10 on Periodical Safety Reviews requests to all the Spanish NPP to develop an assessment and improvement program on Human and Organisational Factors (HOF).

(3) In July 2000, all the Spanish NPPs were required to develop their own procedures to assess organisational changes with impact on human resources. In 2002 all the NPPs were required to extend the scope of such procedures to any kind of organisational changes.

(4) In 2002 all the Spanish NPPs were requested to develop and implement their own Self-Assessment Procedures and Corrective Action Programs.

(5) In October 2002, one Spanish NPP was required to develop and implement a formal Safety Management System. Nowadays, a recently created CSN-Utilities group is working in order to define a similar requirement to all the Spanish NPPs.

(6) In October 2002, the same NPP was required to develop and implement an Investments Management System. Nowadays, all the Spanish utilities have already completed a generic guide that will be used as a common reference to develop the specific systems and procedures at each plant.

(7) All the Spanish NPPs are encouraged (it is not a requirement at this moment) to apply periodically any sounded methodology on organisational self-assessment.

- **If yes, status and content of requirements (describe here or attach documents)**

All these requirements are in force nowadays.

(1) CSN Safety Guide 1.13 describes the contents of the licensing document "Operation Rules". This document includes a description of the utility´s operating organisation.

(2) CSN Safety Guide 1.10 lists the assessment and improvement programs that must be put in place in NPPs. A CSN report distributed to all the NPPs provides detail considerations on how to develop such HOF programs.

(3) All the NPPs has already implemented internal procedures to manage organisational changes with impact on human resources. Nowadays, some NPPs have already completed, and others are still developing, such procedures for any type of organisational change. They are based on internationally accepted standards and good practices, included mainly in IAEA and NEA reports.

(4) The utilities have developed a generic guide on Self Assessment and on Corrective Action Programs. Both guides have been discussed in a working group with the CSN. Nowadays, the NPPs are developing their specific procedures, which will be used as pilot experience along part of 2003 and part of 2004. Around mid 2004 both procedures will be officially implemented in the NPPs.

(5) The Safety Management System has already been designed and partially implemented by this plant. Nowadays, all the plants are elaborating a common proposal that would be based basically in a process management approach developed by the Nuclear Energy Institute in USA. This proposal is under discussion with the CSN.

(6) The Investments Management System has been designed and is almost completely implemented by that plant. Nowadays, the other plants are developing their specific procedures, which are based on a generic guide. This guide was developed by the Spanish utilities taking also into consideration the process management approach developed by the Nuclear Energy Institute in USA.

(7) Two NPPs have already used, as pilot experiences, a methodology oriented to obtain a detailed picture and to assess the organisational factors in a NPP (see part B of this survey, response provided by FEPSI). In 2003 and 2004 the method will be used again in two other NPPs, as part of their own assessment programs.

3. Does the regulatory body assess the management system of the utility?

- Utility actions in response to requirements 1, 2 are assessed and inspected by the CSN.
- Basically, nowadays, the utilities are still completing their activities in response to requirements 3, 4, 5 and 6. The main role of the CSN up to now has been to specify the requirements and to collaborate with the utilities in establishing acceptable guides to answer to these requirements.
- Related to point 7, in the first two experiences the CSN did not participate in the assessment of the results, because the methodology was applied as pilot experiences in a R&D project.

- **If yes, description of the approaches, methods and criteria used in assessment, or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.**
- The main criteria followed by the CSN is that the utilities are the first responsible of nuclear safety in their NPPs. So, the main CSN emphasis in this area is to encourage the NPPs to put in place all the processes needed to maintain adequate safety management systems and that these systems be developed by experts on these matters and taking into account internationally accepted standards. The CSN is following, mainly, a process-based regulatory approach on these issues.
- The CSN is trying to develop similar expertise and competence in these matters within its own organisation.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. Title of the approach

Organisational and Management Assessment Methodology (S. Haber)

2. Scope and Purpose. For which end the approach / tool is used?

The methodology allows construction of a profile of the organization characteristics and the management functions related to the safety of nuclear facilities. After succesive applications an evolutionary profile of those organizational dimensions along the time can also be obtained.

The use of this approach was included in a Spanish R&D project (1998-2002) entitled “Development of methods to evaluate and model the impact of organisation on nuclear power plants safety”, framed in an specific agreement among UNESA (Association of Spanish Utilities), CSN (Spanish Nuclear Safety Council) and CIEMAT (Research Centre for Energy, Environment and Technology).

Up to the present the methodology has been applied to two of the Spanish Nuclear Power Plants and there are plans to apply it to two other plants along current year and the next one. These applications are part of a new R&D project (2003-04) that is now being started by UNESA, CSN and FEPSI-UAB (School of Prevention and Integral Safety of Universidad Autónoma de Barcelona).

3. Brief description of the approach (200 words maximum)

The organisation and management assessment methodology includes a model of the human organisational characteristics that influence safety in a nuclear facility, a set of organisational dimensions with impact on safety and qualitative and quantitative methods to assess them.

The model, Adaptive Machine Model, serves as a basis for creating reliable and defensible methods and standards that can be used in the evaluation of organisation and management processes and structures and to assess 19 organisational dimensions that describe behaviours relevant to the various organisational components of the model.

The organisational dimensions identified are: centralisation, coordination, external communication, formalization, goal setting, interdepartmental communication, organisational culture, organisational knowledge, organisational learning, performance evaluation, performance quality, personnel selection, problem identification, resources allocation, roles and responsibilities, safety culture, time urgency and training.

4. When measurements are involved, please specify required techniques

The techniques used to assess the organisational dimensions identified are:

- Functional analysis
- Semi-structured interview protocol
- Behavioral anchored rating scales, BARS
- Observations to fulfil the behavioral checklists
- Survey

5. Status (in use / published method / piloted / under development / ...)

In use

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

  This methodology was adopted from outside. It was received through a collaboration agreement between the Canadian and the Spanish nuclear regulatory bodies. Up to now, it has been implemented in two Spanish nuclear power plants, as pilot experiences, in the years 2000 and 2002. It is going to be implemented along 2003 in a third Spanish NPP.

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**

- **How is it validated? Is there any qualification or checking done?**

  Three criteria has been used by their authors to validate this methodology: practicality, acceptability and usefulness.

6. Application process

- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**

  In the Spanish project this methodology has been implemented by a CIEMAT research team in co-operation with the author of the methodology,

S. Haber, as a consultant. The responsible of the results from the two pilot experiences performed in Spain was S. Haber.
The implementation was not devoted to any specific organisational level, the data collection includes the whole NPP, site and corporation.

The human resources involved in the two pilot experiences carried out in Spain were somewhat different in accordance with the different dimensions of the plants. In both cases the method's author was a member of the team, as responsible for the application, but in one experience she was joined by two people from Ciemat and in the other one by four. Both experiences began around January and ended at the end of June. In both cases the survey was applied to all the plant employees and the interviews and BARS involved around 15% of all the employees at the plant site and the corporation.

The results always indicate the type of culture of the organization, whether or not the culture is the same at the plant site and in the corporation and in the various components of the organizational model, and the degree of commitment of the employees with their organization. Those organizational dimensions that make up strong points and those that can be improved are highlighted. Recommendations are never made on how to carry out interventions in order to improve the weak points. The methodology produces a diagnosis, but no recommendations.

- **Any detail or examples?**

The application process is not costly although the team must have a generic knowledge about nuclear plants safety and the concepts in the methodology.

We find it difficult to make a general estimate about the team size and the profile of its members since we have only applied the methodology to two Spanish nuclear plants. Based on this limited experience we think that for a plant of around 1000 Mwe an interdisciplinary (technical, psychologic, organizative) team of some four people can be adequate.

A complete application can be estimated to last between five and six months. The final duration will depend on the team's training in the repetitive application of the methodology and the specific characteristics of each case.

In general the following estimates can be made:

- Functional analysis, about two months. Participation of the whole team in this phase is very important, as all of them have to understand how the plant works: the work flow among the different units and groups has to be described and information flows, procedures and training have to be examined. This first phase of the methodology should make the team familiar with the functions and interphases of the organizational units, thus setting up a basis on which they can select the critical organizational dimensions.

- Data gathering in the plant, about one week, with the whole team participating.
- Data processing and preparation of the report and preliminary conclusions, between two and three months.
- The application should not be closed without a presentation to the plant of the results obtained by the external team and their acceptance by the organization. In our experience with the two Spanish NPPs complete acceptance of preliminary results has occurred and, therefore, closing the application and delivering the final report has taken only a week.

It is important to follow up the time evolution of the safety-related organizational dimensions, not only to assess the process of continuous improvement of the plant but also to "alert" on new influences that may arise from today's most dynamic external environment. This has to be considered when deciding on the periodicity of the methodology applications. The time interval chosen should be such as allowing improvements to become visible but, at the same time, it has to take the dynamics of external change into account. In general terms an application every three years might be recommended.

- **Information system requirements?**

A personal computer with the usual office packages and an up-to-date version of the SPSS statistics program.

- **Is it usage restricted? What kind of restrictions?**

This methodology was received through a collaboration agreement between the Canadian and the Spanish nuclear regulatory bodies. One of the methods used, the OCA survey on organizational culture, is copyrighted by the firm Human Synergistics.

7. Experiences

- **Type of results obtained**

Qualitative and quantitative description of the organisational dimensions selected to be reviewed in each specific NPP, an organisational culture profile of the plant and other scales regarding commitment, cohesion, co-ordination, communication, safety, hazard, job satisfaction and environmental safety and health.

- **Were results useful as expected?**

The results obtained from the two pilot experiences implemented in Spain have been considered accurate and useful for the NPPs where the methodology has been used.

- **How the results are exploited? E.g. how findings are used?**

The CSN is promoting the use of well founded assessment methodologies in the area of organisational factors by the Spanish utilities. That means,

methodologies to be used by the very Spanish utilities or with the collaboration of external organisations when appropriate. So, the results of these pilot experiences are to be used by the NPPs in their own assessment programs. Nowadays it is under discussion how to integrate the periodical use of these type of methodologies in a formalised way within the own assessmenmt programmes of the Spanish NPPs.

- **Benefits from the nuclear safety point of view ? Safety enhancement?**

  The methodology implementation provides the NPP with information related to organisational dimensions critical for safety.

  Starting from this information, as seen above, the plants can take actions for improvement. The effectiveness of these actions can be measured periodically (e. g. every three years) by doing a new diagnosis. This is an advisable procedure but for the time being the decision to carry it through rests with the organizations.

- **Any follow-up system?**

  As mentioned, it would be possible to apply the methodology periodically in order to make a follow-up of the plant improvements.

- **Strengths and weaknesses?**

  Strengths: The theoretical organizative model and the data collection techniques.
  Weaknesses: Sometimes, the relationship between the organizational dimensions and safety is not very explicit.

8. Hints for improvement. Further developmental needs for approach /tool ?

The theoretical foundations should be adapted to the current changing environment of the nuclear industry and some of the data collection techniques could require adaptation to the cultural characteristics of the each specific country.

9. Organisation, address and contact person (e-mail address)

Dr. Rosario Solá Farré

Roser.sola@uab.es

FUNDACIÓ ESTUDIS DE PREVENCIÓ I SEGURETAT INTEGRAL
Edifici Blanc 3ª planta
Campus Bellaterra UAB
Cerdanyola del Vallés
08193 BARCELONA

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   Organisational and Human Factors Program

2. **Scope and Purpose. For which end the approach / tool is used?**
   The principal objective of this program is to achieve that the organisation maintains an attitude of attention and ready to promote the topics of Human and Organisational Factors in order to minimise or prevent, negative influence that said factors have an in the security and availability of the station.
   The program's scope is very wide, covering as well the aspects of individual and collective human behaviour and the human influence in the errors as well as the organisational factors that influence said behaviours.

3. **Brief description of the approach (200 words maximum)**
   As a general structure for the program we selected a part of the WANO Actuation Criteria and Objectives (PO&C). To be precise, the Organisation and Administration Areas and the Cross-Functional Areas. For those Areas are defined yearly some specific Actuation Projects. The specific areas are: Organisational Efficiency, Safety Culture, Human Behaviour, Auto-evaluation and management of knowledge, Industrial Safety, Plant status and Configuration Control, Work Management, Status and Actuation of devices. Additionally to the projects there have been established in said areas some activities already consolidated that aim to improve and trace each one of the areas.
   In each Station there has been assigned an expert in Human Factors who drives, promotes and in many cases carries out directly each and every of the projects and activities.
   The actions of the experts of the different plants are coordinated by the coordinator in the main offices, and a tracing is carried out by the maximum levels of the organisation through an ad-hoc committee.

4. When measurements are involved, please specify required techniques
One of the projects in development within the same program is establishing indicators to measure its efficiency.

5. Status (in use / published method / piloted / under development / ...)
Currently it is in use, although, due to its character, it is under constant development.

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**
  Internally adopted. Latest revision of Plan has 9 months of effect.

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**
  The basic principles are the WANO PO&C. The was no consultant engaged. The owners are the Human Factor specialists in the station and the coordinator in the main offices.

- **How is it validated? Is there any qualification or checking done?**
  There will be carried out a periodical study about its efficiency

6. Application process

- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**
  The Organisational and Human Factors program is made with a biannual character, although it is reviewed annually

- **Any detail or examples?**
  As project examples can be mentioned:
  Definition of procedures and guidelines for the application of the Human Factor principles of engineering in the design of the Design modifications and Procedures.
  Auto-evaluation programs. Definition of indicators in the Human Factors Areas. Promotion of the Safety Culture.

- **Information system requirements?**
  No requirements

- **Is it usage restricted? What kind of restrictions?**
  No

7. Experiences

- **Type of results obtained**

  Due to the short duration of the program, no evaluation has been carried out yet.

- **Were results useful as expected?** idem
- **How the results are exploited? E.g. how findings are used?** idem
- **Benefits from the nuclear safety point of view ? Safety enhancement?** idem
- **Any follow-up system?** idem
- **Strengths and weaknesses?** idem
8. Hints for improvement. Further developmental needs for approach /tool ? Not yet evaluated
9. Organisation, address and contact person (e-mail address) UNESA Human Factors Working Group Coordinator: Luis Peña (lpa@cnat.es) Spain
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   Integrated Management System Guideline
2. **Scope and Purpose. For which end the approach / tool is used?**
   Operation of a nuclear power plant is a complex system that has to be managed integrated. The purpose of the guide is to establish common criteria among the Spanish Nuclear Plants for their Integrated Management System (IMS).
3. **Brief description of the approach (200 words maximum)**
   The structure of the IMS follows the PDCA cycle: Plan, Do, Check, Act through a proper Organization. A short description of each element follows:

   Organization

   1. Structure, Functions and Resources: Criteria. Functions that can be delegated.
   2. Interphases
   3. Human factors organization and programs.
   4. Safety analysis of organizational changes
   5. Comunication

   Plan

   1. Definition of Mission, Vision, Values and Policies General requirements
   2. Investment Plan: Detection of the need, Analysis (including priorities), Approval and Planning.

   Do

   Process management approach, based on NEI Standard Model and including Indicator System.

   Check

   Evaluation System: External Assessment, Internal Independent Assessment, Self Assessment.

   Act

   Preventive and Corrective Action Program

When measurements are involved, please specify required techniques
4. Status (in use / published method / piloted / under development / ...) The guide is under development. It is expected to be finalised in 2004 and fully applied in 2005. Many portions of the guide are already in operation. Main pending issues are: Procedure to establish priorities for Investment: End of 2004. Process management approach: At several stages at each plant. Self Assessment and Corrective Action Programs: In trial use till April 2004.
- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**
- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?** The guide includes elements based in WANO Self Assessment and Corrective Action Guidelines, NEI Standard Process Performance Model and own developments.
- **How is it validated? Is there any qualification or checking done?** Typically each portion of the guide is first subject to a pilot project for validation. Once in operation, each activity is subject to periodic evaluation (independent or self assessment)
5. Application process
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?** All the activities included in the guide require significant resources. These resources are not evaluated because most of them are already required before the existence of the guide.
- **Any detail or examples?**
- **Information system requirements?** Data bases are required for the Corrective Action Plan and for the Process Management.
- **Is it usage restricted? What kind of restrictions?**
6. Experiences
- **Type of results obtained**
- **Were results useful as expected?**
- **How the results are exploited? E.g. how findings are used?**
- **Benefits from the nuclear safety point of view ? Safety enhancement?**

- **Any follow-up system?**
- **Strengths and weaknesses?**
7. Hints for improvement. Further developmental needs for approach /tool ?
8. Organisation, address and contact person (e-mail address) Almaraz – Trillo Nuclear Power Plant, José M. Zamarrón jmz@cnat.es Spain
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. **Present needs and challenges in Safety Management / Management of Safety**
   - During the NEA/SEGHOF workshop on safety management, which was held in Paris in April 2002, a set of recommendations for future work was identified. They were structured in six main areas: 1) Operating experience, 2) Indicators and Diagnosis, 3) Intervention and Improvement Tools, 4) In-depth research for specific issues, 5) Regulatory activities needs and 6) Other fields experience as related to nuclear safety. (See workshop report for details).
   - To establish a common understanding of the concept.
   - To identify the relationships between safety management and traditional management systems.
   - To incorporate human and organisational factors in safety management systems.
   - To integrate safety management and safety culture
   - To update safety management systems with modern scientific approaches.

- **What should be developed or done? For what purpose is needed?**
  - Infrastructures needed to cope with those needs and challenges should be created in each country. This includes utilities, regulatory bodies and research centres.
  - Those infrastructures must include not only pure technical people, but also specialists in social disciplines.
  - It is needed because the organisations have to monitor and control in a reasonable way the impact that no technical issues have on nuclear safety.

- **How and who should take care?**
  - All organisations with any type of responsibility on nuclear safety have a role to play in developing appropriate safety management systems.

- **Any further suggestions on how to apply available knowledge to Safety Management?**
  - To set up a NEA international R&D program on Safety Management. There are utilities in different countries moving in the use of state of the art management approaches and they are carrying the whole burden of these pioneering applications. A cooperation among countries (including utilities, regulators and other support organizations) will ease this implementation. The NEA may find a role to play here. Except for Halden, the NEA has no project in the topic of Human and Organizational Factors, while recognizes its high importance.
  - Co-operation with IAEA in this matter is essential.

2. Contact person (name, address, e-mail address): - Benito Gil (Spanish Nuclear Safety Council, CSN) (PSA and Human Factors Division) - C/ Justo Dorado, 11, 28040 Madrid - E-mail: bgm@csn.es
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. Present needs and challenges in Safety Management / Management of Safety

- **What should be developed or done? For what purpose is needed?**

  <u>Knowledge Management Systems</u>.
  To address the problem of knowledge losses due to early retirement or aging work force.

  <u>Change Management Systems towards Learning Organizations</u>

  Moving towards a Learning Organization is a must for any today's Organization. Some characteristics of Nuclear Plants makes them less open to change, so specific efforts are required. They could be: guide lines, work shops, training, benchmarking with non nuclear organizations etc.

- **How and who should take care?**

- **Any further suggestions on how to apply available knowledge to Safety Management?**

2. Contact person (name, address, e-mail address):
Almaraz – Trillo Nuclear Power Plant, José M. Zamarrón jmz@cnat.es
Spain

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Appendix 3.g): Responses from Sweden

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)
SKI, Sweden

2. Are there regulatory requirements of any sort on the utility management system?

- Swedish legislation requires that those who have specific permits to carry out nuclear activities also bear full and sole responsibility for taking all necessary actions to achieve safety. This responsibility extends to ensuring conformity with non-proliferation requirements and to ensuring that all spent nuclear fuels and nuclear waste products are processed and disposed of in a safe and secure way. The requirement in the Law on Nuclear Activities (1984:3) that licensee take all measures necessary to achieve safety includes organisational measures as well as technical measures. As a consequence, SKI:s regulatory supervision/oversight must cover both types of measures.
- The regulations concerning safety in certain nuclear facilities issued by SKI in 1998 (SKIFS 1998:1) have requirements and general recommendations on the utility management system and processes.
- SKI:s operational supervision requires that the licensees carry out self-assessments to ensure that all requirements are met, and that good practices and problem areas are identified and resolved. The regulatory strategy thus requires the licensee to have a management system and processes in place to ensure safe performance and demonstrating how he/she takes the responsibility as a licensee and learn from experience.

- **If yes, status and content of requirements (describe here or attach documents)**
  The regulations concerning safety in certain nuclear facilities (SKIFS 1998:1)
  In particular the following chapters and paragraphs:

Chapter 2 Basic Safety Provisions

3 § The licensee of a nuclear facility shall

1. establish documented guidelines for how safety shall be maintained at the facility as well as ensure that the personnel performing duties which are important to safety are well acquainted with the guidelines,
2. ensure that the activity carried out at the facility is controlled and developed with the support of a quality system which covers those activities which are of importance for safety,
3. ensure that decisions on safety-related issues are preceded by adequate investigation and consultation so that the issues are comprehensively examined,
4. ensure that adequate personnel is available with the necessary competence and of the suitability otherwise needed for those tasks which are of importance for safety as well as ensure that this is documented,

5. ensure that responsibilities and authority are defined and documented with respect to personnel carrying out work which is important to safety,
6. ensure that the personnel is provided with the necessary conditions to carry out work in a safe manner,
7. ensure that experience from the facility's own and from similar activities is continuously utilized and communicated to the personnel concerned,
8. ensure that safety, through these and other measures, is maintained and continuously developed.

4 § The quality system, in accordance with 3§ point 2, shall be kept up-to date and documented in a quality manual or similar document. The routines and procedures necessary for the control of those activities which are important to safety shall be added to this document.

The application, suitability and effectiveness of the quality system shall be systematically and periodically investigated by a quality assurance function which shall have an independent position in relation to those activities which are to be audited.

2 § Design principles and design solutions shall be tested under conditions corresponding to those which can occur during the intended application in a facility. If this is not possible or reasonable, they must have been subjected to the necessary testing or evaluation with reference to safety.

3 § The design solutions shall be adapted to the personnel's ability to, in a safe manner, manage the facility as well as the abnormal events, incidents and accidents which can occur.

4 § Building components, devices, components and systems shall be designed, manufactured, installed, controlled and tested in accordance with requirements which are adapted to their importance for safety.

CHAPTER 4. ASSESSMENT AND REPORTING OF THE SAFETY OF FACILITIES

Safety Analysis

1 § Analyses of conditions which are of importance for the safety of a facility shall be carried out before a facility is constructed and taken into operation. The analyses shall subsequently be kept up-to-date. The safety analyses shall be based on a systematic inventory of such events, event sequences and conditions which can lead to a radiological accident.

Safety Report

2 § A preliminary safety report shall be prepared before a facility may be constructed. A final safety report shall be prepared before the facility may be taken into operation. The safety report shall contain the information specified in Appendix 2. Furthermore, the final safety report shall cover the Technical Specifications specified in Chapter 5.1 § first paragraph. Before the facility may be constructed and taken into operation, the safety report shall be reviewed in accordance with 3 § as well as evaluated and approved by the Swedish Nuclear Power Inspectorate. The safety report shall subsequently be kept up-to-date. Appendix 2 specifies the information of the safety report. One requirement applies to the operation of the facility and states: "A

description of the organisation and principles for operational control, for control room work, for maintenance and for the management of nuclear material and nuclear waste. A description of the organisation and principles of safety work and quality assurance. A description of organisation and of the principles for emergency preparedness."

Safety Review

3 § A safety review shall determine or control that the applicable safety-related aspects of a specific issue have been taken into account and that appropriate safety-related requirements with respect to the design, function, organization and activities of a facility are met. The review shall be carried out systematically and shall be documented. A safety review shall be performed within the parts of a facility's organization which are responsible for the specific issues as well as within a safety review function appointed for this purpose which shall have an independent position relative to the parts of the organization which are responsible for the specific issues.

Safety Programme

4 § After it is taken into operation, the safety of a facility shall be continuously analyzed and assessed in a systematic manner. Any need for safety improvement measures, engineering as well as organizational, which arises as a result of such analyses and assessments, shall be documented in a safety programme. The safety programme shall be updated on an annual basis.

Periodic Safety Review of Facilities

5 § At least once in every ten years, a new, integrated analysis and assessment of the safety of a facility shall be made. The analyses, assessments as well as the measures proposed on the basis of these shall be documented and submitted to the Swedish Nuclear Power Inspectorate.

Modifications

6 § Engineered or organizational modifications to a facility which can affect the conditions specified in the safety report as well as essential modifications to the report shall be reviewed in accordance with 3 §.

Before the modifications may be introduced, the Swedish Nuclear Power Inspectorate shall be notified and the Inspectorate can decide that additional or other requirements or conditions shall apply with respect to the modifications

General Recommendations

On Chapter 2. 3 §

Point 1: Guidelines for safety are the safety policy and the safety goals which determine the direction of safety-related work as well as a strategy describing how the goals are to be attained. The safety policy should be tangible and demonstrate a high level of ambition with regard to prioritizing safety. The safety goals may be both quantitative and qualitative. The goals should be formulated so that they can be followed up.

Point 2: In order be certain that the quality system covers activities which are important to safety, the scope should not be too narrow. The IAEA's code and guides for the quality assurance of the safety of a nuclear power plant and other nuclear facilities can provide guidance for the design of the qualityassurance system which is necessary for safety3.
3 At present: IAEA Safety Series No. 50-C/SG-Q. Vienna, 1996

In connection with the design of the quality system, all of the processes relating to the organization as a whole which are of importance for safety should be taken into particular account. One example is plant modification which usually involves several departments in the facility's organization. The overall processes make particular demands on co-ordination, on an unambiguous division of responsibilities and authority etc.

Point 3: In order to ensure adequate investigation and consultation, in addition to the provisions of Chapter 4. 3 §, a safety committee should be established with the aim of functioning as an advisory group with respect to safety-related issues. The committee members should have a high level of integrity and broadly-based expertise in nuclear safety-related issues.

Point 4: In order to ensure the availability of personnel with adequate competence, competence and staffing plans should be prepared for several years in advance. In order to analyze the need for personnel and the competence that is needed in the activity, a systematic method should be used. Such a method is normally based on analyses of the tasks which must be carried out in order to ensure that a high level of safety is maintained in the activity. In the light of such analyses, staffing and competence requirements as well as training needs are analyzed. The training needs determine the preparation of training programmes and training materials. The method also requires course evaluation, following the completion of training, for the purpose of quality assurance. In order to ensure that the personnel has adequate competence, a systematic competence follow-up should also be carried out. The purpose of this follow up is to ensure that the personnel has the competence required for the tasks as well as to carry out an inventory with respect to additional training and continuing education. In order to fulfill these aims, the follow-up should be conducted with explicit criteria regarding acceptable performance. The competence follow-up should, with regard to tasks of importance for safety, be carried out on an annual basis. In order to develop and maintain adequate competence within the organization of the facility, the advantages and disadvantages of using in-house personnel should be weighed against those of using sub-contractors and other hired personnel, with respect to tasks which are of importance for safety.

The necessary competence should always be maintained within the facility's organization in order to be able to order, manage and evaluate the result of work which is of importance for safety and which is carried out by subcontractors or other hired personnel. For personnel to be evaluated as otherwise suitable, an analysis must be carried out of the medical demands of various tasks which are of importance for safety, i.e. with regard to keenness of vision, ability to distinguish colours and hearing ability. A documented policy should also exist for the handling of different factors which can affect the performance of the personnel in a way that is important to safety, for example, alcohol and other drugs. Such a policy should include tests of the personnel

and measures to be implemented when personnel are found to be under the influence of alcohol or drugs or in the event of abuse. The division of responsibilities for such measures should be clarified and supervisors and other affected personnel should be given training, with respect to these issues.

Point 5: The documentation of responsibilities and authority is a basic requirement within the framework of a quality system. The Swedish SS-ISO 9001 standard states that responsibilities, authority and conditions for cooperation should be defined for all personnel leading, carrying out and verifying work which has an impact on quality. This particularly applies to personnel which must have organizational freedom and the authority to initiate measures, identify problems, initiate, recommend or provide solutions, verify solutions as well as decide on measures to be adopted until the deficiencies or unsatisfactory conditions have been corrected. These guidelines can provide guidance with respect to defining which personnel should be covered by the requirements of the regulations. In those cases where a category of personnel carries out similar tasks of importance for safety, it is sufficient to define responsibilities and authority for this category.

Point 6: A number of different factors at work affect people's ability to function. This includes the layout of the workplace, equipment and aids as well as the physical environment, how work is supervised, organization and procedures, communication with others, the workload and working hours etc. The correction of any deficiencies in the conditions for work which can have a detrimental impact on safety, is an important part of the preventive safety-related work. For these purposes, analyses of the man-technology-organization interaction (human factors) should be carried out as well as recurrent evaluations performed.

Point 7: Efficient procedures should exist for continuous experience feedback within all of the parts of the organization carrying out tasks which are of importance for safety. In the light of experience gained, it should be continuously investigated whether the facility and its activities comply with the applicable conditions and regulations.

Point 8: The possibility of improving safety should be taken into account in every measure resulting in modifications to the facility or in the activities carried out. This particularly applies in the case of engineered modifications, modifications to operating conditions, organizational modifications and rationalizations. To meet the requirement on maintaining safety, all of the consequences of a modification should be analyzed, so that an improvement in safety in one respect does not lead to a deterioration in safety in another respect, in such a way that the level of safety as a whole is degraded. To meet the requirement regarding the development of safety, results from applicable research and development should be successively incorporated into the activity.

On Chapter 2. 4 §

The quality assurance function should be given an adequately strong and independent position in the organization and should be directly subordinated to the highest manager of the facility. With respect to quality audits, continuity should be maintained and this work should be conducted by people who have a good knowledge of the activity which is being audited. Recurrent quality audits are normally audits conducted at four year intervals. When determining a suitable interval, the importance of the different activities for safety and the specific auditing needs which may arise should be taken into

account. The audit activity should be organized and used to ensure that it contributes in the best way possible to the development of safety at the facility. The quality assurance function and the facility management should also periodically be subjected to quality supervision and quality audits, conducted by individuals who are independent from the activity which is being audited.

On Chapter 4. 2 §

In general, a safety report should be of good quality and it should be possible to evaluate all parts of the report. This means that the report should be structured in a logical manner with a clear structure. The preconditions and methodology should be adequately described with clear references to all of the data. The report and its underlying data should be documented so as to enable the report to be effectively kept updated and available.

On Chapter 4. 3 §

In order to fulfill the requirement on a comprehensive review, the safety review should comprise a review of technical factors as well as a review of the man-technology-organization interaction (human factors). Thus, personnel with technical competence within the areas in question as well as personnel with competence in behavioral sciences should participate in this work.

The primary safety review should always be carried out within the part of the organization which is responsible for a particular safety issue. This review of a specific issue should be as comprehensive as possible and should not take into account the fact that there will also be an independent safety review. The independent review should, in the light of how an issue has been handled within the responsible parts of the organization, determine whether the applicable safety aspects have been taken into account and whether applicable safety requirements are fulfilled. Thus, an evaluation should be made of whether the analyses upon which the reported conclusions are based have been carried out with the adequate depth and adequate technical quality. Thus, the intention of an independent safety review is largely to evaluate or control that an issue has been handled in a satisfactory manner from the standpoint of safety and is not intended to be a repetition of the primary safety review of the specific issue carried out by the responsible part of the organization. This also means that a safety issue, including the primary safety review, which will be subjected to independent review, should be documented in such a way that it can be reviewed by another party. In order to be able to fulfill its duties in the necessary manner, the independent function for safety review should be given a sufficiently independent position, in relation to the parts of the organization that are responsible for specific issues. Normally, the independent function should be subordinate only to the highest manager. In order to maintain this independent function, its personnel should not participate in work on analyses or investigations of issues as long as such work is being handled within the responsible organizational parts. If the operation of a facility is contracted out to a third party in accordance with 5 § of the Act on Nuclear Activities, the licensee should clarify and report to the Swedish Nuclear Power Inspectorate how the functions of primary safety review as well as independent safety review are allocated between the licensee and the contractor, for the different cases where safety review is to be carried out in accordance with the requirements of these regulations.

On Chapter 4. 4 §

In the ongoing work with safety programmes, technical and organizational experience from the facility's own activities, experience from similar facilities, results from ongoing safety assessment, research results which may be important for safety assessment as well as the development of such norms and standards which are used in connection with the construction or operation of the facility should be particularly taken into account.

3. **Does the regulatory body assess the management system of the utility?**
   Yes

   - **If yes, description of the approaches, methods and criteria used in assessment, or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.**

Approaches, methods, criteria

Safety management is by SKI considered to be a part of the quality management of the licensee. SKI reviews the quality management system (the formal system) and inspects how it is applied at work (praxis) both on a general level and in the processes reviewed or inspected in more detail. SKI also inspects the audit process of the licensee, how it is applied, action plans and their results. The regulatory strategy of SKI is process-oriented which means that there is a strong focus on the licensee activities and processes and his capability to maintain and continuously develop safety and non-proliferation. The strategy is described in the quality management system of SKI and is translated and implemented in the SKI processes for e.g. inspection, reviews and safety assessments.
Reviews are made of the quality management system of the licensee (against SKIFS 1998:1 chapter 2 3§ point 2, and 4§). An internal guidance is used in planning and performing the reviews "Strategy and method in assessments of the licensee's quality management system and activities" using the recommendations of SKIFS 1998:1 and IAEA Code and Safety Guides for Quality Assurance (IAEA Safety Series No 50 50-C/SG-Q). The following are examples of criteria used:

- The quality management system is valid for all parts of the organisation and its processes (a uniform common control)
- Safety should be emphasised in the quality management system. Within the quality management system identification and evaluation of deviations should be used for improvements.
- The principles of responsibility and authority are defined and documented
- The quality management system is easy to understand (good structure and terminology)
- Management is accountable for the development, implementation, monitoring and measuring of the quality management system.
- The activities and processes of the organisation should be carried out, evaluated and developed from controlled conditions. The main approach should be problem prevention and continuous improvement in particular in safety matters.
- The processes should be controlled and co-ordinated.

- The quality management system manual should cover all internal and external requirements and further a good overview and understanding of how the activities are controlled and developed.

The licensee shall also present the documents that are used for verifying the activities and processes for example

- deviation reports, action plans and results from follow ups
- logs and checklists
- lists of signed maintenance actions
- how competence requirements and needs are complied with
- improvement plans
- management reviews
- audit results

Inspections are made how the quality management system as it is described at a higher level is transformed into processes and how they are actually applied at work. Some important aspects are licensee verification of a right balance between competence and responsibility and authority among the personnel, evaluation of deviations, management of internal and external audits together with action plans and verification of results, the systematic improvement work as a whole and its effects.
Inspections are also made of the licensee processes in more detail e.g.

- for ensuring the competence and personnel needed,
- for management of plant modifications
- for audits
- for safety reviews of technical, organisational and procedure modifications

The inspections are performed and the findings assessed according to the quality system within SKI. Assessments are made in relation to the requirements. Guidance documents, international rules, standards etc as guidance as well as other well-founded research and praxis are used as tools during the assessment.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

The Swedish Nuclear Power Inspectorate´s Regulations Concerning Safety in Certain Nuclear Facilities SKIFS 1998:1 (www.ski.se**)**

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   NILS, Nuclear´s Integrated Management System for Quality, Safety, the Environment and Working Conditions.

2. **Scope and Purpose. For which end the approach / tool is used?**
   NILS is the tool for Studsvik Nuclear AB to meet the demands in the authority regulations, the Swedish Nuclear Power Inspectorate and the Swedish Radiation Protection Authority, in the standards, ISO 9001, ISO 14 001 and AFS:2000, and in the own organization.

3. **Brief description of the approach (200 words maximum)**
   The integrated management system, NILS, is a means for the Studsvik Nuclear AB company to live up to its safety, quality, environmental and working-condition policies. The management system aims at making it possible to meet the set goals, and it should ensure that demands from customers, authorities, employees, the general public, the internal organization and other concerned parties are all met. Programs are defined and resources are allocated to achieve the goals. The system is a learning system and has the demand in the organization to lead to continuous improvements.

4. **When measurements are involved, please specify required techniques**
   The management reviews NILS twice a year. The inputs to evaluate the efficiency and the effectiveness of the system includes: status and results of safety objectives and improvement activities, status of management review actions, result of audits, status of preventive and corrective actions, and recommendations for improvements.

5. **Status (in use / published method / piloted / under development / ...)**
   In use

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?** NILS was internally developed and was implemented in the organization 2000.
- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?** NILS was implemented in the organization by the staff and the QA organization.
- **How is it validated? Is there any qualification or checking done?** NILS is validated at the management reviews and the checkpoints are to meet the requirements of the organization and to meet the set requirements of continuous improvements.
6. Application process
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?** NILS is actively used in all levels in the organization.
- **Any detail or examples?** **-**
- **Information system requirements?** **-**
- **Is it usage restricted? What kind of restrictions?** **-**
7. Experiences
- **Type of results obtained** The status of the safety programs are followed and known by the management.
- **Were results useful as expected?** The management uses the results to develop safety questions and affect organization.
- **How the results are exploited? E.g. how findings are used?** New safety programs are set up.
- **Benefits from the nuclear safety point of view ? Safety enhancement?** **-**
- **Any follow-up system?**
- **Strengths and weaknesses?** Strength: the whole organisation is activated in the safety work.

8. Hints for improvement. Further developmental needs for approach /tool ?
9. Organisation, address and contact person (e-mail address)
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

OECD/NEA Questionnaire: "Management of safety

Part B – Information on specific developments, approaches, tools and methods

1. Title of the approach

FKA apply a Total Quality Management (Oakland (1989), Dahlgaard, Kristensson, Kanji (1992) and others) system where safety requirement and other business requirements are integrated. Nuclear safety requirements are based on Swedish laws and IAEA Safety Series 50-C/SG-Q. The first version of the applied TQM-system was introduced in the early nineties, by the CEO at that time.

Technical safety requirements are documented in the SAR (Safety analysis report) and in the PSA (Probabilistic safety analysis).

2 Scope and purpose

The TQM-system encompasses all activities at the power plant. The system also defines responsibility for safety as well as for the business results. It describes and put demands on all activities performed.

The purpose is to achieve quality at low costs and to achieve continuous improvement. Another goal is that quality and efficiency matters shall engage all employees.

3. Brief descriptions

The quality management system consists of a binder that has 5 sections:

1. Management and control
2. Organisation
3. Quality requirement
4. Each units response to the quality requirements
5. Updates and distribution

The management and control part of the Quality manual describes the structure of the company, the business vision and concept, management philosophy and the policies applied.

The organisational part of the Quality manual describes the distribution of responsibility, operations and work management, safety management, delegation of responsibilities, authorities and delegation of authority and finally the organisational chart.

The third part of the Quality manual, which is the main part, contains detailed requirements divided by units (i.e. the three production units, the support unit, the technical unit, the maintenance unit, the personnel unit, and the four staff units.

The fourth part of the Quality manual contains a response from each unit. An explanation is written, for each individual and detailed requirement given in section three, describing how the requirement is met and which procedures are written in order to fulfil the requirement.

The fifth part of the Quality manual describes how changes in the manual are made and to whom the manual is distributed. It also contains a procedure for evaluating policies issued by the combined group of companies to which FKA belongs.

4. Measurement

The Quality manual stipulates the safety and technical deviations are reported at specific meetings. The reporting goes through the line management of operation, from the operators to the CEO, who is the highest level of operations management.

Besides reporting, all changes are reviewed primarily by the units and independently by an independent staff unit, organised directly under the CEO.

Audits are performed in order to check the conformity to the requirements in the Quality manual. The auditing scheme applied follow the principles of the quality system audit as delineated in ASME NQA adapted to the quality assurance requirements defined in the ISO 9001, 9002 and 9003.

Yet another measurement method in use is enquiries. An enquiry dedicated to safety culture is performed annually. It contains around 60 questions. This enquiry has so far been performed two times. Another enquiry is shared with other companies belonging to the same group of companies as Forsmark. This enquiry is performed every second year and more devoted to work satisfaction, leadership and management. It has been performed two times after replacing an earlier type of "working environment enquiry". Both the safety culture enquiry and the work satisfaction enquiry are thoroughly evaluated and discussed on all levels within the company. Action plans are made in order to improve the results.

When incident occur or when organisational changes shall be made, a so-called MTO (Man-Technology-Organisation) investigation is performed. The MTO methodology is very good in finding barrier functions that are either to week or missing. The methodology is described in several international papers.

5. Status

The system has been in use since 1991. A team, working under the leadership of the CEO at that time originally developed the system. The system is based on the TQM concept, se above.

The general principle of the system is still kept, although the contents in each section and subsection of the manual have developed over time. The Quality manual is continuously developed, partly because the general environment in which the company exists changes, partly because the safety requirements changes and also because the business concept changes. FKA has of today no plans to change the principles of system.

The Quality system is validated through e.g. benchmarking activities, both within the nuclear industry and to other companies and enterprises. One example is the ongoing EU-project LearnSafe in which FKA participate together with all other Swedish nuclear utilities and some Finnish, German, British and Spanish utilities and research centres.

Within recent years several benchmarking activities have been performed. Another validation methodology is to participate in seminars and conferences on TQM, e.g. the Swedish Quality Price and others.

6. Application process

The Quality manual is a CEO-responsibility. The CEO approves all changes. The staff unit for Nuclear Safety and Quality and Environment has as a duty to make sure that all required safety and legal demands put on FKA as a licensee are incorporated in the manual. Likewise other staff units make sure that other business or policy demands are incorporated, e.g. the business development staff make changes in order to make the company more efficient.

The Quality manual is a line management tool. The implementation of the requirements is reported in section four of the manual. This section is the used by the auditing teams when auditing is performed. Although the Quality manual may not be a book which the line management consult every day, it is used frequently. Updates are made several times per year.

The Quality manual does not require any information system support but the manual is available for everybody through the company Intranet. There are no usage restrictions but it is primarily a management tool.

7. Experiences

A very positive thing about the Forsmark Quality manual is the strict and clear safety responsibility that it imposes on the organisation.

The requirement that each unit needs to write its own chapter in reply to the requirements creates a positive participation in the system. Unit managers and their staff become very much involved and engaged in the quality system and management of the power plant. We are convinced that the major strength of our system is the participation.

In order to keep the Quality manual updated much work needs to be devoted by primarily the staff units. If the manual is not updated it will quickly lose its usefulness and non-documented routines will appear within the organisation. This implies that the quality system as well as the manual needs continuously work. A negative experience is the long time it takes from an initial change, e.g. change of a responsibility, until the quality answer in chapter four has been updated. The time from the initial change until finalisation can be as long as one year.

8 Hints for improvements

The participation in the updating process of the Quality manual could be improved.

The time from idea to changes in all relevant chapters could be shortened.

The use of the Intranet version of the Quality manual as reference and support could be increased.

9. Organisation addresses and contact person

Forsmarks Kraftgrupp AB

SE 742 03 ÖSTHAMMAR
SWEDEN

Olle Andersson, +46 173 81367, oas@forsmark.vattenfall.se

Björn Johansson +46 173 81055, bjn@forsmark.vattenfall.se

LearnSafe has an open web-site: www.vtt.fi/virtual/learnsafe

An example from the FKA Quality manual is enclosed. This English version is not the latest update but it illustrates the outline of the document

Titel

MANAGEMENT AND QUALITY HANDBOOK

2 ORGANISATION

Dokumentnamn	Nr / Utgåva	Tillägg
LOK 2.3	Beteckning/System	
Utskriftsdatum	Kontor / Sign	
Giltig	från beslutsdatum ☐	
Ersätter		
Utfärdare/Handläggare	Sign	

Sökord	Tillstyrkt	Samråd etc/Tagit del
Hänvisning till följande dok	Godkänt/Fastställt	Datum

Ärende

2.3 SAFETY MANAGEMENT

Contents

Appendix

Delgivning

Enligt särskild delgivningslista

Noteringar etc	Antal textsidor	Antal bilagor	Antal bil-sidor
	7	1	1

1. RESPONSIBILITY

As the formal holder of permission to operate the plant (licence-holder), and in his/her capacity as part of the most senior management, the Managing Director (MD) of Forsmarks Kraftgrupp AB is responsible for ensuring that the plants are operated safely and in accordance with the prescribed regulations. Operational management responsibility to the Managing Director is defined in two levels for the various parts of the plants (see LOK 2.2). When the Managing Director or other members of the operational management are not available, the necessary authorities will be delegated to special deputies.

2. THE REVIEW STRUCTURE

The Managing Director of Forsmarks Kraftgrupp AB performs safety reviews within the line organisation in the form of safety surveillance, independent examination and technical examination. In addition to the line organisation, the Managing Director convenes a special Safety Committee for dealing with important safety matters and those involving matters of principle (see Appendix).

2.1 Safety surveillance

Operational management is responsible for the safety surveillance of the plants in the short and the long term. The operational management is also responsible for the performance of the primary safety review.

Operational management Level 3 exercises direct surveillance to ensure that the plants are being operated in accordance with the applicable instructions and the Technical Specifications. Any deviation from the Technical Specifications or any other deviations that can have safety implications shall be reported to the next higher level of operational management.

Operational management Level 2 is responsible for the more long-term surveillance of safety in the various parts of the plant, as well as for reviewing decisions taken at lower operational management levels. This responsibility also includes development of safety regulations and safety reports, as well as monitoring non-compliance's, trends and experience. Any deviations from current regulations, standards or policies shall be reported to the most senior level of operational management.

Operational management Level 1 has overall responsibility for ensuring that safety surveillance operates as intended, as well as for review of decisions taken at lower operational management levels. This responsibility also includes the issue of policies and guidelines for safety work, as well as approval of deviation from them.

2.2 Independent safety reviewing

2.2.1 The Safety Unit

The Safety Unit is responsible for on-going independent safety reviewing. Independent from direct production, it checks compliance, non-compliance and deviations from current regulations and standards. This applies particularly to modifications to the plant, modification to the organisation, working methods or regulations, as well as to the collecting of experience.

The Safety Unit also supports the Managing Director in his/her role as the formal holder of the operating licence and as the person responsible for overall safety reviewing. This role also includes a responsibility for the structure of the safety analysis report and those new safety requirements are decided and documented. The role also includes implementation of new safety requirements and monitoring by means of regular quality audits.

2.2.2 The Safety Committee

The Managing Director or his/her deputy shall regularly (about twice a month), and at other times when necessary, convene a special committee, the FKA Safety Committee, for consideration of important matters of safety and those related to safety principles (in accordance with Item 3.4). The Managing Director is chairman of the committee and shall require those persons necessary for comprehensive discussion of matters to attend the committee. The minutes of decisions taken by the committee form part of the monitoring and audit material submitted to the regulator.

If the opinion of the body of the committee, when dealing with a safety matter, differs from that of the chairman, the chairman shall act in such a way as he/she feels is in the best interests of safety. In such cases, the matter shall be reported to the surveillance authority without delay.

2.3 Special reviewing

As part of his/her authority, the Managing Director can call for independent external third party reviewing of specific matters or of activities in more general terms.

2.4 Technical reviewing

The Technical Unit is responsible for specialised technical assessment of questions and matters within its assigned area of specialised responsibility. This ensures that the company's technical expertise, over and above that of the production units and the Safety Unit, is applied to safety technical matters.

With the assistance of appropriate methods of analysis, the safety reviews of the technical unit are concerned primarily with assessment of trends, modifications/changes and non-compliance's with regulations, instructions etc.

The maintenance department shall support the management responsible for the operation with qualified judgements on technical, methodological and safety related important matters.

3. MEETINGS

3.1 Shift changes

Hand-over between off-going and on-coming operational shifts constitute a formal part of the material subjected to the operational management's safety surveillance. As each shift hands over to the next shift, the off-going shift in-charge engineer shall notify events, observations and actions of safety importance for continuing operation of the plant or for the work of the on-coming shift. The shift in-charge engineer's log constitutes formal documentation for the transfers from each shift to the next.

If the assessments of the off-going and on-coming shift in-charge engineers differ in respect of some safety matter notified in connection with changing the shifts, this shall be noted in the log and the matter shall be reported to operational management.

3.2 Daily operational reviews

On each weekday, or as necessary, the operational management of each block shall call the charge personnel to a daily operational review. These meetings shall discuss events that have occurred, completed measures and planned measures concerned with operational or safety aspects occurring in the period between the previous and next meetings.

The minutes of these daily operational reviews shall be circulated to all units within the block and to involved units outside the block.

Operations management Level 2 may summit an operational meeting in order to discuss principally important matters as part of the primary safety review process. At this meeting is the line organisations standpoint and the decision made by the operations management level 3 reviewed.

Minutes from the operational meeting shall be distributed within the unit, other units as well as to the technical and safety departments.

3.3 Production meetings

On the first working day of each week, the most senior operational management shall call a meeting of the entire operational management structure, the engineer on call and representatives of the Safety and Technical Units. At this meeting, the operational management of each block shall describe reported events and completed and planned work having operational, safety or environmental aspects for the previous week and the coming week.

Safety-related matters notified to the meeting will be evaluated and the response of the operational management concerned will be assessed. In addition, an assessment will be made of whether the Safety Committee should discuss the matters presented at the meeting. The minutes of the production meetings shall be copied to operational management and to representatives of other units attending the meeting.

3.4 The FKA Safety Committee

The duties and working procedures of the Safety Committee are described in the Section entitled 'Review structure' (Item 2).

The safety matters to be considered by the committee are as listed below:

- operating conditions, trends and experience,
- start-up after shutdowns,
- events in category 1, 2 or 3 and scrams,
- modification's to the plant and working methods,

- test and experimental programmes,
- changes to the Technical Specification or in the Safety Analysis Reports (FSAR),
- measures requiring approval by the surveillance authority,
- recommendations from Vattenfall AB's Safety Committee,
- changes to the company's safety policy,
- development of safety work,
- changes in the emergency preparedness planning, security system and the fire brigade organisation and
- changes in the organisation that are important to safety.

Minutes of the meetings of the Safety Committee shall be circulated to the surveillance authorities, operational management, the Safety Unit, the Technical Unit and to other persons present at the respective meetings.

4. REPORTING

A wide spectrum of safety reviewing at several levels requires open and systematic reporting not only of normal activities, changes and non-compliance's, but also of events that have occurred. Safety reporting is often defined in regulations or instructions. However, a properly working safety reporting function requires additional reporting which be not and which cannot be, defined down to the last detail. This latter reporting, often determined by events, is based more on knowledge and understanding of the review structure.

4.1 Reporting forms

Reporting occurs in a multiplicity of forms and variants. The following is a description of reporting associated with the review structure.

4.1.1 Operational management Level 3

Operational management Level 3 performs the direct safety surveillance of operation of the plants. Its reporting for this purpose is provided by the direct operational documentation and by special discussions with or information from, the shift in-charge engineer. This level report non-compliance's, trends and experience to Level 2 for more long-term safety surveillance and for review/confirmation of its decisions. Minutes from the operational discussions constitute daily information to the next higher level of operational management, to the Safety Unit and to the Technical Unit.

4.1.2 Operational management Level 2

Operational management Level 2 reports deviations and changes to Level 1 for the overall safety surveillance and for review/confirmation of its own decisions. Trends, experience, disturbances and other events are documented in special reports that form input material for the independent safety review and the technical review. In particular, they provide a basis for presentation of material to the Safety Committee.

Operational management Level 2 reports detected, reportable conditions to the surveillance authority.

4.1.3 Operational management Level 1

Operational management Level 1 has overall responsibility for ensuring that safety surveillance works. Decisions in this capacity are documented in the form of minutes from production meetings and from the Safety Committee meetings.

The Board of FKA is kept informed of the safety status at the plants through the normal activity reporting. It considers events that have occurred and which are of more serious or principal safety significance, such as significant deviations from the company's safety policy.

Reporting to the surveillance authority is in the form of minutes from the meetings of the Safety Committee, special presentations and applications for operating permissions etc. Presentations to, and contacts with, the surveillance authority are co-ordinated by the Safety Unit.

4.1.4 The Safety Unit

The Safety Unit reports safety works developments to the Managing Director in its capacity of staff support to the Managing Director. The unit submits reports concerning matters falling within the remit of safety surveys to operational management Level 2.

The Safety Unit documents and reports audits and other safety-related monitoring to its superior and to other units directly concerned.

4.1.5 The Technology and Maintenance Units

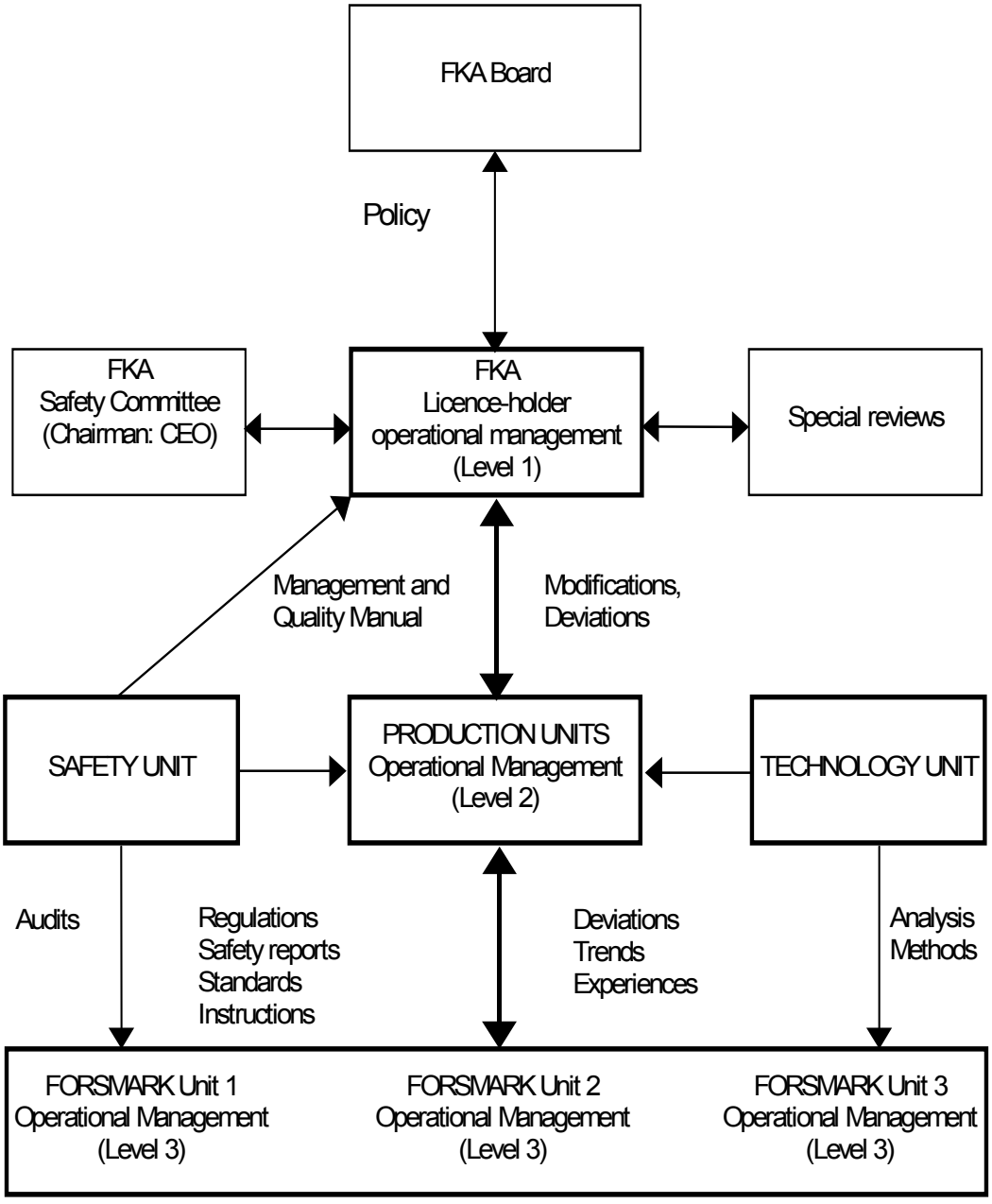
Assessments, analyses and investigations carried out by the Technology or Maintenance Units are documented as special technical submissions or reports. The reports are copied to operational management concerned and to the Safety Unit. More extensive investigations shall be circulated for comments and be reviewed as required.

5. ORGANISATIONAL CHANGES

When technical or organisational changes, that are of a principal significance for the management and control of the operations, maintenance, handling of nuclear materials, work that concerns nuclear safety and quality assurance as well as the plans for the emergency preparedness planning.

No changes of the above mentioned nature are allowed to be put into action until they have been notified to the regulator.

SAFETY MANAGEMENT



Westinghouse Proprietary Class 2

Westinghouse Atom AB
SE-721 63 Västerås
Sweden

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Reply on Survey on "Safety Management" System

General

Westinghouse Atom AB uses an integrated management system for Quality, Environment and Safety. The system is certified according to ISO 9001:2000 as well as ISO 14001. In terms of safety management, our integrated management system, is established so we shall fulfill the various requirements put forwards on us by our regulators. A key part in our safety management is the safety review committee that reviews manufacturing process changes from a safety point of view. It also reviews the impact on safety of organizational changes, as required by SKIFS 1998:1. Procedures for review of MTO aspects (Interaction between man, technology and the organization) are also being introduced into the management system.

We have judged the questionnaire as focusing on systems for identifying and implementing possible safety improvements. One key area in this respect is our system for continuous improvements, including ways to obtain input for continuous improvements. The general methodology used throughout Westinghouse is CAPs, Corrective Actions Process, which is described below.

Further, the management system states that management should annually decide whether any "Business process self-assessment" is needed or not. This can involve both quality, safety and environmental issues. One such possible method is the peer review in accordance with the guidelines established by WANO, also described below.

PART B

1. Title of approach

CAPs – Corrective Actions Process

2. Scope and purpose. For which end the approach/tool is used?

CAPs is the Westinghouse general process for corrective actions and continuous improvements used for any type of issues including safety and environmental issues. CAPs refers both to the process as well as the software used. CAPs is common to all Wesinghouse sites, i.e. information on issues at any of the sites are available to all Westinghouse employees at all sites.

3. Brief description of the approach

Anyone in the organization can report any issue impacting on quality, environment or safety. Near misses should also be reported. All issues, independent of originator (employee, customer, regulatory, et cetera) should be reported and are then reviewed by a group including the safety manager. Here the significance level of the issue is prescribed and an issue owner is determined. Hereafter follows, if the issue is significant, a causal analysis, determination of corrective actions and finally an evaluation of the effectiveness of the corrective actions.

4. When measurements are involved, please specify required techniques

No specific measurements regarding safety.

5. Status

- How it was acquired and for how long it has been used
- If internally developed – not applicable
- How is it validated? Is there any qualification or checking done

CAPs has been in use at Westinghouse Atom since the end of 2002. It has been in operation at other Westinghouse sites before that. Hence, it is developed by Westinghouse Electric Company in cooperation with other companies, but it is inspired by similar processes at nuclear power plants in the U.S.

6. Application process

- How is it used? Responsible organization? At which organization level
- Any detail or examples?
- Information system requirements?
- Is it usage restricted? What kind of restrictions?

A brief description is given under question 3. Usage and available information on the system is restricted to Westinghouse. It is used throughout Westinghouse Atom at all levels. The system

treats actual incidents, near misses as well as suggestion for improvements. Improvement plans are also introduced to the system.

7. Experiences

- Type of results obtained
- Were results useful as expected?
- How the results are exploited? E.g. how findings are used?
- Benefits from the nuclear safety point of view? Safety enhancement?
- Any follow-up system?
- Strengths and weaknesses?

CAPs has been in usage for too short time at Westinghouse Atom for drawing any definite conclusion. However, the system assures that all issues are taken care of and handled by the right people. For serious issues the system also requires a follow up on the efficiency of taken actions, i.e. an issue cannot be closed without verifying the effectiveness of the system.

8. Hints for improvements. Further development needs for approach/tool?

Westinghouse Atom needs more experience before we can make any definite statements regarding further development.

9. Organisation, address and contact person (e-mail address)

Gunnar Hede, General Manager Quality, Environment and Safety
(gunnar.hede@se.westinghouse.com)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here.

PART B

1. Title of approach

Peer Review

2. Scope and purpose. For which end the approach/tool is used?

The purpose (scope) of the peer review is to compare our operations against nuclear industry "state of the art". The focus is on safety and reliability.

The main objective of a peer review is to identify areas for improvements (AFIs) based on actual observations and other facts obtained during a review. One of the strengths of the process is that any AFIs that are generated are supported by actual facts. By comparing against what is considered world class standards there is an encouragement to raise the bar of performance. It is also an opportunity to take a snapshot of where the organization is and examine any major issues that we may have.

3. Brief description of the approach

The review is performed by senior expertise from throughout the industry (representing customers and suppliers as well other parts of BNFL/Westinghouse).

4. When measurements are involved, please specify required techniques

No specific measurement techniques are involved.

5. Status

- How it was acquired and for how long has it been used
- If internally developed – not applicable
- How is it validated? Is there any qualification or checking done

The first peer review of the operation at Westinghouse Atom is being performed this fall. Several peer reviews have already been conducted within BNFL/Westinghouse successfully.

6. Application process

- How is it used? Responsible organization? At which organization level
- Any detail or examples?
- Information system requirements?
- Is it usage restricted? What kind of restrictions?

Application of the BNFL/Westinghouse peer review process is limited to BNFL/Westinghouse. The peer review looks into all organizational levels.

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7. Experiences
- Type of results obtained
- Were results useful as expected?
- How the results are exploited? E.g. how findings are used?
- Benefits from the nuclear safety point of view? Safety enhancement?
- Any follow-up system?
- Strengths and weaknesses?

The peer review results in several areas for improvement. This means that a wide range of possible safety improvements will be presented to the organization. The experience within BNFL/Westinghouse is positive. However, the peer review is always "owned" by the reviewed organization, which means that the results are not available outside the reviewed organization.

After the review, the review organization determines how to go forward with the suggested improvements. The suggested improvements are incorporated into existing improvement programs. The strength of this method is that it employs people with a vast experience from other nuclear organizations. Hence, it can easily see the various strengths and weaknesses of the review organization. At the same time the review organization determines how to proceed which is a strength (since it means that you are committed to the improvements) and a weakness (there is no external pressure) at the same time.

8. Hints for improvements. Further development needs for approach/tool?

Not possible to draw any conclusions yet.

9. Organisation, address and contact person (e-mail address)

Gunnar Hede, General Manager Quality, Environment and Safety
(gunnar.hede@se.westinghouse.com)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

PART C – NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

1. Present needs and challenges in safety management / Management of safety?

- What should be developed or done? For what purpose is needed?
- How and who should take care?
- Any further suggestions on how to apply available knowledge to safety management?

Both methods presented above are rather new to Westinghouse Atom. Hence, the major challenge is to make these methods as efficient as possible. A review needs to be performed within the next year in order to estimate the value of these methods. From this any further safety management improvements may be decided.

Another challenging area goes back to the fact that most regulatory requirements are based on nuclear power plant operations, i.e. some may not be directly applicable to fuel factories. Hence, it is key to us to continue good cooperation with the other fuel factories within BNFL/Westinghouse in order to continue our safety improvement by learning from each other.

2. Contact person (name, address, e-mail address)

Gunnar Hede, General Manager Quality, Environment and Safety
(gunnar.hede@se.westinghouse.com)

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Appendix 3.h): Responses from Switzerland

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

Swiss Federal Nuclear Safety Inspectorate HSK
Ms. Claudia Humbel Haag
claudia.humbel@hsk.psi.ch

2. Are there regulatory requirements of any sort on the utility management system?

Yes

- **If yes, status and content of requirements (describe here or attach documents)**

  In June 2002 HSK published the Guideline R-17 "Organisation of Nuclear Power Plants" where the expectation of the nuclear safety authority are described – based on the Swiss experience in operating nuclear power plants – which need to be taken into account when defining the organisation, and in particular, when introducing organisational changes to nuclear power plants.

  This guideline considers the fact that, as a result of Switzerland's ratification of the Convention on Nuclear Safety, a quality management system is required for all Swiss nuclear power plants. The guideline outlines structures and processes that should be part of such a quality management system.

  Guideline R-17 formulates the organisation of a nuclear power plant based on a concept of safety management as it is descibed in INSAG-13 "Management of Operational Safety in Nuclear Power Plants".

  The guideline R-17 can be accessed via www.hsk.psi.ch (an english copy is available under http://www.hsk.psi.ch/english/files/pdf/R-017e.pdf)

3. Does the regulatory body assess the management system of the utility?

Yes

- **If yes, description of the approaches, methods and criteria used in assessment,**
  or description of regulatory actions or considerations related to

utility management, changes in organization, behaviour, and other related aspects.

HSK is about to develop an inspection tool (Handbook R-17) which will allow HSK to inspect the utilities' management system based on the nuclear safety authority's expections written in guideline R-17.

The Handbook adresses all the arrangements made by the organisation for the management of safety that are specified in the guideline. For each arrangements (e.g. maintenance) the Handbook outlines:
- its specific requirements (as described in the guideline R-17)
- its rating scale
- inspection questions to assess the requirements
- information carriers in the plant (e.g. management, documents etc.)
- methods to collect data (e.g. interview, document analysis, field observation)

In 2004 HSK will conduct the first inspection with the help of Handbook R-17.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   SAFE

   (Remark: The plants did not have the necessary resources to complete the questionnaire. The answers reflect the regulator's view)

2. **Scope and Purpose. For which end the approach / tool is used?**
   Safety Awareness improvement programme. It adresses all the plant's staff.

3. **Brief description of the approach (200 words maximum)**
   A special programme dedicated to improve the safety awareness of the plants staff is introduced in two swiss NPPs. In order to avoid any fatigue of the programme new ideas are brought in regularly to catch the attention of the staff for safety issues. This ist done by different means like workshops, posters, playing cards, mouse pads, etc.

4. **When measurements are involved, please specify required techniques**
   No measurements.

5. **Status (in use / published method / piloted / under development / ...)**
   In use since several years.

   - **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**
     Developed by plant's staff
   - **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**
     External experts were consulted for special activities like the organization of workshops, etc.

- **How is it validated? Is there any qualification or checking done?** No validation. Feedback by staff.
6. Application process
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?** Organized by plant's management, applied to whole staff.
- **Any detail or examples?**
- **Information system requirements?** no
- **Is it usage restricted? What kind of restrictions?** No restriction.
7. Experiences Appreciated by plant's staff.
- **Type of results obtained** Increased safety awareness
- **Were results useful as expected?** Yes. Safety is recognized as highest priority. Near misses are reported.
- **How the results are exploited? E.g. how findings are used?** Recommendations from staff are evaluated and implemented if appropriate.
- **Benefits from the nuclear safety point of view ? Safety enhancement?** Definitely!
- **Any follow-up system?** System is in continuous improvement.
- **Strengths and weaknesses?** Visible effect with a moderate investement of resources.
8. Hints for improvement. Further developmental needs for approach /tool ?

9. Organisation, address and contact person (e-mail address) Dr. Albert Frischknecht Swiss Federal Safety Inspectorate 5232 Villigen HSK Switzerland frischknecht@hsk.psi.ch
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part B. - INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

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To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   Quality Management System
   compatible with ISO-9000:2000 and IAEA Safety Series 50-C/SG-Q Quality Management

   (Remark: The plants did not have the necessary resources to complete the questionnaire. The answers reflect the regulator's view)

2. **Scope and Purpose. For which end the approach / tool is used?**
   Comprehensive Management System with emphasis on nuclear safety

3. **Brief description of the approach (200 words maximum)**
   All Swiss NPPs introduced Quality Management Systems compatible with the ISO-9000:2000 Standard and the IAEA Safety Series 50-C/SG-Q Quality management.
   Further development goes towards integrated Management Systems and Total Quality Management.
   There are plans that all Swiss NPPs acquire the ISO certificate.

4. **When measurements are involved, please specify required techniques**
   Internal and external audits.

5. **Status (in use / published method / piloted / under development / ...)**
   In use since several years.

- **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**
  Developed by plant's staff, some with external experts.

- **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**

Different levels of Management.

- **How is it validated? Is there any qualification or checking done?** Internationally approved standard.
6. Application process
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?** Plant level. Regular programme.
- **Any detail or examples?**
- **Information system requirements?** For system and information maintenance.
- **Is it usage restricted? What kind of restrictions?** No restriction. Audit results are restricted.
7. Experiences Standardization, improved transparency of processes.
- **Type of results obtained** Better traceability, uniformity, document and data management.
- **Were results useful as expected?** Yes.
- **How the results are exploited? E.g. how findings are used?** Results of audits are analyzed. Improvement of processes where appropriate.
- **Benefits from the nuclear safety point of view ? Safety enhancement?** Quality Assurance was done before the introduction of formal systems. Direct effect is not easy to recognize.
- **Any follow-up system?** System is in continuous improvement.
- **Strengths and weaknesses?** Higher systematics.
8. Hints for improvement. Further developmental needs for approach /tool ?

9. Organisation, address and contact person (e-mail address) Dr. Albert Frischknecht Swiss Federal Safety Inspectorate 5232 Villigen HSK Switzerland frischknecht@hsk.psi.ch
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

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To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**
   Self Assessment, Safety Indicators

2. **Scope and Purpose. For which end the approach / tool is used?**
   Continuous improvement, Safety Management

3. **Brief description of the approach (200 words maximum)**
   In a joint project the Swiss NPPs are developing a common set of safety and performance indicators. This set may be expanded according special needs of the individual plant. The purpose of the indicators is to monitor safety and performance of the plant and in addition to evaluate them on a regular base in self assessments. The assessment results will be used by the plants in their improvement programme.

4. **When measurements are involved, please specify required techniques**
   Different techniques are used, depending on the indicator.

5. **Status (in use / published method / piloted / under development / ...)**
   Under development

   - **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

   - **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**
     The development is done by a working group of experts from the individual plants. External information (WANO, IAEA, NEA) is used.

   - **How is it validated? Is there any qualification or checking done?**
     Iterative approach.

6. Application process

- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**
  Resources not known yet.
  Evaluation will be done on a plant base by plant staff.

- **Any detail or examples?**
  Not available yet

- **Information system requirements?**

- **Is it usage restricted? What kind of restrictions?**
  Part of the information will be restricted to the plant's organisation.
  There are plans for a common set of safety indicators to be shared with the regulatory body.

7. Experiences
No experience available. In development

- **Type of results obtained**

- **Were results useful as expected?**

- **How the results are exploited? E.g. how findings are used?**

- **Benefits from the nuclear safety point of view ? Safety enhancement?**

- **Any follow-up system?**

- **Strengths and weaknesses?**

8. Hints for improvement. Further developmental needs for approach /tool ?

9. Organisation, address and contact person (e-mail address)

Manfred Frei
Q-Manager
Kernkraftwerk Gösgen-Däniken AG
Postfach
4658 Däniken
mfrei@kkg.ch

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. **Present needs and challenges in Safety Management / Management of Safety**
   HSK has developed a regulatory guideline (see part A) on the Organizations of NPPs. At the time HSK is about to develop and implement an inspection instrument in this area.
   Currently there is no additional need for research or development preceived. This may change during the implementation phase.

   A description of the development will be published soon in:
   Grote, G., Humbel. C., Künzler, C. & Frischknecht, A. (2003). Instruments for auditing requirements for the safe organization of nuclear power plants. Proceedings of the XVth Triennial Congress of the International Ergonomics Association, Augsut 24-29, Seoul, Korea.

- **What should be developed or done? For what purpose is needed?**

- **How and who should take care?**

- **Any further suggestions on how to apply available knowledge to Safety Management?**

2. **Contact person (name, address, e-mail address):**
   Dr. Albert Frischknecht
   Swiss Federal Safety Inspectorate
   5232 Villigen HSK
   Switzerland
   frischknecht@hsk.psi.ch

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Appendix 3.i): Responses from UK

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

Nuclear Installations Inspectorate
Craig Reiersen (craig.reiersen@hse.gsi.gov.uk)

2. Are there regulatory requirements of any sort on the utility management system?

Licence Condition 17 requires that the licensee develops and implements QA arrangements for all activities that affect safety. This requires the licensee to describe its organisation, detail the responsibilities of personnel who have an impact on safety, develop arrangements that satisfy all other license conditions, review and update documents and audit and review the effectiveness of these arrangements. The licensee can decide how to specify its own management system, but it must be able to demonstrate that the system delivers nuclear safety functions effectively. The Licence Condition 36 Baseline Staffing Assessment should also justify the organisational structures and resources which are in place.

- **If yes, status and content of requirements (describe here or attach documents)**

  See above response

3. Does the regulatory body assess the management system of the utility?

NII may carry out assessments of different aspects of the licensee's management systems. We are taking a holistic view in our examination of the licensees' LC36 Baselines. We also look at specific parts of the licensees management systems when carrying out inspections focused on different topics – for example, training, control and supervision etc.

- **If yes, description of the approaches, methods and criteria used in assessment,**
  or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.

  We may use HS(G)65, which sets out a safety management system framework. We also use internal NII guidance on dealing with organisational change – this is very similar to the guidance contained in the draft SEGHOF TOP.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part B. -INFORMATION ON SPECIFIC DEVELOPMENTS, APPROACHES, TOOLS AND METHODOLOGIES.

The aim of these questions is to collect information on systematic approaches and methods used by organisations in nuclear industry as tools in safety management or under development.

To be filled one document per individual method or development, and to be filled primarily by licensee or utility telling about managerial methods and tools used in their own organisation, but also by consultant, research institution, specialist developing such tools, or by regulator describing managerial tools used in regulatory organisation**.**

It is easier to answer, if you read first all questions !.

There are several sub-questions, part of which may be irrelevant in your case, ignore those!

1. **Title of the approach**

   EFQM

2. **Scope and Purpose. For which end the approach / tool is used?**

   To ensure that NII's organisation and management system is effective.

3. **Brief description of the approach (200 words maximum)**

   EFQM is a well-known business excellence model. I note that Finland (STUK) has already responded to say that they use the EFQM approach, so I would refer you to their description to avoid duplication.

4. **When measurements are involved, please specify required techniques**

5. **Status (in use / published method / piloted / under development / ...)**

   EFQM is in use. We are currently going through a process of external assessment

   - **If in use: how it was acquired (adopted from outside / internally developed) and for how long has it been used?**

     About 3 years –a re-assessment is in progress. Our internal assessments indicate that significant improvements have been made, putting NII in the top 25% of organisations in Europe.

   - **If internally developed: what were the bases or principles used? Any consultant engaged? Owner or person in charge?**

- **How is it validated? Is there any qualification or checking done?** Externally designed and managed.
6. Application process
- **How is it used (effort and resources required, time requirements, sequence or program of activities, frequency of application,...)? Responsible organization? At which organisational level?**
- **Any detail or examples?**
- **Information system requirements?**
- **Is it usage restricted? What kind of restrictions?**
7. Experiences
- **Type of results obtained**
- **Were results useful as expected?**
- **How the results are exploited? E.g. how findings are used?**
- **Benefits from the nuclear safety point of view ? Safety enhancement?**
- **Any follow-up system?**
- **Strengths and weaknesses?**
8. Hints for improvement. Further developmental needs for approach /tool ?
9. Organisation, address and contact person (e-mail address)
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT To be filled for all interested.
1. Present needs and challenges in Safety Management / Management of Safety Development of operational tool for framing/structuring inspections of licensees' safety management systems.
- **What should be developed or done? For what purpose is needed?**
- **How and who should take care?**
- **Any further suggestions on how to apply available knowledge to Safety Management?**
2. Contact person (name, address, e-mail address):
If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here:

Appendix 3.j): Responses from USA

Country	Part A	Part B	Part C	Comments
Belgium	yes (1)	yes (1)	yes (2)	Regulator (1A, 1C), Operator (1B, 1C)
Canada	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
Finland	yes (1)	yes (3)	0	Regulator (1A, 1B), Research (2B)
France	yes (1)	0	yes (1)	Regulator (1A, 1C)
Japan	yes (1)	0	0	Regulator (1A)
Spain	yes (1)	yes (3)	yes (2)	Regulator (1A, 1C), Operator (2B, 1C), Research (1B)
Sweden	yes (1)	yes (4)	yes (1)	Regulator (1A), Operator (1B), Industry (2B, 1C) Research (1B)
Switzerland	yes (1)	yes (3)	yes (1)	Regulator (1A, 2B, 1C), Operator (1B)
UK	yes (1)	yes (1)	yes (1)	Regulator (1A, 1B, 1C)
USA	yes (1)	0	yes (1)	Regulator (1A, 1C)
10	**10**	**16**	**10**	

Part A. –BACKGROUND INFORMATION ON REGULATORY REQUIREMENTS AND PRACTICES.

The aim of these questions is to collect information on regulatory requirements and inspection practices in different countries. This part is to be filled by the regulatory body.

1. Regulatory organisation identification and contact person (e-mail-address)

US Nuclear Regulatory Commission
J. Persensky jjp2@nrc.gov

2. Are there regulatory requirements of any sort on the utility management system?

No

- **If yes, status and content of requirements (describe here or attach documents)**

3. Does the regulatory body assess the management system of the utility?

Only in certain circumstances

- **If yes, description of the approaches, methods and criteria used in assessment,**
  or description of regulatory actions or considerations related to utility management, changes in organization, behaviour, and other related aspects.

There is no fixed approach, method or criteria. Primarily we encourage the utility to do a self-assessment or get an independent assessment by a third party. This only occurs if some problem is noted, e.g. Davis-Besse. Our assessments of these assessments are handled on a case-by-case basis.

If you want to attach documents or refer to material situated elsewhere, as requirements or regulatory guides found in www-pages, please list the material here:

Part C. - NEEDS AND CHALLENGES FOR FURTHER DEVELOPMENT OF SAFETY MANAGEMENT

To be filled for all interested.

1. Present needs and challenges in Safety Management / Management of Safety

- **What should be developed or done? For what purpose is needed?**

  Quantitative measurement approaches that are related to risk, with criteria (thresholds)
  Performance indicators

- **How and who should take care?**

- The international community working together

- **Any further suggestions on how to apply available knowledge to Safety Management?**

2. Contact person (name, address, e-mail address):

J. Persensky
Jjp2@nrc.gov

If you want to attach documents or refer to material situated elsewhere, as in www-pages, please list the material here: