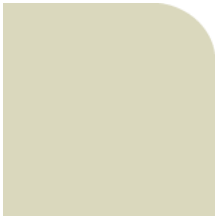


**SAFETY  
ASSESSMENT GUIDE**

**HARMONIZED GENERAL  
REVIEW PRINCIPLES**





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# FOREWORD

For many years, European Technical Safety Organizations Network (ETSON) members have pursued the objective enhancing the harmonization of nuclear safety in Europe by comparing their safety assessment methodologies. Based on a long-standing experience of more than 40 years, in spite of different national nuclear safety regulatory backgrounds, they have developed practical methods to perform safety reviews that present sufficient similarities to encourage them to persevere in building a collection of common good practices.

This general Safety Assessment Guide (SAG), and its specialized guides - the Technical Safety Assessment Guides (TSAG) - have been produced by ETSON members.

The SAG provides general principles concerning the safety review of nuclear facilities performed by TSOs. The objective of the SAG is to promote good practices with regard to safety and safety culture by setting down the harmonized methodology applied by ETSON organizations to ensure a common quality of safety review and to develop higher confidence in these safety reviews.

The TSAG series consists of specialized guides dedicated to specific technical domains of importance to the safety of nuclear facilities.

They provide an overview of the available practical knowledge gained by Technical Safety Organizations (TSO) in conducting safety reviews covering these main technical issues (use of operating experience feedback, assessment of human and organizational factors, prevention and mitigation of severe accidents, probabilistic safety assessment, etc.).

Each guide published by ETSON is updated according to the experience gained as well as to the more recent requirements in nuclear safety. The SAG, the initial version of which was published in 2004, later revised in 2013, has been reviewed by the Technical Board on Reactor Safety (TBRS) of ETSON to reflect the context that has slightly changed since the last fifteen years. In particular, the following points have to be noticed:

- The role of technical safety organisations is highlighted through activities done at an international level, especially at the IAEA with, in particular, the elaboration of the TECDOC-1835 and the organisation of a TSO conference every 4 years;
- The role of technical safety organisations is evolving with an increased involvement in the dialogue with the civil society.

# 2

# INTRODUCTION

IAEA TECDOC-1835 “Technical and Scientific Support Organizations to Providing Support to Regulatory Functions” [2], issued in 2018, develops a common understanding of the roles and general characteristics of TSOs (internal or external to a regulatory body). It describes the services provided by these organizations to support regulatory functions as well as the associated activities and processes necessary to maintain the required level of expertise, state of the art tools and equipment. In line with the GSG-4 guide “Use of External Experts by the Regulatory Body” [3], it provides guidance more focused on TSOs activities.

Safety reviews<sup>1</sup> are the core activity performed by TSOs in supporting regulatory bodies: asked by a regulatory body, a TSO provides technical positions and recommendations on safety demonstrations to the regulatory body in order to contribute to its decisions.

This guide presents further views and good practices related to the activity of safety reviews, based on the experience gained by ETSO organizations. It provides general principles to be

followed when performing safety reviews, agreed among ETSO organizations and recommendations for building TSOs scientific and technical capabilities to support the safety assessments.

This guide is intended to serve as a reference for European TSOs and in particular for newcomers.

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<sup>1</sup> In this guide, no distinction is made between the terms “safety assessment” and “safety review” as regards the nature of the activity. The term “safety review” is preferred when the activity is performed by a regulatory body or a TSO.

# 3

# SAFETY REVIEW OBJECTIVE

The objective of a safety review is to evaluate the safety demonstration provided by the licensee of a nuclear facility with respect to the safety objectives assigned to the facility and nuclear safety regulations in force. The safety demonstration should provide the identification of the risks presented by the nuclear facility and the analysis of the provisions taken to prevent these risks, reduce the probability of accidents and limit their consequences, in accordance with a thorough implementation of the defence-in-depth principle.

The safety demonstration provided by the licensee should provide comprehensive, consistent and coherent information on the safety of the facility that is adequately justified using recognized and proven approaches and techniques, verified and validated analytical tools and models, results of R&D programmes and tests according to the latest state of science and technology.

Detailed discussions should take place between the TSO and the regulatory body on the specifications upstream and the conclusions downstream from the safety review.

Safety reviews play an important role throughout the lifetime of a nuclear facility. Stages for which a safety review is carried out or updated include: site evaluation; development of the design; construction; commissioning; modification of the design or operation (plant modernization, back-fitting programs, core reload licensing submittals); periodic safety reviews; life extension of the facility beyond its original design life; decommissioning and dismantling of the facility [4].

# 4

# SAFETY REVIEW GENERAL PRINCIPLES

## 4.1 The safety review should be based on a consistent and demanding technical reference framework

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The safety review of a nuclear facility is not limited to checking its compliance with nuclear regulations, but is rather based on an in-depth technical analysis which considers if and how appropriately the safety objectives are met, in the light of available knowledge, operating experience and best available technologies and whether the residual risks are reduced as far as practically achievable, while addressing societal concerns.

Besides national nuclear requirements and guides, IAEA standards and WENRA reference levels and safety objectives should be considered. In European countries, the harmonization of regulatory requirements conducted through WENRA contributes to a high safety level of nuclear facilities. TSOs should support the definition, development and revision of these international references. In performing safety reviews, TSOs should ensure that the aim of continuous

improvement of safety is adequately taken into account, in particular in the framework of periodic safety reviews, including more demanding safety objectives and requirements based on updated knowledge and operating experience, as prescribed by the Vienna Declaration on Nuclear Safety [5], the European Nuclear Safety Directive (article 8a) [6, 7] and the corresponding WENRA guidance [8]. In particular, safety objectives and requirements developed for new designs should be used as reference guidance for the evaluation, planning and implementation of plant modifications to older nuclear installations which can be shown to provide significant safety improvements while remaining practically achievable.



## 4.2

# The safety review should be based on up to date scientific and technical knowledge and state-of-the-art methods as appropriate

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As regards safety review, a key part of the TSOs mission is to provide expert support primarily<sup>2</sup> to nuclear regulators for the assessment of the safety of nuclear facilities. TSOs therefore need to rely upon highly qualified staff with specialized knowledge in a wide range of technical areas and knowledgeable in national nuclear regulations, international requirements and guidelines as well as current best practices.

The safety review involves analytical aspects as well as an integration process [9]:

1) The analytical aspects focus on the various aspects of the technical evaluation of the risks and of safety demonstration. To this end, they imply the need for a sufficient number of specialists having a large amount of scientific and technical knowledge as well as information about best available technologies. The relevant scientific and technical domains include, depending on the particular nuclear facility:

- The safety of normal operation (especially with respect to significant modifications such as power uprate or load followed modes as well as lifetime extensions): operating procedures, periodic tests, maintenance, etc.,
- The phenomenology and the plant response for anticipated operational occurrences and design basis accidents: neutronics, criticality safety, thermal-

hydraulics, fuel behavior, chemistry, mechanics, etc.,

- The phenomenology and the plant response (including the multi-unit context) for severe accidents: fuel melting, vessel rupture, core-concrete interaction, hydrogen distribution and combustion, steam explosion, etc.,
- The phenomenology and the plant response in case of internal hazards: fire, explosion, internal flooding, etc.,
- The phenomenology and the plant response (including the multi-unit context) in case of external hazards: earthquake, external flooding, storms and high winds, extreme meteorological conditions, airplane crash, etc., and their combinations,
- The thermomechanical behavior of equipment and structures and their qualification, irradiation damage of materials (fluence/activation),
- Software engineering and qualification (digital I&C),
- Lifetime management of the facility (ageing management, Long Term Operation (LTO)),
- Fission product transfer and release into the environment,
- Human and organizational sciences,
- Operating experience assessment,
- Radiological consequences and emergency preparedness & response,
- Waste and decommissioning aspects.

As numerous technical areas are concerned, a TSO may not have experts in all of these areas: it could rely on some specialized organizations or companies, with which long-term collaboration is established [3]. These organizations or companies should be aware of the nuclear safety framework and have the necessary historical background regarding the assessed issues. Close cooperation with the TSO in charge of the expertise of the safety demonstration is essential, as well as the involvement in the technical dialogue with the licensee.

2) The integration process requires both the collaboration of all the specialists in nuclear safety that are involved in the technical assessment and effective multi-disciplinary coordination mechanisms to highlight the

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<sup>2</sup> Some TSOs might also support occasionally licensees. In such cases it does so in full transparency with respect to the licensee's nuclear regulatory body and is able to demonstrate that conflicts of interest are avoided.

essential safety issues within an integrated assessment of the safety of nuclear facilities. When reviewing plant improvements, it is for instance essential to check that the modifications will not introduce any regression regarding safety. For a new design, the impact of design choices on the different safety functions needs to be carefully assessed, advantages and drawbacks clearly identified. TSO experts should be aware of the latest developments in scientific and technical domains of concern. A TSO must ensure, on the one hand, that its experts access new scientific knowledge for improving the safety of nuclear facilities and, on the other hand, that its expert capabilities keep up with technological innovation and developments introduced by nuclear designers and operators.

It is therefore of prime importance that TSO experts go through continuous training and remain strongly connected with their counterparts and with the international scientific and technical community. In particular, technical working groups or peer reviews of OECD/NEA and IAEA are appropriate fora for in-depth technical exchanges. The situation could be facilitated if research activities are performed within the TSO or if the TSO is directly part of an organization performing research activities.

### 4.3

## The safety review should use well-defined methodologies in a global perspective

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A safety review is based on a safety demonstration provided by a licensee, with the corresponding justifications. The review methodologies should be well-defined, addressing the various types of safety reviews: design acceptance, plant commissioning, periodic safety reviews, etc.

Reviews should be objective and conducted against well-defined principles.

The safety review should integrate various viewpoints in a holistic vision of safety, in particular: deterministic and probabilistic safety approaches; technical, human and organizational aspects of safety and the interfaces between safety and security [9].

When performing the safety review, a TSO must identify the most important safety issues and adapt the depth of its analysis accordingly.

When performing the safety review of a nuclear facility, a TSO should not use a case by case approach but rather be involved in a long term and global perspective on the safety of the nuclear facility (holistic approach). This clearly distinguishes a TSO from an engineering office.

At the end of a safety review, the TSO should issue a report summarizing the review performed and providing the conclusions of the analysis of the licensee's safety demonstration and the positions and recommendations on the most important issues, presented in a prioritized manner.

### 4.4

## The safety assessment should make use of reliable data and knowledge, and of operating experience

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It is necessary that TSO experts have access to pertinent data relevant to the safety review, related to as-built and as-operated nuclear facilities: geometrical and physical data, equipment characteristics, material composition, reliability data, operational data, etc. The responsibility lies with the regulatory body to enable that the TSO has access to the relevant data when performing a safety review. The TSO should ensure adequate protection of restricted data.

Knowledge about the operation of nuclear facilities is of utmost importance for assessing safety. The analysis of operating experience, including identification of precursors and analysis of incident root causes — considering human, organizational and technological aspects — should be performed in order to develop knowledge that can be used for safety reviews. National as well as international operating experience has to be used.

To be able to perform well-informed and consistent review and assessment activities, TSOs must build and maintain over time relevant documentation and databases, supported by an appropriate knowledge management system. This is built up over time, in close relationship with the regulatory body as well as with designers and operators.

## 4.5 The safety review should be knowledge-based, integrated, robust and independent from licensees

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The pertinence of the safety review is first and foremost based on the technical skills of the TSO experts. As previously mentioned, those skills are developed and maintained through: initial and continuous education; former experience; and technical exchanges with industry and peers. Defining and conducting research programmes are also a means for a TSO to develop its competencies and prepare for the future.

It is important for a TSO to have the capability to challenge studies performed by a licensee by performing its own studies, for instance sensitivity studies. Therefore, TSOs should be able to make use of numerical simulation tools, ideally developed by themselves or in collaboration with other organizations but also open source and/or commercial software for

specific types of applications, and validated against appropriate experimental data.

TSOs should have a wide view on the safety issues in order to identify possible key knowledge gaps. If a TSO is to be able to establish conclusive positions with due consideration of the uncertainties and gaps in available knowledge, it should have the ability to initiate experimental programmes to develop knowledge and skills that can be applied to situations of interest for safety.

As mentioned earlier, the robustness of a safety review performed by a TSO is achieved in particular by implementing its collective expertise and paying attention to the consistency of its positions over time.

The TSO's independence of judgement from utilities should be guaranteed by its statute and clear ethical principles. TSO capability to perform its own studies and calculations also contributes to this independence.

## 4.6 The safety assessment should employ an in-depth technical dialogue

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Throughout the ongoing safety assessment of a nuclear facility, a close technical dialogue should be established between the TSO and designers, operators, and other stakeholders.

In-depth technical dialogue with the licensee and mutual understanding are essential for the TSO to take positions that are well-informed, pertinent and appropriate.

In increasingly multinational context of nuclear development and operation, sharing information and positions with other technical safety organizations makes it possible to strengthen the safety reviews performed by the TSOs.

## 4.7

### The safety assessment should demonstrate thoroughness and transparency

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to enhance safety through citizens vigilance: the vigilance exercised by the public indeed reinforces the missions of the safety organizations.

Increasingly, civil society expects transparency in the decision-making processes regarding the safety of nuclear facilities. At the international level, the "Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters" was adopted on 25 June 1998 by the 4th Ministerial Conference in Aarhus, Denmark [10]. Since 2008, the application of this convention to the nuclear energy is discussed within the framework of the "Aarhus Convention and Nuclear" (ACN) process [11].

These discussions showed the importance of giving civil society access to relevant information as early as possible. Therefore, TSOs should strive for an open dialogue with civil society. In this respect, they could, depending on the national context and in close connection with the regulatory body, share the conclusions of their safety reviews in the framework of this dialogue. They should also for instance publish their research findings in the open literature.

In the framework of the dialogue with the civil society, a TSO should be able to provide visibility regarding the thoroughness of its review through: the professional skills of its experts; the use of reliable data and clear review methodologies; and its quality management system, including records of important information or reasoning that are essential to understand and to use the results of the analysis.

The dialogue with the civil society is also a way to enhance the quality of the TSO expertise through the social stakeholders' complementary point of view. The benefits for civil society are to build its own opinion on technical matters, to build gradually a better understanding of various expectations and constraints to be considered. It is then a way

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