

# Technical and Scientific Support Organizations as an Independent Layer of Defence-in-Depth in Licensing of Nuclear Facilities

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## ABSTRACT

Licensing of the nuclear facilities could be described as a process with two independent layers of defence-in-depth. The first layer is controlled by the licensee and its contractors, and the second layer is controlled by the competent regulatory body. Traditionally, competent regulatory bodies base their decisions on independent safety assessments developed internally or by the external technical and scientific support organization (TSO). The safety assessment by an independent external TSO could be considered as an additional, the third layer of defence-in-depth. In the paper we explore some opportunities and challenges that various levels of independence of the TSO may bring to the regulatory process. In particular, some activities implemented at the Jožef Stefan Institute to strengthen its contribution to the defence-in-depth in the regulatory process are discussed and analysed. Strong long-term research and higher education program are shown to be essential to maintain and further develop the independence of the technical and scientific support organizations through advancing the expertise, infrastructures, independence and credibility.

### **1 INTRODUCTION**

Licensing of the nuclear facilities is described as a process with two independent layers of defence-in-depth (DiD). The first layer is controlled by the licensee and its contractors, who are responsible for the safety case supporting the license or license amendment application. The second layer is controlled by the competent regulatory body, who is responsible to evaluate and to decide on the licensing merits of the safety case submitted by the licensee. Traditionally, competent regulatory bodies base their decisions also on the technical and/or scientific assessment of the safety case by the technical and scientific support organizations (TSOs). In such arrangement, the assessments of the safety case developed by TSOs are placed entirely within the second DiD layer, controlled by the regulatory body.

In some cases, it is also possible to consider the safety assessments provided by TSOs as an independent and additional, third layer of DiD. This additional layer of DiD could significantly improve the safety of the underlying processes, but only if it is independent of the other two layers of DiD. If not, the additional layer might be detrimental, as it could introduce simultaneous failures of multiple layers and therefore practical elimination of DiD. Thus, independence of TSOs preparing safety assessment must be ensured. Described structure is schematically shown in Figure 1.

In the paper we explore some opportunities and challenges that the independence of TSOs may bring to the regulatory process. The first objective is to illustrate Slovenian legal

framework in comparison to the international practice. The second objective is to discuss and analyse some activities implemented at the Jožef Stefan Institute (JSI), primarily active in research and higher education and also one among the several Slovenian TSOs, to strengthen the independence of the TSOs and consequently independence of issued safety assessments.



Figure 1: Layers of DiD in the process of licensing of nuclear facility.

## 2 TSO IN SUPPORT OF REGULATROY PROCESS

## 2.1 IAEA TECDOC-1835

In 2018, IAEA has published a TECDOC-1835 (Technical and scientific support organizations providing support to regulatory functions) to provide description on the TSO characteristics and functions supporting regulator [1]. Data from 17 TSOs representing 14 Member States and EU were collected to illustrate the main TSOs characteristics.

As seen in Table 1, TSOs could be either internal, i.e. dedicated organizational unit within the regulatory body, or external, i.e. legally established entity formally engaged with the regulatory body. Approach with internal TSOs is used, for example, in USA (US NRC), Canada (CNSC) and Japan (NRA). The drawback of such approach is lack of competition with other organizations to provide the best possible service [1]. This is compensated with ensuring availability of the state-of-the-art knowledge and expertise for the staff, and to receive additional support from external organization with additional and complementary technical and scientific capabilities.

Type of support to regulator		Established by		Type of funding		Profit	
Internal	3	Regulator	2	Public	9	Yes	1
External	13	Law/government	8	Private	2	No	14
		Both**	3	Mix	5		
No information*	1	No	4	No	1	No	2
		information***		information*		information****	

Table 1: Main characteristics of TSOs in 2015 as given in [1].

\*No information is given for JRC.

\*\*\*No information is given for JRC, CVR (Czech Republic), VTT (Finland) and GRS (Germany).

\*\*\*\*No information for CVR (Czech Republic) and IRSN (France).

Approach with external TSOs is used, for example, in Belgium (Bel V), China (NSC), Finland (VTT), France (IRSN), Germany (GRS), Italy (ITER, ENEA), Lithuania (LEI),

<sup>\*\*</sup>In case of LEI (Lithuania), NSC (China) and SEC NRS (Russia) it is indicated that it was established by regulator and by law/government.

S. Korea (KINS, KINAC) and Russia (SEC NRS). External TSOs may be established by the government, the regulatory body, by a law or be contracted by the regulatory body. External TSO must maintain state of the art knowledge and expertise and an adequate understanding of safety issues. Typically, research and development (R&D) represent important part of the external TSO activities to maintain and build expertise, experts and to respond on variety of demands/challenges. For example, in 2019 IRSN spent ~39 % of its budget on research and ~52 % on technical support and public service missions [2].

TSO may be a state-controlled non-profit entity or commercial organization. Funding might be public, private or mixture of private and public. Relationship between the budget and permanent staff on the TSO activities is seen in Figure 2.





For the independence of TSO, it is better to be managed as independent organization that, for example, sets its own objectives, ensures R&D, knowledge development and preservation for ensuring long term quality, and assessment methods, rather than being controlled by the regulator [1]. Furthermore, independent TSO supports the regulator as an objective expert with independent information and is not directly involved in the regulatory decision process.

#### 2.2 Characteristics of Slovenian nuclear regulatory framework

In Slovenian regulatory framework, the key function of the TSOs (hereafter meaning technical support organization) is to support the licensing process with the independent safety assessment of the nuclear and radiation safety aspects.

In 1980, Slovenia adopted detailed regulatory framework with Act Regulating Protection Against Ionising Radiation and Regulating the Safety Measures for Nuclear Installation (ZIVS) [3]. In 1980, following ZIVS, the TSOs with roles were established [4]. Initially, six established entities, i.e. Jožef Stefan Institute (JSI, Slovenia), Milan Vidmar Electric Power Research Institute (EIMV, Slovenia), Inženirski biro Elektroprojekt (today IBE, Slovenia), Institute of Metal Constructions (IMK, Slovenia), Faculty of Mechanical Engineering (University of Ljubljana, Slovenia) and Institut za Elektroprivredu (IE, Croatia), were accredited as TSO's with well-defined and complementary fields of expertise. The formal establishment of the competent regulatory body (Slovenian Nuclear Safety Administration, SNSA) followed in 1987.

In 2002, ZIVS was replaced by Ionising Radiation Protection and Nuclear Safety Act (ZVISJV) [5]. Comparison of ZVISJV and ZIVS shows changes in the accreditation process and role of the TSOs. The SNSA has been given the authority to accredit several TSOs based on applications demonstrating fulfilment of criteria defined in the regulations [6]. These criteria

include commercial independence from the licensee, past references in the expert safety assessment and quality assurance (QA) program [7]. Currently 17 organisations are accredited [8]. In practice this implies that several TSOs are considered to be equally competent by SNSA. The choice and contracting of the particular TSO for particular licence amendment is left to the licensee.

Long term research programme, non-profitability and performing safety assessments with a global regulatory vision, on a regular basis and with a broad scope, are not formally required for a Slovenian TSO in [7]. They are nevertheless listed among the basic requirements for a TSO as defined by the European Technical Safety Organisation Network (ETSON) [9]. JSI is a member of ETSON.

The nuclear licensing process in Slovenia is schematically depicted in Figure 3. The preparation of the licensing documentation, the selection and contracting of the TSO, the independent safety assessment by the TSO, the final decision by the regulatory body and the accreditation of the particular TSOs (as described above) can be seen as five layers of the defence in depth. In this process the licensee has the prime responsibility for the nuclear and radiation safety and is required to complement any application for a license or license amendment with an independent safety assessment prepared by an accredited TSO [6]. The objectives, scope and the schedule for preparation of an independent safety assessment are controlled by the licensee. Such approach with the licensee being fully in the control of the scope and commercial arrangements with the TSO is imposed by the current legislations and might compromise the TSO's independence and credibility. The regulatory body (SNSA) then takes a legally bounding decision in the form of a license (amendment).

At the end, it is worth to note, that in the licensing process, in case of doubts, the SNSA could require from licensee to order additional TSO opinions or this opinion could be directly ordered by SNSA.





To summarize, the accreditation of the various TSOs of equivalent standing and the selection and contracting of particular TSO by the licensee, may be seen as unique feature of the Slovenian nuclear regulatory framework.

#### **3** ATTRIBUTES OF TSO TO FOSTER INDEPENDENCE OF DID LAYER

In this section, some activities implemented at JSI to strengthen the independence of performed safety assessment are discussed and analysed. The objective is to consider possible

undesirable consequences of the competitive contracting of TSOs by the licensee (see Section 2.2). Assessment of the JSI position in the licensing process follows principles of the DiD concept: independence, separation, diversity, redundancy and transparency.

#### 3.1 Independence and separation

TSO shall pose the ability to perform independent safety assessment that is unaffected by the opinion of licensee or SNSA. Several elements promoting independence of TSO in performing independent safety assessment could be identified.

First, it is important that a TSO has sufficient human resources of heterogeneous and complementary knowledge with expertise related to the field of nuclear and radiation safety. This enables critical and independent safety assessments of information provided either by the licensee or by SNSA. JSI is primarily a R&D organization with approximately 1100 employees in the fields of physics, chemistry, biochemistry, electronics, information technology, nuclear and power engineering [10]. In the field of nuclear and radiation research the following departments and centres with around 15 % of employees are involved: Low and Medium Energy Physics (F2), Reactor Physics (F8), Environmental Sciences (O2), Reactor Engineering (R4), Reactor Infrastructure Centre (RIC), Milan Čopič Nuclear Training Centre (ICJT) and Radiation Protection Unit (SVIPS). In the independent safety assessment process, mainly the R4 and F8 departments with around 40 experts are engaged. For example, and as seen in Figure 4, up to now, R4 was involved in issuing of around 50 independent safety assessments related to the Nuclear power plant Krško (NEK) licensing. The JSI services were pronounced in the period of NEK modernization (performed in 2000) and has started to diminish after 2002, when the ZVISJV act was put into force [5]. In the last few years, some independent safety assessments were issued in relation to the currently on-going safety upgrade program of NEK (defined after the Fukushima-Daiichi accident in 2011) [11]. The R4, F8 and RIC have been also participating in the independent safety assessments of each outages at NEK since the start of commercial operation in 1983. Additionally, it is worth mentioning that JSI operates the TRIGA research reactor since 1966, giving JSI hands on experiences with operating a nuclear reactor and managing the active and spent nuclear fuel, which are unique among the Slovenian TSOs.



Figure 4: JSI Reactor Engineering Division (R4), history of issuing independent safety assessments since beginning of commercial operation of NEK in 1983 till 2020 (Note: R4 outage activities are not considered on this graph).

Second, TSO shall ensure, when applicable, segregation between the members of TSO staff performing the independent safety assessment and the members of TSO staff that may be supporting the licensee on the safety case being subject to the independent safety assessment.

Organizational structure and sufficient staffing at JSI, where each department/centre is autonomous, enables separation in cases when JSI performs the independent safety assessment and professional services for the utility on the same safety case. Such situations are also regulated in the JSI QA documentation [12] and are in line with the current legislation [7] – i.e. persons performing the independent safety assessment are not the same as persons offering service to the licensee.

Finally, contractual independence of TSO from the licences shall be ensured. However, as explicitly illustrated in Figure 3, for the purpose of independent safety assessment this is not the current practice in Slovenia. Typically, the licensee selects one of the TSO based on their response to the tender. One of the consequences of such approach is the perception of commercial dependence of the TSO on the licensee, who directly controls the scope and the commercial circumstances of the production of the safety assessment. To ensure the transparency throughout the independent safety assessment process, JSI discloses key elements of the contract with the licensee as an indispensable part of the independent safety assessments.

Generic financial dependence of JSI on the licensee is nevertheless rather low. Namely, the core financing of JSI is supported by the national research agency through research programs and projects [10].

To summarize, with available human resources of heterogeneous and complementary knowledge, with gained expertise related to the field of nuclear and radiation safety since the establishment of the institute and with low financial dependence on the projects for independent safety assessments, we consider that JSI is sovereign in performing the independent safety assessments.

#### 3.2 Diversity

TSO shall be capable to offer not just a redundant but also a diverse view on the safety case that does not depend exclusively on the view or information supplied by the licensee and/or the regulator. Inherently, the diversity in the licensing process is a method of protection against commonly overlooked issues (common cause failure or dependence of layers of DiD).

As schematically indicated in Figure 5, the active involvement of TSO in R&D promotes diverse view on the safety issues. Additionally, getting familiar with the issue of nuclear and radiation safety through the process of education, either by actively participating in the educational process at the universities and/or during the PhD studies also promotes diversity in relation to the organizations where the employees are primarily familiarized to the nuclear and radiation safety through the training process. Further, typically researchers at TSOs with established R&D programs are regularly publishing their R&D results in the scientific journals. All of those publications are subject of independent international peer reviews. Typically, researchers are also peer reviewers and editors of the international journals. Writing articles and performing peer review are another important involvement enhancing critical and diverse view that may significantly enhance the independent safety assessments process. Furthermore, distributing knowledge and relevant information from the research is a key element of transparency that enables immediate availability of information to all stakeholders for response – i.e. promotes continuous verification of researcher's and consequently the safety assessor's credibility.



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Figure 5: Research, development and education – elements promoting diversity.

Let us now illustrate the diversity as practiced by JSI. The employees of JSI get familiar with the nuclear and radiation safety through active and passive participation in formal higher education and through participation in the relevant R&D, industrial and TSO projects. In the absence of the national long-term R&D strategy for nuclear and radiation safety (top-down approach), the research priorities in the programs and projects are defined through curiosity of the JSI researchers (bottom-up approach). The bottom-up only approach to R&D appears to be a reasonable tool to maintain and further develop the R&D staff and infrastructure. It is nevertheless clear that more top-down engagement of the industry and the regulator would be needed to direct parts of the R&D activities that would contribute towards the current and future needs of the industry and regulators. In Slovenian public R&D funding system, a research program is re-evaluated every six years with success rates of about 90% and thus could only offer a mid-term orientation of R&D. Two to three years basic and/or applied R&D projects are granted based on competitive calls of the national research agency with success rates at approximately 10% and offer short-term orientation of R&D. It is worth to mention, that in the last few years NEK has co-financed some applied R&D projects contracted by the national research agency to JSI. The third sort of R&D projects are financed by the national research agency in association with CEA (France).

At JSI, an important part of R&D is performed in the frame of the EURATOM projects. The research priorities for the EURATOM projects are set by SNETP (Sustainable Nuclear Energy Technology Platform) research strategy agenda (top-down approach) [13]. Internationally, the JSI is also participating in the OECD NEA projects (e.g. SETH-2 (Senior Expert Group on Safety Research - Thermal-hydraulics), SERENA-2 (Steam Explosion Resolution for Nuclear Application), CSNI (Committee on the Safety of Nuclear Installations) international standard problems, benchmarks). Research goes on also in the frame of international bilateral and multilateral arrangements (e.g. EDF (France), CEA (France), IRSN (France), Texas A&M (USA), KAERI (S. Korea)). JSI is also a member of ETSON (European Technical Safety Organisations Network) [9] and is involved at IAEA TSO forum activities [14]. Many results of above research projects and involvements are published in per reviews journals and conferences.

Within research programs and projects, JSI scientists are developing, upgrading and using data, models and codes. This gives them opportunity for detailed and independent interpretation of simulation results that licensee may use to support the licence or licence amendments.

To summarize, JSI activities related to R&D and education strongly enhance the diversity of the independent safety assessment process. The JSI involvement in R&D is not coordinated with Slovenian nuclear stakeholders and therefore makes a clear case of the long term technical

and financial independence of JSI from both the licensee and the regulator. JSI involvement in the R&D projects in the frame of the EURATOM projects is based on the accepted nuclear research strategy in EU (not in Slovenia), i.e. the top-down approach.

#### 3.3 Transparency

Long-term transparency of the main steps during the independent safety assessment is ensured with the information sharing and preservation. Specific attention shall be given to information labelled as confidential.

At JSI, transparency of TSO related work is ensured at different levels. As required by legislation [7], JSI reports annually about direct and indirect TSO activities to SNSA. Information is publicly available on the SNSA web pages [15]. Internally, where relative autonomy between departments and centres exists, basic TSO related information is shared using information portal. Issued independent safety assessments together with the records of relevant supporting documentation (e.g. input documentation, communication, mid-term reports, about performed QA) are documented in the department archives. For example, the well-preserved archive at JSI R4 division gives opportunity for knowledge preservation and transfer – i.e. promotes redundancy within TSO organization (see Section 3.4). In addition, archives allow tracing technical development of licencing projects and give opportunity for profound preparation of the subsequent independent safety assessments.

At JSI, the key element supporting transparency of on-going independent safety assessment projects is effective Quality Assurance Program (QAP) [12] with well-elaborated processes. For example, in the strategic work plan for the independent safety assessment the JSI management on one hand identifies the needs and expectations of potential customers (contractor for safety assessment is the licensee, but the safety assessment needs to be independent of the technical or commercial influence by the licensee) but on the other hand is commitment to the fulfilment of acceptance criteria, ensuring professional integrity, independence, impartiality and transparency of work.

To conclude, JSI invests significant efforts into transparency and preservation of gained information and knowledge.

#### 3.4 Redundancy

Redundancy of human and infrastructural resources is a form of protection against of total or partial loss of capabilities (single failure mode). The key elements for ensuring redundancy within TSO are provisions related to knowledge transfer and maintenance of critical infrastructure (e.g. codes, models). However, preserving the TSO capabilities requires many resources that could be rationally justified when sufficient engagement of TSO by the main stakeholders is made for the TSO related activities.

For JSI is essential that the available incomes are predictable, stable and sufficient to both fulfil its role as a TSO during the independent safety assessments and to ensure the long-term availability of high-level expertise and capabilities. Some examples of the traditional projects with capabilities for knowledge transfer and maintaining critical infrastructure are in the independent safety assessments projects and services related to the outages at NEK (see Figure 6). Other examples are the JSI participation in the CAMP (Code Applications and Maintenance Program) and CSARP (Cooperative Severe Accident Research Program) programs of US NRC, with the support of NEK and SNSA, that could be also considered as relatively stable contribution to the TSO expertise development and maintaining critical infrastructure. In the last few years occasional short-term service, consultant (e.g. MELCOR) projects performed for the main stakeholders (NEK, GEN, SNSA) could be considered relevant

for sustainability of the JSI expertise and the knowledge transfer. On the other hand, planning investments into internal resources development for performing independent safety assessments is limited. For example, over the last few years, in average, JSI replied on three tenders for performing independent safety assessments per year and gains one (see Figure 6).



Figure 6: JSI statistics on independent safety assessment projects between 2012 and 2020.

To summarize, at JSI the preservation, development and transfer of expertise and capabilities need dedicated budgetary support. Currently, the budget obtained by TSO's related activities is limited, only partially predictable and stable. Thus, the effort to maintain high-level expertise remains exclusively in the domain of JSI, supported with occasional short-term contracts of traditional domestic stakeholders.

### 4 CONCLUSIONS

Independent safety assessment of technical support organizations (TSOs) may be viewed as an additional layer of defence-in-depth (DiD) of the licensing process that may potentially uncover a deficiency of license or license amendments application. Several principles supporting the DiD concept are relevant for preparation of independent safety assessment at TSO. First, TSO shall be capable to deliver independent safety assessment (independence). Allowed contractual relation between the licensee and TSO is currently considered as a key potential deficiency of the licencing process in Slovenia that might jeopardize the TSO's credibility and independence. Second, the licensing process is considered robust, if the TSO has capability to provide diverse view on the safety case at hand. It seems that this ability is an integral part of organizations with well-defined research and development (R&D) programs. Thirdly, transferring knowledge and maintaining critical infrastructure are important for the long-term preservation of TSO capabilities (redundancy). Maintaining the availability of TSO and research capabilities including experienced staff, with knowledge of the state-of-the-art tools and facilities, requires significantly more resources than maintaining TSOs which do not perform R&D activities. Fourth, sufficient experienced human resources are needed to separate the TSO activities from direct scientific and technical support to the licensee (separation). Finally, the transparency of the complete independent safety assessment process shall be ensured and documented (transparency). The transparency also fosters credibility.

The independent safety assessments developed by the Jožef Stefan Institute (JSI) are based on experienced personnel and well-elaborated process, which is aligned with the key DiD principles. Strong long-term research and higher education program are considered essential for maintaining and further developing the independence of the JSI through advancing the expertise, infrastructures, independence and credibility.

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