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External Expert Support on Safety Issues

DRAFT SAFETY GUIDE

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New Safety Guide

IAEA

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CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. All organizations involved with safety in relation to radiation risks where their internal resources are not able to meet their needs, 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. In many cases, regulatory bodies, particularly those which are forming, are not able to recruit sufficient staff with the necessary expertise and skills to meet all of their needs. Thus many regulatory bodies have identified the need for using sources of advice external to themselves and potentially external to their State (A conference entitled "Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety" was held in Aix-en-Provence in April 2007 (Ref. [1]) 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 to carry out their responsibilities within their own organization, other regulatory bodies use a range of providers of external expert support[1] (individuals or organizations), which may be specifically dedicated to this task. Depending on the type of regulatory body, the State legal system and traditions, different structures and arrangements may exist. The regulatory body may have insufficient resources, in terms of number of staff, range of expertise and relevant experience to carry out its functions and responsibilities to the extent necessary and within the required schedule. Therefore, the regulatory body should have a process and procedures in place to obtain

[1] : A provider of external expert support, external expert advice or support provider, used here in this Safety Guide with the same meaning, is a person or organisation that is not resident within a regulatory body but is recognized of its expertise and competency in safety and which can provide support to the mission of the regulatory body.

suitable additional external expert support to provide information which can be used in making regulatory decisions (Ref. [2]).

OBJECTIVE

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

1.4. The guidance will be useful both for States which are seeking to develop new facilities or activities (e.g., nuclear power programmes) and need to consider how they can obtain expert support and for States where development or enhancement of the regulatory body is deemed necessary. Expert advice in specialized areas is not always available within a State and so arrangements with organizations in other States may be required, which can raise specific issues that should be considered by the requesting regulatory body.

1.5. This safety Guide is written to cover all forms and uses of external expert advice. Because all States which have, or are planning to have, facilities or activities posing radiation risks have regulatory bodies with responsibilities in relation to inspection and assessment of these facilities and activities (Ref. [3]), this Safety Guide is primarily written as guidance for regulatory bodies.

1.6. Although this Safety Guide has been written with a focus on support to regulatory bodies, much of the advice can, with only minor adjustment, be used by other bodies seeking expert support from outside their own organizations. In particular, a licensee should have 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). Other organizations with legal, professional or functional responsibilities for

safety may benefit from using this Safety Guide and include but are not limited to operators, designers, manufacturers, constructors, employers, contractors and consigners and carriers (Ref. [4], Principle 1).

SCOPE

1.7. This Safety Guide covers all forms of support for safety issues that may be required by a regulatory body, whether technical, legal, analytical or other, but does not deal with support that may be requested for security issues. The expert support providers should be cognizant of synergies and interface that exist between safety and security. Safety and security are complementary 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. Thus in this guide consideration is only given to issues related to the security which should be maintained when making information available to third parties and the need to ensure that appropriate arrangements are made with the authorized security bodies.

1.8. The Safety Guide also considers the ways and forms that external support can be provided: dedicated support organizations (e.g. statutorily mandated technical support organizations); other commercial organizations either through overarching contracts or specific contracts; other regulatory bodies; advisory committees; research organizations; academic bodies; individual experts or others.

STRUCTURE

1.9. This Safety Guide has five sections including this one: Section 2 deals with what a provider of external expert support is and can provide; Section 3 considers the characteristics that a provider of external expert supports should demonstrate; Section 4 expands on the processes that should be used in selecting a provider of expert support and how the advice should be used; and Section 5 describes how interactions between the provider of external expert support and other interested parties should be managed by the regulatory body.

2. CONCEPT OF EXTERNAL EXPERT SUPPORT

GENERAL

2.1. The IAEA's Fundamental Safety Principles (Ref. [4]) state that "an independent Regulatory Body, should be established and sustained" with "adequate ... human and financial resources to fulfil its responsibilities" (Principle 3). Furthermore, the Requirements for Governmental, Legal and Regulatory Framework for Safety (Ref. [3]) state that a "regulatory body shall employ a sufficient number of ... staff ... to perform its functions and to discharge its responsibilities" (Requirement 18). However, Ref. [3] recognizes that a regulatory body may need to "obtain technical or other expert advice ... in support of its regulatory functions" (Requirement 20) emphasizing that such advice "shall not relieve the regulatory body of its ... responsibilities" (Requirement 20). In the Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities (Ref. [2]) some aspects of the use of consultants and Advisory Committees are covered, but there is a perceived need for more detailed guidance.

2.2. In obtaining external expert advice, arrangements should be put in place to ensure that the regulatory body retains the responsibility for making the decision and is not unduly influenced by the support provider. This means that the regulatory body should have an adequate core competence on the subject as a minimum to retain the ability to both frame the request for advice and understand the advice when it is received. In some cases, there may be value in allowing the provider of external support to take part in the decision-making process. In this case the expert advice should be properly justified, explained, documented and clearly understood. It should be used, communicated, and documented, and there should be no ambiguity or dilution in the responsibility of the regulatory body which will make the final decision. It is incumbent on the regulatory body to clearly attribute those recommendations adopted and rejected from the expert organization for the purpose of clarity and transparency.

2.3. The regulatory body's staff 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 and at the end to evaluate the external expert's advice.

2.4. The regulatory body should chose between sourcing work in-house or from external expert support providers. The process employed should be consistent with a clear policy that takes the safety implications of those choices into account. In using a provider of external expert support processes and procedures should be put in place so that the advice is provided in a predetermined manner. Within the context of the available resources and existing infrastructure, this should include:

- How the need for external advice is determined, as well as the usage of external advice in regulatory activity;
- The method to decide which providers have the capability, independency and knowledge to provide that advice, i.e.:
    - The regulatory body should ensure that it only lets contracts for work with safety significance to contractors with suitable competence, acceptable standards and adequate resources.
    - The regulatory body should ensure that all external expert support providers' staff are fully aware of the safety implications of their work and interact in a well coordinated manner with its own staff.
- A process of determining clearance of provider from conflict-of-interest;
- The adoption of code of ethics and confidentiality protocols;
- The arrangements for organizing and managing the procurement;
- How the external expert advice provider and its advice are controlled and the degree to which the advice of the provider is considered in the regulatory decision making process;
- Processes for understanding the external advice and incorporating it in the regulatory decision-making process.

SOURCES OF EXPERT SUPPORT

2.5. External expert support can be obtained through a variety of sources. The source should be an expert in the area of interest and capable of providing the necessary advice. This competence can be clearly demonstrated through formal processes, such as examples of previous work experience, staff experience, etc. If the external source uses experts from outside its own organization as subcontractors, who in turn may use other subcontractors, the primary provider of the expertise should document the independence, reliability and competence of these organizations and individuals.

2.6. Regulatory bodies should consider the availability of expertise and/or service and consider which source is best suited to its needs. When the use of advice from other States is considered, it should be kept in mind that although the other state may have considerable experience with the particular issue; however, it may be difficult, on security information[2] or commercial confidentiality[3] grounds, to have a full interaction with an external expert advice provider in another State. Legal requirements regarding how contracts are let, including tendering requirements may also affect the choice of external expert advice provider.

2.7. Sources of expertise and/or service range from large organizations to specific individual experts. The following list covers most of the main sources of advice, but is not intended to be all inclusive:

- Advisory bodies: many governments and regulatory bodies appoint experts in the form of an advisory committee to assist and provide advice, the experts may be from other

[2] 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 agreement of the owner. Any information supplied to parties outside the regulatory body should be done within the rules set out by the relevant competent authority.

[3] Regulatory bodies 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 put restrictions on those outside the regulatory body made privy to certain aspects of the plant. No restrictions can be placed on information required by the regulatory body, but this does not necessarily give it the authority to provide that information to third parties.

States, but should be appointed under clearly defined terms of reference which include criteria for their selection (see Ref. [2]);

- International organizations: organizations such as the IAEA, Nuclear Energy Agency (NEA), International Organization for Standardization (ISO) etc can be sources of advice on specific issues which may be provided through membership of their committees or by specific contractual arrangements (Ref. [3], Requirement 14). These organizations may be particularly useful for States embarking on nuclear energy programmes;

- 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;

- Other State regulatory bodies: advice can be obtained through individual contacts or international forums, which can be particularly useful when designs utilized in one State are considered in another;

- Vendor State regulatory bodies: advice related to the regulatory structure and its application in a State from where structures, components and services to the applicant licensee are provided; for example reactor vessels. This can be extremely useful but care should be taken not to underestimate the fact that the influence of regulatory conditions in one State may not necessarily apply to another;

- Standards organizations, quality assurance organizations and professional bodies: these bodies which may be national or international can provide advice within their fields of expertise;

- Commercial / manufacturing / industrial organizations: in many States commercial / manufacturing / industrial organizations have been set up to sell technical, engineering, scientific etc services and these can provide a source of advice to regulatory bodies; contracts with these organizations may be overarching so that their advice can be called on when needed or the contracts can be specific as each issue arises; the overarching contracts may cover a range of areas or be restricted depending on the expertise that the provider of external expert support has;

- Government laboratories or research centres; if the issues require experimental investigation or verification, advice from government bodies can be sought;

- 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 required, by organizations offering these services;

- Academic institutions: most universities can, either through their academic staff or by establishing a research programme, provide advice on a range of scientific technical and engineering issues; they can also be a useful source for training the staff of a regulatory body;

- Individual acknowledged experts in specific fields of competence: many acknowledged experts in specific fields do not belong to organizations. This does not mean that they are not appropriate sources of expert advice; recent retirees from regulatory bodies or other bodies could be a particularly useful source of advice;

- Legal organizations: most States have private or governmental legal bodies that can review the language of legal documents and assist in legal enforcement actions;

- Financial and economic organizations: these organizations, private or governmental, can provide advice on such matters such as the financial status of a potential licensee, the appropriateness of investments of decommissioning funds, potential financial conflicts of interest, etc.;

- Other government organizations that may have mandated input on regulatory decisions but without specific decision-making responsibilities

2.8. It is suggested that a regulatory body should consider the specific organizations which exist in their State or to which they have access. For example there may be only a few universities in a State that can give expert advice on a specific nuclear topic, such as mechanical systems, even though in principle all universities may cover mechanical engineering. If there is a need for advice at short notice having sources readily available could be extremely useful.

AREAS FOR EXTERNAL EXPERT SUPPORT

2.9. As mentioned in the previous section, any field of expertise related to safety could be provided through external support. More generally, external experts are used by a regulatory body to assist in performing tasks that necessitate an additional level or area of expertise, which may arise occasionally, or to provide an alternative or confirming view on important issues. These may include:

- Scientific and engineering analysis;
- Legal advice;
- Operations support including development and interpretation of nuclear plant technical specifications;
- Financial advice;
- Testing, measurement and analysis services; training;
- Drafting of regulatory documents;
- Project management and administrative support;
- QA/QC;
- Audit, review, assessment;
- Inspection.

2.10. The support may be continuous, in the form of a fixed arrangement, or as a long-term or overarching contract, which may cover a range of areas. Alternatively short term contracts on specific areas may be used. The choice of approach is not exclusive, with different methods being used at different times or even concurrently. The actual approach will depend on the legal structure of the State and the organization and needs of its regulatory body.

3. CHARACTERISTICS OF EXTERNAL EXPERT SUPPORT

GENERAL

3.1. The IAEA's Safety Fundamentals states that "the regulatory body must.... be effectively independent of the licensee and any other body, so that it is free from any undue pressure from interested parties" (Ref. [4], 3.10). Further, the IAEA Safety Requirements on Governmental, Legal and Regulatory Framework for Safety (Ref. [3]) establishes the following requirement for liaison with advisory bodies and support providers: "The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities" (Ref. [3], Requirement 20).

3.2. It follows that when seeking external expert support, the regulatory body should ensure that these requirements are reflected in the conditions that dictate the relationship between the regulatory body and the provider of external expert support. Exception may be granted due to lack of expertise in certain technical areas (e.g., criticality, climate, and seismology). Furthermore, when selecting a provider of external expert support, the regulatory body should ensure it will not compromise its independence.

3.3. As defined in Section 2 of this publication, 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. From the characteristics analysed below, some might not apply, or only in a partial way, to an individual (e.g. adequate management system).

INDEPENDENCE

3.4. 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 as the need to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice and services. (Ref. [3], paras 4.18 and 4.20).

3.5. Independence of advice means that the provider of external expert support should be able to form and express its technical judgment free from undue pressure from interested parties. Technical competency[4] and a well developed safety culture in the provider of external expert support contribute to the independence of the technical advice.

3.6. However the main element in ensuring effective independence is to develop and implement adequate arrangements that avoid actual, potential, or perceived conflicts of interest. For example, hiring nuclear industry consultants who work primarily for industry may not be the optimum solution. All situations should be analyzed for actual, potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated immediately, to the extent possible. Potential and perceived conflict of interest should be explicitly discussed and managed.

3.7. The independence of an organization providing external expert support to a regulatory body should match that of the regulatory body itself, in relation to the specific issue for which the advice is being given. Therefore, a support provider should make rigorous, demonstrable arrangements to maintain the required independence and should clearly indicate to the regulatory body any potential, actual or perceived conflicts of interest. Any changes of personnel that might affect independence should be discussed with the regulatory body before work continues. Conflicts of interest may potentially occur in a variety of cases including:

- When a financial tie (through a stockholder, through funding, etc.) exists between a potential external expert or organization and the nuclear industry (licensees, designers, etc.);
- When the licensee has to pay for a technical study in order to bring due elements to the regulatory body;

[4] The technical competency represents the ability of the provider of external expert support to develop its own research and therefore develop a state-of-the-art knowledge and techniques, which foster independent judgement.

- When external experts are part of, or closely linked to, an organization that has been assigned responsibilities for the development or promotion of nuclear technologies;
- When external experts are providing support on the same or closely related issues, to potential licensees, designers, or vendors, regulated by the regulatory body;

3.8. It may be impossible for the regulatory body to find a specific external expert free from potential conflicts of interest. This would occur in very rare cases. Such may be the case for example:

- Either when the task to be accomplished requires a very specific knowledge in a field where the few competent experts existing already have links with operators or industry;
- Or when the complexity of the task to be accomplished is such that only a few large providers of external expert support can cope with it that may already have established connections with licensees.

In such cases, the task assigned to this provider of external expert support should be closely monitored and the advice given shall be carefully assessed for bias generated by conflicts of interest (Ref. [3], para. 4.21). Ways of avoiding or detecting actual conflicts of interest include:

- Verifying whether the existence of a code of ethics and organizational structure that promotes a strong safety culture is in force inside the provider of external expert support organization and that it demonstrates that conflicts of interest are avoided;
- Verifying whether the organization of the provider of external expert support structure allows a functional separation and effective independence between units carrying out work for the regulatory body from units carrying out similar work for a licensee or other organization;

3.9. In all cases, the requirements verifying the absence of conflicts of interest, and the way they can be managed and monitored should be thoroughly documented. This can be done by including special clauses in a contract or a convention, or other appropriate document, depending on the legal process used for obtaining external expert support.

TECHNICAL COMPETENCY

3.10. The concept of external expert support, in itself, expresses the need to address the specific technical competence of the external support provider.

3.11. Reference [3] addresses building and maintaining competence. In Requirement 11 it 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". Further, 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 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";
- Appropriate demonstrated experience.

3.12. Depending on the source of external support and on the expected duration of the support required (whether on a temporary or a permanent basis), the expectations on technical competencies and the ways and means to demonstrate skills and knowledge will vary. Some cases are addressed below.

- For an individual expert, technical competency should be ensured by verifying that he has already provided similar external support in a satisfactory way (reference list). For an academic expert, a publication list is a useful additional tool, and documented research activity should be adequate to the task assigned. For such individual or academic expert, certification may be a factor to demonstrating continued competency.
- For an expert organization established in a long term provider of external expert support relationship to the regulatory body, the above mentioned (Ref. [3], para. 2.35) need to

build and maintain competence through technical training, development and research work can be demonstrated by the existence of:

- A strategy for training its own staff and taking part in training activities in the technical safety field;
- Strong research activities in its field of competence;
- A continuous, up to date, technology development programme.

3.13. Competency, as addressed above, often relies on the experience of having done similar, appropriate work before. Confidence in the competency of external expert support can be gained by contracting with a provider of external expert supports (organizations or individuals) having performed safety related tasks and consistently demonstrating a global vision with a broad scope.

MANAGEMENT SYSTEM

3.14. Any potential provider of external expert support should adhere to basic management system principles. Reference [5] establishes the general requirements for the management system, including those relating to safety culture, grading and documentation, the requirements for and responsibilities of senior management, the development and implementation of a management system, the requirements for resource management, the requirements for the processes of the organization, and for the generic processes of the management system, the requirements for measuring, assessing and improving the management system. For an expert organization, the existence of a quality management system is a useful characteristic for the following reasons:

- Through the traceability of processes and documentation, it helps demonstrate the technical competency 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. dedicated support organization), the existence of a quality management system provides confidence that technical competency will be maintained in the long term.

CONFIDENTIALITY

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

Security information

3.16. In most States, the management of security-related confidential information is controlled at the government level, and needs a verification of the trustworthiness of the organization. If such information needs to be transmitted across borders to a foreign provider of external expert support, as a rule there should exist intergovernmental agreements governing the conditions of access, 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 that trustworthiness have been checked and have a "need to know", that the information is kept under secure conditions, and that secure procedures to communicate the information exist (secure fax, encryption capabilities, etc.), specific to the level of sensitivity of the information. Further information on security issues are provided in IAEA Nuclear Security Series.

Proprietary information

3.17. The provider of external expert support should also be made aware of the existence of any confidential proprietary information (including information of commercial value if disclosed), 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 and procedures to protect this type of information as well. The regulatory body should inform the owner of the intellectual property rights (IPR) its intention to pass information to a third party (e.g. an external expert) and give it sufficient time to agree to the arrangements or to raise objections.

SAFETY CULTURE

3.18. The Safety Fundamentals state that a safety culture that governs the attitudes and behaviour in relation to safety of all organizations and individuals concerned should 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 of organizations and individuals at all levels;
- Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety (Ref. [4], Para. 3.13).

3.19. In using a provider of external expert support, whether it is an organization or an individual, 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 policy regarding safety culture that is consistent with the regulatory body's policy. The external expert should be able to raise safety concerns regarding the work they have conducted to the regulatory body. The regulatory body should address any safety concerns raised by the external expert, but the regulatory body is ultimately responsible for making the final safety decision. It is natural for the provider of external expert support to defend its technical positions but these positions should be supported by documentation, for decision making reflecting a high priority for safety (Ref. [6], Para. 2.36).

4. PROCESS TO SELECT AND USE EXTERNAL EXPERT SUPPORT

REASONS FOR THE USE OF EXTERNAL EXPERT SUPPORT

4.1. The regulatory body should include staff with expertise in a wide range of technical matters (Ref. [3], para. 4.22). The phase and scale of the nuclear programme should be considered in deciding how and to what degree these disciplines are to be represented in establishing the organization. The regulatory body should have enough experienced staff to be able to perform all of the necessary regulatory functions and to evaluate the quality and results of the work performed for it by external experts (Ref. [3], para. 4.5).

4.2. If a regulatory body does not have an adequate number of qualified personnel or an adequate diversity of technical skills, or if the workload does not justify the recruitment of full time staff, external experts (individuals or organizations) may be used to perform selected tasks. For example, it may be decided to always use external support for particular specialties that may only be needed infrequently. In other cases, regulatory bodies rely heavily on dedicated support organizations, which provide all the functions that require expert input. However, even in these cases there may be situations where additional support is needed in specific areas. 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.

4.3. There are many reasons why external expert advice may be sought, by an established regulatory body or one considering nuclear power for the first time, these may include:

- Where designs of installation are proposed that are different from those previously regulated;
- The need for expertise in different specialties at different lifecycle stages, e.g. construction, commissioning, operation and decommissioning;

- New licensees either taking over from an existing licensee or wishing to operate a new facility;
- Legal changes that require new regulatory processes and regulations;
- Where new sites for installations are being considered, there may be a lack of experience and expertise or insufficient capability related to a technical discipline (e.g. geology, etc.).

There may also be times when additional support is needed because of short-term workload increase.

4.4. For those States developing new nuclear programmes including facilities or activities there may be a particular need for expert support from an external organization. In some States, the task to provide such support has been assigned to a special organization, a so-called “technical support organization” (TSO). National laboratories, university institutions and consultants could also be used for such support. In some cases, such support may need to be obtained from expert organizations in other States. There is no one model for use of external experts. Much of when and how they can and may be used depends on the legal system within the State. . However, a necessary component of this approach is to exclude this organization from providing the advice and being independent of the advice provider.

ACTIONS TO TAKE IN SEEKING ASSISTANCE

4.5. There are many sources of expert support that may be available to the regulatory body as discussed in para. 2.5. When a regulatory body determines it needs additional expertise it should first:

- Determine the scope 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.
- Identify the possible sources for obtaining the expertise.
- Solicit or select the organization to provide the expertise.

PRINCIPLES TO EMPLOY IN SELECTING THE EXTERNAL EXPERT

4.6. External experts should be chosen with the understanding that they should provide impartial advice. It should be confirmed that the external expert's other activities as a specialist do 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.

4.7. When selecting an external expert, the regulatory body should be guided by the requirements provided in the Safety Assessment for Facilities and Activities (Ref. [7]). These recommendations have to be taken into account:

- The provider of external expert support should have experience in the area needed (for example any accreditation, certification…). It schould be knowledgeable, by direct experience, of the specific methodology, code, tool, or approach for which he is employed. Understanding and competence in the assigned area should be demonstrated by the range of the individual'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;
- The external expert should have the tools (e.g., computer codes) and expertise necessary to accomplish the task. For example:
    - The external expert should be experienced in using the tools;
    - The external expert should have the latest version of computer codes;
    - The external expert should have the computer codes verified and validated for use in the application being considered.
- The provider of external expert support should not have an actual conflict of interest. In case of a potential or perceived conflict of interest, the situation should be explicitly discussed and managed;
- The provider of external expert support should accommodate the regulatory body in the time frame needed to make the regulatory decision;
- Specific documentation should be required to support the regulatory decision;

- The quality of the provider of external expert support's work should be verified. The quality should be checked commensurate with the safety significance or the issue. When the support is provided by a single external expert, the documentation which supports the advice should be sufficient, accurate and relevant to allow the regulatory body to judge the quality of the work.

4.8. Since the regulatory body should utilize and evaluate the work performed by external experts, it should have defined the scope of work to be performed at the outset. The external expert should be required to provide a detailed written report. The report should include the basis for and the method of the external expert's evaluation, the conclusions and any related recommendations that may assist the regulatory body.

THE REGULATORY BODY AS AN INTELLIGENT CUSTOMER

4.9. The regulatory body should maintain an 'intelligent customer' (Ref. [8]) capability for all work carried out on its behalf by external experts that may impact upon nuclear safety.

4.10. As an intelligent customer, in the context of nuclear safety, the regulatory body should provide adequate supervision and oversight of the external experts work. Adequate contractual arrangements are needed to specify the role and responsibilities of external support provider. To perform this function, the regulatory body staff assigned to oversee the contract should:

- Know what is required and how the work will be used;
- Fully understand the need for an external expert's services;
- Understand the expected outcome and time frame for delivery;
- Understand the context in which the work is being performed;
- Specify the requirements so that the product received meets the intended needs;
- Supervise the work in accordance with the regulatory body's procedures;
- Technically review the work before, during, and after implementation;
- Ensure continual interaction with the provider of external expert support.

EVALUATION OF THE WORK PERFORMED

4.11. The regulatory body should evaluate the advice of external experts and determine whether and how it is utilized. The evaluation of the advice should be done appropriately based on the characteristics of external expert support. The regulatory body should document the decisions made based on the input of the external experts. The basis for the decision should be recorded and documented in the appropriate form. The documentation should summarize the review and assessment performed and should present a clear assessment of the safety significance of the decision.

4.12. The regulatory body should evaluate the work performed by external experts accordingly with the defined scope of work performed at the outset. The written report provided by the external expert, should support the regulatory body's evaluation.

5. INTERACTIONS OF PROVIDER OF EXTERNAL EXPERT SUPPORT WITH INTERESTED PARTIES

GENERAL

5.1. The external support provider does not replace the regulatory body when providing support . In instances where the external support provider will interact with interested parties in this role, it should be made clear that the regulatory body retains the responsibility for and makes the final decision (Ref. [9]).

INTERFACES

5.2. There are several possible reasons why a provider of external expert support may need to interact with operators, etc who may be the subject of regulatory activities. This may mean visiting sites, gathering data, observing performance and conducting a dialogue with operating staff. Such interfaces should be properly controlled by the regulatory body and in no way should the external support provider 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 framed by an appropriate regulatory representative with an intelligent customer (Ref. [8]) capability.

5.3. Where it is decided that a provider of external expert support may make direct contact with licensees, without the presence of the regulatory body, the purposes and reasons for such interfaces should be defined in the formal arrangements between the regulatory body and the provider of external expert support. In the same way, the licensees should be made aware by the regulatory body of such potential direct contacts by the external expert support provider. Timely reports on any such contacts should be made to the regulatory body. The advice provider should also inform the regulatory body of any other contacts made which are relevant to the advice being provided.

TRANSPARENCY

5.4. The expert support provider should keep sufficient records, so that the advice can be traced and audited. This includes records of data used for all computer calculations, references

to sources of data and results of any tests carried out. The regulatory body may decide to provide this information to the operator so it can understand and, if necessary dispute, this input of a regulatory decision. In this case it should be assured that no proprietary or confidential information is included.

5.5. Reference [9] states in paragraph 3.2.4. - 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. The regulatory body needs to make information about its regulatory decisions and their underpinning documentation… available as far as possible to the public..." When using external expert support, whose expert advice may have to be made available to the public, consideration should be given to assessing the conditions of this communication to the public. In particular, 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 published to enhance transparency as part of its interested party engagement process. Publication should clearly show that the advice was developed for the regulatory body and who carried it out.

OPENNESS

5.6. Work carried out for the regulatory body, as a public body, should be available to the public, taking into the national legal framework governing public access to documents established or possessed by pubic 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 external support providers should detail the necessary instructions and authorizations needed for the work to be quoted or used and provide guidance on handling proprietary information.

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 under the regulator's control and direction. There should be regular contact between the external support provider 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 external support provider and the need for timeliness of the expected results. In addition, there may be an agreed upon time before which an expert organization is not permitted to discuss work performed specifically for a regulatory body.

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