IAEA TECDOC SERIES

IAEA-TECDOC-1835

IAEA-TECDOC-1835

Technical and Scientific Support Organizations Providing Support to Regulatory Functions

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TECHNICAL AND SCIENTIFIC SUPPORT ORGANIZATIONS PROVIDING SUPPORT TO REGULATORY FUNCTIONS

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

Every year since 2007, Member States have acknowledged in resolutions of IAEA General Conferences the existence and role of technical and scientific support organizations (TSOs). In 2011 and 2012, the Secretariat was encouraged to promote recognition of the importance of TSOs in enhancing nuclear safety. In 2017, Member States were encouraged to consider establishing TSOs, and the Secretariat was requested to promote cooperation and to assist in this regard.

Since the IAEA International Conference on the Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety, in 2007, TSOs from different Member States have been working together to develop a common understanding of the roles and challenges of the organizations providing technical and scientific support to regulatory bodies. A major recommendation of the IAEA International Conference on the Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety and Security, held in 2010 and 2014, was to develop a reference publication for TSOs to facilitate the development, at the national level, of the human, technical, organizational and financial resources needed to perform these key support activities. This publication is the result of that recommendation.

To provide technical and scientific support, TSOs face specific challenges, such as the need to develop and manage specific tools to support nuclear and radiation safety and to maintain an up to date scientific knowledge base. This is the first IAEA publication to present best practices for TSOs based on expert guidance with respect to their specific challenges. This publication introduces the general principles underlying the provision of technical and scientific support to a regulatory body and the characteristics of organizations providing such support. It describes the services provided to support regulatory functions as well as the associated activities and processes to maintain the required level of expertise, state of the art tools and equipment.

The IAEA officers responsible for this publication were L. Guo, K. Ben Ouaghrem and J. Parlange of the Office of Safety and Security Coordination.

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CONTENTS

1. INTRODUCTION

The technical and scientific expertise which is necessary to carry out the regulatory functions can be supported by a technical and scientific organization. In the context of this publication, the term Technical and Scientific Support Organization (TSO) is defined as an organization or organizational unit designated, or otherwise recognized by a regulatory body and/or a government, to provide expertise and services to support nuclear and radiation safety and all related scientific and technical issues, to the regulatory body.

A TSO can also support nuclear security and safeguards. Moreover a TSO can support the regulatory functions either inside the regulatory body, as an organizational unit, or outside it, as an independent entity.

1.1. BACKGROUND

In the interest of examining the support provided by TSOs, the IAEA held the first International Conference on the Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety, in 2007 in Aix-en-Provence, France [1]. At this conference, the TSOs from different IAEA Member States started working together to develop a common understanding of the roles, functions and challenges of organizations providing technical and scientific support to regulatory bodies.

Every year since 2007, Members States acknowledged, in IAEA General Conferences resolutions, the existence and role of TSOs. In 2011 and 2012, the Secretariat was particularly encouraged by the IAEA General Conference "to promote recognition of the importance of technical and scientific support organizations (TSOs) in enhancing nuclear safety"[1]. In 2017, the General Conference encouraged Member States "to consider establishing technical and scientific support organizations (TSOs)" and requested the Secretariat "to promote cooperation between Member States and to assist, upon request, in this regard"[2].
A major recommendation of the International Conferences on the Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety and Security, organized again in 2010, in Tokyo, Japan [2], and in 2014, in Beijing, China, was to develop a reference publication for TSOs. Such a publication would facilitate the development, at the national level, of the human, technical, organizational, institutional and financial resources needed to perform these key support functions, in accordance with the national legal and regulatory framework for safety.

In the Nuclear Safety Action Plan[3] adopted by the 55th IAEA General Conference in 2011, after the Fukushima Daiichi accident, the "need for appropriate technical and scientific support" is clearly highlighted as one of the areas of improvement for strengthening the effectiveness of national regulatory bodies. Subsequent work to highlight and build upon the observations and lessons from the Fukushima Daiichi accident also emphasized the need for

[1] GC(55)/RES/9 and GC(56)/RES/9.

[2] GC(61)/RES/8.

[3] Available at https://www.iaea.org/sites/default/files/actionplanns.pdf [following referencing of the NS Action Plan in the Annual Report].

the identification of latent or hidden technical and organizational issues, before they become regulatory issues and thus for strong technical and scientific support functions in general.

Paragraph 2.35 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [3], lists "organizations providing services or expert advice on matters relating to safety" among the parties having "responsibilities in relation to the safety of facilities and activities" when considering the building of competence for safety. Likewise, Paragraph 1.40 of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards [4], states that the requirements in this publication apply to TSOs. Taking all this into account, this publication will be reporting on the organization and support provided by TSOs to regulatory bodies, focussing on the perspective and the work of TSOs.

1.2. OBJECTIVE

This TECDOC is intended to serve as a reference publication on TSOs to better describe the core characteristics and functions of a TSO supporting regulatory bodies.

This publication is intended for use primarily by organizations that provide technical and scientific support in the field of nuclear and radiation safety. This also includes organizations that acquire such support, and regulatory bodies and governments, as they make decisions on the model of technical and scientific support to be developed at the national level, for example in the case of a country embarking on the development of a nuclear power programme.

1.3. SCOPE

This publication describes the general characteristics, organizational aspects and types of services provided by TSOs to support regulatory functions and infrastructure in the Member States. This TECDOC provides a description, including common core values and characteristics, of TSOs in countries where the regulatory infrastructure is well established, and it focuses largely on nuclear safety issues[4].

As part of the organizational aspects, information will be provided on the types of technical and scientific providers (e.g. internal or external to the regulatory body) and their respective challenges, and on the internal organization of TSOs to provide efficient and sustainable services and maintain expertise and competence.

This TECDOC covers all types of support for safety issues that may be provided by a TSO to a regulatory body to carry out its statutory functions, requiring a technical and scientific expertise in the nuclear and radiation safety field. Such support also applies to activities in related fields such as legal, training, and human resources. A TSO can also support nuclear security and safeguards but this is not within the scope of this TECDOC. More information on TSO supporting nuclear security is provided in the IAEA-TECDOC-1734 "Establishing a National Nuclear Security Support Centre." [5].

[4] In that consideration, further examples will be developed under the IAEA TSO initiative to focus on the specific radiation safety issues and further guidance is under development to explain the process of how to develop and strengthen TSO's capacity in Member States.

This technical and scientific support is applicable to "…all circumstances that give rise to radiation risks [and to] all facilities and activities – existing and new –utilized for peaceful purposes, and to protective actions to reduce existing radiation risks" as defined in para. 1.9 and footnote 3 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [6]. This applies to planned exposure situations as well as to emergency or existing exposure situations as defined in GSR Part 3 [4], including unregulated risk situations.

This publication also provides information on the role of a TSO in the regulatory framework, as described in GSR Part1 (Rev. 1) [3], and its organization and structure and management systems that may be used to provide service to the regulatory body, including their interactions with regulatory bodies and stakeholders, processes for quality management and conflict of interest. The present publication can be considered together with IAEA Safety Standards Series No. GSG-4, Use of External Experts by the Regulatory Body [7], which also addresses the matter of external experts, from the point of view of the regulatory body.

Technical support to nuclear operators applies to a large extent the same technical bases as the technical support to regulatory bodies, however it differs in a number of other respects and is not in the scope of this publication. Information on technical support to operators can be found in another IAEA publication, Technical Support to Nuclear Power Plants and Programmes [8].

1.4. STRUCTURE

Section 2 of this publication sets out the generic characteristics of TSOs. Section 3 outlines internal organizational aspects and the integrated management system for effective technical and scientific support. Section 4 discusses the nature and scope of TSO activities. The appendix provides examples of Member States' TSO characteristics. In addition, the annexes, contained in a CD-ROM, include detailed examples of practices developed by specific TSOs to respond to various challenges.

2. TSOS IN THE REGULATORY FRAMEWORK AND THEIR RELATIONSHIP WITH THE REGULATORY BODY AND OTHER INTERESTED PARTIES

2.1. DESCRIPTION OF TSOs IN THE CONTEXT OF THE REGULATORY FRAMEWORK

2.1.1. TSOs and the regulatory body

GSR Part 1 (Rev. 1) [3] identifies the core functions of the regulatory body as follows: development and/or provision of regulations and guides, notification and authorization, including registration and licensing procedures, regulatory review and assessment, regulatory inspection, enforcement, emergency preparedness and response and communication and consultation with interested parties.[5]

All of the above functions are performed based on technical and scientific work (e.g. data, information and knowledge, safety evaluation and review). The fulfilment of the functions of

[5] A Safety Guide on core functions of the regulatory body is in preparation.

the regulatory body can benefit from the technical and scientific services and expert advice provided by a TSO. Requirement 20 of GSR Part 1 (Rev. 1) [3] states:

> "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."

More detailed information on TSO activities to support the regulatory functions is provided in Section 4.

2.1.2. Role of TSOs as explained in the IAEA Safety Standards

GSR Part 1 (Rev. 1) [3] and GSR Part 3 [4] refer to the provision of technical and scientific support to the regulatory functions and hereby provides several essential pieces of information on the role and responsibilities of a TSO in the governmental, legal and regulatory framework for safety.

Paragraph 1.11 of GSR Part 3 [4] states that: "The government is also responsible for ensuring, as necessary, that provision is made for support services, such as (…) technical services."

Requirement 11of GSR Part 1 (Rev. 1) [3] clarifies the obligations of the government with respect to ensuring the availability of competence for safety. Paragraph 2.35 states that:

> "The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety."

Paragraph 2.36 (b) states that:

> "The government shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety".

The maintenance of expertise supporting the regulatory body's functions and the arrangements between the regulatory body and its support organizations are identified as key pillars of the framework for safety and are under the direct responsibility of the government.

Paragraphs 4.19 and 4.20 of Requirement 20 of GSR Part 1 (Rev. 1) [3] emphasize the different ways of providing the technical and scientific support and the arrangements to avoid the conflict of interest:

- "Technical and other expert professional advice or services may be provided in several ways by experts external to the regulatory body. The regulatory body may decide to establish a dedicated support organization, in which case clear limits shall be set for the degree of control and direction by the regulatory body over the work of the support organization. Other forms of external support would require a formal contract between the regulatory body and the provider of advice or services."

- "Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services."

This TECDOC provides a more detailed explanation on how the role and characteristics of a TSO correspond to Requirement 11 and Requirement 20 of GSR Part 1 (Rev. 1) [3] as highlighted above. It also describes the other aspects and attributes of the technical and scientific support to the regulatory body provided by a TSO.

2.2. PROVISION OF TECHNICAL AND SCIENTIFIC SUPPORT

In line with the definition in the introduction of this publication, several characteristics are common to all TSOs. A TSO is an organizational unit, a department or an institute (as opposed to individual experts). It works in the long term perspective and maintains over time the proven expertise that is necessary to support regulatory functions; this role is acknowledged and supported by the regulatory body or by the government. Its expertise and activities focus mainly on nuclear and radiation safety, and it provides technical and scientific support primarily in this field.

Although their activities are similar, there are several types of organizations providing technical and scientific support to regulatory functions in Member States. Their legal status and relationship with the regulatory body may vary considerably from one Member State to another.

For the technical and scientific support provided to the regulatory body in the field of nuclear and radiation safety, the institutional organization of TSOs can be categorized as described in Section 2.2.1.

2.2.1. Types of TSOs

There are two types of TSO. A TSO can be either internal, as an organizational unit of the regulatory body or external to the regulatory body. Examples of the main characteristics of TSOs in Member States are provided in the Appendix.

Figure 1 summarizes two typical scenarios of interaction between the TSO and the regulatory body and Fig. 2 describes general interactions of the TSO with all stakeholders.

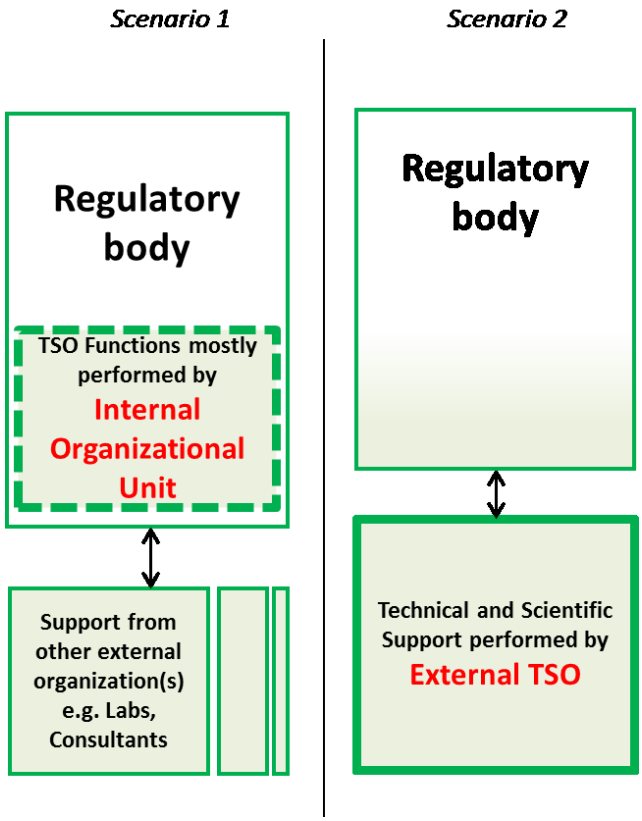

FIG. 1. Typical scenarios of interaction between the TSO and the regulatory body.

Both internal and external TSOs have a direct relationship with the regulatory body, however depending on the Member State they also support, provide services to or interact with other interested parties (such as governments, ministries, operators.). In such cases, the advice or support is also carefully monitored and assessed against the risk of conflicts of interest by the regulatory body itself, as required in GSR Part 1 (Rev. 1), Requirement 20, para. 4.21 [3].

The general interactions of the TSO with the regulatory body and other interested parties in support of regulatory functions are shown in Fig. 2 below.

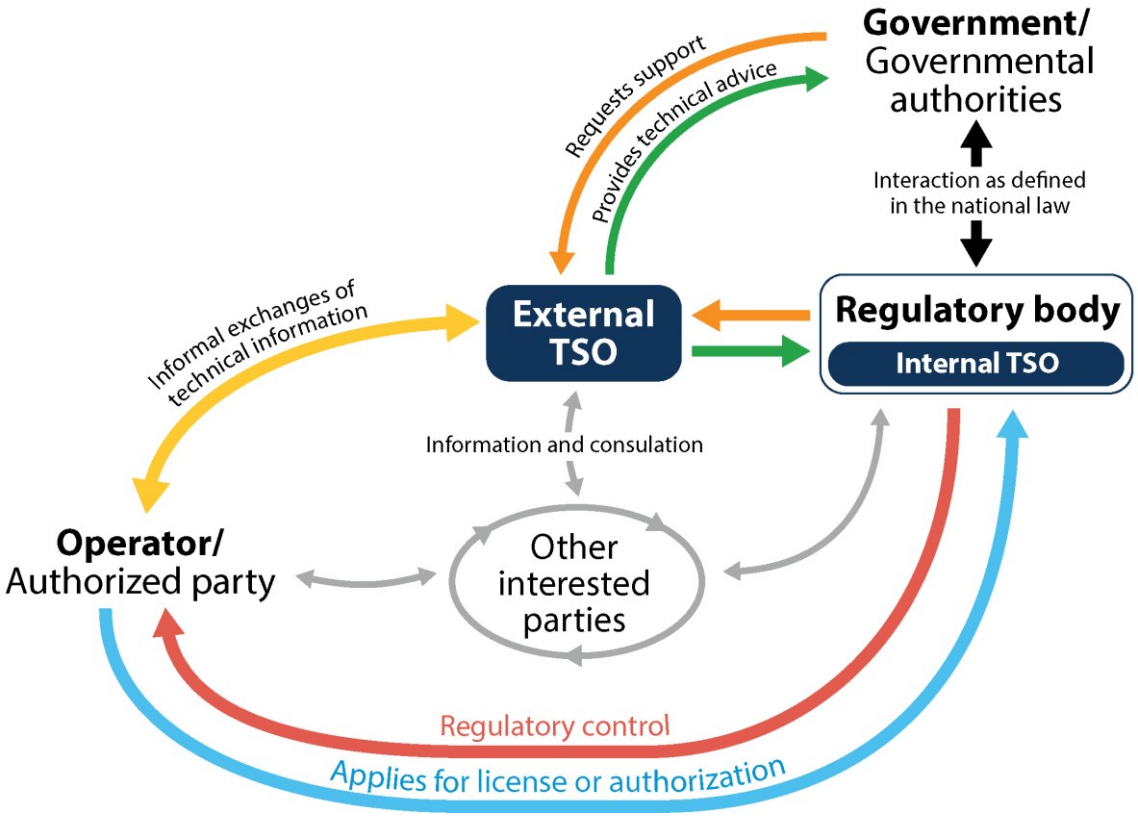

FIG. 2. Illustration of general interactions of the external TSO with the regulatory body and other interested parties in support of regulatory functions.

2.2.1.1. Internal TSO

An internal TSO is a dedicated organizational unit of the regulatory body. Such a model of organization exists for example in the USA, in the Nuclear Regulatory Commission (US NRC), as well as in Canada, in the Canadian Nuclear Safety Commission (CNSC), and in Japan, in the Nuclear Regulation Authority (NRA).

In such cases, technical and scientific resources are readily accessible to the regulatory body. The regulatory body does not need to develop tendering processes or to establish contractual arrangements to receive the necessary support services. In addition, the internal TSO is familiar and consistent with the working methods and processes of the regulatory body and, in general, with the regulatory framework of the Member State.

As the internal TSO is not competing with other organizations to provide the best possible service, it has to pay special attention to ensuring the state of the art knowledge and expertise of its staff.

Many attributes of the technical support integrated with the regulatory body and related considerations for the regulatory body are to be found in IAEA Safety Standards Series No. GS-G-1.1, Organization and Staffing of the Regulatory Body for Nuclear Facilities [9] [6] and IAEA Safety Standards Series No. GS-G-1.5, Regulatory Control of Radiation Sources [10].

[6] A Safety Guide on core functions of the regulatory body is in preparation.

It is common practice that the internal TSO receives additional support from external organizations with additional and complementary technical and scientific capabilities (including laboratories, universities and other external organizations).

2.2.1.2. External TSO

An external TSO is a legally established entity which is assigned to serve primarily the regulatory body. It is separated from but formally engaged with the regulatory body.

External TSOs are comprised of different organizational configurations and business models. Such models exist in most of the European countries for example in Belgium, Finland, France, Germany, Lithuania, the Russian Federation, Slovakia and Ukraine, but also in Asia for example in China, Republic of Korea and Viet Nam. More details on the types, characteristics and the nature and scope of services provided by TSOs are given in the Appendix.

External TSOs can range from relatively small organizations with expertise in a specific technical/scientific area to large research entities with a broad range of expertise and capabilities. External TSOs are also referred to in some IAEA Safety Standards as "dedicated support organization", for example in GSR Part 1 (Rev. 1) [3] and GS-G-1.1 [9] or as "statutorily mandated technical support organizations", for example in GSG-4 [7].

For example, a TSO may be:

- Established by the government, the regulatory body or by a law or contracted by the regulatory body (for example through a tendering process);

- A state-controlled entity of non-profit nature or commercial, which is common for research institutes;

- Funded by public support, private support or mixed.

An external TSO is an independent organization that operates under a formal arrangement with the regulatory body. The relationship between the external TSO and the regulatory body depends on such legal and organizational arrangements. An external TSO can be established, controlled and directed by the regulatory body; contracted by the regulatory body for a specific task, or it can be only bound by general objectives, especially when it is established by a law.

An external TSO is not directly involved in in the regulatory body's decision making process; however, it is sufficiently familiar with these elements to effectively carry out its support activities.

In line with its statutory or contractual obligation, an external TSO has to maintain state of the art knowledge and expertise and an adequate understanding of safety issues in general. Research and development (R&D) activities are typically important parts of its work as they constitute a good way to build advanced expertise and to train new experts. It can also provide some warranty of continuity of the expertise within the organization. Furthermore, a R&D organization has sufficient staff to respond to variations in technical and scientific support demand and has the infrastructure to carry out required tests or regulatory research.

Maintaining the availability of research capabilities including experienced staff, with knowledge of the state of the art tools and facilities, is more costly than maintaining TSOs which do not perform R&D activities but facilitates the maintenance of the required scientific and technical capabilities.

Safety expertise and knowledge necessary to regulatory activities can be fully contained within an external TSO. However, some external TSOs may also access additional expertise through cooperation or through tendering and establishing contractual arrangements to assist with non-nuclear specific expertise, for example in the meteorological or environmental protection field.

2.2.2. Provision of technical and scientific support to other governmental institutions

A TSO may have a role to support other governmental institutions with safety related expertise and cover a wider scope of technical topics than described in this publication, in particular interfaces between safety, security and safeguards, or risks associated with non-ionizing radiation sources, which may not be under the responsibility of the regulatory body..

In certain situations, such as existing and emergency situations, the TSO may provide support to ministries or other governmental authorities, for example those in charge of public health, labour or the environment, to technically assess situations and to help in the definition, implementation and improvement of national protection strategies.

For example, the Institute for Radiological Protection and Nuclear Safety (IRSN) in France provides support to the Ministry of Health and the Ministry of Labor for all issues related to the protection of the public and workers, in particular with respect to the dose register or to unregulated risks. In the field of security, the Korea Institute of Nuclear Non-proliferation and Control (KINAC) in the Republic of Korea, or IRSN in France provide support to the competent national authority for nuclear security.

Some Member States have also implemented the concept of a national Nuclear Security Support Centre (NSSC) as a means to strengthen the sustainability of nuclear security in a State. The primary objectives of NSSCs are to develop human resources through the implementation of a tailored training programme, to establish a network of experts, and to provide technical support for lifecycle equipment management and scientific support for the prevention and detection of and the response to nuclear security events. The NSSC concept is outlined in further detail in the IAEA-TECDOC-1734 [5]. In certain cases, TSOs have established and operated NSSCs to provide technical and scientific support for nuclear security to other competent authorities within the State, such as the customs agency or border guard service.

For example, regarding emergency preparedness and response (EPR), a TSO often provides support to governmental actions for EPR, as further described in subsection 4.5. They are typically part of the response organization and involved in the “radiological assessor/team” as defined in IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [11] and further described in IAEA Nuclear Security Series No. 22-G, Radiological Crime Scene Management [12], IAEA Nuclear Security Series No. 6, Combating Illicit Trafficking in Nuclear and Other Radioactive Material [13], and IAEA Nuclear Security Series No. 12, Educational Programme in Nuclear Security [14] related to Mobile Expert Support Teams (MEST) and other institutions that support detection of and response to nuclear security events.

2.2.3. Provision of technical and scientific support to foreign regulatory bodies

A TSO can provide support to the regulatory body of another country.

In general most of the countries embarking on a nuclear programme receive technical and scientific support from several TSOs, via bilateral agreements, projects, and contracts or for example, through initiatives such as the Instrument for Nuclear Safety Cooperation (INSC) of the European Commission [15].

For example the Scientific and Engineering Centre for Nuclear and Radiation Safety (SEC NRS), from the Russian Federation, provides scientific and technical assistance to regulatory authorities of countries embarking on a nuclear power programme (Viet Nam, Belarus, Turkey, Bangladesh, Jordan, and others). Such services include: support in the development of the national regulatory infrastructure and of the regulatory and legislative framework, scientific and technical consulting of the regulator's activity and joint realization of expert reviews.

Another example can be found with the Korea Institute of Nuclear Safety (KINS) in the Republic of Korea, which provided support to the regulatory body of Jordan and of the United Arab Emirates (UAE). This support focused on the following three aspects: bilateral cooperation, regulatory consulting and joint research. Special attention was given to the on the job training for inspection such as pre-operational and quality assurance inspections, secondment of KINS staff to FANR, the regulatory body of UAE, in addition to basic training on the regulatory review and inspection and partial participation in the licensing.

3. CHARACTERISTICS AND MANAGEMENT OF TECHNICAL AND SCIENTIFIC SUPPORT (CONDITIONS FOR EFFECTIVE TS SUPPORT)

3.1. COMMITMENT, PRINCIPLES AND CORE VALUES

3.1.1. Commitment

Requirement 20 of GSR Part 1 (Rev. 1) [3] states that: "The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions". The TSO thus constitutes an essential technical resource for a regulatory body.

Designated or otherwise recognized by the regulatory body as its support provider, the TSO is intrinsically committed to the regulatory body's principles and values. It is committed to the national policy for safety, to the objective of the regulatory functions and to supporting their implementation.

In addition, it is possible to identify several principles and values which guide the work of TSOs as scientific organizations dedicated to safety.

3.1.2. Principles and core values

Technical and scientific integrity is essential for supporting nuclear and radiation safety. Technical and scientific awareness is essential to ensure sound and conservative decision making on safety without impeding the development of new technologies and applications. The concept of scientific and technical integrity is embedded in the objectives, organization and activities of a TSO.

The activities of a TSO are integrated and consistent with the activities of a regulatory body. The TSO's establishment, structure and activities are also coherent with the national legislation and current policies and strategic plans of the governmental infrastructure, in particular when the TSO is established by a law.

Several principles that guide the activities of a TSO are shared with other safety organizations:

- Ensuring that engineering and technology used in the nuclear or radiation field for technical assessments are sufficient for the task at hand;

- Effective independence and impartiality in their judgement, conclusions and advice and high attention to the prevention and resolution of any conflicts of interest;

- Commitment to the continuous enhancement of safety, including the responsibility at the organizational and individual level to ensure that safety is never compromised when developing technical recommendations;

- Consistency in their approaches and technical judgements.

In addition, other core values are more specific or crucial to their particular role:

- Utmost attention to knowledge, competence and expertise (including through research and development);

- Proactivity and initiative in exploring knowledge as well as technical and regulatory issues;

- Maintaining a global vision, over time and over a broad scope, in their technical areas of expertise, including in particular the knowledge of activities, facilities and new technologies, and, if possible, in broader areas relevant to regulatory matters;

- Sustaining the capacity to provide the needed support in time.

In some cases, TSOs develop and implement a code of conduct or ethics recalling the values above, as exemplified in Annex VII.

3.1.2.1. Safety culture

It is essential that the work of a TSO is based on an effective safety culture. Paragraph 3.13 of SF-1 [6], states that:

"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."

TSOs are structured and managed to ensure that a strong safety culture, or "culture for safety", is established and maintained, as described in IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [16].

Within a TSO, safety is characteristically the main purpose and awareness of radiation risks is obviously high. Therefore, safety culture is to be understood more in relation to organizational culture aspects. Examples include the encouragement of questioning and learning attitudes and of the reporting of operational problems inside the organization. The availability and attendance of safety culture trainings can be an important element in developing and maintaining an effective safety culture within a TSO (see example in Annex VI).

3.1.2.2. Flexibility and adaptability

TSOs need to adapt to changing circumstances and environments: the advances in scientific knowledge or experience feedback lead to revisiting safety measures; the evolution of available technology engenders new types of facilities or activities, which need to be controlled by the regulatory body; new tools are available to support the control itself; the regulatory framework is subject to changes; the best acknowledged international practices also evolve.

In general, flexibility and adaptability involve: the aptitude to adjust successfully to changing information, situations and environments; to respond methodically to difficulties; to plan ahead and to have alternative options; to be able to respond to sudden changes in circumstances; to persist when confronted with unexpected difficulties; to take on new challenges on short notice; and, to be able to manage priorities and adjust workloads while maintaining the output quality. All of the above are done in such a manner that effective support to regulatory functions can continue without interruption and unnecessary burden and uncertainty to the licensee and the regulator. Such adaptability is based on thorough technical knowledge of nuclear science, facilities and activities.

In the case of Member States developing a nuclear power programme, it is important to rely on technical expertise throughout the whole process. During the development of the nuclear power programme, the TSO has to adapt and grow to provide relevant and effective support to the regulatory body. In the meantime, the regulatory body might rely on a TSO from another State.

3.1.2.3. Open and collaborative environment

Within a TSO, an open and collaborative environment stimulates a free exchange of ideas and opinions resulting in a more objective evaluation of technical matters. Such conditions also help the organization assess quickly and proactively safety issues as they emerge. Achieving collaboration and openness within a TSO requires coordination of work within and between teams to foster such behaviour.

TSOs also engage in effective international collaboration as a means of enhancing nuclear and radiation safety worldwide, in line with Requirement 14 of GSR Part 1 (Rev. 1) [3] defining the "global safety regime". Such imperatives and practices for the TSOs are further developed in Section 4.10.

Because of the necessity to use complex information, various and evolving knowledge, and diverse expert opinions associated with multiple interpretation possibilities, a TSO needs to implement shared/collective work processes able to ensure quality and robustness of positions/opinions. This implies, as well, having processes to deal with possible diverging opinions, and possibly not achieving internal consensus.

The handling of differences in scientific opinions within the TSO, or between the regulatory body and its TSO, when they occur are situations which need to be treated with special attention. It is important that processes and functions are in place to adequately address such issues in an open and collaborative way. In this respect, it is important:

- To investigate and record the different expert contributions and opinions, including scientific and/or technical controversies if any, and possibly the absence of internal consensus;

- To identify the TSO's position including uncertainties and identified gaps in state of the art knowledge. Lack of consensus and diverging opinions may be included in the overall opinion if needed;

- To express and substantiate a conclusive opinion.

In general, it is a good practice that the senior management of the TSO is involved in the resolution of difficult issues and disagreement and provides processes for resolving professional differences of opinion.

3.1.2.4. Confidentiality

TSOs, in the conduct of their activities, may need access to and use several types of confidential information: security related or protected, personal, proprietary information including intellectual property.

In such cases processes and procedures have to be in place to ensure confidentiality. TSOs have to possess management and data systems as well as organizational structures that enable them to maintain absolute confidentiality of the data and project results together with the necessary level of confidentiality in interactions with the customer.

In the case of an external TSO providing services to several regulatory bodies in different countries, the TSO typically has separate framework agreements either directly with each regulatory body or as part of a consortium of TSOs providing these services to the various

regulatory bodies. In this case confidentiality has to be ensured by the TSO so that no matters of commercial or technical confidence are disclosed to a third party.

3.1.3. Independence

The independence of the regulatory body is at the core of international conventions and international guidance on nuclear and radiation safety, as it is one of the ten fundamental safety principles of the IAEA Safety Standards. It is thus a pillar of safety. Independence of the TSO is also essential so that the TSO can best achieve its mission of providing technical and scientific support to the regulatory body. The independence of the TSO responds to two main imperatives: the need for the TSO to freely pursue a scientific approach without other influence and the avoidance of conflict of interest.

General considerations on the independence of TSOs and situations of conflict of interest, considered from the viewpoint of regulatory bodies, can be found in GSG-4 [7]. Independent management

It is important that the TSO is managed as an independent organization, rather than fully controlled by a regulatory body. Such independence enables the TSO to behave as a science driven entity as it is then free to set its own objectives, methods, training and research to maintain scientific excellence.

The independence of the TSO encourages forward looking research and development and identification of emerging issues. It is a good practice that the TSO actively develop safety knowledge to ensure the long term quality and relevance of its support to safety regulatory activities. As a scientific and technical organization, a TSO only supports the regulatory body in the decision making process with impartial information and in its role as objective expert.

Ensuring scientific integrity, the availability of highly specialized service and expertise as well as research activities are objectives which are better attained by an organization which focuses mainly on them. Absence of scientific independence can be associated with a lack of impartiality and with a lack of credibility.

The management by the regulatory body, of the services provided by the external TSO is outside the scope of this publication and is addressed in GSG-4 [7].

3.1.3.1. Avoidance of conflict of interest

In accordance with Requirement 20 of GSR Part 1 (Rev. 1) [3], “Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services”. (para. 4.20) “If the necessary advice or assistance can be obtained only from organizations whose interests potentially conflict with those of the regulatory body, the seeking of this advice or assistance shall be monitored, and the advice given shall be carefully assessed for conflicts of interest” (para. 4.21). Furthermore, as mentioned in footnote 9 of GSR Part 1 (Rev. 1) [3], “If an organization that provides the regulatory body with advice or services were also to advise an authorized party on the same subject, the potential conflict of interest could compromise its reliability”.

For the organization providing the support, this translates into the obligation to avoid any situation where a conflict of interest may arise. Specific internal rules and procedures need to be put in place for the TSO to be able to enforce this requirement.

In the case of an internal TSO, providing support exclusively to the regulatory body, the risk of conflict of interest is expected to be lower and is covered in Requirement 4 of GSR Part 1 (Rev. 1) [3] which addresses the conditions for the independence of the regulatory body. However, there are situations where an internal TSO provides technical support services, such as dosimetry, calibration, quality assurance tests at licensed facilities, to authorized parties. Such situations require the same attention and measures as may be required for an external TSO.

In the case of an external TSO, the risk of conflict of interest depends on its relationships with entities having responsibilities or interests that could unduly influence regulatory decision making on safety. If the TSO provides support to an authorized party, the risk is high and its avoidance has to be managed in a systematic way. Such a situation arises when technical and scientific services related to the regulatory functions and related to the implementation of safety measures by the authorized party are similar.

In such cases, it is essential that the TSO has a policy in place to ensure functional separation between entities acting in support of authorized parties and entities providing support to the regulatory body and inform the regulatory body in advance of the existence of such other supporting activity. Adequate arrangements can ensure that the support provided by the TSO to the regulatory body is carried out independently from the support provided to authorized parties.

To that end, the following core approach guides the work of the TSO as thoroughly as possible:

1) not the same analyses,

2) not the same people,

3) not the same equipment,

4) not the same tools/software/methods.

The first aspect of the core approach means that if the TSO is supporting the regulatory body in the safety review of a new nuclear or radiation facility, for example, it is then forbidden to participate in any way in the licensing process of the applicant.

The second aspect of the core approach reflects the general ethical rule that one is not allowed to review and accept one's own work. In the practical sense, it means that if an expert has carried out a certain analysis for the regulatory body, the same expert will not carry out a confirmatory analysis in the next stage for the authorized party using the same or even different tools and methods.

The last two aspects of the core approach imply that if there are different and equally reliable equipment, analysis tools or experimental methods available, it is recommended that the same equipment, tools or methods not be used in the assignments for the regulator and for the authorized party. These last two aspects of the core approach have to be considered within the context of whether the alternative equipment, tool or method is equally reliable and whether

the staff experience is sufficient to use it. Because of this limitation, in practice, in many areas, the same analytical tools and experimental methods are used both for the regulator and for the industry. In such situations, as a minimum, it is recommended that the tools and methods be used independently and by different persons or teams.

In the case of countries embarking on a nuclear programme, or in countries with limited activities generating only radiation risks, it might be difficult to develop two separate technical organizations for the authorized party and for the regulatory body. The need to continuously ensure that there is no conflict of interest within the technical services provided to the regulatory body is a significant challenge, as the technical competences have to grow with limited available resources.

In Annex II, an example of an approach taken by a TSO to address cases of potential conflict of interest is provided.

3.2. ROLES AND RESPONSIBILITIES

Roles and responsibilities of TSOs are in full compliance with the national legal framework and with international legal instruments, such as conventions and codes of conduct.

Roles and responsibilities have to be clearly assigned and structured between the TSO and the organization(s) to which it is providing support and in the general context of the national safety infrastructure. Such assignments need to be clear to all other stakeholders (such as the regulatory body, other competent authorities in related nuclear fields, authorized parties and the public.).

Internally, the TSO staff members have to be aware of these roles and responsibilities in relation to their own individual mission, including when they are involved in other structures, such as advisory groups.

Keeping some possibility of flexibility in the assignment of roles and responsibilities is helpful to be able to cope with unexpected situations and ensure that the TSO will be able to fulfil basic duties in the case of a nuclear or radiological emergency for example. These situations may range from the unexpected absence of a key expert or decision maker, to a major disaster.

In the case of an internal TSO that is part of the regulatory body, the roles and responsibilities of the organizational entity making the regulatory decisions and the organizational entity with the technical and scientific capability are clearly specified.

In the case of an external TSO, a framework agreement with the regulatory body normally provides all necessary information on interactions and assignments of roles and responsibilities, with the final regulatory decision always remaining the sole responsibility of the regulatory body. Such agreement may include explicit requirements on quality management of the TSO, liability and intellectual property rights. In addition, separate agreements or “task orders” are typically prepared to define more precisely the actual support provided (e.g. different types of analyses, tests and evaluations).

3.3. INTEGRATED MANAGEMENT SYSTEM

Operating with an effective integrated management system is essential for a TSO to properly fulfil its duties.

Although the management system of the regulatory body is addressed in specific safety standards (including GSR Part 1 (Rev.1) [3] and IAEA Safety Standards Series No. SSG-16, Establishing the Safety Structure for a Nuclear Power Programme [17]), the following section covers general aspects applicable to TSOs. As a technical body, a TSO may also find it useful to apply technical standards for management systems, such as ISO 9000, and to seek accreditation, e.g. with ISO 17025.

3.3.1. General

An integrated management system contributes to the assurance of high level nuclear science knowledge and professionalism, independence and objectivity of the expert work performed.

The safety guide for establishing a safety infrastructure, SSG-16 [17], recommends that external support organizations begin to build "quality management systems for ensuring safety" (Action 65) in the phase immediately following the policy decision to launch a nuclear power programme (Phase 2). Specific guidance can also be found in IAEA Safety Standards Series No. GSG-7, Occupational Radiation Safety [18].

It is crucial that the integrated management system developed by the TSO is consistent with and complementary to the management system of the regulatory body that it supports.

As outlined in the GSG-4 [7], the management system helps the TSO "to defend its advice on technical matters", in a context where the supporting documentation gathered by the TSO can also be used by the regulatory body to support its decision making.

In line with the approach outlined in GSR Part 2 [16], the integrated management system of the TSO can be classified into: management, core and support processes.

3.3.2. Quality management, measurement, assessment, evaluation and continuous improvement

Quality management within an integrated management system aims to ensure that technical and scientific results correspond to specified standards, and that intended outputs and objectives/deliverables at the organization level are in line with TSO objectives.

An effective quality management framework within a TSO's integrated management system involves several instruments for the monitoring, assessment and continuous evaluation of performance. Certification against international standards such as ISO 9001 can be valuable for TSOs as it provides a framework for high quality work processes and also provides for comparability on an international level.

IAEA Safety Standards Series No. GS-G-3.1, Application for the Management System for Facilities and Activities [19] provides valuable guidance for developing such quality management arrangements within a TSO.

International peer reviews (e.g. ORPAS and IRRS missions), when they involve TSOs, are extremely beneficial to continuous improvement of the TSO's work and processes. Such peer

reviews help TSOs be better adjusted to their national safety infrastructure while benefiting from international guidance and best practices.

An example of a TSO's quality management system is provided in Annex V.

3.4. DEVELOPING AND MAINTAINING TECHNICAL KNOWLEDGE, EXPERTISE AND CAPABILITY

3.4.1. Knowledge management

Knowledge management is a key supporting process for an effective TSO. It focuses on capturing, developing, sharing, and effectively using organizational knowledge for improved performance and innovation. Knowledge management includes a management information system with a comprehensive knowledge strategy, mapping and dissemination of knowledge including a knowledge portal and effective collaboration mechanisms to facilitate work with internal and external partners.

An effective knowledge management and transfer programme within a TSO also facilitates the transfer of expert scientific knowledge between generations. This is a key issue for many TSOs which face challenges related to the ageing demographics of their workforces. The TSO's knowledge management and transfer processes are stronger when experts are encouraged to share knowledge within the organization and outside the organization as appropriate and to ensure that this knowledge transfer adequately considers the lessons learned from past operating experience.

Finally, it is important that TSOs maintain awareness of the immediate and longer term technical and scientific knowledge needs of the regulatory body and other organizations that they support, as further explained in Section 4.11.

3.4.2. Capacity building

Capacity building, including in particular training and human resources development, is an essential objective of the TSO. The acquisition and retention of personnel with the relevant technical and scientific knowledge and experience is crucial for TSOs. These aspects are particularly important for countries embarking on a nuclear programme.

Capacity building activities are managed to ensure continuous availability of technical and scientific competence, through both the creation and maintenance of these competences.

The TSO has a policy addressing the need to develop and maintain adequate competences in the relevant technical and scientific areas. Such a policy normally includes the periodic integrated reviews of the size and composition of the TSO required to fulfil its mandate and operational needs. This operational review process is typically embedded within the organization's strategic planning process required for developing and maintaining capacity. Maintenance and development of the TSO's capacity are addressed in both the short and long term. Continuous learning forms an integral part of the TSO's capacity building arrangements.

Education and training and human resources development are major contributors to knowledge management and capacity building within a TSO. In addition to initial education,

training, and work experience, continuing professional development and refresher training are to be integrated in a competency development plan for TSO staff. IAEA Safety Reports Series No. 79, Managing Regulatory Body Competence [20], is the most relevant IAEA publication in this field and through the definition of a systematic approach to training, it provides the framework for the identification of the competences required across a TSO and links these to the design, development and implementation of the required training. This systematic approach also includes valuable guidance to regularly evaluate the progress in this field. Further information can be also found in the IAEA Report on Capacity Building for Nuclear Safety [21].

Activities such as R&D and participation in international working groups contributes significantly to building and maintaining the capacity of the TSO as outlined in Sections 4.4, 4.10 and 4.11.

It is often considered that the activities developed to gain, maintain and develop safety expertise are as important and resource consuming, for the TSO, as the activities directly dedicated to support to the regulatory body. An illustration of this concept is represented in Fig. 3.

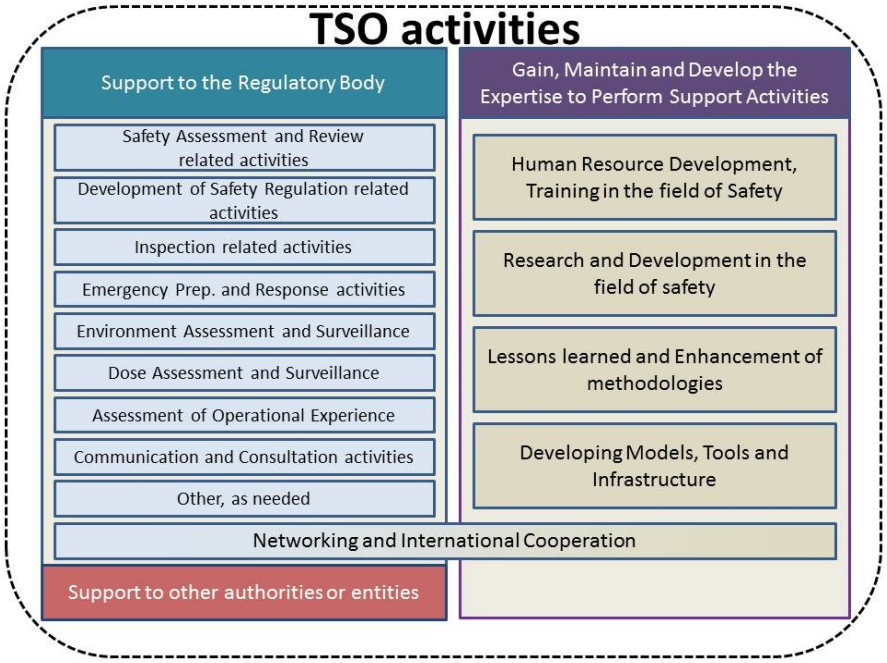

FIG. 3. Two types of TSO activities: regulatory support and expertise acquisition and maintenance.

3.5. HUMAN RESOURCES, BUDGET AND INFRASTRUCTURE

The TSO needs to have at its disposal a sufficient number of qualified and competent staff to deliver technical support functions across its functional areas of responsibility.

It is essential that the available budget is stable and sufficient for the TSO to both fulfil its role as a support to the regulatory body and ensure long term availability of state of the art safety expertise and capabilities. This effort to maintain high level expertise includes many elements which need significant budgetary support, such as safety research, the acquisition of advanced equipment, the training of staff and the exchanges of knowledge with external counterparts and experts from other organizations and countries. The operational budget of the TSO needs to clearly articulate the training and development needs therein, as well as

foreseen research activities, ensuring that the level of investment is adequate to meet the organization's short and longer term needs. It is necessary that the budgetary needs of the TSO are reviewed periodically in view of new emerging needs and in view of changes within the environment in which it operates.

Infrastructure needs of the TSO are part of the management and planning process of the organization. Office and training space and facilities, IT equipment, hardware and software supporting technical and scientific assessments and reviews, access to laboratories with specialized equipment to support the TSO's operational activities, record and database systems and support facilities all form part of the TSO's infrastructure needs.

4. NATURE AND SCOPE OF TECHNICAL AND SCIENTIFIC SUPPORT ACTIVITIES

The TSO has a key role in performing technical and scientific work required to support regulatory functions.

The scope of the TSO activities typically covers the same core functions as the regulatory body, as identified in GSR Part 1 (Rev. 1) [3], with a particular focus on the following aspects: safety review and assessment, development of safety regulation documents, inspection, emergency preparedness and response, and communication and consultation with interested parties. However, the scope varies from country to country depending on the national situation and regulatory system. For example the share of technical support in comparison with regulatory functions is different in a Member State operating a nuclear power programme, in a country embarking on a nuclear power programme and in a country using nuclear technologies for applications other than energy production.

The TSO support can be characterized by three parameters:

- The specific scientific and technical areas under consideration;
- The type of support provided by the TSO;
- The nature of the facility or activity for which the regulatory control is needed.

Figure 4 presents classic lists of the main options for each of these three parameters.

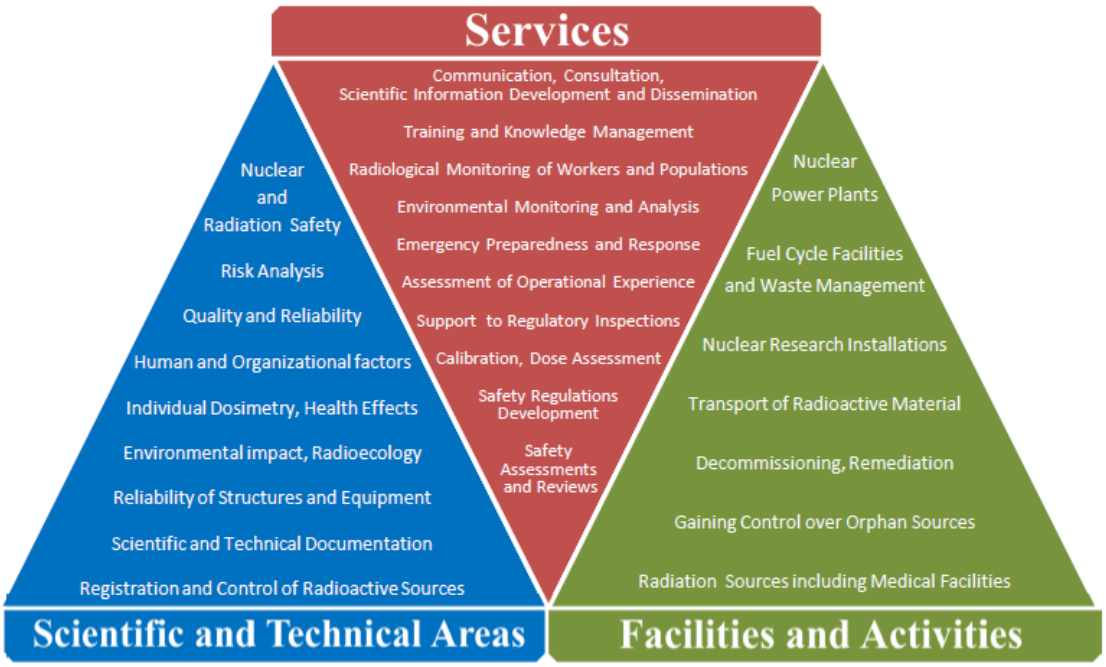

FIG. 4. Characterization of TSO activities supporting the regulatory functions.

In addition, the support can cover any stage of the lifetime of a facility. For example, in the case of a nuclear power plant, this includes design, siting, construction, commissioning, operation and decommissioning.

The TSO also supplies technical tools, analytical models, analyses, scientific information, experimental data, technical advice and guidance.

The involvement of a TSO in the regulatory process related to the licensing of a nuclear power plant is represented in Fig. 5, as an example.

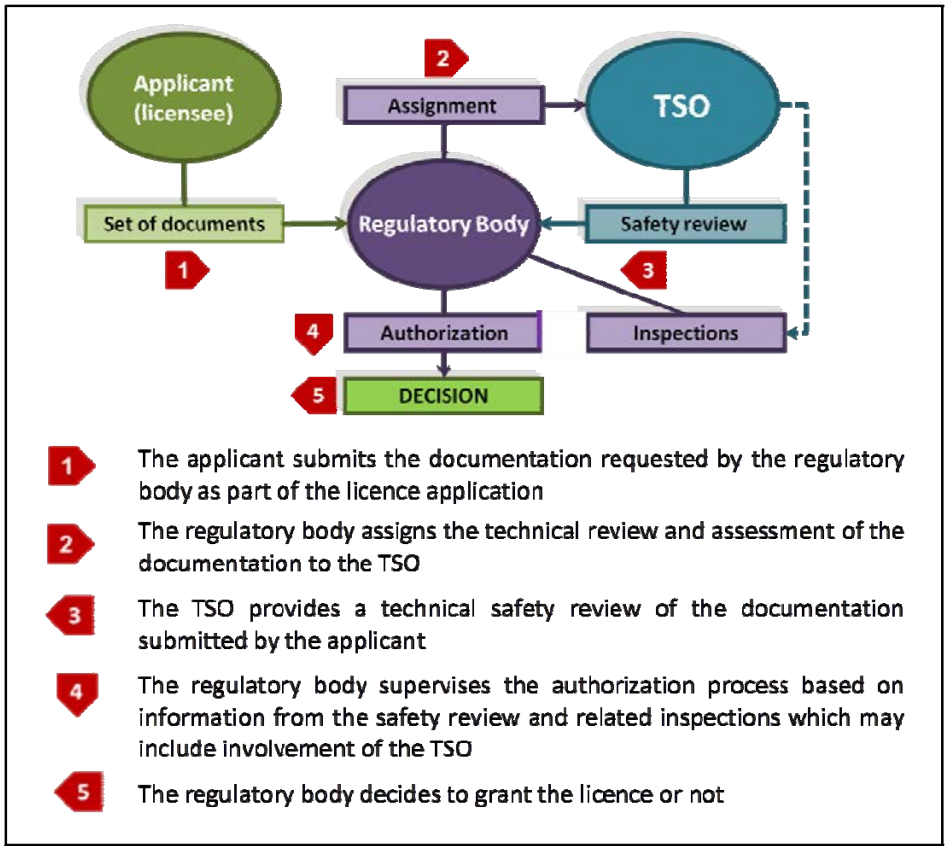

FIG. 5. Type of support provided by a TSO during a licensing procedure.

In addition to supporting the core regulatory functions, the TSO may focus on:

- Research and development;
- Keeping of records relating to facilities and activities, e.g. registers of sources, safety related records, dose records, etc.
- Environmental monitoring and analysis;
- Cooperation and networking;
- Training and knowledge management as is further defined in this Section.

A TSO also has the responsibility to look beyond the daily regulatory support tasks and to work towards maintaining sustainable and state of the art expertise. This effort implies enhancing its own capabilities and working to anticipate arising technical safety issues.

These activities also contribute to serve other governmental authorities, nationally or abroad, as already mentioned in Section 2.2.2. They are essentially the same whether the TSO is internal to a regulatory body or external. Any differences between the activities of internal and external TSOs will be addressed in the following Section.

4.1. SUPPORT SAFETY REVIEWS AND ASSESSMENTS

The TSO performs technical reviews and assessments to evaluate whether an activity or facility meets stipulated safety objectives and requirements, as stipulated in Requirement 25 of GSR Part 1 (Rev. 1), [3], and in IAEA Safety Standards Series No. SSG-12, Licensing Process for Nuclear Installations [22]. Such work is performed to support the regulatory body in determining whether facilities and activities comply with regulatory obligations and the conditions specified in the authorization, or as a specific mission entrusted to the TSO under the national regulatory framework.

As defined in IAEA Safety Standards Series No. GS-G-1.2, Review and Assessment of Nuclear Facilities by the Regulatory Body [23], the review and assessment process is a critical appraisal, performed by the regulatory body, of all information available. This includes the results of technical reviews and assessments performed by the TSO.

The contribution of the TSO to the review and assessment process is composed of analysing the authorized party's submissions and other relevant information on all aspects relating to the safety of the facility or activity and performing verification analysis.

The objectives of the review, as well as specific requirements and other monitoring actions during the implementation of the technical safety review are normally set by the regulatory body.

The safety assessment done by the TSO can never compensate for a lacking or deficient safety analysis by the Applicant/Licensee, who has the prime responsibility for safety.

In the case of several Member States, such assessment and review by the TSO also cover security aspects as explained in Section 4.1.3.

4.1.1. Technical scope of safety assessment

To carry out analyses in context of the review and assessment process, the TSO plans, develops, and manages safety assessment and research programmes based on deterministic and probabilistic approaches.

The TSO develops and maintains expertise on experimental data and tools for numerical-simulation analyses in a broad range of technical areas. A TSO develops analytical capabilities for a wide spectrum of conditions, including normal operations, anticipated operational occurrences, and design-basis and beyond design basis and severe accident conditions for current, new, and advanced reactor designs, at all stages of their lifetime, as well as for other nuclear facilities and activities. It also involves quantifying margins, and reducing uncertainties for areas of potentially high risk or safety significance. In its work, the TSO performs both deterministic and probabilistic safety reviews and assessments. To perform both the deterministic and probabilistic safety reviews and assessments, the TSO conducts activities such as:

- Reactor physics;
- Thermohydraulic safety analysis;
- Performance and reliability analysis;

- Analysis of accident sequences, severe accident phenomenology, accident source term analysis;
- Probabilistic safety assessment and/or probabilistic risk assessment;
- Safety analysis on system, instrumentation, automation, electrical and control;
- Fire safety;
- Hazards analysis (including natural hazards), e.g. Seismic analysis/structural analysis, site assessment;
- Environmental protection analysis, impact assessment;
- Radiation protection analysis: assessment of possible radiation risks and protection measures, assessment of measures intended for the optimization of protection;
- Assessment of operational protocols;
- Assessment of doses and health effects;
- Radioactive waste management;
- Human and organizational factor related risks analysis;
- Lessons learned and operational feedback analysis;
- Software analysis (verification, validation and certification) used for substantiation of nuclear and radiation safety of nuclear facilities.

In addition, the expertise of the TSO is also supporting activities such as surveys, research, tests and reviews as well as assessment of materials and technology, equipment, productions, buildings and building structures, engineering and design documentation and software.

4.1.2. Safety review and assessment process

Safety reviews and assessment of facilities and activities are organized and supervised by the regulatory body. Depending on the request from the regulatory body, some tasks can be performed by the TSO. On the basis of the results of the safety review, including the conclusions of the TSO, the regulatory body takes the relevant decision.

As recommended in IAEA Safety Standards Series No. GS-G-2.1, Arrangements for Preparedness for a Nuclear or Radiological Emergency [24], the review and assessment process is to be conducted in a formalized and efficient way, as defined in the terms of reference prepared by the regulatory body. When the TSO is involved, it is also performed in accordance with its own management system.

With respect to the contribution of the TSO, the assessment process includes the following steps:

- Review of the request from the regulatory body and associated terms of reference;

- Preliminary analysis of the submission, determination and preliminary evaluation of the risks involved;

- Definition of the assessment programme to be followed, methods, tools, etc.;

- Review of the licensee's submission by performing the analysis through verification studies, calculations, etc.;

- Cross- or independent verification of analysis results;

- Reporting of the conclusions of the analysis to the regulatory body or other interested parties;

- Recording of important documents.

It is important that the analysis process performed by the TSO is justified and traceable. To that effect, the TSO uses tangible, verifiable and demonstrable elements and duly records important information or reasoning, that are essential to understand and to use the results of the analysis. Throughout the process, information exchange takes place with the regulatory body and the authorized party or applicant as required by the national regulatory framework.

The analysis report provided by the TSO includes the presentation of the general characteristics of the analysis (terms of reference, scope and limits, safety problems considered), the positions of the authorized party or applicant and of the TSO, any important information and a clear formulation of the conclusions including possible recommendations.

The documents produced and used in the analysis process are recorded in a document control system as well as the sources or references of external information, in line with IAEA Safety Standards Series No. GS-G-1.4, Documentation for Use in Regulating Nuclear Facilities [25].

As a good practice in information and knowledge management, the safety review results and supporting elements can be kept in a database developed and maintained by the TSO. For example, the TSOs in European countries, as members of the European Technical Safety Organisation Network (ETSON), gathered good practices for the assessment process in the ETSON Safety Assessment Guide and the Technical Assessment Guides.

4.1.3. Inclusion of security aspects and interface with safety

The issues addressed by safety assessments and security assessments are sometimes similar, although with different causes and, to some extent, safety measures and security measures overlap. As stated in Requirement 12 of GSR Part 1 (Rev. 1) [3], "Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security".

Both types of measures share a number of common features (e.g. defence in depth and graded approach, the need for a safety or security 'culture'). Safety analyses take into account interface issues and share with security analyses a number of common principles and approaches. As an example, the process to analyse the consequences of an initiating event resulting in accidental conditions is the same regardless of its cause (safety event or malicious act).

With respect to safety-security interfaces, the TSO typically supports regulatory activities by addressing issues of interfaces between safety and security in the context of the following tasks:

- Drafting of regulatory requirements, guidelines and recommendations;
- Analysis and assessment of the current state of regulatory requirements;
- Analysis and assessment of submissions by the licensees;
- Analysis of safety and security interface issues of nuclear facilities, radioactive substances, radiation sources, nuclear materials and storage facilities, including their physical protection;
- Supporting the Member State's system for accounting and control of nuclear materials and radioactive substances as well as physical protection of nuclear facilities, radiation sources, storage facilities of nuclear materials and radioactive substances.

Some NSSCs may also carry out such functions for the regulatory body and for TSOs, particularly when the focus is primarily in the area of nuclear security.

4.2. SUPPORT THE DEVELOPMENT OF SAFETY DOCUMENTS FOR LEGISLATION, REGULATIONS AND GUIDES

The development of safety and security rules and regulations is performed by the regulatory body or other responsible government authorities. When a TSO supports the regulatory body, it normally contributes to the process of updating national regulation as well as to the development and regular updates of international guidance and standards, such as the IAEA Safety Standards.

Depending on the request from the regulatory body, the TSO provides the scientific base and information on which a regulation or guide is developed and, in some cases, also prepares the draft regulation or guide itself to be later reviewed and approved by the regulatory body.

In addition to regulatory documents, the TSO develops documents defining its own views regarding safety approaches to support the safety assessment. This aims at enhancing the robustness of its assessments and the consistency of its technical positions. Development of such documents is also important for the TSO's involvement in harmonization activities and in the development of regulatory documents. Moreover, this could lead the TSO to identify needs for new fields of research, prior to any regulatory action.

4.3. SUPPORT INSPECTIONS OF FACILITIES AND ACTIVITIES

As stated in Requirement 27 of GSR Part 1 (Rev. 1) [3], "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization".

The TSO may support these activities through preparation, observation, assessment, review and direct and/or indirect participation in inspections, as inspectors or as experts. While inspectors usually belong to the regulatory body, the TSO may carry out inspection functions

when designated by the government or when this regulatory function is delegated by the regulatory body.

4.3.1. Establishment of inspection programmes

TSO can support the regulatory body in the establishment of inspection programmes, depending on the request from the regulatory body. This support may include:

- Design of overall structure of inspection programmes to verify the authorized party's operation of a facility in compliance with regulatory requirements. The scope and relationship of each inspection can be taken into account in designing this programme;
- Strategy for allocation of regulatory resources to inspection areas in accordance with their safety significance and previous performance of the licensee;
- Development of inspection procedures and guides.

Specific inspection plans are developed by the regulatory body, which considers particular aspects, as described in IAEA Safety Standards Series No. GS-G-1.3, Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body [26]. To allow the inspectors to make the best use of their skills and knowledge in the inspection plan, TSO can provide support in preparing the inspection plan for the regulatory body. Such preparation may include a review of recent inspection results and performance, of issues related to the inspection areas and an assessment of possible improvements of the applicable regulatory processes.

4.3.2. The TSO role in regulatory inspections

TSOs staff can participate in regulatory inspections either as inspectors or as experts. In the case of the Republic of Korea, KINS carries out the regulatory inspections such as pre-operational, periodic, quality assurance and vendor inspection which are entrusted to KINS by law.

The TSO may be involved in inspection in relation to particular issues, requiring specific technical knowledge. Such inspections may deal with items such as: refurbishment; new findings from R&D and experience feedback from other facilities or activities; investigation of incidents including accidents in determining of root causes; assessment of consequences and identification of preventive and/or corrective actions.

The TSO can provide support in the evaluation, monitoring and management of inspection findings, as required by the regulatory body. Such tasks may include: evaluating inspection findings from a safety significance standpoint; monitoring the resolution of inspection findings by the authorized party and the analysing of trends and root causes of inspection findings to prevent recurrence.

The TSO often provides support in developing and implementing training programmes tailored for regulatory inspectors, to maintain their technical competence with regard to inspection activities. These activities support the fulfilment, by the regulatory body, of Requirement 18 of GSR Part 1 (Rev. 1) [3] on staffing and competence of the regulatory body.

4.4. RESEARCH AND DEVELOPMENT

4.4.1. Research and development support to safety regulation

The regulation of safety is based on state of the art knowledge and safety assessments. Research and development (R&D) activities contribute to developing the knowledge and expertise base required for enhancing safety as well as the protection of people and the environment, and are thus necessary for conducting effective regulatory processes leading to well-founded regulatory decisions. R&D typically represents a significant share of a TSO's activities, as shown in Fig. 6.

R&D is an essential element supporting regulatory functions as it helps the regulatory body assess and review the adequacy of the technical basis supporting its regulations and regulatory activities. It also enables it to evaluate key significant issues that may impact safety.

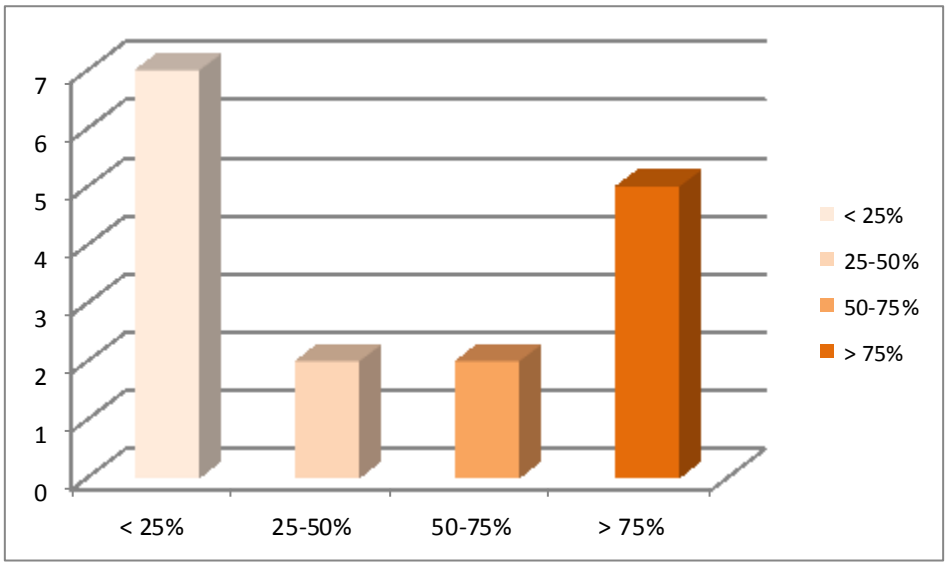

FIG. 6. Number of TSOs and percentage of budget dedicated to R&D (survey based on input from 15 TSOs).

Several initiatives were started to gather information at the international level on R&D activities performed by TSOs in support of nuclear or radiation safety. For example, the IAEA organized the International Experts Meeting on Strengthening Research and Development Effectiveness in the Light of the Accident at the Fukushima Daiichi Nuclear Power Plant on 16–20 February 2015 at its Headquarters in Vienna, Austria, in connection with the implementation of the IAEA Action Plan on Nuclear Safety. Other notable actions include those taken in the context of the European TSO Network (ETSON), such as the ETSON Position Paper on R&D, by the NUclear GENeration II & II Association (NUGENIA), an association dedicated to the research and development of nuclear fission technologies roadmap[7], and by the European radiation protection research platforms: the Multidisciplinary

[7] Position paper of the Technical Safety Organisations: Research needs in nuclear safety for Gen 2 and Gen 3 NNPs, European Technical Safety Organisations Network ETSON, October 2011, http:www.etson.eu; NUGENIA Roadmap 2013, NUGENIA Association, 2013, http:www.nugenia.org; NUGENIA Global Vision document, NUGENIA Association, April 2015, http:www.nugenia.org.

European Low Dose Initiative (MELODI) on low-dose risks, the European Radiation Dosimetry Group (EURADOS) on dosimetry, the European Radioecology Alliance, the European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery (NERIS) for emergency and post-accidental situations.

4.4.2. TSO role and responsibilities in performing R&D

R&D is a core mission of the TSOs, which have a primary role in conducting safety-oriented R&D. An essential characteristic of a TSO is its capability to perform R&D activities to support the regulatory body or other public authorities, e.g. those in charge of public health or the environment.

In this context, it is important that the TSO is able to independently evaluate issues and scenarios which represent potential impacts on safety.

Because R&D provides supporting information on the safety of the operation of a facility and/or the conduct of related activities, the TSO develops R&D in an integrated and systematic way so as to ensure high quality results.

To the extent practicable, the TSO's R&D relies on the scientific and technical state of the art knowledge, expertise, and technologies, deriving from both national and international R&D projects. This TSO R&D programme in safety needs to be organized to maintain and continuously develop the technical knowledge and competency of its personnel as mentioned in section 3.4.

The organizational structure of the TSO complements and/or supplements that of the regulatory body and reflects the TSO's capacity to facilitate R&D. It can do so either by the establishment of a research unit or by recruiting staff members, who can define, implement and coordinate the R&D work and later provide its results to the regulatory body.

The regulatory body may request the TSO to carry out R&D necessary to produce an adequate body of knowledge for safety assessments. In addition, the TSO's research and development methodology and results are assessed for adequacy. The TSO may consult with an appropriate advisory committee for the evaluation and oversight of the research and development programme.

The key objective of TSO R&D is to enable the regulatory body to make independent and informed decisions based on advanced and detailed scientific information, but many TSOs also carry out their own independent research for the purposes of supporting their own long term knowledge expertise and management initiatives. The creation and effective dissemination of scientific knowledge can also constitute an objective for the TSO.

It is essential that TSOs participate in international collaborative R&D projects to optimize their use of information and data regarding the operation of facilities and activities, leverage resources, facilitate cost effective and efficient research, share expertise and facilitate the building of a common understanding at the international level. Information gained through international collaboration is used in support of regulatory decision making. Such collaborative projects allow the TSO to test new facilities, to acquire new methodologies, etc.

4.4.3. Examples of scientific and technical fields for R&D

To support regulatory decisions, TSOs carry out a wide range of R&D activities. Examples of frequent R&D fields for TSOs are listed below:

- Evaluation of composite (i.e., whole site) Probabilistic Safety Assessment (PSA) methodologies;
- Instrumentation and critical equipment survivability under severe accident conditions;
- Risk-informed approach to substantiate safety of NPP units;
- Methodologies for identification of the list of Beyond Design Basis Analysis (BDBAs) to be taken into account in NPP design;
- Evaluation of strength and life-time management of NPP equipment and pipelines and other nuclear facilities, including expert calculations;
- Scientific support and methodological provision algorithms and working programmes;
- Reliability and stability of building structures against internal and external impacts;
- Safety evaluation of radioactive waste, spent nuclear fuel and radiation sources management;
- Reactor physics and dynamics;
- Thermohydraulics;
- Computational Fluid Dynamics (CFD) developments;
- Site evaluation, siting;
- Accounting, control and physical protection of nuclear materials and physical protection of nuclear facilities;
- Decommissioning;
- Nuclear fuel behaviour;
- Development of innovative dose assessment tools (including modelling) and protocols;
- Fundamental research aiming to better understand the mechanisms behind health effects resulting from exposures to ionizing radiation;
- Radiation epidemiology;
- Radioecology.

This list is indicative and other aspects can be the subject of safety related research and development by TSOs.

4.5. SUPPORT EMERGENCY PREPAREDNESS AND RESPONSE

Together with the response organizations and the operating organizations, the regulatory body has an important role in emergency preparedness and response as described in GSR Part 7 [11]. According to Requirements 4.13 and 4.14, the regulatory body is required to verify the adequacy of on-site arrangements of the authorized party.

The role of the TSO on emergency preparedness and response depends on national arrangements (see an example in Annex IV). It can range from performing a technical action requested by the regulatory body to the TSO's full involvement in the national EPR plans. In such a context, the TSO typically supports the regulatory body and/or government and public authorities, notably in the following fields:

- Participation within the response organizations including development and support of its own capacity in the assessment of the potential consequences of an emergency and prognosis of its possible progression (to support the regulatory body);

- Participation in the establishment and operation of emergency response centres and organizations based on national arrangements;

- Implementation of radiological monitoring of people and the environment (early-warning and radiation monitoring) and in field capabilities (e.g. laboratory vehicles, mobile emergency unit, vehicle borne monitoring);

- R&D on the above mentioned issues, technical reviews and the development and review of regulations and guides. These regulations and guides typically include provisions for performing a hazard analysis, protecting emergency workers, analysis of an emergency and emergency response, etc. They may also include definitions of emergency preparedness categories, development of operational criteria, establishment of emergency planning zones and distances, etc.

The TSO can support the establishment of the State infrastructure in support of the regulatory body and government authorities in carrying out their emergency preparedness and response functions. Such infrastructure may include, in practice, clarification of organizational roles and responsibilities, ensuring the availability of qualified and sufficient personnel, coordination of arrangements between authorized parties and local, regional, and national government, and, where appropriate, at the international level. In addition, plans and procedures which are necessary for effective emergency response, adequate and effective support tools such as computer codes, data collection and display systems, training, drill and exercise programmes, and a quality management system for emergency preparedness and response, among other things, may also be incorporated in the infrastructure. The TSO typically supports the development of procedures relevant to EPR. It is also able to support the development and maintenance of infrastructure needs.

The TSO is able to support the periodic evaluation of the regulatory body and authorized parties' emergency preparedness and response programmes and capabilities against designated objectives. Typically, performance evaluation of programmes and processes, via training, exercises, self-assessments, audits and inspections, etc., are carried out in order to identify gaps and possible further improvements. The operation of the coordinating mechanism of the regulatory body and authorized party is to be assessed with regards to whether it is effective, consistent, and is in place for all observed or postulated nuclear or radiological emergencies, including those deemed to transcend borders by national exercises.

TSOs support the emergency response organization and the regulatory body or authorized party by direct and/or indirect participation during the emergency response phase. In this case, a TSO may operate an emergency response centre. Proper assessment of hazards, prompt identification and notification of emergency conditions, determination of necessary mitigation actions, provision of information and issuance of instruction to the public, other governmental bodies, etc. are examples of applicable direct and/or indirect participation areas. Finally, the TSO might also be able to support the regulatory body's communications with the IAEA and other international bodies and organizations at the time of a nuclear or radiological emergency.

Further information on emergency preparedness and response can be found in GSR Part 7 [11], IAEA Safety Standards Series No. GSG-2, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency [27], and GS-G-2.1 [24].

4.6. RADIATION PROTECTION AND SAFETY

TSO activities take place within a broad mission of protecting people and the environment against harmful effects of ionizing radiation. Internationally recognized requirements in that field are described in GSR Part 3, [4].

The TSO contribution to the national arrangements for radiation protection; which has close ties to occupational health and safety, industrial hygiene, environmental monitoring, etc. is significant in several aspects. It is often critical for many Member States having limited activities generating only radiation risks.

The TSO provides support to the regulatory body and other authorities in the field of radiation protection and safety. It typically provides data for dose assessment and performs dose studies and impact studies when necessary. The TSO evaluates exposures due to the presence of radioactivity, including long term monitoring, radiation field or radioactive materials in normal conditions, in accident situations or linked to past activities. These activities may include the development of guidelines and supporting the regulatory body in the evaluation of safety reports.

In existing exposure situations, including NORM and remediation, TSOs participate in the identification and evaluation of such situations, e.g. through radiological characterization, dose evaluations or environmental monitoring, and in the definition and implementation of a protection strategy, for example through the assessment of doses or of reference levels to be established by the regulatory body.

With respect to planned exposure situations, TSOs are involved in radiation protection of workers in their workplaces, including being responsible for pooling and assessing data relevant to monitoring occupational exposure (e.g. national dose registry) and carrying out studies to prevent and assess this exposure. Regarding occupational exposure control, a key role of the TSO is to conduct research and propose tools designed to improve knowledge of occupational exposure and identify dose trends. The TSO can also perform workplace monitoring in to support the regulatory body in assessment and decision making with respect to justification and optimization. These studies can be extended and applied not only to nuclear workers and medical staff but also to radiation exposures such as flight crews.

TSOs are also engaged in radiation protection in healthcare through monitoring exposures, assessing impacts, improving the understanding of effects, e.g. radio-induced lesions on body tissues and organs, and by doing so improving the effectiveness of treatments and reducing patient exposure. The TSO may work for the regulatory body to support the assessment and optimization of patient exposure (radiology, CT scanning, and nuclear medicine). The TSO may also carry out experimental research aimed at improving knowledge of the mechanisms behind the side effects of treatments using ionizing radiation, in order to identify and propose new treatments.

While those activities would normally be conducted for the regulatory body as part of the national regulatory control, attention needs to be paid to possible conflicts of responsibilities in situations where the advice from the regulatory body and the TSO would be used by the authorized parties in defining how to discharge their own responsibilities.

TSOs can perform technical assessments to support regulatory decisions regarding exemption and clearance, or the release from regulatory control. TSOs also play a role in the management of unregulated risk situations, e.g. in providing technical means for the search and safe management of orphan sources.

In addition to all of the above, TSOs carry out specific research on the effects of radiation, such as the effects of chronic low-dose exposure or long-term impacts related to exposure to natural and anthropogenic sources of radiation. Some research may also encompass naturally occurring radioactive materials (NORM) related studies.

4.7. ENVIRONMENTAL ASSESSMENT AND SURVEILLANCE

TSOs can have two major functions in the field of environmental monitoring, as it is described in IAEA Safety Standards Series No. RS-G-1.8, Environmental and Source Monitoring for Purposes of Radiation Protection [28] and Safety Reports Series No. 64, Programmes and Systems for Source and Environmental Radiation Monitoring [29]. They provide support in the following fields:

- To provide data, results, methods to survey the radiological condition of the environment;
- To monitor and evaluate the impact of nuclear activities on both people and the environment;
- To verify the compliance with authorized environmental protection limits and regulatory requirements.

A TSO has a wide vision of the national radiological situation including national environmental radioactivity levels, complementary to the authorized party's knowledge, which can be especially useful to establish baselines or reference levels, e.g. for post-accidental management.

For some TSOs, such as in Canada, these functions are applied to both radiological and non-radiological hazards.

TSOs can carry out activities with respect to the impact of nuclear activities and facilities on the environment, including remediation of legacy situations, as further explained in Sections 4.7.1. to 4.7.3.

4.7.1. Environmental monitoring

In environmental monitoring matters, the role of the TSO is not only to perform measurements of radioactive and other substances in air, food, water, soil and consumer products but more broadly to address all questions related to data collection and support decision making on environmental issues. The TSO may set up networks of monitoring facilities, or facilitate the monitoring networking, define technical specifications, select the most suitable monitoring system and to assure inter-calibration procedure and continuous improvement of applied methods. In France and in the Republic of Korea, for example, the TSO has such responsibility.

The TSO may make monitoring results available to national authorities and other parties, including possibly the general public, according to national regulations and practices.

The TSO has to use monitoring methods and tools based on generally accepted standards, procedures, experimental methods and modelling. In some cases, these methods and tools may be developed by the TSO.

4.7.2. Modelling

TSOs can develop models to assess hazards and evaluate the behaviour and impact of radionuclides in the environment. These models may be used by the TSOs for supporting the regulatory body and authorized parties' emergency preparedness and response recognizing that arrangements for the use of analytical tools early in an emergency response for supporting decision making on response actions need to be made in due recognition of the limitations of such analytical tools and in a way that would not reduce the effectiveness of response actions.

The purpose of modelling tools is to evaluate the dispersion and contamination in a defined geographical area, in a specific period of time. The TSOs use the results for prognosis of dispersion and contamination. This can also be useful as complementary information to measurements. Modelling results are validated against actual data in an iterative process, and are accompanied by information on associated uncertainties.

The TSO provides guidelines as well as manages and coordinates research on modelling and monitoring for environmental assessment, external natural and man-made event assessment, materials performance, air pollution, surface water and groundwater issues related to environmental protection.

In the light of the lessons learned from the Fukushima Daiichi accident, this field of activities, in particular the ability to produce prognosis, has become a significant area of work for TSO.

4.7.3. Environmental studies

TSOs perform general studies on environmental issues associated with nuclear and radiation activities and facilities, and their actual or potential impact on the environment, as well as in support of the development of guidelines on defining the maximum permissible values for discharges into water, soil and the atmosphere and on the methods of appropriate control of compliance with these values. Such studies can be done periodically or in response to a specific issue.

4.8. ASSESSMENT OF OPERATING EXPERIENCE

Assessment of operating experience is a relevant strategy for acquiring knowledge and learning for organizations. This is applicable to all activities and facilities throughout their whole lifetime.

The requirements of GSR Part 3 [4] sets obligations for licensees, and for the regulatory body in the context of its own duties, to investigate and disseminate information on operating experience and to use that information in their management, safety assessment and engineering practice.

The implementation of such a strategy in the nuclear industry allows for learning, maintaining and improving the safety and reliability of nuclear installations: nuclear fuel fabrication plants, nuclear reactors (including subcritical and critical assemblies), research reactors, nuclear power plants, spent fuel storage facilities, enrichment plants or reprocessing facilities. It is essential to collect information about operating experience in a systematic way that conforms to agreed reporting thresholds for events occurring at nuclear installations during commissioning, operation, surveillance and maintenance activities and decommissioning, and on deviations from normal performance by systems and by personnel, which could be precursors of events.

Similar strategies apply with respect to non-nuclear equipment and applications, such as radiation generators, radiation sources, medical applications and consumer products (GSR Part 3, notably requirements 17 and 33 [4]).

On the regulatory side, according to Requirement 3 of GSR Part 3 [4], the regulatory body has to ensure that mechanisms are in place for the dissemination and use of information from operating experience.

The TSO remains cognizant of nuclear facilities operation and reliability data systems in the industry and serves as a focal point for the coordination and evaluation of the safety-data collection programmes as well as for the use of operating experience information for regulatory purposes.

Effective use of operational performance/experience information is an important element in the Member States regulations on arrangements for enhancing operational safety. As required by SF-1 [6], Principle 3 states that:

> "Processes must be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon."

Abnormal events with important safety implications are to be investigated to establish their direct and root causes. More information is provided in Basic Safety Principles for Nuclear Power Plants, 75-INSAG-3 Rev. 1, INSAG-12 [30]. The TSO can support most of the regulatory body's activities related to operating experience feedback for nuclear facilities as described in IAEA Safety Standards Series No. NS-G-2.11, A System for the Feedback of Experience from Events in Nuclear Installations [31]. The activities in which the TSO can be involved are as follows:

- Analysis of incoming early notifications of an event, follow-up and supplementary reports and help and support in setting up criteria for reporting;

- Collection of national and international relevant operating experience (e.g. operating experience databases, international forums, topical studies) to help to classify the potential safety significance of an event including low level events and near misses;

- Screening and investigations; help in establishing the scope of investigations of operating organizations with a focus on safety significance and root causes, to prevent recurrence of events and derive generic lessons learned;

- Performing a detailed analysis to identify trends and patterns and necessary actions taking into account low level events and near misses;

- Assistance in evaluation of the current safety level of nuclear facilities to identify operational weaknesses and safety deficiencies and support in establishment of corrective actions and follow-up process;

- Assist and support in review and improvement of obligatory requirements to conform to national safety regulations. Such assistance and support is provided on the basis of analysis results and regarding nuclear facilities operation and nuclear facilities safety assessments;

- Dissemination and Utilization; Support to the regulatory body in implementing a system of storage, retrieval and searching of operating experience and in the dissemination of operating experience feedback information to relevant organizations and interested parties. Membership in international working groups, forums and networks including bilateral and multilateral agreements are used to strengthen the efforts of regulatory bodies in enhancing safety. TSO may develop and implement its own opinion based on its tools and processes in order to provide its assessments to the regulatory body;

- Operating experience effectiveness reviews support the regulatory body in performing inspections at operating organizations and to review the effectiveness of the operating experience process of the licensee.

4.9. COMMUNICATION AND CONSULTATION

As a scientific body, one of the key roles of a TSO is to develop and disseminate objective scientific and technical information on matters of nuclear and radiation safety including through education and training. Further, the role of a TSO can be extended to the processes for public information and consultation, and to providing an information/communication bridge between the regulator, the other governmental authorities, stakeholders and the general public. It is important to note that dissemination of public information and education around nuclear risks needs to be carried out by credible and independent organizations providing factual information, and that TSOs are well placed to play this role.

Communication and sharing of information by the TSO is generally conducted in coordination with the regulatory body.

In order to achieve this recognition and gain public trust and acceptance, a TSO needs not only deep technical competence in nuclear technology and safety, but also a capability in public communications and knowledge management. Accordingly, the TSO can conduct activities such as: providing updated nuclear information transparently to enable the public to

achieve a balanced and comprehensive understanding of the benefits and risks of facilities and activities; performing education and training systematically and periodically for professionals; conducting seminars and discussions on nuclear and radiation safety, e.g. on potential health effects resulting from exposures to ionizing radiation; developing relevant networks and maximizing the utilization of the existing networks; and developing effective methods of regulatory technical knowledge management, dissemination and transfer to the current and next generations of specialists/experts.

4.9.1. Development and dissemination of scientific information

Development and dissemination of scientific information is a very important activity of a strong scientific organization such as a TSO. This activity has multiple benefits, the main one being the building of the TSO's technical credibility and reputation as a source of unbiased and state of the art information. Other advantages of disseminating scientific objective information include: fulfilment of national regulatory requirements on information generation and dissemination, providing the regulatory body's staff with relevant and state of the art results to benefit the overall regulatory oversight program, facilitating corporate information sharing as part of a management system approach that supports joint work activities within and outside the organization, and ensuring the openness and transparency of the information being used to support regulatory body decision making. For this reason, TSO staff is encouraged to publish conference and journal papers, contribute to technical meetings, as well as deliver presentations at domestic and international fora.

Dissemination of scientific information is also an effective means of TSO networking with scientific research organizations such as research laboratories, universities, teaching hospitals, and professional organizations. This in turn, enhances collaborations and helps the TSO in selecting external technical support partners.

By its nature, publishing the results of TSOs' research projects and technical assessments subjects them to external scrutiny, thus assuring their continued good quality, reliability, and credibility. Finally, development and dissemination of scientific information offers an effective mechanism of collecting relevant scientific information and helps a TSO to be informed about the latest developments in science in areas that may be important to nuclear and radiation safety regulation. Examples of such areas are new technologies, new detection and analysis equipment, new mathematical models and computational techniques, and new medical studies on radiation health effects.

4.9.2. Information and consultation with interested parties

As required by SF-1 [6], Principle 2, "the regulatory body must:

- Set up appropriate means of informing parties in the vicinity, the public and other interested parties, and the information media about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes;

- Consult parties in the vicinity, the public and other interested parties, as appropriate, in an open and inclusive process."

The TSO supports the regulatory body in performing this task. This typically includes the establishment of appropriate means of informing and consulting interested parties about radiation and environmental risks associated with the facilities and activities as well as the related processes.

The regulatory body disseminates information concerning regulatory activities, including outreach and consultations on technical and scientific issues. The TSO is usually requested to contribute to this effort, in particular with respect to technical and scientific matters.

To assure effective consultation, a TSO typically maintains tools and expertise to communicate effectively with the public. Often, TSOs also network with scientific and technical media and publishers. They may also use social media, to share information instantly, as appropriate. Examples of TSO tools/methods used to disseminate information for public outreach include: a comprehensive web site, multiple fact sheets on nuclear risks and effects of ionizing radiation, explanation of nuclear and radiation safety and security related activities, and advice and information to ministers and responses to political inquiries.

These consultations are based on principles such as openness, trust, integrity, mutual respect for the legitimacy and the point of view of all participants, and transparency of purpose and processes. Therefore the TSO needs a good understanding of the public access to information, including regulatory information and adequate legal expertise or communication capability. Thus, through the provision of information and consultation with all interested parties, TSOs often play an important role in the aspects of the regulatory process with public involvement. By doing so, they contribute to strengthening confidence in the scientific expertise of the regulatory body.

In practice, the TSO may contribute to information sharing and consultation with interested parties in the following areas:

- making information available to interested parties;
- establishing and maintaining public web sites containing information and data related to the TSO's and possibly the regulatory body's activities in the field of nuclear and radiation safety, environmental monitoring and other related areas;
- developing and publishing periodicals related to nuclear and radiation safety regulation;
- developing and maintaining a corporate information portal in the field of nuclear and radiation safety regulation;
- participating in, and sometimes, representing the regulatory body in public hearings, other activities related to communication information of interested parties;
- participating in consultation efforts, as well as national and international nuclear exhibitions, seminars, workshops etc.

4.10. NATIONAL AND INTERNATIONAL COOPERATION

Broadly speaking, three main types of cooperation are carried out by TSOs: multilateral cooperation, scientific cooperation and the use of external resources for operational arrangements, as further described below.

In general, TSO international and domestic cooperation activities aim at constantly developing scientific and technical capabilities, and maintaining them at an advanced level. These cooperative activities facilitate increased harmonization of TSO approaches, skills and

competences. Such cooperation also allows for the leveraging and pooling of safety resources, both with respect to valuable skills and expertise that may not exist in sufficient numbers in each country or region, and to financial resources.

Examples of national and international cooperation undertaken by a TSO include activities such as:

- Sharing results with peers; exchanging information and comparing data relevant to TSO activities, in particular operational experience feedback;

- Exchanging information and comparing practices in performing TSO functions, as well as tools and methods, for example through benchmarking, with a view to improving and possibly harmonizing them;

- Participating in joint research projects and conducting common technical projects on technical issues within or sometimes outside the TSO's typical scope of work (e.g. cooperation on foreign safety matters may include new issues which help enlarge expertise and better prepare the TSO for future domestic or international work);

- Participating in technical networks (e.g. the TSO Forum, ETSON, NUGENIA and MELODI) and regional networks, in committees and working groups, notably under the auspices of international organizations such as the IAEA), the Nuclear Energy Agency (NEA), the International Commission on Radiological Protection (ICRP), the World Health organization (WHO) and others, and in professional societies;

- Contribution to the preparation of technical standards;

- Scientific and technical assistance to the regulatory bodies of countries embarking on nuclear energy programmes through: participating to international seminars/conferences/technical visits and technical peer reviews; the implementation of bilateral cooperation agreements including the support to the national regulatory body and TSO; and participating in and conducting international trainings related to key TSO functions. These activities are of particular relevance for the development of expertise and capacity building in countries embarking on a nuclear programme.

4.10.1. Multilateral cooperation

TSOs may participate in the work of technical international organizations and initiatives, in particular at the IAEA. Requirement 14 of GSR Part 1 (Rev.1) [3] requires governments to "promote international cooperation and assistance to enhance safety globally".

Paragraph 3.2 (e) of Requirement 14 further states that: "The features of the global safety regime include regular multilateral and bilateral cooperation between the relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections, by means of sharing of knowledge and feedback of experience".

This Requirement is fully relevant and applicable to TSOs.

A TSO may also contribute to the national obligations under international legal instruments such as: treaties (such as, in Europe, the EURATOM treaty), agreements, conventions and codes of conduct.

4.10.2. Scientific cooperation

Like any organization carrying out scientific activities, a TSO has to be engaged in intense exchanges and cooperation with scientific peers, in an open scientific environment. Such activities are needed to keep scientific and technical capabilities at the leading edge and to benchmark a TSO (as an organization and a scientific and technical body) against the international state of the art in nuclear and radiation safety.

To reach its best performance, a TSO needs to be deeply involved in international networks for technical and scientific collaboration. This includes participation in international organizations' activities, relevant bilateral cooperation and partnerships. Effective participation in such international networks requires a competent, well-prepared, staff with adequate technical and communication skills. TSOs also cooperate with domestic institutions and organizations, through their participation in national institutional experts groups or advisory groups (e.g. scientific and technical council, commissions, societies, etc.) which may be established by the regulatory body, in conjunction with the TSO or separately.

4.10.3. Network of external providers of information and expertise

A competent TSO typically relies upon a network of partners, contractors and consultants to complement its knowledge and expertise, in fields other than nuclear and radiological safety, or to provide various data and raw information. This is a strategic choice of the TSO, to decide which core competences reside solely within a TSO and which can be supplied or supplemented externally. Effective means and protocols for these interactions are in place to ensure that matters such as information security and nuclear emergency response capabilities are appropriately taken into consideration. The TSO makes sure that all mechanisms are in place for timely and effective collaboration with these contractors and consultants.

4.11. TRAINING AND KNOWLEDGE MANAGEMENT

Nuclear and radiation safety integrates a wide spectrum of scientific and technological disciplines. A high level of professional expertise in many areas of nuclear engineering and technology is also needed to properly address nuclear and radiation safety. As a result, building capacity in these domains and maintaining the necessary scientific and practical knowledge is extremely challenging.

Networks (e.g. the TSO Forum, ETSON, NUGENIA, MELODI and the International Network for Nuclear Security Training and Support Centres [NSSC Network]) provide excellent means to share information and knowledge, and at the international level, in the nuclear safety, radiation safety and nuclear security community and to provide training opportunities in particular for countries embarking on a nuclear programme and developing TSOs.

The transfer of practical knowledge and TSO culture are also important to manage in the long term. Practical knowledge transfer is best done by senior specialized experts. Training in safety and security assessment is therefore provided by experienced professionals in the subject fields.

A consortium of TSOs, such as the European Nuclear Safety Training & Tutoring Institute (ENSTTI) or individual TSOs, such as the Korea Institute of Nuclear Safety (KINS), also

provide comprehensive training and tutoring programmes for experts working in research and assessment of nuclear safety, nuclear security and radiation protection. In some cases, such institutions benefit from legal and financial support at the governmental level. They may also provide support to capacity building in countries embarking on a nuclear programme. Further examples of practices of TSOs in the field of knowledge management and training are provided in Annex III.

The implementation of an R&D programme allowing the identification of critical knowledge gaps and helping to develop new knowledge and techniques is critical for an effective TSO. International interactions in this field, as mentioned earlier, are major supports for maintaining scientific excellence and building common understanding at the international level, as well as for leveraging resources and facilitating cost effective and efficient research.

Periodic review of the knowledge management and capacity building system of the TSO is crucial to ensure that such a system meets needs and conditions which might be changing.

APPENDIX

TABLE OF MAIN CHARACTERISTICS OF THE CONTRIBUTING TSOs (DATA 2015)

1. General				2. Types of TSOs									3. Management			
Member State and Organizations	Name of TSO	Abbreviation	Respective RB	Type of support to the respective RB		Establishment in the national context		Type of funding			Profit	Non-Profit	Performance evaluation (AQ, Audit, etc…)	Knowledge management	Budget (M€)	Number of permanent Staff dedicated to TSO activities (nuclear and radiation Safety)
				Internal	External	by RB (contract)	By Law / by Government	Only Public	Mix Public-Private	Only Private						
				Only 1 choice				Only 1 choice			Only 1 choice				M€	Nb permanent
Belgium	Bel V	Bel V	Federal Agency for Nuclear Control		×		×			×		×	×	×	12	80
Canada	CNSC Technical Support Branch (TSB)	CNSC TSB	Canadian Nuclear Safety Commission	×			×	×				×	×	×	24	280
China	Nuclear and Radiation Safety Center of MEP	NSC	Ministry of Environmental Protection /National Nuclear Safety Administration (MEP/NNSA)		×	×	×	×				×	×	×	25	630
Czech Republic	Centrum of Research Rez	CVR	Státní úřad pro jadernou bezpečnost (SÚJB)		×											
European Union	Joint Research Centre, Directorate Nuclear Safety & Security (incl. Safeguards)	JRC	All European regulators (including Member States & European Commission when relevant)	The JRC is the European Commission's science and knowledge service which provides independent scientific advice and support to EU policy and Member States.					×			×	×	×	100	260
Finland	VTT Technical Research Centre of Finland Ltd	VTT	Radiation and Nuclear Safety Authority (STUK)		×				×			×	×	×	20	200
France	Institut de Radioprotection et Sûreté Nucléaire	IRSN	Autorité de Sûreté Nucléaire (ASN)		×		×		×				×	×	280	1624
Germany	Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) gGmbH	GRS	Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit (BMUB)		×				×			×	×	×	60	350
Italy	Independent Technical Evaluation and Review	ITER	ISPRA - Italian National Institute for Environmental Protection and Research		×	×				×		×	×			22

1. General				2. Types of TSOs									3. Management			
Member State and Organizations	Name of TSO	Abbreviation	Respective RB	Type of support to the respective RB		Establishment in the national context		Type of funding			Profit	Non-Profit	Performance evaluation (AQ, Audit, etc…)	Knowledge management	Budget (M€)	Number of permanent Staff dedicated to TSO activities (nuclear and radiation Safety)
				Internal	External	by RB (contract)	By Law / by Government	Only Public	Mix Public-Private	Only Private						
				Only 1 choice				Only 1 choice			Only 1 choice				M€	Nb permanent
Italy	Italian National Agency for New Technologies, Energy and Sustainable Economic Development	ENEA	ISPRA - Italian National Institute for Environmental Protection and Research		×		×	×				×				
Japan	Nuclear Regulation Authority - Secretariat of NRA - Secretary General's Secretariat - Division of Regulatory Standard and Research	NRA	Nuclear Regulation Authority (NRA)	×			×	×				×	×	×		
Lithuania	Lithuanian Energy Institute	LEI	State Nuclear Power Safety Inspectorate (VATESI)		×	×	×	×				×	×	×	6	50
Republic of Korea	Korea Institute of Nuclear Safety	KINS	Nuclear Safety & Security Commission (NSSC)		×		×	×				×	×		88 (in 2015)	530
Republic of Korea	Korea Institute of Nuclear Non-proliferation and Control	KINAC	Nuclear Safety & Security Commission (NSSC)		×		×	×				×	×	×	~16 (in 2015)	81
Russian Federation	Scientific and Engineering Centre for Nuclear and Radiation Safety	SEC NRS	Federal Environmental, Industrial and Nuclear Supervision Service (Rostechnadzor)		×	×	×		×			×	×	×	8.6	266
United States	United States - Nuclear Regulatory Commission - Office of Nuclear Regulatory Research	US-NRC	United States - Nuclear Regulatory Commission	×			×	×				×	×	×	90	205
United Kingdom	Amec Foster Wheeler Regulatory Support Directorate	Amecfw RSD	Defence Nuclear Safety Regulator (DNSR) & Office for Nuclear Regulation (ONR - contracted through Technical Support Framework)		×	×		×			×		×	×		55

1. General		4. Nature and scope of technical and scientific support activities																				
		Facilities and Activities Covered						Services Provided														
Member State and Organizations	Abbreviation	Radiation Sources	Nuclear Research Installations	Transport of Radioactive Material	Fuel Cycle Facilities	Waste Management Facilities	Nuclear power Plants	Support safety assessments and reviews	Support the development of safety regulation documents	Support inspections of facilities and activities	Research and Development	% of R&D budget relative to total TSO budget	Support to Emergency Preparedness and Response	Environmental monitoring and analysis	Assessment of operational experience	Information and consultation of interested parties	Development and Dissemination of Scientific Information	Domestic and international cooperation	Support to training and knowledge management	Support to Security	Support to Safeguards	Support to Foreign Regulatory Body or Government
Belgium	Bel V		×	×	×	×	×	×	×	×	×	10	×		×		×	×	×	×		×
Canada	CNSC TSB	×	×	×	×	×	×	×	×	×	×	3 to 5	×	×	×	×	×	×	×	×	×	×
China	NSC	×	×	×	×	×	×	×	×	×	×	52	×	×	×	×	×	×	×	×	×	×
Czech Republic	CVR		×			×	×	×		×					×	×	×	×	×			×
European Union	JRC	×	×		×	×	×	×	×	×	×	48	×	×	×	×	×	×	×	×	×	×
Finland	VTT	×	×	×	×	×	×	×	×	×	×	72	×	×	×	×	×	×	×	×	×	×
France	IRSN	×	×	×	×	×	×	×	×	×	×	41	×	×	×	×	×	×	×	×	×	×
Germany	GRS	×	×	×	×	×	×	×	×	×	×	54	×	×	×	×	×	×	×	×		×
Italy	ITER	×	×			×	×	×	×	×	×	6	×		×		×	×	×		×	×

1. General		4. Nature and scope of technical and scientific support activities																				
		Facilities and Activities Covered						Services Provided														
Member State and Organizations	Abbreviation	Radiation Sources	Nuclear Research Installations	Transport of Radioactive Material	Fuel Cycle Facilities	Waste Management Facilities	Nuclear power Plants	Support safety assessments and reviews	Support the development of safety regulation documents	Support inspections of facilities and activities	Research and Development	% of R&D budget relative to total TSO budget	Support to Emergency Preparedness and Response	Environmental monitoring and analysis	Assessment of operational experience	Information and consultation of interested parties	Development and Dissemination of Scientific Information	Domestic and international cooperation	Support to training and knowledge management	Support to Security	Support to Safeguards	Support to Foreign Regulatory Body or Government
Italy	ENEA	×	×	×		×					×	90	×	×		×	×	×	×	×	×	
Japan	NRA			×	×	×	×	×	×	×	×		×			×	×	×	×			
Lithuania	LEI					×	×	×	×		×	90	×	×	×	×	×	×	×			
Republic of Korea	KINS	×	×	×	×	×	×	×	×	×	×	15	×	×	×	×	×	×	×	interface only		×
Republic of Korea	KINAC	×	×	×	×	×	×			×	×	23		×	×	×	×	×	×	×	×	×
Russian Federation	SEC NRS	×	×	×	×	×	×	×	×	×	×	75	×	×	×	×	×	×	×	×		×
United States	US-NRC	×	×	×	×	×	×	×	×	×	×	55	×	×	×	×	×	×	×	×	×	×
United Kingdom	Amecfw RSD	×	×	×	×	×	×	×	×	×	×	10	×		×			×	×	×		

LIST OF ABBREVIATIONS

ASN	French Nuclear Safety Authority
CNSC	Canadian Nuclear Safety Commission
ENSTTI	European Nuclear Safety Training and Tutoring Institute
EPR	Emergency Preparedness and Response
ETSON	European Technical Safety Organisation Network
EU	European Union
GRS	Gesellschaft für Anlagen- und Reaktorsicherheit mbH (Germany)
ICRP	International Commission on Radiological Protection
IRRS	Integrated Regulatory Review Service
IRSN	Institute for Radiological Protection and Nuclear Safety (France)
JRC	European Commission Joint Research Centre
KINS	Korea Institute of Nuclear Safety
MELODI	Multidisciplinary European Low Dose Initiative
NEA	Nuclear Energy Agency (NEA) within the Organisation for Economic Co-operation and Development (OECD)
NORM	Naturally Occurring Radioactive Material
NRA	Nuclear Regulation Authority (Japan)
NSSC	Nuclear Security Training and Support Centres
NUGENIA	NUclear GENeration II & II Association
ORPAS	Occupational Radiation Protection Appraisal Service
R&D	Research and Development
SEC NRS	Scientific and Engineering Centre for Nuclear and Radiation Safety (the Russian Federation)
TSO	Technical and Scientific Support Organization

VTT	Technical Research Centre of Finland
US NRC	United States Of America Nuclear Regulatory Commission
WHO	World Health Organization

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CONTENTS OF CD-ROM

The annexes are only available on the CD-ROM.

They provide illustrations and examples of the different aspects of TSOs addressed in this TECDOC, including activities, interactions, management systems, mission statement, code of ethics and methodologies to address potential conflict of interest.

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