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IAEA-TECDOC-1909

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Considerations on Performing Integrated Risk Informed Decision Making

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CONSIDERATIONS ON PERFORMING INTEGRATED RISK INFORMED DECISION MAKING

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For further information on this publication, please contact:

Safety Assessment Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
Email: Official.Mail@iaea.org

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FOREWORD

This publication presents a framework for and the main elements of the integrated risk informed decision making (IRIDM) process, developed based on relevant practices in several Member States, and provides illustrative examples of its implementation. Although the publication mainly discusses safety aspects relating to the application of the IRIDM process, the process may be applied to security related decision making after careful consideration. The IRIDM process is a way of making decisions on any issue with nuclear safety implications that aims to identify and take account of all the factors that affect the decision in a systematic, integrated way. Risk information has been used in various forms as part of the safety decision making process in some Member States for many years and allows for a balanced approach to decision making. The development of probabilistic safety assessment methodologies has led to more formalized approaches for the IRIDM process. The advantages and potential safety benefits of the implementation of the IRIDM process, as well as its potential limitations, are highlighted and methods for taking into account various elements of the IRIDM process are presented. Some examples of decision making are reviewed in the annexes against the IRIDM framework to show how the process has been or can be used. This publication is expected to be of interest to all organizations involved in safety and/or security decision making (e.g. designers, licensees, regulatory bodies) in IAEA Member States.

The IAEA officers responsible for the preparation of this publication were A. Lyubarskiy, I. Kuzmina and A. Amri of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

In the early years of the world's nuclear power plant development and operation, the traditional approach to ensure nuclear safety was based primarily on a deterministic approach where a set of rules and requirements were defined (based largely on engineering judgement) that aimed at achieving a high level of safety. Although these rules and requirements took some, often implicit, account of the likelihood of the adverse events that were considered, it was not sufficient to ensure that they provided a balanced approach to safety since the most emphasis was placed on the worst-case events. Safety is a result of good engineering and sound operational and managerial arrangements, see Ref. [1]: safety analysis, whether deterministic, probabilistic or otherwise is a process to check whether the required level of safety has been achieved.

There are factors that obviously decrease radiation risks, e.g. adequate design, good manufacture and quality of materials, effective qualification and inspection, maintenance and surveillance of equipment. However, poor expertise and poor experience of operational and managerial staff coupled with inadequate organisational arrangements for training, supervision and monitoring of them can cause the best designed facility to suffer unwanted incidents.

In several countries, consideration of risk is a part of the safety decision[1] making process. Consideration of risk is also stipulated by the fundamental principles listed in Ref. [2]. The use of risk in safety decision making was developed in various ways in different Member States. Generally, higher consequence events have lower likelihoods and lower consequence events have higher likelihoods. Risk considerations thus allow different consequences to be considered in a consistent balanced manner.

Since the 1970s, (PSA) methodology has been developed and is now accepted as a mature approach that is being increasingly used to complement the deterministic approach and to provide additional insights that would not otherwise be available. PSA allows numerical estimates of the likelihood of specific consequences (i.e. risk metrics) and allows for consideration of the importance of safety measures and identification of weaknesses in the safety provisions. However, the characterization of risk is not confined to risk metrics; it includes wider contexts that are not necessarily amenable to PSA-type analysis. Indeed, risk as an input to safety decision making was used in some countries before PSA existed, hence the consideration of risk was often implicit, depending on expert judgement, rather than explicit, and even in the latter situation there was rarely a formal process.

As a matter of fact, while evaluating radiation risks, the associated undesirable consequences are expected to be clearly specified and risk metrics defined. It has also to be noted that risk is assessed based on a set of assumptions, approximations and subject to uncertainty arising from modelling and data. Therefore, the risk metrics estimated by PSA cannot be viewed as the absolute complete picture of radiation risk. In addition, different radiation risks are assessed by different techniques (e.g. risk to workers during normal operation is not assessed by PSA).

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[1] The term "safety decision/safety issue/safety measure" will be used in the publication for any decision/issue/measure that has implicit or explicit impact on safety, including the interface of safety with nuclear security.

The international nuclear community increasingly recognizes that an integrated decision making process that combines the insights from the deterministic and probabilistic analysis with other requirements (from the regulatory body or the utility) and considerations (cost-benefit, good engineering practices, etc.) is an effective means of refining and improving safe design and safe operation of nuclear installations which leads to more coherent and balanced decisions. An integrated decision making process also provides an efficient way of ensuring that licensee or regulatory decisions that have an impact on safety are made in a sound, transparent and auditable manner.

The purpose of making integrated risk informed decisions is to arrive at a situation where the highest level of safety can reasonably be achieved. The use of risk-related considerations (understood in a general way as radiation risks to people and the environment in the spirit of SF-1, Ref. [2], Principle 5, is the paradigm to achieve this optimisation by providing a methodology for balancing the various aspects that contribute to achieving the highest level of safety. Moreover, the requirement to follow an integrated approach is specified in the General Safety Requirements (GSR) Part 4 on Safety Assessment for Facilities and Activities, Ref. [3] which states that "the results of the safety assessment have to be used to make decisions in an integrated, risk informed approach, by means of which the results and insights from the deterministic and probabilistic assessments and any other requirements are combined in making decisions on safety matters in relation to the facility or activity".

The importance of the (IRIDM) approach is that it provides a way of bringing together the different aspects and considering them in a single framework. However, the application of IRIDM is not limited only to following a formal structure as set out in this report; the readers are expected to focus on the overall philosophy and approach of how safety decisions of all kinds are reached. When any safety-related decision is required, even where this is apparently straight-forward, a check is done to verify that all relevant factors are considered and none of them that can affect decision is omitted. For example, it is easy to forget when considering the modification or replacement of a piece of plant that even if it provides the same risk during operation, there may be effects on layout, which could affect the ability to carry out maintenance.

The concept of risk informed decision making was described in TECDOC-1436, Ref. [4]. It outlined a process that could be used to make decisions on safety issues and could be also applied to improve regulations. Further discussion of the integrated risk informed decision making process was given in INSAG-25, Ref. [1], which presented a framework for the decision making process. One of the aims of these publications was to provide a common understanding in the international nuclear community (designers, manufacturers, constructors, licensees, operators, technical support organizations, and regulatory bodies) of the general principles and framework of an integrated risk informed decision making (IRIDM) process. However, both publications did not provide detailed examples on how this process can be established and carried out in practical manner, which is in focus of this publication.

1.2. OBJECTIVES

This TECDOC is based on the framework and the descriptions of the main elements of a risk informed decision making process given in the previous two publications - TECDOC-1436 Ref. [4] and INSAG-25 Ref. [1]. The aims of this publication are to: (1) describe the main elements of an integrated risk informed decision making process, and (2) provide practices on how to establish and practically perform the formal IRIDM process through several illustrative examples.

An IRIDM process is a structured approach for making sound, risk informed decisions using existing procedures and protocols, and appropriate resources (e.g. expert panel, and technical specialists) commensurate with the importance of the decision being considered for an identified issue. An IRIDM process that would be conducted in a structured and deliberate environment is not intended for routine decisions. This publication describes a formal IRIDM process that could be used to reach a sound decision on an issue of importance; however, the general aspects of the framework can also be used to support decision making in less formal situations, where decisions are needed on a timescale that does not allow a formal process to be used. It could be of interest to all organizations involved in safety decision making (e.g. designers, licensees and regulatory bodies) in IAEA Member States.

This publication:

- Discusses the main components of the IRIDM process based on Refs. [1] and [4];
- Describes the IRIDM process including all stages of the development starting from the definition of the issue, determining the possible options that could address the issue, the Key Elements (KE) that need to be considered and the Constituent Factors (CFs) of which each KE is comprised, the choice of the relevant CFs for the issue in question, the methods of evaluation of the options, the integration process for combining the evaluations in the decision making process which finally results in selection of the optimal option, then implementation of the selected option, performance monitoring, and analysis of the feedback, including documentation and communication;
- Describes the steps that can be followed in establishing an IRIDM capability in a Member State or an organization that is consistent with the national approach to nuclear regulation;
- Discusses strength and weaknesses, as well as some practical issues, including problems and limitations in applying the IRIDM process;
- Provides illustrative examples on how IRIDM may be applied, and
- Reviews some examples of decision making against the IRIDM framework to show how the process has, in effect, already been used in a simplified and/or partial form.

While the information presented could be of interest to organizations and individuals at various levels of government, academia, industry, the nuclear community in general, and the public, it is primarily focused on designers, operators, regulatory bodies, and technical support organizations for nuclear installations. IRIDM can be the basis for a spectrum of decisions within or among these organizations.

The IRIDM process can be applied to all types of activities and facilities, including non-reactor nuclear installations. However, most of the examples given in this publication relate to nuclear power reactors because the process has a more mature development or has been developed mainly for this type of nuclear facility.

This TECDOC describes the general concept of the use of quantitative and qualitative information and how this can be integrated in making safety-related decisions. By following this approach, the balanced decision option could be selected in systematic and traceable manner.

The publication also provides practical insights on the selection of the various factors that could be included in the IRIDM process and provides suggestions on how the integration of the factors can be practically performed. Practical issues and problems that need to be addressed in adopting an IRIDM approach are discussed in the report, as well.

It is recognized that the way nuclear safety regulation has developed is different in the Member States. Some of them have developed a highly prescriptive approach that has been set by the regulatory body. Others have adopted a more goal setting, performance-based approach where the plant operator and the regulatory body have much more flexibility to determine what can be considered to meet the goals. Any approaches may take benefit of knowledge progress and experience feedback. An IRIDM methodology as discussed here is, in principle, applicable to all regulatory environments

1.3. SCOPE

Although this publication mainly discusses safety aspects related to the application of the IRIDM process, this process may be applied to security decision making after a careful consideration. This subsection provides summary descriptions of the scope of applications of the IRIDM process.

Types of nuclear facilities and activities

The IRIDM process described in this publication can be applied to all types of nuclear facilities and activities. In the General Safety Requirements (GSR) Part 4 Ref. [3] the graded approach is described for safety assessment, which also can be applied for IRIDM process.

This means that the level of effort involved in the process and the scope and quality of the supporting analysis must be consistent with the magnitude of the possible risk associated with the issue.

Application of the IRIDM process to design activities

During the design process, several safety issues will arise and that need preventative and/or mitigative structures, systems and components (SSC). IRIDM can be used to evaluate the safety measures and to determine which measures are the optimum ones to be included in the design. As noted in INSAG-25, Ref. [1], all safety measures, including those affecting the interface with nuclear security have costs and the economic effects need to be part of the IRIDM process. However, this publication is focusing on cost benefit aspects of the safety, including the interface of safety with nuclear security.

Application of the IRIDM process to licensee activities

During all stages of the lifecycle of a nuclear facility, the licensee will make decisions related to modifications to technical, organizational and/or administrative systems and procedures which can affect safety, including the interface with nuclear security, even if the aim of the modifications is to improve operational efficiency. IRIDM provides a route to assist in making these decisions in a structured manner, ensuring adequate safety, including the interface with nuclear security, is maintained, whilst enhancing the interaction with the regulators when seeking permission to implement changes.

Application of the IRIDM process to regulatory activities

This publication does not focus on the application of a risk informed process to regulatory activity. This aspect is presented in TECDOC-1436, Ref. [4], where three areas of application of IRIDM to regulatory activities are discussed in detail and are not repeated here.

Application of the IRIDM process to the interface with nuclear security

The IRIDM process described in TECDOC-1436, Ref. [4] mainly focuses on making decisions on nuclear safety issues. However, as noted in INSAG-25, Ref. [1], this approach can, after careful consideration, also be used to address security decision making, where the aim is to prevent intentional acts that are aimed at causing damage to a nuclear facility in such a way that would lead to radiological releases, or theft of nuclear and other radioactive materials. This approach can also be used to make decisions about changes to the design or operation of a nuclear facility (safety) or changes to the arrangements to reduce the impact on safety of nuclear security event.

The approaches to nuclear safety, including the interface with nuclear security, need to be addressed in a coherent manner so that balanced decisions are made.

Application of the IRIDM process to communication with stakeholders

The outcome of decision making in relation to complex facilities and situations is often difficult to explain to stakeholders who may feel that their concerns are being excluded from consideration. A well-documented IRIDM process can assist in communicating how the decision has been made, the factors considered and the significance of each factor in the final decision. Whilst other stakeholders may wish to include additional factors, or to put different emphasis on the factors considered, the framework of IRIDM is expected to allow a more structured and mature discussion thus facilitating communication. One of the important features of IRIDM process is traceability of any decision made.

1.4. STRUCTURE

Section 2 gives an overview of the IRIDM process. This is based on the framework given in Ref. [4] which was developed further in Ref. [1]. This section presents a definition of the IRIDM process, identifies its objectives, applicability and uses, and gives a general description of each of the KE that must be evaluated.

Section 3 describes, based on a flowchart, how the IRIDM process is followed in making an integrated risk informed decision.

Section 4 describes the steps that need to be taken to set up the IRIDM process to address a specific safety. This includes: the identification of the issue to be addressed; the selection of the team; the identification of the options; consideration of the CFs of each KE; and gathering the detailed information required addressing the specific issue.

Section 5 describes the part of the IRIDM process that relates specifically to evaluating the various options and documenting the process. This includes practices on assessment of the options, selection of the relevant CFs, their relative importance and integration into a robust decision making process.

Section 6 gives practices on the selection and implementation of an option, including seeking regulatory acceptance for the decision where necessary, implementing the chosen option and setting up a monitoring system to provide feedback on the implemented option performance.

Section 7 addresses the steps that need to be taken to introduce or develop an IRIDM capability in any of the Member States or within organizations, where similar approaches are either absent or are not sufficiently developed. It also deals with some practical aspects of setting up an IRIDM process.

Section 8 outlines some limitations/challenges and important issues of an IRIDM process.

Section 9 provides meaning of used abbreviations.

Section 10 clarifies the definition of the main terms used in the TECDOC.

Section 11 lists the references cited in this publication.

Annex I contains a more detailed discussion of the various IRIDM inputs that may be considered.

Annex II gives a description of some decisions that have been made either using the IRIDM process or which have been considered against the IRIDM process to illustrate the IRIDM concept and process described in this publication.

Annex III provides suggestions on how the assessment of the options could be facilitated.

Annex IV provides possible approaches for integration of the various inputs of the IRIDM process while deciding.

Annex V provides illustrative examples on how the IRIDM process described in the publication can be applied to an issue in a formal way.

Annex VI provides suggestions on how uncertainty in the IRIDM process could be considered.

Annex VII addresses documentation of the IRIDM process and results.

Annex VIII discusses the need for integrated consideration of non-radiological hazards in the IRIDM process.

2. GENERAL OVERVIEW OF THE IRIDM PROCESS

2.1. DISCUSSION ON THE ASPECTS OF IRIDM PROCESS

Making decisions about the adequacy of, or changes, to safety, whether they are equipment or personnel based, requires consideration of a range of factors and issues, including risk considerations. Thus, the decision made must balance all consequences, including consideration of the likelihood of the adverse consequences occurring. The term 'risk' encompasses both the likelihood and the consequence and so, is a useful way of considering both these aspects whether as a result of normal operation or accidents. By considering the risk of specific situations it is possible to balance the ways in which harm can be realised and the nature of the harm. Accounting for possible changes in risk (risk-informing) in making decisions thus can lead to improved safety by ensuring that undue reliance is not placed on safety measures in an unbalanced manner nor concentrated on specific consequences.

Assuring that a decision is a good one is not simply a matter of checking whether all safety requirements are met; it does also consider whether less compliance against one safety requirement can be offset against a greater degree of compliance with another or others. Risk considerations have been implicitly involved in most safety decisions and in many situations, risk has been assessed in a qualitative or semi-qualitative manner. The use of PSA gives numerical risk metrics which contribute to a more explicit consideration of risk in the decision making process by giving probabilities or frequencies to specific consequences. Not only a formal PSA, see Refs. [5] and [6], but the whole set of approaches that range from reliabilities/availabilities of Structures, Systems and Components (SSC) to the frequencies of severe accident situations can provide inputs to support risk considerations.

The important part of the IRIDM process is the identification of the factors that may impact the decision and evaluation of the decision options against these factors. These evaluations include the results and information derived from a range of qualitative and quantitative analyses. The evaluations are then integrated within the decision making process. The important factors requiring evaluation typically include mandatory requirements (such as regulatory requirements and licence conditions), the insights from the deterministic analysis (such as defence-in-depth and safety margins), the insights from probabilistic assessment (usually obtained from a PSA for a nuclear facility) and other considerations that are relevant to the issue being addressed (such as radiation doses to workers and members of the public, operational and management procedures and cost-benefit analysis). In addition, the IRIDM process takes account of the relative importance of all the factors identified in making the decision.

In applying the IRIDM approach, it needs to be recognised that the graded approach described in Ref. [3] applies so that the scope and level of detail of the evaluation of each option against the relevant factors carried out are "consistent with the magnitude of the possible radiation risks arising from facility or activity". Other factors such as complexity of the issue, Operational Experience Feedback (OEF) or research and development findings might affect the grading, e.g. if changes have been made to a similar facility elsewhere, the degree of scrutiny of the need for the change may be less.

As safety decision making is related to the prediction of the response of the facility, it must be based to some extent on assumptions and models which introduce uncertainty. To be used most effectively, the IRIDM process requires time and effort to assemble all the relevant information and to evaluate and integrate it to produce a balanced result, taking account of uncertainties.

2.2. PRINCIPLES OF THE IRIDM PROCESS

The decision made by applying the IRIDM process needs to satisfy several principles that serve as the foundation of sound risk informed decision making; these include ensuring that:

- Existing regulations have been complied with (unless exemptions or changes to regulatory requirements are under consideration);
- Defence-in-depth principles have been adequately addressed;
- Engineering, operational and organizational good practices and insights have been considered;
- Adequate safety margins are secured;
- Risks have been assessed and are acceptable;
- Implementation of the option would not adversely affect other features of the interface with nuclear security during the implementation process;
- Relevant insights from research and development activities, and state-of-the-art methodologies have been considered; and
- Ways of measuring the performance of the proposed change have been identified, if the process is applied to issues on an existing facility.

The IRIDM process is particularly applicable to situations where there are several options available to address a safety issue and there are several disparate factors (i.e. it is a multi-attribute problem) that need to be considered to select the optimum, balanced solution. It is particularly powerful when there is no obvious optimum answer and there are many potential options, each of which may not provide a complete solution to a safety issue.

2.3. USES OF IRIDM

INSAG-25, Ref. [1] states that “IRIDM has a growing spectrum of applications for nuclear power plants in areas which include design, licensing, regulatory oversight, operation, maintenance, testing, operator training, modifications (temporary or permanent), periodic safety reviews, life extension, siting, emergency planning, security, asset protection and decommissioning"

As a matter of fact, IRIDM is increasingly being used by regulatory bodies, plant operators and designers to solve multi-attribute problems in a systematic and transparent manner.

The application of the IRIDM process to arrive at a sound risk informed decision requires a method to determine how well the options under consideration meet the expectations of each of the relevant factors. These expectations are usually expressed as safety goals or objectives and the IRIDM factors are expected to be consistent with those established in the Member State (see section 7.1).

The IRIDM process can be used:

- in discussions between regulatory bodies and licensees;
- within regulatory bodies;
- within licensees of nuclear facilities;
- within other organizations (e.g. research and design, technical support organizations, etc.); and
- in discussions with different stakeholders and communication with the public.

These uses of IRIDM are outlined below.

Use of IRIDM in discussions between regulatory bodies and licensees

Where the IRIDM process has been used to address a safety issue, the results of the process followed and the documentation produced can be used in the discussions between a regulatory body and a licensee. The issues where this approach would be useful include the following:

- providing the safety case for a new nuclear facility;
- evaluation and approval of plant modifications and/or upgrades;
- licensing power uprate programmes;
- approval of changes to maintenance practices, operating procedures, organizational arrangements or Technical Specifications;
- improving arrangements regarding the interface with nuclear security, etc.

The way that these discussions would occur would depend on the regulatory processes applied in each of the Member States.

Use of IRIDM within a regulatory body

The way IRIDM is used in regulatory activities is highly dependent on the way that regulatory bodies carry out their responsibilities in different countries. According to GSR Part 1, Ref. [7], these responsibilities typically include:

- licensing of nuclear installations and issuing consents, authorisations, etc. throughout the life of nuclear facilities;
- making decisions on safety issues that arise at the nuclear facility – for example, response to requests to make changes to the design, management or operation of the plant, etc.;
- formulating and making changes to regulations and safety standards;
- planning and carrying out regulatory inspections;
- evaluating operational experience in determining potential improvements, and
- carrying out enforcement actions.

It is recognised that risk considerations have been used, implicitly or explicitly, in deciding on the regulatory approach and in making decisions on safety issues for many years. However, the increased maturity of PSA gives a more systematic way of providing much of the detailed risk information for use in the regulatory and safety decision making processes. Adopting the IRIDM process provides an efficient way of ensuring that safety decisions are taken on a sound basis, proportionate to the risks. The benefits of this approach are that it will enhance safety by focussing the work and the resources of the regulatory body in the areas that are most risk significant, increase public confidence in nuclear regulation through a transparent decision making process, and reduce the unnecessary burdens on nuclear plant operators without compromising safety by allowing greater flexibility in plant operation.

The implementation of IRIDM can also be useful for targeting regulatory oversight activities and supporting judgments on safety reviews, making the best use of the available resources.

Four aspects of the work carried out by regulatory bodies can benefit from applying the IRIDM process, Ref. [4]:

- Making risk informed changes to the regulations that consider new information, analysis or operating experience;
- Evaluating the safety significance of the issue under consideration for authorisations that would be issued by the regulatory body. The types and number of authorisations vary among Member States. Insights from IRIDM are useful contributors to deciding the prioritisation, urgency, and frequency of renewal of such authorisations;
- Prioritising regulatory site inspections by considering the risk significance of SSCs and management and operational arrangements. An IRIDM process can be used to determine the priorities for site inspections across all the nuclear facilities for which the regulatory body has responsibility or within a nuclear facility, and
- Evaluating the significance of any violations that have occurred and prioritising the subsequent corrective and enforcement actions so that they focus on those that have the highest risk significance.

The applicability of the IRIDM process for regulatory activities depends on the complexity of the decision to be made and the action to be taken. The criteria that can be used in deciding on the need to apply a formal IRIDM process would include the following, based on Section 5.3.3 of Ref. [4]:

- potential for improving safety;
- potential for reducing burdens on the operator and/or regulator;
- anticipated complexity and scale of changes;
- resources needed (by the regulatory body and the plant operators) for putting changes in place;
- time needed for full implementation;
- application to current and/or future plants, and
- scope of the risk assessment that is required.

The criteria applied will depend on the regulatory framework in the Member State. In many Member States, there are several different regulatory bodies which have responsibilities for different aspects of safety. The possibility of conflict between the requirements of these bodies can lead to confusion for the licensees and non-optimal solutions unless there is a common approach which all regulatory bodies can employ. In this report, there is an explicit consideration given to the possible conflict between safety and security regulators, but similar consideration must be given to other health and safety issues. The application of an IRIDM approach is expected to enable a better dialogue between regulators and licensees and the development of a clearer, optimal set of safety requirements.

Use of IRIDM by plant licensees

In a similar way to the regulatory bodies, there is a strong movement toward an increased use of a risk informed approach by the licensees of nuclear facilities in making decisions on many aspects of the design, operation of nuclear facilities. The approach being followed combines the insights provided by both deterministic and probabilistic approaches together with any other requirements (such as the cost of making modifications to the design or operation of the plant, the radiation doses that would be incurred by workers in making the modifications, operating experience, the economic benefits, the remaining lifetime for an older nuclear facility, or the cost-benefit ratio).

From the standpoint of the plant licensees, there are two general categories of risk informed decisions that can be taken during operations[2]:

- Decisions aimed at enhancing safety; and
- Decisions aimed at economical optimization (improving operational performance and increasing revenue).

Decisions aimed at enhancing safety: Decisions are routinely made by plant licensees to control risks and enhance safety during plant activities that do not require the intervention of the regulatory body in the decision making process. These include decisions on the following:

- Replacement of obsolete or unreliable equipment;
- Reliability-centred maintenance;
- Configuration control and surveillance test planning.

In addition, there are decisions made by the plant licensees aimed at enhancing safety to comply with existing regulations or with additional mandatory requirements or to incorporate lessons from their own or international operational experience. These decisions include:

- plant modifications;
- analysis and feedback from operational events determining potential improvements;
- accident management strategies and procedures;
- supporting judgements on Periodic Safety Reviews;
- evaluation of safety issues, and
- assessment and upgrading of arrangements regarding the interface with nuclear security.

Decisions aimed at economical optimization: Some of the changes that are proposed for economic optimisation may involve small changes to the licensing bases such as exemptions from, or relaxations of, deterministic and/or plant operator/licensee requirements. These changes are aimed at improving plant economics and include: the introduction of risk informed in-service inspection (ISI) or testing (IST); carrying out on-line maintenance; graded quality assurance and making temporary changes to or exemptions from Technical Specifications. These types of changes are usually initiated by a plant licensee and require regulatory approval.

Some of the changes aimed at increasing revenue require significant changes to be made to the licensing basis for the plant and include: plant power uprate, fuel cycle extension, plant lifetime extension, moving maintenance activities from the refuelling outage to at-power operation, and other changes to the current licensing basis. These decisions are typically made after the issue has been initiated by the plant operator/licensee and require regulatory approval.

A formal IRIDM process could be applied for making any of the decisions listed above. However, it is particularly useful for those cases, which require interaction with the regulatory body because the IRIDM process can provide a clear basis for the necessary discussions.

Use of IRIDM by design organizations

The design organization could also benefit from the application of the IRIDM process with the aim of producing balanced design solutions. The interim decisions made in the design process do not require regulatory approval; therefore, application of IRIDM by designers can be less formal; however, all inputs and steps of the process as discussed in the following sections are applicable.

Use in discussions with different stakeholders and communication with the public:

IRIDM provides a structured basis for discussion with stakeholders including the public.

Safety decisions can be difficult to explain to stakeholders who are not directly involved in the process but who might still have an interest in the safety of the nuclear facility.

Explaining how the decisions have been reached, by a consideration of the range of relevant factors and why these factors are considered important can assist in clarifying the situation. Most safety concerns from the public will be about one or two aspects and the IRIDM process can be used to show how these aspects have been compared with other aspects in arriving at a balanced decision. It is also possible to demonstrate how putting too much importance on reducing one aspect of risk can raise other risks.

Examples of the application of IRIDM process by different organizations are given in Annex II.

2.4. MAIN COMPONENTS OF THE IRIDM PROCESS

The main components of the IRIDM process are shown in Fig. 1, which is based on the descriptions of the process given in INSAG-25, Ref. [1]. The IRIDM process shown in Fig. 1 includes several Key Elements (KE), each of which has implicit risk aspects. Each KE comprises several Constituent Factors (CF) (not shown on Fig. 1), which further define the safety requirements and other conditions, and are used to evaluate the options being considered. In any application, not all the KE, nor all their CF, will be relevant to the issue under consideration. The aim of defining a framework is to better focus licensee and regulatory attention on design, operational issues commensurate with their importance to public health and safety. The components of this framework are described below.

Issue to consider: The starting point in any decision making process is to clearly define the issue under the consideration. Only with a clear and precise understanding of what is the 'issue' is it possible to understand what information is needed about the options that will be proposed to address the issue and which KE and CF are relevant to deciding. The 'issue' can range, for instance, from design features of a new facility or modifications to SSCs at an existing facility, to a minor modification of operational procedures.

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[2] Integrated Risk Informed Decisions made by licensees at design, construction, commissioning and decommissioning phases are not considered in detail here.

Regulatory and licensee considerations: Having defined the issue, consideration must be given to all relevant regulatory and licensee boundary conditions, which must be maintained for any of the options considered. This includes any mandatory regulations and conditions, and cost-constraints.

Options: Based on the definition of the problem, a list of possible options that conform to the regulatory and licensee constraints is developed to be considered to address the issue. The options are supported by sufficient information and analyses that it is possible to gauge the level of compliance with safety requirements. Where an issue relating to an existing plant is being considered, the method of implementation of the option and the safety implications of the implementation are also be included.

Key Elements of the IRIDM decision making process: The CFs against which the options are evaluated are described (see more details in section 4.2 and in Annex I) under the following KE:

- Standards and good practices: this element relates to the standards and good practices recognised in the Member State and includes regulatory requirements, licence conditions, national and international standards produced by professional bodies, and good engineering and managerial practices. Note that unless a change to a mandatory requirement is being explicitly considered, normally only options that conform to these requirements would be proposed;
- Operational experience: this element relates to the operating experience from the nuclear facility itself, from similar facilities and from non-nuclear facilities, related to the issue being addressed and requires that a review of the operating experience is carried out;
- Deterministic considerations: this element relates to the way that the basic deterministic principles have been addressed and includes the insights from: the accident analysis; the analysis of defence in depth; safety margins; and other deterministic aspects;
- Probabilistic considerations: this element relates to the explicit consideration of risks, i.e. the likelihood of specific adverse consequences and includes the risk metrics and other insights of a PSA for the nuclear facility. It includes the assessment of compliance with risk targets; the contributions to the risk from accident sequences; the relative strengths and weaknesses in the design and operation of the plant; and the changes in the risk from the options being considered;
- Human and organizational considerations: this element relates to organizational and administrative arrangement for management for safety of the plant. These may be affected by the issue being considered. This element includes maintenance activities, training and plant procedures, etc.;
- Considerations regarding the interface with nuclear security: this element relates to the physical protection of the facility and requires that the interaction between safety and security measures is considered in addressing the issue. IRIDM may address safety issues, but in each case the other aspect must be considered, and other considerations: this element relates to a range of other requirements that may need to be addressed for specific issues and includes: the radiation doses to workers and discharges to the environment during normal operation; radiation doses in making plant changes; the costs and benefits from making plant modifications; the remaining lifetime of the plant; non-radiation sources of harm, etc. This element also takes account of research being carried out that relates to the issue.

The importance of each KE and associated CFs is dependent upon the issue under consideration and decision to be made. A detailed description of the important aspects of the KE and CF is given in Annex I. The examples of typical CFs for most of KEs listed above are provided in Section 4.2.

Evaluate options/make integrated decision: The next step is then to evaluate each option against the selected KE and their associated CFs. The outputs of the evaluation are considered in an integrated manner to identify potential optimum and balanced decision(s). Iteration is a fundamental part of the IRIDM process as it allows reconsideration of options. The option might be considered acceptable even if it does satisfy some factors to a lesser extent than desirable, but one or several factors can compensate for this by enhancing safety in another way. Such options are further evaluated to ensure the decision making has been robust by considering uncertainty and performing a sensitivity analysis.

This process will lead to determination of an acceptable option or options; in the latter case, it would be normal to indicate the preferred option. The presumption in the process described in this report is that a Decision Maker or Makers (DM), who may or may not, be part of the team evaluating the options, will then decide which of the acceptable options (if there is more than one) is to be implemented – or to approve the single option if that is the case. The DM may be a more senior member of an organization or could be a group of senior personnel.

In some cases, regulatory approval of the selected option may be necessary before implementation is allowed.

It is possible that none of the considered options are acceptable, in which case a further set of options needs to be derived and the process of evaluation is restarted.

Implementation/performance monitoring/corrective actions: Once the decision has been made, the selected option is implemented following any conditions considered to be important. However, this is not the end of the process as good practice dictates that the implemented decision option is monitored and corrective action taken (which may include considering new options), if required, to ensure that the issue has been properly addressed. This step is a part of the Management System of the implementing organization but may include additional review by the regulatory body.

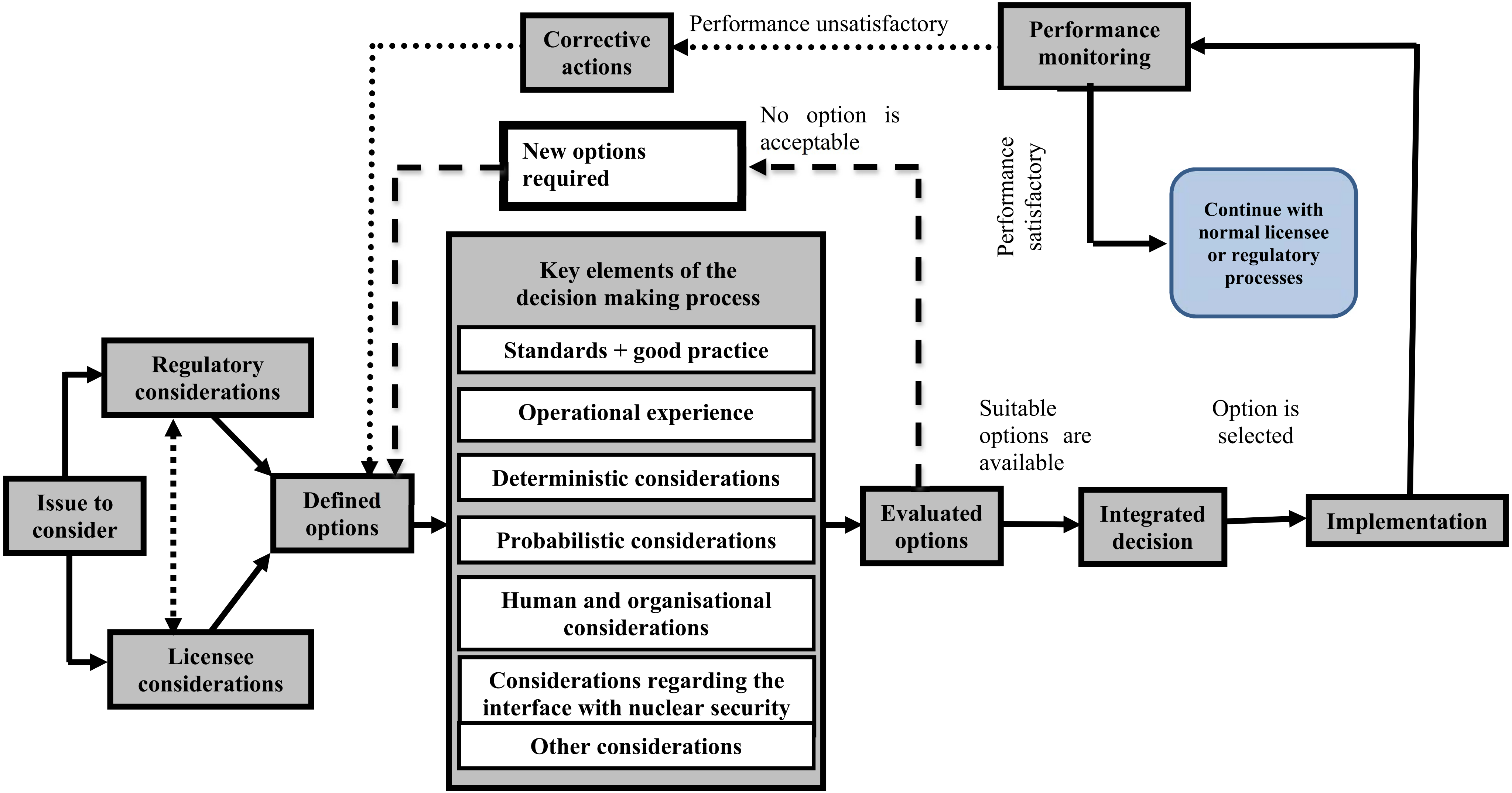

FIG. 1. Main Components of the Integrated Risk Informed Decision Making Process (based on INSAG-25 [1]).

3. DESCRIPTION OF THE IRIDM WORKFLOW

3.1. RULES TO BE FOLLOWED IN THE IRIDM PROCESS

There are several rules that need to be followed to ensure that the IRIDM process is applied in a consistent manner:

- clear definition of the problem, issue and objective for which the IRIDM is applied;
- identification and consideration of all relevant aspects associated with an issue;
- consideration of all sources of uncertainty introduced in the process;
- use of all available information, without discounting conflicting or unconfirmed data. However, the reasons for the conflicts are to be understood and the degree of reliance on the data during the IRIDM process are assessed;
- promotion of a questioning attitude among the people involved and challenging of all the assumptions;
- consideration of qualitative information (e.g. management, environmental and societal) in addition to quantitative data.
- involvement in the assessment of those individuals having practical knowledge relevant to the issue subjected to the application of the IRIDM;
- consideration of changes to other safety features introduced by the chosen option; and
- consideration of both short and long-term implications/consequences of the decision.

3.2. STAGES IN PERFORMING IRIDM PROCESS

The IRIDM process starts with the analysis of its applicability for the issue under consideration as illustrated by Fig. 2. It is expected that the IRIDM process is not applicable for issues requiring immediate decision or those where legal or regulatory requirements enforce a specific solution for the issue under consideration. In this case other decision making methods can be applied that might not consider some or all CFs typical for IRIDM process. Also, when sufficient information is not available to assess all potential options, the full IRIDM process focused on selecting the options that provide solution for the issue under consideration is postponed until all the required information is collected. It may also be necessary to make an intermediate decision, based on incomplete information (e.g. whilst awaiting results of an R&D programme) before a full IRIDM can be carried out. Both the immediate and intermediate decisions are, preferably, such that that they do not mean that another option cannot be implemented, if the full IRIDM process when completed suggests another solution.

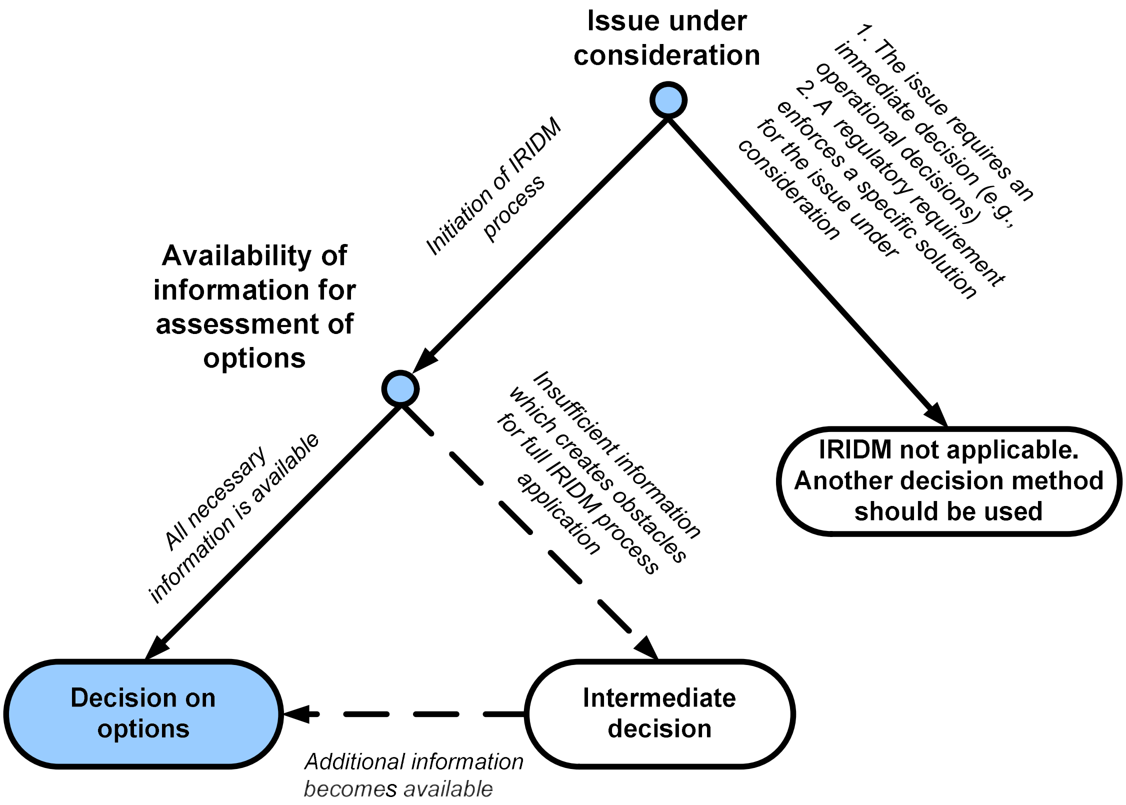

FIG. 2. Applicability of IRIDM for the Issue.

The general process for applying the IRIDM is illustrated in Fig. 3 and includes the following main stages:

Stage I	Characterization of the issue and team formation;
Stage II	Preparation for the evaluation of the options against the CFs;
Stage III	Assessment, integration and documentation;
Stage IV	Selection of the option to implement by the DM; and
Stage V	Implementation of the selected option and performance monitoring.

The stages listed above reflect the logical order of tasks to be performed. Some of the associated activities may be performed in parallel. Hence the order of stages does not represent a sequence in time. Iterations between the different stages may also be necessary.

After implementation of the selected option, the consequences are monitored.

The IRIDM process as carried out in the organization is also periodically reviewed and improved if deemed necessary.

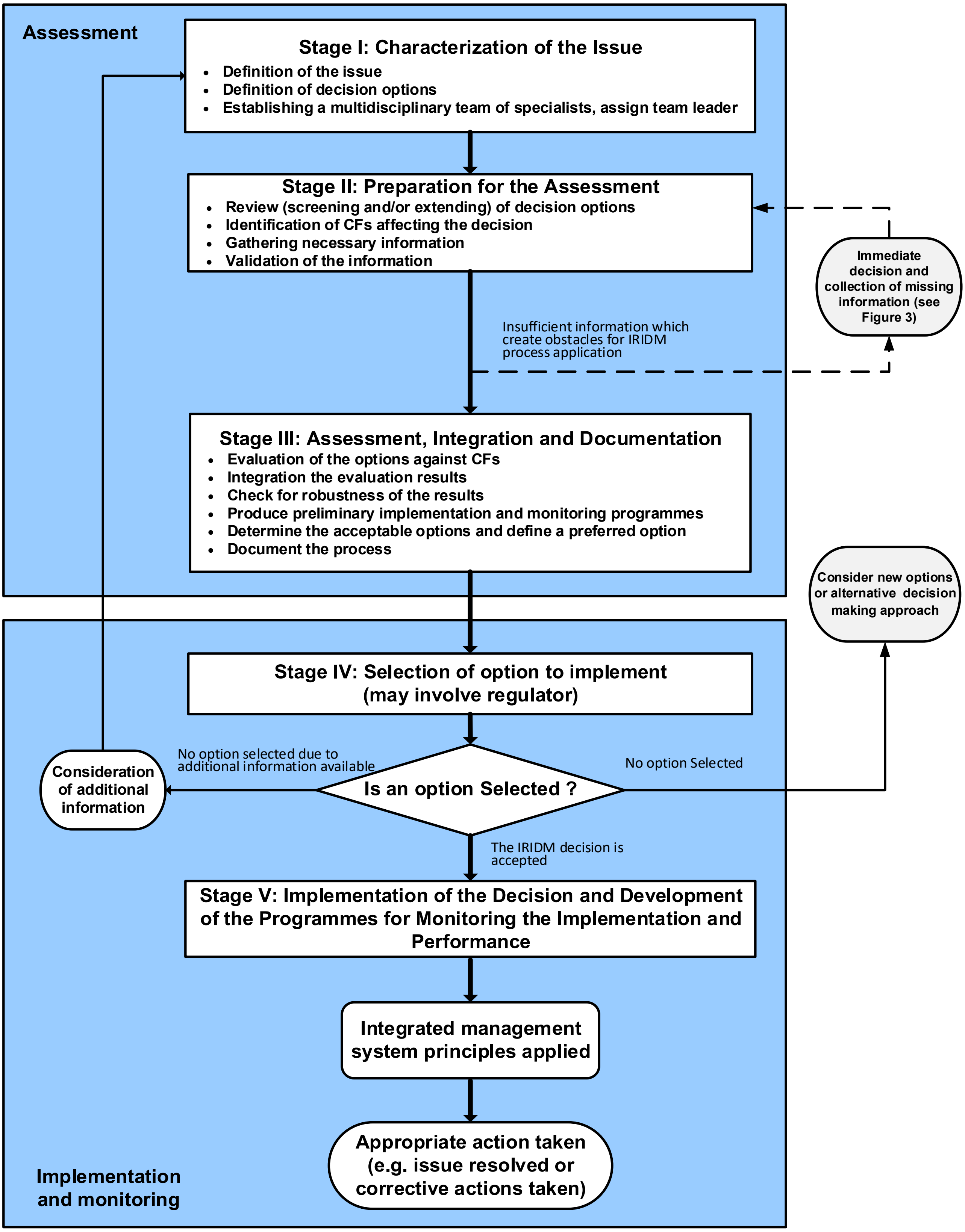

FIG. 3. IRIDM workflow.

3.3. CHARACTERISATION OF THE ISSUE AND TEAM FORMATION

The purpose of Stage I of the IRIDM process is to derive a clear and unambiguous definition of the problem or issue that needs to be resolved, select an initial set of options available, and form a team to analyse the options. Defining the problem or issue may seem at first glance to be an obvious task, but it is possibly the most important step as experience has shown that a failure to adequately define the issue can lead to incorrect, unsound, and unnecessarily costly decisions. Initially, it is the responsibility of the decision maker (DM) and management most closely associated with the issue to decide to apply the IRIDM process[3] and frame the definition of the problem and select the possible options to be analysed. At the beginning, this may be done in summary fashion; it is confirmed by the selected team when it is formed. It is obviously essential that the DM and management understand the IRIDM process and its implications.

The characterization of the issue needs to include a description of why the issue has arisen, the potential impact on safe operation, including possible impacts on human actions, and the time-scale required for resolution, if appropriate. The characterization needs also to include the identification of regulations or requirements (e.g. design basis, licensing basis, technical specifications), organizational factors, and/or arrangements regarding the interface with nuclear security that may be challenged by this issue.

Once the factual description of the issue has been precisely developed using the best available information, the next step is to identify the boundary conditions, i.e. the environment, in which an informed decision on the issue is to be made. This step involves, besides the determination of the time-scale for the resolution, consideration of the severity and expected duration of the conditions associated with the issue. Other aspects include a check of the need for, and availability of, specific analytical methodologies (e.g. PSA models of sufficient scope and quality, engineering models), relevant information and resources (e.g. subject matter experts) to conduct the various analyses in the evaluation of the issue.

Stage I of the process also includes the definition of the initial set of options regarded to be feasible to solve the issue. The number of options may be very different depending on the issue. Examples of issues and possible options and decisions from a regulatory, licensee and designers' perspectives are shown in Table 1.

[3] Implementing an IRIDM process may not require the use of a detailed formal system as described here. The need to consider various safety factors is likely to be necessary for almost all decisions. Whenever a decision is made, it needs to be recorded and the considerations that support the decision have to be referenced, but there may not be a need to carry out the detailed processing of considering options that a formal system requires.

TABLE 1. EXAMPLE OF ISSUES AND DECISIONS/OPTIONS

Issue	Options/decisions
Regulatory perspectives	
Evaluation and approval of a design modification	• Accepting or declining the proposed modification - this action either accepts the change as proposed, accepts the change only with compensatory measures or additional conditions, or rejects the change. • Delaying the decision – the normal rationale for this would be to have time to obtain additional information from the licensee or plant operator, obtain clarification from the regulator or seek change to regulatory requirements including changing licence conditions, etc.
Action following an event at the plant[4]	• Issuing a shutdown order – this action could require a short-term shutdown, a delayed shutdown within a specified period of time, a restriction on plant restart (if the plant was in shutdown state), etc., until certain conditions or compensatory measures are met. • Allowing continued plant operation – this action could allow continued operation with the implementation of compensatory measures, continued operation for a restricted time or until additional information is obtained, operation at reduced power until the next refuelling outage, or continued operation with increased monitoring, etc.
Licensee (plant operator) perspectives	
System modifications	• Select specific technical solutions for the modifications (can be several, each possible solution represents a single decision option)
Procedural changes	• Introduction of new procedures (operational, testing, maintenance, ageing management, etc.) • Modification of existing procedures (increase of testing frequency, extend the scope of surveillance, etc.)
Organizational/ management changes	• Restructure management system • Introduction of training for staff • Recruit more staff, etc.
Designer perspectives (examples are given for technical issues)	
Solve the hydrogen deflagration problem for a given reactor design	• No action is needed (hydrogen deflagration is impossible or cannot impact safety functions) • Install passive autocatalytic recombiners • Install active igniters • Inert the containment • Use the containment venting system for mitigation • Use a combination of the technical means mentioned above
Increase reliability of spent fuel pool cooling	• No action is needed (large time windows for accident management are available) • Reduce thermal loads (e.g. by limiting the amount of fuel elements in the pool or the total heat load) • Install additional cooling system • Increase water inventory in the pool • Use a combination of technical means mentioned above

[4] Depending on the nature of the event, it might not be a subject for IRIDM (see Fig. 2)

In addition, part of Stage I is to establish a multi-disciplinary team of specialists, who will evaluate the information supporting making the decision on the option, and to assign a team leader for the consideration of the issue. The DM and management that had initially framed the issue and the options select an appropriate team leader to lead the IRIDM process. The team leader needs to be experienced in the issue at hand and in project management procedures, appropriate to the issue, to ensure that the IRIDM process delivers the output required, i.e. the option(s) that are deemed acceptable adequately address the issue and meet the safety requirements.

He/she must determine the scope of the work based on its importance and the graded approach, see Ref. [1], decide on the specific disciplines of specialists needed, the means of communicating between the team members and any other organizations involved, whether external support is needed beyond the capabilities of the organization itself, whether the work can begin or more information is needed, and how the process and decision will be documented.

The disciplines represented by the different team members strongly depend on the specifics of the issue under consideration. Different approaches for establishing a multi-disciplinary team of specialists have been found in practice, see examples in Annex II including having a permanently installed core IRIDM team that can be expanded by additional experts; or forming a dedicated team (project team) for an issue.

The team needs to have all the required skills necessary to address the issue and the options under consideration. These skills have to cover technical disciplines such as radiation protection, plant operations, maintenance, engineering, safety assessment (deterministic and probabilistic), licensing, etc. The team leader must assure through the DM and his management that adequate resources in terms of manpower and budget are allocated for the project and responsibilities of the participants of the IRIDM process defined. External resource experts (consultants, contractors, manufacturer representatives) may be engaged to provide the required technical support. Training of the team members and responsible managers for IRIDM process need to be provided to ensure full understanding amongst the team members and to smooth the analysis process.

Due to the problem of revealing sensitive information regarding security, a security specialist is (for a broad class of issues) consulted to determine if he/she needs to be included in the IRIDM team. The security specialist would also determine the dissemination of any security information.

Once the team is formed, the team needs to confirm or to propose modifications to the definition of the problem or issue and the selected options to the DM and applicable management.

4. PREPARATION FOR THE ASSESSMENT

4.1. REVIEW OF PROPOSED OPTIONS TO ADDRESS THE ISSUE

Stage II of the IRIDM process starts with a detailed review of proposed options. This review builds on the confirmatory review of DM/management option selections in stage I that occurs with team formation. The review of the options may lead to extension or reduction of the initial set, because they may have been defined when insufficient information was available and/or not all experts required were involved in the process. The basis for the decision on which options will be developed, and included in the IRIDM process, needs to be clearly recorded.

The reasons to disregard some of the options may include the following:

- The implementation of the option is very complex;
- The time to implement the option is insufficient; or
- The costs of the implementation of the option are very high and it does not provide commensurate benefits to safety.

The reason for extension of the list of options may be additional information provided by the IRIDM team member newly involved in the discussion or additional information became available.

This review of options is useful, because it provides a final set of options, that meet broad acceptance criteria, and defines the factors that are relevant in addressing the issue. A review of options (screening out some of them or adding new ones) can be repeated at later stage of the IRIDM process. In such a case, some of the steps related to gathering and analysing the corresponding technical information may have to be repeated. For implementing an IRIDM process, it is preferable that the retained set of options contains alternatives, although in some circumstances only a single option may be considered.

At this Stage the need to allocate additional resources (e.g. financial, expertise) to the team performing the assessment can be identified.

4.2. IDENTIFICATION OF THE CONSTITUENT FACTORS RELEVANT TO THE IRIDM PROCESS

The next step of Stage II is to identify the CFs relevant to the issue under consideration. The list of CFs associated with each Key Element of the IRIDM process usually includes, but is not limited to, those presented in Table 2. Further details on these CFs, associated requirements and characteristics are provided in Annex I.

TABLE 2. EXAMPLES OF CFs REQUIRED FOR IRIDM PROCESS

Key Elements	**Constituent Factors**
Standards, good practices	• Regulations developed by the regulatory body • Conditions attached to the licence • Technical Specifications • Standards developed by professional bodies • Good practices – technical standards, IAEA safety publications, etc.
Operational experience	• Operational events • Safety performance indicators • Other experience feedback
Deterministic considerations	• Safety criteria • Defence-in-depth including: - Safety margins - Single failure criterion - Fail-safe design - Equipment qualification - Results of accident analyses - Protection against external and internal hazards - Prevention of common mode/cause failures, etc.
Probabilistic considerations	• Qualitative insights • Quantitative measures
Human and organizational considerations:	• Management Systems • Normal Operating Procedures • Maintenance arrangements and procedures • Emergency Operating Procedures (EOPs) • Severe Accident Management Guidelines (SAMGs) • Training received
Considerations regarding the interface with nuclear security	• Physical protection of a nuclear facility • Security of the nuclear material on the site
Other considerations	• Radiation doses during normal operation and implementation of changes • Costs • Economic benefits • Results of research • Remaining lifetime • Waste management • Decommissioning • Environmental impact

Depending on the issue and the options being considered, not all the CFs may be required for the decision; therefore, a systematic analysis must be performed to identify those that are relevant. The completeness of the set of CFs considered is an essential requirement for the IRIDM. The lack of one or more relevant CF may lead to non-optimal or, even wrong, decisions. The identification of CFs relevant to the issue can be represented in a relevance matrix shown in Table 3 where, as an example, identification of the relevance of different CFs related to deterministic requirements is shown against an idealised set of options so that the set to be used can be chosen. The whole team is expected to be involved in this process and agree on which factors are relevant.

TABLE 3. EXAMPLE OF THE RELEVANCE OF THE CFs RELATED TO DETERMINISTIC CONSIDERATIONS TO A SET OF OPTIONS

Considerations	Options	Option 1	Option 2	Option 3	Option 4
Deterministic Considerations/ Defence-in-Depth	Safety criteria	X			
	Safety margins		X	X	X
	Single failure criterion	X	X		
	Fail-safe design				
	Equipment qualification	X		X	
	Physical separation		X		
	Redundancy and diversity	X	X		
	Safety Analysis Results		X		X
	Others			X	

Note: in Table 3 “X” means that the factor is relevant to the issue and option.

For this example, in Table 3, fail-safe design is not considered relevant to the issue for any of the options. Therefore, it can be removed from further analysis and needs not to be included in the list of CFs that will be considered.

Similar analysis must be provided for all KE to identify the relevant CFs. It is important to recognize that the KEs and their CFs s are in many cases interdependent[5] and the dependencies need to be considered in the integration part of the IRIDM process (see Annex IV).

After identifying the relevant CFs, the technical information required to evaluate each option against the factors must be specified. The information requirements need to be specifically stated and documented before the information is gathered in the next step. For the same CF different options may have different technical information requirements. To specify the needed technical information, a set of physical parameters or technical characteristics may have to be defined. For example, with respect to PSA information, it may be necessary to define the most appropriate risk metrics to evaluate the option in relation to the issue. Possible risk metrics that may be used in the IRIDM process are presented in Annex I.

4.3. GATHERING THE NECESSARY INFORMATION

The next step is the gathering of all necessary technical information relating to the relevant CFs identified in the previous step needed to perform the evaluations of the options against the CFs. This provides the IRIDM team with all the necessary information to assess the options, and to select the options that comply with the requirements as expressed in the CFs. It is important that the information be systematically gathered, documented, and filed/cross-referenced to each option based on the information requirements. The gathering of information for the decision making process is distributed among the various IRIDM team members and efforts are taken to avoid duplication of efforts in this step. All technical information collected needs to be available to the whole IRIDM team.

[5] If two or more CFs are dependant, they have to preferably be combined so as not to give the underlying common factor excessive significance. One example is where the probabilistic assessment factor has been broken into several sub-components (such as core damage frequency, system reliability and component reliability). Since these sub-components correlate to each other, keeping them separate would lead to excessive weight being given to the overall probabilistic factor.

The information required is both qualitative and quantitative. It is important to understand that numerical information always includes qualitative considerations as well and these qualitative considerations may be of the same or even higher significance as the quantitative results. In addition, numerical results of analyses, deterministic and probabilistic, cost-benefits, etc. are always influenced by assumptions, boundary conditions, uncertain factors, and other limitations. Accordingly, while numbers are often calculated and reported as a mean or median value, actual numerical results are distributions. This type of information needs also to be included in the package of collected data, where available and essential for the selection of the preferred decision. Likewise, qualitative information may have implicit quantitative aspects, such as the choice of design basis events, or the number of staff available on site at specific times.

Considerations of uncertainty, their importance to the results, and the sensitivity of the results to the uncertain aspects have to be understood. It is beneficial that the numerical calculations are supported by uncertainty analyses, identification of assumptions made and sensitivity analyses to test the significance of those assumptions. Qualitative data is also subject to uncertainty. As far as possible, complete information needs to be clearly communicated to all the IRIDM team members and, where appropriate, other stakeholders.

To evaluate the different options against the relevant CFs as well as the effects of different assumptions, additional requests of information may be made at this step by the IRIDM team. For example:

- Additional safety analysis including sensitivity and/or uncertainty analysis with respect to critical modelling assumptions and uncertain model parameters to assess the range of possible changes in safety margins;
- Evaluation of human factors for operator actions (task analysis);
- The frequency of the incident/event/situation that causes the issue;
- A specific PSA analysis to obtain an assessment of the risk metrics relevant to the options;
- Reliability and availability analyses of SSCs;
- Detailed design documentation to evaluate the options against redundancy, diversity and physical separation requirements;
- More detailed information on equipment qualification and (for example) results of factory acceptance tests;
- The impact of the options on other issues of the interface with nuclear security;
- Stress tests for checking safety margins;
- Information about verification and validation of applied analytical tools; and
- Detailed information on organization and administrative aspects for safety arrangements associated with the option.

Such additional information can support the IRIDM team in its evaluation of the consequences of different assumptions for the individual options. The members of the IRIDM team must be aware about possible limitations of methods, models and tools used to provide the requested technical information. Therefore, this information needs also to be available for the IRIDM team for consideration in the IRIDM process.

It may be that not all the required information is readily available and additional analysis could be requested. This information may be provided by other experts (not members of the IRIDM team).

4.4. QUALITY CHECKING OF THE INFORMATION

All information used in the evaluation against the CFs has to be verified and validated to ensure that it appropriately represents the issue and options proposed based on the specified information requirements. Analytical tools and models used for the development of technical information, including deterministic safety analyses, PSA and/or other relevant probabilistic arguments, and other assessment results, need to have been validated and verified.

The analyses and results are questioned from the following perspectives:

- Has the appropriate cause and effect relationship been clearly established?
- Has the assessment or model been properly verified?
- Does the result make sense?

Aspects related to the validation of the quality of deterministic and probabilistic technical information can be found in Refs. [5–12].

4.5. INTERMEDIATE DECISIONS

As stated in section 3.2 it may be necessary to take an intermediate decision based on available information whilst awaiting further information from, for example, a research and development programme.

In taking intermediate decisions, conservative assumptions, biased in the direction of safety, are to be made in relation to that information which is not available and, to the extent possible, the principles of IRIDM are to be followed. The option chosen to be implemented needs, as far as possible, not to foreclose any alternative option that might result from later decisions. It is implicit that efforts are made to collect additional information and when it is available, a final decision will be made following the process depicted in Fig. 3 (see Stage II).

5. ASSESSMENT, INTEGRATION AND DOCUMENTATION

This section addresses Stage III of the IRIDM process – assessment, integration and documentation. Each of the steps in this part of the process is described. In addition, practices are provided on some of the aspects important for the implementation of the IRIDM process. Examples of applications of the IRIDM process from the Member States are provided in Annex II.

Stage III is an important part of the IRIDM process since, at this stage, an evaluation of the technical information associated with the issue and the proposed options is performed and the option(s) which adequately meet safety goals/expectations are identified, and a preferred option chosen, before being presented to the Decision Maker(s).

It is essential to ensure that all the stages of the IRIDM process are thoroughly documented to allow traceability of the analyses and rationales at all points. The final documentation needs to provide the arguments used to support the option(s) that are presented to the DM(s), including the reasons for choosing the preferred option.

5.1. IRIDM ASSESSMENT AND DOCUMENTATION

Stage III of the IRIDM process consists of the following steps:

- Evaluate the options against the relevant CFs;
- Integrate the results of the evaluation of each option considering evaluations of all the relevant CFs for that option - repeating the process to take account of additional information, if any becomes available. If all options are not in full compliance with one or more CFs consider compensating effects in other CFs. Upon completion of this step, a relatively clear picture of which options might be acceptable is obtained;
- Check the robustness of the results;
- Develop a preliminary implementation and monitoring programme, if appropriate;
- Determine which option(s) are acceptable, indicating, if appropriate, a preferred option, and
- Document the IRIDM process and results.

Each one of these steps is briefly described below.

Evaluation of the options against the relevant CFs

The purpose of this step is to evaluate the options against the applicable CFs to determine the degree of compliance of each option against that CF. This evaluation is based on the information and analysis results that were developed when the options were proposed and may be added to by information or analysis performed by the team members or subject matter experts during the evaluation process. The evaluation results in a statement of the degree of compliance of each option with each of the relevant CFs.

There are many ways to measure the degree of compliance of the option in relation to the CFs. The most direct approach is to measure the relative differences of all the parameters selected to represent the CF. Here we describe, as an example, a three-level approach; more details are given in Annex III.

Three degrees of compliance are defined:

1) Neutral – where the option adequately meets the safety requirements and other relevant acceptance criteria;
2) Reduced compliance– where the option does not fully meet all the safety requirements and/or other acceptance criteria.
3) Enhanced compliance – where the option provides a higher level of compliance than expected for some or all the requirements and/or better satisfy other acceptance criteria.

Qualitative and/or quantitative evaluations are carried out against each CF to determine the degree of compliance with the CFs dependent on the availability of quantitative technical information.

Qualitative evaluations do not, in principle, require sophisticated tools and methods but may still require complicated and detailed analysis. It may be necessary to apply a range of different assessment techniques to determine a suitable basis for judging the degree of compliance with the CFs. Where it is not possible to perform any analysis to obtain information (including quantitative) to support qualitative evaluation, expert judgement will be required, for example in cases where the requirement (e.g. organization and management) has no quantification measure by its nature. Depending on the complexity of the issue to be resolved, different degrees of expert judgement may have to be applied ranging from simple engineering estimates to a formalized expert elicitation process.

Quantitative assessment of the impacts depends on the nature of the CFs. For example, for deterministic or probabilistic considerations, the evaluation of the options can be quantitatively defined by performing appropriate analyses.

For deterministic considerations, analyses are required to establish either the compliance with existing design criteria or to identify the available safety margins should the option be implemented. These analyses may involve:

- Thermo-hydraulic and reactor-physics analyses;
- Structural-mechanical calculations;
- Fatigue analyses;
- Dose considerations to workers and/or the public, etc.

For probabilistic considerations, analyses are required to identify the likelihood of specific consequences that may be associated with the implementation of the option and may involve:

- Use of a full PSA model, if available (the model might require modification and requalification to account for specific aspects of the options if not originally modelled);
- Reliability and maintainability analyses for SSCs affected by the option;
- Development and quantification of specialized risk models for addressing specific issues (e.g. loss of station power, external flood frequency, etc.).

Similar quantitative analyses can be performed for some evaluations for other CFs. For example, risk considerations may be useful as a part of cost benefit calculations or to consider the risks during the implementation of the option. Reliability and maintainability analyses may also be required as a part of the evaluation of operational experience to judge whether a proposed option leads to an improvement of the operational performance of an SSC.

For options where implementation may affect security, an analysis may have to be performed on how the option affects the arrangements for physical protection, see Ref. [13].

Integration of the Evaluation Results for each Option

The overall objective of this Stage is to integrate the CF evaluations for the options to derive an overall evaluation of the options. By the end of this step, it should be clear which options are the most optimal in terms of a balanced compliance with the CFs.

The integration of the assessment results is the process that derives a decision from a consideration of all the factors that affect the issue. It is basically an evaluation of the overall merits of each decision option by combining the assessments of the various factors, usually weighted in some way, into an overall ‘value’. Assigning a ’value’ to each decision option allows the decision maker to have a clearer understanding of the relative merits of each option. A properly organized process is expected to lead to a more robust and defensible decision, and therefore remove a degree of subjectivity from the decision making process. However, the way in which values are assigned and the overall value determined may have a bearing on the final.

It is important, therefore, that the decision making process is chosen in such a way that it is appropriate for the decision in question.

The IRIDM team must determine how to perform the integration of the evaluation results. The integration process needs to be based on a set of common criteria (which have been referred to earlier as safety requirements or goals) and can utilize scoring technique (decision analysis) that allows comparison of all the options, considering all the available information in relation to all the CFs considered. The evaluation process usually involves expert judgement to some extent. To reduce subjectivity a systematic process needs to be used, particularly in taking account of the uncertainty in the analyses used. Even if qualitative aspects are being considered, it is possible to convert the results into some form of quantitative scores.

It is worth mentioning that there is no single method that is universally accepted for carrying out the integration. Decision analysis has been the subject of study by many experts who have noted that most of the proposed approaches have advantages and disadvantages, see Ref. [14]. It is important to recognize that the various factors have different characteristics and different significance. The integration method is expected to reflect the relative importance of each factor and providing common measures for prioritization of the options, either through qualitative or quantitative means. If two or more factors are dependent, then they must be combined so as not to give the underlying common factor excessive significance. One example is where the probabilistic assessment factor has been broken into several sub-components (such as core damage frequency, system reliability and component reliability). Since these sub-components correlate to each other, keeping them separate would lead to excessive weight being given to the overall probabilistic factor. A discussion and short descriptions of possible methods are provided in Annex IV.

It is recommended that a consensus approach be used in the integration process and that it is carried out in some form of meeting of the team members. Good safety decisions usually do not result from voting systems, however well they are defined. Any use of voting must always be done carefully to avoid the pitfalls such as the effects covered by Arrow's Impossibility Theorem, see Ref. [15]. However, if several options are determined to be acceptable, using weighted voting can be a useful way of making a choice between them. In this method, each CF is assigned a weight corresponding to its importance for the issue under consideration and the weight is applied to the degree of compliance with the CF. This approach allows an overall score for each option to be determined, if it is possible to give consistent values to the CFs bearing in mind their different natures (qualitative and quantitative), and hence to select the option with the highest score. Examples of this approach are presented in Annex V.

Note: it is assumed that mandatory requirements are always complied with for each of the options (or that option is automatically rejected), but it may be that some options require small changes to regulatory requirements or licence conditions. If this is the case, a high scaling value is always assigned to the relevant CFs unless the option itself includes the request for changing the regulation.

The process of integration may require that there is a need to return to some earlier phase to repeat the evaluation of an option. There are two reasons why this might be necessary.

1) Firstly, during the evaluation new information may become available or the evaluation open new areas that need to be investigated. This could lead to an option either being removed from or added to the list of acceptable ones and may change the view on which is the preferred option.
2) Secondly, none of the options may be found to comply with all the CFs – to use the terminology of section 5.1, each option will have a 'reduced compliance' for at least one CF. However, the options may also have 'enhanced compliance' for other CFs, so it may be possible to compensate by considering the CFs holistically. This trade-off, which is explored in the iteration process, is an important advantage of IRIDM over methods that simply have a list of requirements, which must all be met. The consideration of the overall risks allows the trade-off to be achieved in a consistent manner so that the overall likelihood of adverse consequences can be balanced and shown to be acceptable. It is important to note that any failure to fully meet the expectations of a CF needs to be considered carefully – and certain factors must be met fully if they are mandatory requirements. The process of integration must also consider whether proposed trade-offs lead to unacceptable results; the lack of compliance with a safety factor may be so great that it is not possible to compensate through other factors.

Check the Robustness of the Results

Checking robustness of results entails understanding the uncertainty in the results and the sensitivities to the uncertainty. All analyses and information that contribute to the IRIDM process will be subject to uncertainty and this must be considered in the decision making process.

To assist in understanding the sources of uncertainty and assessing the effect that they may have on the selection of the preferred option, it is important to classify the technical information submitted to the team into: a) facts, b) assumptions, c) model predictions, d) logical conclusions (derived from the previously listed information). It is also important to identify information gaps.

This approach reflects the taxonomy of knowledge frequently used in risk management distinguishing between:

- The known knowns (treated facts);
- The known unknowns which can be dealt with by considering expert judgement on the model predictions, testing whether the conclusions are logical and applying uncertainty analysis by propagating uncertainty distributions of parameters;
- The unknown knowns (information gaps) which can be dealt with by requesting additional information or additional expert judgement;
- The unknown unknowns which can be dealt with in the integration process by aiming at achieving a robust solution by using conservative assumptions, worst case analysis and data and actively searching for 'cliff-edge' phenomena.

The analyses carried out by the IRIDM team members in evaluating the options against the relevant CFs and integration of the results are inherently associated with significant uncertainty; therefore, the analyses include consideration of the effects of uncertainty in the process. There are many sources of uncertainty that need to be considered in the deterministic and probabilistic assessment processes and they are generally categorized as either aleatory variability (often called 'aleatory uncertainty') or epistemic uncertainty (see Annex VI for details). Aleatory variability is associated with the stochastic or random behaviour (e.g. time to component failure, material properties, plant initial physical parameters) and cannot be reduced by further studies within the boundaries of the same model. Epistemic, or 'state-of-knowledge', uncertainty is due to lack of adequate knowledge and can, in principle, be reduced as more information becomes available. Epistemic uncertainty arises when making statistical inferences from data and from incompleteness in the collective state of knowledge about how to represent plant behaviour in the plant model, both qualitative and quantitative (e.g. probabilistic and deterministic).

Generally epistemic uncertainty relates to the degree of knowledge (or degree of confidence) in the completeness or validity of the plant model in reflecting the design and operation of the plant and predicting the response of the plant to accidents.

The way to address uncertainty depends on the source and nature of uncertainty and the context of the issue under consideration; therefore, no specific method to address uncertainty is recommended in this report. However, it is stressed in that appropriate consideration of uncertainty always to be provided with the objective of achieving a robust decision. More discussion on the uncertainty and how they can be addressed in the IRIDM process can be found in Annex VI.

Treatment of uncertainty in probabilistic analysis

Useful information on the treatment of the uncertainty in probabilistic analysis in the decision making process can be found in Refs. [16–18].

Treatment of uncertainty in deterministic analysis

When evaluating an option against deterministic criteria, the members of the IRIDM team must consider that there may be significant uncertainty associated with the analyses presented to the team. It is important to ensure that the result of the assessment of the options is not sensitive to uncertainty. This can be achieved through considering sensitivity analysis covering the reasonable range of values that represent the uncertainty of input and modelling parameters. If the results of the sensitivity analysis drastically change the evaluation against the CFs and hence the decision on an option, it suggests that it needs to be better defined and a further iteration in the assessment is required. Alternatively, careful conservative assumptions can be used as a way of covering uncertainty.

Treatment of uncertainty related to expert judgement

In some cases, the IRIDM process relies heavily on information obtained from expert judgement. Expert judgement brings additional uncertainty to the IRIDM process. There are no recommended methods on how the uncertainty coming from expert judgement is considered in the decision making process. However, to reduce such uncertainty, a formalized expert elicitation process always to be used. Usually, the formation of an expert panel involving experts of all relevant disciplines is part of such a formalized process. Depending on the issue, different methods for expert elicitation are possible, see for example Refs. [19–21]. Where multiple experts are consulted, care needs to be taken to identify aspects of their judgment that differ significantly. If it is not possible for several experts to arrive at a consensus, then the sensitivity of the result to the relevant aspect needs to be investigated. Disagreements in expert judgement and lack of confidence in the expert's assessment represent significant sources of uncertainty and need always to be documented.

Sensitivity Analyses

Sensitivity analyses are also an important process in understanding the impacts of uncertainty. Sensitivity studies need to be designed to test the results by varying the factors and inputs affecting the decision (e.g. assumptions, input data, parameters used and individual expert opinions.). The acceptable option(s) may change because of a better understanding of the sensitivity to variation in the factors and hence the importance of uncertainty.

An option with an initial high ranking, in terms of its benefit to safety, but with large uncertainty may not be preferable to one that is not ranked as high but has less uncertainty. Consequently, the process for evaluating the options may need to be repeated using better information, less susceptible to sensitivity, until concurrence on the final result is obtained.

Once the uncertainty in the results and their sensitivity to variation are sufficiently understood, it is important to perform a reality check, i.e. 'does the decision make sense?' The option(s) needs to be checked against the basic principles underlying the IRIDM process as listed in Section 2.2.

The IRIDM process described in this publication is defined in a way that the output of the process complies to these principles; however, if the output is not in compliance with the principles, then the team needs to thoroughly revisit earlier stages to identify the reasons for non-compliance. When the reasons are identified, it may be that the options that are now in the acceptable group are different; indeed, it may be that no options are acceptable in which case it will be necessary to define additional options.

Preliminary Implementation and Monitoring Programme

The preferred options need to be supported by a clear understanding of how they will be implemented and monitored; the proposed implementation method to be subjected to evaluation against the CFs. For example, if the option is a modification to an SSC, the proposed implementation method to be evaluated against the relevant CFs (e.g. relevant safety standards) during the IRIDM process and to be employed for implementing the option. A preliminary programme for monitoring implementation and subsequent operation is expected to be a part of the outcome of this stage of the IRIDM process. Details on the implementation and monitoring programmes are described in Section 6.2.

Recommendation of Options

The final step is to present to the DM(s) the list of acceptable options together with a preferred option which is considered optimal in relation to addressing the issue and IRIDM principles. It may be that only one option is acceptable but in cases where there may be multiple acceptable options, the advantages and disadvantages of the other acceptable options are explained to the DM(s) and other stakeholders, as appropriate, with the reasons for the choice of the preferred option. The DM(s) then selects the option for implementation.

Documentation of the IRIDM Process and Results

Decisions made using the formal IRIDM process needs to be fully documented, reviewed and approved in a clear and consistent manner[6]. Documentation is needed to make the results of the IRIDM process transparent, traceable and reproducible, and to assure consistency in its applications. Consequently, data, methods, and assessment criteria used to support the decision of the IRIDM in every step must be well documented. For each evaluation performed, the technical adequacy of the methods and information input data used needs to be thoroughly documented, together with the assumptions used: uncertainty in the analysis also need to be documented.

The assessment of each option in reaching the decision needs to be documented. For each option, the evaluation has to address at least the following:

- How the option addresses each of the principles of IRIDM;
- How the relevant set of CFs has been identified and how options were evaluated against them;
- How sources of uncertainty have been identified and dealt with; and
- The degree of confidence in the conclusion of the process.

Once the acceptable option(s) have been determined, and a preferred option defined, they need to be fully documented.

The process of making the decision must also be documented including the following:

- Insights obtained from the IRIDM team during the process;
- How various factors were considered in reaching the decision;
- Factors not considered in the technical analysis of the issue;
- Any contingencies or need for subsequent decision points; and
- Performance measurement specific to the option(s).

This documentation is used to provide information to the DM(s) (see Section 6.1). It provides a good means of communicating the results of the IRIDM process to all the stakeholders and will help to ensure openness and transparency in the decision making process. In addition, it is now considered to be good practice that a summary of the main issues and results is made available to non-specialists including the public. Normally, the release of the documentation to such parties would not be done until the final decision had been made by the decision maker(s).

Annex VII contains details on the documentation of the IRIDM process.

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[6] This does not mean that in arriving at decisions that are intermediate, documentation is not required. All decisions with an impact on the interface of safety with nuclear security need to be documented, however they are arrived at. This section sets out some good practices on documentation that can be used in all situations.

5.2. IMPORTANT ASPECTS IN APPLYING THE IRIDM PROCESS

This section presents some examples of good practices and limitations that are important for applying the IRIDM process.

Conduct of the Process: The process can be successfully managed using several different methods but experience has shown that the determination of the relative importance of the factors and evaluation of individual options is best achieved using a meeting or (in the case of problems with many potential options) a series of meetings involving the experts from each relevant discipline. Where a meeting is not practicable, a 'round robin' approach[7] may be employed but care needs to be taken to ensure proper communication among participants and to ensure auditable records are kept, see Ref. [14]. There are also other techniques, e.g. Delphi[8], see Ref. [22], which can be used.

Preparation and Representation: Experience has shown that the quality of the result is strongly influenced by the thoroughness of the preparation and the balance in representation of relevant disciplines during the determination of the relative importance of the CFs and evaluation of each option. In the preparation, sufficient information and analyses need to be collected to allow objective decisions to be made.

This material needs to be shared with all participants. In choosing those who will participate, it is important that all relevant disciplines are represented but it is equally important to ensure that representation includes an equitable distribution of all types of expertise.

Managing Participants: When determining the relative importance of the CFs and evaluating individual options, it is important to conduct the process with care. It is important to concentrate on those opinions that are founded upon fact or relevant technical experience. The process needs to ensure that strong characters do not dominate those participants with more relevant knowledge or experience and it may be beneficial to utilise a trained facilitator.

Maintaining Thorough Records: It is critically important that thorough records are maintained at each stage of the IRIDM process. This ensures that the basis of the final decision is traceable and auditable. Experience has shown that it is not unusual to have to revisit earlier stages because of additional information that comes to light as the process proceeds and documentation is expected to allow this to be done. In evaluating the quality of the IRIDM process documentation, the most important attribute is that the documentation is such that the IRIDM process conducted can be faithfully reproduced.

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[7] A "round robin" is an arrangement of two-way communication, when each party is involved equally in some rational order.

[8] Delphi technique is a procedure to "obtain the most reliable consensus of opinion of a group of experts… by a series of intensive questionnaires interspersed with controlled opinion feedback" (see [20]). The technique allows input from a larger number of participants than could feasibly be included in a group or committee meeting and from members who are geographically dispersed.

5.3. EXAMPLES OF THE APPLICATION OF THE IRIDM PROCESS

Since the application of an IRIDM process is not yet mature in many Member States, practical examples are provided in detail. Two Annexes supplement this publication:

1) Annex II gives a description of some real decisions that have been made using the IRIDM process to illustrate the IRIDM concept and process described in this publication.
2) Annex V provides illustrative examples on how the IRIDM process described in the publication can be applied to issues in a formal way.

It is believed that these examples may be helpful for the future development and application of IRIDM process.

6. SELECTION OF THE OPTION, IMPLEMENTATION AND PERFORMANCE MONITORING

This section addresses the final two stages of the IRIDM process as follows: Stage IV – selection of the option to implement by the DM and Stage V –Implementation of the decision and development of the programme for monitoring the implementation and performance. This section also discusses the application of formal management system principles.

6.1. SELECTION OF THE OPTION TO IMPLEMENT

In previous sections, it has been assumed that the evaluation of the options leads to a selection of the preferred option from a possible set of acceptable options. It has also been assumed that the DM(s), who can authorise implementation, may not have been involved in the IRIDM team which has carried out the evaluation of the options. Therefore, it may be necessary to submit the information to the DM(s) for approval to implement the option.

Those decisions that require regulatory approval will need to be submitted to the regulatory body for regulatory review of the proposed option and approval to implement it. The decision reached by the licensee may not be accepted by the regulatory body if it is too much influenced by economic factors (such as the cost of proposed modifications or the costs of plant outages while the modifications are made) which may not be considered or given a very low importance by the regulatory body in making its decision based on safety considerations.

The DM can react in many ways to the information submitted:

1. the preferred option is approved (with or without additional conditions being imposed);
2. the preferred option is not approved based on additional information that the DM has available to him/her (it could be possible that additional information from outside could affect the DM);
3. the preferred option is rejected, but another option from the set of acceptable options is approved;
4. the preferred option is rejected, but the DM may require further evaluation of one of the options that is not in the acceptable set; and
5. the preferred IRIDM option is rejected and none of the options is approved.

Where the DM selects one of the options put forward as result of the IRIDM process (preferred option or another acceptable alternative), the decision is documented, and the option is implemented and monitored. It is also possible that an option is accepted with additional conditions being imposed. In this case, the DM is expected to explain and document the reasons, including any differences in the factors or weightings considered that are different from those used while evaluating the option.

Where the preferred option is not approved by the DM, due to additional information or constraints that should be considered, the IRIDM process needs to be revisited taking into account new information available.

Where all the options are rejected by the DM, the issue has to be reconsidered and another set of options needs to be defined. It is essential that the DM makes clear the reasons for rejecting the options, and this information is to be considered in the next iteration of the IRIDM process both for the current issue and further applications of IRIDM.

6.2. IMPLEMENTATION OF THE SELECTED OPTION AND PERFORMANCE MONITORING

Implementation of the approved option and performance monitoring are also key stages of the IRIDM process. However, no specific processes for implementation and monitoring programme are required that differ from those in the management system of the implementing organization and/or, where appropriate by the regulatory body. Once the implementation has commenced, it is important to ensure that implementation of the option is monitored as part of the relevant management system(s). The objective of this monitoring is to ensure that both the implementation is performed consistently so that the IRIDM decision is effective in addressing the issue.

Implementation of the Approved Option: The approved option is to be implemented according to the details outlined in the IRIDM documentation. Therefore, the IRIDM team needs to periodically review the implementation of the approved option as it progresses. If the implementation is found not to be satisfactory, appropriate actions are to be taken in line with the management systems in place.

Monitoring Programme: Specific monitoring programmes, structured to gather performance information and feedback concerning the implemented option, need to be developed. The objectives of performance monitoring of the option implemented are to ensure that it produces the intended results in relation to the issue and that there are no unintended effects.

The programmes include at the minimum performance monitoring objectives/criteria to be monitored, means to monitor performance, and methods of feeding the information back, and taking corrective actions as necessary.

Feedback from the Monitoring Programme: If the performance is not satisfactory, the option is to be modified if possible or corrective/compensatory actions need to be put in place to enhance the performance. Feedback of information and corrective actions need to be accomplished in a timely manner such that unsatisfactory performance is detected and corrected before safety is compromised. The results need to be traceable to their source and consistent with previously reported results or changes from previously reported results. The process for feedback and reporting has to be clear.

The results of performance monitoring are to be provided to appropriate individuals and organizations. Some aspects can be provided on an on-going basis, some within specific periods, and some on an as-needed basis. The results are expected to be quantitative, wherever possible, and they need to be presented in relation to, and in context with, pre-established criteria and guidelines.

Feedback to the Auditing of the IRIDM process: The feedback from performance monitoring is one of the inputs to any audits performed for further enhancement of the IRIDM process. In case of unsatisfactory performance, the whole IRIDM process needs to be thoroughly reviewed, with reasons for unsatisfactory performance (if so) to be identified and necessary corrections to be implemented. It is important to note that at early stages of the application of the IRIDM process, it is possible that certain hidden problems in the process itself might exist. However, it is expected that less deficiencies in the process will remain as more experience is gained in the practical application of the IRIDM programme.

7. SETTING UP A FORMAL IRIDM CAPABILITY

Setting up the capability to use the IRIDM approach within an organization requires some preparatory work to be carried out.

It is recommended that this be done using a formalized and structured approach that to be set up as shown in Fig. 4 and is discussed below. The IRIDM implementation programme must be supported by sufficient resources and budget.

An IRIDM process can be established in any organization that must make safety decisions (regulatory authority, nuclear power plant, design organization, etc.) at various levels. The main requirement in using an IRIDM process is that the individual experts work as a team, integrating their expertise to reach a decision on the acceptability of options proposed, rather than working independently.

7.1. SAFETY GOALS RELATING TO AN IRIDM PROCESS

One important prerequisite for introducing an IRIDM framework is that there are pre-established safety goals and acceptance criteria in place. Safety goals and acceptance criteria provide a platform for making decision on what is acceptable and what is not while evaluating various IRIDM options.

Ideally, safety goals and acceptance criteria correspond to the level, at which the IRIDM process is going to be applied (e.g. society level, regulatory level, utility level, site level, installation level), and be commensurate with the needs of the organization introducing the IRIDM framework. If safety goals and acceptance criteria have not been developed in the Member State by the regulator, they still may be developed within the organization wishing to implement the IRIDM process. Generally, application of the IRIDM process requires that the goals be developed by an appropriate authority (e.g. it is not appropriate for a licensee to undertake IRIDM at the society level, nor is a licensee authorised to establish safety goals on behalf of a society).

The Fundamental Safety Objective of nuclear and radiation safety is to protect people and the environment from radiation risks, see Ref. [2][9]. Therefore, any safety goals that are used in the decision making process must, ultimately, be linked to this aim.

Reference [23] suggests three levels of safety goals to support the Fundamental Safety Objective placed at the top of the hierarchy of safety goals.

Upper level: The safety goals at this level are aimed at specifying what constitutes sufficient protection of people and the environment from radiation risks considering all operational modes of all facilities and installations. Qualitative terms are used for interpreting what is needed to ensure sufficient protection in normal operation and accident conditions. For the latter, interpretation of the top-level safety goal in qualitative terms specifying risk to life and health may be used.

[9] Reference [2] provides the following fundamental safety objective: «The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation". The ten safety principles are provided, including discussion on protection from radiation risks.

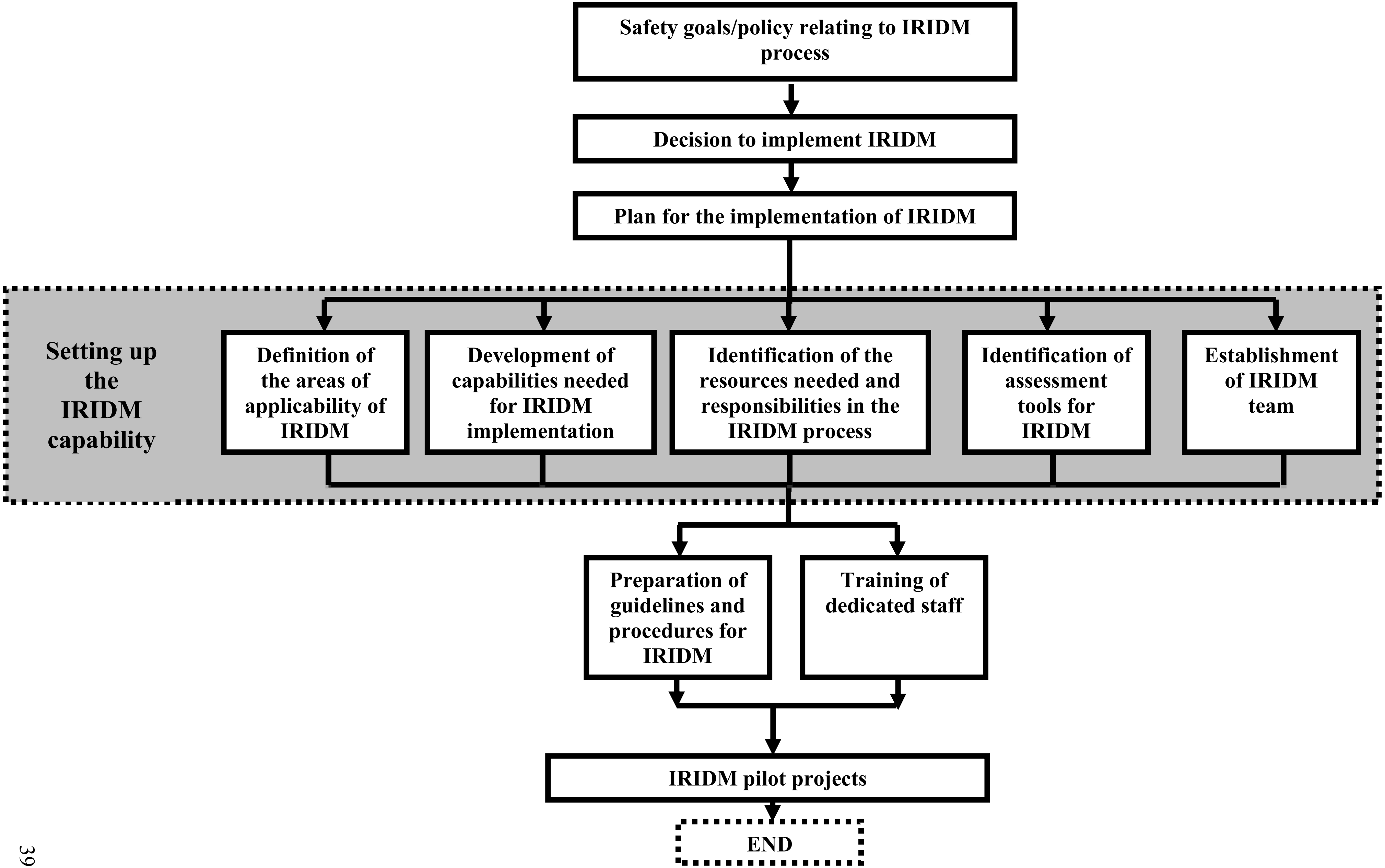

FIG. 4. Establishing the Capability for Setting up a Formal IRIDM Process.

This is often done by comparison with the levels of risks coming from other involuntary sources, e.g. “Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks”, see Ref. [24]. Specific formulations being used in Member States differ: there are examples of referring other voluntary and involuntary risks.

Safety goals at the upper level are technology-neutral and, where appropriate, could be formulated at a site level. It is important to formulate them in the way understandable by the society at large; this facilitates communication with the public.

Intermediate level: The safety goals at this level are aimed at formulating requirements for general safety provisions including technical and organizational measures based on proven approaches and good practices to ensure sufficient protection from radiation risks for normal operation and accident conditions. These provisions may include, for instance, Defence-in-Depth (DiD) considerations, providing sufficient safety margins, meeting International Committee on Radiation Protection (ICRP) criteria for workers and the environment in normal operation, etc.

Safety goals at this level may be formulated in qualitative and quantitative terms; the latter in turn may be either deterministic (e.g. maintaining allowed doses for workers in Design Basis Accidents (DBAs)) or probabilistic (e.g. the frequency of large radioactive releases for the whole site). Mostly, at this level, safety goals are formulated to cover site-wide and technology-neutral considerations.

It is useful to link each safety goal at the intermediate level to at least one upper level safety goal (e.g. using a specially developed labelling scheme); this will promote consistency and clarity in the definition of safety goals.

Low level: The safety goals at this level are aimed at formulating requirements for the necessary specific safety provisions for all facilities and installations at the site. Technology and facility specific safety goals aimed at assuring that all nuclear installations/facilities at the site jointly meet the respective intermediate level safety goals are specified here. These safety goals tend to be mostly quantitative, e.g. large release frequencies (LRF) for each NPP unit at the site. However, qualitative safety goals are also relevant for this level.

Similar to the intermediate level, it is useful to link each safety goal at the low level to at least one intermediate level safety goal (e.g. using the same labelling scheme); this will promote consistency and clarity in the definition of safety goals and help in evaluating compliance with the full hierarchical framework of safety goals.

Numerical safety goals, which are often related to risk metrics, are currently widely used and are considered jointly with qualitative safety goals. In this context consideration of compliance with risk metrics solely may not be appropriate, because in addition the requirement on balanced risk profile and balance between prevention and mitigation aspects need to be addressed. The importance of sound engineering and good management must also be emphasised as their positive impacts may be hidden in risk analyses that do not explicitly model them.

Deriving numerical criteria, in whatever form, that are acceptable to the public must be done in such a way that it is clear on how they are achieved. Understanding the risks posed by any nuclear facility requires a clear understanding of the relationship between likelihood (probability) and consequence. Unless this can be done, there will always be questions about the adequacy and acceptability of any decisions that are made. There are good reasons for suggesting that in communicating with stakeholders' numerical risk values need to be used sparingly and with great care.

7.2. DECISION TO IMPLEMENT IRIDM

The decision to implement IRIDM is a formal decision by management. Management needs to assure that adequate resources, training, and time are allocated for the implementation. The IRIDM process to be implemented needs to be flexible considering the scale of the safety decisions to be made, the time available, and the quantity and type of information that is relevant.

In some Member States, development of the safety policy encouraging IRIDM application by the regulatory authority can be used to promote discussions between regulatory bodies and licensees. In other MSs an agreement on using IRIDM can be the outcome of the consensus process between the regulatory body and the nuclear industry. However, the principles of IRIDM can be used by an organization even where there is no formal agreement.

7.3. PLAN FOR THE IMPLEMENTATION OF A FORMAL IRIDM PROCESS

After the decision to implement the IRIDM process is made, management must assure a plan or programme for IRIDM implementation is developed. Details of what the plan or programme should contain are included in sections 7.4 through 7.7. In providing for the development of an appropriate IRIDM implementation plan, management need to consider several factors that could affect the implementation within the specific organization.

The factors affecting implementation of an IRIDM process include:

- the existing organizational structure and management systems;
- the level of competence and capacity within the organization or available to it from external sources; and
- the availability, scope and quality of safety information and analyses (deterministic and probabilistic).

7.4. IRIDM IMPLEMENTATION PROGRAMME

The IRIDM implementation programme typically involves the following steps that are discussed in more detail below:

- definition of the areas of applicability of IRIDM;
- infrastructure and capabilities for IRIDM implementation; and
- identification of the resources needed and responsibilities, including establishing an IRIDM team[10].

[10] The IRIDM team may be a permanent feature of the organisation or a "virtual" team comprised of trained staff that are brought together when there is a need.

Areas of applicability of IRIDM

The range of decisions where a formal IRIDM process could be used is to be defined. This range is discussed in Section 2.3 and among others includes making decisions on major safety issues. However, the discipline and approach inherent in the IRIDM process can be applied in less formal ways, particularly when the time available is limited due to the need to respond to a safety issue. In these cases, only cursory evaluation of the options against the relevant factors may be possible but considering all the factors and the risks implicit in the options will help to promote the optimal choice. The areas where less formal IRIDM can be applied, and ground rules for doing so, are also to be determined.

Infrastructures and capabilities needed for IRIDM implementation

To apply the IRIDM process within an organization several capabilities need to be established amongst the staff. These capabilities are expected to cover all the components of the IRIDM process. In particular, capabilities for addressing the items listed in section 3.1 are needed.

Identification of resources, responsibilities, and assessment tools, including establishing of an IRIDM team

The resources in terms of areas of expertise, required to carry out IRIDM, need to be defined by an organization where IRIDM is to be implemented. The responsibilities of individuals in these organizations also need to be defined. In performing an IRIDM activity, it is necessary to appoint a team leader who is responsible for the formation of a multidisciplinary team within the organization and for organising the evaluation and subsequent processes. It is good practice to have staff trained in project management skills to take this role.

The multidisciplinary experts who will form the team that will be involved in IRIDM process (see Fig. 3) are expected to be capable of accomplishing all the assessments and analyses needed for the evaluation of the options against the KE and CF in accordance with Fig. 3. For example, experts with detailed knowledge of safety analysis and PSAs will probably be required besides technical tool expertise (e.g. stress analysis, and common mode failure analysis). Provisions for external technical advice may be needed in some specific areas and has to be included in the implementation programme.

In the end, the areas of expertise of the team need to cover all the technical and operational disciplines and include management and organization specialists. The team members need to be familiar with the general aspects of the IRIDM process before undertaking the process. Training in IRIDM, decision making processes, and understanding the importance of risk in all its connotations may be necessary to achieve this (see section 7.6).

7.5. PREPARATION OF GUIDELINES AND PROCEDURES FOR IRIDM

Guidelines and procedures are prepared within the organization preparing to use IRIDM, so that the process when implemented is carried out in a structured and systematic manner. The guidelines and procedures are expected to give practical insights on all aspects of the IRIDM process. The core IRIDM team provides the interdisciplinary experts who will be able to take the lead in drafting the IRIDM guidelines and procedures.

7.6. TRAINING OF IRIDM TEAM MEMBERS

All experts who will be part of the IRIDM teams have to be competent and qualified in their area of expertise, but are expected also to have a wide understanding, as far as possible, of the other factors that will be considered. Training of the team members and responsible project leaders for the IRIDM process needs to be provided to ensure full understanding amongst the team members and to support efficient application of the analysis process. It is also important that the DM is trained in IRIDM and decision making processes, particularly if he/she/they is/are not a member of the IRIDM team.

7.7. IRIDM PILOT PROJECTS

After setting up the IRIDM capability, selecting and training the team members and producing the guidelines and procedures, it is recommended that one or more pilot projects is carried out to test the methodology prior to a full implementation of the IRIDM within an organization. The experience gained from the pilot projects is to be fed back into the programme to refine the IRIDM process. This could include making adjustment on how a team is established, revising the guidelines and procedures, or providing additional training to the team members and DM(s) within the organization. It is particularly useful to encourage the team to consider the CFs together and to consider what trade-offs between them may be allowable by taking account of the effects on risks.

8. CHALLENGES OF THE IRIDM PROCESS

Any process designed to produce decisions will always exhibit some limitations/challenges. It is not feasible to account for all the possible situations that need consideration. The IRIDM process is not different. During operation of a facility, decision making cannot always await the production of detailed analyses yet decisions may have to be made. There are many cases when immediate decision must be taken, though more detailed analysis using IRIDM or other decision making approach can be performed later to clarify the option to be implemented does fit the purposes best (e.g. decision on material testing is done until all the details of different testing techniques are defined). Also, there are several situations where IRIDM may not be applicable (see details in section 3.2).

This publication thus tries to assist the user(s) in the general features of applying IRIDM with due understanding of potential limitations/challenges which may cause difficulties in early application of the process. Some of these limitations/challenges are discussed in this section, starting with those that might be met in setting-up the process.

***Regulatory issues*:** Some countries have prescriptive regulations that specify the approach to be used in decision making and may not include the use of PSA risk metrics. This would mean that change to the overall approach is necessary so that it is possible to establish an IRIDM process. The cost and effort involved in this may prohibit or at least slow down the introduction of IRIDM. A difficulty could be the introduction of regulations requiring the IRIDM process to be used for new NPPs but allowing existing facilities to continue without using this approach, which could lead to different safety measures being required. For existing facilities, it is often found that the requirements were derived from deterministic considerations and resulted in requirements which are unnecessarily stringent. Deterministic approaches often also do not fully cover all the accident sequences that PSA identifies so in some areas for existing facilities there may be an apparent need to increase safety measures. These competing effects may mean that, in cases where IRIDM is only selectively applied to new plants, the overall safety level will not, in fact, be lower when considering all existing plants. This could present issues that operators and regulators must deal with, especially with other stakeholders such as the public.

Scope, level of detail**:** In the initial stages of an IRIDM process the depth and scope of the considerations must be adequately addressed. Care needs to be taken to ensure that this is done based on the hazard/risk of the situation (graded approach) and not based on the information available, the resources or experts available or any time constraints. A formal IRIDM process will not be always possible to be completed in a short time, and does not have to be curtailed by artificial constraints such as time or removal of an expert from the team. If another more urgent or important issue arises affecting the completion of a IRIDM process it can be suspended until the new issue is resolved. However, as described earlier, there may be situations, due the need to take timely decisions, where it is not possible to include all areas of expertise. This may be compensated for by making more conservative assumptions in the applicable areas.

Use of PSA**:** It is important that IRIDM does not become simply PSA-informed: risk is not completely described by PSA and PSA is not the only tool to evaluate risk, though they are closely connected. One danger of over reliance on PSA is that many of the factors that have an obvious impact on risk either are not assessed by or, maybe are not even amenable, to this type of analysis, so their importance can be overlooked. For example, refresher training, provided it is well delivered, can improve safety and reduce the likelihood of human error, but it is difficult to assess the impact of different periodicities of such training on human error probabilities. The risk of radiological dose in normal operation is a concern on nuclear facilities but is derived from other considerations than PSA as it is defined in Refs. [1-5]. Risks can also be determined by simple observation, such as noting the proximity of ignition sources to flammable materials.

Use of Safety Goals**:** Use of safety goals in the IRIDM process requires careful consideration. If a formal well-elaborated hierarchical framework for safety goals is available, it is possible to evaluate what will be the impact of not meeting a specific low-level safety goal on the compliance with the upper level safety goal.

If a formal hierarchical framework for safety goals is not available, it is still useful to compile a list of relevant safety requirements and safety goals in use. Some of those safety requirements may actually fall in the category of ‘mandatory requirements’, some in the category of ‘deterministic considerations’, and some in ‘probabilistic considerations’. To not overlook the impact of certain requirements and to observe consistency in assigning importance factors and weights, it is worthwhile to analyse how certain requirements at lower levels contribute to meeting higher level safety goals.

Resources: Some degree of training may be required in understanding different factors and in applying IRIDM. Several different disciplines may be involved which can use different assessment approaches. It is important that the different experts can understand the importance of the information needs and evaluation approaches used by the other experts. Developing this understanding depends on the range of knowledge and expertise available and requires time. This could obviously affect the speed at which IRIDM can be introduced or implemented. In addition, if the different areas of expertise required to perform the IRIDM are the responsibilities of different organizational units, gathering a team and ensuring that the process can be carried out without undue interruption or interference may require temporary or permanent changes to the organizational structure.

***Composition of the multidisciplinary team*:** In some circumstances it may be difficult, if not impossible, to assemble the full range of expertise needed for an issue.

Attempts to carry out a formal IRIDM in this circumstance are to be avoided; either the issue is deferred until a full team is available, or an alternative approach is used. An IRIDM process in which a proper consideration of all factors is not carried out could potentially result in a misleading decision or outcome. External experts may be added to the team, see Ref. [25] to bring in specialist knowledge. The use of such experts by the regulatory body must not reduce its ultimate responsibility for making the decision, nor if used by a licensee, in any way diminish its prime responsibility for safety.

***Cultural differences*:** There may be difficulties of understanding between experts working on the different inputs due to the different cultures and understanding of how the issue is viewed. This may make developing a consensus view difficult. There may also be major cultural differences between different organizations. This may be a difficulty if this difference exists between the staff of regulatory bodies and those of the operators of nuclear facilities.

Training to understand risk inputs: One of key inputs to the IRIDM process is the results of risk assessments. However, it is hard to develop a multidisciplinary IRIDM team where all members are familiar with risk assessment techniques and its capabilities and limitations. This may lead to either overreliance or neglecting risk insights in a decision making process. To avoid both unacceptable situations it is important that all members of IRIDM team obtain sufficient knowledge on the concepts of risk and risk assessment techniques. All members of the IRIDM team need to understand and be aware of the requirements of radiation protection. Failure to understand these requirements may result in wrong assumptions on the acceptance of workers activities that lead to high exposures in normal and accident conditions.

Also, all members must understand the importance of engineering standards in reducing risk and producing safe designs through including conservative safety margins in designs and how human factors can affect risk and lead to safety problems.

***Balancing safety measures*:** Information evaluated in the IRIDM process may have different measures that cannot always be compared in a way that easily allows evaluating overall impact on safety. The ability to trade-off lower safety in one factor by compensating aspects in other factors is fundamental to the use of risk information in the integration process. For instance, an option may lead to a decrease in safety margins but at the same time result in a decrease of a risk metric quantified with the available PSA model. This may be because: a) safety margins are often established based on conservative assumptions and b) small changes in safety margins might not be captured in a PSA. Similarly, an option may lead to weakening of one or more levels of defence in depth, but the overall safety level could be improved at the same time due to strengthening other levels of defence in depth. More difficult is to balance risks that affect different aspects of safety. For example, comparing the change in risk to workers to risk to the public may be difficult if the result of the change causes an increased dose to workers when their actions for the event are intended to reduce the frequency of the off-site radioactive release to the public. These types of consideration raise a concern on how it is possible to judge the actual changes in safety level that cannot be evaluated using known risk assessment techniques.

In other words, the key questions are: ‘How can the overall effect on the range of risks that exist be evaluated and, importantly, communicated to stakeholders?’, and ‘How can it be demonstrated that sufficient compensation is achieved so that the overall risks are adequately low?’ There are no clear answers to these questions that are applicable to all situations as many factors need to be considered (e.g. assumptions accepted in the assessment, uncertainty involved in the process, absolute and relative changes in safety margins, strength of Defence-in-Depth levels, changes in risk metrics, quality and scope of risk analysis). However, IRIDM does allow a framework for considering these questions and the need to consider them is embedded at the early stage of establishing of the IRIDM process.

***Interface between Safety and Security*:** Nuclear security has many aspects apart from nuclear safety, e.g. personal safety and protection of property and other values; however, this publication focuses on nuclear safety. It is well known that measures taken for security reasons may conflict with safety and vice versa. For instance, security measures aimed at preventing an authorized access to the plant site may slow down the response of a fire brigade in case of emergency[11]. The IRIDM process can be an efficient tool to manage the interface between safety and security issues by considering security aspects as one of the inputs to the decision making process. In practice, the interface between safety and security may present challenges. The design and management of a nuclear facility needs to consider all relevant threats that challenge the ‘defence in depth’ for protection against nuclear accidents, but threats or malevolent actions are not always included in the scope of the assessment.

***Communication of the results*:** The issues above can make communication of the results difficult unless there is clarity in how the process was carried out. It is important that the basic process is maintained for all decision making, so developing guidelines for use by the team members, which are published (so that the public can see how the process is performed), is important. Likewise, documenting the process for an issue is important both for discussions between licensee and regulator, as appropriate, and communication to the public. Using IRIDM like a ‘black box’ from which a result emerges without explanation is likely to be rejected by the public. Communication has to aim at improving understanding about the decisions reached, but must also take account of the concerns of other stakeholders, particularly the public. Setting out the process of how the decision was reached and considering how different stakeholder concerns might affect the decision, are important aspects in gaining the trust and confidence of the public.

Nevertheless, IRIDM, knowing its limitations and areas of applicability, remains a process that is in line with general safety philosophy and can be used to satisfy the best its objectives aimed at providing efficient tool to maintaining adequate level of safety of nuclear facilities

[11] The accident at Fukushima Daiichi NPP on 11 March 2011 gives an example of how measures implemented at the security gate prevented timely relocation of diesel driven pumps and thus delayed the injection of water in the reactor of Unit 1 (see Ref. [26]) aimed to prevent core damage.

ABBREVIATIONS

CF	-	Constituent Factor
CBA	-	Cost Benefit Analysis
DBT	-	Design Basis Threat
DiD	-	Defence-in-Depth
DM	-	Decision Maker
DSA	-	Deterministic Safety Assessment
IRIDM	-	Integrated Risk Informed Decision Making
KE	-	Key Element
MAUT	-	Multi-Attribute Utility Theory
OEF	-	Operational Experience Feedback
PSA	-	Probabilistic Safety Assessment
QA	-	Quality Assurance
TECDOC	-	Technical Document
TM	-	Team Leader

TERMS AND DEFINITIONS

Constituent Factor (CF): Each Key Element (KE) comprises a set of factors called constituent factors (CFs) that define the safety goals/requirements of that KE; the options are then evaluated against the relevant CFs in the IRIDM process.

Decision Maker (DM): the person or group of persons that have the necessary authority to accept the decision option and allow its implementation. Depending on the issue and decision option, the DM could be plant manager(s), director of the design organization, head of Regulatory Authority, etc. The DM is also usually the person(s) who decides to implement the IRIDM process and is responsible for providing the time and resources to implement the process.

Decision (Safety Decision): the decision that has implicit or explicit impact on safety.

Integrated Risk Informed Decisions Making (IRIDM) process: a decision making process that applies to safety issues and takes account of many relevant factors in a systematic and holistic manner. Specifically, in the IRIDM process, risk considerations are explicitly addressed in integrating and balancing the decision, together with other factors (such as good engineering practice, sound organizational and administrative arrangements, knowledge that has been derived from experience, costs, radiation doses for personnel, etc.). It can be used for a wide range of licensee or regulatory issues that have safety implications for any type of nuclear facility.

Key Element (KE): A fundamental safety aspect that is considered in performing an IRIDM process.

Main Components of IRIDM: the main steps of the IRIDM process that typically includes: a) definition of the issue to be considered; b) identification and screening of decision options; c) selection the relevant KEs and CFs and evaluation of the decision options against constituent factors; d) making integrated decisions based on the results of the evaluation; e) implementation of the selected decision option; f) performance monitoring and e) application of corrective actions (if needed).

Option: option that can address the issue of the concern and will potentially be considered in the IRIDM process.

- Selected Option – the option selected by the DM for implementation.
- Preferred Option: the option which is defined from the acceptable options as being the optimal one.
- Acceptable Option: an option which both addresses the issue satisfactorily and adequately complies with the relevant CFs.

Robust Decision: the decision that remains acceptable across the range of technically plausible variations of input parameters.

Safety Goals: Safety goals is the whole set of necessary characteristics which, if achieved, assure that an acceptable level of safety is provided.

Team Leader (TM): the leader of a multidisciplinary team that is responsible for selecting the IRIDM team, leading the IRIDM process, and presenting the recommended decision option to the relevant person according to the management system of the organization (might be the DM or the person(s) who will present the recommended decision option for approval by DM).

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ANNEX I. KEY ELEMENTS AND CONSTITUENT FACTORS ASSESSED IN THE IRIDM PROCESS

One of the first parts of Stage II (see Fig. 4 of the main report) of the IRIDM process is to identify and gather all the information for the key elements and constituent factors, relevant to the options considered, which is required to make the decision on the specific issue being addressed and to validate this technical information. Section 2.4 of the main report identifies seven key elements of the IRIDM process which are briefly described with their constituent factors in Section 4.2:

- Standards and good practices;
- Operational experience;
- Deterministic considerations;
- Probabilistic considerations;
- Human and organisational considerations;
- Considerations regarding the interface with nuclear security; and
- Other considerations.

The following sections of this Annex provides more detailed information related to key elements and constituent factors that can be considered in the IRIDM process.

I-1. ELEMENTS RELATED TO STANDARDS AND GOOD PRACTICES

The basic legislation governing nuclear activities is presented in the laws of the Member State and in subordinate legislation such as governmental decrees[12]. The basic legal practices of the Member State will determine the amount of detail in the primary laws but will usually contain basic provisions for safety regarding nuclear activities. Nuclear activities typically include the construction, operation and decommissioning of nuclear facilities as well as handling of nuclear material and nuclear waste. These laws will also contain the obligations to obtain a licence and the obligations connected with the holding of a licence. In addition, they may outline the protection of the people and the environment against the dangers of ionizing radiation, and legal sanctions in cases of non-compliance with the regulations or the decisions of the regulatory body. In many Member States, more than one regulatory body is involved in the overall regulation of health and safety; in this case it is be necessary to consider all relevant legislation when starting an IRIDM process.

The key element ‘standards and good practices’ comprises four constituent factors that need to be considered in assessing the option. These factors are;

- Regulations developed by the regulatory body;
- Conditions attached to the licence;
- Standards developed by professional bodies;
- Good practices.

It is worth to be noted that the way regulations, standards, and good practices are developed and used will generally be very different in the different Member States depending on the style of the regulatory regime. The terminology used will also be different. It is implicit in the description here that those legally binding regulations that have been included in national law

[12] In some cases, the laws on health and safety will apply more widely than nuclear activities. In addition, there may also be laws relating to other aspects of the health and safety of workers and the public - these must be respected as well.

being passed by government must be met and are outside the process. The IRIDM process is limited here to those regulations etc., which the regulatory body has full power to vary.

It is worth to be noted that the way regulations, standards, and good practices are developed and used will generally be very different in the different Member States depending on the style of the regulatory regime. The terminology used will also be different. It is implicit in the description here that those legally binding regulations that have been included in national law being passed by government must be met and are outside the process. The IRIDM process is limited here to those regulations etc., which the regulatory body has full power to vary.

The first stage requires identification of the regulations, standards, and good practices that relate to the specific issue being addressed. Where the style of regulation is very prescriptive, there may be several very detailed regulations/requirements/guidance that would need to be identified and addressed and many of the standards and good practices may be included in the prescriptive documentation. However, this would not be the case where the regulatory regime is based on a non-prescriptive/goal setting approach since it is accepted that there is likely to be more than one way to achieve the overall safety goals. In general, it would be expected that the relevant regulations, standards, and good practices would be met unless the aim of the issue is to seek an exemption from a current regulation or to enhance the existing good practice.

I-1.1. Regulations developed by the regulatory body

In many Member States, a set of specific regulatory requirements is established to interpret legally binding documents in a more detailed manner or to introduce additional requirements. The requirements of the regulations usually cover the whole life cycle of a nuclear facility and may include requirements related to several topics such as quality assurance, design, safety review and assessment, training of staff, operational instructions and emergency preparedness. With respect to the IRIDM process, only those regulatory requirements which the regulatory body can vary need to be included as part of an option.

During the IRIDM assessment, any changes to the existing regulations that are required by the option are to be identified, and the reasons for the need to change are assessed. An important consideration is whether the change will have adverse effects on other facilities and activities. The assessment includes both the final situation after the change and any temporary suspension during the implementation of the change. It is also part of the assessment at this stage whether the option under consideration could affect regulations introduced by other regulatory bodies – which may include non-nuclear/radiation aspects.

I-1.2. Conditions attached to the licence

Based on and following the laws and regulations, an operating authorization (licence) is issued which will have conditions attached. These conditions can cover a range of detailed requirements for the facility/activity, which have a binding status for the licensee, but can be varied by the regulatory body and often include the appropriate limits and conditions under which the operation of the nuclear facility must be conducted.

The degree to which regulatory requirements are expressed in regulations or licence conditions depends on the regulatory body and the style of regulation.

Also, the level of detail in the documentation will also vary according to the style of regulation.

The IRIDM assessment needs to identify the changes required in any licence condition by the option and the reasons for the changes. Many of the changes will be subject to assessment under other factors e.g. a change to core outlet temperature may require a change in a licence condition but would also need to be considered under aspects of deterministic and probabilistic considerations. However, considering this change under this element ensures that the assessment to be conducted is focussed on the limit or condition.

I-1.3. Standards developed by professional bodies

Many professional bodies and other organisations have developed codes and standards covering such issues as engineering, management, safety analysis methods, and man-machine interfaces. In some cases, these may be specific to nuclear facilities such as relevant ASME codes. Some Member States refer to specific standards in their regulatory requirements, whereas in other Member States specific standards are not legally binding and can be considered more as good practices (see below).

In assessing an option, regardless of the style of regulation, the standards that have been used need to be identified, the reasons for using the standards (if not prescribed), and any deviations from them, justified. Standards provide a benchmark, and options that do not meet existing standards need to be justified.

I-1.4. Good practices

There is a wider set of engineering and managerial practices that fall under the general title of good practices that are derived from experiences from both nuclear facilities/activities and other industries. It is expected that plant operators and regulators will be aware of them and consider their application to options related to specific nuclear facilities. Systematic methods for capturing and disseminating good practices include IAEA publications such as the Safety Standards, Safety Reports, TECDOCs and mission reports. Some regulatory bodies issue guidance on good practices and their expectations to be met by nuclear facilities/activities, though these do not have a binding nature. Good practices include current developments in the design and operation of nuclear facilities.

Consideration of the level to which these good practices are met by an option is likely to be a major factor in the IRIDM decision making process.

I-2. ELEMENTS RELATED TO OPERATIONAL EXPERIENCE

The inputs from operational experience feedback, operational events, inspection findings, and safety performance indicators that relate to the specific issue being addressed by the IRIDM process need to be identified. Experience from operational experience feedback and events has been a major factor in the design and operation of nuclear facilities and includes operational experience from the events that have occurred at the facility itself, similar facilities and other industrial complexes, and evaluating the performance indicators for such facilities[13].

[13] Good practices and operational experience feedback are different aspects: the former is identified during inspections etc. whereas the latter are related to abnormal events and incidents.

In addressing a specific issue, a review of the findings from investigation of relevant events and the identified root causes and findings from analysis of performance indicators needs to be included and incorporated in the evaluation of the proposed options.

In the framework of the IRIDM process safety performance indicators collected for the specific facility/activity provide valuable information on the effective management of safe operation. Whilst the actual values of indicators are not intended to be direct measures of safety, safety performance can be inferred from the results achieved. The IRIDM process is expected to use this information, together with inspection findings, in assessing the potential impact of options on safety management performance.

I-3. ELEMENTS RELATED TO DETERMINISTIC CONSIDERATIONS

The factors related to deterministic requirements include: the safety criteria for the design basis and design conditions applied to the nuclear facility; the provision for defence-in-depth, including single failure criteria, fail-safe design, equipment qualification, physical separation, redundancy and diversity, and multiple barriers to the release of radioactive material; and the provision of adequate safety margins. Deterministic analysis is carried out in a robust manner by using specific techniques to deal with uncertainty.

I-3.1. Design safety criteria

Design safety criteria are the values of parameters and/or performance data of the nuclear facility which need to be met to ensure adequate safety in normal and accident conditions. As noted above, these may be included in regulatory documents or licence conditions. These criteria ensure a high degree of safety by requiring a robust analysis of fault sequences. They include a wide range of limits, e.g. from the limits on the peak clad temperature for the fuel in a nuclear reactor to the limits on the radiological doses to a member of the public at the exclusion zone boundary. Besides regulatory criteria, many licensees will develop their own additional more limiting safety criteria, which will ensure that they meet regulatory requirements.

In developing options, a comparison with existing safety criteria is undertaken. Where the implementation of the option leads to the deviations from the existing safety criteria, a justification must be provided to ensure that there is no breach in the safety criteria. In the IRIDM assessment, the impact of such deviations needs to be considered holistically as small changes to one safety criterion may have more significant effects on other criteria. Even if the criteria are met, there may be effects, such a reduction in safety margins (see below) that will need further assessment.

I-3.2. Defence-in-Depth

The provision for defence-in-depth is one of the basic requirements for ensuring nuclear safety. The overall aim of defence-in-depth is to prevent deviations from normal operation from occurring and, if prevention fails, to detect and limit their consequences, and to prevent any evolution to more serious conditions. This is achieved by a series of SSCs that provide a ‘nested’ set of barriers.

In relation to a NPP, the application of the defence-in-depth approach to the design and operation ensures that there are multiple means of carrying out safety functions and multiple physical barriers in place to prevent the release of radioactive material from the plant. A similar approach applies to other nuclear facilities and activities.

The overall aim is to ensure that sufficient attention is given to the prevention of events that can result in the release of radioactivity and the mitigation of the consequences.

For a nuclear power plant, the IAEA has defined five levels of defence-in-depth and four physical barriers for the confinement of radioactive material – see Ref. [I-1].

The way that each of the levels of defence-in-depth can be challenged and the ways that the defence-in-depth requirement can be met are described in Ref. [I-2].

To ensure independence[14] and the required reliabilities and availabilities of the levels, the following principles are invoked:

- System redundancy, physical separation and diversity;
- Independence of fission product barriers; and
- Defences against human errors.

The IRIDM assessment of an option is expected to ensure that defence-in-depth requirements have been addressed and sufficient reliability and independence of the levels and barriers is ensured. This assessment needs to be carried out systematically, level by level, challenge by challenge, mechanism by mechanism.

The options where the assessment concludes that one or more of the levels of defence-in-depth or one or more of the barriers to the release of radioactive material is significantly reduced (in the case of a modification) or made less effective would require a detailed justification. In some cases, implementation of a modification may result in temporary reduction in defence-in-depth and may require temporary additional compensatory measures.

Assessment of the effects on defence-in-depth can be made qualitatively (for example, in terms – high, medium, low) or quantitatively where the PSA can be used to determine the change in risk.

I-3.3. Safety margins

The provision of adequate safety margins for important safety parameters is a basic requirement for ensuring nuclear safety. In this context, the safety margin for a nuclear facility parameter is the difference between (or ratio of) the limiting value of an assigned parameter and the actual value of that parameter - see Ref. [I-3]. If the limiting value is exceeded then it is assumed that this would lead to the failure of a structure, system or component (SSC) or would lead to an undesired phenomenon or phenomenological transition. (Note that various Member States or organizations have various definitions of safety margin, components of safety margin, or approaches to safety margin.)

The most important safety margins relate to physical barriers against the release of radioactive material, which, for a nuclear power plant, are the fuel matrix and fuel cladding, the reactor coolant system boundary and the reactor containment. The limiting values defined for these physical barriers for a typical PWR include:

- Fuel matrix and fuel cladding: departure from nucleate boiling ratio (DNBR), fuel temperature, fuel enthalpy, clad temperature, clad strain and clad oxidation;
- Reactor coolant system boundary: pressure, temperature, stress and material condition;
- Containment: containment pressure and temperature, design leak rate.

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[14] Independence of the levels of Defence in Depth has to be understood in this publication in the way that each level of defence-in-depth could be maintained by the SSCs that remain available, even if all SSCs relevant to preceding levels fail.

In many cases, both the limiting value and actual value are not known precisely so that the safety margin cannot be quantified precisely. Therefore, for practical purposes, the safety margin is usually understood as the difference in physical units between the regulatory acceptance criteria (regulatory requirement) and the results provided by the calculation of the relevant plant parameter. The limiting value is generally referred to as the safety limit for which the plant is designed based on accepted codes and standards. The acceptance criteria are the criteria stipulated by the regulatory body based on national requirements and international norms for parameters relevant to anticipated operational occurrences, design basis accidents, or other phenomenon which may be under consideration. The regulatory acceptance criteria could be more restrictive or the same as the safety limits depending on the national policy. An illustration of the safety margins is provided in Fig. I-1.

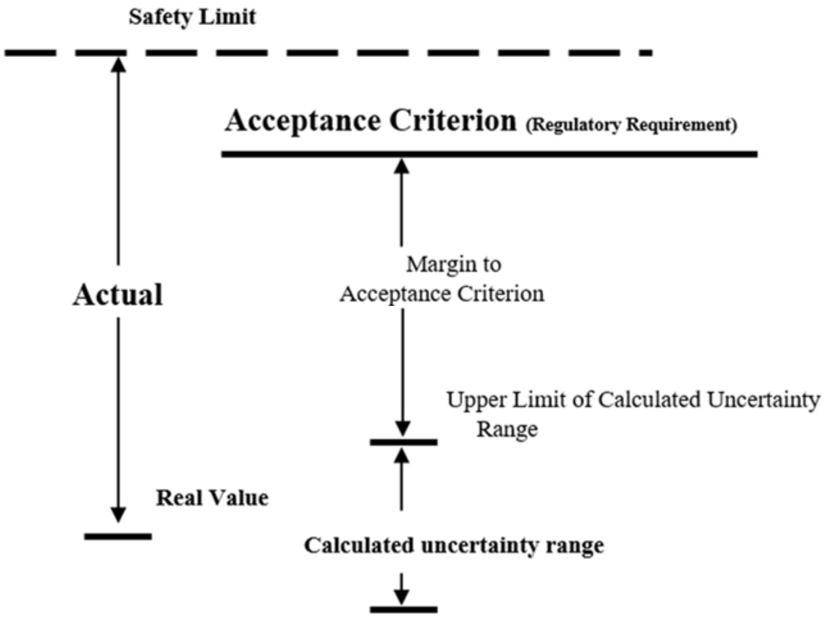

FIG. I-1. Illustration of safety margins.

The actual safety margins that are adequate for safety depend on the precise parameter being considered. In developing an option, all the safety margins that may be affected need to be identified and the effect evaluated. The IRIDM assessment must determine whether the option provides adequate safety margins regarding the applicable safety criterion. In the case of modifications, where safety margins are no longer maintained, the option needs to justify any change in acceptance criteria or what compensatory actions are proposed. If safety margins are reduced, the reduction has to be justified. In both cases, it is worth noting the assessment in terms of the radiological impact on workers, members of the public, and the environment.

The application of the IRIDM process has potential to result in a greater examination and understanding of safety margins. As a result of this, there could be a refinement of safety margins through increased phenomenological understanding, improved codes, additional operating experience, updated SSCs, improved measuring systems, computerized or on-line calibration systems, additional research, and refined understanding of the situations under consideration. In this regard, the conservative calculations may be replaced with best estimate calculations supplemented by uncertainty analyses. A framework for the evaluation of the safety margins is presented in Ref. [I-4] and a detailed example of application of the framework is addressed in Ref. [I-5].

I-3.4. Other deterministic considerations

Other deterministic considerations, which are part of the engineering design or operational procedures, are listed below. As part of the IRIDM assessment, their relative importance to overall safety can be re-evaluated and possibly relaxed by considering other, balancing factors.

Single Failure Criterion

Single failure criterion (SFC) as it is defined in Ref. [I-1] is a criterion (or requirement) applied to a system such that it must can perform its task in the presence of any single failure. A single failure is a failure that results in the loss of capability of a system or component to perform its intended safety function(s) and any consequential failure(s) that result from it.

The IRIDM assessment of an option needs to consider whether the SFC requirement continues to be met – note that this may be covered in the assessment of meeting other limits and conditions (e.g. Technical specifications). In the case of modifications, an option may require that the SFC is not maintained, either temporarily or permanently. It is not normally acceptable to allow violation of SFC, as it is a protection against failures that have not been identified or included in the analysis. The IRIDM process may, however, result in a temporary suspension in relation to the implementation of a modification. In this case, it has to be verified that the calculated risk parameters remain within appropriate regions.

Fail-safe design

Para 5.41 of Ref. [I-1] states: “Systems and components important to safety shall be designed for fail-safe behaviour, as appropriate, so that their failure or the failure of a support feature does not prevent the performance of the intended safety function”. The requirement for fail-safe design is a fundamental method of delivering a high level of safety. However, it is important, also, that the design of the system is such that failure of a support feature does not lead to unexpected performance of the system and allows for terminating the system operation when required.

Fail-safe design requires a clear understanding of what state of the system or the component is actually ‘safe’ in case of failure event. It is not always possible to define ‘fail’ on the deterministic basis and the IRIDM process is a means to adequately address the requirements of Ref. [I-1]. After the ‘fail’ state is defined for each proposed option, the IRIDM assessment has to determine the extent to which the ‘fail’ safe principle is maintained and what is the risk associated with those systems that are not fail-safe. In the case of modifications, any systems that were fail-safe, but are no longer, will require significant justification.

Equipment qualification

All safety-related SSCs will have functional requirements and the design aim is to ensure that they are able to withstand the environmental conditions and loadings that they would experience in normal operation and following different initiating events and the resulting accident conditions in which they are required to survive and operate.

The assessment in the IRIDM process needs to ensure that there are adequate equipment qualification programmes for all SSC included in the option.

Prevention of common mode/cause failure

The reliability of safety systems that have several similar/redundant trains is limited by common mode/cause failures. When a high reliability is required, diverse means of carrying out the safety function need to be incorporated. In developing an option, the necessary reliability or availability requirement of all SSCs must be specified and analysis provided to show how concepts of diversity, redundancy, physical separation and functional independence have been implemented to protect against common mode/cause failures.

The IRIDM assessment must determine whether the diversity is adequate, by considering the physical means of providing the safety function, the segregation of the SSCs and their separation. Where an option reduces the diversity, the reduction must be justified or adequate compensatory measures provided: a reduction in diversity may be allowable during the implementation phase of an option.

Limiting the demands made on the plant operators

One important design objective is to ensure that the demands made on the plant operators in fault conditions are achievable and reasonable. This is done by applying deterministic requirements, which, for example, require that no operator actions need to be carried out in the very short term (defined as within the first 10 to 30 minutes in some Member States) in the main control room or in the short term (within the first two hours) in any plant area following any initiating event.

I-4. ELEMENTS RELATED TO PROBABILISTIC CONSIDERATIONS

Deterministic considerations do not directly consider the likelihood of events. The role of probabilistic considerations is to provide a way of ranking specified adverse events and their consequences based on a systematic assessment of initiating events taking into consideration plant dependencies and interactions, including human and data on component reliability and event frequency. Probabilistic considerations complement deterministic and other considerations. Probabilistic considerations may be based simply on direct measures of observed events (e.g. from the collection and evaluation of data on events such as equipment failures or maintenance).

Alternatively, the analysis may be based on complex analysis such as that carried out in a Probabilistic Safety Analysis (PSA). A PSA provides information on the combinations of initiating events and failures of structures, systems and components that would lead to consequences such as core damage or a large release of radioactive material to the environment.

A PSA also provides quantitative information on the expected frequency of occurrence for each event combination, the consequences of the combinations of failures that occur, and the effectiveness of the measures taken to prevent the event or mitigate its consequences.

Qualitative insights from PSA need to be considered in developing an option and its assessment in the IRIDM process. The objective of such consideration is to derive an understanding of those aspects of plant design and operation that have an impact on plant safety based on the logic structure of the PSA rather than the frequencies/probabilities.

References I-6 and I-7 provide recommendations for performing Level 1 PSA and Level 2 PSA respectively as well as for using quantitative (e.g. core damage frequency, large release frequency, importance measures) and qualitative insights (use of minimal cut-sets, common cause failure analysis) of PSA in IRIDM.

I-5. ELEMENTS RELATED TO HUMAN AND ORGANISATIONAL CONSIDERATIONS

Aspects from organisational considerations that need to be considered in developing options include information related to: The Management Systems; Normal Operating Procedures, Emergency Operating Procedures (EOPs), Severe Accident Management Guidelines (SAMGs); recruitment requirements and training received by the plant staff.

In the assessment during the IRIDM process, it is essential that organisational and management issues are given proper and adequate consideration. The assessment has to focus on different aspects considering whether an existing facility/activity is being modified or a new design being considered. In both cases, however, the preparedness of the management system to accept, implement and monitor the implementation of the options and the additional or changed requirements on, for example, maintenance practises including the effect of implementation on the management system itself needs to be assessed. The IRIDM process has to also consider whether specific training of the staff and/or additional procedures need be incorporated in the management system.

I-6. ELEMENTS FROM CONSIDERATIONS REGARDING THE INTERFACE WITH NUCLEAR SECURITY

Whilst safety and security are both intended to protect people and the environment from the risks of ionising radiation, they may conflict. Security or physical protection of a nuclear facility and the nuclear material on the site need to be considered when developing an option related to safety. On the other hand, it may be that the issue that the options deal with originates from a security concern, in which case the effects on safety of the options need to be considered. A discussion of the security issues for nuclear facilities and the corresponding recommendations are provided in Ref. [I-8]. The interface between safety and security for a nuclear facility is discussed in Ref. [I-9].

The assessment during the IRIDM has to ensure that safety and security requirements have been addressed and that the chosen options represent a balanced position that ensures proper consideration of the safety interface with nuclear security.

I-7. ELEMENTS RELATED TO OTHER CONSIDERATIONS

There are several other considerations that are relevant to making a decision under the IRIDM process.

These elements and factors need to be identified when developing an option and in assessing it in the IRIDM process. These other relevant factors depend on the issue being addressed and typically include the following: radiation doses to workers and members of the public; the costs of making a change; the economic benefits of making a change; the results of research; the remaining lifetime of the facility; waste management; and decommissioning. These inputs to the IRIDM process are described below. However, in considering a particular issue other relevant consideration may also be identified

I-7.1. Radiation doses to workers and members of the public

Consideration of radiation doses plays an important role in IRIDM. Many activities will involve doses to workers and/or may involve radioactive discharges to the environment which may result in doses to the public. In the situations not dealing with core damage accidents, exposure to radiation doses may occur during normal operation or during abnormal conditions that result from failures of SSCs or human errors. In addition, implementing changes to an operating plant may also involve increases in radiological doses to workers received during the implementation activities.

In developing decision options, the doses to workers and members of the public need to be as low as reasonably achievable (ALARA) and the arrangements for doing this would need to be described and accounted for in IRIDM. Any increases in doses due to modifications on an existing site would need justification.

In summary, the IRIDM assessment, therefore must consider: the dose in normal operation to the workers and the public; the potential doses to the workers and the public in abnormal conditions considered in the design; doses that may result from implementation of the option; and any changes to doses on an existing site.

I-7.2. Costs of making a change

The costs of making any modification to an existing facility (or one under construction) may affect the options that are developed to meet a specific issue. The costs involved depend on the issue being addressed and the options proposed but would typically include:

- Hardware costs: the costs of producing the design, procuring the hardware, installation and commissioning;
- Analysis costs: the costs of revising the safety assessment, safety analysis and station procedures;
- Lost revenue: any losses in revenue that would be incurred if the plant needs to be shut down to make the changes;
- On-going costs of maintenance and supplies; and
- Staff costs: the costs of staff training.

In carrying out an IRIDM assessment, in some Member States, the costs are considered directly in a form of cost-benefit (where benefit is restricted to safety benefit). For example, in the UK the requirement is that risks to workers and members of the public are reduced to a level that is as low as reasonably practicable (ALARP), see Ref. [I-10].

This is shown in Fig. I-2, where the triangle represents an increasing level of risk as we move from the bottom of the triangle towards the top. The upper line is the tolerable limit, above which an option is generally unacceptable and represents a region where any option that has the potential to lead to such a level of risks would, as a matter of principle, be ruled out. The lower line defines a region at the bottom of the triangle below which the risk is broadly acceptable. Options falling into this region are generally acceptable and would not usually require further action by the regulator to reduce the risk unless reasonably practicable measures are available. The region of the triangle between the unacceptable and broadly acceptable regions is known as the tolerable region. The level of risk from many nuclear facilities is normally in this region. For any option falling between the limit and the objective, an investigation needs to be carried out to determine if it is possible to make improvements to it to reduce the level of risk further and bring it closer to, or to meet, the broadly acceptable line. It is worth to note that tolerability framework is only an approach to support assessment: it is not typically a legal concept.

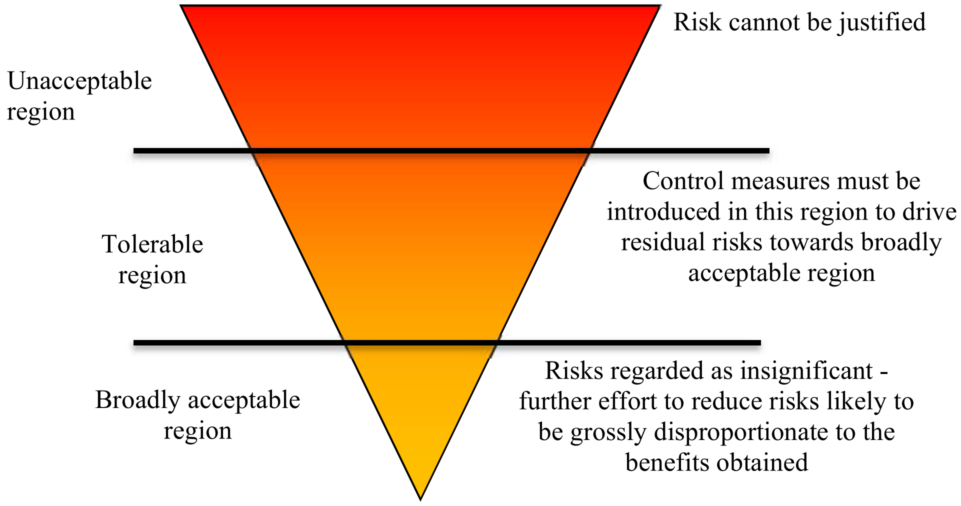

FIG. I-2. Tolerability of risk.

Risks are ALARP when the sacrifice (money, time and trouble) required to reduce the risk further would be grossly disproportionate to the benefit, in terms of risk reduction, that would accrue.

I-7.3. Economic benefits of making a change

The benefits that arise from making any modification to a facility need to be estimated and will influence the selection of the options developed. The benefits that would arise depend on the issue being addressed and the options proposed but would typically include: an increase in the revenue; a reduction in the running costs of the facility; or a decrease in the potential repair or clean-up costs following an accident.

Some of the issues that could be addressed by the IRIDM process are changes that would lead to an increase in the revenue from the facility (e.g. nuclear power plant proposal to increase the power level of the plant or for a fuel reprocessing plant to increase the throughput of the plant). Some of the issues that could be addressed would lead to the maintenance costs for the facility being reduced (e.g. changes aimed to ensure that the inspection/testing/quality assurance carried out are focused on the risk significant SSCs). This would typically lead to a reduction in the effort that needed to be applied to the SSCs with lower risk significance and hence would reduce the costs incurred by the facility operators.

These and other direct or indirect economic benefits need to be estimated and be included in the assessment in the IRIDM process. However, it is recognised that the weighting that is attached to these economic benefits may be relatively high from the plant operators point of view but given a much lower weighting (or not considered) by the regulatory body.

I-7.4. Results of research

The results of research that are relevant to the issue being addressed need to be identified and considered in developing the options. Staying abreast of the status of research in areas affecting nuclear safety needs to be an on-going process.

The assessment during IRIDM is expected to cover whether all relevant research has been included and adequately addressed

I-7.5. Remaining lifetime of the facility

It is often the case that the issues that need to be addressed relate to an older nuclear facility with a limited future life. These may have been identified as part of a Periodic Safety Review or similar study. The remaining lifetime of the plant may limit the options that are feasible due to the time for implementation being longer or a significant fraction of the remaining lifetime.

The IRIDM assessment needs to consider whether it would be acceptable for the plant to continue operation without improvements being made or with less than optimal modifications. It is important that if a less than optimal modification is accepted due to the restricted lifetime, arrangements are in place to ensure that this lifetime is not exceeded

I-7.6. Waste management

Some Member States have separate legislation governing waste management that needs to be taken into account when considering options that have different implications for waste production/management.

The way in which the waste management aspects are integrated into the decision making process will depend critically on the legal requirements of the Member State. However, a common principle is that of the minimisation of waste and a preference for waste being immobile.

All options, whether or not directly related to management of radioactive waste, need to consider their implications for current and future arrangements. The IRIDM assessment is expected to ensure that this has been done and that options do not potentially adversely affect future operations in this regard.

I-7.7. Decommissioning

A common requirement in the Member States is for the operator to incorporate into decision making any implications for ultimate decommissioning. The extent to which such matters can be realistically assessed will vary due to factors such as the specific policy for decommissioning of the Member State, the extent to which decommissioning plans have been developed, and the length of time before decommissioning is due to start. Therefore, all options, whether for new facilities/activities or for modifications to existing facilities/activities, need to consider any potential impacts on eventual decommissioning.

The IRIDM assessment must ensure that this is properly done and that due account is taken of future requirements for decommissioning e.g. some SSCs, particularly civil works, need to be in a usable state for a longer period until the plant can be decommissioned.

I-7.8. Environmental impact

Most Member States require some type of environmental assessment as part of the licensing process for the facility. Options need obviously to be evaluated against the results of that assessment and any impacts be identified and, if negative, fully justified. In some cases, specific licenses or permits that have been issued to the facility covering environmental impacts or emissions may have to be modified? This depends on the specific environmental regulatory regime for the Member State. In some Member States a further environmental assessment is required before decommissioning.

I-7.9. Non-radiological hazards

One of the significant advantages of IRIDM is its use in situations where it is not possible to meet all safety requirements due to conflicts. By considering the risks, a decision can be reached where safety is optimised by balancing the competing requirements. Similarly, it may be possible to compensate for not meeting the requirements in one area by enhanced safety in another.

Some of these conflicts may result from the need to consider non-radiation sources of harm. Generally, IAEA tends to consider mainly radiation risks; however, it is clearly unacceptable to introduce safety measures that reduce radiation risks if they lead to increase in other risks to people and the environment. Indeed, methods of driving down radiation doses may require the use of more hazardous techniques. IRIDM process allows all sources of harm to be considered and balanced (see Annex VIII).

REFERENCES TO ANNEX I

[I-1]. INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Design, Safety Requirements No. SSR 2/1 (Revision of Safety Standards Series No. NS-R-1), IAEA, Vienna, (2012).

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[I-9]. INTERNATIONAL ATOMIC ENERGY AGENCY, The Interface Between Safety and Security at Nuclear Power Plants, A report by the International Nuclear Safety Group, INSAG-24, IAEA, Vienna (2010).

[I-10]. THE OFFICE FOR NUCLEAR REGULATION, Tolerability of Risk from Nuclear Power Plants (1992), http://www.onr.org.uk/documents/tolerability.pdf, HSE.

ANNEX II. EXAMPLE OF DECISIONS THAT HAVE BEEN MADE USING THE IRIDM

II-1. INTRODUCTION

These examples of the use of the IRIDM process have been characterized on the bases of the ‘user’ of the process, of the ‘type of issue’ addressed and particular ‘IRIDM insights’ provided (see Table II- 1)[15].

TABLE II-1. CHARACTERIZATION OF THE EXAMPLES

Example (Section of the Annex, Country)		**User**		**Type of Issue**		**IRIDM Insights**
	Regulator	**NPP**	**Other**	**Practices Procedures**	**Technical**	
II-2, Mexico	X	(X)		X		Regulator/Licensee collaboration
II- 3, Romania	X			X		Weighting factors
II-4, USA	X				X	Constituent Factors/ Uncertainty
II- 5, Sweden		X		X		PSA/DSA integration
II-6, Slovakia		X		X		Outage period assessment
II-7, Switzerland		X			X	CDF/LERF considerations
II-8, Ukraine		X			X	CDF considerations
II-9, UK			X		X	A non NPP application
II-10, Canada	X				X	Constituent factors/ use of R&D

Most of the examples reflect the actual approach used in real cases, and may therefore deviate in some details from the recommendations for the IRIDM process. In all examples several steps of the IRIDM process were applied.

[15] All examples are kept in the original form provided by Member States. The use of the word ‘should’ in this Annex is the opinion of the experts who conducted the analysis and is not intended to imply a consensus recommendation of IAEA Member States.

II-2. EXAMPLE OF AN EVALUATION OF A TECHNICAL SPECIFICATION CHANGE SUBMITTAL BY THE MEXICAN NUCLEAR REGULATORY AUTHORITY

II-2.1. Issue to be considered

The evaluation of a submittal of change of a Technical Specification that requires the isolation of RCIC/RWCU/SDCM systems when a differential temperature sensor (ΔT) is unavailable. This sensor is unavailable when the building ventilation system is out of service. The licensee argued that it had brought damages to pumps seals of safety systems, and greater dose consumed by exposition during the seal change.

II-2.2. Background

The Reactor Core Isolation Cooling System (RCIC) can provide coolant to the BWR reactor vessel during events when the reactor is isolated from turbine (e.g. Loss of Offsite Power event). The Reactor Water Clean Up system (RWCU) has the function to maintain cleaned conditions to the water inside of the reactor vessel during normal operation, and the Shut Down Control Mode system (SDCM) provides cooling to the vessel during low power and shutdown conditions.

The leak detection system for the rooms where RCIC/RWCU/SDCM systems are located includes differential detection temperature (ΔT), room temperature detection, and high flow detection. All those three signals are redundant and independent. The differential temperature sensor is inoperable if the HVAC system of the room is unavailable (which may unintentionally happen under some conditions within the scope of normal operation) due to this sensor being located at the intake vent of the HVAC system. When this ΔT sensor is unavailable, the related Technical Specification indicates that RCIC/RWCU/SDCM systems must be isolated 1 hour later.

II-2.3. Regulatory Considerations

The factors considered by the regulatory body are as follows:

- The Technical Specification indicates that RCIC/RWCU/SDCM systems must be isolated if ΔT sensor is unavailable to protect them of adverse temperature condition that cannot be detected by the ΔT sensor being unavailable.
- The unavailability of the ΔT sensor decrease the number of components (to 2 of 3) to detect a loss of coolant accident outside of the containment (losing redundancy).

II-2.4. Licensee Considerations

The factors considered by the licensee are as follows:

- Every time RCIC/RWCU/SDCM systems are isolated, the pump seals can be damaged; damaged seals must be changed and doses are consumed by exposition during the seals change.
- The time of one hour dictated by the Technical Specification before the isolation of systems, is not sufficient to repair the HVAC system (licensee opinion).
- Due to the configuration of the HVAC system, both trains must be turned off to repair failure of just one component of the HVAC system.
- The design of HVAC system does not allow performing maintenance to the components individually because the system trains share pipes, valves and strainers.

II-2.5. Defined Options

The following four options were considered:

Option 1 The elimination of the Technical Specification totally, i.e. not to isolate systems at any time.

Option 2 The increase of the Allowed Outage Time of ΔT sensor from one hour to 7 days to get more time to repair the HVAC system.

Option 3 Make a divisional spatial separation of trains to avoid the unavailability of the entire HVAC system every time that any of its single components is unavailable.

Option 4 The enhancing of the performance of the HVAC system through its inclusion in the maintenance rule.

II-2.6. Formation of the Team

The integration of a multidisciplinary team, formed jointly from the representatives of the regulatory body and the licensee, allowed sharing of the experience and knowledge from different disciplines. The multidisciplinary team consisted of the head of the Nuclear Safety Department (who takes the final decision), the lead of the Integral Decision Making process, specialists on PSA, mechanical and electrical engineers specialists on systems related, specialists on rule maintenance program, performance systems, evaluator and inspectors.

II-2.7. Constituent Factors

Standards and good practices

The following standards and good practices were found to be relevant to the issue:

- The Technical Specification of Operation of the Nuclear Power Plant;
- Nuclear Safety Regulatory Guide (GRSN-02) that contains guidance for submittal of changes to Technical Specification issued by the Regulatory Body (CNSNS).

Operational experience

The licensee indicated that the problem of high stress on HVAC fans during the presence of high north winds cause erosion and motor damages, and, therefore, the system unavailability.

As part of this operational experience, the licensee presented the trends of the room temperature with the aim to demonstrate that temperature had not exceeded the systems design values. An investigation report presented by the licensee indicates that the operational experience of other similar NPP has not showed the same problem.

Deterministic considerations

The availability of the ΔT sensor is very important to detect the Loss of Coolant Accident outside of the containment.

- *Compliance with regulations*: Options 1 and 2 include the change of the regulation, options 3 and 4 comply with the regulation.
- *Defence in depth: Options*: 1 and 2 are affecting the defence-in-depth of considerations related to loss redundancy for detection of Loss of Coolant Accident because one of three components is unavailable.
- *Safety margins*: The margin between the room temperature and design conditions of

RCIC/RWCU/SDCM systems was evaluated qualitatively, observing that margin is small, and therefore the importance of the redundancy of detectors is higher.

Probabilistic considerations

The available PSA at that time was an analysis for internal events and for full power operation developed by the licensee. The calculated increase of the CDF was as follows:

a) Option 1 slightly similar to option 2.
b) Option 3 and option 4 represented a decrease in risk.

Interface with security

The issue has no impact on security aspects.

Other considerations

Cost benefit consideration were included as an additional factor as well as feasibility of the option.

II-2.8. Evaluation of the Options

Option 1 - The elimination of the requirement of Technical Specification (Not to isolate systems at any time)

Compliance with regulations:	This option represents a change of the regulation itself.
Safety margins:	Margins between the room temperature and design temperature of RCIC/RWCU/SDCM systems remain the same. This option represents a compensation of the weakness of the HVAC system.
Deterministic considerations:	Qualification of systems can be degraded by adverse temperature conditions, and systems can be damaged if they are not isolated during adverse conditions.
Risk assessment:	Even when the availability of systems looks to be higher because the isolation is avoided, the probability of damage of systems is increased because they are less protected against adverse temperature conditions. Also, performance of HVAC would be worse as there will be no limit on Allowed Outage Time.
Other:	
Cost-benefit considerations:	This option represents a reduction in cost for the licensee, because licensee could make maintenance on-line, decreasing the degradation of pumps seals and radiation dose.
Feasibility of the option:	The option is easy for implementation.

Option 2 - The increase of the Allowed Outage Time of ΔT sensor from one hour to 7 days to get more time to repair the HVAC system.

Compliance with regulations:	This option represents a change of the regulation itself.
Safety margins:	Margins between the room temperature and design temperature of RCIC/RWCU/SDCM systems remain unchanged.
Deterministic considerations:	Qualification of systems can be degraded by adverse temperature conditions, and systems can be damaged if they are not isolated during adverse conditions. This option represents a compensation of the weakness of the HVAC system.
Risk assessment:	The availability of systems could be higher because the isolation is delayed. With this option systems are exposed to damage during the AOT, but nevertheless performance of HVAC would be better because there will be a limit on Allowed Outage Time.
Other considerations:	
Cost benefit considerations:	This option represents a reduction in cost for the licensee, because licensee could make maintenance on line, decreasing the degradation of pump seals and radiation dose.
Feasibility of the option:	The option is easy for implementation.

Option 3 – Make a divisional spatial separation of trains to avoid the unavailability of the entire HVAC system every time when any of its single components is unavailable.

Compliance with regulations:	This option is in compliance with the regulations.
Safety margins:	A better system and structures configurations in the room would increase the safety margin between the room temperature and design temperature of RCIC/RWCU/SDCM systems.
Deterministic considerations:	Conditions for qualification of systems would be enhanced. This option represents a corrective action of a weakness of the HVAC system.
Risk assessment:	This option provides better performance of HVAC system and ΔT sensor, increases the availability of HVAC system and finally lead to a decrease of the Core Damage Frequency (CDF) of the NPP.
Other Consideration:	
Cost benefit considerations:	Cost is very high, and there is not enough space to make a divisional separation of trains.
Feasibility of the option:	The licensee argued that this option is not feasible due to high cost and technical difficulties of implementation.

Option 4 - The enhancing of the performance of the HVAC system through its inclusion in the maintenance rule.

Compliance with regulations:	This option is in compliance with the regulations.
Safety margins:	Improving the performance of the HVAC system where safety margins between the room temperature and design temperature limit for the system is increased.
Deterministic considerations:	Conditions for qualification of systems would be enhanced. This option represents a corrective action of a weakness of the HVAC system.
Risk assessment:	This option provides better performance of HVAC system and ΔT sensor, increases the availability of HVAC system, and finally lead to decrease of the CDF of the NPP.
Other:	
Cost benefit considerations:	This option cannot reduce economic costs for the licensee in a near future (licensee cannot make maintenance on-line), but in a later future the licensee would reduce cost through enhancement of the HVAC performance.
Feasibility of the option:	The option is easy for implementation.

II-2.9. Integrated decisions

Option 4 was selected as the final decision based on the consideration of all constituent factors listed above. [16]

The regulator accepted this option because it is a corrective action and is not a compensation of a deficiency of the performance of the plant, and it does not represent an important increase in economic cost for the NPP.

Option 3 was regarded as a potential alternative option.

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[16] This example does not follow all steps of the IRIDM process as nothing is said about the approach for integration, assessment of uncertainties, implementation, monitoring, etc.

II-3. REQUEST TO MODIFY A TECHNICAL SPECIFICATION, AN EXAMPLE FROM ROMANIA[17]

II-3.1. Issue to be considered

The licensee requests to modify the Technical Specification to extend the period that a diesel generator (DG) is out-of-commission from X to Y hours before having to shut the plant down. The purpose is to allow a special periodic maintenance to be performed. The change has been recommended by the manufacturer and increases the reliability of the DG.

II-3.2. Background

The resolution of the issue requires consideration of several inputs that are complex and different in nature:

- Numerical and qualitative inputs need to be compared in a systematic manner;
- Need to assess safety concerns vs. the benefits in a balanced manner;
- Normally not obliged to consider change to technical specifications;
- Need to have a strong case;

Obliged by the regulatory body´s policy to use the IRIDM process when solutions important for safety are proposed.

II-3.3. Regulatory considerations

Brief characterization of the issue in terms of its physical impact on the nuclear installation and the potential impact on safe operation, including possible impact on operator actions, e.g. through performance of actions as instructed in procedures:

- No physical impact on the nuclear installation.
- Extended unavailability of DG has potential to put the plant in a less safe configuration. The acceptability of this situation needs to be balanced against the benefits – overall more safety after the maintenance is performed.
- Need to assess whether these maintenance actions increase probability of human error (i.e. errors leading to undiscovered disabling of the equipment, omission, commissions errors, etc.).

Identification of key elements:

- OP&P – Operating Principles and Policies;
- Regulatory body's CNCAN reliability requirements – unavailability of DG system must never be less than 10^{-3} /year;
- FSAR;
    - Urgency
        - Not urgent – need to initiate process and determine additional info requirements since we are expected to respond in 30 days in some way;
- Deterministic considerations
    - Judgment is that there are no deterministic requirements affected per se by the proposed change –needs to be confirmed later-perhaps need to check that the diesel is designed to operate for y weeks instead of x weeks;

[17] This example does not reflect a real case, but was an exercise on IRIDM performed by the Romanian regulators. However, this fact does not change its relevance as a source of IRIDM insights (e.g. regarding the potential use of weighting factors).

- Probabilistic considerations
    - Verify that CDF and cumulative risk impacts for being without one of the diesels for Y weeks does not exceed regulatory limits;
    - Verify that CDF and cumulative risk impacts with both diesels with improved reliability improves the situation as asserted by the licensee;
    - Reliability analysis of diesel as submitted by licensee is acceptable with the improved maintenance
        - Review/request evidence submitted that change improves reliability;
- Other (security, organizational, cost-benefit, etc.)
    - Organizational impacts need to be checked
        - Surveillance program;
        - Training program;
        - Maintenance program;
        - Verify external companies providing inputs are properly licensed.

II-3.4. Licensee considerations

The licensee request was formulated in the following manner: "Applicant requests the regulatory body CNCAN to approve a modification in the OP&P to allow for on power maintenance of diesel generator of the emergency power supply (EPS). The request implies an increase in the allowable period that a diesel can be out of service before the shutdown of the plant is required".

The licensee presented the advantages of the proposed modification which will increase the reliability of the DGs. They have also proposed compensatory measures to further reduce the risk of station blackout during the maintenance work.

II-3.5. Defined options

The following options have been defined:

1. Accept with no conditions;
2. Accept with conditions;
3. Accept with restrictions for some changes.

II-3.6. Formation of the team

Core Team was unnecessary as sufficient expertise is available at this point

Screen whether can use RIDM:

- Need more information? - no
- Any options to screen out? - no
- Any further obstacles? – no
- Proceed with IRIDM? – yes

II-3.7. Constituent factors

Standards and good practices

- Establish initial technical input requirements
    - The actual submittal from the licensee with the request (includes all information required by the regulatory body CNCAN based on agreed procedure), particularly the justification and presentation of the proposal;

- Standards/mandatory license documents
  - Operating Principles and Policies (OP&P);
  - FSAR;
  - Maintenance program;
  - Any other license support documents which may be affected;
  - Operating experience to support request (internal and external).
- Team leader writes memorandum forming team, schedule, resources, stakeholders, documentation requirements. Memorandum also includes:
  - Establish safety goal/acceptance criteria
    - Key goal is improved CDF in overall operation – due to overall increase in reliability of the emergency power supply system even with slightly higher conditional CDF during DG maintenance;
    - Acceptance criteria
      - yearly unavailability of ECCS < 10^{-3} due to the EPS unavailability for Y weeks;
      - CDF < 10^{-4}/year and cannot be higher than it was before.

Operational experience

- The advisor A reviewed actual operational experience from other plants that made this change. This review confirmed that the result was not significantly different.

Deterministic considerations

- Advisor A: responsible for DG reliability assessment and capability;
- Obtain EPS reliability model and compare with previous one
  - See if it might be advisable to require the operable DG to be running during the maintenance (would need to have a load);
  - Result of analysis – Advisor A writes an internal evaluation report with the following key points
    - Reliability with the new maintenance did in fact improve – but not significantly;
    - Reviewed actual operating experience from other plants that made this change. This review confirmed that the result was not significantly different.
- Verify the operable DG can operate for Y weeks when another DG is in maintenance
  - Result of analysis – could not confirm this, need to ask plant to provide a vendor response on the mission time for one DG;
  - The vendor provided an acceptable response.
- Advisor B responsible for checking all affected licensing documents has been proposed by the licensee to be modified due to the change and no others require change
  - Advisor B writes an internal evaluation report with the conclusion that no other changes are required.

Probabilistic considerations

1. Advisor C responsible for review of PSA/risk monitors focusing on the following aspects:
   i. Perform sensitivity case on proposed new maintenance interval on DG assuming the DG reliability assertion;
   ii. Assess conformity to regulatory limits;
   iii. Evaluate the temporary configuration change on other SSCs using Equipment Out Of Service (EOOS) monitor.
2. An internal evaluation report was written with the following conclusions:
   i. Completed the analysis and the applicants' assertion is correct and regulatory limits are met;

   ii. However, the reliability number for DG cannot be justified;
      - Other SSCs should be specified for which maintenance must not be performed during the proposed DG maintenance; otherwise, unacceptable reliability results will be obtained.

3. PSA result:
   i. Increase of CDF from station blackout by 10.0% while DG maintenance is being performed;
   ii. Decrease of CDF from station blackout of 20% due to improved DG reliability.
   iii. Compensatory measures proposed:
      - Other DGs should be checked before maintenance;
      - Offsite power assured before maintenance – no adverse weather forecast.

II-3.8. Evaluation of the options

An expert judgment based weights and scores' for the options has been developed (See Table II-2).

II-3.9. Integrated decisions

The result of analysis and summing weighted scores shows that the proposal can only be accepted under the condition that operating experience shows that the DG reliability is improved. However, the expected improvement in DGs reliability stated by the vendor cannot be confirmed. In addition, maintenance on other SSCs is not allowed while the proposed DGs maintenance is being performed during the additional time, otherwise overall safety will be compromised.

The regulatory body CNCAN will track DGs reliability both from the plant under consideration and from other plants to draw its own conclusions.

The regulatory body CNCAN will give the resident inspector instructions to pay increased attention to DG performance and maintenance.

TABLE II-2. WEIGHTS AND SCORES FOR THE OPTIONS

		Options					
		Accept		Reject		Accept with Conditions	
Inputs	**Input Weights**	Comment and Score	Weighted score	Comment and Score	Weighted score	Comment and Score	Weighted score
Mandatory Requirements and Standards - checking all affected licensing documents have been proposed by the licensee to be modified due to the change and no others require change	10	meets requirement. Score=10	100	meets requirement. Score =0	0	meets requirements regardless of additional conditions. Score=10	100
Deterministic considerations							
Capability for DG to run for Y weeks	8	did confirm-score = 10	80	did confirm - score=0	0	did confirm - no conditions necessary. Score=0.	0
Probabilistic							
Qualitative - Evaluate the temporary configuration change on other SSCs (using EOOS)	6	there is an impact on other SSCs if maintenance performed at same time. Score=0	0	there is an impact on other SSCs if maintenance performed at same time. Score=10	60	can accept if maintenance of other SSCs is precluded during DG maintenance. Score=7	42
Quantitative-Perform sensitivity case on proposed new maintenance interval on DG assuming the DG reliability assertion. Assess conformity to regulatory limits	9	confirmed it but DG reliability cannot be confirmed. Score=1	9	confirmed it but DG reliability cannot be confirmed. Score=9	81	could not confirm but propose delaying acceptance until OPEX is provided-score = 7	63
Quantitative-reliability of DG is improved	8	could not confirm-score = 2	16	could not confirm-score = 8	64	could not confirm but propose delaying acceptance until OPEX is provided-score = 7	56
Other - other programs that might be affected are included under the mandatory requirements section		Not applicable	0	Not applicable	0	Not applicable	0
Total weighted score:			**205**		**205**		**261**

II-4. EXAMPLE OF THE RESOLUTION OF A GENERIC SAFETY ISSUE BY THE USNRC

II-4.1. Issue to be considered

To determine what regulatory action is needed to be taken by the US Nuclear Regulatory Commission (USNRC) to address the safety issues related to potential flaws in Alloy 82/182 welds in reactor coolant pressure boundary piping nozzles as the result of new information received on weld indications identified in the dissimilar metal (DM) butt welds in a retired pressurizer.

II-4.2. Background

Fracture mechanics study for Plant X: In 2006, a fracture mechanics based scoping study was carried out to assess the safety significance of the flaws in the pressurizer nozzles identified at Plant X using ultrasonic testing. This forced the USNRC staff to conclude that there may be little or no time margin between the onset of leakage and rupture in pressurizer nozzle dissimilar metal (DM) butt welds containing flaws similar to those found at Plant X. These results were potentially applicable to 69 pressurized water reactor (PWR) plants.

As a result of this situation, in March 2007, USNRC issued Confirmatory Action Letters (CALs) to 40 nuclear power plants with PWRs confirming commitments from those licensees to carry out the work to resolve these concerns by the end of 2007.

Crack growth analysis carried out by EPRI: In 2007, the Electric Power Research Institute (EPRI) Materials Reliability Program (MRP) carried out work on behalf of the industry to refine the crack growth analysis pertaining to Plant X pressurizer DM weld ultrasonic indications. This advanced finite element analysis (FEA) was performed to address USNRC's concerns regarding the potential for rupture without prior evidence of leakage from circumferentially-oriented primary water stress corrosion cracking (PWSCC) in pressurizer nozzle welds. The aim was to demonstrate that PWSCC in pressurizer DM butt welds would progress through-wall and exhibit detectable leakage prior to causing a possible rupture event.

These studies, which reduced unnecessary conservatisms and some of the uncertainty in previous analyses, were completed and the results forwarded to USNRC in August 2007 – see Refs. [II-1II-3] and [II-5].

USNRC review of the EPRI analysis: Independent analyses were carried out by the USNRC staff to enable them to perform an in-depth review of the EPRI study and to extend its scope. This included advanced FEA of the fabrication, loading and postulated flaw growth in the pressurizer nozzle welds to assess crack growth rates and shapes based on an array of starting flaw sizes. The conclusion drawn was that PWSCC in pressurizer DM butt welds of the nine plants analysed would progress through-wall and exhibit detectable leakage prior to causing a possible rupture event. Hence, the USNRC staff could conclude that there was reasonable assurance that the nine plants addressed could operate safely until their next scheduled refuelling outages in the spring of 2008.

Inspection results from a retired pressurizer: In February 2008, USNRC received the results of inspections of the nozzles of a retired pressurizer. These inspections found indications using both dye penetrant testing (PT) and manual phased array ultrasonic testing examinations. The nozzle welds of most interest were the three safety nozzles. The inspection concluded that under normal field non-destructive examination (NDE) conditions, these three welds would be reported as containing 360° circumferentially-oriented linear planar flaws and the deepest indications were sized at 89%, 75% and 69% through-wall respectively.

Based on this information, it was determined that the inspection results were needed to be evaluated against the advanced FEA work completed in September 2007, since this formed the basis for the continued operation of 9 plants with pressurizer welds that had not yet been inspected as of the end of 2007, as mandated by industry guidelines.

To help with this evaluation, the USNRC staff requested EPRI to estimate the flaw profile for the safety nozzle with the deepest through wall indication and provide some of the raw ultrasonic testing signals recorded during the inspection. This information was received in March 2008. EPRI estimated that the 'A' safety nozzle weld contained a continuous deep indication 360° around the circumference. This reported flaw profile was more severe than any flaws predicted by the advanced FEA that would have led to leakage that would be detectable with sufficient time for plant shutdown prior to rupture.

This information led the USNRC staff to question whether the advanced FEA would still support the spring 2008 pressurizer inspection schedules.

II-4.3. Regulatory considerations

The USNRC regulations require that structures, systems, and components (SSCs) important to safety be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. Where generally recognized codes and standards are used, they are required to be identified and evaluated to determine their applicability, adequacy, and sufficiency and have to be supplemented or modified as necessary to assure a quality product in keeping with the required safety function. A quality assurance programme has to be established and implemented to provide adequate assurance that these SSCs will satisfactorily perform their safety functions.

The appropriate quality assurance program for safety-related SSCs is Appendix B to 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Criterion IX of Appendix B requires that processes such as welding, heat treating, and non-destructive testing, be controlled and accomplished in accordance with applicable codes, standards, specifications, criteria, and other special requirements. Criterion XVI of Appendix B requires that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures have to assure that the cause of the condition is determined and corrective action taken to preclude repetition. Corrective actions required to address degraded conditions should be in accordance with ASME Code, Section XI, which is incorporated by reference into NRC regulations by 10 CFR 50.55a.

When implementing risk informed regulations, the USNRC uses the following five 'key principles', which are similar to the set of 'Constituent Factors' (CFs) defined for the IRIDM process:

- Consistency with current regulations;
- Consistency with the defence-in-depth philosophy;
- Maintenance of sufficient safety margins;
- Any risk increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement; and

- Performance measurement strategies should be employed.

Hence, the regulatory framework for this risk informed decision involved the five principles above, and included compliance with the applicable codes and standards.

II-4.4. Licensee considerations

Stress corrosion cracking and general environmental corrosion of reactor coolant system (RCS) components have economic impact on nuclear plant licensees due to forced and extended outages, increased inspection requirements, component repairs and replacements, and increased regulatory scrutiny. The EPRI Materials Reliability Program (MRP) conducts research to identify and resolve existing and potential issues impacting pressure boundary materials in pressurized water reactors. Hence, U.S. nuclear licensees use the information provided by the MRP research activities to make technically sound and cost-effective decisions for managing degradation.

II-4.5. Defined options

The following three options were developed based on the estimated severity of the retired pressurizer flaw in safety nozzle 'A' and the concerns identified by the USNRC staff:

Option 1	Base Case - no change to existing regulatory and industry programs or inspection/shutdown schedules. The plants still operating with un-inspected pressurizer nozzle welds would be allowed to proceed on their present schedule to shut down and mitigate/inspect these welds during their planned spring 2008 outages based on the results of the advanced FEA completed in August 2007.
Option 2	Continued operation of the plants for a short time period while USNRC gathers additional information.
Option 3	Issue orders for immediate plant shutdown.

For all three options:

- The **analytical approach** was the probabilistic evaluation carried out in the EPRI study of the nozzle failure probability – see Ref. [II-2];
- The **affected principles** are: compliance with regulations, defence-in-depth, safety margins, failure probability estimates, performance measurement; and
- The **acceptance criteria** are: that there should be an adequate margin on structural integrity of butt welds and there should be compensatory measures.

Additional **factors to consider** are: for options 1 and 2, consideration needs to be given to the continued applicability of the results of the advanced FEA in light of new information from the retired pressurizer and an enhanced leakage monitoring program, with more time available to make the decision for option 2; and for option 3, the lack of an adequate risk tool.

II-4.6. Formation of the team

The evaluation team consists of a senior management official who was the decision authority and team members from USNRC nuclear reactor regulation and regulatory research organizations. The team members from the nuclear reactor regulation organization included the Associate Director for Engineering and Safety Systems, Director of Division of Component Integrity (DCI), a Senior Level Advisor in DCI and an Acting Branch Chief for the Piping and Non-Destructive Evaluation Branch (CPNB). The team members from the regulatory research organization were a Director of Division of Engineering (DE) and a Senior Level Advisor in DE.

II-4.7. Constituent factors

Standards and good practice

The regulatory requirements for assessment of the potential for, and consequences of, degradation of the reactor coolant pressure boundary (RPCB) are provided in 10 CFR 50 Appendix A - General Design Criteria (GDC) for nuclear power plants, 10 CFR 50.55a, and 10 CFR 50 Appendix B – Quality Assurance Criteria. USNRC regulations at 10 CFR 50.55a state that ASME Code Class 1 components (which include the RCPB) must meet the requirements of Section XI of the ASME Code. The EPRI MRP-139 provides generic guidance for inspection and evaluation of PWR primary system piping butt welds subject to PWSCC phenomena – see Ref. [II-3].

Operational experience

Operating experience has demonstrated that Alloy 82/182/600 materials exposed to primary coolant water (or steam) at the normal operating conditions of PWR plants have cracked due to PWSCC. The USNRC has previously issued generic communications regarding the emergence of this phenomenon, and its consequential effects, in other areas of PWR primary systems. In addition, operating experience in the U.S. and other parts of the world, has demonstrated that Alloy 82/182 materials connected to a PWR pressurizer may be particularly susceptible to PWSCC. All available evidence from finite element modelling studies and limited NDE has suggested that RCPB leakage events at some U.S. nuclear plants in 2003-2004 were the result of axially-oriented PWSCC of the pressure boundary portion of pressurizer heater sleeves –see Ref. [II-4].

Deterministic considerations

The U.S. nuclear industry program for inspecting and mitigating welds subject to PWSCC was developed based on the information available prior to the Plant X inspection findings. This program is described in MRP-139. The information available at the time this report was issued indicated that there was a serious safety issue with PWSCC in DM butt welds. Based on operating experience, USNRC believed the industry baseline inspection schedule for pressurizer nozzle welds based on MRP-139 was generally adequate, if completed according to the schedule outlined.

Based on the results of advanced FEA of pressurizer nozzle welds performed after the discovery of the large circumferential indications at Plant X, the USNRC staff concluded that it was acceptable for nine nuclear power plants to continue to operate until their spring 2008 outages to perform the pressurizer weld inspections rather than shutdown by December 31, 2007, consistent with MRP-139.

This decision was based on extensive flaw growth analyses for the pressurizer nozzle welds and the enhanced leakage monitoring and shutdown criteria adopted by these plants. Performing these analyses required nozzle-specific information of the weld configuration and fabrication history, the applied loading, the material properties, crack growth rates for the specific weld materials for each of the 9 plants, and consideration of possible initial flaw shapes, sizes, and locations. The USNRC staff performed a safety assessment to show that there were potential conservatisms and non-conservatisms in the analysis which were difficult to quantify. Therefore, the USNRC staff extended the industry's analyses by considering additional sensitivity cases and applying higher safety factors to evaluate the acceptability of the results. The USNRC staff concluded, based on these analyses and the enhanced leakage monitoring, that if a PWSCC flaw was to initiate and grow in one of the pressurizer nozzle DM welds before the Spring 2008 refuelling outages, there was reasonable assurance that leakage would occur and be detected such that adequate time would be available to safely shutdown the plant prior to rupture at the nozzle weld.

Probabilistic considerations

EPRI probabilistic study showed that pressurizer nozzle failure probabilities for Spring 08 plants are approximately the same for existing PWRs due to PWSCC susceptible pressurizer nozzles during the Spring and Fall of 2007 (on the order of $4.x10^{-3}$ per plant, per six months), see Ref. [II-2].

Summary: USNRC 'key principles'

The assessments of the identified decision options were made against the five key principles (compliance with regulations, defence-in-depth, safety margins, risk assessment and performance measurement) according to the USNRC procedures for risk informed decision making. The key principles are shown on Tables [II-3–II-4] and [II-5] which provide a convenient format for capturing the assessment of each option that was considered, including driving factors and key technical inputs related to each option.

There are no inputs to this decision from the following: human and organisational considerations, security considerations, radiation doses and economic factors. The research results have been addressed in the ultrasonic testing data and the FEA that have been undertaken as described above.

II-4.8. Evaluation of the options

The indications discovered in the nozzle welds of the retired pressurizer were potentially due to PWSCC. If the flaw profile in the March 4, 2008 EPRI report, see Ref. [II-2] was assumed to be due to PWSCC, the weld may have had sufficient ASME Code, Section XI, margin on structural integrity under design basis loadings at the time the retired pressurizer was taken out of service. Regardless, if this flaw was in an operating pressurizer and was due to PWSCC, it could not have been left in service because of the potential high growth rate of PWSCC, and the repair/replacement criteria specified in ASME Code, Section XI.

Therefore, such a degraded condition would have required corrective actions in accordance with the ASME Code, which is incorporated by reference into NRC regulations by 10 CFR 50.55a.

USNRC based its regulatory decision on an assessment of the pros and cons of three identified options using the principles of risk informed decision making.

II-4.9. Integrated decisions

It was concluded that Option 2 was the appropriate decision since it was judged that there was an appropriate basis to take a short period of time (within a week) to gather information to make a more informed decision. The initial inspection results were somewhat uncertain given the type of inspection that was performed. More refined inspection was judged to be prudent to reduce some of this initial uncertainty. Nevertheless, it was determined that the questions raised by the EPRI letter of March 2008 were safety significant questions and the staff put industry on notice that it was considering regulatory action. Proposed actions taken to gather additional information and the conclusions of the evaluation of the additional information were documented in an internal USNRC document.

Relative to Option 1, it was concluded that for the plants to continue to operate until their spring 2008 outages, additional information was needed to determine whether the advanced FEA continued to support continued operation. Without such information, USNRC would have lacked the requisite reasonable assurance that the health and safety of the public would be protected by continued operation of these plants until their spring 2008 outages.

The proposed actions for Option 3 would provide the requisite reasonable assurance that the health and safety of the public would be protected upon restart of the affected plants.

However, it was judged that (i) additional information relevant to the decision could be obtained in a very short time and (ii) continued operation for a very short time frame would not be inimical to public health and safety.

This decision was based on the judgment that taking up to one week to gather additional information considered each of the following factors:

(1) The need to quickly restore confidence in the safety margins of the eight remaining plants potentially impacted by the inspection results.
(2) For the plants to continue to operate until their spring 2008 outages, the USNRC staff needed additional information to determine whether the advanced FEA continued to support operation until the outage.
(3) It was believed that conclusive information could be developed in a short period of time.
(4) It was judged that information from the March 4, 2008 EPRI letter raised safety questions but was not sufficiently conclusive as to warrant immediate plant shutdown.

Factors (1) and (2) led USNRC to reject Option 1. It was judged that a one-week information gathering period is short enough to maintain public health and safety, given typical crack propagation rates and prior operating history.

Option 2 was supported by factor (3). Factor (4) led to Option 3 being rejected.

TABLE II-3. ASSESSMENT OF OPTION 1
BASE CASE: NO CHANGES IN THE EXISTING REGULATORY AND INSDUSTRY PROGRAMS OR INSPECTION/SHUT DOWN SCHEDULE

Preferred [ ] Acceptable [ ] Not Acceptable [**x**]				
No.	Constituting factors	Key Technical Inputs	Validity of Input	Confidence in Assessment
1.	Compliance with regulations	Continue to operate with present schedule to shut down and mitigate/inspect pressurizer nozzle welds during planned spring 2008 outages based on the results of the advanced finite element analyses (FEA) completed in August 2007.		
2.	Defence-in-depth	Potential impact on the integrity of the reactor coolant system (RCS) pressure boundary. Butt weld problem may increase the frequency of loss of coolant accident (LOCA) in the size range requiring emergency core cooling system (ECCS) operation in the recirculation mode.	Enhanced leakage monitoring program to detect increased leakage at pressurizer nozzle welds.	Leakage monitoring programs vary from plant to plant, and are of no value if rupture occurs close in time to initial leakage.
3.	Safety margins	Assessment that uninspected pressurizer welds affected by PWSCC would exhibit detectable leakage prior to causing a possible rupture event.	Based on advanced FEA completed in August 2007.	Uncertainty due to the flaw profile of butt welds assumed in advanced FEA.
4.	Risk assessment	EPRI probabilistic study showed that pressurizer nozzle failure probabilities for Spring 08 plants are approximately the same for existing PWRs due to PWSCC susceptible pressurizer nozzles during the Spring and Fall of 2007 (on the order of $4.x10^{-3}$ per plant, per six months).	Based on Monte Carlo sampling of flaw distribution, and fragility curve to predict nozzle rupture.	Uncertainty in the available data and understanding of the underlying physics of degradation mechanism.
5.	Performance measurement	Enhanced leakage monitoring programs and shutdown criteria in effect at the subject plants.	Effectiveness of enhanced leakage monitoring.	Uncertainty of reliability of monitoring program; no credit if pipe ruptures without detectable leakage occurring.

TABLE 11-4 ASSESSMENT OF OPTION 2.
CONTINUES OPERATION OF THE PLANTS FOR A SHORT TIME PERIOD WHILE NRC STAFF GATHERS ADDITIONAL INFORMATION

Preferred [**x**] Acceptable [ ] Not Acceptable [ ]				
No.	Driving Factor	Key Technical Inputs	Validity of Input	Confidence in Assessment
1.	Compliance with regulations	Continue to operate for a short time period because USNRC staff did not have sufficient information whether the advanced FEA (dated August 2007) continued to be applicable and that information from EPRI letters were not sufficiently conclusive to warrant immediate plant shutdown.		
2.	Defence-in-depth	Potential impact on the integrity of the reactor coolant system (RCS) pressure boundary. Butt weld problem may increase the frequency of loss of coolant accident (LOCA) in the size range requiring emergency core cooling system (ECCS) operation in the recirculation mode.	Enhanced leakage monitoring program to detect increased leakage at pressurizer nozzle welds.	Leakage monitoring programs vary from plant to plant, and are of no value if rupture occurs close in time to initial leakage.
3.	Safety margins	Assessment that potential reduction in safety margin for uninspected pressurizer welds affected by PWSCC would not result in a rupture event for one week of plant operation.	Review of additional information on advanced FEA completed in August 2007.	Sufficient time to review additional information on uncertainty due to the flaw profile of butt welds assumed in advanced FEA; i.e. pipe not considered likely to rupture within the one-week time frame.
4.	Risk assessment	EPRI probabilistic study showed that pressurizer nozzle failure probabilities for Spring 08 plants are approximately the same for existing PWRs due to PWSCC susceptible pressurizer nozzles during the Spring and Fall of 2007 (on the order of $4.x10^{-3}$ per plant, per six months).	Small likelihood that butt welds with PWSCC conditions would result in nozzle rupture in a week of plant operation.	Uncertainty in the available data and understanding of the underlying physics of degradation mechanism.
5.	Performance measurement	Enhanced leakage monitoring programs and shutdown criteria in effect at the subject plants.	Effectiveness of enhanced leakage monitoring.	Uncertainty of reliability of monitoring program; no credit if pipe ruptures without detectable leakage occurring.

TABLE II-5 ASSESSMENT OF OPTION 3.
ISSUE ORDERS FOR IMMEDIATE PLANT SHUT DOWN

Preferred [ ] Acceptable [ ] Not Acceptable [**x**]				
No.	Driving Factor	Key Technical Inputs	Validity of Input	Confidence in Assessment
1.	Compliance with regulations	Compliance with regulations not demonstrated; plant not allowed to restart after outage unless there is requisite reasonable assurance that public health and safety is protected.		
2.	Defence-in-depth	Loss of integrity of the reactor coolant system (RCS) pressure boundary. Butt weld problem may increase the frequency of loss of coolant accident (LOCA) in the size range requiring emergency core cooling system (ECCS) operation in the recirculation mode.	Butt weld problem causes LOCA event due to ruptured pressurizer nozzle welds.	Uncertain whether monitored leakage would indicate nozzle rupture.
3.	Safety margins	Assessment that safety margins are restored to at least the same level as that prior to discovery of potentially adverse conditions of pressurizer nozzle welds.	Inspection results show reasonable assurance that PWSCC would not compromise the RCS boundary.	Very low confidence that margin is adequate.
4.	Risk assessment	EPRI probabilistic study showed that pressurizer nozzle failure probabilities for Spring 08 plants are approximately the same for existing PWRs due to PWSCC susceptible pressurizer nozzles during the Spring and Fall of 2007 (on the order of $4.x10^{-3}$ per plant, per six months).	Some likelihood that butt welds with PWSCC conditions would result in nozzle rupture in a week of plant operation.	High uncertainty in actual risk.
5.	Performance measurement	Enhanced leakage monitoring programs and shutdown criteria in effect at the subject plants.	No enhanced leakage monitoring.	Uncertainty whether any leakage have missed detection.

II-5. EXAMPLE OF A DECISION ON A SAFETY ISSUE MADE BY A LICENSEE IN SWEDEN

II-5.1. Issue to be considered

To determine proper actions following a potential reduced reliability of emergency diesel generators (DG) in one of the three units at the OKG nuclear power plant.

II-5.2. Background

The unit is equipped with four emergency DGs set up in a two plus two single failure tolerant configuration. The two pairs, DGA+DGB and DGC+DGD respectively, serve different safety systems, and in case of a loss of regular power only two DGs, one in each pair, are needed to fulfil the function of providing emergency power.

During a certain period, a notably high number of failures occurred in DGA and DGB. The observed failures were not related to each other in any obvious way, and a common root cause could not be established. However, it was recognized that large maintenance activities were due for the DGs. There was a concern that the observation of failures clustered in time was not coincidental, but an early indication of a reduced reliability of the DGs. In either case, it was judged that the identified maintenance activities would probably secure the reliability at the nominal level.

II-5.3. Regulatory considerations

If the reliability of the DGs would indeed have been reduced significantly, this would imply a deviation from probabilistic assumptions made in the safety analysis report (SAR) and an increased nuclear risk. The licensee would then be required to take corrective actions to restore the reliability, or at least to take relevant compensating measures.

For a certain action or measure to be considered it would either need to be consistent with the constraints given in the technical specifications, or subject to an application for exceptions from requirements. Exceptions may, according to regulations given in SSMFS 2008:17 §28, be granted by the Swedish regulator if the licensee can present good reasons for the need of it, and at the same time demonstrate that the suggested action or measure will not violate the *intentions* of the requirements.

II-5.4. Licensee considerations

According to the technical specifications, preventive maintenance during power operation is allowed given that the single failure criterion can be met, and that the maintenance can be finalized within a certain specified time. To ensure that the single failure criterion is met, there is a prepared option to take credit for emergency gas turbine generators that are available at the site. However, it was estimated that the time needed for the maintenance activities would significantly exceed the allowed time limit. To be able to perform it, OKG would therefore have to apply for an exception from the requirements with respect to the specified time limit.

Another possibility would be to perform the preventive maintenance in a *safe shutdown mode* where there is no time limit for the maintenance.

II-5.5. Defined options

It was identified that more information was needed to decide on proper actions. A safety evaluation should be performed to provide insights on the safety significance of the issue. Three options were considered, the selection depending on the outcome of the safety evaluation. Possible outcomes are '*Negligible', 'Low', 'Medium'* or '*High'* safety significance.

Option 1 Apply for an exception from regulatory requirements, possibly taking interim compensating measures to reduce risk, and perform the necessary maintenance activities during power operation. *This option is viable only if the safety significance is 'Negligible'. Any other result would make it difficult to claim that the intentions of the requirements are not violated.*

Option 2 Wait until the next planned outage period, possibly taking interim compensating measures to reduce risk, and perform the necessary maintenance activities in a safe shutdown mode in compliance with the technical specifications. *This option is viable for 'Negligible', 'Low' or 'Medium' safety significance. For issues with*

'Low' safety significance compensating measures should be considered if practical. For 'Medium' safety significance compensating measures are usually necessary.

Option 3 Go to a safe shutdown mode immediately, and perform the necessary maintenance activities in compliance with the technical specifications. *This option would be the typical response if the safety significance is found to be 'High'.*

II-5.6. Formation of the team

The production manager, who is responsible for taking proper actions, decides on what parts of the OKG organization that should be represented in the decision support team. In the situation, experts on production, maintenance and engineering (including safety analysts) were selected.

II-5.7. Constituent factors

Standards and good practices

Since 2005 OKG has been using a standardized method for safety evaluation of nuclear risks. This decision making support tool is based on the principles presented in a draft version of the IAEA guide "Safety Evaluation of Operating Nuclear Power Plants Built to Earlier Standards" (CB-5 Revision 2, 1996-05-15). These principles include both a deterministic and a probabilistic assessment procedure.

Operating experience

The diverse set of failures indicated that 'ageing' could be the root cause. The recommendation from the supplier of the two DGs was to perform the necessary maintenance activities.

As an input for the safety evaluation, statistics on failures occurring in 2003-2011 were gathered for all four DGs. The failures were categorized according to failure mode, 'failure to start' or 'inadvertent stop'.

Deterministic considerations

Deterministic requirements and safety analysis, as described in the SAR, is the basis for evaluating safety issues from a deterministic viewpoint. The assessment is performed in five steps:

D1. Identify which barriers and safety functions that are affected by the issue.
The DG emergency power was postulated to have a reduced reliability.

D2. Determine the *Robustness* of activity barriers (intact, weakened or broken) and safety systems (intact, reduced redundancy or unavailable): *Robust*, *Adequate* or *Inadequate*
The safety concept was Robust since the single failure criterion would be met even without any corrective actions or compensating measures.

D3. Determine the *Frequencies* of the initial events that challenge the affected barriers and safety functions (frequencies are represented by the corresponding event classes): *H1* (normal operation), *H2* (anticipated events), *H3* (unanticipated events), *H4* (improbable events) or *H5* (highly improbable events)
The DGs are credited in events belonging to event classes H2, H3, H4 and H5.

D4. Estimate and categorize the *Consequences* of the relevant event sequences (new or more frequent sequences): *Moderate* (acceptable for H1 and H2 events), *Significant* (acceptable for H3 and H4 events) or *Serious* (acceptable for H5 events)
The issue did not affect the safety analysis, and the consequences following H2 events were assumed to be Moderate. Consequences for H3 and H4 events were assumed to be Significant, and consequences for H5 events were assumed to be Serious.

D5. Determine the deterministic estimate of the issue's safety significance level by inspection of the decision matrix in Table II-6.

TABLE II-6. DECISION MATRIX FOR DETERMINISTIC ASSESSMENT (N = Negligible, L = Low, M = Medium and H = High safety significance).

CONSEQUENCES	***Moderate***			***Significant***			***Serious***		
ROBUSTNESS	*Robust*	*Adequate*	*Inadequate*	*Robust*	*Adequate*	*Inadequate*	*Robust*	*Adequate*	*Inadequate*
FREQUENCY H1, H2	L	L	M	M	H	H	H	H	H
H3	N	N	L	L	M	H	M	M	H
H4	N	N	N	N	L	L	L	L	M
H5	N	N	N	N	N	N	L	L	L

For H2 and H3 events the issue was found to have Low safety significance, and for H4 and H5 events the safety significance was Negligible. The issue was thus found to have Low safety significance.

Probabilistic considerations

Probabilistic safety analysis, as described in the SAR, is the basis for evaluating safety issues from a probabilistic viewpoint. The assessment is performed in six steps:

P1. Identify relevant aspects where the safety issue under evaluation may have a negative influence on nuclear safety.
The reliability parameters for the DGs were postulated to be invalid.

P2. Determine if the identified aspects are included in the official PSA-model[18], or if similar aspects may be relevant for the evaluation.
The official PSA model includes the DGs.

P3. Estimate affected initiating-event frequencies and/or probabilities (component availability and reliability).
New values for the affected reliability DG parameters were estimated based on the plant specific failure statistics from 2003-2011.

P4. Estimate the contribution to core-damage frequency f_X from issue "X" using either the official model (reasonably valid in situations with small changes in frequencies and probabilities) or a model that has been modified with respect to the safety issue under evaluation. The *Relative safety importance* of issue "X" is given by the expression $S_X = f_X/f_{tot}$, where f_{tot} is the total core-damage frequency according to the official model. (Note that in extreme situations $S_X > 1$ may be possible.)
Two estimates were produced. The relative safety importance with the new parameter values (but no other changes) was found to be 0.35. With a doubled rate of periodic testing (a possible compensating measure) the relative safety importance was found to be 0.15.

P5. Determine the *Probabilistic safety level* based on the total core-damage frequency (f_{tot}) according to the SAR: *Excellent* ($f_{tot} < 10^{-5}$ year^{-1}), *Adequate* ($10^{-5} \leq f_{tot} < 10^{-4}$ year^{-1}), *Questionable* ($10^{-4} \leq f_{tot} < 10^{-3}$ year^{-1}) or *Unsatisfactory* ($f_{tot} \geq 10^{-3}$ year^{-1})
The probabilistic safety level was found to be in the 'Adequate' region.

P6. Determine the probabilistic estimate of the issue's safety significance level by

[18] PSA = Probabilistic Safety Analysis

inspection of the decision matrix in Table II-7.

TABLE II-7. DECISION MATRIX FOR PROBABILISTIC ASSESSMENT (N = Negligible, L = Low, M = Medium and H = High safety significance).

RELATIVE SAFETY IMPORTANCE	PROBABILISTIC SAFETY LEVEL			
	Excellent	Adequate	Questionable	Unsatisfactory
Sx ≥ 100	H	H	H	H
100 > Sx ≥ 30	M	H	H	H
30 > Sx ≥ 10	M	M	H	H
10 > Sx ≥ 3	L	M	H	H
3 > Sx ≥ 1	L	L	M	H
1 > Sx ≥ 0.3	N	L	M	M
0.3 > Sx ≥ 0.1	N	N	L	M
0.1 > Sx ≥ 0.03	N	N	L	L
0.03 > Sx ≥ 0.01	N	N	N	L
0.01 > Sx	N	N	N	N

Without compensating measures, the safety significance was found to be Low. With compensating measures in the form of doubled rate of periodic testing, the safety significance was Negligible.

II-5.8. Evaluation of the options

The evaluation of the options was done in advance, the result depending on the outcome of the safety evaluation.

Postulating that the reliability of the DGs was reduced, the safety significance was found to be Low, both deterministically and probabilistically. Tentative modifications to the PSA-model indicated that an increased rate of periodic testing would probably be a relevant compensating measure, essentially restoring the probabilistic safety level to the nominal value.

II-5.9. Integrated decisions

Based on the result of the safety evaluation, option 2 was selected. As a compensating measure it was decided to increase the rate of periodic testing of the DGs. It was also decided to launch the necessary maintenance activities at the coming outage period.

Finally, it was decided that the compensating measures should not be removed without verifying that the corrective action had secured the reliability of the DGs at the nominal level.

II-6. EXAMPLE OF A DECISION ON A SAFETY ISSUE MADE BY A LICENSEE IN SLOVAKIA

II-6.1. Issue to be considered

To determine whether further measures need to be taken to decrease the contribution to the risk from shutdown states (measured by CDF). A well-balanced risk profile is one of the Regulatory Requirements.

II-6.2. Background

The contribution to the risk (evaluated by a full scope PSA) from shutdown modes of operation is more than 50%, and a major part of this is due to the state when the reactor is opened. The reasons for this are as follow:

- There are only two redundant safety systems available during shutdown operation.
- All the safety systems that can refill the reactor are initiated manually, i.e. operator intervention is always necessary.

II-6.3. Regulatory considerations

The factors considered by the regulatory body are as follows:

- The continuous increase of nuclear safety is a primary regulatory requirement. The licensee is obliged to use a PSA to enhance the level of nuclear safety (Act No. 350/2011 Coll. amending and supplementing Act No. 541/2004 Coll. on the Peaceful Use of Nuclear Energy "Atomic Act").
- One of the required results of the PSA is identification of measures or possibilities for increasing nuclear safety (Regulation No. 31/2012 Coll., amending and supplementing Regulation No. 58/2006 Coll., Sec. 20).
- The obligation to use the PSA is stated in Regulation No. 430/2011 Coll. on nuclear safety requirements (e.g. support management and decision making in ensuring nuclear safety, balanced risk profile).
- All relevant regulatory requirements must be met (e.g. single failure criterion, defence-in-depth concept, national and international standards).

II-6.4. Licensee considerations

The factors considered by the licensee are as follows:

- All PSA studies performed for operating VVER units, demonstrated a high-risk contribution associated with operator actions during the refuelling period.
- Plant policies to carry out refuelling operations are well developed and although refuelling operations and maintenance activities are considered as routine tasks, they are precisely planned by using special 'activity programs'.
- All anticipated events are covered by procedures for abnormal operation as well as by shutdown Symptom Based Operational Procedures (SBOP)

PSA identifies as major contributors to risk such as over drainage of RCS inventory, loss of heat removal via secondary side, loss of natural circulation and boron dilution.

II-6.5. Defined options

Elimination of potential operator errors is considered as the key factor to balance plant risk profile and possible options must be oriented toward decreasing human error probability.

The following five options were considered:

Option 1	Further enhancement of plant maintenance (refuelling) procedures.
Option 2	Further enhancement of shutdown SBOPs including enhancement of monitoring system.
Option 3	Improving operators training process.
Option 4	Substitute operator activity to refill reactor by automatic actions
Option 5	Reasonable combination of previous options.

II-6.6. Formation of the team

The first ideas of potential modification were prepared by the nuclear safety department of Mochovce NPP (units 3 and 4 that are under construction) in cooperation with Vyskumny Ustav Jadrovej Energetiky (VUJE). Mochovce NPP safety department also coordinated the involvement of further organizations that contributed to the evaluation of suggested options.

II-6.7. Constituent factors

Standards and good practices

The following practices and international experience are relevant to this issue:

- In general, the shutdown risk forms a considerable fraction of the PWR reactor risk profile due to the reasons outlined above.
- There is no acceptable solution of this problem for operational PWRs.

Operational experience

A review of plants' operational events demonstrated several cases of loss of natural circulation during nonstandard operation (the probable cause is penetration of nitrogen from the pressurizer via sprays), near over draining events (caused mainly by imperfect measurement) and loss of offsite power causing loss of secondary heat removal. All events were mitigated in time by operator actions and the automatic start of plant diesel generators.

Deterministic considerations

Safety analyses demonstrated that there is a limited time window for operator response, e.g. loss of natural circulation in the states with low reactor level (below the reactor flange) leads to fuel damage in one to two hours. The transient is worsened in case of erroneous opening of the main isolation valve of the maintained loop, and substantially reduces operator ability to mitigate the accident.

The issue is also related to the mitigation of severe accidents because the containment function can be impaired during refuelling.

- *Compliance with regulations:* All the options under investigation follow the requirements of the Slovak regulation on permanent safety enhancement.
- *Defence in depth*: As the containment function can be limited, potential fuel damage must be reduced.
- *Safety margins*: The results of deterministic analyses show that the available safety margins can be violated by the rapid progression of several anticipated events.

Probabilistic considerations

The currently available PSA studies demonstrate a high risk for all units.

Other considerations

There was no international experience at that time indicating a solution of this problem.

Feasibility and risk informed considerations were taken into account as additional input factors that must be considered for all decision options.

Consideration regarding the interface with nuclear security

The issue is not related to the security.

Additional information:

- The plant has an inbuilt emergency heat removal system.
- The plant configuration during refuelling can be complex (pairing loops and safety systems etc.)
- Occupational safety is an integral part of plant refuelling strategy; so, the adopted option can affect this aspect.

II-6.8. Evaluation of the options

Factors considered in ranking the options were: feasibility, effectiveness, occupational safety and capability to reduce the risk (Risk assessment).

Option 1 Further enhancement of plant maintenance (refuelling) procedures.

Feasibility:	Plant uses check lists and special programs for all important manipulations. Implementing additional rules is not feasible; the only exception is for alignment of drainage paths.
Effectiveness:	The effectiveness is limited, only leading to a decrease of a part of the main induced LOCA frequencies by a factor of 0.1 to 0.5
Occupational safety:	The option is neutral
Risk assessment:	Risk of over draining will be lower, however only for events with the slowest progression

Option 2 Further enhancement of shutdown SBOPs including additional monitoring capability.

Feasibility:	Shutdown SBOPs cover all postulated event and their enhancement potential is limited. The same holds for additional monitoring capability, e.g. nowadays reactors are equipped with discrete measurement of level for nonstandard operational state.
Effectiveness:	The entry conditions to shut down SBOPs are too complex, so further extension of the entry conditions can be contrary to the intention and it can reduce capability of adequate crew response. Moreover, additional monitoring capability do not provide an extension of the available time window
Occupational safety:	The option is neutral
Risk assessment:	Evaluation of the option is a complex problem. The benefit of such an option can be evaluated only through analysis of the cognitive part of operator response, and backup by additional monitoring capability will have negligible effect

Option 3 Improving operators training process

Feasibility: There is only a limited capability to perform simulator exercises; so, an extension of training of shutdown design basis accidents will reduce the amount of training in other areas.

Effectiveness: Similar to option 2. More-over, there is also a dependency problem, because many of the most significant shutdown accident scenarios are caused by human errors.

Occupational safety: The option is neutral

Risk assessment: Evaluation of this option is possible using human reliability analysis. However, the benefit of this option will be reduced due to human dependency, i.e. the final human error probability will be limited by the dependent failure factor.

Option 4 Substitute operator activity to refill reactor cavity by automatic actions

Feasibility: This option introduces a complex technical challenge:

- It is necessary to determine a supply of water, or to introduce a water source capable of over flooding the core in a short time and to maintain this for a long time
- The control logic must be consistent with the current plant design, e.g. tap lines, instrumentation, "ESFAS" and local protection signals.

  The conclusion was, despite the complexity of the problem, an automatic start of the low-pressure injection system triggered by reactor level can be implemented.

Effectiveness: Thermo-hydraulic analyses demonstrated that this option can effectively avoid core damage.

Occupational safety: This option introduces a new danger for maintenance personnel, who can be threatened by flooding of the refuelling pool.

Risk assessment: Preliminary PSA results demonstrated that the frequency for fuel damage can be reduced by a factor of 3 to 5.

Option 5 Reasonable combination of previous options

Note: The combination of the previous options consists of the following modifications:

1. Modification of the procedures for reactor drainage - introducing another independent check of the drainage path
2. Use of the current instrumentation and a new independent control system to ensure the automatic start of low pressure injection system, the flow rate of which will be maintained by an in-built control valve.
3. Automatic start will be implemented as a three-stage process:
   a. Stage 1: Additional monitoring capability, facilitating for the maintenance crew to evacuate the refuelling pool plus an alarm for the main control room crew
   b. Stage 2: Start of the working safety train to refill the reactor cavity
   c. Stage 3: Start of the reserve safety train if the working fails

Feasibility:	The feasibility and thermo-hydraulic studies demonstrated that the automatic three stage process is feasible.
Effectiveness:	See Option 4.
Occupational safety:	Occupational safety is maintained by additional monitoring capability and by delaying the low-pressure pump start to provide sufficient time to evacuate the refuelling pool
Risk assessment:	See Option 4.

II-6.9. Integrated decisions

The reasoning given above shows a limited effectiveness of the available options, with exception of option 4. Hence, **Option 5**, combining the most effective modifications, was selected as the preferred option due to its high ranking.

The regulatory authority accepted this decision with the additional requirement to ensure qualification of the control signal according to IEC 61226.

The detail design change considered in option 5 is currently under development.

II-7. EXAMPLE OF A DECISION ON A SAFETY ISSUE MADE BY A LICENSEE IN SWITZERLAND

II-7.1. Issue to be considered

To determine whether further measures needed to be taken to enhance the mitigation provided for hydrogen and carbon monoxide burns during severe accidents that have the potential to affect the integrity of the containment. This was one of the requirements identified during the Periodic Safety Review (PSR) carried out at the Gösgen nuclear power plant (KKG) in 1999.

II-7.2. Background

At the time of the PSR, the position regarding combustible gas control at KKG was as follows:

- There are two thermal recombiners which are sized to cope with the magnitude of hydrogen releases that would occur following a small break LOCA (which were back fitted to the plant following Three Mile Island).
- There are a passive and an active (pneumatic) hydrogen distribution system based on the fracture of shear bolts opening doors and ceilings to create a large containment volume for diluting the hydrogen concentration using natural flow patterns.
- There is a filtered containment venting system that can be used to mitigate the build-up of hydrogen by controlled venting. The system is inerted and has a design pressure that is double the containment design pressure. The system can be operated from a local control panel.

There was no formalized Severe Accident Management Guidelines (SAMG) for the plant at that time.

II-7.3. Regulatory considerations

The factors considered by the regulatory body are as follows:

- Swiss guideline R-103, p. 2.2 requires actions to be carried out to prevent hydrogen concentrations in the containment (local or global) reaching a level that might challenge containment integrity during severe accidents.
- KKG has a highly compartmentalized containment that may have a negative impact on the distribution of hydrogen during a severe accident.
- The concrete used for the reactor building has a high content of carbonate. Molten core - concrete interaction (MCCI) may lead to a significant release of burnable carbon monoxide.
- The effect of carbon monoxide burns was not yet analysed for the plant specific situation.

Some similar plants in Germany have installed autocatalytic passive recombiners based on recommendation issued by the German reactor safety commission (RSK) in 1997. Swiss atomic law requires continuous plant upgrades to be made according to the state of the art in nuclear technology if these upgrades will lead to an improvement in safety and can be made with reasonable effort. Goesgen is a German design of Pressurised Water Reactor (PWR).

II-7.4. Licensee considerations

The factors considered by the licensee are as follows:

- A more detailed analysis of the situation needs to be carried out which needs to take account of information from the plant vendor, information from manufacturers of hydrogen mitigation devices and international experience.
- Internal documents developed by VGB (Germany based licensee group operating the majority of KWU reactor plants) in the contract with the plant vendor did demonstrate that the risk of hydrogen-carbonate burns was rather low due to containment inertisation caused by typical accident sequences – loss of coolant accidents (LOCAs) and station black-out (SBO) with and induced hot leg rupture.
- A research activity supported by the licensee and performed at the Swiss Paul Scherrer Institute (PSI) supported the results of the generic VGB analyses in a plant-specific analysis for Goesgen.
- Risk informed cost-benefit considerations based on criteria developed by the Group of Plant managers of Swiss nuclear power plants. The accepted external costs for the reduction of the core damage frequency (CDF) by 1.0×10^{-6} /year or of the large early release frequency (LERF) by 1.0×10^{-7} /year for a 1000 MWe plant should not exceed 1 million Swiss Francs. Actions leading to a reduction of CDF must be preferred in comparison to actions leading only to a reduction of LERF.

In the USA, the hydrogen issue for severe accidents was considered as resolved for standard Westinghouse dry containments without the installation of additional autocatalytic recombiners based on the analysis of severe accidents. This information was published for the first time at the USNRC water reactor research meeting 1995. Passive Autocatalytic Recombiners (PARs) are not installed at plants in the USA for mitigating the consequences of severe accidents. The USNRC required hydrogen mitigation only after a design basis LOCA accident (are specified in the USNRC Regulatory Guide 1.7 and Part 10 of the Code of Federal Regulations (CFR) 50.44).

II-7.5. Defined options

The common requirement for all the possible options is to perform an in-depth analysis of the problem to obtain a better understanding of the problem including all available sources of information from vendors, from analyses, from experiments as well as the development of plant–specific analytical tools.

The following four options were considered:

Option 1	The existing combination of hydrogen mitigation facilities is sufficient so no changes need to be made.
Option 2	Installation of a full set of hydrogen recombiners with the capacity to cope with all relevant severe accident scenarios.
Option 3	Installation of a reduced set of hydrogen recombiners with the capacity to cope with slow hydrogen and carbon monoxide releases after vessel breach.
Option 4	Similar to Option 1 with the additional development of SAMG considering mitigation strategies to prevent hydrogen/carbon monoxide burns.

II-7.6. Formation of the team

The permanently standing Internal Safety Committee represents the decision making team. It consists of the head of the technical departments (mechanical, electrical, chemistry and radiation protection, plant operations), the general plant manager and his deputy, the person responsible for reactor safety and PSA (joint function), head of external communication, head of administrative support. The person responsible for reactor safety/PSA was assigned as the project manager to provide the necessary technical information and the strength and weaknesses of each of the options. For upgrade options, estimates of the costs also had to be provided.

II-7.7. Constituent factors

Standards and good practice:

The following standards and good practices are relevant to this issue:

- The guideline R-103 of the Swiss Nuclear Safety Inspectorate requires that a means is incorporated for the mitigation of hydrogen burns.
- Many nuclear power plants have installed, or plan to install, passive autocatalytic recombiners. Therefore, the installations of PARs must be looked at as a feasible alternative for preventing high concentrations of hydrogen in the containment after a severe accident.

Operating experience:

The initial international experience of the use of some types of recombiners indicated problems with the maintainability due to a possible degradation of the catalytic coating by environmental effects including accumulation of dirt and dust during normal operation.

Deterministic considerations:

The issue is related to the mitigation of severe accidents which relates to safety level 4 in the defence-in-depth concept. Detailed safety analysis demonstrated the self-inertisation of the containment during important accident sequences such as small break LOCA and SBO with failure of pressurizer relief valves in the open position. The analyses are associated with large uncertainty. The most important uncertainty is related to incomplete verification and validation of the severe accident codes for integral reactor accident conditions. Typical examples are: insufficient accuracy of the prediction of hydrogen generation during the core meltdown phase, limited models for the prediction of reactor vessel rupture, limited models for modelling core cooling for degraded reactor cores. Results from internal initial proprietary factory tests of different types of autocatalytic passive recombiners in a few instances lead to detonations before a final qualification was achieved. The root cause of the problems to some extent was found to be generic – due to the thickness of catalytic layers, a delay until the start of effective action was found as well as spalling effects were identified.

- **Compliance with regulations**: All the options under investigation are justifiable (1999) under the actual Swiss regulation if their efficiency is proven (Swiss Guideline R-103, p. 2.2).
- **Defence in depth**: Containment integrity relies on preventing hydrogen and carbon monoxide deflagrations or detonations that may lead to pressure and heat loads exceeding the capacity of the containment structure. Early filtered containment venting leads to the release of noble gases into the environment jeopardizing the containment function.
- **Safety margins**: Safety margins for the containment integrity in terms of load capacity for hydrogen and carbon monoxide deflagrations or detonations must be evaluated to get a better understanding of the potential impacts of hydrogen/carbon monoxide deflagrations.

Probabilistic considerations:

The available PSA at that time was a full scope analysis that included all relevant internal and external events. The calculated CDF and LERF were 2.0×10^{-6} /year and 2.0×10^{-7} /year respectively. The contribution of hydrogen deflagrations to containment failure was regarded as low due to the containment design. The Swiss regulatory body had fully reviewed the Gösgen PSA model and concluded that hydrogen burns contribute only to 3% to the probability of exceedance of the source term used for the off-site emergency planning.

Other considerations:

There was international experience at that time of plants that had installed passive autocatalytic recombiners of different design, different capacity and for different purpose (mitigation of design basis accidents, design extension accidents or severe accidents)

Maintainability and risk informed cost- benefit considerations were included as additional input factors to be considered for all decision options.

Additional information:

Before the final evaluation, the following additional information was provided to the decision maker (Internal Safety Committee):

- The plant specific severe accident analysis provided by Paul Scherrer Institute (PSI) as well as new analyses performed by a plant-specific severe accident simulator (MELCOR-based) confirmed the self-inertisation of the containment for most accident sequences (except steam generator tube rupture with significant release of steam outside the containment) and the very low potential for hydrogen deflagrations. Local hydrogen burns may occur depending on the modelling parameter used. The relatively large release of carbon monoxide due to MCCI was also confirmed.
- Detailed analysis of the PSA results including sensitivity studies demonstrated that the main contributors to CDF and LERF are from external events especially seismic events leading to an early isolation failure due to a possible failure of air ventilation lines/valves at high ground motion accelerations. The consequences of the resulting releases cannot be mitigated by hydrogen mitigation devices. Therefore, the benefit of the installation of passive autocatalytic recombiners with respect to risk reduction and the reduction of off-site releases is limited.
- Analysis confirmed that filtered venting is a valuable alternative to reduce hydrogen

and carbon monoxide concentration in the containment.

- A very high load capacity of the containment steel shell was confirmed for the case of dynamic loading due to hydrogen deflagrations.
- The main root cause of observed hydrogen detonations during internal factory tests was established. The root cause is a delay in the start of effective operation of the passive autocatalytic recombiner due to the thickness of the catalytic coating. In situations with fast (instantaneous) release of hydrogen, recombiners may surge hydrogen into the proximity of their location, leading to high local concentrations. A subsequent overloading of the recombiner can lead to the formation of a detonation cell or to a deflagration detonation transition (DDT).

Cost benefit considerations for the installation of autocatalytic passive recombiners as developed by the group of Swiss Nuclear Power operators (applicable only if the CDF is below $1.0x10^{-5}$ /year and the LERF is below $1.0x10^{-7}$ /year) led to a negative result. The costs of installation of a full set of recombiners exceeded the acceptable costs by more than a factor of 10. The installation of a reduced set of recombiners would not lead to a significant additional benefit in comparison to the actual situation at the plant.

II-7.8. Evaluation of the options

Ranking of inputs: Compliance with regulations and safety margins were ranked at the top, but no significant differences between the options were identified. The next inputs in ranking were deterministic considerations (including qualification) and risk assessment (for the assessment of the benefit of upgrade options). Maintainability and risk informed cost-benefit considerations were ranked next.

Option 1 - The existing combination of hydrogen mitigation facilities is sufficient, and so no changes need to be made

Compliance with regulations:	This can be demonstrated because the technical means available are capable to prevent significant radioactive releases due to hydrogen burns
Safety margins:	The available safety margins are high. Some concerns were related to the efficient use of the available means due to the lack of formalized guidance
Deterministic considerations:	The containment has a very high load capacity and the technical means available are suitable to mitigate the consequences of hydrogen burns. The complexity of the plant will not increase
Risk assessment:	The risk of radioactive releases due to hydrogen burns is low. It will remain unchanged
Other:	No new maintainability issues are related with this option. The existing thermal recombiners are ageing and some maintainability issues may rise in the future.
Cost-benefit considerations:	A later replacement by another technology (the existing type is not produced anymore) must be considered as an option. No additional costs are related with this option

Option 2 - Installation of a full set of hydrogen recombiners with the capacity to cope with all relevant severe accident scenarios.

Compliance with regulations:	A formal licensing approval process must be launched that could last several years.
Safety margins:	A full proof of the efficiency of the solution *for all accident sequences* is deemed not feasible due to the limitation of passive autocatalytic recombiners to cope with fast hydrogen releases. A certain improvement can be demonstrated for severe accident sequences after vessel breach that is jeopardized by the concern about a possible DDT (deflagration detonation transition) at an earlier accident stage (e.g. SBO with induced 'hot leg failure', steam generator tube rupture with vessel breach). DDT can challenge the existing safety margins of the plant.
Deterministic considerations:	It was established that there is only one design of passive autocatalytic recombiners suitable to reduce the concern related to DDT (and to maintainability). This type was only at development stage (in 2003). Due to incompatible prices, the production of this new type was not started and the development aborted. The qualification of all other types of recombiners for fast hydrogen release sequences was estimated to be unsatisfactory
Risk assessment:	A net risk reduction would result from the installation of recombiners. There is a difficulty to assess trade-off between a possible increase in risk at an early accident stage due to an increased DDT probability
Other:	There are some additional maintainability concerns related to the protection of the recombiners against environmental effects
Cost benefit considerations:	The costs of the installation of recombiners are not justified by the benefit of a possible risk reduction

Option 3 – Installation of a reduced set of hydrogen recombiners with the capacity to cope with slow hydrogen and carbonate monoxide releases after vessel breach.

The assessment is essentially the same as for the installation of the full set of recombiners. The DDT concerns (related to a potential overload) were assessed to be even higher and the risk reduction benefit was assessed as somewhat lower (not much).

Option 4 – Similar to Option 1 with the additional development of SAMG considering mitigation strategies to prevent hydrogen/carbon monoxide burns

The assessment of the options is the same as for option 1) with the following differences:

- The development of SAMG with more detailed guidance on hydrogen mitigation reduces human error risks and the probability of operator action failures in a complex situation;
- A risk reduction in comparison to option 1) was established due to decreased human error probabilities for accident management actions; and
- Because the development of SAMG in general was found to be a good international practice and it was decided to launch a SAMG implementation project, no additional costs were related to this option.

II-7.9. Integrated decisions

Option 4 was selected as the decision for the reasons given above.

Option 3 was regarded as a potential alternative for the replacement of existing thermal recombiners in the future.

The regulator accepted this decision with the consideration to re-review the issue in case of new technological developments as well as in case of a future replacement of thermal recombiners. The PSR requirement was legally closed.

II-8. EXAMPLE ON DEALING WITH A DECISION RELATED TO RISK OF HIGH-ENERGY LINE BREAKS WITHIN THE TURBINE HALL OF WWER-440 REACTORS IN UKRAINE

II-8.1. Issue to be considered

To determine appropriate measures to reduce overall risk related to dependent multiple failures of SSC due to spatial interactions resulting from high-energy line breaks within the turbine hall (steaming, spray, pipe whip, jet impingement, etc.) at Rivne NPP Units 1 and 2 with WWER-440 reactors.

II-8.2. Background

Due to the lack of separation of equipment in the secondary heat removal systems for Rivne NPP Unit 1, there is a potential for failure of secondary equipment due to consequential effects following secondary pipe breaks in turbine hall elevation + 15 m. The area situated between the turbine hall and the intermediate building is particularly vulnerable due to the accumulation of vital equipment (main steamlines, feedwater lines, emergency feedwater piping, SG valves) at around 14.7 m level and underneath. The possibility of damage to the equipment directly by flooding, spraying, and steam flooding was addressed in the Flooding PSA.

As a result, requirement on elimination of the safety deficit was stated in the Safety Upgrade Program for Ukrainian NPPs (2006-2010), approved by Cabinet of Ministers of Ukraine.

II-8.3. Regulatory considerations

Insufficient protection against multiple failures resulting from high-energy pipe breaks could seriously affect defence-in-depth to level 3 of protection. The safety functions would be questionable depending on the loss of redundant trains in Design Basis Accident (DBA) and Beyond Design Basis Accident (BDBA). To prevent loss of safety functions, adequate measures must be developed and effectively implemented. Specifically, the series of measures aimed at preventing consequences concerned with secondary circuit piping rupture outside the containment should include implementation of Break Exclusion Region (BER) concept ('superpipe concept') or other compensatory measures (in case of impossibility) should be developed (so called 'measure 2.4.2').

II-8.4. Licensee considerations

Implementation of the BER concept in turbine hall elevations is very difficult due to complicated geometric arrangements of pipes, compartments and structures. Full-scope implementation of the BER concept requires complete reconstruction of some compartments and pipe layouts. It is very expensive and time-consuming, and cannot be performed in terms prescribed by the Safety Upgrade Program for Ukrainian NPPs.

After evaluations, the licensee proposes to use a compensatory measure, such as the newly constructed auxiliary emergency steam generator feedwater system (AEFS). The AEFS system is a two-train system dedicated to providing feedwater to steam generators in case of common-cause failure of all main and emergency feedwater supply systems.

The system was installed during preparation of RNPP Units 1 and 2 for long-term operation and commissioned in full scope in 2010. The AEFS is in a separate building that was specially constructed; feedwater tanks are located outside the AEFS building on individual foundations and are connected with the AEFS building by an underground channel. The system is designed to: keep the required coolant level in steam generators to ensure heat removal from the core and prevent overheating and damage of fuel rods, provide emergency shutdown of unit 1 and 2 reactors and their safe transfer to cold shutdown state in case the main and emergency feedwater supply systems fail under different initiating events.

II-8.5. Defined options

To address the issue, four options have been defined and evaluated:

- Option A: Reject implementation of measure 2.4.2 (i.e. preservation of the current safety state);
- Option B: Implementation of AEFS as a compensatory measure, excluding the BER concept from consideration;
- Option C: Implementation of the BER concept only, without additional measures;
- Option D: Consideration of both proposed measures to eliminate safety deficit: BER concept and AEFS.

II-8.6. Formation of the team

The review team consisted of one inspector from the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) and four engineers from SSTC NRS (TSO for SNRIU), including specialists on system analysis and data analysis.

II-8.7. Constituent factors

Standards and good practices:

Measures under the Safety Upgrade Program for Ukrainian NPPs are part of licensing conditions for RNPP, and must be performed. The scope of justifications should satisfy requirements of NP 306.2.106-2005 “Requirements for modifications of nuclear installations and their safety assessments”.

The overall level of safety must meet the General Safety Provisions, which require that core damage frequency should be less than $1.x10^{-4}$ /year.

Operating experience:

The licensee indicated that the problem of high-energy line breaks (steam and feedwater lines) with a high potential to cause a combination of safety-related SSC faults. In the worst case, this leads to complete loss of secondary heat removal function.

Although guillotine breaks of high-energy lines were not observed at RNPP Units 1 and 2, the plant operational experience of SSC leaks and ruptures was used to evaluate frequencies of postulated initiating events.

Deterministic considerations:

Insofar as, except for LOCAs, the steam generators are the only way to cool the reactor core, the feedwater supply must be ensured in all accident conditions, including internal and external hazards. This requires that the steam generator inventory be preserved and able to cope with the main common-cause failures which would prevent decay heat removal via the steam generators. In the original design of RNPP Unit 1 and 2, all the systems feeding the SGs are in the turbine hall and are not protected against common-cause failures such as a big fire, flooding, earthquake. Furthermore, all the pipes go through the intermediate building between the reactor building and the turbine hall, where all the main steam and feedwater lines are located, which may lead to a total loss of feedwater in case of a steam line break with a pipe whip. Therefore, the emergency feedwater systems should be installed in or relocated to a separate building and the routing of the pipes should prevent the total loss of the system in case of a single event.

Compliance with regulations: Scope of justifications for all options should satisfy requirements of NP 306.2.106-2005 “Requirements for modifications of nuclear installations and their safety assessments”. All the options should satisfy probabilistic criteria stated in section 4.1 of the General Safety Provisions.

Since implementation of safety upgrade measures was included in licensing conditions, Option A does not meet regulations, Options B, C and D follow regulations.

Defence in depth: Insufficient protection against multiple failures resulting from high-energy pipe breaks could seriously affect defence-in-depth to level 3 of protection.

Safety margins: Sufficient safety margins and qualification of SSC located in the turbine hall in terms of SSC vulnerability to harsh environment conditions (pressure, temperature and humidity) should be ensured.

Probabilistic considerations:

Special PSA study was performed to evaluate impact of the options in question on the core damage frequency of RNPP Unit 1. The scope of analysis includes steam line ruptures and feedwater line breaks outside the containment. Regulatory review of base case PSA and PSA study was performed. Correctness and adequate technical quality were checked. According to the PSA results, for Options D and B decrease in CDF is the highest and constitutes about 2.0×10^{-5} /year, while Option C has less impact on CDF (2.30×10^{-6} /year). Option A does not change the baseline CDF.

Other considerations:

Maintainability and cost considerations were considered as important, but not vital input factors to be taken into consideration for all decision options

II-8.8. Evaluation of the options

Option A - Reject implementation of measure 2.4.2.

Compliance with regulations:	Non-implementation of the Safety Upgrade Program is treated as negative impact.
Defence-in-depth	Due to insufficient protection against multiple failures, the option is treated as negative impact
Safety Margin	Safety margins remain the same.
Equipment qualification	No change comparing to current state, however presence of safety deficit is considered as negative
Probabilistic	No change comparing to current state, neutral impact

Cost	No change comparing to current state, neutral impact

Option B: Implementation of AEFS as a compensatory measure, excluding the BER concept from consideration

Regulations:	Although exclusion of the BER concept from consideration does not comply with regulations, implementation of the compensatory measure is treated as slightly positive
Defence-in-depth	Due to compensatory measures, additional protection against multiple failures is considered as slightly positive
Safety Margin	Positive impact due to additional sources of feedwater to SG
Equipment qualification	No change comparing to current state, however presence of safety deficit is considered as negative
Probabilistic	Decrease in CDF of $1.96x10^{-5}$ /year was considered as very positive. Total CDF meets regulatory requirements
Cost	No change comparing to current state, neutral impact

Option C: Implementation of the BER concept only, without additional measures

Compliance with regulations:	Implementation of the BER concept meets requirements from the Safety Upgrade Program. Positive impact.
Defence-in-depth	Protection against multiple failures is considered as positive
Equipment qualification	Implementation of the BER concept is considered as positive
Probabilistic	Decrease in CDF of $2.30x10^{-6}$ /year was considered as very positive. Total CDF meets regulatory requirements
Cost	Complete implementation of the BER concept is time-consuming and very expensive. Serious negative impact

Option D: Consideration of both proposed measures to eliminate safety deficit: BER concept and AEFS

Compliance with Regulations:	Implementation of the BER concept meets requirements from the Safety Upgrade Program. Positive impact.
Defence in depth	Protection against multiple failures is considered as positive
Safety Margin	Positive impact due to additional sources of feedwater to SG
Equipment qualification	Implementation of BER concept is considered as positive
Probabilistic	Decrease in CDF of $1.98x10^{-5}$ /year was considered as very positive. Total CDF meets regulatory requirements
Cost	Complete implementation of the BER concept is time-consuming and very expensive. Serious negative impact

II-8.9. Integrated decisions

Regulatory review of safety justifications was performed. Correctness and adequate technical quality were checked, compliance with decision making principles is ensured. Integration of the analysis results was done without scoring of listed considerations. However, assessment of the decision options impact on different inputs showed that:

- Option A should be rejected since only negative impact is found;
- The cost of Option D is extremely high, meanwhile risk decrease is almost the same

with Option B;
- The cost of Option C is much higher than Option B, meanwhile much lower risk decrease is achieved.

Hence Option B was selected as a decision. Measure 2.4.2 was treated as fulfilled and implementation of the BER concept can be abandoned.

Probabilistic considerations were important for this decision.

II-9. EXAMPLE ON DEALING WITH A DECISION RELATED TO A ONE-OFF EVENT (UK)

This is an example on how to manage different risk related aspects during the replacement of a crane in a high-hazard area.

II-9.1. Issue to be considered

Agreement was needed from the regulatory body to the procedures for replacement of an ageing crane in a building containing waste silos. The silos tops were about 15 metres above ground, the building about twice as high.

The crane was needed to allow for decommissioning of the silos. The silos were filled with water and contained material from activities from the 1950s onwards. They were known to consist of a range of radioactive substances which led to the production of radiolytic hydrogen.

II-9.2. Background

Due to the deterioration with age of the building, it was decided that the removal of the waste from the silos was necessary; however, the agreed method required the use of the building crane. The existing crane was no longer fit to be used and would have to be replaced. This would require moving heavy structural items over the flat concrete tops of the silos. It was accepted that dropping these items from the crane height would cause failures of the tops. In addition, the necessary cooling systems and ventilation systems would not withstand a drop. The contents of the silos would lead to significant offsite effects as the building is open to the atmosphere. In addition, the background radiation level in the building was high so it restricted some operations.

II-9.3. Regulatory considerations

The regulatory body considerations clearly required that the silos needed to be emptied and agreed with the planned way to do this. However, the state of the existing crane and its supports were such that it was too great a risk to use it. This decision was based on an examination of the crane, which had not been used for many years. Having decided that the crane needed replacing, the issues were to ensure that the work was carried as safely as reasonably practicable, but at the same time the concerns about the building deterioration and the background radiation in it meant that options were limited.

II-9.4. Licensee considerations

The building was one of the high hazard stores on the site and so removal of the waste in it to a safer storage mode was a high priority. The building was surrounded by other buildings and systems containing significant amounts of radioactive material and so the work had to be scheduled to prevent risks to them.

II-9.5. Defined options

The size and structure of the existing crane and the risks of dropping onto the silo tops meant that removing some parts of the building roof was necessary to enable lifting through the roof of the building, using a mobile crane.

The new building crane could be designed to be installed in pieces that it could be lifted into the building through hoist wells so avoiding high lifts over the silo tops, using the mobile crane. The possibility of using helicopter lifts was ruled out due to the risk of a crash on one of any other buildings.

The main issues to be considered were the safety measures necessary given the broad outline of the process had been defined. The options were concerned with the:

- Safest way to use the crane;
- Procedures for protecting the workers;
- Potential methods for protection against dropping items;
- Protection against impacts on neighbouring buildings; and
- Necessary remedial preparations should a drop occur.

II-9.6. Within each of these areas, an approach was carried out. Formation of the Team

The regulatory body team comprised three experts: fault studies, radiation protection and mechanical engineering. The site inspector acted as the project manager.

II-9.7. Constituent factors

Standards and good practice:

The use of cranes in the UK is subject to the legal requirements in the Lifting Operations and Lifting Equipment Regulations (LOLER), which set procedures and lift capabilities. Radiation doses are subject to the Ionising Radiation Regulations (IRR), which follow the ICRP. Overall safety must meet the Health and Safety at Work Act (HSWA), which requires risks should be controlled so far as is reasonably practicable.

Operational experience:

This was a new operation that had not been performed before, though the use of mobile cranes was a standard procedure. Structural calculations showed that a drop of a mass equivalent to most of the crane parts would lead to damage to the silo tops even from a height less than the building crane height. The contents are a slurry with some solid material (the precise inventory is unknown) that requires cooling to control the rate of hydrogen produced by radiolytic processes. Previous PSA studies of the building had indicated the potential consequences of accidents involving the silos. Calculations of offsite doses showed that these would be significant. The importance of the cooling and ventilation systems was identified and the so-called 'cross-over' position where several of these systems came together was noted as a weak point. The background radiation varying throughout the building was such that control of worker access was necessary.

Deterministic considerations:

The main requirement was to ensure that doses to workers remained as low as reasonably practicable, and that the likelihood of accidents should also be as low as reasonably practicable. It was clear that in accidents, doses to workers would be high and that rapid evacuation would be needed. Also, a dropped crane or parts could penetrate the silo top or damage the silo cooling systems and the ventilation systems and hydrogen monitors.

Other considerations:

The issues can be considered under several headings:

- Doses to workers due to accidents;
- Possible scenarios that could cause dropping of crane parts;
- Prevention of dropping of crane parts;
- Protection against the effects of dropping crane parts;
- Mitigation of the effects of dropping crane parts.

II-9.8. Evaluation of the options

The options to control the risks during the operation can be considered under the following headings:

a. The procedures for use of the mobile crane;
b. The protection against the effect of item drops;
c. The protection of neighbouring buildings;
d. The route for lifting the new building crane parts;
e. The emergency procedures in the event of an item drop.

II-9.9. Integrated decisions

A mobile crane with capacity for lifting 500 Te would be sufficient for the lift, but to have extra margin a 1000 Te crane was considered. However, this had two effects: firstly, the greater difficulty of moving the crane to the required position and the fact that only a few such cranes were available in the UK and needed to be booked in advance. A walkthrough of the potential route was carried out to be sure that it could be done, with some small modifications to the roadways. The issue of fixing the time for hiring the crane meant that a delay of several months was necessary to avoid the winter period when bad weather was more likely.

The crane driver was specifically trained for the tasks involved. The preparation of the ground where it would stand was to include a check for possible subsidence. It was agreed that the lifts would only be carried out at low wind speeds to reduce the likelihood of movement of the load. During the lifts, only essential workers for the task could be in the building both to reduce normal exposures and to minimize the possibility of accidental doses.

An optioneering study of potential methods for protecting the silo tops and the other safety systems was undertaken. Protecting the silo tops was deemed to not be feasible due to the large areas, however, some protection of the cross-over point by collapsible structures was implemented. However, putting this in place had to be done so that, if necessary, remedial work could be undertaken (see evaluation heading e).

One of the problems of using a large crane at the building location was the number of other sources of hazard nearby. A diagram imposing the maximum radius of the crane jib if it fell, was compared with the site layout, and the impact in terms of the consequences was evaluated. Activities such as transfer of highly active liquor or rail movements were embargoed during the lifts. Buildings which contained radioactive materials were put on alert with defined emergency process, should they be struck. When the mobile crane was not in use, it was required that it should be laid down to minimise the chance of falling due to adverse weather or seismic events.

The building has two hoist wells, one wider than the other. The larger crane parts could only be lifted horizontally in the large well: to lift these in the smaller well required using a hoist system in which one leg could be varied in length. This clearly increased the possibility of impacts or drops during lifting and required the levelling of the item above the silo tops before installation. However, the dose levels at the wider hoist well were significantly higher than at the smaller well. It was agreed to use the smaller well and to level the items needing this, at the lowest level possible.

Besides the measures taken in other buildings, specific measures to deal with accidents were implemented in the building itself. All workers involved went through a training programme on fast evacuation. Necessary equipment for reinstating cooling, ventilation and hydrogen monitoring were to be ready to be used by a team of trained workers so rapid reinstatement would be possible. Emergency preparedness arrangements for the whole site and offsite were already in place as normal, but certain key staff would be made aware of when the lifts would occur.

The replacement of the crane was carried out without incident with a minimal increased dose to workers. As an aside, when the ground preparation for the mobile crane was undertaken, contamination was found which required a remediation process.

II-10. EXAMPLE ON DEALING WITH A DECISION RELATED TO ECC SUMP SCREEN ADEQUACY (CANADA)

This is an example on how to manage different aspects related to the risk of ECC sump screen clogging.

II-10.1. Issue to be considered

The thermal insulation used inside containment, dust and debris in containment, and chemical reactions with containment materials may result in conditions that could impact on maintaining ECCS circulation after a loss of coolant accident (LOCA).

II-10.2. Background

Containment is equipped with sumps to collect the water lost from the primary circuit after a LOCA to recirculate the water in the ECC recovery phase of the accident.

A postulated LOCA would cause break-up of thermal insulation around equipment and pipes and dislodge significant quantities of insulation material, both fibrous and particulate. The debris in the sump may be generated in one of five ways – dislodgement of insulation and other material due to direct impingement by the jet of reactor coolant from the failed piping, transportation of pre-existing debris from on or near the floor in the flow path from the break discharge to the sump screen, peeling of coatings from walls, floors or equipment, which could be carried by the flow of the condensate to the sump, or chemical effect leading to precipitation of dissolved materials over long term ECC recovery operation. Affected downstream components may include: heat exchangers, orifices, containment spray nozzles, reactor internals and fuel assemblies (core flow).

Much of this debris is expected to be transported to the reactor building sump with the coolant lost from the reactor through the break. ECC recirculation recovers water from the sump, cools it and returns it to the reactor to cool the core. The sumps are covered with a screen which is intended to protect the ECC recirculation flow path by preventing the debris from entering the ECC system.

Operational experience based on events in Sweden and in the USA, has demonstrated that even a relatively small amount of similar fibres can effectively block a large portion of the screen area. Partial blockage of the sump screens and debris may also clog the plant's downstream components located in the ECCS and Containment Spray System (CSS) thereby impairing ECCS recirculation. Hence, sump screens must be designed and installed to ensure that the screening function is maintained.

In addition, preliminary research findings of the Integrated Chemical Effects Test (ICET) program in the United States have raised concerns about the formation of deposits on ECCS sump screens. The ICET program assessed the impact of reactor building sump chemistry following a LOCA and possible implications for ECC sumps screens during recirculation following a LOCA. In some of the ICET tests certain chemicals could cause a thin impervious layer to be formed on ECC sump screens causing a large enough pressure to drop that recovery pump Net Positive Suction Head (NPSH) requirements would not be met and ECC recirculation would be impaired.

II-10.3. Regulatory considerations

The only events that may be significantly affected by the issue are LOCAs, since they are the only events where ECCS recirculation is credited.

The main concern is that even though there have been recent improvements made to CANDU ECC sump screens and debris reduction programs these initiatives did not fully consider chemical effects in the building sumps.

The severity of LOCA with consequential loss of recirculation (with or without containment failure) depends on the degree of sump screen fouling, and the time at which ECCS begins to be impaired.

The regulatory requirements that are the most directly affected by the issue are the requirements on the ECC system (from CNSC REGDOC-2.5.2, *Design of Reactor Facilities: Nuclear Power Plants*):

"The ECCS shall meet the following criteria for all DBAs involving loss of coolant:

1. All fuel assemblies and components in the reactor shall be kept in a configuration such that continued removal of the residual heat produced by the fuel can be maintained.
2. A continued cooling flow (recovery flow) shall be supplied to prevent further damage to the fuel after adequate cooling of the fuel is re-established by the ECCS.

The ECCS recovery flow path shall be such that impediment to the recovery of coolant following a loss of coolant accident by debris or other material is avoided."

A risk evaluation was undertaken to determine the significance of ECCS impairment. The risk significance in risk areas evaluated are provided below, details are provided in Table II-1. The primary risk area related to this issue is 'Negative Impact on Safety'. The uncertainties on safety margins lead to impact on the other risk areas, mainly radiological risk to public at DBA and severe accident risks.

TABLE II-1: RISK SIGNIFICANCE LEVELS VS RISK AREAS

Risk Area	Risk Significance Level (RSL)*
Risk of Negative Impact on Safety	RSL 3
Radiological Risk to Public at DBA	RSL 2
Severe Accidents Risks	RSL 3

* Definitions of Risk Significance Levels.

RSL2:

The matter of concern (MC) causes a moderate increase of the risk but it is still well-within the tolerable region. Margins to accepted limits are eroded. There are uncertainties in risk estimation but they are relatively well understood such that it is judged that meeting the accepted limits is not challenged. Risk control measures should be taken if it is reasonably practicable to do so.

RSL3:

The increase of the risk from the state when the MC is absent is significant. RSL3 lies at or near the upper limit of the tolerable range and, as such, it represents significant concerns. It is possible that epistemological uncertainties, and uncertainties in the largely qualitative estimations of the potential consequences and of their probabilities, could render it difficult to determine whether the regulatory limits are exceeded or not. Interim measures may have to be recommended.

II-10.4. Licensee considerations

The ICET showed that addition of Tri-Sodium Phosphate (TSP) to the water in LWR sumps led to accelerated aluminium corrosion and the formation of deposits. CANDU reactors operating in Canada do not make use of TSP to raise sump pH after a LOCA. However, the possibility of other chemical effects specific to CANDU could not be eliminated; and therefore, there remains some uncertainty in assessing the likelihood of this impairment. To address this concern risk, licensees initiated a R&D program to close this gap in knowledge. The experimental program provided the information required by Licensees to estimate the quantity of deposits expected from aluminium corrosion. The amount of deposit was then compared to the loading margin for the ECC sump screen.

II-10.5. Defined options

The RSL 3 ranking for this safety issue indicated that taking no action was not an option.

The options available to address this issue were rather limited, however. It was evident that licensees needed to assess the design of the ECCS sump screens and determine whether design or operational changes were needed to ensure ECCS effectiveness.

Furthermore, tests under CANDU-specific sump conditions were necessary to determine if the effects observed in the ICET tests were observed under CANDU-specific conditions.

II-10.6. Formation of the team

A team with knowledge of reactor sump chemistry and ECC behaviour was established to assess this item, and identify risk control measures, and evaluate licensee submissions on this matter.

II-10.7. Constituent factors

TABLE II-2: CONSTITUENT FACTORS USED IN ADDRESSING ECC SUMP SCREEN ADEQUECY

Key Elements	**Constituent Factors**
Standards, good practices	• CNSC REGDOC-2.5.2, *Design of Reactor Facilities: Nuclear Power Plants* • CSA standard N290.2-11, *Requirements for emergency core cooling systems of nuclear power plants*
Operational experience	• Operational events • Safety performance indicators • Other experience feedback
Deterministic considerations	• Evaluation against dose limits and demonstration that dose limits are met though implementation of options • Safety criteria - Operating Policies and Principles (OP&P), and Safe Operating Envelope (SOE) • Defence-in-depth including: - Safety margins - Single failure criterion - Fail-safe design • Equipment qualification • Results of accident analyses • Protection against external and internal hazards • Prevention against common mode/cause failures, etc.
Probabilistic considerations	• Qualitative insights • Quantitative measures - evaluation against safety goals and demonstration that safety goals are met though implementation of options
Other considerations	• Radiation doses during normal operation and implementation of changes • Costs • Economic benefits • Results of research • Remaining lifetime • Environmental impact

II-10.8. Evaluation of the options

As described above, the RSL 3 ranking for this safety issue indicated that taking no action was not an option.

The options available to address this issue were rather limited, however. It was evident that licensees needed to assess the design of the ECCS sump screens and determine whether design or operational changes were needed to ensure ECCS effectiveness.

Furthermore, tests under CANDU-specific sump conditions were necessary to determine if the effects observed in the ICET tests were observed under CANDU-specific conditions.

II-10.9. Integrated decisions

Upon learning of the incident of ECC sump screen blockage at Barseback, Sweden, the CNSC took the following measures:

- A comprehensive study was done and concluded that licensees needed to evaluate properly the quantity and characteristics of the debris that could be generated, that fine as well as large pieces should be considered, that existing sump screens in some stations were inadequately sized and that sump screens may be susceptible to significant mechanical loads due to pressure differentials.
- Licensees were asked to consider design changes, if necessary.

The licensees undertook the following actions:

- A comprehensive program was carried out to evaluate debris generation, transport and accumulation.
- An experimental program was initiated under the CANDU Owners Group (COG) to study the pressure drop characteristics, the type of insulation, the effect of particulates and the long-term behaviour of the debris bed.

As discussed above, a related issue was identified in US research into chemical effects in sump water– the ICET tests. Industry was advised of CSNC staff's concerns and immediately established a COG research program to address it, including:

1. Licensees are to evaluate the ICET tests and demonstrate that CANDU ECC sump screens are not vulnerable to deposits such as those identified in the ICET tests.
2. If closure criterion 1 cannot be achieved or if additional supporting information is needed, licensees are to perform appropriate research to identify what deposits may form in CANDU reactors and show their effects on ECC performance are acceptable.
3. If closure criterion 2 cannot be achieved, licensees are to propose appropriate mitigating measures to ensure that ECC remains effective, in the presence of debris and any deposits that may form in the sump environment.
4. Licensees are to identify the physical phenomena that are important to ECC recirculation and use this information to demonstrate that existing designs are adequate.

Licensees had submitted information giving confidence that the chemical environment in CANDU reactors does not include the features that led to possibly harmful deposits in the ICET tests. The study showed that addition of tri-sodium phosphate to the water in the ICET tests led to accelerated aluminium corrosion and the formation of the deposits. CANDU reactors do not make use of TSP to raise sump pH after a LOCA. CNSC staff accepted the conclusions of the study and agreed that Closure Criterion 1 has been met for all licensees. However, licensees could not completely exclude chemical effects under CANDU sump conditions. Therefore, an experimental program was established to close this gap in knowledge.

Recommended risk control measures are as follows:

- *Operating Reactors*: Address the closure criteria, which include performing the planned chemical effects tests to improve knowledge understanding of the potential chemical effects.
- *Life Extension*: Address the closure criteria, which include performing the planned chemical effects tests to improve knowledge understanding of the potential chemical effects. Consider implementing practicable design changes.
- *New Build*: It is expected that this issue will be addressed via improved design.

Status of the Issue

The outcomes of the work on sump screen design are as follows:

- A fin-type sump screen to provide a larger surface area was developed.
- Methods and guidelines have been developed for assessing ECCS sump screens for individual NPPs to fulfil the requirements of:
  - the maximum allowable pressure drops across the sump screen at the expected flow rate and temperature
  - assessing the debris type, flow path assessment, water hold-up and quantities of debris transported
  - larger replacement sump screens are installed at Darlington, Pickering A & B, Point Lepreau and Gentilly-2. Old sump screens have been enlarged at Bruce "A" and old sump screens have been determined to be sufficient at Bruce B.

Additional research was performed and the problems of sump chemistry were found to be almost non-existent for CANDU reactors. The small amount of additional deposits found to be relevant to the Canadian designs was dealt with in various ways, for example small changes to water chemistry, removal of surplus of aluminium from the sump region and modification to operating procedures.

TABLE II-3: RISK EVALUATION FOR ECC SUMP SCREEN EFFECTIVENESS

RISK AREA	**SCENARIO**	**LIKELIHOOD**		**CONSEQUENCES**		**RISK SIGNIFICANCE LEVEL**
		Category	***Comments***	***Category***	***Comments***	***Category***
Negative Impact on Safety	Sump screen partially blocked due to fouling/chemical effects and subsequent pump cavitation results in recirculation pumps not being able to inject water into core to cool the fuel	Medium	There are still uncertainties with regards to the effect of chemical effects on sump screen fouling and subsequent blockage. Based on current knowledge of chemical effects, the likelihood for impairment due to chemical effects is estimated to be 25 to 50% (the range in sump screen area is quite large amongst the Canadian plants). The results of testing may reduce uncertainties in estimating the likelihood of sump screen blockage.	Medium	Defence in depth is degraded and the safety function of cooling is impaired, and public dose may be increased.	3

TABLE II-3: RISK EVALUATION FOR ECC SUMP SCREEN EFFECTIVENESS (cont.)

RISK AREA	SCENARIO	LIKELIHOOD		CONSEQUENCES		RISK SIGNIFICANCE LEVEL
		Category	***Comments***	***Category***	***Comments***	***Category***
Increased Doses to Public	LOCA + consequential loss of recirculation	L2	Frequency of LOCA (10^{-2} (small LOCA) to 10^{-4} (Large LOCA)) as a DBA is not changed	C2	Consequential loss of ECC recirculation will lead to additional fuel failures For Darlington, public doses for this scenario is less than dose limits for LOCA (the dose is estimated to be .3% of the Class 3 dose limit in Regulatory Guide C6, “Requirements for the Safety Analysis of CANDU Nuclear Power Plants”), but with loss of ECC recirculation, the dose is estimated to be 11mSv (~40% of the Class 3 dose limit of 30 mSv in Regulatory Guide C6).	2
	LOCA + Consequential Loss of recirculation + Failure of containment	L2	Frequency of LOCA + Loss of Containment as a DBA is not changed if there is sump screen blockage	C3	For Darlington, the LOCA with consequential loss of recirculation and with containment failure could be as much as 12 times the Class 5 dose limit in Regulatory Guide C6 (250 mSv). However, this estimate is based on early impairment of ECC. If the impairment is later, the consequences will be less. The severity depends on the degree of sump screen fouling and the time at which ECC begins to be impaired.	**3**

TABLE II-3: RISK EVALUATION FOR ECC SUMP SCREEN EFFECTIVENESS (cont.)

RISK AREA	SCENARIO	RISK SIGNIFICANCE LEVEL	COMMENTS
Severe Accidents Risks	Sump screen blockage leads to increased probability of failure of ECC recirculation in comparison with that determined in the PSA. Therefore, we expect that if ECC is impaired the likelihood of core damage frequency (CDF) and other Safety Goals, and the potential release, may be greater than previously determined in the PSA.	3, but could be 2	The ranking will depend on the risk significance of ECC recirculation for specific plants

REFERENCES TO ANNEX II

[II-1]. ELECTRIC POWER RESEARCH INSTITUTE, Advanced FEA Evaluation of Growth of Postulated Circumferential PWSCC Flaws in Pressurizer Nozzle Dissimilar Metal Welds: Evaluations Specific to Nine Subject Plants; MRP-216, Revision 1. EPRI, Palo Alto, CA (2007).

[II-2]. ELECTRIC POWER RESEARCH INSTITUTE, Evaluation of Pressurizer Alloy 82/182 Nozzle Failure Probability; Appendix E, MRP-216, Revision 1. EPRI, Palo Alto, CA (2007).

[II-3]. ELECTRIC POWER RESEARCH INSTITUTE, Materials Reliability Program (MRP): Primary System Piping Butt Weld Inspection and Evaluation Guidelines; MRP-139. EPRI, Palo Alto, CA (2005).

[II-4]. NUCLEAR REGULATORY COMMISSION, NRC Bulletin 2004-01: Inspection of Alloy 82/182/600 Materials Used in the Fabrication of Pressurizer Penetrations and Steam Space Piping Connections at Pressurized Water Reactors. (2004).

[II-5]. ELECTRIC POWER RESEARCH INSTITUTE, A Pressurizer Safety Nozzle Dissimilar Metal Weld Circumferential Indication Profile; MRP Report 2008-14. EPRI, Palo Alto, CA (2005).

ANNEX III. COMPLIANCE OF THE DECISION OPTIONS WITH THE CONSTITUENT FACTORS

This Annex provides suggestions on how the degree of compliance of the decision options with constituent factors (CFs) can be accessed within the process of Integrated Risk Informed Decision Making (IRIDM). The information presented below should not be viewed as formal guidelines, but rather as a general approach that can be adopted to specific needs and integration methods.

III-1. APPROACH FOR THE ASSESSMENT OF THE DEGREE OF COMPLIANCE OF THE DECISION OPTIONS WITH THE CONSTITUENT FACTORS

The degree of the compliance of the option with the CF can be measured using relative difference ΔV of all the parameters selected to represent the CF using the formulas (III-1 and III-2*):*

$$\Delta V = \Sigma \Delta V(i)\ ,\ (i=1,n) \qquad (III\text{-}1)$$

$$\Delta V(i) = \begin{cases} \frac{Vdo(i) - Vbase(i)}{Vw(i) - Vb(i)}, \text{if } Vw(i) \neq Vb(i) \\ 0, \text{if } Vw(i) = Vb(i) \end{cases} \qquad (III\text{-}2)$$

Where:

i – the parameter associated with the CF under consideration;

Vdo (i) – value of the parameter “i” assuming the decision option is implemented;

Vbase (i) – value of the parameter “i” for the decision that is not implemented (base state);

Vw (i) – the worst value of the parameter “i” from all the proposed decision options (or the worst value allowed by the national regulations);

Vb (i) – best value of the parameter “i” from all the proposed decision options.

Formula (III-1) accounts for the fact that it is often not possible to select single parameter to represent the CF, therefore the sum of all relative differences of parameters is considered.

The value of the parameters can be also assessed based on qualitative judgement and applying scoring scheme systems that need to be developed by the IRIDM team. There is no universally accepted method for defining a scoring scheme. It is possible to use a 0 to 10 scale, when ‘0’ is assigned to the parameter of the input for the worst possible case Vw(i) case and ‘10’ to the best case Vb(i). This approach tends to produce a positive result inflating the overall score for the option when the results are combined for all the inputs for that option. It is also possible to assign a negative number for a reduced compliance, a positive number for an enhanced compliance, and assigning ‘0’ for ‘neutral’. Alternatively, a qualitative score can be given (e.g. low, medium, high). It is essential that the scoring system and the basis for the determination of the scores are well documented.

III-2. CONSIDERATION TO BE TAKEN INTO ACCOUNT

Table III-1 presents a summary of considerations that could be taken into account while assessing the compliance of the decision options with the CFs of the IRIDM process. The list of key elements and CFs is given in accordance with Table 2 in section 4.2 of the main report and in Annex I.

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs)

Key Elements	Constituent Factors	Considerations in the assessment of the compliance	Degree of compliance of the option in relation to the CFs		
			Neutral	**Reduced compliance**	**Enhanced compliance**
Standards, good practices	Legally binding documents (mandatory requirements and regulations, national laws, rules and regulations)	Determination of the level of satisfaction of the requirements or regulations listed in legally binding documents.	Implementation of the decision option will not affect requirements and regulations in any legally binding documents.	Implementation of the decision option will lead to the situation when one or more requirements or regulations in legally binding documents will not be fully satisfied.[19]	After the implementation of the decision option the satisfaction of the requirement or regulations in legally binding documents will be more complete or will be better justified in comparison with current situation (considering all uncertainties).
	Specific regulations and guidelines	Determination of the level of compliance with the recommendations and preferred methodologies provided in regulations and guidelines.	Compliance with recommendations and preferred methodologies provided in regulations and guidelines is not affected after implementation of the decision option.	After implementation of the decision option it will not be possible to fully follow all recommendations and preferred methodologies provided in applicable regulations and guidelines.	After implementation of the decision option it will be possible to follow the recommendations and preferred methodologies provided in applicable regulations and guidelines in an easier way or in a more complete manner.
	Legally binding documents for licensee	Determination of the level of satisfaction of the requirements listed in legally binding documents for licensee and Determination of the level of compliance with recommendations and preferred methodologies provided in licensees regulations and guidelines.	Implementation of the decision option will not affect any legally binding requirements for licensee and compliance with recommendations and preferred methodologies provided in regulations and guidelines is not affected.	Implementation of the decision option will lead to the situation when one or more requirement will not be fully satisfied or it will not be possible to fully follow all recommendations and preferred methodologies provided in applicable regulations and guidelines.	After the implementation of the decision option the satisfaction of the requirement will be more complete or better justifiable, considering of all uncertainties and it will be possible to follow the recommendations and preferred methodologies provided in applicable regulations and guidelines in an easier way or in a more complete manner.

[19] Note that for this CF the term “reduced compliance” is not applicable and the term “failure to comply” needs to be used instead.

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs) (cont.)

Key Elements	**Constituent Factors**	**Considerations in the assessment of the compliance**	**Degree of compliance of the option in relation to the CFs**		
			Neutral	**Reduced compliance**	**Enhanced compliance**
	Good practices (technical standards, IAEA safety guides, etc.)	Determination of the level of compliance with the recommendations, methodologies and procedures, provided in international standards and guidelines. Good practices may also be noted that are not in standards and guides e.g. obtained from OSART missions.	Compliance with international standards and guidelines are not affected after implementation of the decision option.	After implementation of the decision option it will not be possible to fully follow all recommendations, methodologies and procedures in international standards and guidelines.	After the implementation of the decision option it will be easier or in more complete manner to follow the recommendations, methodologies and procedures in international standards and guidelines.
Operational Experience	Operational events, safety performance indicators, experience feedback	Determination of the impacts on safety or operational performance based on observed operational experience.	The decision option has never been implemented; therefore, there is no relevant operational experience or the issue under consideration is unique in nature and has no relevant previous international experience.	Similar or identical decision option had been implemented in the past with negative impact on safety or operational performance.	Similar or identical options had been implemented in the past with positive impact on safety or operational performance.

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs) (cont.)

Key Elements	Constituent Factors	Considerations in the assessment of the compliance	Degree of compliance of the option in relation to the CFs		
			Neutral	**Reduced compliance**	**Enhanced compliance**
Deterministic requirements	Safety criteria	Determination of the impacts on values of parameters and/or performance data of the nuclear facility established in regulatory documents and/or by regulatory bodies.	It is confirmed that implementation of the decision option will not change values in compliance with which safety of the facility is justified.	Implementation of the decision option may lead to the increase (negative change) of one or several parameters in the design basis (e.g. peak clad temperature, radiological doses to a member of the public at the exclusion zone boundary).	Implementation of the decision option proved to lead to the decrease (positive change) of one or several parameters lying in the design basis (e.g. peak clad temperature, radiological doses to a member of the public at the exclusion zone boundary).
	Defence-in-depth	Evaluation of the compliance with the principles of Defence-in-Depth: – Safety margins – Single Failure Criteria – Fail-safe design – Equipment Qualification – Common mode failure prevention, etc.	It is confirmed that implementation of the decision option has no impact on the conditions associated with the principles of Defence-in-Depth. The option does not have any measurable influence on the current way that defence-in-depth is provided or on any of the barriers to the release of radioactive material	Satisfaction of one or more principles of Defence-in-Depth is diminished (e.g. interdependence between levels) and implementation of the decision option leads to a reduction in the effectiveness of the way that defence-in-depth is provided for one or more of the levels or a reduction in the effectiveness of one or more of the barriers to the release of radioactive material.	Satisfaction of one or more principles of Defence-in-Depth is enhanced and implementation of the decision option heightens one or more of the levels of defence-in-depth or one or more of the barriers to the release of radioactive material.

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs) (cont.)

Key Elements	Constituent Factors	Considerations in the assessment of the compliance	Degree of compliance of the option in relation to the CFs		
			Neutral	**Reduced compliance**	**Enhanced compliance**
Probabilistic insights	Qualitative insights	Assessment of the insights from the PSA logic model itself and changes in the 'minimal cut sets (MCSs)' obtained. Note that the level of details and scope of the PSA model have to allow analysis of the changes associated with the decision option.	Implementation of the decision option will not affect the PSA model, PSA results and insights.	The qualitative results obtained with the help of PSA model or other PSA-type arguments show increased vulnerability of the facility, including decreased compliance with the key defence-in-depth principles.	The qualitative results obtained with the help of PSA model or other PSA-type arguments show decreased vulnerability of the facility including better compliance with the key defence-in-depth principles.
	Quantitative measure	Assessment of probabilistic quantitative measures (See Annex I).	Implementation of the option will not impact the PSA model and PSA results.	Expected increase of one or more quantitative measures (see Annex I) after implementation of the decision option.	Predicted decrease of one or more quantitative measures (see Annex I) after implementation of the decision option.
Human and Organizational considerations	Management Systems, procedures (normal, maintenance, emergency) and Training	Evaluation of the preparedness of the management system to accept, implement and monitor the option, including availability of adequate training and adequacy of all procedures.	The decision option does not require any changes in the management system, training practices, and procedures.	Implementation of the decision option will require changes in the management system, training practice, or procedures that possibly worsen or more complicate the system.	The existing management system easily accommodates the implementation of the option and training practices and procedures are minimally impacted, improved, or simplified.
Considerations regarding the interface with nuclear security	Physical protection of a nuclear facility and security of the nuclear material on the site	Assessment of the impact on security or physical protection of a nuclear facility and the nuclear material on the site.	The decision option has no impact on security or physical protection.	Implementation of the decision option can decrease the level of security or physical protection.	Implementation of the decision option might lead to increase of the level of security or physical protection.

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs) (cont.)

Key Elements	**Constituent Factors**	**Considerations in the assessment of the compliance**	**Degree of compliance of the option in relation to the CFs**		
			Neutral	**Reduced compliance**	**Enhanced compliance**
Other considerations	Radiation doses	Evaluation of radiation doses to workers due to making modifications or to the workers and to members of the public from normal operation and from accidents.	Implementation of the decision option does not change the radiation doses.	Implementation of the decision option may lead to the increase of the doses to the workers and/or to the members of the public.	Implementation of the decision option potentially reduces doses to the workers and to the members of the public.
	Costs	Estimation of the direct costs of making the change and the direct impact of the change on long term costs (maintenance, etc.).	Costs are not considered an impact.	Overall costs due to the implementation of the option increase (long term and/or short term.	Short term implementation costs are not considered significant or long-term costs are reduced. *Note: it may be that short-term costs are significant but long-term cost are reduced. The overall cost impact is then a judgement based on present value considerations.*
	Economic benefits	Estimation of the economic benefits of making the change such as direct impacts on changes of revenue, other operational costs, etc.	No economic benefits arise from implementation of the decision option.	After implementation of the decision option the following is expected: - decrease in the revenue or - increase in the running costs of the facility or - an increase in the potential repair or clean-up costs following an accident (for example due to increased frequency or consequences of the accidents).	After implementation of the decision option the following may be achieved: - increase in the revenue or - reduction in the running costs of the facility (e.g. the maintenance costs for the facility, cost of the inspections) or - decrease in the potential repair or clean-up costs following an accident (e.g. hidden economic benefits from the reduced risk of economic damage to the facility or radiation doses to workers and members of the public).

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs) (cont.)

Key Elements	Constituent Factors	Considerations in the assessment of the compliance	Degree of compliance of the option in relation to the CFs		
			Neutral	**Reduced compliance**	**Enhanced compliance**
	Results of research	Evaluation of the results of ongoing research that are relevant to the issue being addressed.	Current research does not provide supporting or unfavourable information with regards to the decision option.	Current research does not support the decision option to be implemented.	Current research does support the decision option to be implemented.
	Remaining lifetime	Evaluation of whether the remaining lifetime of the facility impacts the change. It is assumed the change is necessary for health and safety reasons.	Not applicable.	The remaining lifetime of the plant is short and it may not be reasonably practicable to implement the decision option and it is not expected that extension to this lifetime will be possible. A decision on whether continued operation is acceptable needs to be taken.	The remaining lifetime of the plant is long enough to implement the option or it is expected that after implementation the extension to this lifetime will be accepted by regulators.
	Waste management	Evaluation of the change for its implications for waste production, disposal, and management.	The decision option has no impact on waste production and management.	The implemented decision option may lead either to increased amount of waste or to the need for more difficult treatment or disposal of the waste. Spent fuel is a special consideration in this regard and any impacts on the spent fuel system need to be carefully considered.	The implemented decision option will lead to the reduction of the waste or simplify the waste's treatment or disposal. Impacts on spent fuel treatment, if any, are positive.
	Decommissioning	Evaluation of the change on any plans or options for decommissioning.	The decision option does not impact ultimate decommissioning plans and procedures.	Implementation of the decision option may complicate or make more difficult decommissioning plans.	Implementation of the decision option will support or make decommissioning simpler.

TABLE III-1: CONSIDERATIONS IN THE ASSESSMENT OF THE COMPLIANCE OF DECISION OPTIONS WITH THE CONSTITUENT FACTORS (CFs) (cont.)

Key Elements	Constituent Factors	Considerations in the assessment of the compliance	Degree of compliance of the option in relation to the CFs		
			Neutral	**Reduced compliance**	**Enhanced compliance**
	Environmental impact	Evaluation of the change for any impacts to the environment as they may be permitted for or described in the plant's environmental assessment.	The decision option does not change environmental conditions.	Implementation of the option may lead to the changes in the environmental conditions: - causes a negative impact to plant release limits that exist in regulatory permits; - causes a negative change in environmental conditions described in the plant's environmental assessment.	Implementation of the option may lead to the changes in the environmental conditions: - causes a positive impact to plant release limits that exist in regulatory permits; - causes a positive change in environmental conditions described in the plant's environmental assessment.

ANNEX IV. INTEGRATION OF ASSESSMENT RESULTS AND DECISION RECOMMENDATION

IV-1. INTRODUCTION

The integration of the assessment results is the process that derives a decision from a consideration of all the factors that affect the issue. It is basically an evaluation of the overall merits of each decision option by combining the assessments of the various factors, usually weighted in some way, into an overall 'value'. Assigning a 'value' to each decision option allows the decision maker to have a clearer understanding of the relative merits of each option. A properly organized process is expected to lead to a more robust and defensible decision, and therefore remove a degree of subjectivity from the decision making process. However, the way in which values are assigned and the overall value determined may have a bearing on the final. It is important; therefore, the decision making process is chosen in such a way that it is appropriate for the decision in question.

There is a broad spectrum of methods related to multi-attribute decision analysis, several which are briefly described below. The reader is encouraged to consult definitive references to gain a more complete understanding of the methods.

IV-2. OVERVIEW OF METHODS FOR INTEGRATION

A short overview on available methods of integration of the information considered in the decision making process from a practitioner's point of view can be found in Refs. [IV-1–IV-2]. A wider review of decision making and associated topics applied in nuclear decision making are given in Ref. [IV-3]. Usually they are distinguished between normative methods and descriptive methods. Normative methods are based on models which refer to an ideal reference (a rational decision maker). The most popular method is the Multi-Attribute Utility Theory (MAUT). MAUT is essentially an extension of traditional (single) utility analysis to the case of multiple decision attributes. It is based on the preposition that the set of expected values of the utility of each attribute is related to the desirability of the decision option by the decision maker. Most frequently MAUT is implemented by a Decision Tree Analysis [IV-4]. Practical examples can be found in Ref. [IV-1].

Descriptive methods (see chapter 8 in Ref. [IV-4]) are the Structured Value Analysis (a linear weighting method), the Analytic Hierarchy Process (AHP), or the Severity Score Analysis, see Ref. [IV-5].

Although multi-attribute analysis has been studied extensively, it has to be emphasized that it cannot guarantee the highest level of precision in the decision being made: the quality of the decision depends on many facets such as the accuracy of the analyses, the ranking of factors, etc.

A safety decision needs to be robust and not subject to significant change in case of minor variations in inputs, slightly varied weightings or the selected method of integration. The ability to deconstruct the decision and review the individual inputs is essential to establish the quality and robustness of the decision.

Whereas the use of decision making tools can help distinguish between different options, it cannot replace good judgement and great care needs to be exercised when interpreting the results.

IV-3. WEIGHTING FACTORS

A common feature of all multi-attribute decision processes is that for each of the various elements of the decision, which need to be balanced, a weight which indicates its relative importance when compared with the other elements being considered is assigned. Weighting factors can be qualitative in nature, such as high, medium and low, or quantitative such as on a scale of 1 to 10. The aim of this step is to determine the weight that needs to be attached to each of the factors being considered by the IRIDM process. Much of this weighting is subjective and relies on issues such as political or social considerations as well as engineering judgments.

In assigning weightings, it is important to keep the significance of individual inputs in perspective. For example, an option may involve an increased occupational dose to workers, albeit planned and well controlled, and this may have to be assessed against, say, a reduction in an assessed core damage frequency. Clearly, there is a fundamental difference between the actual risk due to a dose received by a group of workers and the calculated risk of a probable event, which may increase doses to more people. The decision maker needs to consider how to balance these risks.

The way inputs are weighted depends on the issue being addressed and on the practice in the Member State. Therefore, it is not possible to give definitive conclusion on which weighting factors need to be used. The relative weights given to the deterministic and probabilistic considerations may vary among the Member States and among organisations carrying out the IRIDM process as well as the confidence that the regulatory body has in the inputs[20].

The determination of the weighting factors to be applied is in part subjective, clearly certain considerations can be judged to be more important than others, but as to whether one consideration is twice or tenfold more important than another is very much a matter of debate. Various techniques and procedures have been developed to help determine the most reasonably weighting factors (see, for example, Refs. [IV-6–IV-7] and [IV-8]). Generally, the weights have to be correlated with the confidence the experts have in the quality of the inputs.

After the weighting factors have been initially determined, the IRIDM team has to review the assigned weighting and ensure that they make sense. Since weighting factors are so important in the integrated evaluation, the justification of selection and weighting needs to be documented and reviewed. An important aspect is how much precision will be used in reaching a decision: will results varying by small margins be considered significant or is there a need for a significant margin in ranking the decisions? The choice of weightings has to be made bearing in mind how the final decision will be made. If numbers are used, will the decision be made on cardinal or ordinal grounds? This difficulty in using actual numbers is an argument for using a less numerical weighting scheme.

Some aspects that need to be taken into consideration in assigning the weighting factors are briefly discussed below.

Consideration of Mandatory Requirements: Mandatory requirements carry the highest weight. Inputs which represent mandatory requirements must be assessed separately and compliance with the requirements must be demonstrated. Generally, the weighting process is not applicable for such inputs as the options which do not satisfy mandatory requirements must be screened

[20] The general expectation is that deterministic and probabilistic insights are in agreement; however, if deterministic and probabilistic insights are not in agreement, often greater weight will be given to the more conservative and less uncertain insight. It has to be noted that the weight given to the probabilistic considerations needs to take account of the type of probabilistic input that was provided into the IRIDM process the scope and quality of the analysis carried out: a higher weight of the probabilistic input would correlate with its higher quality and scope.

out at an early stage. The only exception is where the issue being considered involves a proposal to change the mandatory requirement or seek regulatory exemption.

Ranking of inputs: As a first step the inputs can be ranked by relative importance beginning with the highest to facilitate the allocation of weightings. This helps to ensure a balanced approach to the assignment of weightings and to ensure that the relative weightings are proportionate to their significance. After ranking, a weighting factor is assigned dependent on the relative importance of the input for the issue under consideration.

Assignment of Qualitative Weightings: Traditionally, qualitative weighting factors have been commonly used. In the initial assignment of the weightings, expert judgement is used to determine the relative weightings of the ranked inputs. Determining the correct relative weighting is not an easy task and can be fundamental to ensuring that the optimum decision is arrived at; therefore, care must be taken to ensure that each assessment factor is given a realistic and meaningful weighting. However, when using a qualitative approach, it is usual to have a small number of weightings (e.g. high, medium and low). In such a case it is likely that many inputs will have the same weighting. This results in increased importance being placed on the impact evaluation which is described in Annex III.

Assignment of Quantitative Weightings: Quantitative weighting factors are numerical values, usually ranging from 1 to 10 or from 1 to 100 or from -10 to 10, etc. Similar to qualitative weightings, expert judgement is used to determine a weighting factor for a given issue. Care has to be taken also since giving too much or too little numerical weight can unreasonably skew the results when the integrated evaluation is performed.

Iterations in the Weighting Process: During the IRIDM process, the choice of options may change as more information becomes available; therefore, the process of determination of weights for inputs and decision options is iterative with a feedback loop to the first task (definition of decision options).

Cost-Benefit Considerations: The weighting would be expected to take account of the outcome of any cost-benefit analysis that had been carried out. If this has shown that the costs of making the changes are excessive when compared with the benefits for safety that would be obtained, this would lead to a low weighting for the change to be made.

IV-4. SPECIFIC INTEGRATION METHODS

IV-4.1. Structured value analysis

The structured value analysis is based on the evaluation of the value of each decision option:

$$V = \sum_i F_i W_i \qquad \text{(IV-1)}$$

In this equation, the factors W_i reflect the normalized weight of the input *i* under consideration. The weight represents the relative importance of each input to the decision. The factors F_i reflect the values that the decision maker assigns to the input of interest. Negative values can be used for negative consequences (losses) while positive values can be used to characterize positive outcomes (gains). The factors have to be related to the results of the assessment of the impact of the different decision options on the inputs to the decision (see Annex III).

The value V is computed for each of the decision options. The decision option with the highest value is selected as the recommended decision.

IV-4.2. Analytic Hierarchy Process (AHP)

AHP was developed by Saaty, see Ref. [IV-9], and applied to many applications including risk informed decision making.

In the simplest form, the hierarchy of a decision task is comprised of three levels: the goal (the problem to be solved by the decision), the inputs to be evaluated, and the decision options. The process begins by determining the relative importance of the inputs to be considered in solving the problem (making the decision). Secondly, the impacts of the different decision options on the inputs are measured. Finally, the results of the two previous analyses are combined to compute the degree to which the problem is solved by the different decision options.

In this process, the IRIDM team carries out pair wise comparison between the different decisions options with respect to all the inputs relevant for the decision. The comparison is based on a measurement scale expressing the relative preference of one decision option in comparison to the other. For each of the pair wise comparisons (for each of the inputs) the result can be represented in the format of a square matrix resulting in a separate matrix for each of the inputs. Table IV-1 shows an example of a measurement scale adapted from Ref. [IV-4].

TABLE IV-1: AHP – MEASUREMENT SCALE

Numerical Rating	**Definition**	**Comment**
9	Extremely preferred	Highest possible affirmation of preference of one option over another
7	Very strongly preferred	One option is strongly preferred and the preference is demonstrated in practice
5	Strongly preferred	One option is strongly preferred by subjective judgment
3	Moderately preferred	One option is slightly favoured
1	Equally preferred	Both options are equally acceptable
Ratings 2, 4,6,8	Used for additional levels of discrimination	When a finer assessment is requested (e.g. compromise in a group discussion)

An example of the square matrix for one input (e.g. impact on risk (CDF)) for the comparison of 4 options is given in Table IV-2. The comparison is performed along the rows by assigning the relative preference values to each of the comparisons.

TABLE IV-2: EXAMPLE OF A COMPARISON MATRIX A OF DECISION OPTIONS

Option	**DO1**	**DO2**	**DO3**	**DO4**
DO1	1	2	3	4
DO2	1/2	1	5	6
DO3	1/3	1/5	1	7
DO4	1/4	1/6	1/7	1

The selection of the preferred solution (in this case for a single input) is defined by the solution of the eigenvalue problem:

$$AW = \lambda W \tag{IV-2}$$

As was shown by Saaty (see Ref. [IV-9]), the preferred option corresponds to the option with the highest weight in the eigenvalue vector with the largest (principal) eigenvalue (in case of consistent assessments, this value needs to be close to the rank of the matrix).

In case of several inputs, as it is the case in IRIDM, eigenvalue vectors are developed for each of the inputs. They can be represented by a m x n matrix (denoted as R), where m is the number of decision options and n is the number of inputs with the corresponding eigenvalue vectors forming the n columns of the matrix (see Table IV-3). The sum of the weights in each column equals 1.

TABLE IV-3: EXAMPLE OD RESULTS' MATRIX R for AHP (case of 4 options and 4 inputs)

Option vs. Input	**Input 1 (e.g. PSA)**	**Input 2 (e.g. DSA)**	**Input 3 (e.g. costs)**	**Input 4 (e.g. interface with security)**
DO1	w11	w12	w13	w14
DO2	w21	w22	w23	w24
DO3	w31	w32	w33	w34
DO4	w41	w42	w43	w44

To define the final decision, the results of the evaluation of the decision options for each of the inputs must be multiplied by the importance weights of the inputs. The latter are defined by the same process of pair wise comparison and the solution of the eigenvalue problem. The results can be written into the importance weight vector denoted here as IW.

The preferred solution is then defined by the product:

$$R \bullet IW \tag{IV-3}$$

That results in a row vector containing the final weights for each of the decision options. The decision option with highest weight is the preferred decision according to the AHP process.

In case of the consideration of many options and many inputs the AHP model becomes increasingly more complex. Therefore, the process is frequently simplified by using subjective judgment for defining the preferences between all options considering all inputs in the evaluation. The problem then reduces to the solution of a single eigenvalue problem.

An instructive example for an application of AHP can be found in chapter 4.8 in Ref. [IV-1].

IV-4.3. Severity score analysis

The severity score analysis has originated from qualitative risk analysis, see Ref. [IV-5]. It can be regarded as a special form of the structured value analysis. It is typically used for decisions aiming at the minimization of negative consequences, at risk reduction. Risk is here understood in a broader sense rather than PSA results. The method is based on the development of P (probability) – I (impact) tables. Similarly to the structured value analysis, it can also be used to assess benefits by assigning a negative ranking value to the impacts.

For each input and each decision option an assessment is performed regarding the risk of losses (negative consequences) and the chance of wins (gains, positive consequences). This assessment includes an assessment of the probability of the outcome (P) and a measure of the consequences (I).

Typically for the risk of losses, the impact (the consequence) is ranked in categories from 1 to 5 (0 being neutral), the chance of a win (gain) is ranked in categories from -1 to -5. These risks are associated with a qualitative assessment of the probability of occurrence, typically ranked in a scale between 1 and 10 (0 would be the impossible event).

In case of equal weights of the inputs, the final severity score for each of the decision options is evaluated as:

$$S = \log 10 \left[\sum_{i=1}^{k} 10^{P_i + I_i} \right] \tag{IV-4}$$

Where k is the number of inputs evaluated.

In case of unequal weights, the latter must be defined and normalized by the IRIDM team. In this case the scoring equation takes the form:

$$S = \log 10 \left[\sum_{i=1}^{k} 10^{w_i (P_i + I_i)} \right] \tag{IV-5}$$

The decision option with the lowest score (minimization of adverse consequences) is the preferred and recommended decision.

IV-4.4. "Value Tree" method

The class of decision problems that involve multiple conflicting objectives and uncertain outcomes is generally known as Multi-Attribute Decision Making under Uncertainty (MADMU), see Ref. [IV-10]. In this kind of problem, the decision maker is presented with a set of conflicting objectives and a few alternative courses of action each of which addresses one or more of the conflicting objectives.

A value tree is simply a representation of the conflicting objectives arranged in a hierarchy. At the highest level or 'trunk' of the tree, there would be a single cardinal objective that characterises the overall objective of the decision maker. The main branches of the tree consist of several fundamental objectives; some of which may be conflicting. Each fundamental objective is then explained in terms of more specific objectives at the next level and so on. At the lowest level, the outer branches, the objectives need to be characterised in terms of an attribute that can be measured in terms that demonstrate the degree to which an alternative accomplishes the detail objective.

The value tree is used in the following manner:

- The branches at each level of the hierarchy are assigned a weight (w) that denotes the relative importance of the associated objective in contributing to the next higher-level objective with which it is associated. In other words, the weight is assigned to indicate to which degree a lower level objective contributes to achieving the higher-level objective it is connected to.
- Each alternative course of action is assigned a score (s) against all the objectives at the lowest level of the hierarchy's outer most branches of the tree, to indicate to which degree the outcomes of the course of action will address the objective.
- The overall score of a specific course of action is calculated as its additive weighted score against the hierarchy of objectives.

Expressed more formally for the case of a two level hierarchy: let w_i represents the weight of fundamental objective i; let w_{ij} be the weight of detail objective j under fundamental objective i; and, let s_{ij} be the score of the course of action against detail objective j of fundamental objective i. The additive weighted score is then:

$$S = \sum_{i=1}^{m} w_i \left[\sum_{j=1}^{m_i} w_{ij} s_{ij} \right] \qquad \text{(IV-6)}$$

The preferred alternative course of action is the one with the highest additive weighted score S.

In assigning weighting values to the branches at each level it is important to recognise that simply specifying the relative importance of two attributes, i.e. A is more important than B, is not enough. The degree of relative importance of the attributes has to be quantified in some manner. Similarly, when establishing the scoring for the alternative courses of action, the quantification method chosen is to be based upon the degree of importance of the actions and not just their rank, e.g. A result in twice the product of B, and therefore has a score double that for B.

IV-4.5. Selection of recommended decision

To arrive at the ultimate decision, irrespective of how the input data are integrated, a set of 'rules' are used that provide the basis for the evaluation of options. Such rules are used either explicitly or implicitly embedded in the judgment process of the evaluators.

A typical and very common rule is that the final decision selected from the considered decision options maximizes the benefits[21] and minimizes the possible adverse consequences in the eyes of the decision maker when all factors are considered without specific preferences.

A modified version of this rule, with respect to safety issues, is that all regulatory requirements have to be met while costs or project schedules (also affecting costs) have to be minimized. Implicitly, this rule presumes that compliance with regulatory requirements has the highest priority and available decision options are evaluated under this constraint. This decision rule is frequently applied in practical decision making by utilities as for example in less formalized decision making approaches like "Facts, Options, Risks, and Benefits, Decision, Execution (FORDEC)" that is in use in the aviation industry, see Ref. [IV-11].

[21] All benefits are considered (safety, security, costs, radiation doses, etc.)

These decision rules can be applied directly to the evaluation of decision options and do not necessarily require a formalized mathematical approach to decision making. They can equally be applied to qualitative approaches where the collective judgment is used to determine the relative merit of each option, either using the simple rule of maximizing benefit and minimizing adversity, or with the modified rule taking regulatory issues into account.

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ANNEX V. SAMPLES OF IRIDM PROCESS

V-1. INTRODUCTION

This Annex presents three hypothetical examples of the application of the IRIDM process whereby a nuclear power plant operator is considering:

1) Selection of the best design change to the RHR suction line to improve the reliability of isolation from the primary circuit
2) Whether to change the maintenance regime for the diesel generators (DGs) to take account of new recommendations by the DG manufacturers. This change would improve the reliability of the DGs. Since the outage time for the maintenance activity would be longer, this change would require the Technical Specifications to be amended to lengthen the time that a DG would be allowed to be inoperable before requiring a plant shutdown.
3) Whether it is advisable to convert to a new fuel which will allow the plant to increase the time between refuelling outages from 12 to 18 months, and increase the maximum power to 104%.

These examples are intended to give an overview of the steps in the IRIDM process as set out in the main body of this TECDOC. The technical details of these examples are for illustration only and are not intended to be technically complete. In addition, the examples have been simplified in that only three or four options have been considered. Experience has indicated that, in real situations, the number of options that would be addressed would be much higher.

This Annex describes the 5 stages of the IRIDM process for the hypothetical examples. The stages are shown in Figure 3 of the main TECDOC and listed below:

Stage I	Characterization of the issue, definition of options, and team formation.
Stage II	Preparation for the assessment including screening the options, identification of constituent factors, and gathering the information.
Stage III	Assessment, integration and documentation.
Stage IV	Selection of the option and approval by the decision maker
Stage V	Implementation of the decision and performance monitoring.

It is worth to note that all examples are structured in a similar manner; however, some specific details may be emphasised differently (e.g. the initial meeting is not discussed in the third example).

The integration of the assessment results is the process that derives a decision from a consideration of all the factors that affect the issue. It is basically an evaluation of the overall merits of each decision by combining the assessments of the various factors, usually weighted in some way, into an overall ‘value’. Assigning a ‘value’ to each decision option allows the decision maker to have a clearer understanding of the relative merits of each option. A properly organized process is expected to lead to a more robust and defensible decision and therefore remove a degree of subjectivity from the decision making process. However, the way in which values are assigned and the overall value determined may have a bearing on the final decision. It is important, therefore, that the decision making process is chosen in such a way that it is appropriate for the decision in question.

V-2. IMPROVEMENT TO THE RHR SUCTION LINE ISOLATION RELIABILITY

V-2.1. Stage I - characterization of the issue

Description of the Issue to be Addressed

During the design stage of a new nuclear power plant, the design review indicated that the risk of Residual Heat Removal (RHR) shutdown line isolation valve leakage would not meet the Design Safety Guideline (DSG) target. Leakage of the RHR motorised isolation valves (MOVs) at full or reduced power could lead to over pressurisation and possible failure of the RHR system. Un-isolable relief or rupture of the RHR effectively bypasses the containment (See Fig.V-1) and would be classed as a ‘V sequence’ LOCA (VLOCA). Failure to meet the DSG targets could result in the design CDF and/or LERF not being met and the possibility that the plant would not be licensed for use by the regulatory body.

Various options were proposed to ensure that the RHR Suction Line Isolation reliability would meet the DSG target.

The initial design of residual heat removal system (RHR) is shown in Fig. V-2. MOV leakage failure rate data used in the preliminary design probabilistic safety assessment (PSA) was based on generic data used in previous licencing submissions updated with reported leakages obtained from an analysis of Licensee Event Reports (LERs) of US PWR RHR systems.

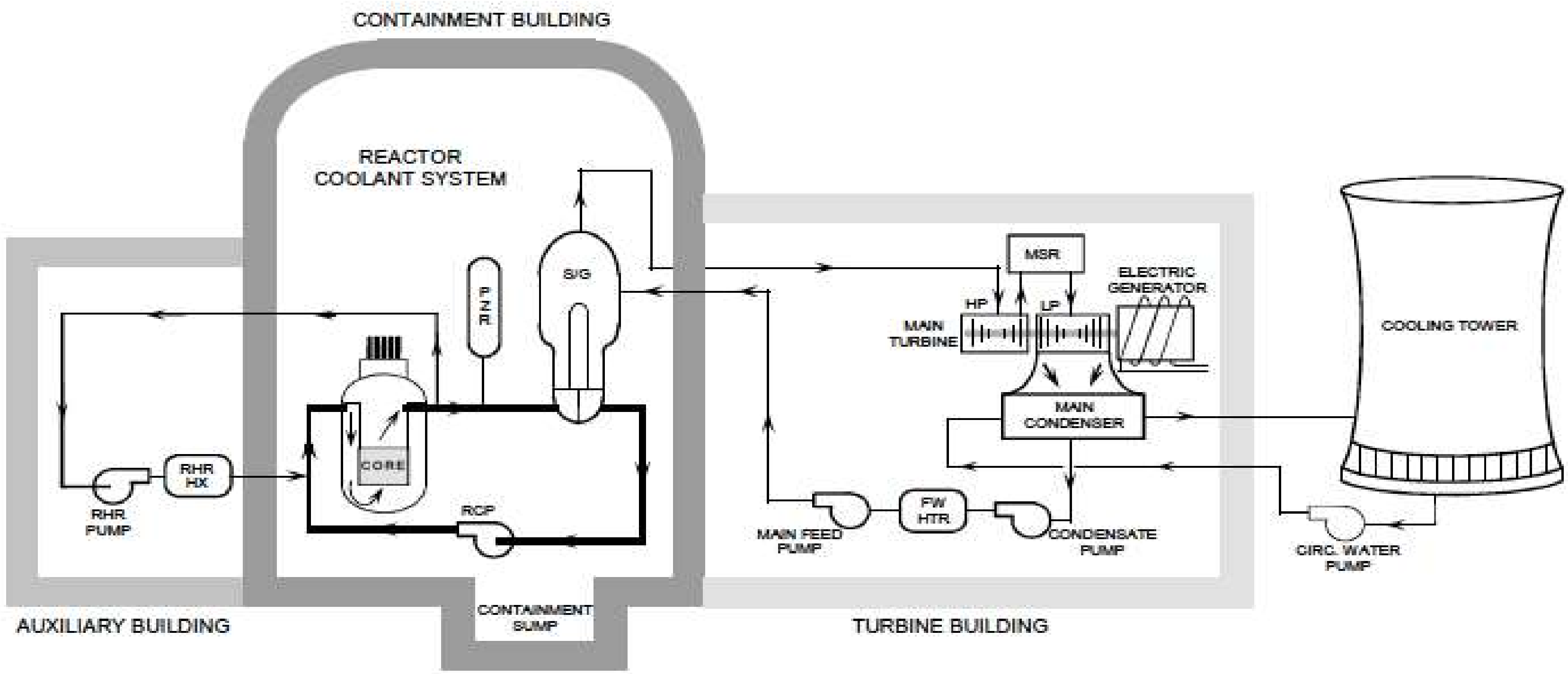


FIG. V-1. Simplified plant drawing.

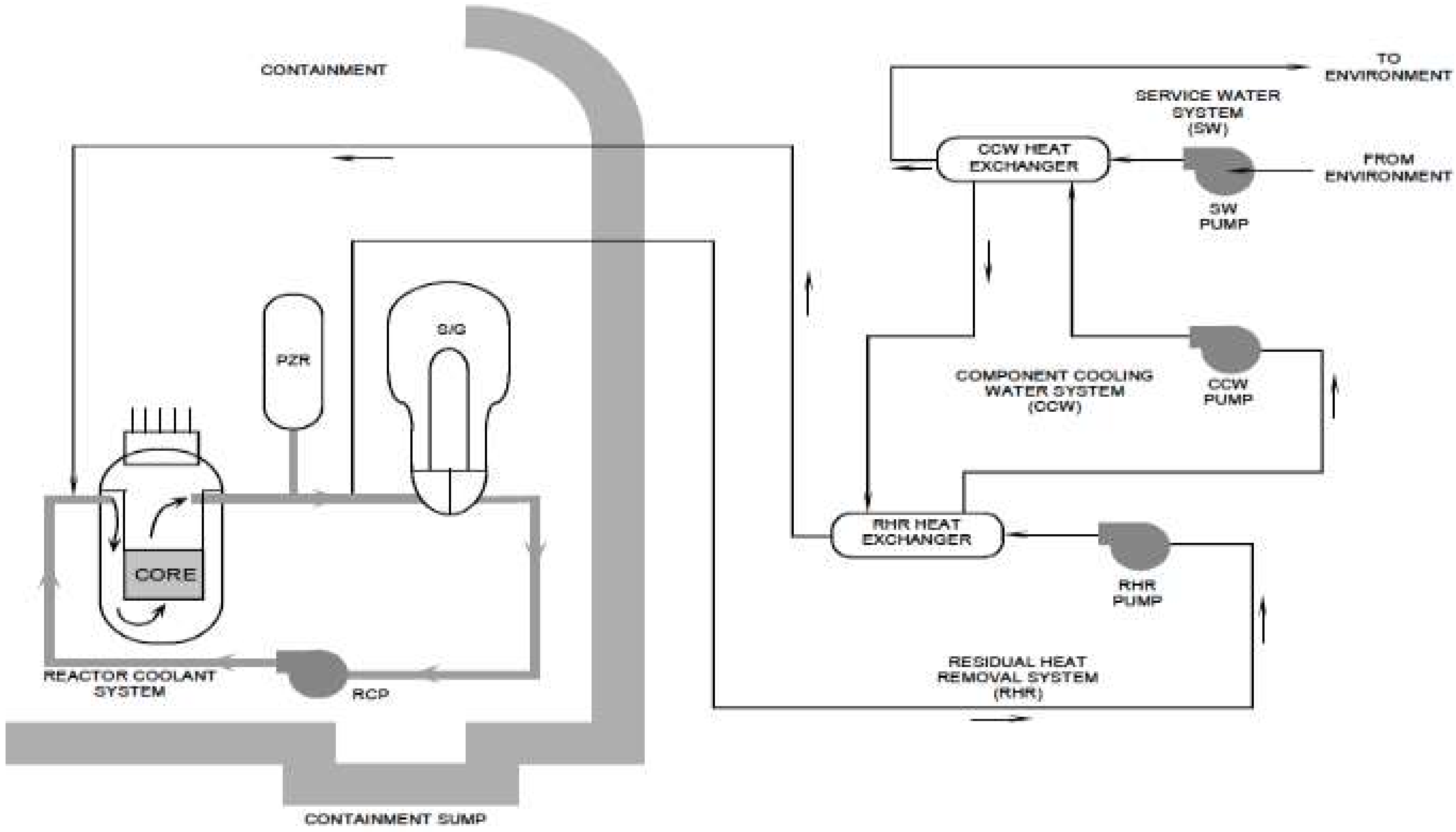


FIG. V-2. Residual Heat Removal System simplified drawing.

The design safety guideline set by the utility and the design body for all safety systems was that:

- No single accident sequence contributes more than 10^{-8} /y to CDF or LERF. This goal was defined based on the following considerations:
- Design goal target for the NPP was to achieve a CDF of 10^{-5}/y, or as near as possible, to meet the Basic Safety Objective (BSO);
- As there are thousands/tens of thousands of sequences which make up the CDF, it was specified that no individual sequence contributes more than 10^{-8}/y.

Overall legal requirement is that risks must be reduced:

- As Low as Reasonably Practicable (ALARP) (See illustration on Fig. V-3);
- Measures need to be taken to avert risks unless their cost (in terms of money, time, trouble) is grossly disproportionate to risk averted;
- 'Reasonably practicable' is not defined in law but would be established in the courts;
- There is no formal requirement for a PSA, but it would be difficult to demonstrate ALARP for a nuclear power plant without one.

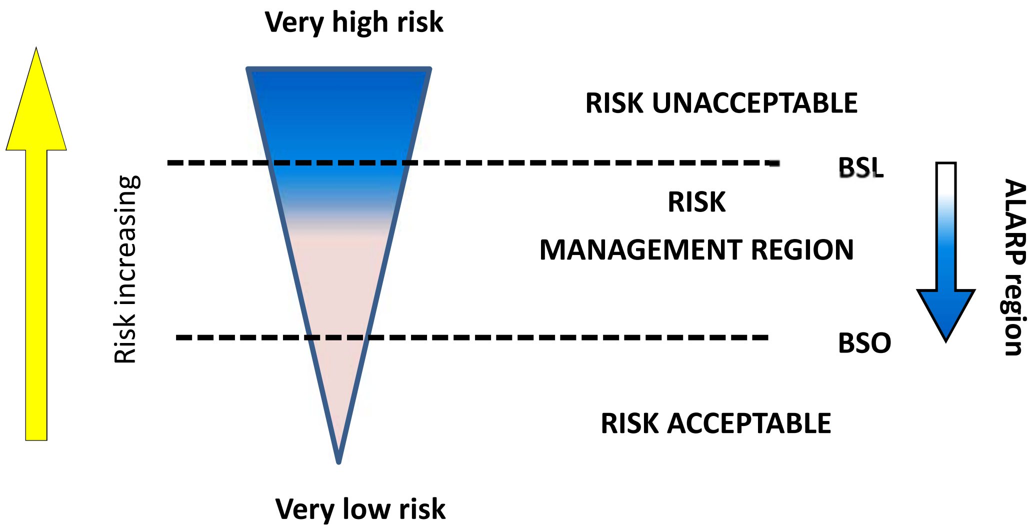


FIG. V-3. Illustration of ALARP.

It was normally assumed that the acceptable BSO and Basic Safety Level (BSL) for core damage (CDF) were 10^{-5}/y and 10^{-4}/y respectively. Whilst for large early release (LERF) the corresponding BSO and BSL were 10^{-7}/y and 10^{-5}/y respectively.

Note: For VLOCA sequences the LERF and CDF values are the same as the nature of the sequence involves bypassing the containment.

The main reasons for the need to consider change of the design were as follow:

- The newly developed PSA used MOV leakage failure rate that was based mainly on plants specific information (LERs). The derived failure rate appears to be higher than the failure rate based on generic data that was used in previous licencing submissions;
- Leakage of the RHR motorized isolation valves RHR1B, RHR2A and RHR1C (see Fig.V-4) at full or reduced power could lead to over pressurization and possible failure of the RHR system. A pressure operated Safety Relief Valve (SRV) is provided on the RHR suction line outside of the containment to reduce the probability of failure by relieving to a relief tank. Such external relief or rupture of the RHR effectively bypasses the containment and would be classed as a 'V sequence' LOCA (VLOCA). Valve reliability indicates the design goal CDF or LERF would not be achievable;
- In addition, the suction line of RHR system outside of the containment and downstream of Relief Safety Valve (SRV) is Safety Class 2 (SC2) pipework and as such is not designed to withstanding full power reactor pressures and temperatures;
- The PSA indicated that the risk of RHR suction line leakage is unacceptable;
- There is a legal requirement to demonstrate that the design goal is ALARP.

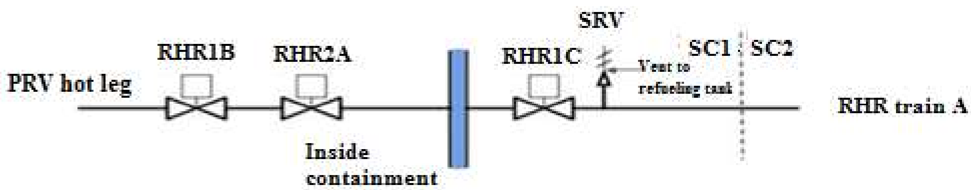


FIG. V-4. Residual Heat Removal System line drawings.

Applicability of the IRIDM Process to this Issue

Before any IRIDM process is begun, it has to be determined whether IRIDM is appropriate for the issue or decision being considered. This may be done by a permanent IRIDM team if one exists or by personnel experienced in IRIDM at the request of management. In this example, design bureau management requested several personnel experienced in IRIDM to review the issue for its suitability to the IRIDM process.

The first factor that was considered was whether the IRIDM process was feasible as it pertained to this issue. The conclusion reached was affirmative. The reasons for the application of IRIDM process were as follows:

- There were several inputs that involved trade-offs or apparent contradictions;
- The inputs needed to be integrated in a systematic manner;
- There was a need to assess safety detriments versus the safety benefits in a balanced manner;
- The design engineers were generally reluctant to consider changes without detailed backup information; and
- There was also a need to have a strong case since it would form part of the overall plant safety case to be approved by the regulatory body.

The following questions in addition were asked and answered in this review:

- Is necessary expertise available within the design bureau to address the issue? Yes, sufficient expertise was available at this point.
- Is sufficient information available to initiate the IRIDM process at this time? Yes.
- Is the problem possible to solve using IRIDM process? Yes.
- Any further obstacles? No.

Based on the answers above it was decided to proceed with the IRIDM process. Note that in other circumstances it may have been decided to carry out an abbreviated version of the IRIDM process or to address the issue in some other way. The design bureau manager then instructed the IRIDM experts that had completed the initial feasibility review to proceed with Stage 1 until a full IRIDM team was selected.

Stage I comprised of the following three steps:

- Definition of the issue;
- Definition of decision options;
- Establishing a multidisciplinary team of specialists; assign team leader.

Definition of the issue

The issue was defined as follows: **"*To identify design changes which will improve RHR Suction Line Isolation Reliability*".**

Definition of decision options

Based on this framing of the issue, a meeting was organized by the design bureau manager with the involvement of the IRIDM experts and additional technical staff from all relevant departments to define the possible decision options.

After detailed consideration the following options were defined:

- Option 1: Assume plant specific data (derived from the LER analysis) is conservative and accept that the existing design will ultimately be shown to be adequate to meet the design safety target.
- Option 2: Move pressure safety relief valve (SRV) inside the containment.
- Option 3: Fit an additional manual isolation outside of the containment, within the SC1 pipework.

At this meeting, possible candidates to lead the IRIDM review were also discussed.

Establishing a multidisciplinary team of specialists; assign team leader

The design bureau manager decided to assign the Systems Functions Manager (SFM) as the team leader. The SFM then drew up an implementation plan for carrying out the IRIDM process and estimated the resources required to address the issue. The team leader then obtained the concurrence of the design bureau manager - the decision maker (DM).

The IRIDM implementation plan for the issue included the following:

- A description of the problem and options as identified at the initial meeting;
- A description of the disciplines necessary to perform the investigation and their approximate time requirements, and definition of the specific personnel to fulfil those disciplines to form a multidisciplinary team;
- An estimate of the schedule/cost for the investigation;
- A definition of the stakeholders/approvers of the investigation results.

Following the approval of the plan by the design bureau manager, the team was formally created and progressed to perform the investigation.

V-2.2. Stage II - preparation for the assessment

Stage II comprised of the following four steps:

- Screening the options;
- Identification of constituent factors;
- Gathering the information, and
- Validation of the information.

Review and screening of the decision options

The specialists of the IRIDM team carried out some initial analysis and provided initial feedback on the suitability of the options.

All initially drafted options were reviewed and found to be feasible.

The IRIDM team agreed that no other options were necessary; however, at later stages of the IRIDM process when more information would be available it was recognized that new options might be apparent.

It was agreed that the IRIDM team can perform all needed assessment steps and there was no need for involvement of additional specialists. In addition, it was recognized that additional information from the manufacturer of the motorized isolation valves would be needed as well as additional information from the LER analyses.

The result of this initial review of the options was submitted to the team leader who then authorised the team to proceed with the assessment phase.

The options retained for further analysis received additional clarification as described below:

- *Option 1: Accept existing design as adequate with minor enhancements to the pressure sensor system between the two motorized isolation valves.*
  While implementing this option the design of the RHR system remains practically unchanged (see Fig. V-4). The reliability of the RHR suction line isolation is determined using generic design data rather than plant specific data. The weak point of this option is that by use of generic design data the overall safety goal might not be met, and/or that the use of generic design data might not be acceptable to the regulators. Following the initial review, the proposed leak detection and testing system between the two motorised isolation valves RHR1B and RHR2A was enhanced to include a main control room leakage alarm. Upon detection of leakage through the upstream (nearest to the reactor primary circuit) MOV, the operator would be instructed to shut down the plant to minimise the potential for leakage through the second MOV.
- *Option 2: Move pressure safety relief valve (SRV) inside the containment*
  This option would be accomplished by relocation of Safety Relief Valve inside containment with valve discharges ultimately to the containment sump.
  The relief tank will be relocated within the containment; the relief tank is retained to minimise potential contamination and clean-up of the containment sump (see Fig. V-5).
  Note, following the initial review the proposed leak detection and testing system between the two motorised isolation valves RHR1B, RHR2A was enhanced to include a main control room leakage alarm. Upon detection of leakage through the upstream MOV the operator would be instructed to shut down the plant to minimise the potential for leakage through the second MOV.

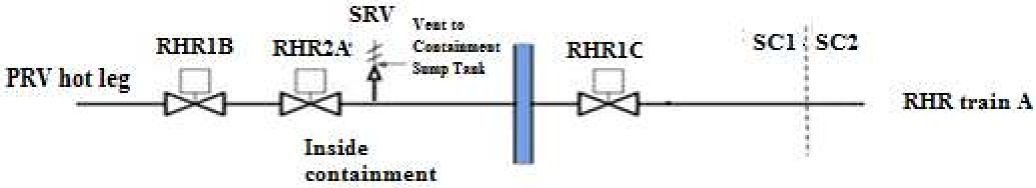


FIG. V-5. Residual Heat Removal System line drawings for Option 3.

Implementation of this option provides only a partial solution in that VLOCAs are still possible when the leak rate through the valves is higher than relief valve capacity.

- *Option 3: Fit an additional manual isolation outside of the containment, within the SC1 pipework.*
  Installation of a SC1 manually operated isolation valve (capable to withstand primary temperatures and pressures) outside of the containment and upstream of the SRV, which will provide the possibility to isolate the RHR system manually should leakage through all MOVs occur (see Fig. V-6). The manual activation hand wheel of the valve to be placed in a room easily accessible and shielded from the RHR system. Once again, following the initial review the proposed leak detection and testing system between the two motorised isolation valves RHR1B, RHR2A was enhanced to include a main control room leakage alarm. Upon detection of leakage through the upstream MOV the operator would be instructed to shut down the plant to minimise the potential for leakage through the second MOV.

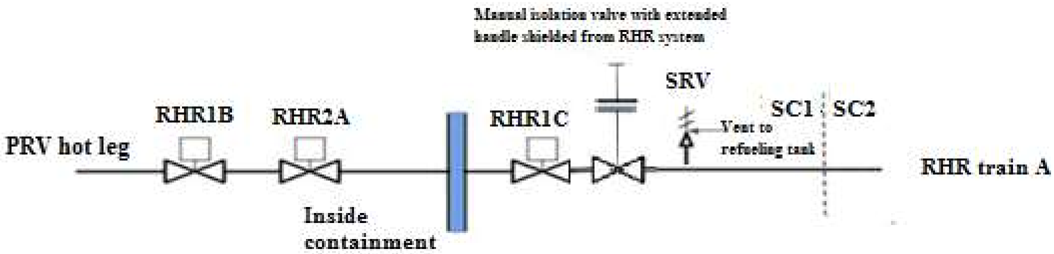


FIG. V-6. Residual Heat Removal System line drawings for Option 4.

Identification of constituent factors affecting the decision

The inputs or key elements to the IRIDM process have been characterised in the main part of this TECDOC as follows:

- Standards and good practices;
- Operational experience;
- Deterministic considerations;
- Probabilistic considerations;
- Human and organisational considerations;
- Considerations regarding the interface with nuclear security; and
- Other considerations.

The IRIDM team carried out a systematic review to identify the constituent factors (CFs) that were relevant to each key element. At this stage, the initial set of CFs was defined and unnecessary ones screened out. The summary outcome from this review is presented in Table V-1.

TABLE V-1: INPUTS INTO THE IRIDM PROCESS (change to RHR system)

Key Elements	Generic Constituent Factors	Reviewed areas[22]	Selected Constituent Factors[23]
Standards, good practices	Regulations developed by the regulatory body and conditions attached to the licence	1) Regulatory requirements 2) FSAR	1) Regulatory requirements towards CDF/LERF (ALARP) 2) Requirements to the reliability of RHR system (defined in FSAR) 3) Other requirements
	Standards developed by professional bodies, technical standards, IAEA safety guides, etc.	• ANS code • ASME B&PV codes • IAEA PSA guides	Recommendations for the design aspects and accident sequence modelling and data assessment in PSA
Operational experience	• Operational events • Other experience feedback	Operating experience related to RHR systems operation from different NPPs with similar designs	Positive and negative experience of those NPPs that already use designs of RHR system similar to those proposed in the options
Deterministic considerations	• Safety criteria • Defence-in-depth	Potential impact on defence-in-depth of different options	Impact on: • Compliance with the defence-in-depth concept • Safety margins • Single failure criterion • Fail-safe design • Equipment qualification • Prevention against common mode/cause failures • Spatial separation
Probabilistic considerations	• Qualitative insights • Quantitative measures	• The factors associated with risk assessment important for the issue under consideration. • Quality of the PSA.	• The calculated frequency of VLOCA • Risk benefit that could be gained from implementation of the design change (e.g. the change in the CDF from accident sequences due to leaks through isolated motor operated valves). • Quality of the PSA

[22] Areas reviewed to identify the relevant CFs

[23] CFs that have been found to be applicable for the issue and decision options related to the key element

TABLE V-1: INPUTS INTO THE IRIDM PROCESS (change to RHR system) (cont.)

Key Elements	Generic Constituent Factors	Reviewed areas[24]	Selected Constituent Factors[25]
Human and organisational considerations:	• Management Systems • Proposed Normal and Emergency Operating Procedures • Proposed Maintenance arrangements and procedures • Proposed Severe Accident Management Guidelines (SAMGs) • Training recommendations	• Operating procedures • Surveillance programme • Training programme • Maintenance programme • Severe Accident Management Guidelines (SAMGs)	• Required changes to operating and emergency procedures • Required changes to surveillance, inspection and maintenance programmes • Required changes to training programme (including maintenance personal) • Required changes to Severe Accident Management Guidelines (SAMGs)
Considerations regarding the interface with nuclear security	• Physical protection of a nuclear facility • Security of the nuclear material on the site	Not applicable	Not applicable
Other considerations	• Radiation doses • Costs • Economic benefits • Results of research • Potential lifetime • Waste management • Decommissioning • Environmental impact	Different factors were also reviewed (costs, radiation doses, implementation efforts, etc.)	• Potential lifetime • Electricity production • The cost of implementation of each design • Additional cost of maintenance during operation • Additional radiation doses received by workers during maintenance of the RHR system • Regulatory Acceptance

[24] Areas reviewed to identify the relevant CFs
[25] CFs that have been found to be applicable for the issue and decision options related to the key element

Gathering the necessary information

Assignment of specialists of the IRIDM team to gather the necessary information to carry out the analyses required to provide inputs to the IRIDM process was made by the team leader based on their expertise. A summary of the information gathered is provided below:

The following information sources were reviewed to collect the information required for the IRIDM assessment:

- Proposed Emergency and Operational Plant procedures;
- Draft Final Safety Assessment Report (FSAR) including PSA report
- Proposed maintenance programmes (for all options);
- Proposed Technical Specifications;
- Liability agreements with RHR valve manufacturers;
- Tests performed by the MOV manufacturer to demonstrate valve reliability;
- Available information from similar NPPs on the experience with existing RHR schemes;
- Available data related to spurious operation and leakage through MOV isolation valves at similar NPPs.

In addition, as part of information gathering, specific analyses were performed by the IRIDM team specialists as follows:

- The risk changes for the various options was calculated;
- The potential radiation burden received by plant personnel during maintenance of the various options was calculated;
- Cost estimates were generated for the various design options;
- The maintenance cost estimates for the various options was calculated.

The results of these efforts are summarized in the Table V-2 below.

Validation of the information

The specialists of the IRIDM team validated the necessary information to carry out the analysis required to provide inputs to the IRIDM process. The validation of the information was mainly required in the part of risk assessment results performed by the design bureau with the available PSA model, using generic and plant specific reliability data. Similar analyses were made on request of the IRIDM team by a consultant company using the same PSA model and data. The independent evaluation showed the same results. These results were used further in the assessment.

V-2.3. Stage III –Assessment, Integration and Documentation

Stage III comprised of the following steps:

- Evaluation of the options against the relevant CFs;
- Integration of the Evaluation Results for each Option;
- Checking the Robustness of the Results;
- Recommendation of the Options;
- Implementation and Monitoring Programme; and
- Documentation of the IRIDM Process and Results.

Evaluation of the options against the relevant CFs

The analyses to evaluate the impact of each option on the identified CFs were carried out by the responsible analyst. These analyses were fully documented and summarized in Table V-3. Table V-4 presents the resulting list of CFs with brief conclusions from the evaluation.

TABLE V-2: INFORMATION COLLECTION SUMMARY FOR THE IRIDM

Key Elements	Selected Constituent factors	Information source	Summary of the information collected
Standards and good practices	CDF/LERF Requirements in the Design Safety Guidelines (based on Regulatory requirement)	Design Safety Guidelines (DSG) /Regulatory requirements	• For design option 1 the probabilistic results based on component specific feedback data are likely to fall between the basic safety level (BSL) and the basic safety objective (BSO), thereby requiring an As Low As Reasonable Practicable (ALARP) justification to be made as to why it is impractical to improve the design. For other design options the probabilistic results are shown to be below the basic safety objective (BSO). • Note that in this example the BSL and BSO for CDF/LERF are 10^{-4}/y and 10^{-5}/y correspondingly. For design purposes, the BSL and BSO of any individual accident sequence are set at 10^{-7}/y and 10^{-8}/y correspondingly.
	Requirements regarding the reliability of RHR system (defined in DSGs)	Design Safety Guidelines (DSG)	No specific reliability targets for RHR systems were defined in the DSGs. As part of the FSAR, reliability analyses of RHR system have been performed for different accident conditions and reliability indexes have been obtained. However, these indexes have not been used as target values.
	Other mandatory or non-mandatory requirements	Existing industrial and regulatory norms and regulations	A regulatory requirement is that the reactor design must be licensable in the country of origin (USA). All options proposed are adjudged to be licensable in the country of origin. No effect on other mandatory requirements and criteria was determined.
	Recommendations for the accident sequence modelling and data assessment in PSA	TECDOC-1511 Ref. [V-1], SSG-3, SSG-4 Refs. [V-2,V-3]	The IAEA publications recommend using both generic and plant specific data for deriving valve failure rates. For option 1 this recommendation is violated as only generic data is used.
Operational experience	Positive and negative experience of those NPPs that already use designs of RHR system similar to those proposed in the options	Available information on different designs of RHR systems on NPPs and operational experience from these NPPs.	The designs of RHR system vary from plant to plant. Several plants operate with the system design similar to all options.

TABLE V-2: INFORMATION COLLECTION SUMMARY FOR THE IRIDM (cont.)

Key Elements	Selected Constituent factors	Information source	Summary of the information collected
Deterministic considerations	Compliance with defence-in-depth concept	System design has been reviewed for all design options	Compliance with the defence-in-depth concept was justified for all options under consideration. The standards code requires two motorised isolation valves for pipework which penetrates through the containment. All options comply with this requirement; thus, this CF is removed from further considerations.
	Safety margins		All proposed options result in improved safety margins.
	Single failure criterion		All options meet the single failure criterion. Note: the two motorised valves are powered by different electrical supplies.
	Fail-safe design		The design of motor operated valves for all options satisfies fail safe design principle.
	Equipment qualification		All options result in additional equipment qualification, to varying extent. Option 1 being the least, whilst option 2 is the greater.
	Redundancy and diversity, Prevention against common mode/cause failures		No changes for options 1-3. For option 4, where an additional manual valve is installed, higher diversity and redundancy is provided.
	Spatial separation		No changes for options 1-3. For option 4, where an additional manual valve is installed, the impact of a VLOCA can reduce the feasibility of operator action to close the manual valve; the option therefore provides for a hand wheel activation room, separated and shielded from the RHR system.
Probabilistic considerations	The frequency of VLOCA via RHR suction line leakage	Probabilistic Safety Analyses performed as a part of the design process and additional probabilistic studies performed for the assessment of the design options.	The frequency of VLOCA was calculated for all options.
	Risk benefit that could be gained from implementation of the design change (e.g. the change in the CDF from accident sequences due to leaks through isolated motor operated valves).		Option 2 and 3 offer risk reductions over Option 1.
	PSA Quality	Regulatory PSA review report	Internal review accepted the quality and level of detail of the PSA and the supporting data to be sufficient for a decision to be made on all design options.

TABLE V-2: INFORMATION COLLECTION SUMMARY FOR THE IRIDM (cont.)

Key Elements	Selected Constituent factors	Information source	Summary of the information collected
Human and organisational considerations:	Required changes to proposed operating and emergency procedures	Currently proposed procedures, programmes and guidelines and those that will be developed if design options are implemented	Requirements of the proposed plant operating and emergency procedures of RHR system including those that are dealing with prevention and mitigation of accidents with VLOCA through RHR system, will need to be revised for all options. In case of valves leakage, operators must perform actions needed either to isolate the leak or to reduce pressure to mitigate the consequences of the leak. Different design options will allow different actions to be taken and these actions need to be considered while assessing decision options: • For design option 1 and 2 minor changes are expected; • For design option 3 additional procedures need to be developed.
	Required changes to proposed surveillance, inspection and maintenance programmes		All design options will require changes in the proposed plant maintenance/test procedures. Different options require different level of changes of the maintenance, test and inspection procedures. Surveillance programme will remain unchanged for all options; however, inspection and maintenance programmes will be changed for Options 2 and 3.
	Required changes to proposed training programme (including maintenance personal)		Training programmes (including maintenance personal training) will be changed for all options.
	Required changes to proposed Severe Accident Management Guidelines (SAMGs)		No impact on the proposed Severe Accident Management Guidelines (SAMGs) is expected for all options.

TABLE V-2: INFORMATION COLLECTION SUMMARY FOR THE IRIDM (cont.)

Key Elements	Selected Constituent factors	Information source	Summary of the information collected
Other considerations	Potential lifetime	Relevant analysis and estimations.	For all options potential lifetime is 20 years and is not impacted by any option. However, the potential life-time has an impact on the CF “Additional cost of maintenance during operation” (see below)
	Electricity production		Changes in maintenance might lead to certain changes in electricity production.
	Equipment and installation costs		Relatively small or medium costs for all options.
	Cost of maintenance during operation		Various levels of cost for different options: • Minor additional cost for option 1 • Medium additional cost for option 3 • Medium/high additional cost for option 4 • High additional cost for option 2.
	Additional radiation doses received by workers during maintenance of the RHR system		Different levels of radiation doses for different options: • Minor levels of radiation doses for option 1 • Medium levels of radiation doses for options 2 and 3 • All radiation doses are adjudged acceptable
	Regulatory Acceptance		**Option 1:** Unlikely to be accepted by regulator **Options 2-3:** Most likely to be accepted by regulator

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
Standards, good practices	1) CDF/LERF: Requirements in the Design Safety Guidelines (DSG) (based on Regulatory requirement)	Enhancement of the pressure sensing capability between the two RHR MOVs in the suction line will reduce the frequency of VLOCA sequences due to the higher probability to detect the leak through the first valve in sequence. The estimated mean frequency of VLOCA sequences after implementation of this option is 2.0×10^{-8}/y with error factor 7 when generic data is used. This frequency is still above the desired BSO (10^{-8}/y) which requires an ALARP justification to be made as to why it is impractical to further improve the design.	The estimation of frequencies of VLOCA sequences for this option provided a mean frequency equal to 7.0×10^{-9}/y with error factor 4. The estimation was based on data using both generic and plants specific information for failure rates of the MOV valves and accounts for the failure to open of the relief valve. This frequency is below BSO; however, the 95th percentile of the frequency of VLOCA is 2.8×10^{-8}/y (and associated CDF and LERF) falls between the BSO and BSL.	The VLOCA frequency remains unchanged for this option, however the leakage would be detectable and the leak can be isolated and the VLOCA terminated. The estimation of un-isolated VLOCA sequences provided a mean frequency equal to 9.5×10^{-9}/y with error factor 7. This estimation was based on the data using both generic and plants specific information for failure rates of the valves and accounts for the failure to close of the manual isolation valve due to equipment failure or operator error. This frequency is slightly below the BSO; however, the 95th percentile of the frequency of non-terminated VLOCA is assessed as 6.7×10^{-8}/y (and associated CDF and LERF) which falls between the BSO and BSL.	Note: LERF for VLOCA sequences was assumed to be equal to CDF due to direct environmental releases. An ALARP justification is required for option 1 as the mean VLOCA sequence frequency falls between the design BSO and BSL. For other options the BSO is met. However, it is advisable to prepare ALARP justifications for options 2 and 3 due to the degree of uncertainty associated with the calculation of the mean VLOCA frequency.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
	2) Requirements regarding the reliability of RHR system (defined in the DSGs)	No impact	No impact	No impact	The CF is removed from further considerations as all options have no impact on the CF.
	3) Other mandatory or non-mandatory requirements	ALARP justifications need to be prepared	No impact	No impact	The CF is removed from further considerations because ALARP justification is already included in CF#1.
	4) Recommendations for the accident sequence modelling and data assessment in PSA	When generic data only is used the BSO for VLOCA sequences are met. However, the use of only generic data is not recommended by the IAEA standards. When, CDF and LERF are calculated with updated generic and plant specific data they fall between the basic safety level (BSL) and the basic safety objective (BSO) even with the minor modification associated with the option.	When generic data and plant specific data are used the BSO objective for VLOCA sequences are met.	When generic data and plant specific data are used the BSO objective for VLOCA sequences are met.	The CF is removed from further considerations due to the following reasons: 1) Use of only generic data is not allowed by the IAEA standards and will not be accepted by regulators. 2) The non-satisfaction of BSO for option 1 is already accounted for in CF #1.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
Operational experience	5) Positive and negative experience of those NPPs that already use designs of RHR systems similar to those proposed in the options	No negative experience on RHR system operation has been found at operating plants with similar design.	No negative experience on RHR system operation has been found at operating plants with similar designs. The placement of the relief line within the containment will result in a slight increase in radiation doses to workers during inspections and maintenance.	No negative experience on RHR system operation has been found at operating plants with similar designs. At a plant, where option 3 was implemented the maintenance of the class I manual valve led to a slight increase in maintenance and surveillance with a resulting small increase in radiation doses for workers during inspections.	The CF is removed from further considerations due to the following reason: the negative impact of higher efforts and radiation doses are already accounted for in CFs16 through 24.
Deterministic considerations	6) Compliance with the defence-in-depth concept	Satisfied	Satisfied	Satisfied	The CF is removed from further considerations as all options satisfy the CF.
	7) Safety margins	Satisfied	Satisfied	Satisfied	The CF is removed from further considerations as all options satisfy the CF.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
	8) Single failure criterion	Satisfied	Implementation of this option leads to the situation where 3 equipment failures would have to occur for a VLOCA to happen (i.e. leakage through both valves and failure of relief valve to open).	Implementation of this option leads to the situation where 3 equipment failures or two equipment failures and one human error would have to occur for a VLOCA to happen (i.e. leakage through both valves and failure of manual valve to close or operator error to close manual valve).	All options satisfy the single failure criterion; options 2 and 3 surpass the criterion. It is judged that satisfaction of single failure criteria is sufficient for all options and other benefits such as higher redundancy is accounted for in CF 14. Therefore, the CF is removed from further considerations.
	9) Fail-safe design	Satisfied	Satisfied	Satisfied	The CF is removed from further considerations as all options satisfy the CF.
	10) Equipment qualification	Satisfied	No changes	For option 3 equipment qualification is required for the manual isolation valve.	The re-classification of the equipment will have the impact on the following aspects: 1) Cost of implementation 2) Additional maintenance cost 3) Reliability of the equipment 4) Radiation doses to workers These aspects are accounted for in the CFs 13, 14, 17, 18, 21, 22 & 23. Therefore CF 10 can be removed from further considerations.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
	11) Redundancy and diversity, prevention against common mode/cause failures	Satisfied	Satisfied. For option 2, where relief is moved to inside containment although no additional redundancy or diversity is provided, leakage through the 2 isolation MOVs does not bypass the containment, assuming the leakage rate is within the relief capability of the SRV.	Satisfied For option 3, where an additional manual valve is installed higher diversity and redundancy is provided.	Options 2 and 3 have positive impact on this CF.
	12) Spatial separation	Satisfied	Satisfied	Satisfied. The placement of the manual closure hand wheel in a shielded compartment separate from the RHR compartment protects the operator from the environmental impact of the VLOCA leakage.	As all options satisfy the spatial separation considerations this CF is removed from further consideration with the following condition: for option 3, confirmation must be obtained that access to the hand wheel compartment is not affected by a LOCA in RHR compartments.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
Probabilistic considerations	13) The frequency of VLOCA via the RHR suction lines.	The initial estimation of the mean VLOCA frequency using generic and plant specific data was $1.7x10^{-7}$/y with error factor 9. Using only generic data a mean VLOCA frequency of $9.5x10^{-8}$/y was obtained. The addition of enhanced pressure monitoring and alarms between the two isolation MOVs allows for leakage from the upstream MOV (closest to the RPV) to be detected prior to failure of the second (downstream) MOV, thereby providing an opportunity to shut down the reactor and possible prevent or mitigate the consequences of a VLOCA. The enhanced monitoring system reduces the mean VLOCA frequency to $2.0x10^{-8}$/y with error factor 7 (using both generic and plants specific data). See discussion in CF 1.	The frequency of VLOCA sequences is reduced. The estimation of VLOCA mean frequency is reduced to $9.3x10^{-9}$/y with error factor 4. See discussion in CF 1.	The estimation of non-terminated VLOCA sequences provided mean frequency equal to $9.9x10^{-9}$/y with error factor 5. See discussion in CF 1.	The frequency of VLOCA sequences is reduced for all options. However, the reduction of frequency for option 1 is relatively low. Reductions associated with options 2 and 3 are of a similar range. The impact of reduced VLOCA frequencies is considered in CF 14 and the requirement for ALARP justification is covered under CF 1. Therefore, it was concluded that this CF is redundant and can be removed from further considerations.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
	14) Risk benefit that could be gained from each design option (e.g. the change in the CDF from accident sequences due to leaks through isolated motor operated valves).	The reduction of the contribution to the overall CDF and LERF due to implementation of option 1 is equal to the reduction of VLOCA sequences frequencies - estimated to be $2.0x10^{-8}$/y with error factor 7 (see CF 1). This reduction would reduce the overall CDF and LERF by: • ΔCDF: 0.22% • ΔLERF: 1.43%	The reduction of the contribution to the overall CDF and LERF due to implementation of option 2 is equal to the reduction of VLOCA sequences frequencies - estimated to be equal $1.6x10^{-7}$/y with error factor 7 (see CF 1). This reduction would reduce the overall CDF and LERF by: • ΔCDF: 1.8% • ΔLERF:11.4%	The reduction of the contribution to the overall CDF and LERF due to implementation of option 3 is equal to the reduction of VLOCA sequences frequencies - estimated to be equal $1.6x10^{-7}$/y with error factor 7 (see CF 1). This reduction would reduce the overall CDF and LERF by: • ΔCDF: 1.8% • ΔLERF:11.4%	The reductions in CDF and LERF are about the same for options 2 and 3. For option 1 the reduction is relatively low. Notes: 1) The mean CDF and LERF quantified prior to the implementation of the options when both generic and plant specific data are used: CDF=$9.1x10^{-6}$/y with error factor 4.5 and LERF $1.4x10^{-6}$/y with error factor 7. 2) The reduction in LERF was quantified based on the assumption made in PSA that VLOCA leads directly to a large early release. 3) Mean CDF estimated with only generic data was $8.2x10^{-6}$/y with error factor 4.5.
	15) PSA quality	Internal review accepted the quality and level of detail of the PSA and the supporting data to be sufficient for the decision	Internal review accepted the quality and level of detail of the PSA and the supporting data to be sufficient for the decision	Internal review accepted the quality and level of detail of the PSA and the supporting data to be sufficient for the decision	The CF is removed from further considerations as all options have identical impact on this CF.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	**Selected Constituent factors**	**Option 1**	**Option 2**	**Option 3**	**Comment**
Human and organisational considerations:	16) Required changes to proposed operating and emergency procedures	The operating procedure will require plant shutdown if leak through the upstream MOV on the RHR suction line is detected.	The operating procedure will require plant shutdown upon activation of the relief valve.	The emergency procedures will include a requirement for operator action to close the manual isolation valve upon activation of the relief valve.	Options 1, 2 and 3 require the initially drafted EOPs to be amended.
	17) Required changes to proposed surveillance, inspection and maintenance programmes	Minor changes related to the inspection and tests of the enhanced detection line and pressure measuring and monitoring system between the two isolation MOV's.	Medium/major changes related to the inspection and testing of relief valves moved inside containment.	Medium changes due to addition inspection and testing of a SC1 manual isolation valve.	The inspection and maintenance programmes will be changed only for options 2, 3 and 4.
	18) Required changes to proposed training programme (including maintenance personal)	Changes in operational staff training related to the need to shut down the plant in case of leak detection.	Changes in operational and maintenance staff training related to the need to shut down the plant in case of relief valve opening and in maintaining equipment within the containment.	Changes in operational staff training related to the need to cooperate the manual isolation valve. Additional changes in maintenance staff training (although they will already be familiar with the processes applied for class 1 valves).	The proposed training programmes will require modification for all options.
	19) Required changes to Severe Accident Management Guidelines (SAMGs)	No impact on Severe Accident Management Guidelines	No impact on Severe Accident Management Guidelines	No impact on Severe Accident Management Guidelines	The CF is removed from further consideration as none of the options impacts upon this CF.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
Other considerations	20) Potential lifetime	No impact	No impact	No impact	The CF is removed from further consideration as neither of the options has impact in the CF.
	21) Equipment and installation costs	Minor cost estimated in the range of 3000 – 6000 $MU for implementation	Medium cost estimated in the range of 10000 – 15000 $MU for implementation	Medium cost estimated in the range of 5000 – 10000 $MU for implementation	Minor cost for option 1, medium cost for options 2 and 3.
	22) Additional* cost of maintenance during operation	Minor costs (500-1000 $MU per year) during maintenance. For 20 years of remaining lifetime this will lead to a total of 10000-20000 $MU over the life of the unit.	Minor costs (500-1000 $MU per year) during maintenance. For 20 years of remaining lifetime this will lead to a total of 10000-20000 $MU over the life of the unit.	Minor costs (500-1000 $MU per year) during maintenance. For 20 years of remaining lifetime this will lead to a total of 10000-20000 $MU over the life of the unit.	Minor cost for all options. Note that CFs 21 and 22 can be combined in one CF "Cost of implementation and maintenance".
	23) Electricity production	No change to electrical production	Slightly longer outage time due to SRV maintenance inside containment, electrical production unlikely to be affected	Slightly longer outage time due to additional valve maintenance electrical production unlikely to be affected.	Options 2 and 3 are likely to have a slight negative impact on electricity production.
	24) Additional* radiation doses received by workers during maintenance of the RHR system	Minor additional doses estimated in the range of 5-10 mSv per year during maintenance	Medium additional doses estimated in the range of 10-20 mSv per year during maintenance	Medium additional doses estimated in the range of 30-60 mSv per year during maintenance	Option 1 has low impact on this CF. Other options have medium impact.

TABLE V-3: SUMMARY OF EVALUATION OF THE IMPACT OF THE OPTIONS ON CFs (RHR suction line) (cont.)

Key Elements	Selected Constituent factors	Option 1	Option 2	Option 3	Comment
	25) Regulatory Acceptance	Implementation of this option might not be supported by regulators due to sole usage of generic data to justify adequate safety provisions.	Implementation of the option may be supported by regulators.	Implementation of the option will be fully supported by regulators as it provides clear benefits to safety	The following observations have been made for different options: **Option 1:** Might require significant efforts to obtain regulatory approval. Additional compensatory measures would likely be requested. **Option 3:** Most likely will be accepted by regulators without additional justifications and measures **Option 2:** Most probably will be accepted by regulators with proper justification as to the feasibility of operator action to shut down the reactor prior to failure of the downstream isolation MOV. It is seen that only option 1 has high negative impact on the CF. Other options will probably be acceptable to the regulators. As the negative impact of Option 1 on the CF is already accounted for in CF#1. Therefore, the CF is removed from further considerations.

* The original Option 1 only had basic leak detection between the MOV isolation valves. The proposed Option 1 has enhanced leak detection and control room alarms.

TABLE V-4: SUMMARY AND IMPORTANT CONSIDERATION FOR REMAINING CFs (RHR suction line isolation)

Key Elements	Remaining Constituent Factors	Important Considerations
Standards and good practices	Regulatory requirements regarding CDF/LERF	An ALARP justification is required for option 1 as the mean VLOCA sequence frequency falls between the design BSO and BSL. For the three other options the BSO is met. However, it is advisable to prepare ALARP justifications for options 2 and 3 due to the degree of uncertainty associated with the calculation of the mean VLOCA frequency.
Deterministic considerations	Redundancy and diversity, prevention against common mode/cause failures	Options 2 and 3 have positive impact on this CF. For option 1 CCF of three valves can lead to VLOCA and undesirable consequences.
Probabilistic considerations	Risk benefit that could be gained from implementation of the design change (e.g. the change in the CDF from accident sequences due to leaks through isolated motor operated valves).	**Quantitative insights** **Option 1:** the PSA showed that the use of RHR MOV leakage data based on data derived from actual experience would result in a higher VLOCA frequency which in turn would not allow the design CDF and LERF to be met **Option 2:** the VLOCA frequency with the SRV discharge inside of the containment indicates that the design CDF and LERF might be met. However there remains the possibility of leakage from the RHR system outside of the containment should the SRV fail or be unable to sufficiently relieve the system pressures. For **Option 3:** the VLOCA frequency would satisfy the design CDF and LERF goal. However there remains the possibility of leakage from the RHR system outside of the containment should the manual isolation valve fail or the operator fail to close the manual valve. The most important results from the PSA were as follows: • The reduction in the overall CDF and LERF is about the same for options 2 and 3. • For option 1 the reduction is relatively small. Note: the mean CDF estimated with only generic data was about $1.2x10^{-5}$/y with error factor 4.5. This information is not issued in further assessment as it was decided that the use of only generic data is not acceptable.
Human and organisational considerations	Required changes to propose operating and emergency procedures	All options require changes to the proposed operating and emergency procedures. Changes are required to TSs and/or in equipment qualification.
	Required changes to proposed surveillance, inspection and maintenance programmes	The inspection and maintenance programmes will be significantly changed for options 2. For options 1 and 2 changes are required to test enhanced pressure measuring and alarm system.
	Required changes to proposed training programme (including maintenance personal)	The training programme will be changed for all options due to the need for additional human intervention. For all options only minor changes are expected as the plant staff has already to be familiar with the plant operational and maintenance aspects introduced by these options.

TABLE V-4: SUMMARY AND IMPORTANT CONSIDERATION FOR REMAINING CFs (RHR suction line isolation) (cont.)

Key Elements	Remaining Constituent Factors	Important Considerations
Other considerations	Cost of implementation and maintenance	**Option 1:** Minor implementation and additional maintenance costs in total in the range of 13000-26000 $MU for the remaining lifetime **Option 2:** Medium implementation and small increase in maintenance cost due to SRV maintenance inside containment in total in the range of 20000-35000 $MU for the remaining lifetime **Option 3:** Medium implementation and minor increase in maintenance cost due to additional valve maintenance in total in the range of 15000-30000 $MU for the remaining lifetime.
	Electricity production	**Option 1:** No change to electrical production **Option 2:** Longer outage time due to increased maintenance of SC1, slight decrease in electrical production **Option 3**: Slightly longer outage time due to SRV maintenance inside containment, electrical production unlikely to be affected **Option 4:** Slightly longer outage time due to additional valve maintenance, electrical production unlikely to be affected
	Additional radiation doses received by workers during implementation of the options and maintenance of the RHR system	**Option 1:** Minor change in radiation doses (in total 100-200 mSv for design lifetime) **Option 2:** Major change in radiation doses (in total 2000-4000 mSv for design lifetime) **Option 3:** Medium change in radiation doses (in total 200-400 mSv for design lifetime) **Option 4:** Medium change in radiation doses (in total 600-1200 mSv for design lifetime)

Based on the results from the initial analysis, the IRIDM team agreed on the need for more detailed specification in the definition of the options:

1) For option 1 and 2 the requirement for immediate plant administrative shutdown in case of detection of leak after the first isolation valve in the sequence (the upstream valve) needs to be added to Technical Specifications
2) For option 3 in case of detection of leak after the first isolation valve in the sequence the manual isolation valve has to be closed and consideration given to plant administrative shutdown.

Integration of the Evaluation Results for each Option

The IRIDM team met to discuss the weighting factors to be applied to the inputs into the IRIDM process for each of the four identified options, this was done by a two-stage approach. Firstly, the inputs were ranked in order of importance and then assigned a 'weighting' on a 1- 10 scale. This ranking is simply a tool to facilitate the assignment of weights. The ranking and the correlated weight as assigned by the IRIDM team are given in Table V-5.

TABLE V-5: RANKING AND WEIGHTING OF THE INPUTS INTO THE IRIDM PROCESS (RHR suction line)

Key Elements	Selected Constituent Factors	Ranks and Weights Assign
Standards and good practices	1. Regulatory requirements towards CDF/LERF (ALARP)	There is a regulatory requirement to provide an ALARP justification should the CDF or LERF fall within the BSO and BSL. Failure to provide an adequate ALARP justification would present major problems during the licensing process; this has a major impact/high ranking/high weight. Rank = 1, Weight = 10
Deterministic considerations	2. Redundancy and diversity, prevention against common mode/cause failures	All options have low impact on the deterministic requirements; however, the deterministic considerations are always given high priority; therefore, they have a high ranking/high weight. Rank = 1, Weight = 10
Probabilistic considerations	3. Risk benefit that could be gained from implementation of the design change	The main reason for changes of the design was the high CDF/LERF for original RHR suction line design. Consideration of the ALARP principle is already accounted for in CF 1; however, the intention to reduce risk of plant operation is in line with regulatory policy. It is shown that all options reduce the risk, but level of reduction differs significantly. Rank = 3, Weight = 8
Human and organisational considerations:	4. Required changes to proposed operating and emergency procedures	The impact on operating and emergency procedures is minimal/low ranked. Rank = 8, Weight = 2
	5. Required changes to proposed surveillance, inspection and maintenance programmes	The impact on surveillance, inspection and maintenance programmes is medium/low ranked. Rank = 7, Weight = 6
	6. Required changes to proposed training programme (including maintenance personal)	The impact on training programme is minimal/low ranked. Rank = 9, Weight = 1
Other considerations	7. Cost of implementation and maintenance	IRIDM team agreed that cost of maintenance is an important factor for the options under consideration and must be appreciated in the decision making process while selecting the options; however, it was judged to be of lower importance than risk considerations. Rank = 4, Weight = 7
	8. Electricity production	The rank and weight of electrical production is similar to the cost of maintenance for the same reasons. Rank = 4, Weight = 7
	9. Additional radiation doses received by workers during maintenance of the RHR system	The rank and weight of radiation dose is similar to the cost of maintenance for the same reasons. Rank = 4, Weight = 7

Note: in a real application of the IRIDM process, the basis and rational used in the ranking and weighting process have to be fully described and documented.

For assessing the impact of each of the key elements/inputs the team decided to use a numerical system as follows:

- 10 to 1 = positive impact compared to the original Option 1* (with "10" being the highest)
- 0 = no impact or change compared to the original Option 1*
- -1 to -10 = negative impact compared to the original Option 1* (with "-10" being the worst)

*The original Option 1 only had basic leak detection between the MOV isolation valves. The proposed Option 1 has enhanced leak detection and control room alarms.

It is worth noting that the team could have chosen to use some other system, e.g. qualitative.

Each CF for all four options was assigned a score based on the analysis of the inputs. In each case the basis for the score was described and documented. In this process, uncertainty associated with the input and the effect that this would have on the score have been identified and documented.

The impact value assigned to each CF along with the associated justification and uncertainty is shown in Tables V-6 through V-10.

A Structured Value Analysis method (see Annex IV) was then used to determine an overall weighted score. The overall weighted score is given by the product of the weighting and the assigned impact value.

The integration is simply a sum of the different inputs for the options. The overall scores for all options are shown in Table V-11.

The following options are evaluated in Tables below:

- **Option 1:** Accept existing design with minor enhancement to the leak detection system design: installation of enhanced pressure sensors between the two MOV isolation valves and the installation of alarms within the main control room. In additions requirement for immediate plant administrative shutdown in case of detection of leakage through the upstream MOV need to be added to Technical Specifications.
- **Option 2**: Move the RHR suction line pressure safety relief valve (SRV) inside the containment
- **Option 3:** Fit an additional manual isolation outside of the containment, within the SC1 pipework. The hand wheel of the valve is in an isolated shielded room with the access not affected by any potential LOCA in RHR system.

The preliminary result of the evaluation was that ***Option 2*** is the preferred design solution.

TABLE V-6: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT 'Standards and good practices'

Constituent factors / Options	Regulatory requirements towards CDF/LERF (ALARP)			
	Assessment for the options			
	Mean Score	Justification	Uncertainty range	Comments
Option 1	**1**	This option requires an ALARP justification. Enhancement of the pressure sensing system between the two MOVs, alarmed in the main control room, and with a requirement to shut down in the event of leakage, would reduce the risk of a VLOCA; however, the BSO is not satisfied when plant specific and generic reliability data are used for evaluation of VLOCA frequency. It is still possible to select the Option 1 if other options would be shown to be less beneficial considering all CFs. The IRIDM team members agree that the score to be assigned for the option has to be the lowest positive (equal to 1).	Point estimate is used	Non- satisfaction of BSO requires an adequate ALARP justification.
Option 2	**8**	For this option the design BSO is met. However due to the uncertainty associated with the frequency determination, the upper bound VLOCA sequence frequency for CDF and LERF are slightly higher than the design BSO (95th percentile of the frequency of VLOCA equal to 2.8×10^{-8}/y compared to the design BSO of 10^{-8}/y). There was no consensus between IRIDM team members and each expert was asked to provide his own estimation of the score value. Based on aggregation of all members' opinions the mean value of the score for the option was defined as 8.	The score value is assumed to be equally distributed in the interval [7,9]	-
Option 3	**6**	For this option the design BSO is met. However due to the uncertainty associated with the frequency determination, the upper bound VLOCA sequence frequency for CDF and LERF are slightly higher than the design BSO (95th percentile of the frequency of VLOCA equal to 6.7×10^{-8}/y compared to the design BSO of 10^{-8}/y). There was no consensus between IRIDM team members and each expert was asked to provide his own estimation of the score value. Based on aggregation of all members' opinions the mean value of the score for the option was defined as 6.	The score value is assumed to be equally distributed in the interval [5,7]	-

TABLE V-7: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT ‘Deterministic considerations’

Constituent factors / Options	Redundancy and diversity, prevention against common mode/cause failures			
	Assessment for the options			
	Score	**Justification**	**Uncertainty range**	**Comments**
Option 1	**0**	This option has very small impact on the CF as there is no substantial change to systems design or qualification. The score value assigned is 0.	Not applicable	-
Option 2	**6**	This option has medium impact on the CF. Moving the safety relief valve inside containment will lead to the reduction of the frequencies of VLOCA. Therefore, IRIDM team agreed that the option has a positive impact on the CF. Based on aggregation of all members’ opinions the mean value of the score for the option was defined as 6.	The score value is assumed to be equally distributed in the interval [4,8]	-
Option 3	**6**	This option has medium impact on the CF due to additional diversity introduced in the system against VLOCA sequences. It was conservatively assumed by the IRIDM team that the installation of a manual isolation valve will not reduce the frequency of VLOCA, but will significantly improve the potential to terminate a VLOCA if occurred. Therefore, IRIDM team agreed that the option has a positive impact on the CF. Based on aggregation of all members’ opinions the mean value of the score for the option was defined as 6.	The score value is assumed to be equally distributed in the interval [4,8]	-

TABLE V-8: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT ‘Probabilistic considerations’

Constituent factors / Options	Risk benefit that could be gained from implementation of the design change			
	Assessment for the options			
	Score	**Justification**	**Uncertainty range**	**Comments**
Option 1	**1**	This option has the smallest positive impact on the CF: • ΔCDF: 0.22% • ΔLERF: 1.43% The IRIDM team members agree that the score to be assigned for the option has to be the lowest positive value (equal to 1).	Point estimate is used	-
Option 2	**9**	This option has the second highest positive impact on the CF: • ΔCDF: 1.8% • ΔLERF:11.4% The IRIDM team members agree that the score to be assigned for the option has to be the second highest positive value (equal to 9).	Point estimate is used	-
Option 3	**9**	Same as Option 2	Point estimate is used	-

TABLE V-9: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT ‘Human and organizational considerations’

Constituent factors / Options	Required changes to proposed operating and emergency procedures			
	Assessment for the options			
	Score	**Justification**	**Uncertainty range**	**Comments**
Option 1	**-5**	This option will require changes to the proposed operational procedures due to the need to shut down the reactor in case of alarmed leak detection. The IRIDM team members agreed that the score assigned for the option has to be the medium negative value (equal to -5).	Point estimate is used	-
Option 2	**-3**	This option will require changes to the proposed operational procedures due to the need to shut down the reactor in case of alarmed leak detection. This change is different from Option 1, leak inside containment are already considered within the proposed Technical Specifications. The IRIDM team members agree that the score to be assigned for the option has to be a low negative value (equal to “-3”).	The score value is assumed to be equally distributed in the interval [-4; -2]	-
Option 3	**-4**	This option will require changes to the proposed operational procedures due to the need to shut down the reactor in case of alarmed leak detection. The emergency procedures will include a requirement for operator action to close the manual isolation valve. IRIDM team agreed that the option has a negative impact on the CF. Based on aggregation of all members’ opinions the mean value of the score for the option was defined as “-4”.	The score value is assumed to be equally distributed in the interval [-6; -2]	-

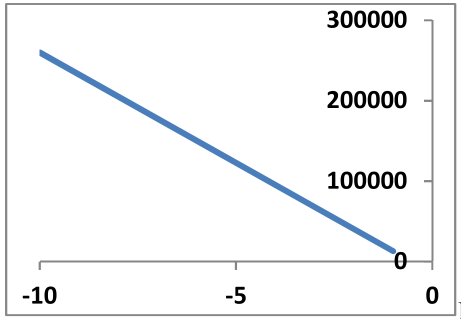
TABLE V-9: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT ‘Human and organizational considerations’ (cont.)

Constituent factors / Options	Required changes to proposed surveillance, inspection and maintenance programmes			
	Assessment for the options			
	Score	**Justification**	**Uncertainty range**	**Comments**
Option 1	**-1**	Only minor changes related to the inspection and testing of the enhanced leak detection and alarm system will be needed. The IRIDM team members agreed that the score to be assigned for the option has to be the highest negative value (equal to “-1”).	Point estimate is used	-
Option 2	**-2**	Only minor changes related to the inspection and tests of the relief valve moved inside containment, and inspection and testing of the enhanced leak detection and alarm system will be needed. The IRIDM team members agreed that this option has a low negative impact on CF (score is equal to “-2”).	Point estimate is used	-
Option 3	**-4**	Changes related to surveillance, inspection and maintenance of the manual isolation valve are required. As well as changes related to the inspection and testing of the enhanced leak detection and alarm system will be needed. The IRIDM team members agreed that this option has a negative impact on CF (score is equal to -4).	Point estimate is used	-

TABLE V-9: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT ‘Human and organizational considerations’ (cont.)

Constituent factors / Options	Required changes to proposed training programmes			
	Assessment for the options			
	Score	**Justification**	**Uncertainty range**	**Comments**
Option 1	**-1**	Only minor changes in operational staff training related to the need to shut down the plant in case of leak detection is required for the option. The IRIDM team members agreed that the score to be assigned for the option has to be the highest negative value (equal to “-1”).	Point estimate is used	-
Option 2	**-1**	Minor changes in operational staff training related to the need to shut down the plant in case of relief valve opening. The IRIDM team members agreed that the score to be assigned for the option has to be the highest negative value (equal to “-1”).	Point estimate is used	-
Option 3	**-2**	Minor changes in operational staff training related to the need to shut down the plant in case of relief valve opening, and training in closing the manual isolation valve. Minor changes in maintenance staff training as they are already familiar with the processes applied for class 1valves. The IRIDM team members agreed that the score to be assigned for the option has to be a negative value (equal to “-2”).	Point estimate is used	-

TABLE V-10: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT 'Other considerations'

Constituent factors / Options	Cost of implementation and maintenance			
	Assessment for the options			
	Score	Justification	Uncertainty range	Comments
Option 1	**-1**	Overall additional cost ranges from 13000 to 26000 $MU (averaged 19500). The mean score value is the highest negative value (equal to "-1").	Point estimate is used	• The lowest and highest estimated costs for the options are 13000 and 260000 $MU correspondingly. • Following recommendations give in Annex III the lowest negative score (-10) is assigned for the cost 2600000 $MU and the highest negative score (-1) for the cost 13000 $MU. • All options receive the scores based on linear approximation of the highest and lowest costs and their corresponding scores (see Figure below).  M
Option 2	**-1**	Overall additional cost ranges from 20000 to 35000 $MU (averaged 27500). The mean score value is the highest negative value (equal to "-1").	Point estimate is used	
Option 3	**-1**	Overall additional cost ranges from 15000 to 30000 $MU (averaged 22500). The mean score value is the highest negative value (equal to "-1").	Point estimate is used	

Constituent factors / Options	Electricity production			
	Assessment for the options			
	Score	Justification	Uncertainty range	Comments
Option 1	**0**	No changes to CF. The score is 0.	Not applicable	-
Option 2	**0**	Negligible impact on CF. The score is 0.	Point estimate is used	-
Option 3	**0**	Same as for option 3.	Point estimate is used	-

TABLE V-10: SCORES ASSIGNED FOR OPTIONS FOR CFs OF THE KEY ELEMENT 'Other considerations' (cont.)

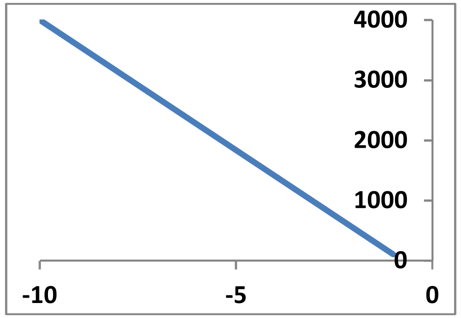
Constituent factors / Options	Radiation doses received by workers			
	Assessment for the options			
	Score	**Justification**	**Uncertainty range**	**Comments**
Option 1	**-1**	Overall additional doses range from 110 to 220 mSv (averaged 165). The mean score value is the highest negative value (equal to "-1").	Point estimate is used	The lowest and highest estimated doses for the options are 110 and 4000 mSv correspondingly. Following recommendations give in Annex III the lowest negative score (-10) is assigned for the dose 4000 mSv and the highest negative score (-1) for the option 110mSv. Other options receive the scores based on linear approximation of the highest and lowest doses and corresponding scores (see Figure below). 
Option 2	**-1**	Overall additional cost ranges from 200 to 400 mSv (averaged 300). The mean score value is the highest negative value (equal to "-1").	Point estimate is used	
Option 3	**-3**	Overall additional cost ranges from 600 to 1200 mSv (averaged 900). The mean score value is defined equal to -3.	The score value is assumed to be equally distributed in the interval [-4; -2]	

TABLE V-11: INTEGRATION OF THE RESULTS OF THE IRIDM PROCESS (RHR suction line)

		Options						
		Option 1: Minor modifications to the system design		**Option 2:** Move pressure safety relief valve (SRV) inside the containment		**Option 3:** Fit an additional manual isolation outside of the containment		
CFs	Input Weight	Score	Weighted score	Score	Weighted score	Score	Weighted score	General Remarks
Regulatory requirements towards CDF/LERF	10	1	10	8	80	6	60	High uncertainty in score values for options 2 and 3
Redundancy and diversity, prevention against common mode/cause failures	10	0	0	6	60	6	60	High uncertainty in score values for option 3
Risk benefit that could be gained from implementation of the design change	8	1	8	9	72	9	72	
Required changes to operating and emergency procedures	2	-5	-10	-3	-6	-4	-8	
Required changes to surveillance, inspection and maintenance programmes	6	-1	-6	-2	-12	-4	-24	
Required changes to training programme (including maintenance personal)	1	-1	-1	-1	-1	-2	-2	
Cost of implementation and maintenance	7	-1	-7	-1	-7	-1	-7	High uncertainty in score values for option 3
Electricity production	7	0	0	0	0	0	0	
Additional radiation doses received by workers during implementation of the options and maintenance of the RHR system	7	-1	-7	-1	-7	-3	-21	High uncertainty in score values for option 3
Total Weighted score		-13		**179**		130		

Checking the robustness of the results and recommendation of options

The next step was to test the result, to verify that it is sound and robust.

The first check was: ‘Does the integrated result ‘feel right’, satisfy defence-in-depth, etc.?’

The team agreed that the result seemed reasonable, as the option with the highest weighted score has involves no additional or upgraded plant items whilst providing additional VLOCA protection.

It was noted by the team that certain CFs that might not be of concern to a regulatory body (such as costs) were assigned high weighting by the IRIDM team. Accordingly, the team decided that a sensitivity and robustness analysis had to be performed to support the decision making process.

To this end, the weightings of the following CFs were reduced in importance:

- Required changes to surveillance, inspection and maintenance programmes: from 6 to 2;
- Cost of implementation and maintenance: from 7 to 2;
- Electricity production from 7 to 2.

The sensitivity assessment was performed and is shown in Table V-12. The conclusion of the sensitivity assessment is that the results of the initial assessment are robust.

In addition, it was recognized that for several CFs the IRIDM team had not reach a consensus and uncertainty had been introduced in the score values.

Tables V-13 and V-14 present the results of integration when lowest and highest score in uncertainty ranges have been used for the original input weights (Table V-13) and reduced input weights (Table V-14).

Again, it was shown that the overall decision was not changed with ***Option 2*** always having the highest weighted score.

In this example, the uncertainty of the input information was accounted for through sensitivity studies in verifying whether it would be possible to change the order of the options based on the uncertainty. In this it was possible to combine the uncertainty assessment with the inputs using a bounding and conservative approach.

In addition, it was decided to perform a more comprehensive analysis of the uncertainty using a Monte Carlo simulation process. For this purpose, the following approach was utilized (see Annex VI):

1) The F (W,Si) - Total Weighted Score function for the option I was defined as:

$$F(W, Si) = \sum_{j} Wj*Sij$$

Where:
Wj – input weights for CFj
Sij – score for the option i for CFj

TABLE V-12: SENSITIVITY STUDY ON THE RESULTS OF THE IRIDM PROCESS (RHR suction line) IN RELATION TO INPUT WEIGHTS

		Options						
		Option 1: Minor modifications to the system design		**Option 2:** Move pressure safety relief valve (SRV) inside the containment		**Option 3:** Fit an additional manual isolation outside of the containment		
CFs	Input Weight	Score	Weighted score	Score	Weighted score	Score	Weighted score	General Remarks
Regulatory requirements towards CDF/LERF	10	1	10	8	80	6	60	High uncertainty in score values for options 2 and 3
Redundancy and diversity, prevention against common mode/cause failures	10	0	0	6	60	6	60	High uncertainty in score values for option 3
Risk benefit that could be gained from implementation of the design change	8	1	8	9	72	9	72	
Required changes to operating and emergency procedures	2	-5	-10	-3	-6	-4	-8	High uncertainty in score values for option 3
Required changes to surveillance, inspection and maintenance programmes	2	-1	-2	-2	-4	-4	-8	
Required changes to training programme (including maintenance personal)	1	-1	-1	-1	-1	-2	-2	
Cost of implementation and maintenance	2	-1	-2	-1	-2	-1	-2	High uncertainty in score values for option 3
Electricity production	2	0	0	0	0	0	0	
Additional radiation doses received by workers	7	-1	-7	-1	-7	-3	-21	High uncertainty in score values for option 3
Total Weighted score			-4		**192**		151	

TABLE V-13: RESULTS OF THE IRIDM PROCESS FOR UNCERTAINTY RANGES FOR THE INITIALLY ASSIGNED INPUT WEIGHTS

		Options						
		Option 1: Minor modifications to the system design		**Option 2:** Move pressure safety relief valve (SRV) inside the containment		**Option 3:** Fit an additional manual isolation outside of the containment		
CFs	Input Weight	Score	Weighted score	Score	Weighted score	Score	Weighted score	General Remarks
Regulatory requirements towards CDF/LERF	10	1	10	7 9	70 80	5 7	50 70	Lowest (upper) and highest uncertainty ranges
Redundancy and diversity, prevention against common mode/cause failures	10	0	0	4 8	40 80	4 8	40 80	Lowest (upper) and highest uncertainty ranges
Risk benefit that could be gained from implementation of the design change	8	1	8	9	72	9	72	
Required changes to operating and emergency procedures	2	-5	-10	-4 -2	-8 -4	-6 -2	-12 -4	Lowest (upper) and highest uncertainty ranges
Required changes to surveillance, inspection and maintenance programmes	6	-1	-6	-2	-12	-4	-24	
Required changes to training programme (including maintenance personal)	1	-1	-1	-1	-1	-2	-2	
Cost of implementation and maintenance	7	-1	-7	-1	-7	-1	-7	Lowest (upper) and highest uncertainty ranges
Electricity production	7	0	0	0	0	0	0	
Additional radiation doses received by workers	7	-1	-7	-1	-7	-4 -2	-28 -14	Lowest (upper) and highest uncertainty ranges
Total Weighted score		-13 -13		**147** **211**		89 171		

TABLE V-14: RESULTS OF THE IRIDM PROCESS FOR UNCERTAINTY RANGES FOR THE REDUCES INPUT WEIGHTS

		Options						
		Option 1: Minor modifications to the system design		**Option 2:** Move pressure safety relief valve (SRV) inside the containment		**Option 3:** Fit an additional manual isolation outside of the containment		
CFs	Input Weight	Score	Weighted score	Score	Weighted score	Score	Weighted score	General Remarks
Regulatory requirements towards CDF/LERF	10	1	10	7 9	70 80	5 7	50 70	Lowest (upper) and highest uncertainty ranges
Redundancy and diversity, prevention against common mode/cause failures	10	0	0	4 8	40 80	4 8	40 80	Lowest (upper) and highest uncertainty ranges
Risk benefit that could be gained from implementation of the design change	8	1	8	9	72	9	72	
Required changes to operating and emergency procedures	2	-5	-10	-4 -2	-8 -4	-6 -2	-12 -4	Lowest (upper) and highest uncertainty ranges
Required changes to surveillance, inspection and maintenance programmes	2	-1	-2	-2	-4	-4	-8	
Required changes to training programme (including maintenance personal)	1	-1	-1	-1	-1	-2	-2	
Cost of implementation and maintenance	2	-1	-2	-1	-2	-1	-2	Lowest (upper) and highest uncertainty ranges
Electricity production	2	0	0	0	0	0	0	
Additional radiation doses received by workers	7	-1	-7	-1	-7	-4 -2	-28 -14	Lowest (upper) and highest uncertainty ranges
Total Weighted score		-8 -4		**152** **224**		94 192		

2) The distribution functions for each Sij has been constructed based on the information on the uncertainty ranges for each Sij. All Sij are assumed to be equally distributed in the intervals defined in Tables V-6 through V-10. For those Sij where no intervals have been defined only mean value has been used in the uncertainty analysis.
3) The distribution functions for each Wj have been constructed. In this example the assumption was made the Wj are equally distributed on the defined interval for the following CFs:
   - Required changes to surveillance, inspection and maintenance programmes: [2,6];
   - Required changes to training programme: [2,7];
   - Cost of implementation and maintenance: from [2,7];
   - Electricity production from [2,7].
   - For other Wj only mean value has been used in the uncertainty analysis.
4) The probabilities Pi+ = P (F(W,Si) > F(W, Sk) for each k$\neq$ I)) have been quantified using a Monte Carlo simulation.
5) The probabilities Pn- = P (F(W,Sn) < F(W,Sk) for each k$\neq$ I)) have been quantified using a Monte Carlo simulation.
6) The product of Pi+ and (1-Pi-) is quantified (Pi)
7) The option with the highest Pi is selected.

The results of the quantification are shown in Table V-15.

Based on the information presented in Table V-15, one can see that P3 (Option 3) has the highest value. This again confirms the results of the sensitivity studies that Option 3 has the highest total weighted score of all options under consideration.

TABLE V-15: RESULTS OF A MONTE CARLO SIMULATION FOR THE PROBABILITIES Pi

Option	Pi+	Pi-	Pi
1	0.01	0.98	0.00
2	0.87	0.14	0.75
3	0.14	0.12	0.12

The final recommended option was to accept Option 2 ‘Move pressure safety relief valve (SRV) inside the containment’ and to approve the design changes to safety systems and changes to the proposed Tech Spec, requiring plant shutdown in case of the RHR suction line safety relief valve opening.

Implementation and Monitoring Programme

Recommendations on implementation included the following actions:

- Changes need to be made to the design of RHR suction line;
- Changes need to be made to the relevant documentation (maintenance and emergency procedures) and Tech Spec.;
- Training needs to be provided for relevant staff on the maintenance and emergency procedures.

For monitoring purposes, a system has to be established to collect information on the experience with the maintenance and training programme.

Proposed actions would be implemented within Stage V of IRIDM process.

Document the Process

The team then documented the entire process to the satisfaction of the team leader in the form of a formal design report.

V-2.4. Stage IV - selection of the option to implement by the DM

The team then submitted the formal report to the DM (design bureau manager) and gave the DM a summary presentation of the results. The DM accepted the results and agreed with the selection of Option 3. The DM instructed a request to change to the proposed design and associated amendment of the proposed operating, maintenance and training programmes.

The IRIDM report was eventually incorporated within the FSAR. The decision was ultimately accepted by the regulator.

V-2.5. Stage V –implementation of the decision and development of the programme for monitoring of the implementation and subsequent performance

The required changes were made to the design and station documentation including the Maintenance Procedures and the Safety Assessment Report. Training was given to the operating and maintenance staff on the system design.

A system was set up at the plant to collect information on the maintenance and operating experience of the RHR suction line isolation.

V-3. CHANGING THE MAINTENANCE REGIME OF THE DIESEL GENERATORS (DGS)

V-3.1. Stage I - characterization of the issue

Description of the Issue to be addressed

The operators of a nuclear power plant wish to consider changing the current maintenance regime of the DGs to a new one that has been recommended by the manufacturer. The change of regime is due to new methods of maintenance that would reduce the failure probability of the equipment and it is strongly advised by the manufacturer. However, the length of time for having a DG inoperable to perform the recommended new maintenance is longer than that allowed in the current Technical Specification (Tech Spec). It is assumed for this example that the option of performing the maintenance during a scheduled outage is not available. The plant under consideration has three (3) DGs.

The following information is initially available:

- The manufacturer has recommended that a special periodic maintenance be performed on the emergency DGs;
- This special periodic maintenance will improve the reliability of the DGs;
- To perform the maintenance. it will be necessary to extend the period of unavailability of the DG beyond the current Tech Spec limits;
- If the change is implemented, there is a trade-off between overall improved reliability of the DGs versus the increased length of time one DG is inoperable during plant operation.

Applicability of the IRIDM Process to this Issue

Before the IRIDM process is begun, it has to be determined whether IRIDM is appropriate for the issue or decision being considered. In this example, it is assumed that management (in this case, the NPP plant manager) has requested several personnel experienced in IRIDM to review the issue for its suitability to the IRIDM process.

It was management policy to apply the IRIDM technique when issues related to improvements in nuclear safety are being addressed.

The first factor that was considered was whether the IRIDM process was feasible as it pertained to this issue. The conclusion reached was positive. The reasons for the application of IRIDM process were as follows:

- There were several inputs that involved trade-offs or apparent contradictions;
- The inputs needed to be integrated in a systematic manner;
- There was a need to assess safety detriments versus the safety benefits in a balanced manner;
- The nuclear power plant managers were generally reluctant to consider changes to the Tech Specs without detailed backup information; and
- There was also a need to have a strong case since it would need to be presented to the regulatory body and the IRIDM process supports this.

The following questions in addition were asked and answered in this review:

- Is necessary expertise available at the NPP to address the issue? Yes, sufficient expertise is available at this point.
- Is sufficient information available to initiate the IRIDM process at this time? Yes.
- Is the problem possible to solve using IRIDM process? Yes.
- Any further obstacles? No.

Based on these answers it was decided to proceed with the IRIDM process. The NPP plant manager then instructed the IRIDM experts that had completed the initial feasibility review to proceed with Stage 1 until a full IRIDM team was selected.

Stage I comprises the following three steps:

- Definition of the issue;
- Definition of decision options;
- Establishing a multidisciplinary team of specialists; assign team leader.

Definition of the issue

The issue: is: Whether it is of sufficient net benefit to safety to justify requesting a Tech Spec change that allows extended time of DGs maintenance, suggested by the manufacture.

Definition of decision options

Based on this framing of the issue, a meeting was then organized by the NPP plant manager with the involvement of the original IRIDM experts and additional technical staff from the Engineering and Electrical departments to define the possible decision options.

The following options that needed to be considered were defined as follows:

- Accept the manufacturer’s recommendation and request the regulator to allow a change to the Tech Specs;
- Reject the manufacturer’s recommendation and keep the status as it is.

It was recognized that a third option may arise in which the 'accept' option is amended with conditions – this would be determined later.

Establishing a multidisciplinary team of specialists; assign team leader

The NPP plant manager (the decision maker (DM)) decided to assign the Engineering Manager as the team leader based on the previous meeting and assured him that he would be provided with the support and resources required to do the investigation. The Engineering Manager (team leader) then drew up an implementation plan for carrying out the IRIDM process and estimated the resources required to address the issue. The team leader then obtained the concurrence of the NPP plant manager on the plan.

The IRIDM implementation plan for the issue included the following:

- A description of the problem and options as identified at the initial meeting;
- A description of the disciplines necessary to perform the investigation and their approximate time requirements, and definition of the specific personnel to fulfil those disciplines to form a multidisciplinary team;
- An estimate of the schedule/cost for the investigation;
- A definition of the stakeholders/approvers of the investigation results.

Following the approval of the plan by the NPP plant manager, the team was formally created and progressed to perform the investigation.

V-3.2. Stage II - preparation for the assessment

Stage II comprises the following three steps:

- Screening the options;
- Identification of constituent factors; and
- Gathering the information.

Review and screening of the decision options

The specialists of the IRIDM team carried out some initial analysis and provided initial feedback on the suitability of the options. All initially drafted options were reviewed and found to be suitable.

However, it was agreed that the list of initially drafted options was incomplete and it was reasonable to define a third option that would allow requested changes to DG maintenance, but at the same time would define certain compensatory measures aimed to decrease risk during the period when a DG would be in maintenance.

At this initial stage of the analysis, it was not possible to specify these measures; therefore, it was decided that a more specific definition of option 3 would be needed when more information would be collected and more assessment results would become available. The IRIDM team agreed that no other options were necessary; however, at later stages of the IRIDM process when more information would be available, it was recognized that new options might be apparent (in addition to the more specific definition of option 3).

It was also recognized that the IRIDM team could perform all needed assessment steps and there was no need for involvement of additional specialists in the IRIDM team. In addition, it was recognized that additional information from the manufacturer on the reliability parameters of the DGs after implementation of the new maintenance programme would be needed as well as information from operational experience on other NPPs where such modifications had been already implemented.

The results of this review of the options were then submitted to the team leader and based on the information received, the team leader authorised the team to proceed with the assessment phase.

Identification of constituent factors affecting the decision

The inputs or constituent factors to the IRIDM process have been characterised in the main part of this TECDOC as follows:

- Standards and good practices;
- Operational experience;
- Deterministic considerations;
- Probabilistic considerations;
- Human and organisational considerations;
- Security considerations; and
- Other considerations.

The IRIDM team carried out a systematic review to identify the constituent factors (CFs) that are relevant to this issue. At this stage, the initial set of CFs was defined and unnecessary ones screened out. The summary outcome from this review is presented in Table V-16.

TABLE V-16: INPUTS INTO THE IRIDM PROCESS (DG Maintenance)

Key Elements	Reviewed areas	Constituent factors
Standards and good practices	A review has been carried out of the following areas to identify the relevant CFs: • Requirements of plant operating procedures; • Conditions under which the conclusions of the Final Safety Assessment Report (FSAR) have been drawn (e.g. reliability of the system functions that are quantified based on the existing DGs reliability parameters); • Maintenance programmes (for both the existing and proposed schemes); • Tech Specs	The following CFs have been found to be applicable for the issue and decision options related to standards and good practices: • Tech Spec requirements; • Requirements to the reliability of emergency power supply system and DGs (defined in FSAR); • Maintenance/test procedures for original and proposed maintenance regime.
Operational experience	A review has been carried out of the operating experience from the plant related to DG maintenance, outages and reliability for the plant itself and for other plants applying the new maintenance regime.	Positive and negative experience of those NPPs that already moved to new maintenance regime.
Deterministic considerations	A review has been carried out to determine how the issue can have an impact on defence-in-depth	The following CFs have been identified: • Safety margins; Single failure criterion; Fail-safe design; • Equipment qualification; • Redundancy and diversity; Spatial separation.
Probabilistic considerations	A review has been carried out to identify the factors associated with risk assessment that are important for the issue under consideration.	The following CFs were identified as being important: • The reliability analysis of DG with the new maintenance programme that has to provide evidence that the latter improves reliability of DGs. • The change in the CDF from applying the new maintenance programme; this need to take account of the benefits due to increased reliability of the DGs and the disadvantages due to the longer outage time.
Human and organisational considerations	A review has been carried out to determine the organizational impacts in the following areas: • Surveillance programme; • Training programme; and • Maintenance programme.	The following CFs have been identified and include changes due to the new maintenance programme to: • Surveillance programme; • Maintenance programme and • Maintenance personal training programme.
Security considerations	Not applicable.	Not applicable
Other considerations	Different factors were also reviewed (costs, radiation doses, implementation efforts, etc.)	The following CFs were selected to be applicable for the issue: • The cost of implementation of the changes in the DG maintenance practices; • The benefit that could be gained from implementation of the new maintenance programme.

Gather the necessary information

Assignment of specialists of the IRIDM team to gather the necessary information to carry out the analyses required to provide inputs to the IRIDM process was then made by the team leader based on their expertise. A summary of the information gathered is provided below:

The following information sources were reviewed to collect the information required for the IRIDM assessment:

- Emergency and operation plant procedures;
- Final Safety Assessment Report (FSAR);
- Maintenance programmes (for both the existing and proposed schemes);
- Requirements of Tech Specs;
- Liability agreement with DG manufacturer;
- Test performed by the DG manufacturer to demonstrate improved reliability of DGs;
- Available information from the NPP and other NPPs on the experience with existing and proposed maintenance programme for DG.

In addition, as part of information gathering, specific analyses were performed by the IRIDM team specialists as follows:

- Cost estimates were generated for the implementation and maintaining of the new maintenance programme;
- The risk increase due to prolonged DG maintenance was calculated;
- The change in risk matrices due to both prolonged DG maintenance and expected improvement in DG reliability parameters was calculated.

The results of these efforts are summarized in the Table V-17 below.

TABLE V-17: INFORMATION COLLECTION SUMMARY FOR THE IRIDM

Information source	Summary of the information collected
Emergency and operation plant procedures	The DGs have to start automatically. If any DG fails to start, operators have to perform actions aimed to initiate DGs start-up and successful loading. When a DG is in test or in maintenance, operators need, as soon as possible, to return DG to operable condition.
Final Safety Assessment Report (FSAR)	The FSAR provides the following reliability parameters for DGs: - Probability of failure to start: $1.2x10^{-2}$/demand - Failure rate to run: $7.0x10^{-5}$/h The emergency power supply system failure probability quantified with the DGs reliability parameters listed above for 24 h mission time is $2.3x10^{-4}$. For all internal initiating events, internal and external hazards and for all modes of operation core damage frequency was equal to $2.7x10^{-5}$/y. The contribution from Loss of Off-site Power events is about 11% ($2.9x10^{-6}$/y).
Maintenance programmes (for both the existing and proposed schemes);	The existing maintenance programme requires not more than 8 hours for DGs monthly maintenance performed after DG tests. The restoration of DGs from maintenance requires 1 h to enable a DG. The new maintenance programme recommended by the manufacture requires at least 24 h for DGs monthly maintenance performed after the DGs tests. The restoration of DGs from maintenance requires at least 8 hours.
Requirements of Tech Specs	Technical specifications do not allow one DG to be disabled for more than 8 hours before a plant shutdown is required.
Liability agreement with DGs manufacturer	The manufacturer guarantees the reliable behaviour of DGs under conditions of implementation of the new maintenance programme. In the case where the existing maintenance programme is kept, the manufacturer may refuse to keep its liability obligations.
Test performed by the DGs manufacture to demonstrate improved DGs reliability	The following reliability parameters of DGs under the new maintenance programme were demonstrated by manufacturer through the series of tests: - Probability of failure to start: $9.1x10^{-3}$/demand - Failure rate to run: $4.0x10^{-5}$/h Both parameters are log-normally distributed with error factor equal to 3.
Available information from the NPP and other NPPs on the experience with existing and proposed maintenance regime for DGs.	Several NPPs implemented programmes similar to the proposed one for the DGs; however, the accumulated operational experience was not sufficient to make any conclusion on the improved reliability of the DGs. However, unexpected behaviour of DGs was not observed.
Cost estimates for the implementation and maintaining of the new maintenance regime;	The cost of implementation of the new maintenance programme was relatively low and was partially compensated by the savings due to reduced repair forecasts of the DGs (if improved reliability is confirmed).
Risk increase due to prolonged DGs maintenance;	The change in CDF due to prolonged maintenance is estimated as 10% addition to the CDF of Loss of off-site power event (assuming existing reliability parameters for DGs).
Change in risk estimates due to both prolonged DGs maintenance and expected improvement in DGs reliability parameters.	If new reliability parameters are applied, the overall change to CDF, calculated with new maintenance duration and new reliability parameters of DGs, is decreased by 7% comparing to the CDF for existing maintenance regime.

Validation of the information

The specialists of the IRIDM team validated the necessary information to carry out analysis required to provide inputs to the IRIDM process. The validation of the information was mainly required in the part of risk assessment results performed by the NPP with the available PSA model. Similar analyses were made on request of team by a consultant company using the same PSA model. The independent evaluation showed the same results. These results are used further in the assessment. It was recognized that the third option of applying compensatory measures had not been sufficiently defined and that further risk analysis might be required.

V-3.3. Stage III – assessment, integration and documentation

Stage III comprises the following five steps:

- Evaluation of the options against the relevant CFs;
- Integration of the Evaluation Results for each Option;
- Checking the Robustness of the Results;
- Recommendation of Options;
- Implementation and Monitoring Programme; and
- Documentation of the IRIDM Process and Results.

Evaluation of the options against the relevant CFs

The analyses to evaluate the impact of each of the options identified on each CF were carried out by the responsible analyst. These analyses were fully documented and led to the following conclusions summarized in Table V-18.

TABLE V-18: CONCLUSIONS ON THE CFs OF THE IRIDM PROCESS (DG Maintenance)

Key Elements	Important Considerations
Standards and good practices	Options which accept the proposal under any condition violate the Tech Specs and therefore cannot be implemented without regulatory approval. The recommendation is from the DG manufacturer and therefore not following it may be a liability risk. However, there was disagreement among the team regarding the extent of this liability. This shows that the amount of risk is uncertain and this will be considered in the robustness check later in the analysis.
Operational experience	(See discussion under probabilistic considerations)
Deterministic considerations	Investigation of the defence-in-depth inputs yielded the following: • Safety margin – no direct impact. • Single failure criterion – no direct impact since the Tech Specs allow taking one DG out for maintenance for limited periods as long as other conditions are normal. • Fail-safe design – no impact. • Equipment qualification – investigation of the manufacturer's requirement for the maintenance results in conclusion that there is no impact. • Spatial separation – no impact. • Redundancy and diversity – conclusion was that this is covered by the probabilistic evaluation and the Tech Specs (with any required changes) if they are approved.
Probabilistic considerations	The most important results from the PSA were as follows: • Due to the increased outage time, the DG is offline during the extended maintenance period, the CDF from loss of offsite power is increased by only 10 % while DG maintenance is being performed (which was estimated by carrying out a re-quantification of the PSA for the initiating event group that was expected to have the greatest significance). • Considering the improved DG reliability stated by the manufacturer, the overall decrease of the average CDF during normal operation of the plant is 7%. • Even though overall CDF is reduced, the analyst and the licensing manager recommended that there needed to be some commitment to introducing compensatory measures during the DG maintenance period (the third option). The suggestion was to check that the other DGs are available by doing a start test and assuring no adverse conditions exist that would affect grid stability during the maintenance period. <u>Reliability of the DG</u>: The significant issues were as follows: • Reliability data for DG: the reliability data obtained from the manufacturer showed that the new maintenance practices did in fact improve the reliability of the DGs as stated by manufacturer – although the exact amount as stated by the manufacturer is judged uncertain (error factor 3). • The operating experience from other plants that made this change was reviewed. This confirmed that the results did show an improvement, but the exact amount could not be confirmed due to insufficient length of time of the observation. • Information was required to demonstrate that the DGs can operate for a long-time period. The result of analysis did not confirm this; hence, there was a need to ask the manufacturer to confirm the run time for one DG. The manufacturer provided an acceptable response.
Human and organisational considerations	It was concluded that here would be minimal impact to the existing plant documentation; the changes were typical of what needed to be done for a change to the plant design or operation
Considerations regarding the interface with nuclear security	Not applicable
Other considerations	Costs were modest for the maintenance changes and for paying the manufacturer; this was considered by the plant management to have a moderate impact on the decision making process

Based on the results from the initial analysis, the IRIDM team agreed on the need for a third option – namely, to accept the manufacturer's recommendations with conditions**.** The conditions applied (as recommended by PSA analyst and licensing manager) are to start the other DGs (not to be maintained) and to provide assurance that no adverse conditions are predicted that would affect grid stability during the maintenance period. (This example is intended to show in a simple way that new options may (and usually do) emerge during the course of the investigation. Sometimes it is necessary to go back and repeat some earlier steps when this happens).

As a result of the iterative process in the assessment, the set of options to be considered are now as follows:

- Accept the manufacturer's recommendation and request the regulator to allow a change to the Tech Specs;
- Reject the manufacturer's recommendation and keep the status as it is; or
- Accept the manufacturer's recommendation with conditions (perform a start test on the other DGs before maintenance and assure that no adverse conditions exist that would affect grid stability during the maintenance period (e.g. no adverse weather conditions) and request the regulator to allow a change to the Tech Specs.

Integration of the Evaluation Results for each Option

The IRIDM team met to discuss the weighting factors to be applied to the inputs into the IRIDM process for each of the three options identified and this was done by a two-stage approach. Firstly, the inputs were ranked in order of importance and then weighted on a 1- 10 scale. The ranking was simply a tool to facilitate the assignment of weights and is not used in further scoring. The ranking and the correlated weight as assigned by the IRIDM is given in Table V-19.

TABLE V-19: RANKING AND WEIGHTING OF THE INPUTS INTO THE IRIDM PROCESS (DG Maintenance)

Key Elements	Ranks and Weights Assign
Standards and good practices	It is good practice to implement the manufacturers recommendations; there would be a liability risk if these were not implemented; this has a major impact/high ranking/high weight Rank = 1, Weight = 10 The Tech Specs is a mandatory requirement and is a part of licensing basis; the need to change the Tech Specs has high impact/high ranking Rank = 2, Weight = 8
Deterministic considerations	The proposal has no effect on the deterministic requirements; however, the deterministic considerations have always high priority; therefore, they do have high ranking/high weight Rank = 1, Weight = 10
Probabilistic considerations	There is a major impact due to the perceived conflicting risk result/high ranking This also encompasses the DG reliability which must be confirmed; contributes to major impact since reliability estimate given by manufacturer is the basis for the investigation Combined PSA Rank = 2, Weight = 10
Other considerations	The costs have a moderate impact/medium ranking Rank = 3, Weight = 5
Human and organisational considerations	The organizational impacts are minimal/low ranking Rank = 5, Weight = 2
Note: in a real application of the IRIDM process, the way that the ranking and weighting has been done would be fully described and documented.	

The team decides to follow through with assessing the impacts by using a numerical system as follows:

- 10 to 1 = positive impact comparing to existing situation (with 10 being the highest);
- 0 = no impact or change (Option 2);
- -1 to -10 = negative impact (with -10 being the worst), comparing with existing situation.

It is worth noting that the team could have chosen to use some other system, e.g. qualitative.

Each input for all three of the options was assigned a score based on the analysis of the inputs. In each case, the basis for the score was described and documented. In this process, any uncertainty associated with the input and the effect that this would have on the score need to be identified.

A Structured Value Analysis method (see Annex IV) is used here. The overall weighted score is given by the product of the weighting and the score. The integration is simply a sum of the different inputs for the options. The Table V-20 below provides the results of the scoring and integration.

Note: in a real situation, it would be expected that the scoring system is fully described and the justification for the scores assigned is documented.

The preliminary result is that the option 'accept manufacturer recommendation with conditions' is the preferred one.

TABLE V-20: INTEGRATION OF THE RESULTS OF THE IRIDM PROCESS (DG Maintenance)

		Options						
		Accept Manufacturer's recommendations - no conditions		Reject Manufacturer's recommendations - no change		Accept Manufacturer's recommendations with Conditions		
Inputs	Input Weight	Comment and Score	Weighted score	Comment and Score	Weighted score	Comment and Score	Weighted score	General Remarks
Standards, mandatory license documents, good practices – Mandatory license document - Tech Spec	8	It is recognized that tech spec will have to be changed - is a major effort - impact score = -10	-80	No change, impact score = 0	0	It is recognized that tech spec will have to be changed - is a major effort, but could be easier with the conditions - impact score = -5	-40	
Standards, mandatory license documents, good practises – good practices – liability risk if do not implement	10	No new liability risk if fully accept - impact score = 0 (no change from current)	0	Liability risk is considered major, impact score = -8	-80	No new liability risk if fully accept - impact score = 0 (no change from current)	0	There is uncertainty in the analysis about the degree of liability risk.
Deterministic								
Deterministic – no effect	10	No impact, impact score = 0	0	No impact, impact score = 0	0	No impact, impact score = 0	0	
Probabilistic								
Probabilistic – PSA – major impact due to perceived conflicting risk result – Also encompasses DG reliability	10	Improved overall risk, but increased CDF for a short period of maintenance, impact score = 7	70	No change, impact score = 0	0	Improved overall risk, but increased CDF for a short period of maintenance is mitigated by compensatory measures, impact score = 10	100	There is uncertainty about the exact amount of improvement in DG reliability.
Other								
Other – costs	5	Moderate cost impacts, impact score = -5	-25	No change, impact score = 0	0	Moderate cost impacts, impact score = -5	-25	
Other –organisational impacts	2	Minimum impact, impact score = -3	-6	No change, impact score = 0	0	Minimum impact, impact score = -3	-6	
Total Weighted score			-41		-80		29	

Checking the robustness of the results and recommendation of options

The next step was to test the result and to verify that it is sound and robust.

The first check is: 'Does the integrated result 'feel right', satisfy defence-in-depth, etc.?'

The team agreed that the result seemed reasonable, since the current condition incurs a liability and the proposed conditions for acceptance are not excessive. Also, that they mitigate the period of higher CDF risk during maintenance of the DG.

It was noted by the team that there was uncertainty in the DG reliability values and the degree of risk from this liability. Accordingly, the team decided that a robustness case has to be run to test this. The impact of liability was thus reduced in severity from -8 to -5 and the impacts of improved reliability were reduced from 7 to 4 in option 1 and from 10 to 6 in option 3. This was done and the decision was not changed as shown in Table V-21.

In this example, the robustness check consisted in verifying whether it would be possible to change the order of the options based on the uncertainty. In this simple case, it was possible to combine the uncertainty assessment to one case since both uncertainty inputs caused changes in the same direction (decreases of negative impact for option 2 for the liability change, and decreases of positive impact for options 1 and 3 for the probability change). This is a bounding and conservative approach. In more complicated situations it may be necessary to run multiple cases varying the uncertain inputs individually.

The final recommended option was to accept the manufacturer's recommendations with the proposed additional conditions: to perform a start test on the other DGs (not scheduled for maintenance) and to provide assurance that no adverse conditions are predicted that would affect grid stability during the maintenance period (e.g. weather conditions). It was also suggested to proceed with a request to the regulatory body for the Tech Spec change.

TABLE V-21: SENSITIVITY STUDY OF THE RESULTS OF THE IRIDM PROCESS (DG Maintenance)

		Options						
		Accept Manufacturer's recommendations - no conditions		Reject Manufacturer's recommendations - no change		Accept Manufacturer's recommendations with Conditions		
Inputs	Input Weight	Comment and Score	Weighted score	Comment and Score	Weighted score	Comment and Score	Weighted score	General Remarks
Standards, mandatory license documents, good practices – Mandatory license document - Tech Spec	8	It is recognized that tech spec will have to be changed - is a major effort - impact score = -10	-80	No change, impact score = 0	0	It is recognized that tech spec will have to be changed - is a major effort, but could be easier with the conditions - impact score = -5	-40	
Standards, mandatory license documents, good practises – good practices – liability risk if do not implement	10	No new liability risk if fully accept - impact score = 0 (no change from current)	0	Liability risk is considered not as major, impact score = -5	-50	No new liability risk if fully accept - impact score = 0 (no change from current)	0	There is uncertainty shown in the analysis about the degree of liability risk - this case reduces reliability from the base case
Deterministic								
Deterministic – no effect	10	No impact, impact score = 0	0	No impact, impact score = 0	0	No impact, impact score = 0	0	
Probabilistic								
Probabilistic – PSA – major impact due to perceived conflicting risk result – Also encompasses DG reliability	10	Improved overall risk, but increased CDF for a short period of maintenance, impact score = 4	40	No change, impact score = 0	0	Improved overall risk, but increased CDF for a short period of maintenance is mitigated by compensatory measures, impact score = 6	60	There is uncertainty shown about the exact amount of improvement in DG reliability to + or - 50% - this case reduces the DG reliability by 50%
Other								
Other – costs	5	Moderate cost impacts, impact score = -5	-25	No change, impact score = 0	0	Moderate cost impacts, impact score = -5	-25	
Other –organisational impacts	2	Minimum impact, impact score = -3	-6	No change, impact score = 0	0	Minimum impact, impact score = -3	-6	
Total Weighted score			-71		-50		-11	

Implementation and Monitoring Programme

The next step was to provide suggestions on implementation of the decision and to establish possible monitoring programmes. Recommendations on implementation included the following actions:

- Changes need to be made to the relevant documentation;
- Training needs to be provided for relevant staff on the new DG maintenance practices.

For monitoring purposes, a system has to be established to collect reliability information on the DGs as well as experience with the new maintenance programme. Proposed actions would be implemented within Stage V of IRIDM process.

Document the Process

The team then documented the entire process to the satisfaction of the team leader in the form of a formal report.

V-3.4. Stage IV - selection of the option to implement by the dm

The team then submitted the formal report to the DM (NPP plant manager) and gave the DM a summary presentation of the results. The DM accepted the results and instructed the licensing manager to request a change to the Tech Specs to increase the allowed outage time for the DGs. This change required that an application be submitted to the regulatory body review to allow this so that the maintenance regime for the DGs could be changed. The IRIDM report formed a part of the submission to the regulatory body. The decision was ultimately accepted by the regulator.

V-3.5. Stage V – implementation of the decision and development of the programme for monitoring of the implementation and subsequent performance

The required changes were made to the station documentation including the Maintenance Procedures and the Safety Assessment Report. Training was given to the maintenance staff on the new DG maintenance practices.

A system was set up at the plant to collect information on the DGs including maintenance outages and operating experience for the DGs following the introduction of the new maintenance programme.

V-4. CONVERTING TO A NEW FUEL WHICH WILL ALLOW THE PLANT TO INCREASE THE TIME BETWEEN REFUELLING OUTAGES FROM 12 TO 18 MONTHS AND INCREASE OF MAXIMUM POWER TO 104%.

V-4.1. Stage 1 - characterisation of the issue

Description of the Issue to be addressed

For this example, the management of the NPP considered the possibility of converting to a new fuel that would allow the plant to increase the time between refuelling outages from 12 to 18 months and increase the maximum power to 104 %. The management, seeing the obvious cost benefits to this, requested a comprehensive review of the proposal be undertaken, if possible, using IRIDM since that was management policy. The NPP manager (the decision maker - DM) organized a preliminary team to begin work on the issue.

Applicability of the IRIDM Process to this Issue

The preliminary team first reviewed whether the IRIDM process was the appropriate model to analyse the issue. The conclusion reached was that it could be applied as the issue requires consideration of many inputs of different nature. It was decided to proceed with the IRIDM process.

The NPP manager then instructed the experts that had completed the initial feasibility review to proceed with Stage 1 until a full IRIDM team was selected.

Stage 1 comprised of the following three steps:

- Definition of the issue;
- Definition of decision options;
- Establishing a multidisciplinary team of specialists; assign team leader.

Definition of the issue

The issue was defined as follows: 'Analyses of the feasibility of converting to a new fuel that would allow the plant to increase the time between refuelling outages from 12 to 18 months and increase the maximum power to 104 % and definition of the required conditions'.

Preliminary Definition of Decision Options

A brainstorming session was then held by the preliminary team to develop a list of options. It was understood that a power uprate to 104% would require regulatory approval under all options.

After detailed consideration the following options were defined:

Option 1: To allow the change under the existing conditions which require an annual shut down for maintenance – somewhat negating the advantages of a longer duration between refuelling outages

Option 2: To allow the change with modified conditions

- The previous annual maintenance requirement would be modified to be consistent with refuelling intervals every 18 months;
- Manufacturer immediate approval of this change would be required with formal manufacturer's documentation updated within 2 years.

Option 3: To postpone the change until all the specified conditions are met (maintenance requirements and documentation revised to be consistent with refuelling outages)

- Formal manufacturer's documentation update is provided before implementation.

Option 4: To decline the change.

Establishing a multidisciplinary team of specialists; assign team leader

A team leader was assigned to investigate the issue by the plant's chief engineer. The team leader then drew up an implementation plan for carrying out the IRIDM process including the proposed schedule, resources, stakeholders, documentation requirements, etc. This report was then approved by the chief engineer (designated DM) who agreed with the plan and agreed to provide the resources to implement it.

A multidisciplinary team was then selected by the team leader to conduct the IRIDM process. Specialists of different areas were engaged:

- PSA specialists;
- Safety-related systems specialists;
- Specialists in Thermal Hydraulic analyses;
- Water chemistry specialists;
- Specialists in metal, I&C and electrical engineers;
- Operational experience specialists;
- Specialists in radiation protection.

V-4.2. Stage II – preparation for the assessment

Stage II comprises the following three steps:

- Screening the options;
- Identification of constituent factors; and [26]
- Gathering the information.

The specialists in the IRIDM team carried out some initial analysis as they saw fit and provided initial feedback on the suitability of the options and the applicability of the IRIDM process. Based on the information received, the team leader found everything to be suitable and authorised the team to proceed.

Review and screening of the decision options

At this stage the options were evaluated against mandatory requirements that could possibly eliminate an option from consideration or modify the option. The principal mandatory requirement was the manufacturer's requirement that maintenance be performed on important safety components at yearly intervals. This maintenance requires the plant to be in a shutdown condition. Conclusions of this screening process were as follows:

Option 1 – Existing conditions under option 1 result in the following:

- Once per year, the plant would be in shutdown for yearly components tests;
- Fuel cycle would still be prolonged for 18 months operation.

Note that these special conditions eliminate some of the advantages of making the change since an annual shutdown period would be required, somewhat reducing the advantages of the option.

Option 2 – This option violates manufacturer's requirements unless approval is obtained from the manufacturer.

Option 3 - This option is similar to option 2, but will be implemented only after manufacturer's documentation is changed.

Option 4 – This option is maintained in that there is basically no change.

Identification of the Constituent Factors for each option

The inputs to the IRIDM process were characterised in the main part of this TECDOC as follows:

- Standards and good practices;
- Operational experience;
- Deterministic considerations;
- Probabilistic considerations;
- Human and organisational considerations;

- Security considerations; and
- Other considerations.

The IRIDM team carried out a systematic review to identify the inputs that were relevant to this issue. At this stage, the initial inputs were defined and unnecessary ones screened out.

Gather necessary information

The specialists in the IRIDM team gathered the necessary information to carry out any analysis required to provide inputs to the IRIDM process.

Validation of the information

The specialists in the IRIDM team performed the necessary studies to validate the information.

V-4.3. Stage III – assessment, integration and documentation

Evaluation of the options against the relevant CFs

Assessment of technical information associated with each input:

The specialists in the IRIDM team assessed the technical information associated with each input as follows:

Affected mandatory requirements - The mandatory requirement is the manufacturer's specification that preventive maintenance of certain equipment (Steam Generator safety valves, Pressurizer safety valves, Spray System) is performed once per year (12 months)

- For option 2, the preventive maintenance for the Steam Generator safety valves, Pressurizer safety valves, Spray System will not be in compliance with documented mandatory manufacturer requirements if fuel cycle is changed from 12 to 18 months (unless the regulator accepts informal manufacturer's approval);
- For options 1, 3 and 4 this requirement is met.

Other requirements and criteria

- No effect on other mandatory requirements and criteria were determined.

Insights from deterministic analysis:

- Defence-in-depth - Compliance with the defence-in-depth concept was justified for all options under consideration.
- Safety margins - A slight decrease of safety margins was observed due to higher parameters of the reactor operating at 104% rate for options 1, 2 and 3, However, the thermal hydraulic analyses confirmed that adequate safety margins were maintained.
- Other deterministic criteria - No other deterministic criteria are violated (fail-safe design, single failure criterion, redundancy, diversity, etc.)

[26] This section is shortened to allow focus on the integration and evaluation section in stage III

Insights from probabilistic analysis:

Quantitative insights

- Option 1 - the PSA was not re-evaluated
  - However, it is expected that overall CDF will increase only slightly
- Option 2 - the PSA showed that:
  - CDF for full power operation is increased by about 5%
  - Fuel damage frequency (FDF) for shutdown operation practically does not change
  - Total FDF averaged over 3 years cycle period (for full power and shutdown modes) of the Unit decreased from 7.31×10^{-5} /year to 7.21×10^{-5}/year due to one less shutdown.
- Option 3
  - Same as Option 2 with 2 years delay
- Option 4 - no changes in risk results.

Qualitative insights:

- Qualitative results of the PSA do show that the decrease of average yearly FDF is explainable and makes sense (Option 2);
- Changes to importance ranking were minimal for options 2, 3, and were believed to be of no significance for option 1 and no impact for option 4.

Explanation: Slight increase in CDF during power operation is compensated by decrease of FDF during shutdown (averaged over 3 years' period) due to one less shutdown.

Probabilistic safety targets:

- Probabilistic safety targets in terms of CDF stated in regulatory documents are met.

PSA Scope:

- Level-1 PSA for internal initiators and internal hazards (fires/floods) for power operation and shutdown modes was used;
- It is accepted that change associated with Options 1, 2 and 3 will not impact the external hazards PSA results and will have negligible impact on Level-2 PSA.

Note: it is understood that source term for the options 1, 2 and 3 will be different and slightly worse than for option 4. However, the overall radiological risk and doses to the workers will be reduced in Options 2 and 3 due to reduction of the averaged shutdown duration over 3 years cycle.

PSA Quality

- Regulatory review accepted the quality and level of detail of the PSA and PSA conclusions to be sufficient for this decision making issue.

Other factors were also considered by the IRIDM team including equipment qualification, electricity production, maintenance costs, and radiation doses for workers. Evaluations of these factors resulted in the following conclusions:

Option 1

- Moderate increase in electricity production;
- Increase in maintenance costs due to more test/maintenance of certain components comparing to Options 2 and 3.

Option 2

- Based on the preliminary feedback from the manufacturer, the changes of preventive maintenance periodicity of equipment were assumed to be acceptable;
- Significant increase in electricity production;
- Reduction in maintenance costs due to less frequent maintenance of certain components;
- Decrease in radiation doses for workers due to less frequent maintenance and inspections.

Options 3

- Same as Option 2, but benefits are delayed by 2 years.

Option 4

- No changes.

Integration of the results

Determination of the weighting factors:

The IRIDM team then defined weighting factors for the above inputs based on expert judgment:

- Weights from 0 to 10 were assigned based on importance perceived by IRIDM team;
- Scores were assigned from 1 to 7 with 4 being no change, 1-3 – negative impact, 5-7 positive impact.

Scoring and integration of the results:

The lists of IRIDM factors, weights and impacts are shown for each Option in Tables V-22 through V-24.

The overall score is a sum of the products of weighs and scores. The weighted score has been normalized to the 'no change case' (Option 4).

TABLE V-22: EVALUATION FOR OPTION 1

The list of factors and their weights (for Option 1)		
Factor	Weight (W) (0-10)	Impact (I) (1-7, 4 – no change from existing case i.e. Option 4)
Mandatory requirements	High (10)	4
Defence-in-depth	High (10)	4
Safety Margins	Medium (3)	3
Risk changes	Medium (3)	5
Equipment qualification	Medium (3)	4
Electricity production.	High (10)	5
Maintenance costs	Low (1)	2
Radiation doses for workers	Medium (3)	3
Overall score = Sum (W*I)	177 Normalized to no change case score of 172: 1.03	

TABLE V-23: EVALUATION FOR OPTION 2

The list of factors and their weights (for Option 2)		
Factor	Weight (W) (0-10)	Impact (I) (1-7, 4 – no change from existing case i.e. Option 4)
Mandatory requirements	High (10)	3
Defence-in-depth	High (10)	4
Safety Margins	Medium (3)	3
Risk changes	Medium (3)	6
Equipment qualification	Medium (3)	4
Electricity production	High (10)	7
Maintenance costs	Low (1)	6
Radiation doses for workers	Medium (3)	6
Overall Score = Sum (W*I)	203 Normalized to no change case score of 172: 1.18	

TABLE V-24: EVALUATION FOR OPTION 3

The list of factors and their weights (for Option 3)		
Factor	Weight (W) (0-10)	Impact (I) (1-7, 4 – no change from existing case i.e. Option 4)
Mandatory requirements	High (10)	4
Defence-in-depth	High (10)	4
Safety Margins	Medium (3)	3
Risk changes	Medium (3)	6
Equipment qualification	Medium (3)	4
Electricity production.	High (10)	5
Maintenance costs	Low (1)	5
Radiation doses for workers	Medium (3)	5
Overall Score = Sum (W*I)	189 Normalized to no change case score of 172: 1.1	

Checking the results for robustness and proposing IRIDM decision

Feedback from the manufacturer had been received that the increased maintenance interval was acceptable. Based on this feedback it was believed that regulatory body would approve Option 2 (with some conditions). Detailed sensitivity studies were not deemed necessary since the preferred option was deemed obvious given the manufacturer and regulatory feedback.

Suggestion of implementation and monitoring programme

The team recommended development of detailed performance monitoring programmes commensurate with the increased maintenance intervals and power uprate and would include this with the application to the regulatory body.

Defining the preferred option

The team selected Option 2 based on the highest score.

Final documentation of IRIDM process and results

The IRIDM team completed the documentation of the IRIDM process and its result.

V-4.4. Stage IV - selection of the option to implement by the decision maker

The report of the IRIDM process was presented to the DM who agreed with the results. A request to make the change was then formally submitted to the regulatory body. The final decision, as approved by the regulatory body, was to allow temporarily the fuel cycle change and power uprate with the following conditions:

- Test of the equipment will be performed at the end of fuel cycle;
- Assuming equipment testing and maintenance is satisfactory in 2 years, change the mandatory maintenance requirement formally.

Implementation of the change

A trial operation programme was developed and agreed between the regulatory body and the plant management.

Monitoring of the change

A monitoring programme was set up involving assessment of plant failure data of the affected equipment to ensure that the reliability of the affected components was maintained.

REFERENCES TO ANNEX V

[V-1] INTERNATIONAL ATOMIC ENERGY AGENCY, Determining the Quality of Probabilistic Safety Assessment (PSA) for Applications in Nuclear Power Plants, IAEA-TECDOC-1511, IAEA, Vienna (2006).

[V-2] INTERNATIONAL ATOMIC ENERGY AGENCY, Development and Application of Level-1 PSA, 2010, IAEA Safety Standards, Specific Safety Guide SSG-3, IAEA, Vienna (2010).

[V-3] INTERNATIONAL ATOMIC ENERGY AGENCY, Development and Application of Level-2 PSA, 2010, IAEA Safety Standards, Specific Safety Guide SSG-4, IAEA, Vienna (2010).

ANNEX VI. UNCERTAINTY IN INTEGRATED RISK INFORMED DECISION MAKING PROCESS

VI-1. INTRODUCTION

Uncertainty can be defined as the effect of randomness of nature and "knowledge incompleteness due to inherent deficiencies in acquired knowledge" Ref. [VI-1]. In the context of the integrated risk informed decision making (IRIDM) process, knowledge is "... a mixture of experience, values, contextual information, and insight that provides a framework for evaluating and incorporating new experience and making rational decisions", see Ref. [VI-2]. Uncertainty arises from lack of or insufficient knowledge about events, states, processes, and phenomena.

Any modelling and decision making must deal with incomplete information, i.e. uncertainty that affects the final decision. Therefore, to make a robust decision, appropriate consideration of uncertainty and sensitivity needs to be made at all stages of the IRIDM process. Inadequate treatment of uncertainty may lead to poorly supported or even wrong conclusions that ultimately could have an adverse effect on safety.

For complex facilities such as nuclear power plants, much of the uncertainty concerning the potential challenges to the plant and its ability to cope with those challenges are typically considered in the formulation of the regulations and standards that govern the design and operation of the plant. Deterministic analyses that form the basis for the plant designs are usually focused on achieving a robust design by applying the defence-in-depth principles and providing high safety margins (e.g. in the design of structures, systems, and components (SSCs)). These deterministic analyses are typically conservative in nature to help compensate for the uncertainty created by the incompleteness in our knowledge.

While the deterministic approaches have resulted in plants that are considered safe, these approaches may not focus on all the aspects of the plant that are important to safety. Furthermore, the assessment of the level of safety can change as new information is obtained about potential hazards or failure mechanisms that were previously not considered significant or were unknown. The essential value of risk informed decisions associated with issues related to plant design and operation is in focusing on those aspects of the plant that are most critical to safety. Application of IRIDM and uncertainty analysis can identify areas where the conservatism is excessive and could be relaxed, but it can also be used to identify areas where additional defence-in-depth or safety margins might be appropriate.

The use of safety margins and defence-in-depth is certain to remain inherent in the design process; however, the IRIDM process calls for these to be enhanced by consideration of other tools, such as probabilistic safety assessment (PSA).

As PSA can provide an integrated risk characterization of the plant, it is therefore an essential tool to the development of IRIDM. However, there are also many sources of uncertainty that impact the construction and the results of PSA models, and it is crucial, when using a PSA model within IRIDM, that these sources of uncertainty be identified, and their impact on the risk insights understood and accommodated.

This Annex discusses the uncertainty associated with all key elements of the IRIDM process and how they can be addressed within IRIDM process. Due to the probabilistic nature of PSA, the approaches to dealing with PSA uncertainty is more highly developed and are discussed in section VI-5 of this annex.

VI-2. SOURCES OF UNCERTAINTY

VI-2.1. High level classification of uncertainty

Uncertainty is typically classified as being either: aleatory (stochastic, random) variability, or epistemic uncertainty, see Refs. [VI-3] through [VI-7].

Aleatory uncertainty (variability) is associated with the natural randomness in a process, e.g. the unpredictability of the events contributing to accidents. The variability is perceived to be an objective property of the process. Principal sources of aleatory uncertainty in nuclear safety analyses may include:

- Timing and nature of accidents;
- Manufacturing tolerances;
- Initial conditions (state) of the plant at the beginning of an accident;
- Failures of system, components and humans during an accident;
- Physical and chemical properties, etc.

In general, aleatory uncertainty cannot be reduced by the accumulation of more data or additional information. Aleatory uncertainty is considered by constructing explicit probabilistic models for the random processes and applying the conservative assumptions in deterministic analysis.

In the context of IRIDM, aleatory uncertainty can be addressed by comparison of the estimated risk metrics (e.g. CDF, LERF), acceptance criteria, safety goals, guidelines, etc., for the decision being made.

Epistemic uncertainty is associated with limitations in a collective knowledge which leads to uncertainty in the predictions of models. Epistemic uncertainty reflects a lack of complete knowledge. This lack can, in principle, be reduced by obtaining additional information.

The sources of epistemic uncertainty are identified and characterized within an uncertainty analysis, see Refs. [VI-3] through [VI-7], which is the inherent part of any risk assessment (probabilistic or deterministic), and other analyses (i.e. cost estimates). These sources are generally classified as parameter, model, and completeness uncertainty.

Parameter uncertainty relates to parameters that are inputs to the assessment, but whose exact values are unknown or whose values cannot be exactly inferred by statistical methods.

In the deterministic context, examples are the various material properties[27] in a finite element analysis for engineering.

In the PSA context, this might relate to the input parameter values used to quantify the probabilities of the basic events.

In all cases, the parametric uncertainty range is influenced by the amount of statistically significant data, and the approach used to estimate the parameters.

Model uncertainty arises because different models may be available to evaluate the behaviour of some systems or physical processes that can affect equipment failure or the nature of the accident progression, and there is no clear reason why one is the most appropriate.

The models used in IRIDM include: human reliability models (HRA) and probability models

[27] Physical and chemical properties have both an aleatory and epistemic aspect. Material changes during use and the way it ages may not be in a fully predictable way.

for equipment failure, thermal-hydraulics or integral models used both in PSA and DSA, other models that can be used for the assessment of other constituent factors of the IRIDM (e.g. costs, radiation doses).

Generic sources of model uncertainty in PSA are listed in EPRI 1026511 and EPRI 1016711, Refs. [VI-4] and [VI-5].

Completeness uncertainty represents uncertainty as to whether all the significant phenomena and all the significant relationships have been considered.

Two subcategories of completeness uncertainty can be distinguished:

(1) Contributor uncertainty (e.g. uncertainty as to whether all factors and all the important considerations have been included in the model) and
(2) Relationship uncertainty (e.g. uncertainty as to whether all the significant relationships are identified, which exist among the contributors and variables).

This type of uncertainty is also typically subdivided into two classes:

(1) Known unknowns – e.g. phenomena, mechanisms or failure modes that are known, but might not be included in the model;
(2) Unknown unknowns – e.g. phenomena, mechanisms or failure modes that are unknown or unanticipated.

Since the completeness uncertainty reflects an unanalysed contribution, it is hard or even not possible to estimate its magnitude. The completeness uncertainty is applicable to several key elements of the IRIDM, including PSA, DSA, CBA, dose, etc. considerations.

A precise distinction between the different types of epistemic uncertainty cannot be definitive. As discussed earlier, the parameter uncertainty is dependent on the assumption of the form of the model for which the parameter is an input, and the form of the model may itself be important. However, in most cases, the models can be treated as consensus models and the model uncertainty can be allocated to the parameter.

The remainder of this Annex is focused on the treatment of epistemic uncertainty in IRIDM process, and understanding the impact of the epistemic uncertainty on the comparison of the acceptance criteria or guidelines.

It is worth to note that there is a specific type of uncertainty that has importance in the IRIDM process: uncertainty dealing with the information obtained from expert judgment. This uncertainty can be treated as epistemic uncertainty due to incompleteness of information available to the experts.

VI-2.2. Main sources of uncertainty in key elements of IRIDM process

When completing the disposition of the impact that uncertainty may have on the decision being made, it is essential to consider uncertainty associated with all key elements of the integrated risk informed decision making process.

There are two areas where uncertainty is introduced in the IRIDM process:

- Uncertainty in the assessment of the importance (e.g. weights) of the constituent factors for the issue under consideration. This uncertainty is typically expressed in the range of weights assigned for the constituent factors for the issue under consideration in the IRIDM and, for instance, is mainly caused by the different opinions of the experts involved in the decision making process on the relative importance of the constituent factors (CFs).

- Uncertainty in the assessment of the level of compliance of the decision options with the constituent factors (e.g. scores). This uncertainty is typically dealing with the uncertainty in the results of the assessment and with the different opinions of the experts involved in the decision making process on the level of compliance of the decision option with the constituent factor.

Main sources of uncertainty that can influence the results of the IRIDM process for all key elements and selected constituent factors are briefly discussed in sections VI-2-2 and VI-2-3 below for both areas mentioned above.

It is worth noting that information provided below is for only illustrative purposes and is meant neither to be complete nor comprehensive.

VI-2.3. Uncertainty in the assessment of the importance of constituent factors

Calculation of uncertainty range based on expert judgement

The mean value for the importance of CFs of the key element can be assessed by averaging opinion of the IRIDM team members with uncertainty range defined based on the lowest and highest weights assigned for the CF (i.e. when scoring schemes e.g. "Structured Value Analysis" is used for integration – see Annex IV). Note that this approach for the assigning of the uncertainty range for the importance of the CFs is applicable for all key elements discussed below.[28]

Standards and good practices

The uncertainty associated with the assignment of the importance (e.g. weights) for the CFs of this key element depends on the particular CF under consideration.

For instance, the CF "Regulations developed by the regulatory body and conditions attached to the licence" typically has the highest weight and the lowest uncertainty[29]. The weights can be only slightly lowered when, for example, regulations allow certain flexibility or are stated in the form of a goal or targets rather than criteria.

On the other hand, the CF "Standards developed by professional bodies, technical standards, IAEA safety guides, etc." might have lower importance and higher uncertainty in those Member States where in-country regulations are advanced and comprehensive, but may be weighted at the highest level, when Member State heavily relies on international standards and/or professional experience of more advanced Members States.

Operational experience

Operational experience (e.g. events occurred, feedback from maintenance and operation) might not be completely relevant to the issue under consideration.

Experience is not always comprehensively documented and may not account for all operational experience worldwide and may neglect some root causes related to particular aspect.

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[28] Arithmetic averaging is typically used. However, it is not essential how the mean value is derived; it is essential that the process is clear, consistent and technically sound.

[29] In practical sense generally, the experts are surer regarding high or low importance. Therefore, uncertainty associated with high and low averaged importance of the CF is low, while for medium importance it could be high. For instance, when all experts assign importance of the CF equal or higher than 9 the uncertainty range could be only between 9 and 10 on the [1;10] scale; similarly, if importance of the CF is equal or lower than 2 the uncertainty range could be only between 1 and 2.

In addition, operational experience is not always complementary (e.g. for the same design option it is possible to observe positive operational experience at one NPP and negative at another). Therefore, typically it is not always possible to rely on the associated information and the importance of the CFs of this key element is relatively low, and associated uncertainty is medium.

Deterministic considerations

CFs of this key element have some of the highest importance and weights.

The uncertainty in the assigning of the weights for these CFs is typically low (similar to CF "Regulations developed by the regulatory body and conditions attached to the licence").

Probabilistic considerations

The importance of the CFs of this key element are heavily dependent on how PSA results are used in the decision making process. In those Member States where PSA information is an essential aspect of the decision making policy and requirements towards risk reduction are in place (e.g. ALARP principle) the importance of the CFs of probabilistic considerations is high and uncertainty range is low; however, in those Member States where risk information is less formalised, the importance of the CFs might be medium and uncertainty range could be high. The importance of the CFs of this key element also depends on the issue under consideration, for example, when the issue is dealing with the need to justify ALARP principle towards risk reduction, the importance of the CFs is high and uncertainty range is low. But when the issue is irrelevant to the risk aspects, the importance could be even lower and uncertainty range is widened.

Human and organisational considerations

The importance of the CFs of this key element and associated uncertainty range vary depending on the issue under consideration. Typically, when the issue is aimed to improve managements system, training and/or operational/maintenance programmes the importance of the CFs is high and uncertainty is low; otherwise the importance of the CFs is medium/low and uncertainty is high/medium.

Considerations regarding the interface with nuclear security

CFs of this key element are believed to have a high importance in the IRIDM process, and it is typically possible to understand whether the various options impact security aspects or not and in which direction. However, it is not always easy to identify the actual importance of the CFs when enhanced security aspects compromise safety. Therefore, it might be the case when members of IRIDM team have opposite opinions on the importance of the CFs, that high uncertainty can be introduced. Nevertheless, the importance of the CFs of this key element needs to be kept high, but the uncertainty range could be also high.

Other considerations

The CFs included in these key elements have very different nature and, therefore, have different importance (weights) from the utility and regulatory points of view as shown below for selected CFs:

- Radiation doses, environmental impact, waste management, decommissioning aspects: typically, important for both utility and regulators and the public;
- Costs, economic benefits, remaining lifetime: typically, very important for utility, but

less important for regulators;
- Research results typically have the same importance for both utility and regulators and depend on the issue under consideration (e.g. high when the issue is raised following newly available information from recent research).

Therefore, the uncertainty associated with those CFs that have high importance for both utilities and regulators is relatively low; but those that have low importance for regulators, but high for utility could be very high.

VI-2.4. Uncertainty in the assessment of the compliance with constituent factors

Standards and good practices

For the CFs of this key element, the requirements and recommendations of regulations and conditions or recommendation of internationally accepted guidelines or professional bodies that can be affected by the options are typically understood and known. However, when the level of compliance with the CF for decision option is evaluated, it is not always possible to define it precisely.

The uncertainty in this part might be dealing with the following aspects:

- Uncertainty in the information used to evaluate the compliance with the regulations, conditions, recommendations, etc.;
- Different opinion of IRIDM team members on the level of compliance with the CFs.

Example: When level of compliance with probabilistic safety goals is evaluated, the following uncertainty factors are typically involved:

- Uncertainty in risk assessment results;
- Different opinions of IRIDM team members on the level of compliance/non-compliance given the uncertainty in risk results and potentially unclear statements on the probabilistic safety goals/targets/criteria (e.g. when they are stated in terms of mean or point estimates form).

The approach in the evaluation of the uncertainty in the level of compliance with the CFs can be based on averaging opinion of the IRIDM team members with uncertainty range defined based on the lowest and highest scores for the options for the CFs (i.e. when scoring schemes approach, e.g. 'Structured Value Analysis', is used for integration – see Annex IV).

Note that this approach for the assigning of the uncertainty range for the level of compliance with the CFs is applicable for all key elements discussed below and will not be repeated, unless another approach will be suggested.

Operational experience

As it was already noted operational experience might not be completely relevant to the issue under consideration, might not be comprehensively documented and might not be complementary.

The uncertainty dealing with the operational experience therefore has the following sources:

- Incomplete or ambiguous information from operational experience;
- Different opinion of IRIDM team members on the level of compliance with the CF.

Example: A design change at one NPP might have shown very positive operational feedback in terms of improved maintenance, higher systems reliability and performance, etc.; however, the same change at another NPP might show less positive or even negative impact.

It is possible that the reasons for positive and negative impact are not known by the IRIDM team.

Deterministic considerations

Identifying the critical safety functions and how they are affected by an option is the key to determining whether the safety margin is sufficient or whether it needs to be enhanced.

However, in many cases it is extremely difficult to define the changes in safety margins due to different levels of uncertainty, and to large uncertainty (see discussion in Section VI-6). Therefore, the uncertainty in the assignment of the relative scores associated with level of compliance with the Safety Margins for different option could be high.

Some challenges associated with an option can undermine defence-in-depth, especially those associated with potential cliff-edge type scenarios. They do so by providing mechanisms that invalidate the implementation of the defence-in-depth philosophy by overriding the diversity and redundancy that are designed into the plant. Similar to the Safety Margins case, large uncertainty (see discussion in Section VI-6) may compromise the validity of the assessment as to the level of Defence-in-Depth compliance.

The sources of uncertainty that might impact the assessment of compliance with the Safety Margins and Defence-in-Depth concept for different options, include:

- Absence of validated tools to quantitatively assess the changes in Defence-in-Depth for different options, etc.
- Different opinions of IRIDM team members on the level of compliance with the CF;

Example #1: An option might be to increase the height of flood barriers when sufficient safety margins cannot be assured; however, given the uncertainty in the frequencies of flood levels other solution could be preferable (e.g. better isolation of the safety related compartments).

Example #2: The fail-safe design principle is one of the basic principles of Defence-in-Depth; however, when comparing different options, it might be almost impossible to define what state of the system/component is a 'safe' state: the state when the system/component performs its intended function, or the state when the system/component is prevented from spurious actuation. Note that during the Fukushima accident, the isolation condenser could not perform its intended safety function as it was effectively 'isolated', because of the 'fail-safe' design of the valves located inside containment aimed to prevent spurious actuation in case of loss of DC power.

Probabilistic considerations

The results of a PSA and the insights drawn from those results are subject to uncertainty for many reasons. These include:

- The necessity of using modelling approximations to construct a PSA model within the resources available believed to be either conservative or having insignificant impact on the final results and insights;
- Lack of directly applicable data (on component reliability for example);
- Insufficient understanding of some of the key phenomena that affect accident occurrence and accident progression;
- Omission of potential contributors to risk.

The first of these is related to the level of detail in constructing the PSA model, while the last three are examples of the types of epistemic uncertainty discussed in the PSA literature and for which an approach is provided on how to address them. The uncertainty in the results that is introduced as a result of using approximate methods is not normally addressed in a formal way in an uncertainty analysis. However, it does result in a bias in the results which is unquantified and can either affect the results in a conservative (i.e. overestimation) or non-conservative (under-estimation) direction. When using the PSA, it is important to recognize this and account for it whenever possible.

Detailed approach on the treatment of uncertainties in PSA is provided in Refs. [VI-3] through [VI-6] and discussed in further detail in the section [VI-5].

Human and organisational considerations

Information on how management system is prepared for the implementation of the decision options for the issue under consideration as well as information on the scope of the required changes to the procedures, guidelines and training programmes is typically quite reliable and available for the IRIDM team. However, when the level of compliance with CFs for each option is evaluated, it is not always possible to define precisely the degree of changes required.

The uncertainty in this part mainly is dealing with the potentially different opinions of IRIDM team members on the level of compliance with the CF.

Example: When one decision option requires major changes in the operating procedures and another in maintenance procedures, it is hard to define what changes are more important for decision making from organizational point of view.

Considerations regarding the interface with nuclear security In assessing the options, it is important to keep in mind that this assessment during the IRIDM has to ensure that safety and security requirements have been addressed and that the chosen options represent a balanced position that ensures proper consideration of the interface of safety with nuclear security. This could introduce high uncertainty in the assignment of scores for the options while assessing level of compliance with the CFs of this key element.

Other considerations

The assessment of the level of compliance with the CFs of this key element have large factors of uncertainty as it is not possible to precisely define, for example, what radiation dose will be received by individual workers. However, doses can be measured using various means so that operational experience can be collected on the dose levels. In design, shielding calculations can be used to estimate doses to workers and the cost of implementation, maintenance, etc. can also be assessed.

Large uncertainty associated with these CFs can be quantitatively assessed and defined in the form of distribution functions. It is typically possible to provide reasonable quantitative estimations of the mean, upper and lower boundaries for the costs, doses, economic benefits, etc. associated with each option under consideration.

However, for other CFs in this category (e.g. results of research, decommissioning) the sources of uncertainty are similar to those discussed for key elements ‘Standards and good practices’ and ‘Human and organisational considerations’.

VI-3. ASSIGNMENT OF THE UNCERTAINTY RANGES IN RISK INFORMED DECISION MAKING PROCESS

In accordance with the information presented in Section VI-2, there are two major areas where uncertainty arises in IRIDM process:

1) Uncertainty associated with the assignment of the importance (e.g. weights) for each of the selected CF for the issue under consideration;
2) Uncertainty associated with the assessment of the level of compliance with selected CFs for each option under consideration due to many reasons including Uncertainty associated with lack of information or knowledge regarding the options.

There are no specific methods currently available that provide clear procedure on how to address uncertainty in the IRIDM process. However, various general methods exist that in principle could be applied on a case-by case basis and will depend on the methods of integration of all inputs aimed to develop the preferred option(s) using the IRIDM process.

The subsections below provide some ideas on the possible way of the understanding and treatment of mentioned uncertainty if simple scoring scheme method (e.g. Structured Value Analysis method described briefly in Annex IV) is used.

VI-3.1. Assignment of the uncertainty associated with the weights of CFs

When using the Structured Value Analysis method, the ‘weights’ of the CFs must be assigned (See Annex IV). Typically, this is done by considering opinions of all members of the IRIDM team and assigning averaged weights received from all experts. The lowest and highest weights could be used as the uncertainty bound for the CF. In this process it is essential to consider the composition of the IRIDM team and the nature of the issue under consideration. When the issue requires regulatory approval and regulators are not members of the IRIDM team, it is highly probable that weights of certain CFs will be over or under-estimated. For example, importance of the CFs related to the costs and economic benefits could be overestimated by the IRIDM team and CFs related to the aspects considered to be important by regulators could be underestimated (e.g. standards and good practices). Therefore, it is important to assign weights to CFs considering both regulatory and utility perspectives. This aspect also could be realized through assigning higher uncertainty range to those CFs where utility and regulator might have contradictory opinions.

Table VI-1 below provides general considerations on the typical weights and typical approaches to evaluate uncertainty range for selected CFs of the key elements of the IRIDM process.

VI-3.2. Assignment of the uncertainty associated with the scores of CFs

When using the Structured Value Analysis method, the ‘scores’ of the options for each CF must be defined (See Annex IV). Similar to the ‘weights’ of the CFs, this could be done by considering opinions of all members of the IRIDM team and assigning averaged scores received from all experts.

However, the approach for assigning scores is different from those for weights as it is less based on expert opinion but utilises more technical information in evaluation of the level of compliance of each option with CFs. Therefore, the uncertainty in scores in many cases depends on the uncertainty of the information used to evaluate the level of compliance with CFs for each option.

It is important to note that for part of CFs the information used to evaluate the level of compliance of the options with the CFs can be of qualitative nature (e.g. CFs of the key element 'standards and good practices') and for some has clear quantitative measures (e.g. for CFs 'cost', 'radiation doses', 'probabilistic considerations').

When information regarding a specific CF is purely qualitative, obviously, it is not possible to directly use numerical evaluation techniques. Therefore, the information is converted to the scores of the options for the CF by using purely expert judgement of the IRIDM team. In this case for estimation of uncertainty of the scores assigned by experts, the mean estimate is calculated as the average score received from all experts. The lowest and highest scores are used as the uncertainty bounds.

Example: The following quantitative information is available for different decision options for the CF 'Cost of implementation and maintenance':

- Option 1 - estimated cost is in the range of [200, 400] monetary value (MV) with the mean 300 MV;
- Option 2 - estimated cost is in the range of [2000, 4000] with the mean 3000 MV;
- Option 3 - estimated cost is in the range of [1500, 5000] with the mean 3500 MV.

The mean scores and uncertainty ranges assigned for the options using the scoring scale [-10,10] and approach described in Annex III are:

- Option 1 – mean score: -1, no uncertainty range can be assigned as upper and low bounds are both at minimal level;
- Option 2 - mean score: -7, uncertainty range: [-8, -4];
- Option 3 - mean score: -6, uncertainty range: [-10, -3].

These scores are defined using the linear approximation of the scores with the highest (5000 MV) and lowest (200 MV) values of the costs (see Fig. VI-1 below).

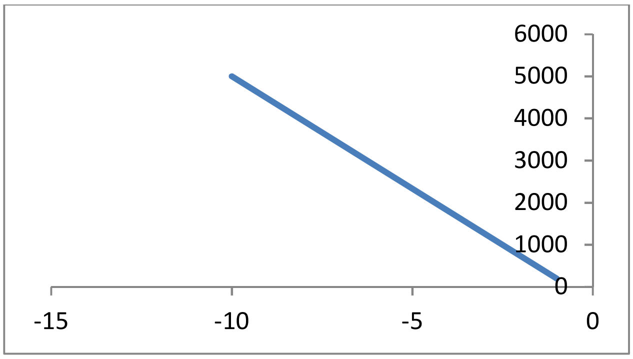

Fig. VI-1. Correlations between costs (ordinate) and scores (abscissa).

When evaluating options against different CFs, the members of the IRIDM team must consider all possible uncertainty sources involved in the analyses presented to the team.

TABLE VI-1: CONSIDERATIONS AND TYPICAL APPROACHES TO EVALUATE WEIGHTS OF CFs AND THEIR UNCERTAINTY RANGES

Key Elements	Generic Constituent factors	Typical weights and uncertainty ranges	Comments
Standards and good practices	Regulations developed by the regulatory body and conditions attached to the licence	This CF typically has the highest possible weight and lowest uncertainty range. On [1, 10] scale it is typically get the weigh 10. When regulations allow certain flexibility (e.g. they establish targets rather than criteria) the weight could be reduced up to 8 on [1, 10] scale	When assigning distributions for the weight of the CF it is possible to assign probabilities for the weights (e.g. 0.7 for weight 10, 0.2 for weight 9 and 0.1 for weight 8)
	Standards developed by professional bodies, technical standards, IAEA safety guides, etc.	This CF typically is weighed lower than previous and the weight is highly dependent on the national policies. In those countries where national regulations are well developed the weight of the CF can be lower; however, in the countries that more rely on international standards the weight of the CF can be high. The uncertainty range can be defined based on averaged, lowest and highest weights assigned by IRIDM team members.	The weights for this CF can be assigned to be equally distributed on the interval [Wl,Wh], where Wl and Wh – lowest and highest weights assigned by the members of IRIDM team for the CF. Alternatively, probabilities can be assigned for the possible weights as described above.)
Operational experience	• Operational events • Experience feedback	The CFs of this key element typically are weighed higher when operational experience related to the issue under consideration is available and lower when the issue is of the unique nature. The uncertainty range can be defined based on averaged, lowest and highest weights assigned by IRIDM team members.	Same as above
Deterministic considerations	• Safety margins • Defence-in-depth	Same as for 'Standards and good practices'	Same as for 'Standards and good practices'

TABLE VI-1: CONSIDERATIONS AND TYPICAL APPROACHES TO EVALUATE WEIGHTS OF CFs AND THEIR UNCERTAINTY RANGES (cont.)

Key Elements	**Generic Constituent factors**	**Typical weights and uncertainty ranges**	**Comments**
Probabilistic considerations	• Qualitative insights • Quantitative measures	The importance of the probabilistic considerations depends on the national policy and on the issue under consideration. In those Member States where probabilistic criteria are defined as target values the importance is typically weighed lower, and where it is defined as safety goals or regulations allows decision to be taken based on the risk results it is weighted higher. Also, the nature of the issue under consideration may impact the estimation of the weights assigned for the CF: if the issue was raised because of the need to meet reliability or risk targets the weight of the CF is higher; otherwise it is lower than for previously discussed CFs. The uncertainty range can be defined based on averaged, lowest and highest weights assigned by IRIDM team members.	Same as for 'Standards developed by professional bodies, technical standards, IAEA safety guides, etc.'
Human and organisational considerations	• Management Systems • Normal and Emergency Operating Procedures • Maintenance arrangements and procedures • Severe Accident Management Guidelines (SAMGs) • Training received	The CFs of this key element typically are weighted relatively lower comparing to 'Deterministic considerations'. The uncertainty range can be defined based on averaged, lowest and highest weights assigned by IRIDM team members.	Same as above

TABLE VI-1: CONSIDERATIONS AND TYPICAL APPROACHES TO EVALUATE WEIGHTS OF CFs AND THEIR UNCERTAINTY RANGES (cont.)

Key Elements	Generic Constituent factors	Typical weights and uncertainty ranges	Comments
Considerations regarding the interface with nuclear security	• Physical protection of a nuclear facility • Security of the nuclear material on the site	The CFs of this key element typically have the highest weights, but might have high uncertainty as well, as it is not always possible to identify the actual importance of the CFs when enhanced security aspects compromise safety. In those cases when all proposed options for the issue under consideration have similar impact on safety, the importance of the CF is the highest and point estimate can be used. In those cases when one or several options has negative impact on safety, but potential positive impact on the security aspects the higher uncertainty range can be used, even the mean weight is to be kept high.	When all options have similar impact om safety the highest weight is assigned for the CF a point estimate can be used. When options have different impact on safety aspects it is possible to assign probabilities for limited choices of weights (e.g. 0.6 for weight 10, 0.2 for weight 8, 0.1 for weights 7 and 6 based on the highest and lowest weights assigned by the IRIDM team members).

TABLE VI-1: CONSIDERATIONS AND TYPICAL APPROACHES TO EVALUATE WEIGHTS OF CFs AND THEIR UNCERTAINTY RANGES

Key Elements	Generic Constituent factors	Typical weights and uncertainty ranges	Comments
Other considerations	• Radiation doses • Costs • Economic benefits • Remaining lifetime • Waste management • Decommissioning • Environmental impact	The weights of the CFs for this key element typically vary: • Radiation doses, waste management, decommissioning and environmental impact has typically high weight as they are considered important from both utility and regulatory point of view. • Costs and economic benefits have high weight when only utility considerations are accounted for, but have the lowest weight from regulatory point of view. • Remaining lifetime has typically little weight or can even be excluded from independent consideration and can be accounted for in other CFs (cost, benefits, doses, etc.) when the issue under consideration and possible decision options require time for implementation much lower than remaining lifetime. However, the CF can get very high weight when the options require long implementation time that makes the implementation of certain decision options impractical in case of short remaining lifetime. For most of the CFs listed above the uncertainty range can be defined based on averaged weights, lowest and highest weights assigned by IRIDM team members. However, for those CFs that might receive different weights from utility and regulatory point of view the uncertainty range could be significantly increased.	The distribution for most of these CF can be assigned either as equally distributed on the interval [Wl,Wh], where Wl and Wh – lowest and highest weights assigned by the members of IRIDM team for the CF. For those CFs that have different importance from utility and regulatory point of view the uncertainty range can be expanded and can even cover complete interval [1,10].

This can be achieved through propagation of parameters and/or considering sensitivity analysis covering the reasonable range of values that represent the uncertainty of input and modelling parameters. If the results of the sensitivity analysis drastically change the evaluation against the CFs and hence the decision on an option, it suggests that further iteration in the assessment is required. Alternatively, conservative assumptions can be used as a way of covering uncertainty, keeping in mind that the results become conservative too.

VI-3.3. Uncertainty Related to Expert Judgement

In some cases, the IRIDM process relies heavily on information obtained from expert judgment and its effect on uncertainty may be positive or negative. Expert judgment, if no other information is available, may compensate for a lack of knowledge and could bring additional information, thus reducing uncertainty. However, when expert judgement is used to treat and interpret available information, it may bring additional uncertainty. There are no completely agreed methods on how the uncertainty of expert judgment has to be considered in the decision making process. However, to reduce such uncertainty, it is recommended that a formalized expert elicitation process always be used.

Usually, the formation of an expert panel involving experts of all relevant disciplines is part of such a formalized process. Depending on the issue, different methods for expert elicitation are possible, see for example, Refs. [VI-8] through [VI-9].

Where multiple experts are consulted, care needs to be taken to identify aspects of their judgment that differ significantly. If it is not possible for many experts to arrive at a consensus then the sensitivity of the result to the relevant aspect needs to be investigated. Disagreements in expert judgment and lack of confidence in the expert’s assessment represent significant sources of uncertainty and need always to be considered and documented.

VI-4. TREATMENT OF THE UNCERTAINTY IN IRIDM PROCESS

In the IRIDM process, it is important to ensure that decision is not sensitive to the uncertainty sources; therefore, all uncertainty sources involved in the analysis need to be considered and addressed.

As mentioned earlier there are no specific methods currently available that provide clear procedure or tools on how to comprehensively address uncertainty in the IRIDM process.

However, various general methods are available which in principle could be applied on a case-by case basis, e.g. Multi-Attribute Decision Making under Uncertainty (MADMU) method, see Ref. [VI-15]. It is worth to note that the IAEA is in the process of developing a toolkit which will utilize MAUT methods and other approaches to address uncertainty in IRIDM. For the current publication, only simplified approaches are suggested as described below.

VI-4.1. Treatment of the Uncertainty through Sensitivity Analyses

The most straightforward way to understand the impact of uncertainty and to determine which options are sensitive to the uncertainty is to perform various sensitivity analyses.

When using the Structured Value Analysis (see Annex IV) method, these sensitivity analyses can be defined by varying both weights of the CFs and scores of the options in the various ranges defined by the uncertainty ranges discussed in sections VI-1–VI-4.

The options that have the highest total weighted scores in most of the cases of sensitivity analysis are less affected by uncertainty and can be selected as preferred options.

An example of the application of such an approach is presented in Annex V (example #1 "RHR suction line reliability").

VI-4.2. Treatment of the uncertainty using Monte-Carlo simulations

In those cases when it is not possible to derive the preferred options using sensitivity analyses, the uncertainty analysis could be performed using the Monte Carlo simulation process.

For this purpose, the following steps can be suggested:

Step 1: The function F (W,Si) for each option ***i*** is defined as:

$$F\,(W, Si) = \sum_{j} Wj * Sij \qquad \text{(VI-1)}$$

Where
Wj – input weights for CFj
Sij – score for the option ***i*** for CFj

Step 2: The distribution functions for each Wj and Sij is constructed based on the information on the uncertainty ranges for each Wj and Sij.

For those Wj and Sij where no uncertainty range was defined, only the mean value has to be used in the uncertainty analysis.

Step 3: The probabilities Pi+ = P [F(W,Si) > F(W,Sk) for each k≠ I)] is quantified using Monte Carlo simulation for each ***i***.

Step 4: The probabilities Pi- = P [(F(W,Sn) < F(W,Sk) for each k≠ I] is quantified using Monte Carlo simulation for each ***i***.

Step 5: The Pi = Pi+*(1-Pi-) is quantified and the option(s) with the highest Pi is (are) selected as preferable option(s).

The example of the application of the suggested approach is shown in Annex V (example #1 "RHR suction line reliability").

VI-5. PSA UNCERTAINTY IN IRIDM

VI-5.1. Characterizing PSA uncertainty for use in IRIDM

The goal of IRIDM is to use the PSA to make the most appropriate decisions from the standpoint of safety. For any decision in which a PSA is used as input, the first thing to determine is which PSA results are to be used and how. For many types of decisions, this is determined by documents specific to those applications. For unique decisions, the analyst will need to formulate how the PSA is to be used to assess the risk significance of the issues to be addressed.

For many decisions, the primary PSA results are the metrics that are used as guidelines or criteria that have been established to assess whether the level of risk associated with a decision is acceptable. The most commonly used acceptance criteria or guidelines are expressed in terms of the surrogate metrics for risk, namely CDF, LERF, and LRF (large release frequency) and others that are related to these metrics, such as ΔCDF, CCDP, etc. These metrics are evaluated using a Level 1 and Level 2 PSA, and are typically expected to include contributions from all hazard groups relevant to the decision as determined by the acceptance criteria or guidelines.

Some decision guidelines are expressed in terms of importance measures. Other metrics that are more directly related to risk include curves that characterize the frequency of exceedance of specific consequences, such as early fatalities or latent cancer fatalities, and require a Level 3 PSA.

In the absence of uncertainty, the comparison of the PSA results with the decision criteria or guidelines would be a simple task; the calculated metric would be sufficient to determine whether the risk was acceptable or not. However, if uncertainty is considered the comparison becomes more complicated.

As discussed earlier, when input uncertainties such as parameter uncertainty and some model uncertainty are characterized by probability distributions, the uncertainty on the estimates of the metrics derived from the PSA can also be characterized as a probability distribution. The appropriate statistical measure of the metric that is to be used in comparison with the acceptance criteria or guidelines is specified by the formulation of the acceptance guidelines.

For example, in Regulatory Guide 1.174, Ref. [VI-11], the appropriate measure to be compared with the guidelines was specified to be the mean value of that distribution. It is not inconceivable that other statistical measures, such as the 95th percentile or the median could also be used as the acceptance guidelines. With these specifications, the comparison of the PSA results with the guidelines or criteria would be straightforward. However, as indicated earlier, a PSA model is constructed using several approximations and is based on a set of assumptions. Some approximations are deliberate omissions of potential risk contributors based on the assumption that they are not significant. Other assumptions are made to allow the model to be formulated in a manner that enables it to be used for quantification, and many assumptions are made as a result of model uncertainty. This cannot be captured in the probability distribution obtained by propagating the parameter uncertainty.

Therefore, confidence that the comparison is providing an appropriate acceptability of risk can only be obtained considering the effect of these approximations and assumptions impacting the results. This is done by performing screening or bounding analyses to demonstrate that missing contributors are not significant to the decision, and by identifying the sources of uncertainty that are most significant to the results and performing sensitivity studies to assess the impact of using alternate, reasonable assumptions. Techniques for performing these analyses are discussed at length in Refs. [VI-3] through [VI-5] and will not be reiterated here. To achieve this, it is crucial to understand what is driving those results, as discussed in the next section. This is particularly true when the PSA results challenge the acceptance guidelines.

Furthermore, even when the PSA results can confidently demonstrate that the risk associated with a change or an option for change is acceptable, it is still important to identify the contributors to the PSA results and associated uncertainty.

VI-5.2. PSA Input in the IRIDM

The information that needs to be assembled for the decision-maker includes the quantitative results, the qualitative insights, and an assessment of the uncertainty of those results, that can have an impact on the decision.

The PSA inputs that will be needed by the decision maker in the context of an application are the following:

- The base risk metric quantification. The statistical measure (e.g. mean or median) required is specified by the acceptance guidelines or criteria associated with the application. This may or may not include a characterization of the uncertainty, such as that is provided by the 5th and 95th percentile results.
- An identification of the significant contributors (including for example, hazard groups, initiating events, accident sequences, functions, systems, components, operator actions, etc.) to the risk metrics. The analyst has to provide a characterization of the degree of realism associated with each level of this decomposition. For example, if a contributor is known to be conservative, and there is no realistic alternative way of modelling that contributor, this needs to be identified. Furthermore, if, in a hazard group assessment, credit is not given for certain systems, components, operator actions, etc., this has to be noted particularly if the decision is related to those systems.

An identification of the key sources of uncertainty for the application, documented in a manner that characterizes the results of the associated sensitivity analyses and the impact on the risk metrics. In the characterization an assessment of the reasonableness of the results of sensitivity analyses (when compared to the base case assumptions) needs to be included.

VI-5.3. Addressing PSA uncertainty in IRIDM applications

IRIDM may be used for different types of decisions, including:

- Decisions related to approving a licensee proposed change to the plant design or operational practices;
- Assessing whether a plant design conforms with a safety goal given new information about hazards;
- Evaluating different options on an appropriate response to new information that appears to challenge the safety goals or significantly erodes defence-in-depth or safety margins.

For all types of decision, a definitive assessment of the acceptability of risk may not be possible because of uncertainty. The challenge to the acceptance guidelines can come from several different sources, for example:

- A conservative treatment of certain aspects of the base case risk model;
- One or more sensitivity studies associated with specific sources of model uncertainty;
- Uncertainty in modelling the issue in the PSA model;
- The uncertainty associated with some aspect of the analysis may be so large that the assessment of acceptability is indeterminate.

Once the reason(s) for the challenge to the acceptance guidelines is understood, depending on the nature of the reasons, different approaches are possible, as discussed below.

VI-5.3.1. Refinement of the PSA model

If the results are known to be affected by conservative modelling, this is under the control of the developer of the PSA model for those cases where it is possible to improve the model and analyse uncertainty to be more realistic. This is typically only likely to be a realistic approach when the conservatism is a result of approximations that have been made to limit resource expenditure.

VI-5.3.2. Decisions Associated with licensee proposed plant changes

If, even with the refinement of the PSA model, the acceptance guidelines are still challenged, whether it is from the baseline evaluation or from a realistic sensitivity study associated with a source of model uncertainty, there is several options that can be exercised. These include: a restriction of the implementation of the application, the use of compensatory measures, or reliance on a specific performance monitoring programme.

The definition of these options is based on an understanding of the cause of the challenge, and a demonstration that the design of the implementation is such that it effectively removes, reduces or neutralizes a potential contribution to risk.

- When proposing compensatory measures, it is necessary to provide a justification explaining how the contributor(s) that challenge the risk metric may be taken out of risk consideration as a result of the compensatory measure(s).
- When proposing a limitation in implementing a proposed plant change it is necessary to provide a description of why the limitation is effective in removing from consideration the contributors that are causing the challenge. It is worth noting that limiting the implementation is an approach that is also used for dealing with risk contributors that are not addressed by the PSA model and whose impact is unknown (completeness uncertainty).
- When the challenge comes from the uncertainty in modelling the effect of the change, on the reliability of affected components for example, one approach is to tie this uncertainty to a performance monitoring programme that is designed to demonstrate that the effect of the change does not exceed that assumed in the demonstration of the acceptability of the change in risk.

No consensus approach to model the cause-effect relationship on equipment unreliability has been developed. Therefore, the approach adopted in NEI 00-04, Ref. [VI-12] as endorsed in Regulatory Guide 1.201, Ref. [VI-13] is to:

- assume a multiplicative factor on the SSCs unreliability that represents the effect of the relaxation of special treatment requirements,
- demonstrate that this degradation in unreliability would have a small impact on risk,
- establish a performance monitoring regime to ensure that the target of acceptable degradation in reliability will not be exceeded.

VI-5.3.3. Assessing options for plant improvement

A PSA may be used by a licensee or a regulator to assess whether a response is needed to new information, for example, indications of a previously unknown failure mechanism, or new information on an external hazard, such as earthquakes or external floods. It may also be used to assess the need to impose plant changes to comply with safety goals. Such an evaluation of options requires an assessment of the risk of the plant as currently configured, and an assessment of the value of the various options in reducing that risk. Both these assessments involve uncertainty. An example of how this may be addressed for the base risk is included in the next section for the case of very large uncertainty. Dealing with uncertainty in the assessment of benefits of the various options, is an additional layer. For example, there may be no currently accepted methodology for evaluating accurately the benefit of increased training on operator reliability for specific responses, although the training will be of some benefit, and may even be considerable. Thus, the task of the decision-maker is to determine what benefit is possible, where it has its greatest impact, and how much credit is realistic.

This requires a thorough understanding of the contributors to the base risk. It is particularly important to identify those contributors with the greatest uncertainty; an option that reduces these contributions also reduces the uncertainty in the overall risk metric. While there may still be considerable uncertainty in the results, a shift to lower values is important to demonstrate. Furthermore, understanding how the options affect the results provides insight into whether they provide additional means of providing defence-in-depth or safety margins.

VI-6. PROCESS FOR ADDRESSING LARGE UNCERTAINTY

A step-by step process for addressing large uncertainty in the decision making process is proposed in EPRI 1026511, Ref. [VI-4], whilst this process is primarily aimed at probabilistic assessment the underlying philosophy is equally applicable to other types of assessment.

The three most relevant steps of the process are discussed below.

Step 1: Understand the Role of Large Uncertainty in Risk informed Decision

This step involves consideration of the decision to be made versus the contributors to the assessment that involves large uncertainty. The goal is to either determine that large uncertainty is not relevant to the decision or identify the sources that are relevant.

In some cases, this can be quite straightforward. For example, if a plant desires to make a change to a technical specification requirement, and the plant is potentially susceptible to an external flooding hazard with very large uncertainty, it may be simple to qualitatively describe why the technical specification change is not relevant to the capability of the plant to respond to an external flood.

If, on the other hand, a technical specification change does relate to a system, structure, or component that would be required to respond to or mitigate an external flood, then a further evaluation of the potential for uncertainty to impact the decision needs to be undertaken, as described in Step 2.

Using the example of external floods, when new information has indicated that the frequency of the flood for which the potential for a cliff edge effect cannot be shown definitively to be very low, this source of uncertainty is clearly the key to any decisions made on possible improvements to the plant.

Step 2: Understand the Potential for Large Uncertainty to Impact Decision

In cases where the decision does relate to a source of large uncertainty, there are three ways that the computed risk results could impact the decision as discussed below:

1. Potential or Known Overestimation of Risk – Areas of PSA with large uncertainty is commonly addressed using conservative or bounding assumptions that bias the results toward an overestimation of the computed risk. For example, the assumption of completely correlated seismic failures is a bounding assumption that leads to a conservative assessment of risk. However, conservative approaches can lead to potential masking effects as discussed in the second bullet below. The use of conservative or bounding assumptions can be appropriate when the total contribution

to risk is very small or the contributor is inconsequential in the assessment of a change. In these cases, the overestimation of the risk does not impact the decision making process and such an approach can be acceptable.

However, when this is not the case (i.e. the contributor is relevant to the decision), the use of conservatisms to deal with this large uncertainty can confound the decision making process.

2. Masking of Change in Risk – While adoption of conservative treatments can be necessary and/or expedient in a base model, reliance on conservative assumptions may not always yield conservative risk results, especially in delta risk calculations. This is particularly true for cases in which the impact or response to the hazard has been bounded. For example, in the case of seismic correlation, an assumption of 100% correlation would mask the impact of the removal of equipment from service for seismic events.

   That is, if all redundant components are assumed to fail every time one fails, then removing one from service has zero impact on the calculated system or function failure probability due to the seismic event. By contrast, if no such correlation were assumed, removal of one train from service would have an impact on the calculated risk by virtue of the seismic failure probabilities of the redundant components.

   Another example involves the assumption of a conservative fire damage footprint for a specific ignition source. In this case, if the fire damage is overstated, it may lead to an assumption of damage to equipment that would have been undamaged by the fire. When considering the risk change due to removal of that equipment from service, the delta risk could be understated by the assumed damage. Thus, in these cases, a decision to use a 'conservative' treatment masks the change in risk and needs to be investigated to determine whether this treatment is significant to the decision being made.

3. Potential Under-estimation of Risk – In cases where there is large uncertainty, the mean value of the hazard may be insufficient to characterize the potential risk impact. This is particularly true when there is insufficient data to characterize the severity vs. likelihood relationship. One example is river flooding, which is difficult to model and extrapolation from experience is highly uncertain over the range of frequencies of interest (e.g. 10^{-6}/yr or lower) making it difficult to credibly determine median values and confidence intervals.

   Another example is likelihood of seismic events, where recent re-estimations have produced mean values that exceeded the 95th percentile confidence interval of the previous models.

   In cases where the risk informed decision is relevant to such uncertainty, it may be necessary to investigate the sensitivity of the computed mean risk results to changes in the estimate of the mean frequencies as part of Step 3. Depending on what frequency is chosen as the representative frequency, the risk may be under-estimated, or over-estimated.

Step 3: Disposition of Significant Large Uncertainty

The most straightforward means to accomplish the disposition of significant large uncertainty for decisions related to acceptance of a change to the plant is to perform sensitivity calculations on the areas of large uncertainty to evaluate the potential impacts on results versus the acceptance guidelines, and:

a) demonstrate that the effects do not alter the decision;

b) demonstrate that the cases that would lead to a rejection of the proposed change can be argued to be implausible;

c) use performance monitoring to provide a corrective mechanism should the effects be larger than anticipated; or

d) limit the extent of the implementation of the change, noting the following amplifications:

- Overestimation of Risk – In cases where the use of conservative or bounding assumptions are utilized and the overestimation of risk impact does not adversely impact the overall risk metrics for the application, it is acceptable to rely on these conservatisms, as long as it can be concluded that these conservatisms do not create a masking effect.
- Underestimation of Risk Impact – In cases where the mean estimates are highly uncertain, it is appropriate to evaluate the sensitivity of the risk metrics due to changes in the mean estimate. Often, the easiest way to address this is to vary the uncertain input over a range to illuminate the impact on risk and qualitatively explain why it is reasonable to assume that these sources of large uncertainty do not present a threat to the decision. An example could be in the area of seismic hazard, which is known to have large uncertainty. In an application where seismic risk is potentially relevant to the decision, sensitivities can be performed on the mean hazard inputs to demonstrate that extremely large changes would be needed to influence the decision.
- Consideration of Masking Effects – A specific effort must be undertaken to determine whether the treatment of the large uncertainty have created the potential for masking of risk changes. This would generally involve a sensitivity study that removes the conservative treatment in a manner that skews the results to uncover the potential risk change, e.g. assume no correlation for the seismic-induced failures of those SSCs affected by the change.

Potential for Cliff-edge Impacts – Areas of large uncertainty combined with the potential for cliff-edge effects warrant specific consideration as they relate to the risk informed decision. The most straightforward approach is often to perform a sensitivity analysis to identify the magnitude of the change in assumed hazard likelihood that would be required to change the decision, i.e. to determine at what likelihood the cliff edge would have to occur to affect the decision, and, if possible, to provide an argument of why this likelihood of hazard magnitude is implausible.

VI-7. CONCLUSIONS

This Annex discussed the main sources of uncertainty involved in the Integrated Risk informed Decision Making (IRIDM) process that might have significant impact on the decision being made. Both uncertainty in the assessment of the importance of specific CFs for the key elements of the IRIDM and the uncertainty in the assessment of the level of compliance of the decision options with the CFs are discussed.

The suggestions on how uncertainty can be evaluated and treated in the overall IRIDM process are also provided.

Model uncertainty and uncertainty due to approximations made to simplify the model must be accounted for. Equally important is developing an understanding of which contributors to the analytical results are significant to the decision and why. These quantitative and qualitative insights can be used to inform the assessment of the adequacy of defence-in-depth and safety margins, and if necessary, to identify where additional measures would be beneficial or even necessary, and under which conditions. This type of information can be used as input to design plant modifications or operational practices.

In addition, discussion on the PSA results that are being used to support a risk informed decision is provided in the Annex. It is highlighted that while some uncertainty may be propagated through the model to characterize the uncertainty of the results, i.e. the uncertainty of the risk metrics, this does not provide the complete picture with respect to uncertainty.

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ANNEX VII. PROPOSED STRUCTURE FOR AN IRIDM REPORT

VII-1. INTRODUCTION

This Annex proposes a structure that could be used to document a decision that has been made applying the formal IRIDM process.

The IRIDM report needs to be written in a way that is suitable for all the stakeholders, which could include the organization management, the regulatory body and the public. The aim of this Annex is to provide a format for presenting the result of the IRIDM process in a clear and consistent manner. This will ensure that the way the issue has been characterised and the decision has been made follows the key stages of the IRIDM process as described in section 3 and Figure 3 of the main part of this TECDOC.

The basic structure of the report is given in Table VII-1 and the contents of sections 1 to 8 of the report are described below. Table VII-2 shows an example of a summary table for different options.

VII-2. PROPOSED STRUCTURE OF THE IRIDM REPORT

Contents of Section 1 – Introduction

Section 1 needs to give a brief description of the issue, which is being addressed using the IRIDM process, the relevant nuclear facility, how this issue has arisen, its significance for the safety (or security) of the facility and any factors that are unique to this issue. It also needs to identify the organizations involved in the issue.

This section also needs to briefly describe the framework that has been adopted for applying the IRIDM process and the core members of the IRIDM team.

Contents of Section 2 – Characterisation of the Issue

2.1. Description of the Issue to be addressed
This section gives a detailed description of the issue that is being addressed and includes the relevant background, how the issue was identified and the urgency with which it needs to be addressed.

2.2. Applicability of the IRIDM Process to this Issue
This section needs to describe why the IRIDM process is applicable to this issue and how it will be applied.

2.3. Options Identified
This section has to provide a sufficient description of each of the options that have been identified to resolve the issue. It will also identify any options that were identified but not taken forward into the detailed IRIDM process and the reasons for screening them out.

Contents of Section 3 – IRIDM Team Formation

3.1. Skills Required for the Multi-disciplinary Team
This section needs to identify the range of skills required by the multi-disciplinary team to address the issue. This would depend on the issue being addressed but could include experts in: plant operation, civil engineering, mechanical engineering, electrical engineering, instrumentation and control, structural analysis, neutronic analysis, thermal-hydraulic analysis, radiological analysis, PSA, security, etc.

3.2. Composition of IRIDM Team
This section needs to provide brief information on the personalities included in the

IRIDM team and areas of their responsibilities in assessment of the options.

Contents of Section 4 – Key elements to the IRIDM Process

4.1. Key Elements Required to Address the Issue

This section needs to identify all the inputs to the IRIDM process that are required to address this issue and the options identified.

It has to be demonstrated that a systematic approach has been applied to identify all the factors that are relevant to the issue (See Annex I).

This section also needs to identify the information that already exists and any new analysis that will need to be carried out. For example, if the issue relates to an increase in the rated power level of a nuclear power plant, this may require additional thermal-hydraulic analysis to be carried out.

4.2. Information on Constituent Factors (CFs)

This section needs to present the information taken forward into the IRIDM process for the inputs that have been identified as relevant for each of the options. This needs to address each of the principles that relate to the IRIDM process and could include details of the processes used:

- To identify the relevant **standards and good practices** which would include regulations, regulatory requirements, licence conditions, Technical Specifications, etc.; the extent to which the options meet these requirements; any areas where the options improve the degree to which these standards and good practices have been met and any shortfalls;
- To identify the relevant **operating experience** that has been carried out; the relevant operating experience identified from the facility under consideration, any similar facilities and any relevant generic operating experience; the relevance of this operating experience to the issue under consideration;
- To identify the relevant **deterministic requirements** including the high level requirements (defence-in-depth and safety margins) and the lower level requirements (such as diversity, redundancy, equipment qualification, etc.); the assessment/analysis that has been carried out to address the relevant deterministic requirements; the extent to which the options meet these requirements; the levels of defence-in-depth and safety margins affected by the proposed options; any areas where the options improve the degree to which these requirements have been met and any shortfalls;
- To determine the inputs required from the **probabilistic analysis**; the basis for the probabilistic inputs; the technical adequacy of the PSA and the extent to which it meets national PSA requirements and current practices such as those specified in relevant IAEA safety standards; any additional probabilistic analysis that has been carried out to address the issue; the results of the probabilistic analysis (including the high level results such as CDF/LRF/LERF and the lower level results such as cut-set frequencies and importance functions); the changes in the risk for each of the options addressed; the uncertainty in the results of the probabilistic analysis; the results of any sensitivity studies that have been carried out; any limitations in the probabilistic analysis that has been carried out and the implications of this for the issue being addressed;
- To determine the **human** and **organisational considerations** that are relevant to the issue being addressed; the information input into the IRIDM process;
- To identify the **considerations regarding the interface with nuclear security** that are relevant to the issue being addressed; the information input into the IRIDM process; the issues at the interface of safety with nuclear security; and

- To identify all the **other factors** that need to be considered in the IRIDM process for the issue being addressed; the information input into the IRIDM process; and the results of any additional analysis carried out to address the issue (which could include thermal-hydraulic analysis, radiological analysis, estimates of the costs of making a change to the design or operation of the facility and cost-benefit analysis).

The documentation has to demonstrate the extent to which each of the principles associated with each CF has been met and any areas where there are shortfalls or improvements (See also Annex 3).

This section also needs to describe how the uncertainty has been addressed in both the probabilistic and deterministic inputs and any assumptions that have been made in dealing with this uncertainty. In addition, it needs to describe the quality of the information and its applicability to the IRIDM process for the issue and options being addressed.

This section also needs to describe how the inputs to the IRIDM process have been validated to ensure that they have addressed the issue correctly and have used the correct methods, data, boundary conditions, etc. These factors need to be considered for both the qualitative and quantitative inputs.

It is suggested that this information could be presented in the form of a table which gives a summary for each option regarding the inputs to the IRIDM process from each of the categories identified above for each of the inputs - see Table VII-2.

Contents of Section 5 – Assessment of the IRIDM Options

This section needs to begin with a brief review of the IRIDM team member's reports, pointing out aspects of any of the options which are not fully acceptable and other concerns. Any completely unacceptable option would have led to that option being discarded. The section needs to describe how the ranking of the options are assessed, if this assessment has been performed on a qualitative or quantitative basis.

The basis for the applied scoring system and the justification for the chosen weightings and impacts that have been assigned have to be explained. The information provided in Annex III could be used to support the assessment of the compliance of the options with CFs.

This section also needs to describe how the assessment results for the various factors are integrated to be able to compare the options that have been identified (see also Annexes IV and V). This also includes a description of the checks that have been made to test the robustness of the results from the IRIDM process, to determine whether the results are reasonable and are not sensitive to small changes in the weighting or impact factors.

Contents of Section 6 – Selected Option

6.1. Option Selected

In this section the option that has been selected needs to be described in detail including the arguments why this is the preferred option. It also needs to document any insights obtained in carrying out the IRIDM process and the degree of confidence in the conclusion reached. A brief description of the reasons for discarding or not choosing the other options has to be included.

There is a need for a demonstration that the basic criteria considered in the IRIDM process have been addressed.

Contents of Section 7 – Proposals for Implementation and Performance Monitoring

This section needs to describe the changes that are needed to be made to implement the selected option and how they will be carried out. This will cover all changes in the hardware, operation, safety assessment/analysis reports and the additional training that must be provided for the station staff. The safety considerations have not only to focus on the plant situation after implementation, but also on the actual process of making the change.

Moreover, proposals to monitor the performance of the facility following the changes that have been made need to be described. This covers the measures that will be taken to verify that the chosen option has been implemented as intended, the performance criteria to be applied, the boundary conditions assumed in the IRIDM process are being met, the benefits from the change are being realised and how any deficiencies will be identified and rectified.

Contents of Section 8 - References

All the references must be listed that support the IRIDM process that has been carried out for the issue and options being addressed. This includes the documents that have been used as the starting point for the IRIDM process and any the documents that provide the additional information generated/analysis carried out during the IRIDM process.

TABLE VII-1: PROPOSED STRUSTURE FOR AN IRIDM REPORT

TITLE PAGE
CONTENTS OF THE REPORT
LIST OF ACRONYMS
1. INTRODUCTION
2. CHARACTERISATION OF THE ISSUE
2.1 Description of the Issue to be Addressed
2.2 Applicability of the IRIDM Process to this Issue
2.2 Options Identified
3. IRIDM TEAM FORMATION
3.1 Skills Required for the IRIDM Multi-disciplinary Team
3.2 Composition of IRIDM Team
4. KEY ELEMENTS TO THE IRIDM PROCESS
4.1 Key Elements Required to Address the Issue
4.2 Information on Constituent Factors (CFs)
5. ASSESSMENT OF THE IRIDM OPTIONS[30]
5.1 Brief description of the IRIDM team members reports
5.2 Weightings and Impacts Assigned
5.3 Integration of the Weightings and Impacts
6. SELECTED OPTION
6.1 Description of the Option Selected
6.2 Reasons for selection
7. PROPOSALS FOR THE METHOD OF IMPLEMENTATION AND PERFORMANCE MONITORING
7.1 Proposals for the method of Implementation
7.2 Proposals for the method of Performance Monitoring
8. REFERENCES
Annexes, including individual reports from the specialists

[30] In this Table the outline of the report is shown for the case when "Weighting" approach for integration is used

TABLE VII-2: OPTIONS SUMMARY TABLE

Option	Standards/good practices	Operational experience	Deterministic considerations	Probabilistic considerations	Etc.
1	Note 1				
2					
3					
4					
5					

Note 1: Each of the cells of the matrix gives a summary of all key elements and CFs considered as the inputs to the IRIDM process for each of the options identified.

ANNEX VIII. CONSIDERATION OF NON-RADIOLOGICAL HAZARDS IN IRIDM PROCESS

The aim of any safety decision is to determine and prioritise the measures needed to protect people and the environment from risks to their health and safety: this is in effect an extension of the IAEA Fundamental Safety Objective. Although the main focus of the IRIDM approach described in this publication is related to making informed decisions to manage radiation risk, on any nuclear facility there will be several other hazards to people and the environment. In making decisions regarding radiation safety the risk from non-radiological hazards must also be considered in the decision making process in a holistic manner, as protecting people and the environment from radiation risk has not to lead to greater risk from other sources of harm. Similarly, for decisions regarding non-radiation safety the potential to increase radiological risk needs to be also considered. In making an informed decision, the overall decision must be balanced to achieve the optimum level of safety for people and the environment that are potentially affected. In the following paragraphs some examples of non-radiological hazards that may need to be considered in making safety decisions are discussed.

In any nuclear facility, there is a range of measures needed to protect workers from hazards such unsafe scaffolding and high ladders that cause accidental falls, leaking storage containers of asphyxiating, noxious and poisonous substances, confined spaces which can become oxygen depleted environment, fires which block egress or escape routes, electrical hazards and dropped loads to mention only a selection. In the daily operational activities, which may be related to ensuring that radiation risks are prevented, the nuclear facility must have arrangements to consider the consequences of these non-radiological hazards. For example, dropping of flasks being moved by cranes can lead to damage to SSCs and/or cause injury to workers. This hazard of dropped loads may be eliminated or reduced by reducing the height of the lift or restricting the pathway over which the movement of heavy loads occurs. The physical layout of a building and compartments is often a major factor to ensure separation from the hazard (e.g. ensure that escape routes are available), which do not compromise the control of radioactive contamination.

In addition to hazards affecting the daily operational activities in a nuclear facility, there are hazards which may affect the public as well as, in some cases, the workforce. These hazards include:

- Explosive materials which can lead to direct damage or noxious or poisonous leaks in the form of liquids or gas clouds spreading to the offsite environment;
- Fluorine at an enrichment facility that may well be a hazard of greater consequence than the radioactive material on the site;
- Asbestos in old nuclear facilities undergoing decommissioning, can be spread offsite if proper control measures are not taken; and
- Acids and alkalis used in all nuclear facilities, can affect water sources if these chemical substances leak out into the environment.

In considering any options within an IRIDM process, the effect on all aspects related to safety needs to be included by an analysis of effect on non-radiological hazards. In most Member States there will be legal requirements on non-radiological safety which need to be complied with and may conflict with radiological requirements. As such, in making safety decisions, a balance needs to be achieved. It may be that the IRIDM is in fact driven by some change that at first appears not to affect radiation risks such as a case described in Annex II-9. In some cases, it may be necessary to carry out a probabilistic assessment to determine the extent of the off-site non-radiological risk (usually referred to as Quantitative Risk Analysis - QRA- in the chemical field), but in many situations a simpler analysis will suffice (e.g. task analysis is generally sufficient when considering a safety decision involving worker safety).

It is suggested that risk of non-radiological hazards be included in the IRIDM process; however, additional considerations might need to be developed.[31]

[31] A guide to when such considerations are needed could be developed based on the risks comparable to those that equate to the limits for radiation exposure. For example, the 1mSv/yr dose limit for the public, is equivalent to a probability of death ~$4x10^{-5}$/yr, and for workers the dose limit of 20 mSv/yr is equivalent to a probability of death ~10^{-3}/yr. Statistics on deaths due to various non-radiological causes are generally available in each Member State so that risks from these causes can be assessed.

CONTRIBUTORS TO DRAFTING AND REVIEW

Ahmed, S.	Karachi Nuclear Power Plant (KANUPP), Pakistan
Adamec, P.	State Office for Nuclear Safety, Czech Republic
Alzbutas, R.	Lithuanian Energy Institute (LEI), Lithuania
Amri, A.	International Atomic Energy Agency
Aparkin, F.	International Atomic Energy Agency
Ashwort, A.	Atomic Energy of Canada Limited (AECL), Canada
Asmolov, V.	WANO (World Association of Nuclear Operators)
Backstrom, O.	Relcon Scandpower AB, Sweden
Berg, H-P.	Bundesamt für Strahlenschutz (BfS), Germany
Cimesa, S.	Slovenian Nuclear Safety Administration, Slovenia
Ciurea-Ercau, C.	National Commission for Nuclear Activities Control (CNCAN), Romania
Dinca, E.	National Commission for Nuclear Activities Control (CNCAN), Romania
Earle, K.	Consultant, United States of America
Einarsson, S.	Gesellschaft für Anlagen- und Reaktorsicherheit (GRS), Germany
El Tawila, F.	Federal Authority for Nuclear Regulation, United Arab Emirates
George, A.	EDF Energy, United Kingdom
Godinez, V.	Comision Nacional De Seguridad Nuclear Y Salvaguardias (CNSNS), Mexico
Hlavac, P.	RELKO Ltd., Slovakia
Hussain, A.	Karachi Nuclear Power Plant (KNPC), Pakistan
Hustak, S.	Nuclear Research Institute (Rež), Czech Republic
Kichev, E.	Kozloduy NPP, Bulgaria
Kiss, T.	Paks Nuclear Power Plant, Hungary
Kluegel, J-U.	Kernkraftwerk Goesgen-Daeniken AG, Switzerland
Kuzmina, I.	International Atomic Energy Agency
Lankin, M.	Scientific and Engineering Centre for Nuclear and Radiation Safety (SEC NRS), Russian Federation
Lindahl, P.	OKG Nuclear Power Plant, Sweden
Lungu, S.	International Atomic Energy Agency
Lyubarskiy, A.	International Atomic Energy Agency
Miller, D.	Canadian Nuclear Safety Commission
Nitoi, M.	European Commission-Joint Research Centre, The Netherlands
Parry, G.	Erin Engineering, United States of America
Poghosyan, S.	Nuclear and Radiation Safety Center (N&RSC), Armenia
Preston, J.	Consultant, United Kingdom
Rebleanu, I.	National Commission for Nuclear Activities Control (CNCAN), Romania
Samokhin, G.	Scientific and Engineering Center for Nuclear and Radiation Safety (SEC NRS), Russian Federation
Sanda, I.	International Atomic Energy Agency
Shepherd, C.	CHS Nuclear, United Kingdom
Strasser, G.	Cernavoda Nuclear Power Plant, Romania
Tribelev, A.	JSC OKB “GIDROPRESS”, Russian Federation
Vaughan. G.J.	Consultant, United Kingdom
Viktorov, A.	Canadian Nuclear Safety Commission, Canada
Volkanovski, A.	Jozef Stefan Institute, Slovenia
Wells, P.	International Atomic Energy Agency
Wong, S-M.	US Nuclear Regulatory Commission (USNRC), United States of America

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