INSAG-26

Licensing the First Nuclear Power Plant

INSAG-26

A REPORT BY THE
INTERNATIONAL NUCLEAR SAFETY GROUP

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LICENSING THE FIRST NUCLEAR POWER PLANT

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A report by the International Nuclear Safety Group

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The International Nuclear Safety Group (INSAG) is a group of experts with high professional competence in the field of nuclear safety working in regulatory organizations, research and academic institutions and the nuclear industry. INSAG is constituted under the auspices of the International Atomic Energy Agency (IAEA) with the objective of providing authoritative advice and guidance on nuclear safety approaches, policies and principles for nuclear installations (defined as nuclear power plants, fuel cycle facilities, research reactors and support facilities). In particular, INSAG provides recommendations and informed opinions on current and emerging nuclear safety issues, to the international nuclear community and public through the offices of the IAEA.

FOREWORD

by the Chairman of INSAG

The accident at the Fukushima Daiichi nuclear power plant has appropriately served to stimulate extensive examination of the systems for ensuring the safety of nuclear operations. The accident will assuredly result in new requirements and a special focus on the vulnerabilities that the accident has revealed. One of the important lessons is the need for a regulator with the competence, authority, capacity and willingness to ensure safety in design, construction, operation, and decommissioning.

Although the accident has resulted in the reconsideration of the commitment to nuclear power in some countries, many of the so-called new entrant countries — countries without an existing nuclear power plant but with an interest in acquiring one or more — have indicated an intention to proceed with construction and operation. The Fukushima Daiichi accident reinforces the importance of the difficult challenge that many of these countries will face in establishing a regulatory system that will enable them to fulfill their safety obligations in the licensing and oversight of their first nuclear power plant. This report seeks to provide a practical and high level guide for decision makers in the new entrant countries that can help them succeed in this important endeavour.

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SUMMARY

This report is primarily addressed to policy makers and nuclear safety regulatory bodies in IAEA Member States planning to establish their first nuclear power plant. It outlines the key challenges with suggestions on how the regulator and policy makers might address them and also prepare for further development of nuclear power in the country. INSAG believes that development of technical competence of the national regulatory body is a necessary condition for the safe development of nuclear power. Therefore, regulatory infrastructure development should be a national policy requirement, as opposed to being a challenge only for the regulator.

A major challenge in the deployment of the first nuclear power plant is the development of the underlying nuclear safety infrastructure and knowledge base. Since an independent regulatory body is an important part of such infrastructure, its establishment and development must be addressed at an early stage and adequate resources must be made available for this purpose. This is to ensure smooth and efficient conduct of the licensing process and regulatory oversight of the first nuclear power plant through an informed decision making process.

It is essential that the legal framework starts to be implemented with a main component being the issuance of a nuclear law establishing fundamental principles and defining the responsibilities of the principal organizations, particularly the operating organization and the regulatory body. The regulatory body on its part should develop the regulatory framework that includes the establishment of regulations against which the nuclear power project will be assessed, definition of the licensing steps and corresponding documentation to be submitted by the applicant, and the implementation of a quality management system.

It is expected that the 'reference plant' concept will be employed whereby the country's first nuclear power plant would have essentially the same design and safety features as a nuclear power plant that is already licensed by an experienced regulator. Consequently, an option is to start development of national regulations by adopting or adapting regulations from a country that has licensed the same type of nuclear power plant. However, if the intention is to have an open technology selection process, care should be taken to establish a set of technology neutral regulations, such as by using the IAEA safety standards as the foundation. This set of technology neutral regulations can then be complemented by more design specific regulations after the technology is chosen.

Since the development of technical competences requires considerable time, the regulatory body needs to plan for human resources development at a very early stage. As a first step, the essential competences required for the different phases of the nuclear power programme should be identified. Thereafter,

formal training arrangements should be established between the regulatory body and one or more experienced regulators that have licensed a similar facility. This should include early interaction between senior managers of the two regulators followed by detailed training of selected staff who will form the technical core of the regulatory body. The regulatory body should also identify outside organizations that will act as its technical support organizations (TSOs) and should provide for conduct of nuclear safety R&D by these TSOs, including the appropriate research facilities and expertise. If additional nuclear power plants will be constructed in the new entrant country in the future, the new nuclear power plant units may not be of the same design as the first plant. This aspect should be kept in mind when developing both the licensing methodologies and staff. Regulatory staff can also obtain significant benefit from participation in international cooperation activities such as the Convention on Nuclear Safety, technical cooperation forums of regulatory bodies of countries having nuclear power plants of similar design, and the various technical cooperation activities conducted by international organizations, in particular the IAEA.

The first major task for the regulatory body will be carrying out a review of the safety evaluation report of the proposed site for the first nuclear power plant. For this, the regulatory body must lay down the safety requirements that could be developed or adopted from IAEA safety standards on the subject. It will also require a set of specialized competences in areas such as seismology, hydrology, geochemistry and geology that is not necessarily nuclear related. In developing the strategy to secure and maintain a technically competent regulatory body, a decision should be made early whether to recruit staff with those competences or to outsource these activities to agencies where competences in such areas may already be available in the country. Notwithstanding this, the regulatory body still requires a core technical group in the key disciplines to be able to understand and compile the information from the site evaluation reports as input to the site licensing process.

During the design safety review process for issuance of the construction licence for the first nuclear power plant, use of the design safety review conducted earlier by an experienced regulator for the reference plant could be appropriately made. However, it is essential that the regulatory body has a good understanding of the design and due attention is paid to the design differences on account of factors such as site related parameters, plant layout and incorporation of new design features based on operating experience and advancement in technology. This strategy is proposed primarily to ensure a high level of safety which incidentally, may also help expediting the licensing process.

Considerable technical information for the safely assessments will be transferred from the reactor vendor to the new entrant country. If the languages of the vendor country and recipient country are different, then care has to be taken in

deciding on the working language for the safety review and in ensuring quality in translation of documents and in interpretations.

The regulatory body may consider the use of the IAEA's safety review services to review the compliance of reactor designs against the IAEA safety standards. While such assistance is generic in nature and cannot replace the detailed review required to licence a particular design, it provides the regulatory body with a valuable starting point for its future activities.

During the period between the issue of the construction licence and start of commissioning, the regulatory body would develop its competence to the point where it could perform a detailed safety review with participation of an experienced regulator's experts as advisors. This would have three main objectives: (1) to verify and secure ownership of the licensing process; (2) to position the regulatory body for approving the operating license; and (3) to prepare the regulator for the oversight of the operational phase of the nuclear power plant.

On completion of construction, the next stage of licensing is commissioning of the various structures, systems and components (SSCs) towards bringing the nuclear power plant into operation. Commissioning work is generally completed over a relatively short time, typically a few months, but constitutes a period of intense activity. Therefore, the regulatory body should develop a detailed plan for review of commissioning work that ensures efficiency without any compromise in quality or safety. The review of commissioning activities provides a unique opportunity to the regulatory staff to gain deeper insights into the behaviour of the individual reactor systems and the nuclear power plant as a whole. The information obtained from commissioning should also be used for fine tuning the regulatory requirements during operation.

The regulatory body will require substantial assistance from an experienced regulator for a quality review of the data on various plant parameters and results of commissioning tests conducted at different power levels. Such assistance will also be necessary for a thorough review of the technical specifications for operation proposed by the operator and their comparison with those for the reference nuclear power plant.

Regulatory oversight of the nuclear power plant during its operational phase is a long term activity, covering the licensed operating period as well as its possible future extension. The major activities of regulation during operation are: review of day to day operation and safety related incidents; review of activities during extended outages; control of plant configuration; and assessment of the ageing status of SSCs. Periodic safety reviews are also conducted, typically every ten years, to verify that the nuclear power plant continues to meet the applicable current safety requirements and that adequate safety margins are maintained. However, regulatory oversight during operation should not be limited only to

verifying compliance with the licensing conditions but should strive to enhance safety on a continuing basis.

A high level of technical competence is necessary in the regulatory body for effective discharge of its responsibilities over the entire operating life of the nuclear power plant and this will take considerable time to achieve. Hence, support from an experienced regulator would still be necessary for a few years to deal with off-normal and complex situations. Such assistance can be progressively reduced as the regulatory body gains experience and enhances its technical and managerial capabilities.

The new entrant regulator will have to periodically inform the government, the public and the media about the safety status and the operating experience of the nuclear power plant. In the case of occurrence of any safety related incident, information needs to be provided promptly, including information on corrective actions. It is therefore important that regulatory staff acquire the necessary communication skills for this purpose.

The timely development of a competent operating organization in addition to the development of the regulatory body is also a fundamental requirement for safety since the primary responsibility for safety of the nuclear power plant rests with the operator. Towards this, INSAG notes the importance of external support for the operating organization from an experienced operator of the reference technology and also from international nuclear operations organizations such as the World Association of Nuclear Operators.

Apart from recommendations to policy makers and regulatory bodies on issues related to licensing of the country's first nuclear power plant, the report also includes suggestions to the IAEA on assisting the new entrant countries to nuclear power towards enabling them to achieve and maintain a high standard of safety for the entire lifetime of their nuclear power plants.

1. INTRODUCTION

1.1. BACKGROUND

1. A major challenge in the deployment of the first nuclear power plant in a country is the development of the underlying nuclear safety infrastructure and knowledge base. The IAEA Fundamental Safety Principles state that regulating nuclear and radiation safety is a national responsibility and that an effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained [1]. Therefore, establishment and development of the regulatory body must be addressed at an early stage of the nuclear power programme and must not be constrained by lack of resources.

2. The accident at the Fukushima Daiichi nuclear power plant (hereinafter 'the Fukushima Daiichi accident) has initiated an extensive re-examination of all aspects of reactor safety, including the regulatory framework. While the detailed lessons learned from the accident may take several years to be fully characterized and applied, it is evident that the ongoing development of an effective regulatory framework will be a key part of enhancing the global safety regime. Therefore, it is appropriate to consider on an urgent basis the early development of new entrant regulatory bodies to ensure that a solid foundation for regulatory oversight and decision making is established right from the start of a new nuclear programme.

3. The nuclear safety infrastructure is defined in INSAG-22 as the set of institutional, organizational and technical elements and conditions established in a Member State to provide a sound foundation for ensuring a sustainable high level of nuclear safety [2]. INSAG-22 identifies five main phases of safety infrastructure development for the life-cycle of a nuclear power plant:

- Phase 1: Safety infrastructure considerations before a decision to launch a nuclear power programme is taken;
- Phase 2: Safety infrastructure preparatory work for the construction of a nuclear power plant after a policy decision has been taken;
- Phase 3: Safety infrastructure activities to construct a first nuclear power plant;
- Phase 4: Safety infrastructure during the operation phase of the nuclear power plant;
- Phase 5: Safety infrastructure during the decommissioning and waste management phase of the nuclear power plant.

4. INSAG-22 notes that a regulatory body needs to be established quite early in a nuclear power programme (ideally at the beginning of phase 2), since the new entrant regulator must establish safety regulations, and related guidance material, against which the facility will be assessed. In phase 3, the regulatory body must be prepared to start the safety review of the proposed nuclear power plant design, to provide the licences required for the start of construction, and to perform the regulatory oversight activities during construction. By the end of phase 3, the new entrant regulator should have developed the necessary competence level to oversee commissioning, to grant an operating licence, and to provide regulatory oversight of plant operations in phase 4.

5. Countries that decide to include nuclear power plants in their national development plans may have various levels of experience and understanding of the elements of the nuclear safety infrastructure required for a nuclear power programme. Some countries may be already operating nuclear installations (such as research reactors or subcritical facilities). These countries should have, in general, a reasonable understanding of the role and responsibilities of both the operating organization and the regulatory body, should have a licensing process in place, and should be familiar with the need for high quality standards in nuclear activities. Moreover, these countries would likely have a core of human resources with a basic knowledge of nuclear technology and, in general, academic courses on nuclear science and technology would be available. Other countries interested in developing a nuclear power programme may have less familiarity with nuclear reactor technology and safety principles. For example, their main experience may be limited to the application of radiation sources in medicine and industry. The latter countries face a significant challenge in establishing the necessary safety infrastructure.

6. For all new entrant countries, although their starting points are different, the resources (both human and financial) needed to secure a competent and fully functional regulatory body for licensing the first nuclear power plant are considerable. Therefore, the development of the regulatory body needs to be planned and implemented at an early stage of the programme. In particular, to conduct the licensing process as well as to provide oversight of the construction activities for the first nuclear power plant, the regulatory body needs to develop an extensive set of specialized competencies and processes to ensure an informed decision making process. INSAG-17 provides more information on the regulatory decision making process [3].

7. As indicated in INSAG-22, it is expected that a new entrant country will use the ‘reference plant’ concept for its first nuclear units. Using this approach, the

first nuclear plant would have essentially the same design and safety features as a plant already licensed by the regulatory body of a country with an established nuclear power programme. This approach would facilitate the licensing process in the new entrant country: the newly established regulatory body could learn considerably from the existing Safety Evaluation Report (SER) written as part of the licensing process for the reference plant and could obtain important insights from the results of various safety analyses that were completed for the reference plant.

1.2. PURPOSE

8. This report is primarily addressed to the policy makers and senior management levels in the regulatory body in new entrant countries.[1] It outlines some of the key challenges the new entrant regulator will face throughout the lifetime of the first nuclear power plant, with suggestions on how the regulator and policy makers might address the requirements and take advantage of the opportunities from this experience for further development of nuclear power in the country. INSAG stresses that development of technical competence of the new entrant regulator is a necessary condition for the safe expansion of nuclear power. Therefore, regulatory infrastructure development should be a national policy requirement, rather as a challenge only for the regulator.

9. The main focus of this report is on the challenging activities the new entrant regulator must carry out during phase 3 of the nuclear power deployment programme. During this phase, the regulator will be required to review in depth a substantial amount of specialized and highly technical information to support the decision to grant a construction licence. However, the competency level of the new entrant regulator may not be sufficient to perform this review at the time the construction licence is required without substantial assistance. Therefore, a strategy is proposed that uses some elements of prior assessment work performed by an experienced regulator in a country where the reference plant has already been licensed. The primary objectives of this strategy are: (1) to achieve a high level of safety for the first nuclear power plant; and (2) to establish an effective ongoing regulatory role early in the programme. This strategy is also likely to

[1] It is noted, however, that the need to sustain the regulatory characteristics discussed in this publication throughout the life of a nuclear power programme is an ongoing responsibility for all countries that have adopted nuclear power.

assist the new entrant regulator in providing the construction licence for the first nuclear power plant in a timely manner.

10. This approach is based on the recognition that achieving a fully competent and functional regulatory body for a nuclear power programme takes many years and that external expert support will be needed for a considerable time period even after the power plant goes into operation to help maintain a high level of safety regulation. However, the new entrant regulator must progressively enhance its technical competence so as to be able to take informed decisions without extensive reliance on support from an experienced regulator.

11. In parallel with the need to develop its safety infrastructure, the new entrant countries must also meet their obligations for safeguards and security. We believe that the fulfillment of the safety obligations may present the most difficult technical and management challenge and hence this report does not encompass these other matters. As discussed in INSAG-24 [4], there is an important interface between safety and security that should be given careful consideration.

1.3. SCOPE

12. There are nine key activities that a regulatory body must carry out for licensing its first nuclear power plant:

— Establishment of the licensing framework;
— Approval of the site;
— Understanding of the design SER of the reference plant;
— Review of the design;
— Issue of a construction permit;
— Oversight of manufacturing and construction;
— Oversight of commissioning;
— Issue of an operating licence;
— Oversight of operations

13. It is not the intent of this publication to consider all aspects of these activities, which are covered thoroughly in existing IAEA Safety Guides. Rather, this publication focuses on the main challenges facing the new entrant regulator in carrying out these activities. Sufficient detail is provided so that both new entrant policy makers and regulators can appreciate the breadth and depth of the requirements. Suggestions have also been made for developing a strategy whereby a high level of safety is ensured while issuing the various licences, in

particular the construction licence, pending the full development of technical competence in the new entrant regulator.

14. The material presented in this report assumes that a new entrant country will be most likely to adopt a proven nuclear power plant design that has already been licensed in a country with a mature nuclear power programme.

15. The use of the terms ‘regulatory body’ and ‘regulator’ in this publication refers to one or more national agencies authorized to approve and oversee the siting, construction, commissioning, and operation of a nuclear power plant. In our view, these activities are linked to each other, and thus a single regulatory entity with comprehensive authority is desirable.

2. REGULATORY INFRASTRUCTURE

16. IAEA Safety Guide SSG-16 [5] sets out the main phases of a nuclear power programme and identifies some important safety steps for each phase. The first three phases are summarized in Fig. 1.[2]

17. INSAG-22 identifies phase 2 as being critical for the establishment of the regulatory body. Once a nuclear law has been adopted that provides the regulatory body with a clear mandate and authority to carry out its mission, the regulatory body needs to develop regulations and guides by which the nuclear power project will be assessed, and to develop a licensing process. The new entrant regulator must also establish a strong human resources programme on the specialized areas of competence to conduct its activities in phases 2 and 3.

18. The IAEA Safety Requirements publication GSR Part 1 establishes requirements that are considered necessary for the safe implementation of a

[2] The actual deployment plan followed by a new entrant will, of course, depend on its national vision and policy. For example, the approach of the United Arab Emirates, where considerable international expertise has been engaged to establish the regulatory body, will likely result in a shorter time frame for regulatory development than would be the case without the benefit of that expertise. We recognize that such an approach may not be followed by many new entrant countries.

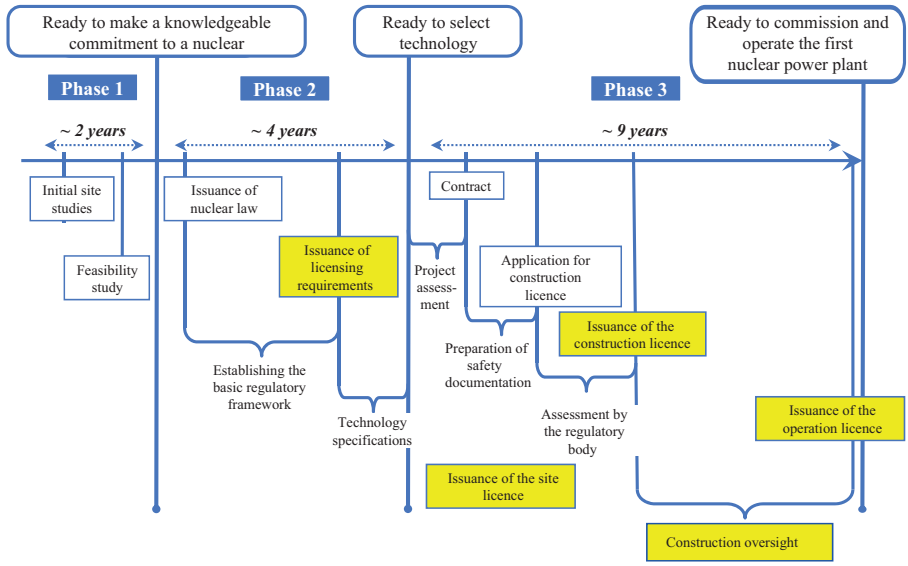

FIG. 1. The first three phases of a nuclear power programme. Note that the timelines for specific activities are not necessarily to scale. This diagram is based on Fig. 3 of SSG-16 [4].

nuclear energy programme [6]. One of the main areas addressed in GSR Part 1 deals with the establishment of a system for authorization, which is explained in more detail in SSG-12 [7]. SSG-12 covers the authorization stages, from siting of a new nuclear power plant through to its decommissioning and release from regulatory control. In addition, an IAEA Safety Report is in preparation that will provide guidance and information on the preparation of regulations and guides and on the authorization stages, process, and regulatory submissions [8]. Countries embarking on a nuclear power programme should refer to these publications when establishing their detailed regulatory processes for licensing nuclear power plants.

19. The new entrant regulator must conduct the licensing process for the first nuclear power plant in an informed manner. The main tasks that are the responsibility of the regulatory body in Phases 2 and 3 are highlighted in Fig. 1. They are complex technically and of a specialized nature. For example, the regulator must be capable of granting a construction licence following a thorough evaluation of the preliminary safety analysis report (PSAR) submitted by the licensee (with considerable detailed technical content from the designer), and then the evaluation of an event more final safety analysis report (FSAR) in order

to support the issuance of an operating licence.[3] The licensing process involves the development by the regulator of a comprehensive safety evaluation report (SER). To perform this work, the regulator will need staff with competencies in several technical areas. Many of those areas are specific to nuclear power technology and safety, and all of them are not likely to be completely available in the new entrant country. Therefore, new entrant regulators must start very early to establish the required competencies.

20. However, a recent IAEA survey has shown that some new entrant regulators are facing difficulties in responding to the initial nuclear programme needs in a timely manner. There are various reasons for this:

— Very aggressive schedules for the nuclear power programme, not taking into account the necessary early regulatory activities (building the regulatory framework, conducting the licensing process);
— Lack of an appropriate, well structured, and effective legal and regulatory framework;
— Delayed establishment of the regulatory body and the recruitment of staff;
— Insufficient financial resources allocated to the regulatory body for external support;
— Insufficient knowledge by the regulator to enable the adaptation of other countries' regulations or international safety standards;
— Lack of a quality management system to ensure quality and consistency in the regulations and guides; and
— Insufficient experience in establishing a human resources development plan and a training programme to ensure the required competencies in the regulatory body in a timely fashion.

21. Regardless of the level of the domestic regulatory infrastructure in a new entrant country, it is expected that a long development time will be needed to secure the required competencies and methodologies. For a new entrant regulator with experience regulating research reactors, a typical development time could be seven years, depending on the resources available. For a new entrant regulator

[3] If the new entrant's nuclear power plant is identical to a reference plant that has already been constructed, the PSAR should be quite comprehensive and complete. In such a case, the FSAR for the new entrant's plant may modify the PSAR slightly to include, for example, minor design and layout modifications that were made during construction. If the design of the reference plant is less firm, or if there are extensive site specific modifications that must be made for the new entrant's nuclear power plant, the FSAR may of necessity be considerably more extensive than the PSAR.

that lacks that experience, the time period could be even longer. Given this, it is apparent from Fig. 1 that there can be a mismatch between the development of the regulator and its ability to assess the first safety analysis report (SAR).

2.1. CHARACTERISTICS OF A MATURE REGULATOR

22. To appreciate the challenges associated with development of the regulatory body, it is useful to examine the desired endpoint. Appendix I provides a summary of 14 characteristics of a fully mature and effective regulatory body, and gives some considerations for a new entrant regulator. These characteristics could be used to establish the developmental goals for new entrant regulators and could also be used as criteria for periodic high level evaluations of the development process. While even mature regulators may not have all the elements of Appendix I completely in place at any particular time, the gaps are generally recognized and are addressed through ongoing planning, training, and development programmes.

2.2. REGULATORY FRAMEWORK

23. After the decision is taken to proceed with a nuclear power programme, it is essential that an action plan for the establishment of the legal framework starts to be implemented. A main component of the action plan should be the issuance of a nuclear law establishing fundamental principles and defining the responsibilities of the principal organizations comprising the nuclear power programme, particularly the operating organizations and the regulatory body. For the regulatory body, the nuclear law should address unambiguously, among other things, (1) the scope of its responsibilities, functions, and authorities, (2) the position of the regulatory body in the government structure, and (3) the means for regulatory body financing. Detailed guidance on the elements of a nuclear law is provided in the IAEA's Handbook on Nuclear Law [9].

24. One of the first activities of the new entrant regulator is the development of the regulatory framework. The regulatory framework includes the establishment of regulations and guides by which the nuclear power project will be assessed, definition of the licensing steps and corresponding documentation to be submitted by the applicant, and the implementation of an integrated management approach that fully incorporates a robust quality management system. This regulatory framework should ideally be established before the operating organization completes the project specifications because regulatory

requirements should be incorporated into the technology selection process. Requirements that need to be satisfied for establishment of an effective regulatory framework are explained extensively in GSR Part 1 [6].

25. An option that several new entrant countries have used in the past was to start development of their national regulations by adopting or adapting regulations from a country that has licensed the same type of nuclear power plant. However, if the new entrant country intends to have an open technology selection process, the regulatory body should first establish technology neutral regulations, such as the IAEA Safety Standards, as the foundation. These technology neutral regulations can then be complemented by more design specific regulations after the technology is chosen. In addition, since nuclear power technology and the respective regulations will continue to advance, there should be provisions for accommodating these advances in future amendment of national regulations.

2.3. HUMAN RESOURCES DEVELOPMENT

26. For a systematic approach to regulatory human resources development, the IAEA has proposed a competency model wherein four broad groups of competencies are identified [10]. This model will be enhanced in a forthcoming Safety Report [11], using the following four areas or "quadrants" of competencies[4]:

— Quadrant 1: Legal basis, regulatory policy and approach;
— Quadrant 2: Technical disciplines;
— Quadrant 3: Regulatory practices;
— Quadrant 4: Behavioural, managerial, leadership, communication.

27. Since the development of these competencies requires time, the new entrant regulator needs to plan for human resources development at a very early stage of the nuclear power programme. As a first step, the new entrant regulator must establish a competent leadership and senior management core that has the expertise and commitment to develop a strong regulatory body. The new entrant regulator should then identify the essential competencies required for the

[4] The IAEA has noted that a common challenge for emerging regulators is that they focus on technical disciplines (Quadrant 2) and do not always emphasize the other three required competency areas. New entrant countries should recognize the need for competency in all quadrants.

different phases of the nuclear power programme. Among those competencies, some will be required within the regulatory body itself and these should be the subject of a systematic and dedicated competency building programme. For others, the regulatory body may identify outside organizations to act as technical support organizations (TSOs) and to provide nuclear safety research and development. These organizations should have access to appropriate nuclear safety research facilities and to international expertise. These outside organizations may be internal or external to the country.

28. Once the nuclear power plant technology has been selected, there is a need for formal arrangements between the regulatory body of the new entrant country and one or more experienced regulators that have licensed a similar facility. This should include early interaction between senior managers,[5] followed by detailed training of selected staff who will form the technical core of the new entrant regulator. Training should involve actual work through internships with the experienced regulator and/or its TSO. Participation of an experienced regulator's experts in design safety review meetings and in subsequent operational safety review meetings as advisors for a few years after the nuclear power plant starts operating is strongly encouraged. The new entrant regulator should establish relationships for long term technical support in order to augment and reinforce the capabilities of its staff.

29. The human resources development programme for the regulatory body could be based on a two track approach. The first track is intended to provide to the regulatory body the means to respond to the nuclear power project in a timely manner without compromising safety. It involves the extensive use of external support and, to a certain extent, relies on the work done by an experienced regulatory body that has licensed a similar facility. In this phase a training programme should be established by the new entrant regulator aimed at providing a general understanding of the safety issues to be dealt with and to allow the local staff of the new entrant regulator to render informed decisions with the support of external expertise. The second track is aimed at providing longer term sustainability of the regulatory body by developing the competencies required to regulate the future operation of the plant. These competencies should be available

[5] The importance of these management interactions cannot be overly emphasized. For example, through attachments or exchanges, new entrant managers would get firsthand experience with the leadership, behavioural, attitudinal, and communications attributes needed for establishing an effective regulatory body and for maintaining effective relationships with stakeholders.

at the commissioning phase. The goals of the training programme in this case should be to provide the necessary skills to perform the regulatory functions by the end of the construction period with limited support from external experts.

30. The development plans should include extensive interactions with experienced nuclear countries. Those interactions might appropriately include the following:

— Interactions with senior policy makers from experienced nuclear countries to develop understanding of the required nuclear power infrastructure.
— Assignment of senior regulatory managers to an experienced regulator to understand regulatory management requirements and processes.
— Assignment of selected senior staff to experienced regulatory bodies for gaining hands-on work experience; these experts would then train local staff.
— Assignment of experienced regulatory staff to the new entrant regulator to assist with training, the development of processes, and assistance with the early regulatory activities.

31. If additional nuclear power plants will be constructed in the new entrant country in the future, the new nuclear power plant units may not be of the same design as the first nuclear plant. This should be taken into consideration when developing both the licensing methodologies and staff.

32. Regulatory staff can also obtain significant benefit from participation in international cooperation activities such as the Convention on Nuclear Safety [12], technical cooperation forums of regulatory bodies of countries having nuclear power plants of similar design, and the various technical cooperation activities conducted by international organizations, in particular the IAEA and the OECD/NEA.

Establishing the licensing process

33. The capability of the regulatory body to make regulatory decisions in a timely manner will depend on the level of nuclear knowledge available to the regulator and on the ability of senior regulatory management to anticipate and address the programme needs. As indicated in Fig. 1, the regulatory body should define the licensing process and establish rules and regulations by which the project will be assessed in phase 2, since these elements are necessary for the technology selection process. In that regard, early in phase 2 the regulatory body should recruit and train the staff that will be responsible for those developments.

In phase 3 the regulatory body should be prepared to assess the safety documentation provided by the future operator and to deliver licences for construction at the beginning of phase 3 and for the start of nuclear power operation at the end of phase 3.

34. In most cases, it is not realistic to expect a new entrant regulator to develop all the competencies required to perform the critical tasks shown in Fig. 1 by itself, nor to have all the characteristics of Appendix I in place before the construction licence is needed for the first nuclear power project. Therefore, a strategy should be developed to identify critical areas where the regulator could concentrate its initial efforts. An example of such an approach is to focus resources on deviations from the reference plant — for example, design changes to meet site requirements — while working with an experienced regulator to understand and, as appropriate, incorporate the experienced regulator's generic work on the reference plant. Such a methodology would facilitate a thorough design review with no compromise on safety and would avoid delays to the project.

35. In addition to the core competencies, the new entrant regulator's safety requirements and review processes may be much less well defined at the time of contract approval, particularly if the nuclear programme has been launched on the basis of technology neutral requirements. The incorporation of existing work from an experienced regulator will be most effective if the new entrant regulator follows the same regulatory approach as the experienced regulator.[6] Such an approach will also help ensure coherence and internal consistency, which is of particular importance for licensing the first nuclear power plant. On this basis, a three step process could be followed:

(1) As part of its initial development of the review process and compilation of the set of safety requirements, the new entrant regulator could use the processes and requirements of the experienced regulatory body as a reference. The state of regulatory development would then be assessed by a study of those requirements. Such a study would allow the new entrant

[6] Since the approaches used by an experienced regulator may be tied to its national laws and standards, they might not have the same legal basis in the new entrant country. Therefore, an analysis should be carried out to ensure that the experienced regulator's approach is enforceable in the new entrant country. As the new entrant regulator gains experience, it will be in a position over time to assess and adopt best practices from experienced regulators around the globe.

regulator to identify clearly the areas where gaps exist in the processes and respective expertise, as well as in safety requirements.

(2) Taking into account the gaps identified in step 1, the new entrant regulator would then enhance its understanding of the review methodologies and results, and ascertain the critical safety issues in the safety case/process. A key activity would be to determine the information from the experienced regulator that could be used to support the issuance of the construction licence. For this purpose, Appendix II of this report provides some guidance for implementation of an existing evaluation of a SAR.

(3) The final step would take place between the construction licence and commissioning, at which stage the new entrant regulator should develop its competence to the point where it can perform a detailed review of the FSAR, including those areas where results of the experienced regulator's assessments were incorporated. This would have three main objectives: (i) to verify and secure ownership of the licensing process; (ii) to position the new entrant regulator for assessing the submissions and approving the operating licence; and (iii) to prepare the regulator for the oversight of the operational phase of the nuclear power plant.

Longer term sustainability

36. Step 3 of the process described in the previous paragraph is extremely important. During the period from the start of construction to the start of commissioning, it is necessary to implement an intensive programme to enhance the managerial and technical competencies of the regulatory body. The regulator should develop a capability to conduct a thorough technical assessment of the FSAR since this is essential for understanding the underlying safety of the design. This understanding is needed for all the regulatory activities that follow the construction licence: approving the commissioning programme and understanding the significance of the commissioning results, particularly the testing of the safety related systems, structures, and components; reviewing the FSAR and issuing an operating licence with appropriate technical specifications to govern operations; and providing regulatory oversight for operations. The goal of the programme should be to reduce the reliance on external expertise over time as the project advances.

37. The regulator and government should also take steps to ensure that the characteristics that are listed in Appendix I are either in place or under development. Moreover, it is important for decision makers to appreciate that the regulator's competency level must be maintained over the entire lifetime of the nuclear plant and not just during the period in which the initial licences are

issued. Indeed, the oversight of operations is the longest phase of a nuclear power programme and is of great importance in ensuring the fulfillment of safety obligations. This phase requires the maintenance of strong technical and managerial capabilities. Therefore, long term and sustainable plans need to be established to ensure the ongoing effectiveness of the regulatory body.

3. ROLE OF THE OPERATING ORGANIZATION

38. Principle 1 of the IAEA Fundamental Safety Principles states that "the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risk" [1]. The licensee retains this responsibility throughout the lifetime of the licensed facilities, and this responsibility cannot be delegated. There should be no confusion between the role of the operator and the role of the regulator: the operator is responsible for safety, whereas the regulator is responsible for approving and providing independent oversight of the operator's activities that could impact safety.

39. The responsibility for safety requires that the new entrant operator establish and maintain the necessary competencies of both staff and management for safe operations. This entails providing adequate training and effective knowledge management, establishing the culture and methodologies to maintain safety under all conditions, and verifying that all activities and processes are safe. The new entrant operator must also verify on a continuous basis, due to ageing and to nuclear power plant configuration changes over the operating period, that the design and quality of facilities and equipment continue to meet safety requirements. In addition, the operator must take into account advancements in scientific and engineering knowledge and the potential effects of changes to the environment. All safety related issues must be identified and promptly addressed through operating experience (OPEX) and R&D. As a result, the operator should identify the external technical organizations required to sustain safe operations, particularly for R&D support to secure the ongoing effectiveness of the safety related structures, systems and components (SSCs) over the life of the nuclear power plant. Finally, the operator must also ensure the safe control of all radioactive material that is used, generated, stored, or transported. This includes provisions for the continuity of responsibilities and fulfilment of funding requirements over the long term for waste management.

40. To make certain that these responsibilities are met, the new entrant operator must establish early in the project how it will manage safety and perpetuate a safety culture that will underlie all its activities. Therefore, in the pre-project period the operator should develop robust safety policies, preferably with the assistance of an experienced and effective nuclear power plant operator, and communicate these to staff and stakeholders. The policies should include the organization's safety values, management's leadership of safety, and the safety behaviours that will prevail throughout the entire lifetime of the programme. These policies should extend beyond the organization's immediate staff to include the behaviour expected of all the stakeholders involved in the programme — contractors, suppliers, constructors, vendors, and support groups. To promulgate this, the operator should develop formal communication programmes on the organization's safety culture for these stakeholders, with clear articulation of the behaviours expected.

41. A challenge for the new operating organization is that it is the focus of all the activities surrounding the new project. It is managing simultaneously several interfaces with the various stakeholders, such as the government, the public, the media, the designer/vendor, construction companies, and manufacturers and suppliers. The operator must also ensure that there are effective interfaces with the regulator. This is crucial for the success of the construction project since any potential misunderstandings between the operator and the regulator could be exacerbated if they are not recognized at an early stage and addressed. As part of the interface, regular informal meetings between senior management of the operator and the regulatory body are most useful because they provide direct communication on potential concerns identified by either side.

42. As early as possible, and before the contract is signed for the first project, the new entrant operator and the regulator should review and make certain that there is a common understanding of the various licensing processes that will be followed. An important aspect of this is the documentation required by the regulator. Some of this documentation will have to be requested by the operator from the vendor. Experience has shown that it is much easier to do this when the licensing process and required licensing information are provided to the potential vendors before the technology is selected, and provisions governing the transfer of the required documentation is included in the contract between the vendor and the operator.

43. It is evident from the above discussion that the timely development of a competent operating organization, in addition to the development of the regulatory body, is also a fundamental requirement for safety. While the full

exploration of this important subject is beyond the scope of this publication, we note the value of external support for the new entrant operator from an experienced operator of the reference technology and also from international nuclear operations organizations such as the World Association of Nuclear Operators (WANO).

4. USING THE DESIGN SAFETY EVALUATION OF A REFERENCE PLANT

44. The review of a SAR is likely to be the major initial technical challenge faced by the new entrant regulator. In a two step licensing process, the PSAR will be submitted by the operating organization to support the construction licence approval and the FSAR will be submitted to support the operating licence approval.[7]

45. As discussed previously in this report, the regulatory body needs several years to develop the specialized competencies required to assess a SAR fully. Therefore, at the time of the application for the construction licence, support from an experienced regulatory body that has licensed a similar facility will very likely be needed. This support will considerably facilitate the licensing process in the embarking country because the new entrant regulator can benefit from the analyses and decisions undertaken by the experienced regulatory body. However, the new entrant regulator must recognize that that the responsibility for the authorization process cannot be delegated and that the final goal is to have a fully competent organization by the time of plant commissioning.

46. It should be recognized that every nuclear power plant must meet requirements for safety that result from local conditions. It may often be the case that modifications of the reference plant will be required so as to meet site specific circumstances, such as seismic conditions, differences in power

[7] Another approach is the implementation of a single step license for both construction and operation, such as the new US licensing methodology given in NRC Regulations 10CFR52. Because the one step process requires that the regulator have a capacity to conduct significant technical analyses early in the process, it is not recommended for a new entrant regulator.

frequency (i.e., 50 versus 60 Hz), the temperature and nature of the heat sink, local population density and distribution, and so forth. Because modifications of the design can have significant safety implications, the PSAR for the reference plant may be inapplicable in some respects for the nuclear power plant contemplated by the new entrant. As a result, the new entrant regulator must be capable of assessing modifications of the reference plant, presumably with assistance from the experienced regulator.

47. A major area of external support can arise from usage by the new entrant regulator of the experienced regulator's SER for an existing reference plant in the evaluation of the PSAR. The PSAR is a complex document covering a variety of technical areas. Appendix II summarizes the 15 PSAR chapters and the 90 topical areas contained therein, as described in IAEA Safety Guide GS-G-4.1 [13]. Appendix II also provides guidelines for the degree to which the new entrant regulator could make use of an existing assessment for a similar plant. As noted above, assessment areas that are more generic in nature are more likely to be applicable than those that are more dependent on local conditions.

48. It is apparent from Appendix II that a considerable amount of information from an experienced regulator could be relevant to the new entrant regulator's assessment. The use of this information would greatly facilitate the regulatory process for issuing the construction licence of the first nuclear power plant. The new entrant regulator could then focus its nascent resources on those areas that cannot be addressed by the experienced regulator's work. However, it is emphasized that the new entrant regulator must work closely with the external regulator to ensure that any incorporation of the existing evaluation is appropriate. It is also emphasized that a key objective of this approach is to achieve a level of technical independence that would eventually allow the new entrant regulator to carry out an independent assessment of the FSAR without extensive external assistance.

5. SITE APPROVAL

49. Site approval in the form of a 'site licence' or 'site permit' is likely to be the first licence for a nuclear power programme to be issued by the new entrant regulator. At this point in the licensing process, the plant design details may not be known. However, site evaluation and licensing by the regulator require that an

envelope of key generic characteristics (such as the power generated by the plant) of the nuclear power plant be specified that are consistent with the technology requirements as established by the operating organization.

50. Site criteria should be established by the new entrant regulator early in the overall nuclear power programme (ideally at the beginning of phase 2), so that the future operating organization can specify the site characteristics in any documentation used to develop the project requirements with vendors. If this is not possible, then envelope conditions covering all potential sites should be specified.

51. At the stage of site approval it is also appropriate to undertake a thorough review to ensure that the site is acceptable from an overall environmental perspective. Such a review might typically include the assessment of the impacts of the proposed nuclear power plant on the environment, adverse environmental impacts that cannot be avoided, the consideration of alternatives, and any irreversible and irretrievable commitments of resources. This report focuses on the safety implications of site approval, rather than the environmental impacts.

52. The IAEA Safety Requirements for site selection mandate that three aspects be considered [14]: the effects of external events, both human accidents and natural; characteristics of the site and its environment that could influence the transfer of radioactive material to persons and the environment; and population density and distribution and other characteristics of the external zone that might affect the implementation of emergency procedures. If there are any deficiencies in these three areas that cannot be compensated for by means of design features, measures for site protection, or administrative procedures, then the site shall be deemed unsuitable.

53. The process for site selection normally follows a logical sequence. The detailed information and assessment methodologies are well developed in the various IAEA Safety Guides relating to site selection [15–21].[8] First, a number of sites or regions are selected based on national priorities and are subjected to a screening process that eliminates the unsuitable sites. The screening process would use existing historical data such as seismic phenomena, subsurface conditions, the potential for volcanic activity, soil types, groundwater characteristics, flooding, meteorological data and population distributions. Next,

[8] These guides may be accessed through the IAEA web site at http://www-ns.iaea.org/standards/documents/default.asp?s=11&l=90&sub=10&vw=4#sf .

the remaining sites are verified according to predefined site exclusion criteria. This is followed by confirmation of the results of the previous steps through site investigations and laboratory measurements, along with the preliminary plant characteristics such as loads, physical dimensions and preferred layouts. Once a site has been selected and an application for a site licence has been made, the regulator will evaluate the site information as part of the licensing process.

54. The site approval process also establishes the basis for longer term requirements that will remain in place throughout the lifetime of the plant. The pre-operational phase includes ongoing assessment work during construction to refine the characterization of the site. During the operational phase, continuous monitoring and assessment of site characteristics will be required as part of the operating licence. Also, if there are any significant changes in population distributions or human activities surrounding the plant, or a change to the nuclear capacity on the site, these changes will have to be taken into consideration. Therefore, it is important that a new entrant regulator establish the authority and capacity to deal with site phenomena early in its development.

55. It is evident that the new entrant regulator must have the means, authority and competence to evaluate all the submissions that relate to the approval of a site. This process will require a set of specialized competencies in areas that are not necessarily nuclear related, such as seismology, meteorology, hydrology, geochemistry, and geology. In developing the strategy to secure and maintain a technically competent regulatory body, a decision should be made early in phase 2 whether to recruit staff with those competencies or to outsource this activity to external experts. For example, those competencies may already be available in the existing national expert bodies of the new entrant country and the regulator might wish to make use of these resources to broaden the national experience base for supporting the safety of the nuclear programme. Nonetheless, the regulatory body still requires a core technical group in the key disciplines to be able to understand and compile the information from the site evaluation reports as input to the site licensing process.

6. DESIGN REVIEW

56. The design review leading to issue of the construction licence and the more detailed design review incident to an operating licence are major undertakings for

a new entrant regulator. Such a review involves comprehensive assessment of the PSAR at the construction licence stage and of of the FSAR at the operating licence stage, as well as other highly technical supporting documentation, including R&D results and mathematical analysis. As outlined in Section 4 and Appendix II, to ensure both high quality and timely regulatory decisions, extensive use of the SER for the reference plant may be essential. In addition, support from external expertise could facilitate and build confidence in the new entrant regulator's decisions. However, as for other approvals, the new entrant regulator must take full responsibility for licensing the design, no matter what assistance the regulator receives or the degree to which the regulator incorporates an experienced regulator's evaluations.

57. The design review is a formal systematic assessment procedure to determine whether the design meets the required national safety regulations. It is expected that the national safety regulations will be consistent with the IAEA Safety Standards. The IAEA Safety Standards constitute the international consensus on nuclear safety in the form of Principles, Requirements, and Guides and provide the basis for a high level of safety [6].[9] These should be used as a reference for the development and review of the national safety standards against which the reactor design will be assessed.

58. The new entrant regulator may consider the use of the IAEA safety review services to review the compliance of reactor designs against the IAEA Safety Standards. While such assistance is generic in nature and cannot replace the detailed review required to licence a particular design, it provides the new entrant regulator with a valuable starting point for its future activities.

59. The design safety review work will involve industry codes and standards that are not specific to nuclear power plants. These codes and standards may be different in the country with the licensed reference plant than in the new entrant country. The use of established codes and standards from a country experienced in the use of nuclear power with the licensed reference nuclear power plant may be desirable. However, the degree to which a new entrant country can accept the codes and standards used in the design of the reference nuclear power plant must be evaluated very early in the design review process. For instance, the national codes for fire protection, civil construction, pressure vessels and worker safety

[9] The IAEA Safety Standards are subject to continuing review and amendment. They may be accessed through the IAEA web site at http://www-ns.iaea.org/standards/default.asp?s=11&l=90.

vary among countries, and it is necessary to understand at an early stage how the potential differences between such national codes could be taken into account. Carrying out sample checks on the design using the codes and standards that are in use in the new entrant country could also provide a good degree of confidence that the design meets the technical specifications.

60. Considerable technical information will be transferred from the vendor country to the new entrant country for the safely assessments. If the languages of the vendor country and recipient country are different, then care has to be taken in deciding on the working language for the safety review, ensuring quality in the translation of documents, and interpreting the information.

61. A new entrant regulator must also establish control of the design changes that will occur throughout the operating life of the nuclear power plant. The initial design approval is only the first step in ongoing design reviews that will occur over the operating life of the nuclear power plant. For example, as additional information becomes available from R&D or safety assessments, the new entrant regulator must be prepared to evaluate this information and to determine its safety impact on the reference design. In addition, the operator will continue to make design changes to improve and upgrade plant performance. It may also be necessary to install replacement parts based on new technology when some of the original parts are no longer available. INSAG-19 emphasizes the role of a "design authority" within the operating organization that has the mandate to approve formally all design changes [22].

62. The new entrant regulator should establish ongoing formal arrangements with established regulators from countries with similar nuclear power plant technology to ensure that the new entrant regulator is well informed of any safety implications arising from external findings concerning the design of the plant.

7. MANUFACTURING AND CONSTRUCTION OVERSIGHT

63. The regulator needs to confirm that all the SSCs of the nuclear power plant are manufactured and constructed following established industry and quality standards and proven engineering practices. This is to ensure that the SSCs are able to perform their design intended functions during normal operational states

and also under accident conditions. The confirmation is achieved through design document review and assessment, and by ensuring that appropriate audits and inspections are in place. A thorough design document review by the domestic regulator is necessary regardless of whether the manufacturing and construction is done by local or foreign organizations.

64. The regulator must be assured that audits and inspections are conducted in a systematic and organized manner to ensure that no items affecting safety are missed. In particular, special attention is required for the manufacturing and construction of components that will be subjected to high levels of neutron irradiation, as well as for those that are not easy to maintain, inspect or replace during operation. Depending on the regulatory approach, the regulator may seek assurances that the licensee has robust procurement, inspection, and auditing processes in place. In some cases, however, the regulator may also perform independent audits and inspections. In that case, the designated regulatory staff must be trained and qualified as inspectors and the inspection procedures formally documented. Foreign or domestic accredited inspection organizations might also be used to conduct the inspections on behalf of the new entrant regulatory body.

65. Generally, a graded approach should be employed in inspections whereby the rigour of inspection is commensurate with the level of importance to safety of the SSC being inspected. Deficiencies observed during inspections should be categorized according to their importance to safety and documented. Procedures and time frames for their correction should be agreed upon between the utility and the regulator. The regulatory staff should continue to follow up until the deficiencies are corrected or alternative methods for their resolution are approved and implemented.

66. It is likely that at least some of the construction and manufacturing will be carried out by local contractors based on their experience in executing similar work for conventional industry. But since these contractors in a new entrant country are not likely to be experienced with nuclear power plants, care must be taken to ensure that they are capable of meeting the stringent quality standards of the nuclear industry. In this respect, both licensees and regulators are encouraged to engage with contractors to provide the required knowledge and training.

67. Some deviations from the design may become necessary during manufacturing and construction due to a variety of reasons. Methodologies for dealing with such deviations should be developed and communicated by the regulator before these activities start.

68. Regulatory work associated with the construction and manufacturing of the first nuclear power plant will involve many new activities for the regulator and it is likely that external experts will be needed both for training and for implementation. Experts from an experienced regulator may be included as advisors in the regulatory inspection teams and in the review of the inspection reports. This will assist with the efficiency and quality of regulatory oversight and in advancing the knowledge of the new entrant regulator staff. The extent of involvement of the advisors may be progressively reduced as the new entrant regulator staff gain experience and improve their level of competence. In addition, other domestic or foreign accredited inspection organizations might be employed.

8. COMMISSIONING OVERSIGHT

69. Commissioning has a number of objectives. The SSCs of the nuclear power plant are prepared for operation and their design functions are verified. Also, confirmation is obtained that the performance of components and the integrated behaviour of systems both meet the design requirements for normal operation, anticipated operational occurrences, and design basis accidents. Verifying the design provisions for management of accidents beyond the design basis is done to the extent that this is feasible. Details on the regulatory approval and oversight of commissioning are provided in an IAEA Safety Guide [23].

70. Commissioning work generally is completed over a relatively short time, typically a few months. However, it is a period of intense activity. There is likely to be pressure from various stakeholders for expediting commissioning to bring the nuclear power plant into production as early as possible, and thus the new entrant regulator should develop a detailed plan for review of commissioning work that ensures efficiency without any compromise in quality or safety.

71. The review of commissioning activities provides a unique opportunity for the new entrant regulator staff to gain deeper insights into the behaviour of the individual reactor systems and the nuclear power plant as a whole under different operating conditions. This is beyond the knowledge that can be acquired through training, including the study of the PSAR and FSAR and other technical documents. The new entrant regulator should utilize this opportunity not only for augmenting the technical skills of its staff, but also to use the information

obtained from commissioning for fine tuning the regulatory requirements during operation, such as those related to operating procedures, in-service inspections, and surveillance of safety related SSCs.

72. For certain commissioning work, the regulatory staff together with the regulator's technical support personnel should be physically present at the site. For instance, the regulator should witness the performance tests of safety systems. This establishes the role of the new entrant regulator for on-site regulatory oversight and also allows the regulator to gain first- hand information on important safety related commissioning activities required for approving the various stages of commissioning. These clearances can be given by the regulatory staff at the site themselves, if so authorized, or in consultation with designated senior regulatory officials, or after review by a safety committee. The new entrant regulator should identify all such activities in advance and make appropriate arrangements, including logistics for ensuring their efficient and effective regulatory review.

73. The commissioning review conducted previously by an experienced regulator of the reference nuclear power plant or a plant of similar design can be gainfully utilized by the new entrant regulator in its oversight of commissioning. It should, however, be understood that no two nuclear power plants are exactly the same and there are bound to exist some design differences due to specificities of the site and plant layout. Also, some modifications to the design of the reference nuclear power plant are likely based on operating experience and new information from ongoing research to enhance safety or operating efficiency.

74. Expertise from experienced regulators acting in an advisory capacity could be used in the oversight of commissioning to enhance the quality and efficiency of the new entrant regulator's work. This advice would also be of considerable help in regulatory oversight of the nuclear power plant during its operational phase.

9. OPERATIONS OVERSIGHT

75. For the operating licence, depending on the regulatory approach, the regulator may require the operator to demonstrate how the operating safety envelope has been determined and how it will be maintained, or the regulator may

prescribe the operating safety envelope in the form of technical specifications that include the operational limits and conditions and in-service inspection, testing, surveillance and administrative requirements. These specifications are based on the SAR and other relevant documents that have been duly revised taking into account the commissioning results and the design changes made during construction to reflect correctly the as-built plant design. Various other licensing conditions are specified by the regulator, such as the radiation dose limits for plant personnel and members of the public, limits on radioactive discharges to the environment, and requirements on radiological surveys of the environment in the vicinity of the nuclear power plant.

9.1. LICENSING FOR OPERATION

76. The nuclear power plant is licensed for start of operation after confirmation that a sufficient number of trained and qualified operating personnel is available, operating procedures including emergency operating procedures are issued, requisite security measures are implemented, and emergency preparedness plans are in place and tested satisfactorily. It may be challenging for the new entrant operator to assess the knowledge level of the control room operators and securing their licenses. This is one of many areas where the new entrant operator would benefit from working with an experienced operator.

77. Following thorough commissioning of the various systems, the operating power of the nuclear power plant is raised in pre-identified steps and the plant parameters, especially the thermal and radiological parameters, are checked at various power levels. Some of the commissioning checks that have to be conducted with reactor at power are also carried out. After confirming the results of these commissioning tests and that the plant parameter values are consistent with the design, the regulator authorizes operation of the nuclear power plant at its rated power.

78. The new entrant regulator will require substantial assistance from an experienced regulator for a quality review of the data on various plant parameters and the results of commissioning tests. Such assistance will also be necessary for a thorough review of the technical specifications for operation and to ensure that all other prerequisites for issuance of the operating licence have been identified and completed. Comparison with the technical specifications approved by the experienced regulator and a review of their basis is recommended to enhance the knowledge of the new entrant regulator. This support from an experienced regulator is of great importance as the licensing conditions must comprehensively

cover the safety requirements for operation of the nuclear power plant over a licensed period that is likely to extend to several decades.

79. The technical specifications for operation and other licensing conditions for the reference nuclear power plant or other plants of similar design can be used effectively for developing the operational safety requirements for the plant being licensed. However, care has to be taken that the design differences and site specific conditions are taken into account. Assistance from an experienced regulator will be of great value in the judicious use of such information from other nuclear power plants.

9.2. REGULATORY OVERSIGHT DURING OPERATION

80. Regulatory oversight of the nuclear power plant during its operational phase is a very long term activity, covering the licensed operating period as well as its possible future extension. The major activities of regulation during operation are review of routine operation and safety related incidents, review of activities during outages, control of plant configuration and safety related changes in hardware and procedures, and assessment of the aging status of SSCs. Periodic safety reviews are also conducted, typically every ten years, to verify that adequate safety margins are maintained and that the nuclear power plant meets the current applicable safety requirements.

81. Regulatory oversight during nuclear power plant operation should not be limited to verifying compliance with the licensing conditions, but should also strive to make a positive contribution to enhancing safety on a continuing basis. This includes giving adequate attention to operational issues, such as management systems and safety culture.

82. A high level of technical competence in a variety of technical and other disciplines is necessary in the new entrant regulator and its technical support personnel to be able to discharge all regulatory responsibilities effectively over the entire operating life of the nuclear power plant. The technical knowledge and other capabilities acquired by the regulatory staff through initial training and participation in the licensing process for siting, construction and commissioning may be sufficient only for the regulatory oversight of normal operation of the nuclear power plant. Strong support from an experienced regulator is necessary for a few years to deal with off-normal situations; appropriate arrangements should be in place for ensuring such support. The assistance from the experienced

regulator can be progressively reduced as the new entrant regulator gains experience and enhances its technical and managerial capabilities.

83. It may not be possible for the new entrant regulator to develop fully its own safety standards for nuclear power plant operation in its formative period. Available international safety standards, such as the IAEA Safety Standards, could be adopted with suitable modifications as necessary. After gaining a few years of experience, the task of developing national safety standards can be undertaken by the new entrant regulator and its technical support organizations.

84. The new entrant regulator should periodically inform the government, the public and the media about the safety status and the operating experience of the nuclear power plant. In the case of any safety related incident, information should be provided promptly, including information on corrective actions. It is important that staff acquire the necessary communication skills to be able to convey the information in simple and easily understandable language to a non-technical audience.

10. CONCLUSIONS AND RECOMMENDATIONS

FOR NEW ENTRANT COUNTRIES

85. The licensing of the first nuclear power plant requires early development of the regulatory body. The time, resources and complexity involved with this development are considerable and should not be underestimated. Development of the new entrant regulator must start as early as possible and should not be constrained by the failure to plan or to provide necessary resources. An overall plan should be established that is consistent with IAEA recommendations and that recognizes fully the necessary regulatory capabilities and capacities required to address the successive stages of deploying and operating a nuclear power plant. The early stages of development of the new entrant regulator are particularly important. Even if the regulator has experience with research reactors, there is likely to be a mismatch between the schedule for issuing a construction licence and the ability of the regulator to carry out an independent review of the PSAR. This must be minimized to avoid undue pressures on the regulatory body that could impact its effectiveness. One approach is to utilize some of the generic assessment work performed on the reference design by an

experienced regulator that has licensed the same technology. Although the new entrant regulator must stand behind its decisions, it can appropriately work closely with the experienced regulator in this review. It is emphasized that the new entrant regulator must gain the competence to perform an independent assessment of the FSAR by the time of commissioning, at the very latest.

86. The knowledge requirement for each stage of licensing and regulatory oversight builds on the previous stages, but adds in additional requirements both in terms of technical knowledge and processes. For example, the regulatory oversight of operations not only requires that the regulator have a thorough understanding of the reactor design, achieved from an independent assessment of the PSAR and FSAR, but also requires new competence relating to reactor operations and inspections. For each stage, the new entrant regulator should make use of experienced regulators and other external expertise, although dependence should diminish over time.

87. The development of the regulatory body does not end with the licensing of the first plant. Continuing development should be an ongoing process throughout the entire life of a nuclear power programme. As safety technology, knowledge, and methodologies continue to evolve, the regulator must be able to incorporate this new information into its regulatory requirements and processes. Therefore, robust development programmes and the interaction of the regulator with the international safety and regulatory communities are both essential. The regulator must avoid complacency by continuously striving to maintain the characteristics summarized in Appendix I.

88. It is of course possible that expansion of the nuclear power programme in the new entrant country will take place in the future. Any additional nuclear power plants may be at different sites and may not be of the same design as the first plant. These possibilities need to be considered when developing the plans for establishing the safety infrastructure, including the required human resources.

89. This report has outlined some of the major issues that a new entrant regulator will need to address when licensing its first nuclear power plant. It is recommended that new entrant regulators and policy makers review these considerations and take them into account early in the planning process. These plans could also include those areas where external assistance is desirable, such as:

— Interactions with senior policy makers from experienced nuclear countries to develop understanding of the required nuclear power infrastructure;

— Assignment by senior regulatory managers of an experienced regulator to understand regulatory management requirements and processes;
— Assignment of selected senior staff to experienced regulatory bodies for gaining hands-on work experience; these experts would then train local staff;
— Assignment of experienced regulatory staff to the new entrant regulator to assist with training, the development of processes, and assistance with the early regulatory activities.

FOR NEW ENTRANT OPERATORS

90. Although this report does not focus on the obligations of the new entrant operators, the new entrant operator has the prime responsibility for ensuring safety. The many challenges outlined in this report of the new entrant regulators impose counterpart obligations on the new operators to develop the competence and capacity to meet their responsibilities.

91. All those involved in the nuclear enterprise must establish an appropriate safety culture. Experienced nuclear countries have learned that perhaps the most difficult challenge for an operator is the establishment and maintenance of an appropriate safety culture. This involves a management commitment to make safety the highest priority and to instill an awareness in every employee that he or she has a responsibility to ensure safety. The development of an appropriate safety culture should be seen as the foundation for everything that the new operator does.

FOR EXPERIENCED COUNTRY REGULATORS

92. The success of the new entrants in the fulfilment of their safety obligations will be vitally dependent on assistance from experienced country regulators in helping the new entrant regulators to fulfill their responsibilities. This will involve assistance in training, assistance and education in adapting the safety evaluations for the reference plant, and, perhaps most importantly, guidance on the appropriate role and activities of the regulator at the various stages of the licensing process.

93. The experienced regulator should be creative in finding effective means for nurturing the development and capabilities of the new entrant regulator. Various means by which this may be accomplished are outlined in the counterpart recommendation to the new entrant regulator. The key is an openness to productive exchange. The success of the new entrants is to the benefit of all.

FOR IAEA ACTIVITIES

94. Ensure that both this INSAG publication and the new Specific Safety Guide, SSG-16 [5], which provides detailed guidance for establishing the safety infrastructure including the regulator, are both widely distributed to new entrant countries.

95. Provide further assistance for the ongoing development of new entrant regulators:

- Prepare a summary guide laying out the various services, development and training programmes, and information provided by the IAEA that is relevant to new entrant regulators;
- Consider increasing the scope and depth of the various safety services, with an emphasis on new entrant requirements;
- Stress the importance of human resources by developing more focused peer review services for new entrants in the areas of human resources development, and education and training;
- Facilitate networking, regional and international cooperation, such as encouraging new entrant regulators to be part of the Global Nuclear Safety and Security Network (GNSSN).

96. Communicate a strong message to policy makers that the development of an effective regulatory body is essential for establishing and maintaining a nuclear power programme. Two specific recommendations for early implementation are:

- Establish a high level programme for new entrant policy makers to familiarize them with the principles of effective regulation, including the characteristics summarized in this publication and the gaps that new entrant regulators are likely to experience. This programme would be designed to ensure that policy makers understand the importance of, and provide the support for, the development and maintenance of a fully competent and independent regulator. The familiarization programme could be included in the events associated with the IAEA General Conference and could also be part of high level IAEA missions to countries that have expressed interest in initiating a nuclear power programme.
- Publicize/distribute the IAEA Safety Standards more widely to the various stakeholders in Member States contemplating the adoption of nuclear power.

Appendix I

CHARACTERISTICS OF A FULLY FUNCTIONAL AND EFFECTIVE REGULATORY BODY

No.	Characteristic	Description	New entrant considerations
1	**Independence**	Regulator is independent of industry and licensees, and also independent of, but not isolated from, government. Regulator is responsible to government for performance.	Independence must be incorporated into national legislation. The regulator must also be provided with the financial and human resources to carry out its mandate. INSAG-17 is a definitive reference on regulatory independence [3].
2	**Transparency and communication**	Must act in a reasonably transparent manner and communicate openly, clearly, and professionally with all stakeholders. A communications strategy for the licensing process should be in place.	Some regulatory functions, such as licensing hearings, should include public processes. Assessments and decisions must be understood by stakeholders and open to legitimate challenges. INSAG-20 discusses the role of stakeholder scrutiny [24].
3	**Authority to make decisions**	Has the full authority (and capacity, see Characteristic 4) to make informed licensing decisions for all licensing phases including site evaluation, design evaluation, construction, commissioning, operations, and decommissioning.	The new entrant regulator may request managerial and technical assistance from experienced regulators to help secure informed regulatory decisions. Such external assistance or support is of an advisory nature and does not in any way diminish the new entrant regulator's authority or responsibility to make licensing decisions.

No.	Characteristic	Description	New entrant considerations
4	**Technical and managerial capacity**	Must be able to reach independent decisions during each licensing phase. This means that leadership, communication, behavioural, managerial, and technical capabilities are all present. Technical knowledge and leadership in the relevant disciplines are in place and there is access to TSO(s) and research, as appropriate. Has an ongoing human resources recruitment and development strategy in place.	The full technical capacity for a new entrant regulator will take time to develop. This can be ameliorated in the short term by incorporating some generic (not site-specific) technical analyses with support from the experienced regulator that produced the analyses. The existing review of a SAR can be used as a staff development tool. Managerial and other attributes can be augmented by establishing strong relations with an experienced regulator, including staff exchanges to gain hands-on experience with managing regulatory processes and interfaces.
5	**Regulatory ownership**	Has the authority and resources to take full ownership of a licensee's safety case.	Safety cannot be outsourced. Even if a new entrant regulator incorporates technical analyses from established regulators, the new entrant regulator is still responsible for making regulatory decisions.
6	**Authority to obtain information**	The authority to request all information from a licensee that is necessary to make informed decisions.	A new entrant regulator should take steps to ensure that access to such information is explicitly included in contractual agreements between licensees and vendors. To provide the licensee with indisputable contractual arrangements, the authority to obtain information should be confirmed in legislation.

No.	Characteristic	Description	New entrant considerations
7	**Access to expertise**	Access to one or more TSOs with the appropriate technical resources to undertake detailed reviews of the technical aspects of licensing evaluations.	A new entrant should consider the use of foreign TSOs and R&D results in the initial phases of regulatory development. Formal relations between domestic and foreign R&D organizations should be encouraged.
8	**Access to legal advice**	Access to legal expertise to ensure effective regulation and enforcement.	The regulatory infrastructure must be based on a robust legislative framework and a legal support system must be in place with the expertise to support regulatory activities.
9	**Capacity to meet international obligations**	The government may assign responsibilities to the regulator to ensure that obligations arising from relevant international conventions and treaties are met, in particular the Convention on Nuclear Safety.	The Global Nuclear Safety Framework requires all countries to meet international obligations in safety, security, and safeguards.
10	**Regulatory research**	The ability to access and to fund independent research in support of regulation.	Ultimately, a regulatory body must be able to make decisions based on a firm technical understanding of the various phenomena affecting safety. Such understanding should be based on independent R&D that can point out new or unforeseen results. Mechanisms for funding the necessary R&D should be provided in legislation. INSAG-16 contains more information [25].
11	**International collaboration**	The capacity to carry out collaborative relationships with its international counterparts and international bodies such as the IAEA and the OECD/NEA.	Participation in the international regulatory community is essential for development of the new entrant regulator. Regulation and safety technology are both constantly evolving.

No.	Characteristic	Description	New entrant considerations
12	**Capacity to deploy national and international standards**	The capacity to understand the relevant national and international standards.	The regulator must ultimately be responsible for incorporating international and national standards into its regulatory documents.
13	**Coordination with other national regulatory agencies**	Mechanisms and practices for coordination of work with other regulatory agencies at all levels of government to ensure roles and responsibilities are clear.	This is particularly important where there could be jurisdiction questions that could impact safety or security. INSAG-24 describes the interfaces between safety and security [4].
14	**Quality management system**	Quality management processes for the conduct of all activities, including licensing, compliance, enforcement, safety evaluations, and decision making.	This is important for the conduct of all regulatory activities. A new entrant regulator should obtain hands-on experience with an established regulator in each of these critical management areas. Ultimately, a regulator should develop the capacity for self-evaluation and audit, and agree to undertake international evaluations, such as an IRRS mission.

Appendix II

GUIDELINES FOR A NEW ENTRANT REGULATOR TO MAKE USE OF AN EXPERIENCED REGULATOR'S EVALUATION BASED ON SAR TOPICS IN IAEA SAFETY STANDARDS No. GS-G-4.1 [13]

Chapter	SAR subject	Representative content	Implementation of existing regulatory assessments[a]
I	**Introduction**	Deals with general considerations that are country and project specific.	N/A
II	**General plant description**	Applicable regulations,codes and standards; basic technical characteristics; information on layout; operating modes; and material incorporated by reference.	Applicable regulations and codes are country and project specific, and will need to be prepared by the new entrant regulator. General plant information from the vendor and material incorporated by reference are areas where a very high percentage could be implemented.
III	**Management of safety**	Specific aspects of management processes; monitoring and review of safety performance.	This information could vary considerably from organization to organization so the existing material may not be relevant, depending on the degree to which the corporate management levels are consistent.

Chapter	SAR subject	Representative content	Implementation of existing regulatory assessments[a]
IV	**Site evaluation**	Site reference data; evaluation of site specific hazards; proximity of industrial, transport and military facilities; activities at the plant site that may influence the plant's safety; hydrology; meteorology; seismology; radiological conditions due to external sources; site related issues in emergency planning and accident management; monitoring of site related parameters.	These subjects are all site specific and require the new entrant regulator to perform the assessment with minimal reliance on an existing assessment. Cooperation with other national authorities and experts is necessary. Since site approval is an early requirement, the new entrant regulator needs to prioritize its development activities to deal with some of these issues at an early stage.
V	**General design aspects**	Safety objectives and design principles; conformance with the design principles and criteria; classification of structures, systems and components; civil engineering works and structures; equipment qualification and environmental factors; human factors engineering; protection against internal and external hazards.	A very high percentage for all content areas could be implemented but in-depth knowledge should be acquired before plant commissioning. Also, care must be taken to ensure that the specific criteria required to address particular site related loads and events are clear.
VI	**Description and conformance to the design of plant systems**	Reactor; reactor coolant and associated systems; engineered safety features; instrumentation and control; electrical systems; plant auxiliary systems; power conversion systems; fire protection systems; fuel handling and storage systems; radioactive waste treatment system; other safety relevant systems.	A very high percentage for all content areas could be implemented but in-depth knowledge should be acquired before plant commissioning.

Chapter	SAR subject	Representative content	Implementation of existing regulatory assessments[a]
VII	**Safety analysis**	Safety objectives and acceptance criteria; identification and classification of PIES; human actions; deterministic analyses; probabilistic analyses; summary of results of the safety analyses.	A high percentage for all content areas could be implemented. The new entrant regulator must work closely with an experienced regulator to understand fully the significance of these areas and in addition contacts are needed with technical support organizations that are able to conduct independent analysis for verifying the vendor results. Ongoing development of the implemented areas must proceed as rapidly as possible for the evaluation of any future changes to the design used for the PSAR.
VIII	**Commissioning**	Process and organization for demonstrating that the plant will be suitable for service prior to operation.	A high percentage of work on this topic could be implemented, with new entrant regulator work focusing on assessing site and plant design specific characteristics.
IX	**Operational aspects**	Organization; administrative procedures; operating procedures; emergency operating procedures; guidelines for accident management; maintenance, surveillance, inspection and testing; core management and fuel handling; management of ageing; control of modifications; qualification and training of personnel; human factors; programme for the feedback of operational experience; documents and records; outages.	A high percentage of work in these content areas could be implemented depending on the extent to which the utility will use a reference plant's operational methodologies. This will also require complete transfer of the onsite management and organizational model from a very similar licensed nuclear power plant. The new entrant regulator should have a plan for the required submittals for the development of the operating organization including a schedule for operator examinations.

Chapter	SAR subject	Representative content	Implementation of existing regulatory assessments[a]
X	**Operational limits and conditions**	The controls, limits, conditions, rules and actions derived from the safe operating limit.	A very high percentage for this topic could be implemented.
XI	**Radiation protection**	Application of the ALARA principle; radiation sources; design features for radiation protection; radiation monitoring; radiation protection programme.	A very high percentage for these content areas could be implemented. The new entrant regulator should have a plan for the required submittals for the operator's programmes for radiation protection.
XII	**Emergency preparedness**	Emergency management; emergency response facilities; capability for the assessment of accident progression, radioactive releases and the consequences of accidents.	A medium percentage for these content areas could be implemented, but there will be site specific areas that require new entrant regulator assessment.
XIII	**Environmental aspects**	Radiological impacts; non-radiological impacts.	A high percentage of the base information assessment for these content areas could be implemented. Site specific issues will have to be assessed by the new entrant regulator.
XIV	**Radioactive waste management**	Control of waste; handling of radioactive waste; minimizing the accumulation of waste; conditioning of waste; storage of waste; disposal of waste.	A very high percentage could be implemented for waste conditioning and storage content areas. A high percentage of the control, handling, and minimizing of waste content areas could be implemented. Waste disposal is not usually evaluated at this time.

Chapter	SAR subject	Representative content	Implementation of existing regulatory assessments[a]
XV	**Decommissioning and end of life aspects**	Decommissioning concept; provisions for safety during decommissioning; differing approaches to decommissioning; planning of the preliminary work.	A medium percentage for these content areas could be implemented.

[a] Possible implementation of an established regulator's assessments is classified as: very high (≥90%), high (≥70%) and medium (≥50%). Other areas can use little or no input from an existing safety evaluation report.

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