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External Expert Support for the Regulatory Body

DRAFT SAFETY GUIDE

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New Safety Guide

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1. INTRODUCTION

BACKGROUND

1.1. Organizations with responsibilities for safety and the control of radiation risks¹ may need to obtain expert advice from organizations or individuals external to their own organization. The rapid expansion of nuclear and radiation related activities in many States has highlighted the limited number of skilled and experienced persons available. Many regulatory bodies have generally identified a need to use, to a greater or lesser degree, sources of advice external to themselves and potentially external to their State. SF-1, "Fundamental Safety Principles", states that a State's regulatory body has the responsibility, among others, to maintain adequate technical competence to fulfill its duties as a regulatory body. Recent conferences on assisting regulators in their missions [1] have highlighted the roles, functions and value of technical and scientific support organizations in enhancing nuclear and radiation safety and drew attention to the subject of providing external expert support to States developing and maintaining nuclear power programmes.

1.2. While some regulatory bodies have sufficient staff and expertise to carry out their functions within their own organization, other regulatory bodies use a range of providers of external expert support² (both individuals and organizations), which may be dedicated to this

¹ The term 'radiation risks' is used in a general sense to refer to:

- Detrimental health effects of radiation exposure (including the likelihood of such effects occurring).
- Any other safety related risks (including those to ecosystems in the environment) that might arise as a direct consequence of:
 - Exposure to radiation;
 - The presence of radioactive material (including radioactive waste) or its release to the environment;
 - A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation.

² A 'provider of external expert support', a 'provider of external expert advice' or a 'support provider', used here in this Safety Guide with the same meaning, is an individual or organization that is not part of the regulatory body but which is recognized for its expertise and competence in safety and can provide support to the regulatory body.

task. Depending on the type of regulatory body, the State legal system and culture and the national nuclear programme, different structures and arrangements may exist. A regulatory body may not have the resources, in terms of number of staff, range of expertise and relevant experience, to carry out its functions to the extent necessary and within the required schedule. It may also choose to call on external support for other reasons, for example in order to benefit from the best expertise available. Therefore, the regulatory body should have a process and procedures in place to obtain suitable external expert support to gain input that can be used in making regulatory decisions [2].

OBJECTIVE

1.3. The objective of this Safety Guide is to provide guidance and recommendations on meeting the requirements of Ref. [3] on obtaining expert advice or services for the regulatory body. This Safety Guide aims to provide guidance on both how the regulatory body should obtain advice and how to use that advice. It addresses the process the regulatory body should use to determine the need for external expert advice, and the processes and procedures for identifying a suitable support provider and making contractual arrangements for the work. It also addresses how the support provider's advice should be taken into account by the regulatory body to retain responsibility in making its decisions.

1.4. The guidance will be useful both for States that are seeking to introduce and develop new facilities or activities (e.g. new nuclear power programmes, advanced nuclear activities) and need to consider how they can obtain expert support and for States where development or enhancement of the regulatory body is deemed necessary. This may also cover the case, that a regulatory body issues or revises regulations and needs input from specialists.

1.5. This Safety Guide is primarily written as guidance for regulatory body to cover all forms and uses of external expert advice. Also other organizations with legal, professional or functional responsibilities for safety may benefit from using this Safety Guide. These may include, but are not limited to, designers, manufacturers, constructors, employers, contractors and consigners (Ref. [4], Principle 1). In particular, the licensee of a facility or an activity should put in place similar control and quality requirements, together with internal arrangements for decision making, as the prime responsibility for safety rests with it (Ref. [4], Principle 1 and Ref. [3], Requirement 5).

SCOPE

1.6. This Safety Guide covers all forms of support for safety issues that may be required by a regulatory body, whether technical, scientific, legal, analytical or other types of logistic support. It also addresses the ways and forms that external support can be provided: by dedicated organizations (e.g. statutorily mandated technical support organizations); by other commercial organizations through either generic contracts or specific contracts; by other regulatory bodies; by advisory bodies; by research organizations; by academic bodies; by consultants, individual experts or by others.

1.7. The Safety Guide does not deal with support that may be requested for security issues of nuclear facilities, nuclear activities and issues relating to accounting and control of nuclear material. Nevertheless, providers of external expert support should be cognizant of the synergies and interfaces that exist between safety and security. Safety measures and security measures have complementary aims and there could be advantages if the processes and procedures applied to both safety and security are similar. However, it is also recognized that special requirements are needed when dealing with security issues. In this Safety Guide consideration is given mainly to issues relating to the security measures and controls that should be maintained when making information available to third parties and the need to ensure that appropriate arrangements are made with the various bodies with responsibilities for nuclear security. Further recommendations on security issues are provided in publications of the IAEA Nuclear Security Series.

STRUCTURE

1.8. Section 2 of this Safety Guide deals with definition and scope of the external expert provider, its functions, and roles; Section 3 addresses the characteristics that a provider of external expert supports should demonstrate; Section 4 provides recommendations on the process that should be used in selecting a provider of external expert support, in managing its support activity and how the advice should be used; and Section 5 describes how interactions between the provider of external expert support and the regulatory body and other interested parties should be managed by the regulatory body.

2. CONCEPT OF EXTERNAL EXPERT SUPPORT

GENERAL

2.1. The Fundamental Safety Principles [4] states that “an independent regulatory body must be established and sustained” with “adequate ... human and financial resources to fulfil its responsibilities” (Principle 2). Furthermore, Ref. [3] states that “The regulatory body shall employ a sufficient number of qualified and competent staff ... to perform its functions and to discharge its responsibilities” (Requirement 18). However, Ref. [3] states that “The regulatory body shall obtain technical or other expert professional advice ... as necessary in support of its regulatory functions”, emphasizing that the obtaining of such advice “shall not relieve the regulatory body of its assigned responsibilities” (Requirement 20). In Ref. [2] recommendations are provided on some aspects of the use of consultants and advisory committees; this Safety Guide provides additional, more detailed guidance.

2.2. The regulatory body should have, as a minimum, an adequate core competence in every core regulatory function, in order to retain the ability both to frame and manage the request for advice and to understand the advice when it is received. The regulatory body’s personnel should have sufficient technical knowledge to enable them to identify problems, to determine whether it would be appropriate to seek assistance from an external expert, to manage the external support while the advice is being developed and, at the end, to understand, evaluate and use any relevant advice from the external expert.

2.3. The regulatory body should put in place arrangements to ensure that it retains its responsibility for making all decisions on regulatory and safety issues and is not unduly influenced by any provider of external expert support. Processes and procedures should be put in place in advance to ensure that external expert advice is provided in accordance with an established system or infrastructure. Subject to available resources and within the existing infrastructure, such processes and procedures should include the following:

- The identification of the need for external advice (the internal process employed for making the choice between sourcing work in-house or obtaining advice from a provider of external expert support should be consistent with a clear policy that takes the safety implications of this choice into account);

- The method to decide which providers have the capability, independence and knowledge to provide that advice in order to ensure that contracts for work with safety significance are placed only with contractors with suitable competence, and adequate resources;
- A process for verifying that the provider of external expert support is free from conflicts of interest (see paras 3.2 to 3.8);
- A process for checking that the provider of external expert support has the required level of security clearance to undertake the work, when such clearance is necessary;
- The adoption of a code of ethics and confidentiality protocols (see paras 3.18 to 3.21);
- The arrangements for organizing and managing procurement;
- How the provider of external expert support and its advice are managed including processes for understanding and evaluating the external advice and for incorporating it into the regulatory decision making process (see paras 4.8 and 4.9).

SOURCES OF EXTERNAL EXPERT SUPPORT

2.4. External expert support can be obtained through a variety of sources. The source should have expertise and competence in the area of interest and should be capable of providing the necessary advice. This competence and capability should be clearly demonstrated to the regulatory body by formal means, such as the provision of examples of previous work experience or licences of staff. Paragraphs 3.9 to 3.15 provide detailed recommendations on demonstration of technical competence.

2.5. If the source of external expert support uses experts from outside its own organization as subcontractors, who in turn may use other subcontractors, the primary external expert support provider should document the independence, reliability and competence of these organizations and individuals. Furthermore, the employment of subcontractors should be properly communicated to the regulatory body.

2.6. Expert advice in specialized areas may not be available within a State and so arrangements with organizations in other States may be necessary, which can raise specific issues that should be considered by the requesting regulatory body. This may also be the case when a regulatory body issues or revises regulations and needs input from specialists. When the use of advice is considered, the regulatory body should be aware that, although a provider

of external expert advice may have considerable experience with the particular issue, it may be difficult, on the grounds of security of information (see paragraph 3.19) or commercial confidentiality (see paragraph 3.21), to have full interaction with that provider of external expert advice. Legal requirements regarding how contracts are placed, including tendering requirements, may also affect the choice of provider of external expert support. Consideration should be given to the fact that the regulatory infrastructures in different States may not necessarily be compatible in this sense.

2.7. The following list covers most of the main sources of advice, but is not intended to be all inclusive:

a. Sources of advice from within the State include:

- Advisory bodies: many governments and regulatory bodies appoint experts in the form of an advisory committee to assist and provide advice. Such experts may be from other States, but should be appointed in accordance with clearly defined terms of reference that include criteria for their selection (see Ref. [2], paras 3.30 – 3.32);
- Dedicated organizations: some States have within their legal structures arrangements for particular independent organizations to dedicate part of their resources to assisting the regulatory body on a regular basis;
- Government laboratories or research centres: if the issues require experimental investigation or verification, advice from such bodies can be sought;
- Legal organizations: most States have private or governmental legal bodies that can review the language of legal documents and assist in legal enforcement actions;
- Other government organizations: these may be mandated to provide input on regulatory decisions but do not have specific decision making responsibilities.

b. Sources of advice from outside the State include:

- International organizations: organizations such as the IAEA, ICRP, the OECD Nuclear Energy Agency (NEA), the World Association of Nuclear Operators (WANO), the World Health Organization (WHO), can be

sources of advice on specific issues. This may be provided through membership of their committees or by specific contractual arrangements (Ref. [3], Requirement 14);

- Academic and research institution particularly those funded by state and government authorizes can provide external expert support without conflict of interest;
- Multi-lateral and/or bilateral agreements can provide external support and technical exchange;
- Regulatory bodies of other States: foreign regulators can be consulted for input through individual contacts, international cooperation agreements or international forums, on the decision making process used in a given area, which can be particularly useful when designs or regulatory procedures utilized in one State are considered in another;
- Regulatory bodies of vendor States: regulatory bodies from vendor States can be consulted with respect to the regulatory structure and its application in a State from which structures, such as the reactor pressure vessel, components or services are provided to the licensee;

c. Sources of advice from either within or outside the State include:

- Standards organizations, quality assurance organizations and professional bodies: these bodies, which may be national or international, such as the International Organization for Standardization (ISO), can provide advice within their fields of expertise;
- Engineering or service organizations: in many States engineering or service organizations have been set up to provide services in technical, engineering and scientific fields;
- Certified testing and analytical services: certain measurements required on a regular basis, such as dose monitoring or water quality, can be carried out for the regulatory body or the State, if necessary, by organizations offering these services;

- Academic institutions: universities and other academic institutions such as engineering schools or institutes of technology can, either through their academic staff or by establishing a research programme, provide advice on a range of scientific, technical and engineering issues;
- Individual experts in specific fields of competence (i.e. consultants): many experts in specific fields do not belong to organizations. Recent retirees from a regulatory body or other bodies could be a particularly useful source of advice;
- Financial and economic organizations: these organizations, which can be private or governmental, can provide advice on matters such as the financial status of an applicant, the appropriateness of investments or decommissioning funds or potential financial conflicts of interest.

2.8. The regulatory body should obtain relevant information on the specific organizations that exist in their State or to which they have access, including human resources, knowledge of their field of competence, provisions made for building and maintaining the competences and capability for technical support, in order to have sources readily available when there is a need for advice.

2.9. Contracts with different types of organizations, institutions, bodies, individual experts, etc., may be framework contracts so that their advice can be called on when needed, or may be specific contracts that are concluded as each issue arises. Framework contracts may span a range of areas or be restricted, depending on the expertise of the provider of external expert support. The support may be continuous, in the form of a fixed arrangement, or through a long term or generic contract, which may cover a range of areas. Alternatively short term contracts on specific areas may be issued. This choice of approach is not exclusive, as different methods can be used at different times or even concurrently. The actual approach will depend on the legal structure of the State and the structure and needs of its regulatory body.

AREAS FOR EXTERNAL EXPERT SUPPORT

2.10. The areas for which external expert support may be necessary are the following:

- Research activities;
- Licensing, review and assessment (management system, engineering analysis, safety analysis, independent verification...);

- Development of regulations and regulatory implementations (e.g.; inspections, enforcement, regulatory guidance development)
- Advanced technical analysis and computer simulations and modeling; and technical evaluations of tenders and technical specifications).
- Emergency response support and guidance, assessment and evaluation of different professional views including transparency in addressing these views
- Development of regulatory infrastructures
- Technical support for conventions
- Legal or financial advice;
- Communication support;
- Testing, measurement inspection and analysis services;
- Staff training;
- Drafting of regulatory documents;
- Project management and administrative support.

3. CHARACTERISTICS OF EXTERNAL EXPERT SUPPORT

GENERAL

3.1. As set out in Section 2 of this Safety Guide, the sources of external expert support may be very different and the characteristics required of a provider of external expert support will vary in consequence. Of the characteristics set out in this section, some might not apply, or only in a partial way, to an individual (e.g. the need for an adequate management system).

INDEPENDENCE

3.2. In Ref. [3], Requirement 17 states: “The regulatory body shall perform its functions in a manner that does not compromise its effective independence”. This is reflected further in the requirement to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice and services (Ref. [3], para 4.20).

3.3. Independence of advice means that the provider of external expert support should be able to form and express a technical judgement that demonstrates integrity, and is impartial and free from commercial, financial and other pressures from interested parties. The provider

of external expert support should not be bound to directives from any other organization regarding the results of its work. Independence should be a basic attitude of the expert but moreover, the experts' judgement should be based solely on technical knowledge, on results of analyses and applicable regulatory requirements and guidance and should in no case be biased owing to political opinion. Technical competence (see paras 3.9 to 3.15) and sustainable improvement in safety culture and security awareness in the provider of external expert support contribute to the independence of the technical advice.

3.4. An important element in ensuring effective independence is to develop and implement adequate arrangements that avoid actual, potential or perceived conflicts of interest. All reasonable situations should be analysed for actual, potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated. This should be done as soon as possible. Way of avoiding or detecting actual conflicts of interest include:

- Verifying whether the provider of external expert support has a code of ethics and an organizational structure that promotes a strong safety culture and that these demonstrate that conflicts of interest will be avoided;
- Verifying whether the organizational structure of the provider of external expert support and its internal procedures provides functional and personal separation to ensure effective independence between units carrying out work for the regulatory body and units carrying out similar work for a licensee or other organization. The links between such units should be carefully monitored.

If neither of these can be verified, an alternative opinion from other providers should be sought. Potential and perceived conflicts of interest should be explicitly discussed and managed.

3.5. The provider of external expert support should make rigorous, demonstrable arrangements to maintain the required independence and should clearly indicate to the regulatory body any actual, potential or perceived conflicts of interest. Any changes of personnel that might affect independence should be discussed with the regulatory body before the changes are made. Conflicts of interest may potentially occur in a variety of cases, including the following:

- When a financial tie (e.g. through a stockholder or through funding) exists between a potential external expert or organization and the nuclear industry (e.g. a licensee, a designer or a vendor);

- When the licensee has to arrange for and pay for an independent technical study in order to submit required analyses or documentation to the regulatory body;
- When the external expert, or organization, is part of, or closely linked to, an organization that has been assigned responsibilities in relation to promotion of nuclear technologies for profit or any form of payment;
- When there may be a conflict of national or commercial interest;
- When the external expert, or organization, is providing support on the same or closely related issues to potential licensees, designers, or vendors that are regulated by the regulatory body;
- When the external expert have worked or is working also to licensees or regulatory bodies abroad.

3.6. It may be impossible for the regulatory body to find an external expert who is free from all potential conflicts of interest. This may be the case, for example, when:

- The task to be accomplished requires very specific knowledge in a field where the few existing competent experts already have links with licensees or other organizations in the nuclear industry; or
- The complexity of the task to be accomplished is such that only a few large providers of external expert support are capable of coping with it and they may already have established connections with licensees or other organizations in the nuclear industry.

3.7. If a provider of external expert support is not entirely free from potential conflicts of interest, the task assigned to him should be closely monitored. The advice given should then be carefully assessed by the regulatory body for bias generated by conflicts of interest (Ref. [3], para. 4.21).

3.8. In all cases, the requirement to verify the absence of conflicts of interest, and the way any conflict of interest is to be managed and monitored should be thoroughly documented. This can be done by including appropriate clauses in the contract between the regulatory body and the provider of external expert support, or other appropriate document, depending on the legal framework used for obtaining external expert support.

TECHNICAL COMPETENCE

3.9. Technical competence represents a profound knowledge of the state of science and best available technology that is necessary for a broad and comprehensive assessment of the safety of facilities and activities. Technical competence is the ability of the provider of external expert support to implement state-of-the-art knowledge and techniques. The technical qualifications and experience of external experts should be at the same level as or greater than those of the staff of the regulatory body who are performing similar tasks (see Ref. [2], paras 3.28 and 3.29).

3.10. The provider of external expert support should have experience in the relevant area (for example an accreditation, certification, list of references). It should be knowledgeable, by direct experience, of the specific methodology, applicable criteria and requirements, code, tool, or approach for the work it undertakes.

3.11. The provider of external expert support should have available, directly or through subcontractors, the necessary tools (e.g. computer codes, data reference), standards and expertise to accomplish the task. For example:

- Capability and experience in using the tools;
- Adequate knowledge of national or international standards;
- The most up to date versions of verified and validated computer codes, as well as permission from the proprietor of the codes for their use.

3.12. Individual experts and expert organizations should know the relevant national legislative requirements and the regulatory requirements that are in force in the State whose regulatory body is supported.

3.13. Building and maintaining of competence in expert organizations should be ensured. Requirement 11 of Reference [3] states that “The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities”. Furthermore, para. 2.34 of Ref. [3] states: “As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available” and para. 2.35 states that “Competence shall be built, in the context of the regulatory framework for safety, by such means as:

- Technical training;

- Learning through academic institutions and other learning centres;
- Research and development work.”

Other means of building competence include:

- Becoming a member of regional and/or international safety networks;
- Implementation of sustainable improved nuclear knowledge management;
- Gaining appropriate experience; lessons learnt from incidents, or events and potential implications to modification of procedures, structures or system components;
- Technical exchange through bilateral/multilateral agreements
- Peer Reviews and self-assessment
- International conventions
- In-house seminar;
- Participating conference, workshop, seminar, and symposium.

3.14. Depending on the source of external expert support and on the expected duration of the support, expectations in relation to technical competence and the ways and means to demonstrate skills and knowledge will vary. Some cases are addressed in the following:

- For an individual expert, technical competence should be ensured by verifying that he or she has already provided similar external expert support in a satisfactory way, for example through recommendations from other experienced well-known experts (e.g. a reference list). For an academic expert, a publication list is a useful additional tool, and documented research activity should indicate skills and knowledge that are adequate for the task to be assigned. Finally, certification may demonstrate continued competence in their specialty area;
- For an organization that has an established, long term relationship as a provider of external expert support to a regulatory body, there is still a need to build and maintain competence (Ref. [3], para. 2.35). Competence can be demonstrated by the following:
 - All the personnel of providers of external expert support are fully aware of the safety implications of their work;
 - The existence of a strategy for training its own staff and implementing it in its technical field of competence;

- Involvement in significant research activities in its field of competence;
- Experience gained in performing safety related tasks at national and international level;
- Bilateral cooperation with the regulatory body, covering areas such as: experience exchange, sharing of skills, and organization of activities relating to familiarization with operating procedures and documentation of the licensee;
- International activities aimed at research analyses, participation in international activities related to safety, purchasing of software products and other cooperation areas;
- The existence of an ongoing, up to date, research and development programme.

3.15. Competence often relies on the experience of having done similar, appropriate work before. Understanding and competence in the assigned area should be demonstrated by the range of the individual's or organization's experience in the number of different, independent activities performed in the assigned area, as well as the different levels of complexity of these activities.

MANAGEMENT SYSTEM

3.16. Any potential provider of external expert support should adhere to basic management principles. Reference [5] establishes the general requirements for the management system. For a provider of external expert support, the existence of a quality management system is a useful characteristic for the following reasons:

- Through the traceability of processes and documentation, it can help to demonstrate the technical competence of the organization, for example through the processes of assigning qualified people to a specific task or of reviewing advice before finalizing it;
- In case of the establishment of long term support (e.g. a dedicated support organization), the existence of a quality management system may provide confidence that technical competence will be maintained in the long term.

3.17. The management system should be such as to help the provider of external expert support to defend its advice on technical matters; this defence should be supported by technical arguments, justified according to applicable requirements and supported by documentation. The documentation can be used by the regulatory body to support its decision

making, which should reflect the high priority given to safety (Ref. [6], Para. 2.36). Since the regulatory body has to utilize and evaluate the work performed by the provider of external expert support, the external expert should be required to provide a detailed written report consistent with the work plan agreed with the regulatory body. The report should include the objective of the work, references, the basis for, the methods, the results, conclusions and any related recommendations that may assist the regulatory body.

CONFIDENTIALITY

3.18. The organization providing external expert support may have to address two types of confidential information: security or protected information and proprietary information.

Security or protected information

3.19. In most States, the management of security related confidential information is controlled at the government level, and verification of the trustworthiness of the organization and individuals working for it is required. If such information needs to be transmitted to any other organization outside the regulatory body or even across borders to a provider of external expert support in another State, this should be done in accordance with relevant agreements, including intergovernmental agreements, governing the conditions of access, and the transfer and management of security related confidential information. In these cases, the provider of external expert support should be able to demonstrate that the access to such information is effectively restricted to individuals whose trustworthiness has been checked and who have a 'need-to-know' the information, that the information is kept under secure conditions, and that secure procedures are in place for communicating the information (secure fax, encryption capabilities, etc.), specific to the security level of the information.

3.20. It is assumed that organizations and individuals in other States (or even within the State itself) would not be allowed to disclose certain security information without the agreement of the owner, taking into account any international agreement or regulatory requirement. Any information supplied to parties outside the regulatory body should be done within the rules established by the relevant authority.

Proprietary information

3.21. The provider of external expert support should also be made aware of the existence of any confidential proprietary information (including information of commercial value), of its

precise scope, restrictions on its use and the organizations to whom it may be disclosed. The provider of external expert support should have in force management rules, procedures and organizational conditions to protect this type of information as well. The regulatory body should be aware that commercial entities designing or selling facilities normally do not allow proprietary information to be made available to other parties. Even within a State, a company may wish to place restrictions on individuals or organizations outside the regulatory body who may be made privy to certain aspects of the plant. No such restrictions can be placed on information required by the regulatory body, but this does not necessarily give it the authority to provide this information to third parties. The regulatory body should inform the owner of intellectual property rights to any information of its intention to pass that information to a third party (i.e. the provider of external expert support) and should establish commonly agreed arrangements.

SAFETY CULTURE

3.22. The Fundamental Safety Principles [4] states that “A safety culture that governs the attitudes and behaviour in relation to safety of all organizations and individuals concerned must be integrated in the management system. Safety culture includes:

- Individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;
- Accountability for safety displayed by organizations and individuals at all levels for safety;
- Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety” (Ref. [4], Para. 3.13);

Training and promotion of safety culture are also important in enhancing safety culture.

3.23. The regulatory body should ensure that its safety culture requirements are reflected in or similar to those of the provider of external expert support. The provider of external expert support should have a stated commitment to safety culture that is consistent with the regulatory body’s policy. The provider of external expert support should be able to perform and provide the requisite technical support in accordance with the attitudes to safety culture of the regulatory body and to raise any safety concerns regarding the work they have conducted with the regulatory body. The regulatory body should address any safety concerns raised by the provider of external expert support. On that regard the regulatory body should develop:

- A process for addressing different professional views;
- Transparency in reaching consensus in providing advice;
- Transparency in dealing with issues of significance to safety concerns;
- A public involvement and awareness in technical policy decisions supported by providers.

DRAFT

4. PROCESS TO SELECT AND USE EXTERNAL EXPERT SUPPORT

REASONS FOR THE USE OF EXTERNAL EXPERT SUPPORT

4.1. Despite the core competence of the regulatory body there are many reasons why external expert advice may be sought. These reasons may include the following:

- For assessment of a new design of nuclear installation that is different from those previously authorized in the State;
- There is a need for a variety of expertise in different specialties at different stages in the lifetime of a facility or activity, e.g. site selection, design, construction, commissioning, operation and decommissioning or closure;
- To respond to legal changes that require new regulatory processes and regulations;
- To support the review of application of new technologies for process and safety systems;
- To support the establishment of new safety criteria and requirements;
- To perform detailed independent verification;
- To evaluate analysis of new sites for facilities;
- To compensate lack of experience and expertise or insufficient capability related to a technical discipline (e.g. an issue relating to site evaluation that requires expertise in geology);
- To compensate a lack of specific resources for tasks at hand, e.g. a lack of experience relating to the infrastructure for commissioning including project management;
- To deal with an increase in the short term workload;
- To provide advice under emergency conditions.

4.2. For States developing new nuclear power programmes, or new facilities or activities, the regulatory body may need expert support from an external organization for developing its processes and procedures, for identifying its needs and technical areas for support and for determining suitable external sources of advice. One possible way to do this, without compromising the independence of the regulatory body, would be to establish a partnership with a provider of external expert support that could assist in the process of procurement of

external advice. This could be of assistance in ascertaining the availability and suitability of external expert support and the necessary questions to ask.

ACTIONS TO TAKE IN SEEKING ASSISTANCE

4.3. There are many sources of external expert support that may be available to the regulatory body as listed in para. 2.7. When a regulatory body determines it needs external expert support it should first:

- Determine the objective, the scope, the schedule and the different steps of the work required. This can be as narrow as a single task or as broad as a general arrangement for technical services.
- Determine the expertise required to perform the work and the kind of product that is expected;
- Identify the possible sources for obtaining the expertise;
- Solicit or select an organization or individual to provide the expertise;
- Develop regulatory infrastructure;
- Ensure continuity in providing support until completion of project or assignment;
- Allocate funds to establish continuity in expert provider support until completion of project.

CONSIDERATIONS TO EMPLOY IN SELECTING THE EXTERNAL EXPERT

4.4. External experts should be chosen with the understanding that they will provide impartial advice. It should be confirmed by the regulatory body that the external expert's other activities as a specialist will not give rise to a bias in the advice given; the potential for any such conflict of interest should be minimized and when recognized, dealt with immediately (see paras 3.2 to 3.8).

4.5. When selecting an external expert, the following recommendations should be taken into account:

- The provider of external expert support should be able to demonstrate technical competence (see paras 3.9 to 3.15);

- There should be no actual conflicts of interest. In case of a potential or perceived conflict of interest, the situation should be explicitly discussed with all involved parties and managed (see paras 3.4 and 3.5);
- The provider of external expert support should be able to conduct its work within the time frame specified by the regulatory body to make the decision. The time allowed for the work to be performed by the provider of external expert support should be commensurate with the scope of the work and consistent with the applicable regulations;
- The provider of external expert support should be able to prepare and deliver specific documentation as required to formalize the advice and its rationale. This documentation can be used by the regulatory body as an auditable input into its decision making (see para. 3.17);
- The quality of the work of the provider of external expert support should be reviewed by the regulatory body. The documentation that supports the advice should be sufficient, accurate and relevant to allow the regulatory body to judge the quality of the work;
- When the use of advice from other States is considered it should be ensured that all parties involved communicate in a common language. All parties should be aware that the use of translation services in a highly specialized technical area bears a risk of misunderstandings.

THE REGULATORY BODY AS AN INTELLIGENT CUSTOMER³

4.6. The regulatory body should maintain its status as an ‘intelligent customer’ capability for all work carried out on its behalf by external experts.

4.7. The regulatory body should provide adequate management, supervision and oversight of the work of the provider of external expert support. Adequate contractual arrangements are necessary to specify the role and responsibilities of the provider of external expert support.

³ An ‘intelligent customer’ capability is the capability of the organization to have a clear understanding and knowledge of the product or service being supplied. The ‘intelligent customer’ concept mainly relates to a capability required of organizations when using contractors or expert support.

The staff of the regulatory body assigned to oversee the work of the provider of external expert support should:

- Fully understand the need for an external expert's services and the context in which the work is being performed;
- Know what is required and how the work will be used;
- Specify the objective, scope and requirements so that the product received meets the intended needs;
- Set the time frame for delivery of the work;
- Provide any information that could be useful to the external expert;
- Understand the expected outcome;
- Not inappropriately influence the outcome or advice from the external expert or allow any other body to influence the provider of external expert support, in order that its advice clearly reflects its own technical opinion;
- Supervise the work in accordance with the regulatory body's procedures, and technically review it whenever necessary;
- Ensure regular interaction with the provider of external expert support and facilitate the interaction of the provider of external expert support with the other parties related to the task if necessary.

EVALUATION AND USE OF THE WORK PERFORMED

4.8. The regulatory body should evaluate the work performed by the provider of external expert support in accordance with the defined objective and scope of work set at the outset. After the work is completed, the regulatory body should consider the advice received from the provider of external expert support and determine whether and how it is going to be utilized. The advice should be evaluated in accordance with the role and the level of responsibility of the provider of external expert support. Such evaluation should be used also for the purposes of assessing the suitability of this external expert for potential further work.

4.9. The work performed by the provider of external expert support should be used to provide input into regulatory decision making. The written report provided by the external expert should contain detailed results of the technical analysis that support its conclusions, on

the basis of which the regulatory body can make appropriate decisions. The regulatory body should document the decisions it has made on the basis of input from the provider of external expert support. The basis for the decisions should be recorded and documented appropriately.

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5. CONTROL OF THE PROVIDER OF EXTERNAL EXPERT SUPPORT AND COMMUNICATION

GENERAL

5.1. The provider of external expert support does not replace the regulatory body when providing support. In instances where the provider of external expert support will need to interact with other interested parties, it should be made clear that the regulatory body has approved such contact and that the regulatory body retains its responsibilities and makes the final decision (Ref. [3], Requirement 20).

INTERFACES

5.2. A provider of external expert support may need to interact with a licensee that is subject to regulatory control. This may mean visiting sites, gathering data, observing performance and conducting technical meetings and dialogue with staff or management of the licensee. Such interfaces should be properly controlled by the regulatory body and in no way should a provider of external expert support be allowed to make comments or take actions that might be construed as regulatory requests or requirements. For this reason, all such interfaces should be led or supervised by an appropriate representative of the regulatory body.

5.3. Where it is decided that a provider of external expert support may make direct contact with a licensee, without the presence of a representative of the regulatory body, the purposes and reasons for such contact should be defined in the formal arrangements between the regulatory body and the provider of external expert support. Furthermore, the licensee should be made aware by the regulatory body of the potential for direct contact by the provider of external expert support, including the scope of and limits to such contact. Timely information on any such contacts should be provided to the regulatory body. The support provider should also inform the regulatory body of any other contacts needed with other interested parties that may be relevant to the advice being provided.

TRANSPARENCY AND OPENNESS

5.4. The provider of external expert support should explain the basis of achieving consensus and how different professional views (DPVs) were accommodated and addressed.

DPVs' resolution should be addressed in coordination with the regulators. The provider of external expert support should keep sufficient records, so that its advice can be traced and audited. This includes, inter alia, records of data and models used for all computer calculations as well as associated uncertainties, references to sources of data, reference to documentation that has been examined (safety analysis report, safety justification, design documentation, etc.) and results of any tests carried out. The regulatory body may decide to provide this information to the licensee. In this case it should be ensured that proprietary or confidential information is appropriately controlled.

5.5. Reference [7] states in para. 27 that "Transparency is a means to promote independence in regulatory decision making and to demonstrate such independence to politicians, licensees and other stakeholders, as well as the general public." If information that results from expert advice may have to be made available to the public, the regulatory body should give consideration the nature of this communication with the public. In particular, issues relating to the copyright of documents submitted by the provider of external expert support should be explicitly addressed. Unless there are confidentiality issues, all external advice should generally be made public to enhance transparency as part of the process of engagement with interested parties. Publications should clearly show the identity of the provider of external expert support and should indicate that the advice was developed for the regulatory body by this provider.

5.6. Work carried out for the regulatory body should be made available to the public in accordance with the national legal framework governing public access to documents established or possessed by public bodies. Experts may, from time to time, wish to draw on this work in other contexts or may wish to refer to advice that was not, for some reason published. The regulatory body should then reconsider whether such advice should be made public or sent to the person requesting it, taking into account confidentiality or security issues. Arrangements with providers of external expert support should detail the necessary instructions and authorizations for the work to be quoted or used and should provide guidance on handling proprietary information. In addition, the regulatory body may specify a time before which a provider of external expert support is not permitted to discuss the work with other parties.

COMMUNICATIONS

5.7. All communications regarding the work performed by the provider of external expert support at the request of the regulatory body should be carried under the control and direction

of the regulatory body. The provider should not publish technical results or technical evaluations or lessons learnt and should not release to public media any results or technical findings, or technical/policy positions without mutual consent with the regulatory body.

5.8. There should be regular contact between the provider of external expert support and the regulatory body. The frequency of meetings will depend on the extent of the work being performed, the knowledge and confidence the regulatory body has in the provider of external expert support and the need for timeliness of the expected results.

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6. REFERENCES

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, (a) Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety, Proceedings of an International Conference held in Aix-en-Provence, 23-27 April 2007, IAEA, Vienna (2007); (b) Challenges faced by Technical and Scientific Support organizations (TSO) in Enhancing Nuclear Safety and Security, Proceedings of an International Conference held in Tokyo, 25-29 October 2010, IAEA, Vienna (2010).
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Staffing of the Regulatory Body for Nuclear Facilities, IAEA Safety Standards Series No. GS-G-1.1, IAEA, Vienna (2002).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1, IAEA, Vienna (2010).
- [4] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006).
- [7] INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Independence in Regulatory Decision Making, INSAG-17, IAEA, Vienna (2003).

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