

IAEA Safety Standards

for protecting people and the environment

Use of External Experts by the Regulatory Body

General Safety Guide

No. GSG-4



IAEA

International Atomic Energy Agency

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Information on the IAEA's safety standards programme is available at the IAEA Internet site

<http://www-ns.iaea.org/standards/>

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at PO Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

RELATED PUBLICATIONS

The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

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Security related publications are issued in the **IAEA Nuclear Security Series**.

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This publication has been superseded by GSG-12.

USE OF EXTERNAL EXPERTS BY THE REGULATORY BODY

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

This publication has been superseded by GSG-12.

IAEA SAFETY STANDARDS SERIES No. GSG-4

USE OF EXTERNAL EXPERTS BY THE REGULATORY BODY

GENERAL SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2013

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FOREWORD

by Yukiya Amano
Director General

The IAEA's Statute authorizes the Agency to "establish or adopt... standards of safety for protection of health and minimization of danger to life and property" — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

NOTE BY THE SECRETARIAT

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. The process of developing, reviewing and establishing the IAEA standards involves the IAEA Secretariat and all Member States, many of which are represented on the four IAEA safety standards committees and the IAEA Commission on Safety Standards.

The IAEA standards, as a key element of the global safety regime, are kept under regular review by the Secretariat, the safety standards committees and the Commission on Safety Standards. The Secretariat gathers information on experience in the application of the IAEA standards and information gained from the follow-up of events for the purpose of ensuring that the standards continue to meet users' needs. The present publication reflects feedback and experience accumulated until 2010 and it has been subject to the rigorous review process for standards.

Lessons that may be learned from studying the accident at the Fukushima Daiichi nuclear power plant in Japan following the disastrous earthquake and tsunami of 11 March 2011 will be reflected in this IAEA safety standard as revised and issued in the future.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection

of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered ‘overarching’ requirements, are expressed

¹ See also publications issued in the IAEA Nuclear Security Series.

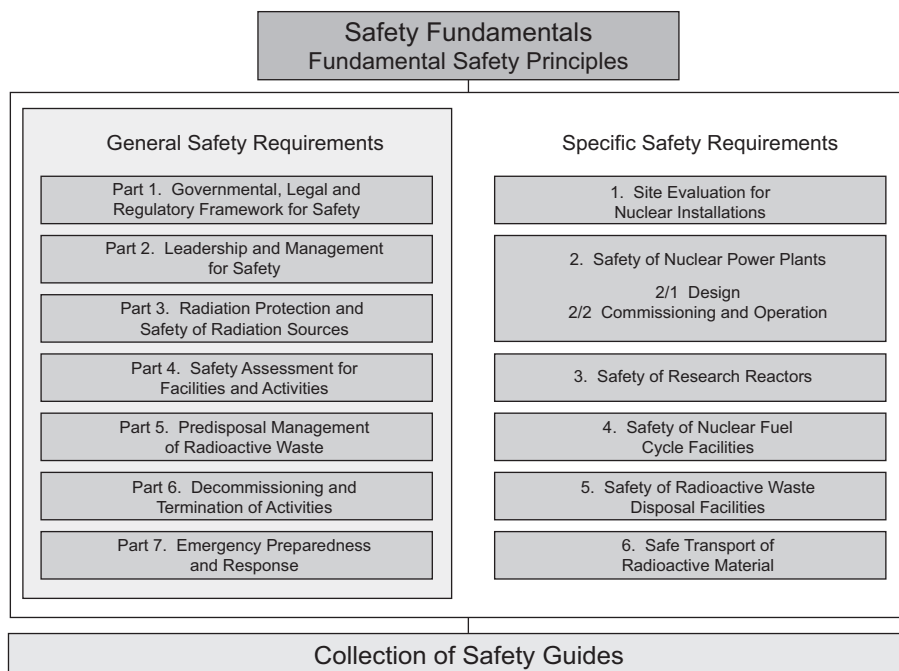


FIG. 1. The long term structure of the IAEA Safety Standards Series.

as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as ‘should’ statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety

standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four safety standards committees, for nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

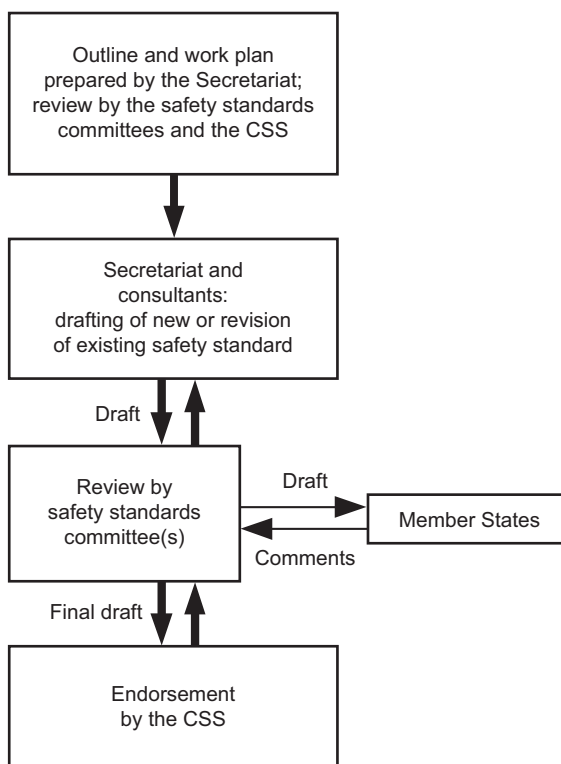


FIG. 2. The process for developing a new safety standard or revising an existing standard.

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see <http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

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1. INTRODUCTION

BACKGROUND

1.1. Organizations with responsibilities for safety and the control of radiation risks¹ may need to obtain expert advice from organizations or individuals external to their own organization. The rapid expansion of nuclear and radiation related activities in many States has highlighted the limited number of skilled and experienced experts available. Many regulatory bodies have generally identified a need to use, to a greater or lesser degree, sources of advice external to themselves and potentially external to the State. The Fundamental Safety Principles state that a State's regulatory body must maintain adequate technical competence to fulfil its responsibilities [1]. Recent conferences aimed at assisting regulatory bodies in their mission have highlighted the roles, functions and value of technical and scientific support organizations in enhancing nuclear and radiation safety. This has drawn attention to the subject of the provision of external expert support in States that are developing or maintaining nuclear power programmes [2, 3].

1.2. While some regulatory bodies have sufficient staff and expertise to carry out their functions within their own organization, other regulatory bodies use a range of providers of external expert support² (both individuals and organizations). Depending on the type of regulatory body, the State's legal system and the national nuclear programme, different structures and arrangements may exist. A regulatory body may not have the resources, in terms of number of staff,

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

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

² A 'provider of external expert support' or a 'provider of external expert advice' is an individual or organization that is not part of the regulatory body but that is recognized for its expertise and competence in safety and can provide support and/or advice to the regulatory body.

range of expertise and relevant experience, to carry out its functions to the extent necessary and within the required schedule. It may also choose to call on external support for other reasons, for example, in order to benefit from the best expertise available. Therefore, the regulatory body should have a process and procedures in place for obtaining suitable external expert support to gain input that can be used in making regulatory decisions [4].

OBJECTIVE

1.3. The objective of this Safety Guide is to provide recommendations and guidance on meeting the requirements of Ref. [5] on obtaining expert advice or services for the regulatory body. This Safety Guide provides recommendations and guidance on the process the regulatory body should use to determine the need for external expert advice and the processes and procedures it should use for identifying a suitable support provider and making contractual arrangements for the work. It also provides recommendations on how the regulatory body should take the advice of external experts into account while still retaining responsibility in making its decisions.

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

1.5. This Safety Guide primarily provides guidance for the regulatory body. Other organizations with legal, professional or functional responsibilities for safety may also benefit from using it. These may include, but are not limited to, designers, licensees, manufacturers, constructors, employers, contractors and consignors (Ref. [1], Principle 1).

SCOPE

1.6. This Safety Guide covers all types and uses of support for safety issues that may be required by a regulatory body, whether technical, scientific, legal or analytical issues or issues necessitating other types of logistical support. It also addresses the ways and forms in which external support can be provided: by dedicated organizations (e.g. statutorily mandated technical support

organizations), by other commercial organizations through either generic contracts or specific contracts, by other regulatory bodies, by advisory bodies, by research organizations, by academic bodies, by consultants, by individual experts or by others.

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

STRUCTURE

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

2. CONCEPT OF EXTERNAL EXPERT SUPPORT

GENERAL

2.1. The Fundamental Safety Principles [1] state that “an independent regulatory body ... must be established and sustained” with “adequate ... human and financial resources to fulfil its responsibilities” (Principle 2). Furthermore, Ref. [5] states that “The regulatory body shall employ a sufficient number of qualified and competent staff ... to perform its functions and to discharge its responsibilities” (Requirement 18). However, Ref. [5] also states that “The regulatory body shall obtain technical or other expert professional advice ... as necessary in support of its regulatory functions”, emphasizing that the obtaining of such advice “shall not relieve the regulatory body of its assigned responsibilities” (Requirement 20). In Ref. [4] recommendations are provided on some aspects of the use of consultants and advisory committees; this Safety Guide provides additional, more detailed recommendations.

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

2.3. The regulatory body should put in place arrangements to ensure that it retains its responsibility for making all decisions on regulatory and safety issues and is not unduly influenced by any provider of external expert support. Processes and procedures should be put in place to ensure that external expert advice is provided in accordance with an established set of principles and rules. These principles and rules should ensure that the identification of the need for such advice — as opposed to performance of the work in-house — is consistent with a clear policy that takes the safety implications of this choice into account. The method of selection of an external expert or experts should ensure that the expert has suitable competence and adequate resources, is free from conflicts of interest (see paras 3.2–3.8) and has the required level of security clearance. A suitable code of ethics and confidentiality protocols (see paras 3.18–3.21) should be adopted. Arrangements should be put in place for initiating and managing procurement that is impartial and that respects the principles of safety and

security. There should be a proper model — including acceptance criteria — for evaluating the external expert advice and for reflecting it in regulations and guidance, as well as in regulatory decision making and enforcement processes (see paras 4.8 and 4.9).

PROVIDERS OF EXTERNAL EXPERT SUPPORT

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

2.5. If the provider of external expert support uses experts from outside its own organization as subcontractors, who in turn may use other subcontractors, the primary provider of external expert support 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 in accordance with the contractual arrangements between the regulatory body and the provider of external expert support.

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

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

- Sources of advice from within the State include:
 - Advisory bodies: many governments and regulatory bodies appoint experts in the form of an advisory committee to assist and provide advice. Such experts may be from other States, but should be appointed in accordance with clearly defined terms of reference that include criteria for their selection (see Ref. [4], paras 3.30–3.32).
 - Dedicated organizations: some States have within their legal structures arrangements for particular independent organizations to dedicate part of their resources to assisting the regulatory body on a regular basis.
 - Government laboratories or research centres: if issues require experimental investigation or verification, advice from such bodies can be sought.
 - Legal organizations: most States have private or governmental legal bodies that can review the language of legal documents and assist in legal enforcement actions.
 - Other governmental organizations: these may be mandated to provide input on regulatory decisions but do not have specific decision making responsibilities.
- Sources of advice from outside the State include:
 - International organizations: the IAEA, and organizations such as the International Commission on Radiological Protection (ICRP), the OECD Nuclear Energy Agency (OECD/NEA), the World Association of Nuclear Operators (WANO) and the World Health Organization (WHO) can be sources of advice on specific issues. This may be provided through multilateral and/or bilateral agreements or membership of their committees or by specific contractual arrangements (Ref. [5], Requirement 14).
 - Regulatory bodies of other States: foreign regulatory bodies can be consulted for input through individual contacts, international cooperation agreements or international forums on the decision making process used in a given area, which can be particularly useful when designs or regulatory procedures utilized in one State are considered in another.
 - Regulatory bodies of vendor States: regulatory bodies of vendor States can be consulted with respect to the regulatory structure and its application in a State from which structures such as the reactor pressure vessel, components or services are provided to the licensee.

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

- Standards organizations, quality assurance organizations and professional bodies: these bodies, which may be national or international, such as the International Organization for Standardization (ISO), can provide advice within their fields of expertise.
- Engineering or service organizations: in many States, engineering or service organizations provide services in technical, engineering and scientific fields.
- Certified testing and analytical services: certain measurements required on a regular basis, such as dose monitoring or water quality monitoring, can be carried out for the regulatory body or the State, if necessary, by organizations offering these services.
- Academic institutions: universities and other academic institutions such as engineering schools or institutes of technology can, either through their academic staff or by establishing a research programme, provide advice on a range of scientific, technical and engineering issues.
- Individual experts in specific fields of competence (e.g. consultants): many experts in specific fields do not belong to organizations. Recent retirees from a regulatory body or other bodies could be a particularly useful source of advice.
- Financial and economic organizations: such organizations, which can be private or governmental, can provide advice on matters such as the financial status of an applicant, the appropriateness of investments or decommissioning funds or potential financial conflicts of interest.

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

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

concurrently. The actual approach will depend on the legal structure of the State and the structure and needs of its regulatory body.

AREAS FOR EXTERNAL EXPERT SUPPORT

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

- Research activities;
- Licensing, review and assessment (relating to the management system, engineering analysis, safety analysis or independent verification);
- Development of policy;
- Development of regulations and implementation of regulatory functions (e.g. inspections, enforcement, development of regulatory guidance);
- Advanced technical analysis and computer simulations and modelling;
- Technical evaluations of tenders and technical specifications;
- Emergency response support and guidance;
- Assessment and evaluation of different professional views, and ensuring transparency in addressing these views;
- Testing, measurement, inspection and analysis services;
- Development of regulatory infrastructures;
- Technical support for meeting the obligations of international conventions;
- Legal or financial advice;
- Communications support;
- Staff training;
- Project management and administrative support.

3. CHARACTERISTICS OF EXTERNAL EXPERT SUPPORT

GENERAL

3.1. As set out in Section 2 of this Safety Guide, the providers of external expert support may be very different and the characteristics required of a provider of external expert support will differ as a consequence. Of the characteristics set out

in this section, some might not apply, or might apply only in a partial way, to an individual (e.g. the need for an adequate management system).

INDEPENDENCE

3.2. In Ref. [5], Requirement 17 states: “The regulatory body shall perform its functions in a manner that does not compromise its effective independence.” This is further reflected in the requirement to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice and services (Ref. [5], para 4.20).

3.3. Independence of advice means that the provider of external expert support should be able to form and express a technical judgement that demonstrates integrity, and is impartial and free from commercial, financial and other pressures from interested parties. The provider of external expert support should not be bound to directives from any other organization regarding the results of its work. Independence should be a characteristic of the expert. Moreover, the experts’ judgement should be based solely on technical knowledge, on results of analyses and on applicable regulatory requirements and guidance and should in no case be biased owing to political opinion. Technical competence (see paras 3.9–3.15) and safety culture and security awareness in the provider of external expert support contribute to the independence of the technical advice.

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

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

If neither of these things can be verified, an alternative opinion from other providers should be sought. If there is any doubt, legal advice should be sought. Potential and perceived conflicts of interest should be explicitly discussed and managed.

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

- When a financial tie (e.g. through a stockholder or through funding) exists between an external expert or organization and the nuclear industry (e.g. a licensee, a designer or a vendor);
- When the external expert or organization is part of, or is closely linked to, an organization that has been assigned responsibilities in relation to the promotion of nuclear technologies, for example, for profit or any form of payment;
- When there may be a conflict of national interest or commercial interest;
- When the external expert or organization is providing support on the same or closely related issues to potential licensees, designers or vendors in the State or in other States.

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

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

3.7. If a provider of external expert support is not entirely free from potential conflicts of interest, the assigned task should be closely monitored. The advice is then required to be carefully assessed by the regulatory body for bias generated by conflicts of interest (Ref. [5], para. 4.21).

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

TECHNICAL COMPETENCE

3.9. Technical competence represents a profound knowledge of the state of science and the best available technology that is necessary for a broad and comprehensive assessment of the safety of facilities and activities. Technical competence is the ability of the provider of external expert support to apply such state of the art knowledge and techniques. The technical qualifications and experience of external experts should normally be at the same level as or exceed those of the staff of the regulatory body who are performing similar tasks (see Ref. [4], paras 3.28 and 3.29). The regulatory body should ensure that the competence of the provider of external expert support is adequate.

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

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

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

3.12. Individual experts and expert organizations should know and take into account the relevant legislation and regulations and the regulatory requirements that are in force in the State whose regulatory body is being supported.

3.13. Expert organizations should ensure that competence is built and maintained. Requirement 11 of Ref. [5] states that “The government shall make

provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.” Furthermore, para. 2.34 of Ref. [5] states: “As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available,” and para. 2.35 states that:

“Competence shall be built, in the context of the regulatory framework for safety, by such means as:

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

Other means of building competence include:

- Becoming a member of regional and/or international safety networks;
- Improving nuclear knowledge management;
- Gaining appropriate experience, by learning lessons from incidents and events and their implications for modifications of procedures, structures, systems or components;
- Exchange of technical information through bilateral and multilateral agreements;
- Participation in peer reviews and undertaking self-assessment;
- Participation in conferences, workshops, seminars, meetings of international conventions and symposia.

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

- For an individual expert, technical competence should be ensured by verifying that he or she has already provided similar external expert support in a satisfactory way, for example through recommendations from other experienced experts (e.g. a reference list).
- For an academic expert, a publication list is a useful additional tool, and documented research activity should indicate skills and knowledge that are adequate for the task to be assigned. Certification may demonstrate continued competence in the expert’s specialized area.

- For an organization that has an established long term relationship as a provider of external expert support to a regulatory body, there is still a need to build and maintain competence (Ref. [5], para. 2.35). The necessary resources for building and maintaining the technical competence of the provider of external expert support should be made available. Competence can be demonstrated by the following:
- Full awareness by all the personnel of the provider of external expert support of the safety implications of their work;
 - The existence of a strategy for training the provider's own staff and implementing this training in its technical field of competence;
 - Involvement in significant research activities in its field of competence;
 - Experience gained in performing safety related tasks in the State and in other States;
 - Bilateral cooperation with the regulatory body, covering areas such as: exchange of experience, 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, procurement of software products and other areas of cooperation;
 - The existence of an ongoing up to date research and development programme.

3.15. Competence depends 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 a number of different, independent activities performed in the assigned area, as well as the levels of complexity of these activities.

MANAGEMENT SYSTEM

3.16. Any potential provider of external expert support should adhere to basic management requirements. Reference [6] establishes the general requirements for the management system. For a provider of external expert support, the existence of a quality management system is a useful characteristic for the following reasons:

- Through the traceability of processes and documentation, it can help to demonstrate the technical competence of the organization, for example, through the processes of assigning qualified people to a specific task or of reviewing its advice before finalizing it.

- For long term support (e.g. a dedicated support organization), the existence of a quality management system may provide confidence that technical competence will be maintained in the long term.

3.17. The management system should be such as to help the provider of external expert support to defend its advice on technical matters. This defence should be supported by technical arguments, justified according to applicable requirements and supported by documentation. The documentation can be used by the regulatory body to support its decision making, which should reflect the high priority given to safety (Ref. [7], para. 2.36). Since the regulatory body has to utilize and evaluate the work performed by the provider of external expert support, the external expert should be required to provide a detailed written report consistent with the work plan that has been agreed with the regulatory body. The report should include the objective of the work, references, the basis for the work, the methods used, the results obtained, conclusions and any related recommendations that may assist the regulatory body.

CONFIDENTIALITY

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

Security related or protected information

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

3.20. It is assumed that organizations and individuals in other States (or even within the State) would only be allowed to disclose certain security information, including to subcontractors, with the agreement of the owner, taking into account any relevant international agreements or regulatory requirements. Any provision of information to parties outside the regulatory body should be in accordance with the rules established by the relevant authority.

Proprietary information

3.21. The provider of external expert support should also be made aware of the existence of any confidential proprietary information (including information of commercial value), and of its precise scope, restrictions on its use and the organizations to whom it may be disclosed. The provider of external expert support should have in force management rules, procedures and organizational conditions to protect this type of information. The regulatory body should be aware that commercial entities designing or constructing 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 proprietary information. No such restrictions can be placed on information required by the regulatory body, but this does not give it the authority to provide such information to third parties. The regulatory body should inform the owner of the intellectual property rights to any information of its intention to provide that information to a third party (i.e. the provider of external expert support) and should establish commonly agreed arrangements (see also paras 5.4–5.6).

SAFETY CULTURE

3.22. The Fundamental Safety Principles [1] state that:

“A safety culture that governs the attitudes and behaviour in relation to safety of all organizations and individuals concerned must be integrated in the management system. Safety culture includes:

- Individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;
- Accountability of organizations and of individuals at all levels for safety;

- Measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety” (Ref. [1], para. 3.13).

Safety culture should be enhanced by means of training and promotion.

3.23. The regulatory body should ensure that its requirements for safety culture are reflected in or are similar to those of the provider of external expert support. The provider of external expert support should have a stated commitment to safety culture that is consistent with the regulatory body’s policy. The provider of external expert support should be able to provide the requisite technical support in accordance with the policy on safety culture of the regulatory body and to raise with the regulatory body any safety concerns regarding work. The regulatory body should address any safety concerns raised by the provider of external expert support. In this regard, the regulatory body should develop a process for addressing different professional views.

4. PROCESS FOR THE SELECTION AND USE OF EXTERNAL EXPERT SUPPORT

PURPOSES FOR THE USE OF EXTERNAL EXPERT SUPPORT

4.1. Although the regulatory body must have adequate technical competence [1], there are many purposes for which external expert advice may be sought. These may include the following:

- Assessment of a new design of nuclear installation that is different from those previously authorized in the State;
- A need for a variety of expertise in different specializations at different stages in the lifetime of a facility or activity, e.g. site selection, design, construction, commissioning, operation and decommissioning or closure;
- To respond to legal changes that require new regulatory processes and regulations;
- To support the review of the application of new technologies for processes and safety systems;
- To support the establishment of new safety criteria and requirements or guidance;

- To perform detailed independent verification;
- To evaluate analysis of new sites for facilities;
- To compensate for a lack of experience and expertise or insufficient capability relating to a technical discipline (e.g. an issue relating to site evaluation that requires expertise in geology);
- To compensate for a lack of specific resources for tasks at hand, e.g. a lack of experience relating to the infrastructure for commissioning, including project management;
- To deal with a short term increase in workload;
- To provide advice in an emergency;
- To perform quality assurance and regulatory inspection services if permitted within the national regulatory framework.

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

ACTIONS TO TAKE IN SEEKING EXTERNAL EXPERT SUPPORT

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

- Determine the objective, the scope, the schedule and the different steps of the work required. This can be as narrow as a single task or as broad as a general arrangement for technical services.
- Determine the expertise required to perform the work and the kind of product that is expected.
- Identify the possible providers of external expert support.
- Solicit or select an organization or individual to provide the expert support.

CONSIDERATIONS IN SELECTING AN EXTERNAL EXPERT

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

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

- The provider of external expert support should be able to demonstrate technical competence (see paras 3.9–3.15).
- There should be no actual conflicts of interest. In case of a potential or perceived conflict of interest, the situation should be discussed with all involved parties and managed (see paras 3.4 and 3.5).
- The provider of external expert support should be able to conduct its work within the time frame specified by the regulatory body. The time allowed for the work to be performed should be commensurate with the scope of the work and consistent with the time frame set by the regulatory body.
- The provider of external expert support should be able to prepare and deliver specific documentation as required to formalize its advice and the 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 should be reviewed by the regulatory body. The documentation that supports the advice should be sufficient, accurate and relevant to allow the regulatory body to judge the quality of the work.
- When the use of advice from experts in 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 could lead to misunderstandings.

THE REGULATORY BODY AS AN INTELLIGENT CUSTOMER

4.6. The regulatory body should maintain its status as an ‘intelligent customer’³ for all work carried out on its behalf by external experts.

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

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

EVALUATION AND USE OF THE WORK PERFORMED

4.8. The regulatory body should evaluate the work performed by the provider of external expert support in accordance with the objective and scope of work specified at the outset. After the work is completed, the regulatory body should consider the advice received and should determine whether and how it is to be used. The advice should be evaluated in accordance with the role and the level of responsibility of the external expert. Such evaluation should also be used for the

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

purposes of assessing the suitability of this external expert for possible further work.

4.9. The work performed by the external expert 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 supports 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 external expert. The basis for the decisions should also be recorded and documented appropriately.

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

GENERAL

5.1. The provider of external expert support does not replace the regulatory body when providing support. In instances where the provider of external expert support will need to interact with interested parties, it should be made clear that the regulatory body has approved such contact and that the regulatory body retains its responsibilities and makes the final decision (Ref. [5], Requirement 20).

INTERFACES

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

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

TRANSPARENCY AND OPENNESS

5.4. The provider of external expert support should keep sufficient records so that its advice can be traced and audited, including how different professional views were addressed. This includes, inter alia, records of data and models used for all computer calculations as well as associated uncertainties, references to sources of data, reference to documentation that has been examined (safety analysis report, safety justification, design documentation, etc.) and results of any tests carried out. The regulatory body may decide to provide this information to the licensee. In this case, it should be ensured that proprietary information or confidential information is appropriately controlled subject to the applicable legislation (see also para. 3.21).

5.5. Reference [8] states in para. 27 that “Transparency is a means to promote independence in regulatory decision making and to demonstrate such independence to politicians, licensees and other stakeholders, as well as the general public.” If information that results from expert advice may have to be made available to the public, the regulatory body should give consideration to the nature of such communication. 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, external advice should generally be made public to enhance transparency as part of the process of engagement with interested parties. Publications should clearly state the identity of the provider of external expert support and should indicate that the advice was developed for the regulatory body by this provider.

5.6. Work carried out for the regulatory body should be made available to the public in accordance with the legislation and regulations governing public access to documents established or possessed by public bodies. Experts may wish to

draw on this work in other contexts or may wish to refer to advice that was not published. The regulatory body should then reconsider whether such advice should be made public or provided to the person requesting it, taking into account confidentiality or security issues. Arrangements with providers of external expert support should detail the instructions and authorizations necessary for the work to be quoted or used and should provide guidance on handling proprietary information (see also para. 3.21). In addition, the regulatory body may specify an embargo time prior to which a provider of external expert support is not permitted to discuss the work with other parties.

COMMUNICATIONS

5.7. All communication regarding the work performed by the provider of external expert support at the request of the regulatory body should be under the control and direction of the regulatory body. The provider of external expert support should not publish technical results or technical evaluations or lessons learned and should not release to public media any results or technical findings or policy positions without the consent of the regulatory body.

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

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