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## ~~External Expert Support on Safety Issues~~ for the Regulatory Body

DRAFT SAFETY GUIDE

**DS429**

New Safety Guide

IAEA

International Atomic Energy Agency



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## 1. INTRODUCTION

### BACKGROUND

1.1. ~~All organizations involved~~Organizations with responsibilities for safety in relation to and the control of radiation risks ~~where their internal resources are not able to meet their needs,~~<sup>1</sup> 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~~Many regulatory bodies have generally identified the need for using to use, to a greater or lesser degree, sources of advice external to themselves and potentially external to their State. ~~(A international 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]); this was followed by a second international conference entitled “Challenges faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety and Security”, which was held in Tokyo in October 2010 [1]. These conferences 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 ~~responsibilities~~functions within their own organization, other regulatory bodies use a range of

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<sup>1</sup>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.

providers of external expert support<sup>2</sup> (both individuals ~~or~~and organizations), which may be specifically dedicated to this task. Depending on the type of regulatory body, the State legal system and ~~traditions~~culture and the national nuclear programme, different structures and arrangements may exist. ~~The~~A regulatory body may ~~not~~ have ~~insufficient~~the 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. ~~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 ~~additional~~ external expert support to ~~provide information which gain input that~~ can be used in making regulatory decisions (Ref. [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 ~~considers~~addresses the process ~~in~~ 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, ~~and~~. It also addresses how the support provider's advice ~~is~~should be 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~~that are seeking to introduce and develop new facilities or activities (e.g., new nuclear power programmes; advanced nuclear

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<sup>2</sup>⇒ A 'provider of external expert ~~support~~, support', a 'provider of external expert ~~advice~~advice' or a 'support ~~provider~~provider', used here in this Safety Guide with the same meaning, is ~~a person~~an individu or organisationorganization that is not ~~resident within~~apart of the regulatory body but which is recognized ~~of~~for its expertise and ~~competency~~competence in safety and ~~which~~ can provide support to the ~~mission of the~~regulatory body.

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. ~~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~~This may also cover the case, that a regulatory body issues or revises regulations and needs input from specialists. This Safety Guide is primarily written as guidance for regulatory body to cover all forms and uses of external expert advice.

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.~~

1.6.1.5. ~~Although this Safety Guide has been written with a focus on support to regulatory bodies, much of the advice can, also be used~~ with only minor adjustment, ~~be used~~ by other ~~bodies~~organizations seeking external expert support from outside their own organizations. In particular, ~~a~~the licensee of a facility or an activity should have put in place similar control and quality requirements, together with internal arrangements for decision making, as the “prime responsibility for safety”<sup>2</sup> 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~~. These may include, but are not limited to ~~operators,~~ designers, manufacturers, constructors, employers, contractors and consigners ~~and carriers~~ (Ref. [4], Principle 1).

## 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, ~~but issues. 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 individual experts or by others.~~

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1.7. The Safety Guide does not deal with support that may be requested for security issues. ~~The~~ and issues relating to accounting and control of nuclear material. Nevertheless, providers of external expert support providers should be cognizant of the synergies and interface interfaces that exist between safety and security. Safety measures and security are 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. Thus in In this guide Safety Guide consideration is only given mainly to issues related relating to the security which 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 authorized security bodies various bodies with responsibilities for nuclear security. Further recommendations on security issues are provided in publications of the IAEA Nuclear Security Series.

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~~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

~~1.9.1.8. This Section 2 of this Safety Guide has five sections including this one: Section 2~~ deals with what a provider of external expert support is and what it can provide; Section 3 considers addresses the characteristics that a provider of external expert supports should demonstrate; Section 4 expands provides recommendations on the processes process that should be used in selecting a provider of external expert support 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.

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## 2. CONCEPT OF EXTERNAL EXPERT SUPPORT

### GENERAL

2.1. The IAEA's Fundamental Safety Principles (Ref. [4]) ~~state~~ states that "an independent ~~Regulatory Body, should~~ regulatory body must be established and sustained" with "adequate ... human and financial resources to fulfil its responsibilities" (Principle 32). Furthermore, ~~the Requirements for Governmental, Legal and Regulatory Framework for Safety (Ref. [3]) state~~ Ref. [3] states that a "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] ~~recognizes~~ states that a "The regulatory body ~~may need to~~ shall obtain technical or other expert professional advice ... as necessary in support of its regulatory functions" (Requirement 20), emphasizing that the obtaining of such advice "shall not relieve the regulatory body of its ~~assigned~~ responsibilities" (Requirement 20). In ~~the Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities (Ref. [2])~~ Ref. [2] recommendations are provided on some aspects of the use of consultants and ~~Advisory Committees are covered, but there is a perceived need for advisory committees; this Safety Guide provides additional,~~ 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~~ The regulatory body should have, at a minimum, an adequate core competence ~~on in~~ on in the subject ~~as a minimum, in order~~ to retain the ability ~~to~~ both to frame the request for advice and to 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.~~

2.3.2.2. The regulatory body's staff personnel should have sufficient technical knowledge to enable them to identify problems, to determine whether it would be appropriate to seek

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assistance from an external expert, to manage the external support during its development and, at the end, to understand, evaluate the external expert's and use any relevant advice from the external expert.

2.3. The regulatory body should choose put in place arrangements to ensure that it retains its responsibility for making all decisions on regulatory and nuclear safety issues and is not unduly influenced by any provider of external expert support. Processes and procedures should be put in place 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:

2.4. The identification of the need for external advice. The process employed for making the choice between sourcing work in-house or obtaining advice from a provider of external expert support providers. The process employed should be consistent with a clear policy that takes the safety implications of those choices this choice 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:

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- 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 independence and knowledge to provide that advice, i.e.:
- The regulatory body should in order to ensure that it only lets contracts for work with safety significance to are placed only with contractors with suitable competence, acceptable standards and adequate resources;
- The regulatory body should ensure A process for verifying that all the provider of external expert support providers' staff are fully aware of the safety implications is free from conflicts of their work and interact in a well coordinated manner with its own staff interest (see paras 3.2 to 3.8);
- A process for checking that the provider of determining external expert support has the requisite level of security clearance of provider from conflict of interest to undertake the work;
- The adoption of a code of ethics and confidentiality protocols; (see para 3.4);

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- The arrangements for organizing and managing ~~the~~ procurement;
- How the provider of external expert advice provider support and its advice are controlled and the degree to which managed;
- Processes for understanding and evaluating the external advice of the provider is considered in and for incorporating it into the regulatory decision making process; (see paras 4.8 and 4.9).
- ~~Processes for understanding the external advice and incorporating it in the regulatory decision making process.~~

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#### SOURCES OF EXTERNAL EXPERT SUPPORT

2.4. External expert support can be obtained through a variety of sources. The source should be an expert 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 through to the regulatory body by formal processes means, such as the provision of examples of previous work experience, or licences of staff experience, etc.. Paragraphs 3.9 to 3.15 provide detailed recommendations on demonstration of technical competence.

2.5. If the source of external source expert support uses experts from outside its own organization as subcontractors, who in turn may use other subcontractors, the primary external expert support provider of the expertise 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. ~~Regulatory bodies~~ The regulatory body should consider the availability of expertise and/or ~~services~~ services and ~~considers~~ should determine which source is best suited to its needs. 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 from other States is considered, ~~it~~ the regulatory body should be ~~kept in mind~~ aware that, although ~~the other state~~ a provider of external expert advice in another State may have considerable experience with the particular issue; ~~however,~~ it may be difficult, on the grounds

of security of information<sup>3</sup> (see paragraph 3.19) or commercial confidentiality<sup>4</sup> grounds, (see paragraph 3.20), to have a full interaction with ~~an~~that provider of external expert advice ~~provider in another State.~~ Legal requirements regarding how contracts are ~~let~~placed, including tendering requirements, may also affect the choice of provider of external expert advice provider.

~~2.6. Sources of expertise and/or service range from large organizations support. Consideration should be given to specific individual experts. the fact that the regulatory infrastructures in different States may not necessarily be compatible in this sense. This covers the regulatory body itself as well as the work of providers of external expert support.~~

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, ~~the~~ Such experts may be from other States, but should be appointed underin accordance with clearly defined terms of reference ~~which~~that include criteria for their selection (see Ref. ~~[2];~~[2], paras 3.30 – 3.32);
- ~~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~~

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<sup>3</sup> ~~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.~~

<sup>4</sup> ~~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.~~

~~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;
- Government laboratories or research centres: if the issues require experimental investigation or verification, advice from government 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 State-government organizations: these may be mandated to provide input on regulatory decisions but do not have specific decision making responsibilities.

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b. Sources of advice from outside the State include:

- International organizations: organizations such as the IAEA, 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);
- Regulatory bodies of other States: advice can be obtained through individual contacts, international cooperation agreements or international forums, which can be particularly useful when designs or regulatory procedures utilized in one State are considered in another;
- ~~Vendor State regulatory~~Regulatory bodies of vendor States: advice ~~related~~may be obtained relating to the regulatory structure and its application in a State from ~~where~~ which structures, such as the reactor pressure vessel, components ~~and/or~~ 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~~ 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;
- Commercial / manufacturing / industrial Engineering or service organizations: in many States commercial / manufacturing / industrial engineering or service organizations have been set up to sell provide services in technical, engineering, and 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; fields[does not require repetition];
- ~~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 necessary, by organizations offering these services;
- Academic institutions: ~~most~~ 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; ~~they can also be a useful source for training the staff of a regulatory body;~~
- Individual acknowledged experts in specific fields of competence: (i.e. consultants); 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~~ Recent retirees from a regulatory bodies-body 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, which can be private or governmental, can provide advice on ~~such~~ matters such as the financial status of a potential licensee an applicant, the appropriateness of investments of decommissioning funds, or potential financial conflicts of interest, ~~etc.;~~

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- ~~Other government organizations that may have mandated input on regulatory decisions but without~~ The regulatory body should obtain relevant information on the specific decision-making responsibilities.

2.8. ~~It is suggested that a regulatory body should consider the specific organizations which that~~ 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, including knowledge of their field of competence and capability for technical support, in order to have sources readily available that~~ there is a need for advice ~~at short notice having sources readily available could be extremely useful.~~

2.9. Contracts with different types of organizations, institutions, bodies, individual experts, etc., may be generic so that their advice can be called on when needed, or may be specific contracts that are concluded as each issue arises. Generic 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

2.9. ~~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:~~

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

- Research activities;
- Scientific and engineering analysis;
- Review of safety analysis;
- Independent verification of analyses;

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

~~3.3.3.1. As defined/set out in Section 2 of this publication 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. From/Of the characteristics analysed below/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

~~3.4.3.2. 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 as in the need/requirement 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 para 4.20).~~

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~~3.5.3.3.~~ Independence of advice means that the provider of external expert support should be able to form and express ~~its a technical judgement~~ judgement that demonstrates integrity, and is impartial and free from undue pressure ~~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 and should in no case be biased owing to political opinion. Technical competency<sup>5</sup> ~~—and a well developed~~ 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.

~~3.6.3.4.~~ However ~~the main~~ an important 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~~ analysed for actual, potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated ~~immediately, to the extent.~~ This should be done as soon as possible. Potential and perceived ~~conflict~~ conflicts of interest should be explicitly discussed and managed. Way of avoiding or detecting actual conflicts of interest include:

- ~~The independence of an organization providing~~ Verifying whether the provider of external expert support ~~to has a regulatory body should match~~ code of ethics and an organizational structure that ~~of the regulatory body itself, in relation to~~ promotes a strong safety culture and that these demonstrate that conflicts of interest will be avoided;
- Verifying whether the specific issue for which ~~organizational structure of the advice is being given. Therefore, a provider of external expert support and its internal procedures provides functional and personal separation and effective independence between units carrying out work for the regulatory body and units carrying out similar work for a~~

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<sup>5</sup> ~~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 judgment.~~

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 experts should be sought.

3.7.3.5. 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, actual or perceived conflicts of interest. Any changes of personnel that might affect independence should be discussed with the regulatory body before work continues; 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, etc.) exists between a potential external expert or organization and the nuclear industry (licensees, designers, etc.); e.g. a licensee or designer);
- When the licensee has to pay for an independent technical study in order to bring due elements; submit required analyses or documentation to the regulatory body;
- When the external experts are expert is part of, or closely linked to, an organization that has been assigned responsibilities for the development or promotion of in relation to nuclear technologies;
- When there may a conflict of national or commercial interest;
- When the external experts are expert is providing support on the same or closely related issues; to potential licensees, designers, or vendors, that are regulated by the regulatory body.

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

3.6. Either, when the:

- The task to be accomplished requires a very specific knowledge in a field where the few existing competent experts existing already have links with operators or licensees or other organizations in the nuclear industry; or

- ~~Or when the~~The complexity of the task to be accomplished is such that only a few large providers of external expert support ~~can cope~~are capable of coping with it ~~that~~and they may already have established connections with licensees or other organizations in the nuclear industry.

3.7. In ~~cases~~ such cases as these, the task assigned to ~~this~~the provider of external expert support should be closely monitored ~~and the~~. The advice given ~~shall~~is required to 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;~~

~~3.9.3.8.~~ In all cases, the ~~requirements~~verifying requirement to verify the absence of conflicts of interest, and the way ~~they can~~any conflict of interest is to be managed and monitored should be thoroughly documented. This can be done by including ~~special~~appropriate clauses in ~~a the~~ contract ~~or a convention~~between the regulatory body and the provider of external expert support, or other appropriate document, depending on the legal process used for obtaining external expert support.

#### TECHNICAL ~~COMPETENCY~~COMPETENCE

3.9. ~~The concept~~ Technical competence is the ability of the provider of external expert support, ~~in itself, expresses the need to address the specific~~ implement state-of-the-art knowledge and techniques. The technical competence of the 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 ~~provider~~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.

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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 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. 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.

3.11.3.13. Reference [3] addresses the building and maintaining of 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~~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;”

~~Appropriate demonstrated~~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.

3.12.3.14. Depending on the source of external expert support and on the expected duration of the support ~~required (whether on a temporary or a permanent basis), the,~~

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expectations ~~on-in relation to~~ technical ~~competencies~~ competence and the ways and means to demonstrate skills and knowledge will vary. Some cases are addressed ~~below-in the~~ following:

- For an individual expert, technical ~~competency~~ 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 ~~be-indicate skills and knowledge that are~~ adequate ~~to-for~~ the task to be assigned. For such ~~individual-or academic-expert~~ experts, certification may ~~be-a-factor-to-demonstrating~~ demonstrate continued ~~competency-~~ competence in their specialty area;
- For an ~~expert-organization~~ that has an established ~~in-a-~~ long term ~~provider-of-external expert-support-relationship~~ as a provider of external expert support to ~~the-a~~ regulatory body, ~~the-above-mentioned (Ref. [3], para. 2.35)~~ there is still a need to build and maintain competence (Ref. [3], para. 2.35). ~~through technical training, development and research work~~ 2.35. Competence can be demonstrated by the ~~existence-of~~ following:
  - A ~~The~~ provider of external expert support interacts in a well-coordinated manner with its own staff. 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 taking part in training activities in ~~theirs~~ technical safety field of competence;
  - ~~Strong~~ Involvement in significant research activities in its field of competence;
  - ~~A continuous~~ Experience gained in performing safety related tasks;
  - 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, ~~technology~~ research and development programme.

3.13.3.15. Competency, as addressed above, 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. Confidence in the competency of external expert support can be gained by contracting with competence of a provider of external expert supports (organizations or individuals) having support can be gained by placing contracts with providers of external expert support that have performed safety related tasks in the past, has knowledge of the regulatory function and view of the regulatory body and consistently demonstrating demonstrates a global vision with a broad scope multidisciplinary capabilities.

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## MANAGEMENT SYSTEM

3.14.3.16. 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 ana provider of external expert organizations support, the existence of a quality management system is a useful characteristic for the following reasons:

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- Through the traceability of processes and documentation, it helps can help to demonstrate the technical competency 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 provides may provide confidence that technical competency 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 on the basis of an approved work plan. The report should include the objective of the work, references, the basis for and the method of the external expert's work, conclusions and any related recommendations that may assist the regulatory body.

## CONFIDENTIALITY

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

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### **Security or protected information**

3.16.3.19. 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- 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 ~~foreign~~ provider of external expert support, ~~as a rule there in another State, this should exist~~ 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 ~~that whose~~ trustworthiness ~~have has~~ been checked and who have a ~~“need-to-know”, know~~ the information, that the information is kept under secure conditions, and that secure procedures ~~to communicate~~ are in place for communicating the information-~~exist~~ (secure fax, encryption capabilities, etc.), specific to the security level of ~~sensitivity of the information.~~ Further the information-~~on security issues are provided in IAEA Nuclear Security Series.~~

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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

~~3.17.3.21.~~ The provider of external expert support should also be made aware of the existence of any confidential proprietary information (including information of commercial value ~~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 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 ~~the~~ intellectual property rights ~~(IPR)~~ to any information of its intention to pass that information to a third party (i.e.g. ~~an~~ the provider of external expert support) and give it sufficient time to agree to the should establish commonly agreed arrangements ~~or to raise objections.~~

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## SAFETY CULTURE

~~3.18.3.22.~~ The Fundamental Safety Fundamentals state Principles [4] states that a “A safety culture that governs the attitudes and behaviour in relation to safety of all organizations and individuals concerned should must be integrated in the management system. Safety culture includes:

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- 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 for safety;
- Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety” (Ref. [4], Para. 3.13)-):

~~In using a provider~~ Training and promotion of external expert support, whether it is an organization or an individual, the safety culture are also important in enhancing safety culture.

~~3.19.3.23.~~ 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

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external expert support should have a stated ~~policy regarding~~commitment to safety culture that is consistent with the regulatory body's policy. The provider of external expert support should be able to ~~raise~~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 ~~to~~with 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).~~provider of external expert support.

DRAFT

## 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.~~

4.3.4.1. ~~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. These reasons may include the following:~~

- ~~Where designs of~~ For assessment of a new design of nuclear installation are proposed that are ~~is~~ different from those previously ~~regulated~~ authorized in the State;
- ~~The~~ There is a need for a variety of ~~There is a need for a variety of~~ expertise in different specialties at different lifecycle stages ~~stages in the lifetime of a facility or activity, e.g. site selection, construction, commissioning, operation and decommissioning~~ or closure;
- ~~New licensees either taking over from an existing licensee or wishing to operate a new facility;~~

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- Legal ~~To respond to legal~~ changes that require new regulatory processes and regulations;
- Where ~~To support the review of application of new technologies for process and safety systems;~~
- To support the establishment of new safety criteria and requirements;
- There is a need to perform detailed independent verification;
- There is a need to evaluate analysis of new sites for ~~installations are being considered, there may be~~ facilities;
- There is a lack of experience and expertise or insufficient capability related to a technical discipline (e.g. ~~geology, etc.-~~) an issue relating to site evaluation that requires expertise in geology);
- There may also be times when additional support is needed because a lack of specific resources for tasks at hand, e.g.. a lack of experience relating to the infrastructure for commissioning including project management;
- There is an increase in the short-term workload ~~increase.~~

4.4.4.2. For ~~those~~ States developing new nuclear power programmes ~~including, or new~~ facilities or activities ~~there, the regulatory body may be a need for~~ expert support from an external organization ~~in for~~ developing its processes and procedures ~~, for identifying its needs and technical areas for support~~ and for determining suitable external sources of advice. ~~There is no one model for use of external experts. Much of when and how they can and will be used will be based on the legal system within the State. 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 which that could assist in organizing a system for coordinating the provision of external advice. For many newcomer nuclear programmes, this~~ This could be of assistance ~~to know in~~ ascertaining the availability of external expert support available and the necessary questions to ask.

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#### ACTIONS TO TAKE IN SEEKING ASSISTANCE

4.5.4.3. There are many sources of external expert support that may be available to the regulatory body as discussed in para. 2.5.4. When a regulatory body determines it needs ~~additional expertise~~ external expert support it should first:

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- Determine the ~~scope~~objective, the scope, the timescale 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 ~~the an~~ organization or individual to provide the expertise.

#### PRINCIPLES TO EMPLOY IN SELECTING THE EXTERNAL EXPERT

~~4.6.4.4.~~ External experts should be chosen with the understanding that they ~~should will~~ provide impartial advice. It should be confirmed by the regulatory body that the external expert's other activities as a specialist ~~do 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).

~~4.7.4.5.~~ 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~~following recommendations ~~have to~~should be taken into account:

- ~~The provider of external expert support should have experience in the area needed (for example any accreditation, certification...). It should 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.~~

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- ~~The provider of external expert support should not have an~~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~~There should be no ~~conflict~~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 ~~accommodate~~be able to conduct its work within the time frame specified by the regulatory body ~~in the time frame needed to~~to make the ~~regulatory~~ 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;
- ~~Specific~~The provider of external expert support should be able to prepare and deliver specific documentation ~~should be as~~required to ~~support~~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's work should be~~verified. The quality ~~support~~ should be checked commensurate within regard to the safety significance ~~or~~of the issue. ~~When the support is provided by a single external expert, the~~The documentation ~~which~~that 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.~~

- 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 CUSTOMER<sup>6</sup>

4.9.4.6. 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.~~

4.10.4.7. \_\_\_\_\_ The regulatory body should provide adequate supervision and oversight of the ~~work of the provider of external experts work expert support.~~ Adequate contractual arrangements are ~~needed~~necessary to specify the role and responsibilities of the provider of external expert support provider. To perform this function, The staff of the regulatory body ~~staff~~ assigned to oversee the ~~contract~~network 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;
- ~~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 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;

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<sup>6</sup> ~~Intelligent Customer Capability can be defined as "The An 'intelligent customer' capability is the~~ capability of the ~~organisation~~organization to have a clear understanding and knowledge of the product or service being supplied. The ~~'Intelligent Customer' principle~~intelligent customer' concept mainly relates to a capability required of ~~organisations~~organizations when using contractors or expert support.

- 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;~~
- Technically, and technically review the work ~~before, during, and after implementation~~ whenever necessary;
- Ensure continual 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 OF THE WORK PERFORMED

4.8. 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.

~~4.11. The regulatory body should evaluate the advice of external experts 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 was utilized. The The advice should be evaluated in accordance with the role and the level of responsibility of the provider of external expert support. Such 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.~~~~

4.9. 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 be used also for the purposes of assessing the suitability of this external expert for potential further work.

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## 5. INTERACTIONS OF **THE PROVIDER OF EXTERNAL EXPERT SUPPORT** WITH INTERESTED PARTIES

### GENERAL

5.1. The provider of external expert support provider does not replace the regulatory body when providing support-. In instances where the provider of external expert support provider will need to interact with other interested parties ~~in this role~~, it should be made clear that the regulatory body retains the responsibility foris required to retain its responsibilities and makes the final decision (Ref. ~~{9}~~-[3], Requirement 20).

### INTERFACES

5.2. ~~There are several possible reasons why a~~ A provider of external expert support may need to interact with ~~operators, etc who may be the a licensee that is~~ subject ~~of to~~ regulatory ~~activities-control~~. This may mean visiting sites, gathering data, observing performance and conducting ~~a-technical meetings and~~ dialogue with ~~operating-staff- or management of the licensee~~. Such interfaces should be properly controlled by the regulatory body and in no way should ~~thea provider of~~ external expert 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 framedsupervised by an appropriate regulatory representative of the regulatory body.

5.3. Where it is decided that a provider of external expert support may make direct contact with ~~licenseesa~~ licensee, without the presence of a representative of the regulatory body, the purposes and reasons for such ~~interfacescontact~~ should be defined in the formal arrangements between the regulatory body and the provider of external expert support. ~~InFurthermore~~, the ~~same-way, the licenseeslicensee~~ should be made aware by the regulatory body of ~~such-the~~ potential for direct eontactscontact by the provider of external expert support ~~provider~~, including the scope of and limits to such contact. Timely ~~reportsinformation~~ on any such contacts should be madeprovided to the regulatory body. The ~~advicesupport~~ provider should also inform the regulatory body of any other contacts made which-arewith other interested parties that may be relevant to the advice being provided.

## TRANSPARENCY AND OPENNESS

5.4. The provider of external expert support ~~provider~~ should keep sufficient records, so that ~~theirs~~ 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 ~~operator so it can understand and, if necessary dispute, this input of a regulatory decision.~~ licensee. In this case it should be ~~assured~~ ensured that ~~no~~ proprietary or confidential information is ~~included~~ appropriately controlled.

5.5. Reference [97] states in ~~paragraph 3.2.4. 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.” ~~When using external expert support, whose.~~ If information that results from expert advice may have to be made available to the public, the regulatory body should give consideration ~~should be given to assessing the condition~~ the nature of this communication ~~to~~ 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 published to enhance transparency as part of ~~its~~ the process of engagement with interested ~~party engagement process.~~ 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 ~~and who carried it out.~~ by this provider.

## OPENNESS

5.6. Work carried out for the regulatory body, ~~as a public body,~~ should be made available to the public, ~~taking into~~ in accordance with the national legal framework governing public access to documents established or possessed by ~~publie~~ 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 ~~providers~~ should detail the necessary instructions and authorizations ~~needed~~ 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 ~~regulator's~~ control and direction. ~~of the regulatory body.~~

~~5.7.5.8.~~ There should be regular contact between the provider of external expert 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 provider of external expert 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.~~

## REFERENCES

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