ETSON

EUROPEAN
TECHNICAL SAFETY
ORGANISATIONS
NETWORK

SAFETY ASSESSMENT GUIDE

ETSON/2013-001 January 2013

FOREWORD

Since the beginning of EUROSAFE initiative (1999), IRSN, GRS and Bel V (former AVN) have pursued the objective to advance the harmonisation 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 assessments that presented sufficient similarities to encourage them to persevere in building a collection of common best practices. The first version of their common Safety Assessment Guide was thus approved in 2004.

The general Safety Assessment Guide (SAG), and its specialized guides, the Technical Safety Assessment Guides (TSAG), have been written by the members of the European Technical Safety Organisations Network with progressive improvements brought by the new members of ETSON.

The SAG provides general principles such as safety assessment objectives or transparency and traceability of the process, and describes the general process for performing the safety assessment of nuclear installations. The goal of this SAG is to set down the harmonized methodology applied by ETSON organisations to ensure a common quality of safety assessment and to develop higher confidence in delivered safety assessments.

The TSAG series consists of specialized guides dedicated to specific technical domains of importance to the safety of nuclear installations. They provide an overview of the available practical knowledge gained by Technical Safety Organisations (TSO) in conducting safety assessments covering these main technical issues (use of operating experience feedback, assessment of human and organisational factors, prevention of severe accidents, probabilistic safety assessment, etc.).

Each guide published by ETSON is updated according to the extension of experience gained as well as to the new requirements in nuclear safety.

The 2012 guides present the common views and practices of ETSON members:

- Bel V - Belgium
- GRS - Germany
- IRSN - France
- VTT - Finland
- UJV Rez - Czech Republic
- LEI - Lithuania
- VUJE - Slovakia
- PSI - Switzerland

With the contribution of ETSON associated members:

- SSTC - Ukraine
- JNES - Japan
- SEC NRS - Russia

CONTENTS

1 SCOPE

Protection of the workers, the public and the environment from undue radiation hazards requires a high level of safety in nuclear activities. Reviewing and assessing the various safety related issues raised by the nuclear activities to determine whether the activities comply with the applicable safety objectives and requirements is essential to achieve and maintain such a high level of safety in nuclear activities.

The purpose of this guide is to provide principles to expertise bodies on reviewing and assessing the safety questions raised in nuclear activities. It applies to the nuclear facilities, the use of sources of ionizing radiation, the radiation protection, the management of radioactive waste and the transport of radioactive materials.

2 SAFETY ASSESSMENT OBJECTIVES

The basic objective of review and assessment is to determine whether the operator's submissions demonstrate that a nuclear activity complies with the stipulated safety objectives and requirements. For a nuclear facility, review and assessment aim at checking that it complies with the safety objectives throughout its lifetime. The associated specific objectives depend on the stage of its lifetime, for instance review and assessment aim at determining whether:

- the site chosen is suitable for the proposed facility;
- the design of the facility is suitable from a safety and radiation protection point of view;
- the commissioning test programme is complete and contains a well defined set of test acceptance criteria appropriate for confirming the adequacy of all safety related features of the facility;
- the operational limits and conditions are consistent with the regulatory requirements and an adequate level of safety is being maintained;
- the proposed modifications to the facility, at whichever stage in its lifetime, have been conceived and their implementation planned so that safety is not compromised;
- the safety reviews performed by the operator comply with the safety requirements;
- the operator's plans and commitments in respect of decommissioning meet the regulatory requirements;
- the monitoring programme proposed by the operator confirms that the safety systems performances are acceptable;
- the radiation protection requirements for the workers, the public and the environment are fulfilled.

3 REQUIREMENTS FOR SAFETY ASSESSMENT OF NUCLEAR ACTIVITIES

The quality of an assessment depends on the professional competence, independence and integrity of the experts and on the assessment process itself, for which transparency and justification are required.

3.1 Expertise body independence, competence and ability to cover its full area of competence

To ensure its independence the expertise body shall not undertake work likely to compromise its neutrality or likely to lead it to assess its own work. Particularly, persons conducting assessment should not have participated in the work being assessed.

The expertise body shall have organisation enabling it to steer clear of and/or suspend any assessment or expertise subject to internal or external commercial, financial or other pressures or influences, liable to call the quality of its work into question. If the expertise body forms part of an organisational structure which performs activities other than expertise activities, the organisational provisions should be such that any divergent interests between the different activities of the body do not affect the opinion of any expert. The responsibilities of the personnel involved in the assessment or who may influence the assessment shall be defined in order to prevent any conflicts of interest.

3.1.1 PROVISION OF RESOURCES

The expertise body shall possess the financial and human resources required to accomplish its expertise work in an independent manner. The expertise body shall possess a sufficient number of experts in order to cover its entire area of competence, possibly by cooperation between different expertise bodies.

3.1.2 COMPETENCE AND PERSONAL QUALITIES OF THE EXPERT

The expert's competence and personal qualities contribute considerably to the quality

and the relevance of the assessment and of its result. Consequently, personnel performing the assessments shall be competent on the basis of education, vocational training, skills or experience, be aware of the relevance and importance of their activities and of how they contribute to the achievement of the assessment.

Depending on his/her role for an assessment, the expert's competence includes technical competency in the expertise subject areas as well as managing a team of experts and drawing up an assessment report. Moreover, the expert shall be trustworthy, fair, sincere, honest, discrete, open-minded, while remaining critical and independent. He/she shall be capable of understanding, observing, analysing, discerning, persevering and taking different opinions and points of view into consideration. He/she shall also be able of drawing conclusions based on reasoning and logical analysis as well as describing situations and complex phenomena in comprehensible verbal or written forms.

3.2 Traceability and transparency of the process

In case the assessment activities concern nuclear safety, traceability is a requirement. Consequently, the expertise body shall identify the products of the assessment and their status by suitable means throughout the conducting of the assessment. The expertise body shall file the elements important for the result of the assessment, namely:

- elements at the origin of the assessment (*e.g.* correspondence, scope and applicability, review reports, contract and possible amendments, etc.);
- data sources (or references), elements of the assessment (*e.g.* specific expertise, contributions, etc.);
- if necessary, record of particular approach which led to the working out of the assessment report.

These elements as well as the results of the evaluations shall be recorded and maintained for an appropriate period in compliance with legal and regulatory obligations, under storage conditions that enable their effective consultation (particularly considering information storage media change).

All along the assessment, the expertise body shall determine and implement effective arrangements for communicating with the operator in order to improve the understanding of the phenomena considered and the knowledge of their consequence on safety. All along the assessment and after delivery of the report, communication shall also be ensured with the customers about assessment-related information, customer feedback, including customer complaints.

When conducting the assessment, the expertise body shall take all necessary measures in order to guarantee the confidentiality of the information which is given to it and/or which is given to its subcontractors.

3.2.1 REASONING SUPPORTED BY TANGIBLE AND VERIFIABLE ELEMENTS

The assessment shall rely on tangible, verifiable and demonstrable elements: current knowledge stands, valid and representative observations, tests, inspection results, etc. and on the use of expert judgment. The source of these data shall be traceable and the reasoning followed shall be supported by tangible proof and the opinions formulated shall be based on objective elements. Particular care shall be taken to avoid generalisations and unjustified extrapolations of these elements.

3.2.2 PURCHASING AND SUBCONTRACTING

Suppliers and sub-contractors whose

product is likely to affect the quality of the assessment shall be evaluated and selected by the expertise body on the basis of specified criteria.

3.3 Method for conducting the assessment

The expertise body shall define the method for conducting the assessment. The method applied can be designed specifically for a requested assessment or cover a type of assessments.

The method shall ensure that all the assessment work is planned and performed in a suitable and effective manner. Work shall be performed under controlled conditions, using approved current instructions, procedures, drawings or other appropriate means that are periodically reviewed to ensure adequacy and effectiveness. All expertise processes participating to the safety assessment shall have a clearly nominated person who is responsible and accountable for:

- developing and documenting their process and supporting documentation;
- monitoring the performance of the assessment process to ensure the process remains effective;
- cooperating with the persons responsible for and accountable for interfacing processes.

The method shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved corrective action shall be taken.

3.3.1 ASSESSMENT METHOD CONTENT

The assessment method shall satisfy the assessment requirements and shall at least include:

- the verification of the availability of the information appropriate for conducting the assessment, of the provision of necessary resources and of possible purchasing;
- the definition of the interfaces between the different groups involved in conducting the assessment, in order to ensure effective communication;
- the definition of responsibilities and authorities for conducting the assessment;
- the a priori definition and planning of the execution stages;
- the verification and approval process needed to allow release of the assessment.

Management shall regularly evaluate the assessment process for which they are responsible. Process weaknesses and barriers that hinder the achievement of the objectives of the organisation shall be identified and corrected.

3.3.2 ESSENTIAL PRINCIPLES FOR CONDUCTING THE ASSESSMENT

While conducting the assessment the expertise body shall verify that the different aspects of the query raised have been properly considered. It shall ensure that the nuclear safety objectives and the safety policy principles are not impaired and that the technical requirements and criteria are fulfilled.

The expertise body shall take into account all duly argued positions on the subject, in particular the conflicting ones and carefully examine the elements which call into question its knowledge or convictions. State of the art and applicable documents, current knowledge in the relevant field, other analyses carried out, national or international experience and jurisprudence will be accounted for.

Very often safety assessment is multi-disciplinary and involves several safety experts. In such a case, the expertise

body shall ensure coherence of the safety assessments when integrating the different contributions and verify their consistency.

3.4 Assessment report requirements

The assessment report shall be written so as to enable the customer to fully appreciate its content and to be able to take profit from its conclusions.

The assessment report shall be approved prior to release.

The recommendations included in the assessment report shouldn't result in providing design element, or technical or organisational process that would constitute a particular solution towards fulfilling the recommendation.

Prior to delivery to the customer, the expertise body's management shall verify the accuracy of the assessment report and its conformity to the request to ensure that customer requirements are met, with the aim of enhancing customer satisfaction.

3.4.1 ASSESSMENT REPORT CONTENT

The assessment report shall at least include the following:

- general information relating to the assessment (scope, information concerning the query raised, the safety problems to be considered, etc.);
- the limits of the assessment performed;
- the positions of the parties (operator and expertise body);
- the clear formulation of the opinion, including the recommendations resulting from the assessment.

4 BASIS FOR SAFETY ASSESSMENT

Nuclear safety is defined in the IAEA safety glossary terminology as *"the achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards"*.

The operator of a nuclear installation is primarily responsible for the safety of his installation and consequently has to perform safety analysis in order to demonstrate that his installation complies with the applicable safety objectives and regulatory requirements.

On the request of the safety authority, the justifications presented by the operator to demonstrate the safe operation of the installation are assessed by the expertise body in order to evaluate the validity and adequation of these justifications, the efficiency of safety provisions made by the operator and their compliance with regulatory requirements.

The safety assessment by the expertise body follows the approach described below:

- determining and analysing the risks which the installation may have to face rather than only checking the compliance to applicable regulations. Particularly, the potential consequence of the phenomena considered including the possible evolution have to be taken into account;
- consideration of the operator file, the safety analysis report of the installation, the similar analysis previously performed while taking into account their applicability limits, the previous decision of the authority and its advisory committees, the jurisprudence and the national and international experience feedback with the aim of:
  - assessing the implementation of the defence in depth concept: defence levels to face the situations considered, failure of the lines of defence, limitation of the possible accident consequence to an acceptable level, etc.;
  - checking that the equipments, the protection systems and the safeguard systems have the required characteristics to fulfill the safety and radiation protection objectives;
  - identifying and assessing containment barriers implemented to avoid the release of radioactive material, while taking into account their possible failure or bypass;
  - calling for cross-evaluation, probabilistic safety analysis, or additional examination as required;
- favouring iterative technical interchange with the operator enabling any difficulties to be expressed without necessarily coming to an agreement but with the objective to identify and explain the reasons for agreement or disagreement on possible recommendations;
- ranking the recommendations to avoid those which are the most important for safety to be diluted among the less important ones.

5 SAFETY ASSESSMENT PROCESS

Assessment activities give rise to contract between the customer and the expertise body; however an expertise body has the right to deliver opinions on its own initiative.

Prior to carry out the assessment, the expertise body shall perform the request review.

5.1 Request review

The examination of the assessment request includes some or all of the following stages, which have varying importance depending on the type and extent of the query raised.

This review shall enable to ensure that:

- the query raised falls in the scope of the activity of the expertise body;
- the expertise body is able to respond to the query raised;
- the expertise body possesses the elements required for conducting the assessment (available existing elements, availability of specific means, etc.), specifically that the information transmitted by the operator is appropriate and sufficiently complete to perform the assessment;
- the expertise body possesses the means and knowledge required to properly conduct the assessment;
- the query is adequately defined, documented and understood;
- the significance for safety of the query raised has been correctly appraised.

Results of the request review and actions arising from this review shall be recorded (identification of the request and the scope of the related assessment, reference of the documents concerned, contribution commitment, delivery date agreed on with the customer, etc.).

5.2 Preliminary assessment

The expertise body shall plan and control activities and manage the interfaces between different groups involved in one activity to ensure effective communication and clear assignment of responsibility.

When receiving the request, the person of the expertise body in charge of managing the assessment performs a preliminary assessment in order to:

- confirm the importance of the assessment

and to determine the associated priorities and the allocated means;

- check that the requirements relating to the assessment and the associated outputs are clearly specified;
- determine the different aspects of the query raised, the different possible approaches and the safety problems raised;
- identify the information required to successfully carry out the assessment with respect to the information provided;
- determine the additional information needed from the customer or the operator;
- work out the assessment planning and precise the milestone necessary to comply with the assessment schedule;
- precise the content of the experts' contribution, their potential interaction and their delivery date as well as the experts' role and responsibility in the process;
- precise, when necessary, the required validation, verification, monitoring, inspection and test activities specific to particular expertise.

5.3 Conducting the assessment

The expertise body shall appoint a nominated person to answer the request and who is responsible and accountable for:

- gathering information needed to perform the expertise (data supplied by the operator or the customer, where applicable, information derived from previous similar conducted expertise activities, applicable regulatory or legal requirements and other information essential for the expertise);
- monitoring the experts' work in order to get their opinion in an adequate and timely manner;
- making critical analysis of the data provided;
- carrying out of actions specific to the expertise performed including relations with the operator;
- ensuring that the expertise results were compared with the state of the art, current knowledge in the relevant field, the other analyses carried out and other applicable documents such as, for instance, fundamental safety rules;
- examining the elements which call into question its knowledge or convictions, taking into account all duly argued positions on the subject, in particular the conflicting ones, combining the different expertise to make a coherent assessment;
- ensuring that the different aspects of the query raised have been properly considered and that the requirements specified by the customers are addressed;
- ensuring the verification of the expertise product before its delivery;
- ensuring the records requirements and filing information having an influence on the result of the expertise product.

The customer shall be informed of difficulties, which may occur when conducting the assessment.

5.3.1 MODIFICATIONS DURING TERM OF REQUEST

Where requirements related to the assessment are changed, the modifications shall form the subject of an amendment. In such a case the expertise body shall ensure that the relevant documents are amended and that relevant personnel are made aware of the modified requirements.

5.4 Independent verification of the assessment

The assessment shall be verified or validated by individuals or groups other than those who originally directly performed the work.

At suitable stages, verification of the expertise activities contributing to the assessment, shall be carried out in order to evaluate:

- the adequacy of the expertise results to meet requirements;
- the relevance of the selected method in order to obtain the expertise result;
- the adequacy of the expertise performed with regard to the assessment objective.

Prior to delivery to the customer, the adequacy of the assessment report to the specified requirements shall be verified to assure that it does not call into question the validity or the quality of the assessment. Moreover, the expertise body shall verify the conformity of the assessment to the assessment contract.

Note: The control of subcontracted expertise shall be identified within the management system.

5.5 Delivery and filing

The expertise body shall file elements important for the result of the assessment, in particular if necessary:

- elements at the origin of the assessment (*e.g.* correspondence, application, review reports, contract and possible amendments, etc.);
- data sources (or references);
- elements of the expertise performed (*e.g.* records, procedures, processes, contributions, etc.);
- record of the approach which led to the working out of the assessment report, in particular the discussions and conflicting elements;
- elements relating to the release of the assessment.

These elements shall be maintained for an appropriate period, in compliance with legal and regulatory obligations, under storage conditions that enable their effective consultation, specifically in case of development of computer programmes and information storage media.

APPENDIX

TERMS AND DEFINITIONS

Assessment contract

Agreement between the customer and expertise body which specifies at least the query raised and the assessment report to be provided.

Note: According to customs and professions, the term « assessment contract » may be replaced by terms such as order, mission, request, referral, etc.

Assessment report

Response to the query raised, according to the terms specified in the assessment contract.

Customer

Entity that receives the assessment report performed by the expertise body.

Expert

Person whose competence, independence and integrity earn him/her formal recognition as someone capable of conducting expertise work.

Expertise

Series of activities intended to provide a customer with a response to the query raised, in the form of an interpretation, opinion or recommendation, as objectively based as possible, formulated on the basis of available knowledge and demonstrations, accompanied by a professional judgment.

Note: Demonstrations include tests, analyses, inspections, simulations, etc.

Expertise body

Body possessing the recognised codes of practice and professional competence in a specific sector in order to conduct and carry out expertise activities under its own responsibility.

Note: An expertise body may comprise a single person, a freelancer for example.

Operator

Any organisation or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionising radiation.

Note: Operator includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc.

Opinion

Judgment resulting from an analysis or assessment in response to the query raised and which is not decisive, formulated by the expertise body on the basis of information known by the expert(s) and of current knowledge.

Query raised

Question defining the subject of the assessment to be carried out and the nature of the expected response: interpretation, opinion or recommendation.

Recommendation

Opinion formulated by the expertise body regarding what should or should not be done.

Safety

The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.

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