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***Development of measures
to assess the safety of
existing NPPs and the
effectiveness of regulations and
regulatory actions
(including 'prescriptive' and
'performance based' approaches)***

Peer discussions on regulatory practices



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INTERNATIONAL ATOMIC ENERGY AGENCY, 1996

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DEVELOPMENT OF MEASURES TO ASSESS THE SAFETY OF
EXISTING NPPs AND THE EFFECTIVENESS OF
REGULATIONS AND REGULATORY ACTIONS
(INCLUDING 'PRESCRIPTIVE' AND 'PERFORMANCE BASED' APPROACHES)
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FOREWORD

This report arises from the fourth series of peer discussions on regulatory practices entitled "Development of measures to assess the safety of existing nuclear power plants and the effectiveness of regulations and regulatory actions (including 'prescriptive' and 'performance based' approaches)". Senior regulators from 23 Member States participated in four peer group discussions during 1995-1996. This report presents the outcome of these meetings and recommendations of good practices identified by these senior regulators.

EDITORIAL NOTE

In preparing this publication for press, staff of the IAEA have made up the pages from the original manuscript(s). The views expressed do not necessarily reflect those of the governments of the nominating Member States or of the nominating organizations.

Throughout the text names of Member States are retained as they were when the text was compiled.

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CONTENTS

1. INTRODUCTION	7
1.1. Background	7
1.2. Objective	7
1.3. Structure and scope	7
1.4. The meetings	8
2. 'PRESCRIPTIVE' AND 'PERFORMANCE BASED' APPROACHES TO REGULATION	8
3. COMMON FEATURES OF REGULATORY APPROACHES	9
3.1. The operating organization's responsibility for safety	9
3.2. Independence of the regulator	9
3.3. Inspection and assessment	9
3.4. Safety requirements and objectives	10
3.5. Safety justification and review	10
3.6. Continuous assessment of safety	11
3.7. Licensing and training of operating staff	12
3.8. Management of safety	12
3.9. Safety culture and human factors	12
3.10. Quality assurance	13
3.11. Severe accident management and emergency planning	13
3.12. Public opinion and the provision of information	13
4. EFFECTIVENESS OF THE REGULATOR AND REGULATORY ACTIONS ..	13
4.1. The regulatory body	14
4.2. The regulatory body and the operating organization	14
4.3. The regulatory body and the public	15
5. RECOMMENDATIONS OF GOOD PRACTICES	15
CONTRIBUTORS TO DRAFTING AND REVIEW	19

1. INTRODUCTION

1.1. BACKGROUND

In 1986, at a special session of the IAEA General Conference, it was suggested that the IAEA could play a role in assisting Member States in the enhancement of regulatory practices with the objective of increasing the confidence of the public in the safety of nuclear power. The IAEA subsequently sent out questionnaires on regulatory practices and on inspection and enforcement. Summaries of the replies to these questionnaires were issued as TECDOCs.

In 1988 it was agreed that the most useful way to develop peer review of regulatory practices was for small groups of regulators to meet, together with an IAEA co-ordinator, to discuss selected topics. It was intended that senior regulators from different groups of Member States would discuss the same topic in a series of peer group discussion meetings, putting emphasis on identifying beneficial aspects of practices rather than on comparing regimes.

This objective was further enhanced when the Nuclear Safety Standards Advisory Group (NUSSAG) recommended in 1989 that "to promote the sharing of experience through increased professional contacts between nuclear safety regulators, a system should be provided for the identification of commonly accepted good practices and to disseminate them widely among Member States".

There have been three earlier series of meetings, the first during 1989–1990 discussed "Regulatory Inspection and Enforcement of Good Practices"; the second, during 1991–1992, discussed "Regulatory Good Practices Relating to Monitoring and Assessment of Ageing Nuclear Power Plants", and the third, during 1993–1994, discussed "Policy for Setting and Assessing Regulatory Safety Goals" and resulted in the publication of IAEA-TECDOC-831.

The present report arises from the fourth series of meetings, held during 1995–1996, which addressed the subject defined by the IAEA and endorsed by NUSSAG as: "The Development of Measures to Assess the Safety of Existing Nuclear Power Plants (NPPs) and the Effectiveness of Regulations and Regulatory Actions (Including 'Prescriptive' and 'Performance Based' Approaches)" and is published in this special report series.

1.2. OBJECTIVE

The purpose of this report is to disseminate the views which the senior regulators presented at the meetings relating to measures used for assessing the safety of existing nuclear power plants and evaluating the effectiveness of regulators and regulatory actions. The intention in doing this is to assist Member States in the enhancement of their regulatory practices by identifying commonly accepted good practices.

1.3. STRUCTURE AND SCOPE

This report is structured so that it covers the subject matter under the main headings of:

- 'Prescriptive' and 'Performance Based' Approaches to Regulation
- Common Features of Regulatory Approaches
- Effectiveness of the Regulator and Regulatory Actions
- Recommendations of Good Practice.

It is important to note that recommendations of good practice are included if they have been identified by at least one of the groups. It does not follow that all of the groups or individual Member States would necessarily endorse all of the recommendations. However, it is considered that if a single group of senior regulators judge that a particular practice is worthy of recommendation then it should be included for serious consideration. In some cases the same recommendations arise from all of the Groups.

1.4. THE MEETINGS

Four separate meetings were held, one each in the months of May, July and October 1995, with the fourth and final meeting in February 1996. The list of participants and their countries of origin is given at the end of this report. In the interest of continuity and consistency the same consultant was invited by the IAEA to chair all the meetings. Each meeting was independent with no details of the discussions at previous meetings being disclosed. The meetings proceeded in the same way with each participating member describing his or her national regulatory regime and practices in turn, with the subsequent discussion examining points of similarity and their merits.

The discussions addressed in particular the relative advantages of the 'prescriptive' or 'performance based' regulatory approaches, points of similarity in the regulatory approaches and nuclear power plant safety assessments and how the effectiveness of the regulator and regulatory actions could be judged. In each case recommendations of good practice were made and a report summarizing the views of the participants drawn up and agreed.

2. 'PRESCRIPTIVE' AND 'PERFORMANCE BASED' APPROACHES TO REGULATION

A 'prescriptive' regulatory approach has been described as one where the operating organization (the licensee) has to carry out an agreed upon prescription of requirements in meeting a particular rule concerning the nuclear plant's design, construction and operation. A 'performance based' regulatory approach focuses on the results obtained through the operating organization's activities to demonstrate compliance with regulations. In the 'prescriptive' case the operating organization's means of meeting particularly desired ends are carefully examined by the regulator against the prescription whilst in the 'performance based' approach the regulator focuses on the ends.

The relative merits of these alternative forms of regulation were considered by each group. Each group was consistent in the view that a combination of the 'prescriptive' and 'performance based' approaches was actually used and that this was desirable. The view was expressed that neither approach on its own was completely sufficient. Further, it was clear that there was a reluctance by regulators to attempt to dictate solutions to problems to the operating organization although in exceptional circumstances it would be done.

It was also considered that there were various factors which tended to influence the extent to which one or other of the approaches was used. For example, at one extreme, if a country's nuclear power programme was small and in its early stages, and consisted of reactors brought in from a country with an established programme of similar reactors, then there were strong reasons for a 'prescriptive' approach to be used where the codes, standards

and guides and the prescribed way of meeting them from the established programme would be appropriate. On the other hand, if the resources supplied to the regulator were limited, and the operating organization was strong technically and financially, a 'performance based' approach was likely to be more appropriate with the regulator concentrating on ensuring that the required ends had been achieved. The point was also made that 'performance based' regulation is simplest where there are quantifiable objectives but it was noted that not all objectives are quantifiable and, in some cases, a more precise statement of a requirement would be best.

There was general agreement that a combination of the 'prescriptive' and 'performance based' approaches to regulation should be used with a recommendation from one group that the judgement of performance should be related to the development of probabilistic safety assessments and risk based regulations. However, the consensus was that where a 'performance based' approach could be used it should.

3. COMMON FEATURES OF REGULATORY APPROACHES

As a result of the discussions from all of the groups the following points of similarity between the regulatory regimes emerged. These similarities were generally considered to be beneficial and were identified as common contributors to the effective regulation, assessment and assurance of NPP safety.

3.1. THE OPERATING ORGANIZATION'S RESPONSIBILITY FOR SAFETY

It was a common feature of all the countries represented that the operating organization is legally responsible for safety and that any actions of the regulator should not be interpreted as reducing that responsibility.

3.2. INDEPENDENCE OF THE REGULATOR

Independence was seen as a fundamental prerequisite to regulation whereby the regulator is totally independent. Also the regulator should not be unduly dependent on other organizations for technical or scientific support nor affected unacceptably by outside influences. It was considered important that the independence of the regulator is established and this was the case in almost all the countries, although one country had both organizations under the same government department. However, in this case a process is under way to increase the independence of the regulator.

3.3. INSPECTION AND ASSESSMENT

All of the regulators used deterministic methods and probabilistic assessments to varying extent and employed an approach based on a combined inspection and assessment regime to evaluate the degree of compliance with regulatory requirements for safety. One approach was the use of a 'process based regulation' where the regulator makes a careful study of the way or 'process' whereby the operating organization identifies, evaluates and implements solutions to particular problems. The advantage claimed being the encouragement of a careful, thinking approach to the solution of safety problems with a subsequent benefit of identifying developing problems and the promotion of a more pro-active approach to safety.

It was considered that the regulatory approach was strongly influenced by national factors, such as legal system requirements, the strength and size of the regulatory organization and whether the NPP designs were nationally based.

Regulatory inspection programmes were defined, in most cases, to enable efforts to be directed into areas of priority. This includes witnessing tests and inspections carried out by the operating organization. Assessment of plant safety provided an input into the formulation and definition of these inspection programmes taking into account the regulator's assessment of those areas of the plant important to safety. The linkage between assessment and inspection activities was considered to be very important. Inspection frequency of particular areas would be dependent on the performance of the operating organization in that area. The inspection and assessment regimes required the operating organization to commence with a safety analysis report or safety case for the plant and for the updating of this safety case throughout the life of the plant. The general practice regarding inspection staff seemed to be that the association of an inspector with a specific site would be limited to between 2 and 5 years depending on the country.

3.4. SAFETY REQUIREMENTS AND OBJECTIVES

It was commonly agreed that the regulators in each country imposed requirements on the operating organizations; however, the manner in which this was done varied. Some countries established their requirements as conditions related to licences, others used more general communication methods and in one case it was achieved by Royal Decree. It was agreed that the regulator had the responsibility of defining safety requirements but these could be derived or developed outside the regulator's organization provided that they were endorsed and recommended by the regulator. There was general agreement that whatever the method there must be clear communication of the regulator's requirements to the operating organization to remove any doubt of what is expected in all areas of activity, e.g. maintenance, testing, inspection, emergency arrangements, etc. In addition to safety standards, most regulators agreed that they should define high level goals. A general view was that if these could be numerical, where appropriate, it would be useful in providing targets against which the operating organization's performance could be assessed. It was felt that engineering requirements were important such as the single failure criterion, diversity, segregation and redundancy. Although it was considered that differences may exist in the precise definition of safety goals it was agreed that both the operating organization and the regulator should define high level statements of their safety policy, aims and proposed achievements. It was felt that without these there would be a lack of safety direction to the staff of the organizations.

Where the safety targets were mandatory it was essential for the operating organization to meet them, and where they are considered to be desirable, but not mandatory, the operating organization is obliged to strive to meet them and to justify the position if it is not possible to achieve them. It was commonly acknowledged that standards and criteria should include good engineering practice and deterministic requirements as well as numerical limits.

3.5. SAFETY JUSTIFICATION AND REVIEW

A feature common to the regulatory approaches was the requirement for the operating organization to produce a sequence of safety reports to justify their operations, activities and performance. These safety reports cover the design, construction, commissioning, operating and decommissioning phases of the NPPs.

There was general agreement that periodic reviews of the safety of existing NPPs should be carried out and safety improvements introduced where necessary. These reviews are the responsibility of the operating organization and are evaluated by the regulator. It was recognized that these reviews are expensive to undertake but were nevertheless necessary to ensure that safety improvements suggested by experience and the evolution of safety standards were considered.

The concept of periodic reviews at stages of plant life to comprehensively re-evaluate and re-establish its safety basis was considered to be valid. Timing of the review is dependent on various factors, but principally the basis is the plant's operational history in relation to its accepted design parameters.

Particular importance was attached to the control of modifications to the plant. These should be categorized for safety significance and carefully assessed, controlled and recorded with the requirement that the operating organization must inform the regulator in advance and also undertake an assessment of the safety implications of the proposed changes. The common feature was that all changes important to safety had to be authorized by the regulators.

Independent evaluations or 'peer reviews' were seen as a common requirement to varying degrees in each country and were considered to be a valuable method of checking the adequacy, accuracy and acceptability of safety reports. This type of review requires, for the most important safety issues, that the organization carrying out the work must be competent and totally independent of the operating organization.

3.6. CONTINUOUS ASSESSMENT OF SAFETY

The general position following the issue of a licence or authorization to the operating organization was that the basis for the safe operation of the plant had been established and that this was recorded in various documents. After that any matter which arose and might affect the safe operation of the plant had to be assessed and addressed. The concept of continuous assessment was supported where the documents which defined the basis for safe operation are amended as the need arises, but according to established procedures and appropriate authorization by the regulator. Some countries required the operating organization to upgrade plant safety, when justified, by experience and events.

Therefore, it was seen as particularly important that operational experience, both national and international, should be reviewed and its impact on the safety justification for the plant analysed. Analysis of incidents and lessons learned were common requirements, both through the establishment of in-house reporting systems or international collaborative arrangements.

Each group recognized the importance of analysing safety performance indicators, such as the number of automatic scrams, number of safety system actuations, trends, incidents, etc.; however, there was a general feeling that caution should be observed in their interpretation. It was clear that the regulators expected the operating organizations to analyse the causes of events and incidents which might have an impact on the safety of their plants. Examination of trends and statistical analyses were a requirement for many plants and arrangements for reporting and collation of operational occurrences was supported.

3.7. LICENSING AND TRAINING OF OPERATING STAFF

The practice for most of the regulators was to license key personnel of the NPPs, although the extent to which the regulator defined the training programmes and examinations varied. It was considered that the need for operators to be trained in their functions and to be able to demonstrate their competency was an important common requirement for all countries. Whilst it was agreed that the need for detailed training arrangements and competency testing were essential the means for achieving this varied between regulators. In some countries the operating staff were licensed by the regulators to perform their functions, but in one country the requirements set out in the licence conditions ensured that the appropriate operators were formally 'authorized' by the operating organization. It was considered that key operators must be assessed as being suitably qualified, experienced and trained. The precise manner in which this was achieved could vary from country to country, provided that the regulator had the requisite power to remove the authorized status of key personnel if necessary.

3.8. MANAGEMENT OF SAFETY

This is a general term applicable to the manner in which matters affecting safety are organized and managed. The need for the identification of management responsibilities, chains of command, auditing of management performance was strongly emphasized by the regulators. Safety arrangements of the operating organization are carefully examined and inspected by the regulators and the need for the operating organization to accept 'ownership' for their management systems and actions was stressed. It was considered that over-regulation could adversely affect the operating organization's sense of ownership with a consequent deleterious effect on safety, and it was felt that regulators should be aware of this possibility. Most regulators felt that it was of value for the regulator to interact regularly with the operating organization, particularly when technical issues arose.

3.9. SAFETY CULTURE AND HUMAN FACTORS

The value of safety culture was commonly supported and recognized and it was felt that the regulators should encourage the development of a safety culture in all the organizations involved. The appropriate motivation and safety awareness of all staff from top management downward was considered most important. It was also considered that both the regulators and operating organizations should be conditioned to discriminate between what was important and what was not. Therefore, it was commonly held that important issues need early attention but those of less importance to safety or of reduced significance should be appropriately prioritized. How safety culture was to be assessed was considered and it was thought by many that experienced inspectors and assessors, with the assistance of certain indicators could recognize the level of safety culture. In addition, it was felt that praising the operating organization when its safety performance was good and welcoming initiatives in improving safety would aid the development of a good safety culture. However, it was agreed that representation should be made to the operating organization if it appears that safety culture is lacking.

The application of the techniques of human factor assessment to the procedures and activities of the operating organization were considered by many to be of increasing importance. It was commonly felt that there might be more gains to safety to be made in this field than in any other at the moment. Common agreement was evident for the integration of human factors expertise into the design and operational processes of the NPPs.

It was commonly recognized that the efficient and effective use of resources was an important issue for both regulator and operating organizations. Careful consideration of total systems, including those outside the nuclear island was strongly emphasized. This ensures that the resources are applied to where the safety return would be greatest. Neither the regulator's nor the operating organization's resources are infinite and this was a commonly recognized point. It was felt that the application of human resources should be considered and reflected as an integral part of the safety systems. The use of external technical organizations to support the regulator was also a common practice.

3.10. QUALITY ASSURANCE

Each participant was convinced of the need for QA arrangements to be applied to the design, manufacture, construction, commissioning, operating and decommissioning of the NPPs. It was considered that these played an important role in the achievement of appropriate safety levels. Whilst it was recognized that the value of QA applied to the operations and procedures adopted by the operating organization was significant it was also felt that certain elements of the process should also be applied to the regulators organization, particularly in the following areas:

- Assignment of priorities
- Evaluation and follow up of events
- Corporate memory (i.e. the ability to recall information on earlier events)
- Checking the implementation of the regulatory requirements.

3.11. SEVERE ACCIDENT MANAGEMENT AND EMERGENCY PLANNING

There was unanimity on the need for the operating organization to have emergency plans and the requirement for their acceptance or approval by the regulator. A general view was taken that the issue of severe accident management was an important development which warranted the operating organization paying special attention to measures to prevent severe accidents and also to consider the way events should be controlled following the occurrence of a severe accident.

3.12. PUBLIC OPINION AND THE PROVISION OF INFORMATION

The influence of public opinion, including pressure group actions, was commonly recognized as a factor to be considered in the regulatory process. Several countries drew attention to public interest in the safety of their NPPs and the importance of public perception of the risks which their operation entailed. The provision of sensible information to the public from both the regulator and the operating organization was felt to be of increasing importance in the future and, therefore, a necessity for all concerned if there were to be continued acceptance of NPP operations.

4. EFFECTIVENESS OF THE REGULATOR AND REGULATORY ACTIONS

Determining the effectiveness of the regulator and regulatory actions was seen by each of the groups as potentially difficult. It was considered that the main output the regulator wished to achieve was high levels of safety in the national nuclear industry and that the

effectiveness of the regulator and regulatory actions was, thus, strongly related to a parameter which could not be directly measured. One of the groups also considered that this question could not be divorced from that of "what were the regulator's responsibilities?" It was recognized that the operating organization had the primary responsibility for safety but it was clear that the regulator also had certain responsibilities with respect to the health and safety of the public and the workforce. Generally this group saw these responsibilities as ensuring that the regulatory procedures and systems worked effectively and efficiently, that high standards of safety were achieved and that appropriate safety precautions were taken by the operating organization.

Each group concluded that although the effectiveness of the regulator and regulatory actions could not be measured directly there were various characteristics and indicators which, taken together, could be considered to give an indication of effectiveness. These were divided into several main areas as follows:

4.1. THE REGULATORY BODY

It was considered that the regulatory body had to define its objectives clearly and set down the standards it wanted the operating organization to achieve in order to regulate effectively.

The regulatory body had to be competent and appropriately sized to carry out its functions with the ability to ask for more means and resources if necessary and to have sufficient power to impose its decisions in accordance with its independent viewpoint.

It could be helpful in promoting effectiveness if the regulatory body is subjected to the disciplines of QA.

The regulatory body should be prepared to carry out self-assessments of its performance. In particular, the use of regulatory guidelines or the establishment of principles to assess regulatory performance would be necessary.

Principles such as independence, openness, clarity, reliability and efficiency were highlighted as applicable to effective regulatory organizations.

The standing of the regulatory body within the international community is seen as important in considering whether it is effective or not. The review of regulatory performance by international peer review groups for example, examining a vertical section of the organization could provide a representative sample of effectiveness.

4.2. THE REGULATORY BODY AND THE OPERATING ORGANIZATION

The regulatory body must have a separate and independent approach from the operating organization on safety matters if it is to be effective.

Efficient pro-active use of operational experience and developments in regulation and advancements in technology to promote safety improvements are measures of the regulator's performance.

The regulatory body's relationship with the operating organization is important; if it is respected and consulted it is likely to be performing properly.

Although, there are certain weaknesses and difficulties associated with them various aspects of the plant and operating organization's performance could be taken as a reflection of the quality of the regulatory body's work. These could include:

- The number and outcome of appeals against regulatory decisions,
- The number of changes made to regulatory requirements due to time and events proving them to be misjudged,
- Whether the operating organization is perceived as being regulated and working in an optimum manner,
- The outcome of IAEA safety review missions to plants licensed by the regulator as well as international peer review discussions,
- Availability of safety functions, incidents, scrams, safety system failures, radiation exposure data, etc.,
- The quality of the regulator's formalized working arrangements with the operating organization and the manner in which safety problems and anomalies are dealt with,
- The ability of the regulator to follow through issues which may take years to resolve,
- The operating organization's record of compliance with regulatory requirements could be a reflection of regulatory effectiveness.

4.3. THE REGULATORY BODY AND THE PUBLIC

The public perception of the competence of the regulator could be an indicator of effectiveness. The manner in which the regulator interfaces with the public, pressure groups, journalists, etc., and keeps them informed on important issues and deals with questions could be particularly relevant.

Various reports published by the regulatory body on its activities and submitted to the public, government and international groups of regulators could be an indicator of effectiveness. These would include certain safety goals, easily understood objectives related to the work programme, health and safety responsibilities and the achievements of the regulatory body.

5. RECOMMENDATIONS OF GOOD PRACTICES

At the conclusion of each of the meetings the groups made recommendations which covered assessment practices for existing NPPs and for the organization and practices of the regulator. It was evident from the meeting reports that a number of the recommendations were common to all of the groups. The other recommendations of good practice have been made by at least one of the groups. Since the meetings were held separately and independently it is reasonable to assume that these particular recommendations are widely held to be good practice. All of the recommendations are worthy of careful consideration because of their potential to enhance assessment arrangements for existing NPPs and to ensure effective regulation. The recommendations which follow have been marked with an * if they are common to all groups.

1. There should be a solid legal basis in place which provides the regulator with the necessary authority to discharge his responsibilities.

- *2. The operating organization must have the primary responsibility for the safety of its NPPs.
3. The regulator should be independent and adequately resourced and competent to discharge his responsibilities.
- *4. The regulator should clearly define the standards, criteria and objectives he requires the operating organization to achieve. These should be clearly understood by and communicated to the operating organization. Certain safety targets which are not mandatory, but recommended, should be strived for by the operating organization and any deviations justified.
- *5. A combination of both the 'prescriptive' and 'performance based' approaches to regulation should be used according to a country's needs, but there should be a trend towards the 'performance based' approach. The regulator should not try to dictate the means by which the required ends are met. Consideration should also be given to the merits of the 'process based' system of regulation.
6. Regulators should be aware of the potential disadvantages of over-regulation.
7. In placing requirements upon the operating organization the regulator should be aware that resources are not infinite and should try to ensure that they are applied where they will produce the highest benefits to safety.
- *8. The regulator should establish both inspection and assessment programmes to monitor the safety performance of the operating organization. These programmes should, where necessary, target any weakness in the operating organization's safety performance.
9. The regulatory organization should be free to use external technical resources to supplement its own but should not become unduly dependent on them.
10. The regulator should encourage the development of a good safety culture both within its own and the operating organization.
11. The regulator should have clear programmes of work and should regularly assess his effectiveness in achieving them. Regular and systematic self-assessment of performance should be a feature of these programmes.
12. The regulator should be pro-active in providing safety improvements and in the identification of precursors to safety problems.
13. The regulator should consider the possibility of using other national regulators to assess his effectiveness, and regulators should take part in international exchanges of experience of regulatory practices.
14. The regulator should pay special attention to the provision of information to the public in order to maintain confidence in regulatory activities, and should also be receptive to proper expressions of public concern.

- *15. The regulator should ensure that the operating organization clearly defines its organizational structure for the management of safety.
- *16. QA arrangements are an important regulatory requirement and should be maintained and reinforced as necessary.
- *17. A continuous assessment of the licensing basis and the safety of the plant should be maintained, particular consideration should be given to the effects and consequences of ageing.
- *18. It is important that periodic safety reviews of NPPs should be carried out.
- 19. Probabilistic safety assessment is a powerful analytical tool and should be used where possible in safety assessment. It is also useful for prioritizing the use of resources.
- 20. Independent evaluation or 'peer reviews' should be required for important safety issues.
- *21. Control of modifications to components, systems, structures, procedures and documents which may affect safety should be incorporated into regulatory requirements.
- *22. The regulator should require the operating organization to report safety related incidents and carry out regular analyses of operating experience, including root cause analysis of events.
- 23. A systematic approach to training and qualification should be adopted and the arrangements included in the operating organization's management system.
- 24. Consideration should be given to the aspects of human factors and behaviour in the design and operation of NPPs where they impact on nuclear safety.

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**Consultants Meeting
Vienna, 18-21 March 1996**

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