



# **SAFETY ASSESSMENT GUIDE**

## **FOREWORD**

For many years the French, German and Belgian Technical Safety Organisations (IRSN, GRS, AVN) have developed a very close cooperation in the field of Nuclear Safety.

This cooperation concerns the participation to common research programmes as well as the sharing of information to improve the knowledge about the Nuclear Installations and associated components behaviour, and consequently improve the TSOs' capacity to anticipate possible accidental situations and the TSOs' ability to assess the licensees' capacity for accident prevention and mitigation. This cooperation also includes common activities on various technical investigations to reach a better understanding of the phenomena encountered, exchange of opinion and reciprocal safety assessments of nuclear installations in order to get a fully independent assessment and to have as far as possible a stronger safety opinion.

This cooperation has shown that beyond the national and international standards and recommendations, the three organisations have a very similar approach and way of working to ensure an independent, objective and technically strong evaluation of the nuclear installations safety.

The goal of this Safety Assessment Guide is to set down the harmonised principles applied in the three organisations to ensure that, whatever the technical analysis could be, the IRSN, GRS or AVN safety assessments are performed according to the same lines and can therefore be used with the same confidence by the people concerned.

## INTRODUCTION

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 concerning: nuclear facilities at different stages (siting, design, construction, commissioning, operation and decommissioning or closure), waste treatment, transport of radioactive materials and radioprotection, to determine whether the activities comply with the applicable safety objectives and requirements is one of the principal ways to achieve and maintain such a high level of safety in nuclear activities.

The purpose of this guide is to provide recommendation 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 ionising radiation, the radiation protection, the management of radioactive waste and the transport of radioactive materials.

**Note:** The terms and definitions used are defined in the French Standard NFX 50-110 /3/ and the IAEA Safety Guide N° GS-R-3 /1/, nevertheless for the purpose of this document some definitions have been modified according to appendix 1.

## 1 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 or 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 construction is in accordance with the construction license,
- ✓ The commissioning test programme is complete and contains a well defined set of test acceptance criteria adequate for confirming the adequacy of all safety related features of the facility,
- ✓ The operational limits and conditions are consistent with the regulatory requirements and whether an adequate level of safety is being maintained,
- ✓ The operator's personnel meet the regulatory requirements, in terms of both number and competence,
- ✓ 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 to confirm that the performance is acceptable (particularly for waste disposal facilities),
- ✓ The radioprotection requirements for the workers, the public and the environment are fulfilled.

## **2 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.

### **2.1 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 independent assessment should not have participated directly in the work being assessed.

The expertise body shall have rules 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 latter shall be precisely defined in order to prevent any conflicts of interest.

The expertise body should be able to prove its independence with regard to any commercial, financial or other pressures or influences likely to affect its technical opinion. On account of its independence, the expertise body is duty bound to separate its activity from that of consultancy and consequently shall not provide any specific solutions to the query raised.

#### ***Provision of resources***

The expertise body shall possess the financial and human resources required to accomplish its expertise work in an independent manner, namely it shall determine the necessary competence for personnel performing work affecting the quality of the assessment and possess a sufficient number of experts in order to cover its entire area of competence with redundancy to the extent possible in the expert organisation.

Note: Such a redundancy can also be achieved by co-operation between different expertise bodies.

The expertise body shall possess competence criteria and rules for selection, recruitment, role adaptation, empowerment and monitoring of the competence of its personnel: experts and persons with responsibilities in conducting the assessment. It shall determine and provide the resources needed to maintain and improve its professional competence and efficiency in its expertise work and to enhance customer satisfaction.

#### ***Competence and personal qualities of the expert***

The expert's competence and personal qualities contribute considerably to the quality and the reliability of the assessment and of its result. Consequently, personnel performing work affecting the quality of the assessment 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 and on the type of expertise body, 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 shall be capable of understanding, observing, analysing, discerning, persevering and taking different opinions and points of view into consideration. He 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.

**Note:** Appropriate records pertaining to education, vocational training, skills and experience of those persons involved in the assessment shall be maintained.

The expertise body shall monitor the actions carried out by the persons directly involved in the expertise activities, in particular, to highlight the need for corrective actions, if necessary.

## **2.2 Transparency and traceability of the process**

In case the assessment and/or related expertise activities concern nuclear safety, traceability is a requirement. Consequently, the expertise body shall identify the intermediate and final products of the assessment and their status by suitable means throughout the conducting of the assessment. The expertise body shall maintain records of the expertise products with a unique identification system.

The expertise body shall file all elements having an influence on 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), constituent elements of the assessment (e.g. records, procedures, expertises, processes, contributions, etc.),
- ✓ Record of the approach which led to the working out of the assessment report, in particular the discussions and conflicting elements.

These elements as well as the results of the evaluations and of any necessary actions arising from the evaluation 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, processing of enquiries, customer feedback, including customer complaints.

### ***Reasoning supported by tangible and verifiable elements***

The assessment shall rely on tangible, verifiable and demonstrable elements, as far as current knowledge stands, and on valid and representative observations, tests or inspection results. The source of these data shall be traceable so that their validity can be demonstrated as required.

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. The process leading to the result and the associated actions, which at least have contributed to the final result, shall be traceable. Appropriate records shall be made for the inputs, the investigation as well as the associated uncertainties.

### ***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.

The parts of assessment falling in the area of competence of the expertise body shall not be systematically subcontracted and assessment shall never be completely subcontracted. In any case, the expertise body remains responsible towards the customer for the work carried out by the sub-contractor, except in the case where the sub-contractor to be engaged has been specified by the customer or a legal or regulatory authority.

### **2.3 Assessment conducted according to a defined method**

The expertise body shall plan the design and the realisation of the assessment and possibly develop the methods required for conducting the latter. The method applied can be designed specifically for the requested assessment, or be selected from existing ones as an assessment method adapted to the type of assessment requested and to the subject to be assessed.

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.

The assessment method shall define the interfaces between the different groups involved in conducting the assessment, in order to ensure effective communication and clear assignment of responsibilities.

#### ***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, for the provision of necessary resources and for possible purchasing,
- ✓ The definition of responsibilities and authorities for conducting the assessment and related expertises,
- ✓ The a priori definition and planning of the execution stages,
- ✓ The verification and validation activities appropriate to each stage,
- ✓ The records required to provide evidence that the realisation processes and resulting assessment meet the requirements,
- ✓ The acceptance criteria (verification and approval) needed to allow release of the assessment.

The assessment method shall be validated prior to the beginning of any expertise in order to ensure that the assessment method is capable of meeting the specified requirements. Records of the results of the validation and of any necessary actions shall be maintained.

Management at all levels shall regularly evaluate the assessment process and associated expertises processes for which they are responsible. Management evaluation shall determine the effectiveness in establishing, promoting and achieving objectives. Management process weaknesses and barriers that hinder the achievement of the objectives of the organisation shall be identified and corrected.

### ***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.

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. It shall also compare the expertise results with the state of the art and the applicable documents, the current knowledge in the relevant field, other analyses carried out, national or international experience and jurisprudence.

Before finishing the assessment, to avoid any misunderstanding or misinterpretation due for instance to an incomplete information or knowledge of the situation encountered, the expertise body shall present the assessment conclusions to the operator and/or to any stakeholder concerned with the assessment in order to confront opinions and identify agreement or discrepancy topics.

Note: The procedure for contacts between the expertise body and the operator and/or stakeholder shall be in accordance with national practice.

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 determined and met, with the aim of enhancing customer satisfaction. Records of the results of the verification and of the possible changes together with any necessary actions shall be maintained.

Where an assessment report includes elements provided by different experts, they shall verify that their contributions are correctly taken into account prior to release of the final document.

## **2.4 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 (intermediate product as well as the final report) shall be provided in a form that enables verification against the input and shall be approved prior to release. Where the quality of items and services cannot be verified the process producing the item or service shall be previously validated /1/.

Note: This particularly applies to the results of computer codes.

Whenever the assessment report includes a recommendation, the expertise body shall not provide any design element, or technical or organisational process that would constitute a particular solution towards fulfilling the recommendation.

Information necessary to provide evidence of conformity of the assessment to the requirements shall be determined and recorded. The assessment report or any other document unquestionably related shall enable to identify the names of the experts involved in the expertises and their respective role.

### **Assessment report content**

The assessment report shall at least include the following:

- ✓ General information relating to the assessment (scope, date of issue, identification of the customer and of the expertise body, information concerning the input data, the query raised, the safety problems to be considered),
- ✓ The limits of the scope of the assessment and the depth of the analysis performed,
- ✓ Reminder of the facts, the current state of knowledge at the time of the assessment and any additional information aiding understanding, and allowing the recipients to verify the relevance and the validity of the assessment,
- ✓ Reminder of the positions of the parties and of any element required for verifying the relevance of the assessment and of its conclusions, particularly in the case of conflicting positions,
- ✓ The assessment and related expertises execution conditions (data sources and investigations performed), resources used, inspections and verifications carried out and the limits of validity (transparency of the approach),
- ✓ The summary of the safety demonstration by the operator, the preliminary discussions, the summary of the reasoning followed together with the appropriate references of the related documentation and of the conflicting opinions, if any, to support the conclusions to which the expertise body came and to ensure that the result itself is properly understood,
- ✓ The clear formulation of the opinion, recalling to mind, if necessary, the limits of the assessment and related expertise as well as the additional work to be carried out, in order to facilitate its use by the customer.

## **3 BASIS FOR SAFETY ASSESSMENT**

*"Nuclear safety implies the prevention of accidents – including those induced with malicious intent – and the mitigation of their effects. It also encompasses the technical provisions made to ensure the normal operation of facilities, without excessive exposure of workers, by optimising the production and management of radioactive wastes and effluents." /4/*

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

The justifications presented by the operator to demonstrate the safe operation of the installation are assessed by the technical adviser of the safety authority in order to appraise the validity and exhaustiveness of these justifications, the efficacy of safety provisions made by the operator and their conformity to regulatory requirements.

Appraisal of the safety justifications for an installation consists of:

- Checking that safety principles and method of approach, together with any regulatory requirement are effectively applied by the operator and that the resulting technical solutions fulfil their purpose,

- Examining the principles and method themselves in greater depth and identifying weak points or inconsistencies in these approaches and their applications.

This guide does not aim at reviewing all the methods in use to technically appraise the safety analyses related to various potential risks for nuclear safety or to assess the safety of each type of nuclear installation. Such specific methods depending from the particular risks or from the installation considered should be the topic of typical technical sheets (see appendix 2).

Nevertheless, the safety assessment by the expertise body has to meet the following requirements:

- ✓ 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,
- ✓ Referring to the operator file, the safety analysis report of the installation, the similar analysis previously performed while taking into account their applicability limits, the advisory committees previous decision, the jurisprudence and the national and international experience feedback,
- ✓ Checking that the equipment, the protection systems and the safeguard systems are available and have the required characteristics to face the event considered,
- ✓ Identifying and assessing containment barriers implemented to avoid radioactivity release, while taking into account their possible failure or bypass,
- ✓ Applying the defence in depth concept by checking the number of lines of defence that could be used to face the situation considered and assessing their effectiveness, to prevent the failure of the lines of defence, and to restrict the possible accident consequence to an acceptable level,
- ✓ 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

### ***Nuclear power reactors***

Safety assessment of nuclear power reactors shall take care of their specific characteristics:

- Large quantity of radioactive products from which people must be protected and the dispersal of which to the environment would constitute a major accident,
- Significant heat generation continuing for a very long time after the reactor shutdown.

Therefore the prevention of these specific risks requires maintaining the safety functions, which are the key of the reactor safety:

- Efficient control of the chain reaction and hence the power produced,
- Fuel cooling assured under thermal hydraulic designed conditions, to maintain fuel clad integrity,
- Containment of radioactive products in the fuel, in the primary coolant, or at least in the reactor building, which constitute the barriers to prevent radioactive product release.

### ***Other nuclear installations***

In addition to basic nuclear installations concerned in the fuel cycle upstream or downstream from the power reactors, various different facilities, such as experimental reactors, research laboratories, irradiators, particle accelerators, etc. have some specific characteristics that should be considered in their safety assessment.

For these various types of installations, safety appraisal begins with the identification of potential risks, which vary considerably from one plant or part of a plant to another. For instance, some typical factors to take into account are:

- ✓ Use of sodium as coolant in fast breeder reactor,
- ✓ Exposure and contamination hazard of staff working in the fuel cycle facilities,
- ✓ Dispersion of radioactive products in case of fire in an installation where the fuel is in a powder form,
- ✓ Criticality hazard due to a sufficient quantity of fissile materials in fuel cycle facilities,
- ✓ Human factor in plants such as laboratories where reliance on human intervention is very important.

In these types of installations, conventional hazards (chemical, electrical or fire risks) may have a greater impact than in power reactors, since many of them deal with chemical reactions of radioactive substances. Moreover, in these installations specific care has to be taken for the worker protection, as they are closer to the radioactive substances than in power reactors.

## **4 SAFETY ASSESSMENT PROCESS**

All 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.

**Note:** The assessment contract may be a request for the relevant assessment, all of the other conditions being specified in a general contract: framework contract, multi-annual contract.

Prior to undertaking to conduct an assessment, the expertise body shall appoint a responsible to answer the request, who shall review the assessment-related requirements (e.g. contract or request review).

### **4.1 Request review**

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

The request review aims at:

- ✓ Determining the requirements specified by the customer (possible reformulation of the submitted query when necessary), the regulatory and legal requirements relating to the assessment and any additional requirements deemed necessary,
- ✓ Ensuring provision by the customer of the elements under his control required for conducting the assessment (available existing elements, right to carry out on-site inspections, availability of specific means, etc.),

This review shall enable to ensure that:

- ✓ The query raised falls in the scope of the activity of the expertise body, namely that the request is valid regarding nuclear safety concern.
- ✓ The expertise body is able to respond to the query raised in accordance with the applicable rules (fulfilment of specification requirements, compliance with the codes of practice, etc.).
- ✓ The expertise body possesses the means and knowledge required to properly conduct the assessment, specifically that the information transmitted by the operator is appropriate and sufficiently complete to perform the assessment.
- ✓ The requirements are adequately defined, documented and understood, and the customer agrees on the scope and depth of the assessment foreseen. Where limitations of any type are specified, these limitations shall be explicitly mentioned in the request.
- ✓ The significance for safety of the query raised and the urgency for the assessment have been correctly appraised, and that the delivery date has been accepted by both parties. Where an assessment requires elements provided by different experts, the latter shall approve the delivery date for the release of their contribution.

Note: It could happen, mainly if the operator file is technically complicated, that this review needs a detailed analysis of the information transmitted and possibly a meeting gathering the stakeholders involved in the query raised. In such a situation, particular attention shall then be taken in order to avoid the request to be unjustifiably delayed.

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

#### **4.2 Preliminary analysis of the request**

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 analysis of the request in order to check its compliance with the contract review (to complete it as required), to design and plan the assessment.

The objectives of this analysis are:

- ✓ To confirm the importance of the assessment and to determine the associated priority and the allocated means,
- ✓ To check that the requirements relating to the assessment and the associated outputs are clearly specified,
- ✓ To determine the different aspects of the query raised, the different possible approaches and the safety problems raised,
- ✓ To identify the information required to successfully carry out the assessment with respect to the information provided,
- ✓ To determine the additional information needed from the customer or any other stakeholders,

- ✓ To design the assessment and to define the needed expertises, to provide necessary procedures or documents, and the resources specific to the expertises,
- ✓ To work out the assessment planning and precise the signpost necessary to comply with the assessment schedule,
- ✓ To confirm the experts possessing adequate competence required to carry out the specific expertises,
- ✓ To precise the content of the experts' contribution and their delivery date as well as the experts' role and responsibility in the process;
- ✓ To identify interaction between the experts' activities and to ensure that the process flow is understood,
- ✓ To precise, when necessary, the required validation, verification, monitoring, inspection and test activities specific to particular expertises.

**Note:** Data collected during the conducting of the expertises may lead to modifying the scheduled assessment conducting planning.

### **4.3 Assessment processing**

Suitable methods shall be applied for monitoring the assessment processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved corrective action shall be taken.

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 sub-contractors,
- ✓ Carry out a critical assessment of the inputs, in particular of their field and conditions of validity, with regard to the assessment subject,
- ✓ Rely in its work on tangible, verifiable and demonstrable elements, as far as current knowledge stands,
- ✓ Ensure the validity and representativeness of the inspection results, observations, tests, analyses, etc., to which reference is made and avoid generalisations and unjustified extrapolations,
- ✓ Take appropriate records of the inputs, the type of investigation means employed, the assessment of the measurement means, the uncertainty of measurement results,
- ✓ Apply methods, procedures and processes, which allow ensuring the traceability of those actions, which have led to the results (which have served, at least in part, to develop the final assessment).

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,
- ✓ 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),
- ✓ Making critical analysis of the data provided,

- ✓ Providing signposts to supporting documents,
- ✓ Co-operating with the persons responsible for and accountable for interfacing processes,
- ✓ Carrying out of actions specific to the expertise performed including relation with the operator,
- ✓ Comparing the expertise results 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,
- ✓ Ensuring the verification of the expertise product before its delivery,
- ✓ Ensuring the records requirements and filing all information having an influence on the expertise product.

In addition, the person appointed to answer the request is responsible and accountable for:

- ✓ Monitoring the performance of the assessment process to ensure the process remains effective,
- ✓ Monitoring the experts work in order to get their opinion in an adequate and timely manner,
- ✓ Comparing the results of the different investigations carried out and verify their consistency,
- ✓ Examining and recording those elements which call into question its knowledge or convictions, taking into account all duly argued positions on the subject, in particular the conflicting ones,
- ✓ Ensuring that the different aspects of the query raised have been properly considered and that the requirements specified by the customers/stakeholders are identified and addressed,
- ✓ Combining the different expertises to make a coherent assessment,
- ✓ Ensuring the verification and the approval of the assessment before its delivery.

The customer shall be immediately informed of all difficulties encountered in fulfilling the contract, which may occur when conducting the assessment, and records of these difficulties shall be maintained.

#### ***Modifications during term of request***

Where requirements related to the assessment are changed, the modifications shall form the subject of an amendment and give rise to a new review of the requirements. 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.

#### **4.4 Independent verification of the assessment**

The assessment as well as all the intermediate expertises shall be verified or validated by individuals or groups other than those who originally performed the work.

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

- ✓ The ability 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.

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

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.

Records of the results of the verifications, of the changes and of any necessary actions shall be maintained.

Provisions shall be taken to preclude bypassing required verification and to prevent inadvertent use of assessment, which has not passed the required verification. Deviation from requirements shall be reported as specified.

#### **4.5 Delivery and filing**

The expertise body shall file all elements (intermediate and final reports) having an influence on the result of the assessment, in particular:

- ✓ Elements at the origin of the assessment (e.g. correspondence, application, review reports, contract and possible amendments, etc...),
- ✓ Data sources (or references),
- ✓ Constituent elements of the expertises 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 distribution of the assessment.

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

On delivery of the assessment, the expertise body shall ensure compliance with the confidentiality rules linked to the assessment, particularly when delivered by electronic mail.

## APPENDIX 1: TERMS AND DEFINITIONS

### **Assessment contract**

Agreement between the customer and expertise body which specifies at least the query raised, the conditions for conducting the assessment 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

### **Area of competence**

Extent and limits of declared or recognised in-depth knowledge on a specific matter, subject or subject matter

### **Customer**

Entity that receives the assessment report in compliance with the contract passed with the expertise body

**Note:** According to customs and professions, the term « customer » may be replaced by terms such as partner, claimant, safety authority, etc.

### **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 judgement

**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.

### **Expertise method**

Way of reasoning, thinking and acting according to certain principles and in a fairly methodical manner, with a view to providing the assessment product

### **Facilities and activities**

A general term encompassing nuclear facilities, uses of all sources of ionising radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources.

### **Interested party**

Person or group having an interest in the performance or success of an organisation.

**Note:** Interested party includes customers, owners, and people in an organisation, suppliers, bankers, unions, partners or society.

### **Interpretation**

Action taken by the expertise body in response to the query raised in order to explain and/or give a sense to data on the basis of a professional judgement

**Organisation**

Group of people and facilities with an arrangement of responsibilities, authorities and relationships

**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**

Judgement 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

**Professional judgement**

Intellectual process of appreciation, assessment, estimation or explanation leading to the formulation of an opinion on an issue or subject, based on professional experience in a specific field

**Query raised**

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

**Regulatory body**

An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. The national competent authority for the regulation of radioactive material transport safety is included in this description.

**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.

**Stakeholder**

Any individual, group or organisation that may affect, be affected by, or perceive itself to be affected by, the risk

**Note:** Stakeholder includes but has a broader meaning than interested party

## **APPENDIX 2: SAMPLE OF SAFETY ASSESSMENT TECHNICAL GUIDES**

According to the safety assessment to be performed, it could rely on safety guides based on the considered risk assessment or rely on safety guides related to techniques or to the various type of nuclear installation. Here below are listed some topics to which safety guide could be devoted.

### **RISK BASED ASSESSMENT**

- ✓ External hazards: Earthquake, aircraft crash, flooding, extreme weather conditions, fire, surrounding industrial or transportation activities....
- ✓ Internal hazards: Radiological or toxic material spreading, exposure to radiation, criticality, radioactive material behaviour, fire, explosion, internal flooding, mechanical incident (handling), auxiliary system failure, human factor...
- ✓ Loss of safety function: total loss of power, total loss of the heat sink, loss of steam generator feedwater supply.

### **TECHNIQUES BASED ASSESSMENT GUIDE**

- ✓ Core physics, fuel behaviour,
- ✓ Thermal hydraulics,
- ✓ Mechanics and electricity system,
- ✓ Civil engineering: building behaviour, containment leak tightness,
- ✓ Instrumentation and control,
- ✓ Systems design and components qualification,
- ✓ Operating conditions: normal and accidental conditions, long term cooling, severe accident,
- ✓ Containment principles: static containment, dynamic containment,
- ✓ Probabilistic safety assessment,
- ✓ Incident and precursors analysis,
- ✓ Reactor survey, periodic tests appraisal,
- ✓ Human factor and organisations analysis.

### **INSTALLATION OR ACTIVITY TYPE BASED ASSESSMENT**

- ✓ Power reactors,
- ✓ Research reactors,
- ✓ Irradiators, particle accelerators, laboratories,
- ✓ Front-end fuel cycle installations,
- ✓ Back-end fuel cycle installations,
- ✓ Spent fuel reprocessing installations,
- ✓ Waste management and packaging installations,
- ✓ Spent fuel storage,
- ✓ Decommissioning and dismantling of nuclear facilities,
- ✓ Fuel cask and radioactive material transportation.

## REFERENCES

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- /4/ Jacques Libmann:  
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