INSAG-25

A Framework for an Integrated Risk Informed Decision Making Process

INSAG-25

A REPORT BY THE
INTERNATIONAL NUCLEAR SAFETY GROUP

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A report by the International Nuclear Safety Group

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The International Nuclear Safety Group (INSAG) is a group of experts with high professional competence in the field of nuclear safety working in regulatory organizations, research and academic institutions and the nuclear industry. INSAG is constituted under the auspices of the International Atomic Energy Agency (IAEA) with the objective of providing authoritative advice and guidance on nuclear safety approaches, policies and principles for nuclear installations (defined as nuclear power plants, fuel cycle facilities, research reactors and support facilities). In particular, INSAG provides recommendations and informed opinions on current and emerging nuclear safety issues, to the international nuclear community and public through the offices of the IAEA.

FOREWORD

by the Chairman of INSAG

There is general international agreement, as reflected in various IAEA Safety Standards on nuclear reactor design and operation, that both deterministic and probabilistic analyses contribute to reactor safety by providing insights, perspective, comprehension and balance. Accordingly, the integration of deterministic and probabilistic analyses is increasing to support design, safety evaluation and operations. Additionally, application of these approaches to physical security is now being considered by several Member States.

Deterministic and probabilistic analyses yield outputs that are complementary to each other. There is thus a need to use a structured framework for consideration of deterministic and probabilistic techniques and findings. In this process, it is appropriate to encourage a balance between deterministic approaches, probabilistic analyses and other factors (see Section 3) in order to achieve an integrated decision making process that serves in an optimal fashion to ensure nuclear reactor safety. This report presents such a framework — a framework that is termed 'integrated risk informed decision making' (IRIDM). While the details of IRIDM methods may change with better understanding of the subject, the framework presented in this report is expected to apply for the foreseeable future.

IRIDM depends on the integration of a wide variety of information, insights and perspectives, as well as the commitment of designers, operators and regulatory authorities to use risk information in their decisions. This report thus focuses on key IRIDM aspects, as well considerations that bear on their application which should be taken into account in order to arrive at sound risk informed decisions.

This report is intended to be in harmony with the IAEA Safety Standards and various INSAG reports relating to safety assessment and verification, and seeks to convey an appropriate approach to enhance nuclear reactor safety.

We appreciate contributions to the preparation of this report by former INSAG members, including in particular A. Birkhofer. We also appreciate the assistance of A. Thadani, F. Eltawila and G. Vaughan. Of course, responsibility for the report rests with INSAG.

CONTENTS

1. INTRODUCTION

1. Human activities and natural phenomena present risks and are possible sources of harm. The term 'risk' implies that harm to people and the environment needs to be considered both in terms of the magnitude of the possible harm and its likelihood. Safety is achieved by ensuring that risks are maintained as low as reasonably practicable (ALARP). Under the ALARP concept, measures to reduce risks should be applied unless there is a gross disproportion between the achievable level of risk reduction and the effort needed to reduce it.

2. Countries have safety, security and safeguards policies and goals that define the basis for the design and operation of their nuclear power plants. The overall objective of meeting these goals is to minimize radiological exposures from normal operations and to prevent, with high confidence, accidents from occurring at nuclear power plants. Another objective is to mitigate consequences if an accident should occur.

3. One fundamental objective in nuclear safety is to protect people and the environment from the risks of ionizing radiation. The IAEA has promulgated fundamental principles and requirements that encourage the consideration of risk information and analyses along with deterministic safety analyses. This evaluation can be appropriately accomplished using an integrated risk informed decision making (IRIDM) process. In particular, the Fundamental Safety Principles [1] relating to legal authority, leadership and management for safety, justification of facilities and activities, optimization of protection, limitation of risks to individuals, prevention of accidents, and emergency preparedness and response can be addressed using IRIDM.

4. The IAEA's Safety Standards also highlight the need for integrated assessment for decision making. In particular, GSR Part 4, on Safety Assessment for Facilities and Activities [2], states in para. 5.8:

> "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."

5. Probabilistic safety assessment (PSA) and probabilistic safety targets provide risk metrics to support decisions related to nuclear safety and to strengthen their basis. Many risk informed applications have been successfully

employed for purposes of considering and comparing the safety of alternative design solutions and operating practice. Also, targets set for the probability of core damage and off-site releases have been found useful for assessing safety in an integrated manner. However, in any application the strengths and weaknesses of a PSA must be understood and taken into account. The increasing use of PSA techniques is being made in many countries because it provides valuable complementary insight, perspective, comprehension and balance to the deterministic safety assessment of nuclear installations. Experience has shown that an integrated decision making process, including deterministic and probabilistic analyses together with good engineering practices, consideration of operating experience and sound managerial arrangements, is effective in refining and improving safe design and safe operations of nuclear installations. This report describes the foundations of such an integrated decision making process.

6. This report is intended to promote a common understanding among the international nuclear community (designers, suppliers, constructors, licensees, support organizations and regulators) of how the concept of risk can be used in making safety decisions relating to nuclear installations. The integration of operating experience, deterministic considerations, probabilistic considerations, consideration of uncertainties and other factors (see Section 3) serves to help ensure coherent and balanced decisions [3].

7. This report identifies the framework, principles and key elements for IRIDM. It describes the interrelationship between the key elements, and the integration of their inputs. The need for documentation, communication and follow-up on the implementation of the decisions, including performance monitoring and corrective action, is emphasized.

8. The IRIDM process brings transparency to complex decisions involving several key factors and its added value is explained in Section 2.4. These factors may be of different forms and can be weighed differently to reflect their relative importance to the situation under consideration. Explicit documentation of these factors and how they are weighed can enable the determination of how a final decision is dependent on the different factors and how it is affected by differences in the perception of the importance of the factors by different decision makers. This allows decisions to be reviewed and, if appropriate, reconsidered to reach a robust conclusion.

9. Although this report is focused on the use of IRIDM in the context of nuclear power plants, including their fuel handling and storage systems, it can be

equally applied with appropriate adjustments to other nuclear facilities and activities as well as to non-nuclear applications.

2. OUTLINE OF THE IRIDM PROCESS

2.1. IRIDM OBJECTIVE

10. IRIDM is a systematic process aimed at the integration of the major considerations influencing nuclear power plant safety. The main goal of IRIDM is to ensure that any decision affecting nuclear safety is optimized without unduly limiting the conduct of operation of the nuclear power plant. It underpins nuclear safety decisions and ensures consistency with the safety goals of the Member State.

11. The outcome of IRIDM should also satisfy the following principles:

- Defence in depth is maintained;
- Safety margins are maintained;
- Engineering and organizational good practices are taken into account;
- Insights from relevant operating experience, research and development, and state of the art methodologies are taken into account;
- Adequate integration of safety and security is ensured;
- Relevant regulations are met.

The success of the measures implemented as a result of the decision should be reviewed against observed performance.

2.2. IRIDM USERS

12. The users of IRIDM are primarily designers, operators, regulators, and individuals or organizations providing support to regulators and utilities.

13. The information used in the IRIDM process, the results and insights obtained, and the justification for the decisions made will no doubt also be of interest to other stakeholders, including organizations and individuals at various levels of government, academia, industry and the public.

2.3. AREAS OF IRIDM APPLICATION

14. 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.

15. The IRIDM process is used to establish requirements that focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety.

16. The IRIDM process has been used to ensure that a decision made in one area is not in conflict with other decisions (e.g. safety and security interfaces) and to identify regulations which warrant re-examination.

2.4 ADDED VALUE OF IRIDM

17. An IRIDM process allows a consistent, transparent and balanced approach to safety. Its benefits include:

- *Improved safety by providing enhanced awareness of factors influencing safety and taking each of these factors into account in a decision and its implementation*. Significant safety improvements have been made, especially in the design features of nuclear power plants, as a result of risks not initially recognized being identified in systematic probabilistic analyses, leading to appropriate corrective measures using additional deterministic justification.
- *Reduced radiation exposure by focusing maintenance on more risk significant areas and reducing unnecessary activities in high radiation areas*. Applications such as risk informed in-service inspection have resulted in a significant reduction in radiological exposure.
- *Increased installation performance, operational flexibility, cost effectiveness of operations and reduction of unjustified regulations*. A comprehensive and balanced understanding of an installation’s risk spectrum allows effective use of resources to address the more risk significant aspects while conserving resources that would otherwise be applied to less risk significant aspects.

— *Development of accident management measures and procedures aimed at ensuring that the risk of accidents with undesirable consequences is extremely low.*

2.5. THE IRIDM PROCESS

18. The key elements of the IRIDM process are depicted in Fig. 1 and are discussed in Section 3.

19. The first step in any decision making process is to clearly define the issue to be resolved and the options to be considered.

20. After defining the safety issue, consideration must be given to all relevant regulatory and utility considerations. The inputs to the decision then need to be established. These normally include various key elements: standards and good practices, operating experience, deterministic considerations, probabilistic considerations, organizational considerations and security considerations. Other relevant considerations can be included in the decision making process, such as expected radiation doses, insights from research and economic factors.

21. The importance of each element is dependent upon the decision to be made; as the issue changes, the relative importance of each element may also change. Having evaluated the importance of each element and considered the potential safety measures, a decision should be derived that achieves an appropriate balance among the various considerations. A tentative decision should be checked by iterating the process to ensure that all safety requirements are met. When this has been done, the chosen safety measure(s) can be implemented. However, this should not be the end of the process: the implemented decision should be monitored, and corrective action should be taken, if required, to ensure that the decision has achieved the desired outcome.

3. KEY ELEMENTS OF THE IRIDM PROCESS

22. The key elements of the IRIDM process are depicted in Fig. 1. Depending on the nature and purpose of the decision, and the timescale in which the decision has to be taken, some or all of these elements should be evaluated. Clearly, the more information that is taken into account, the better the decision is likely to be in meeting the overall objectives. None of these elements is new — it is the

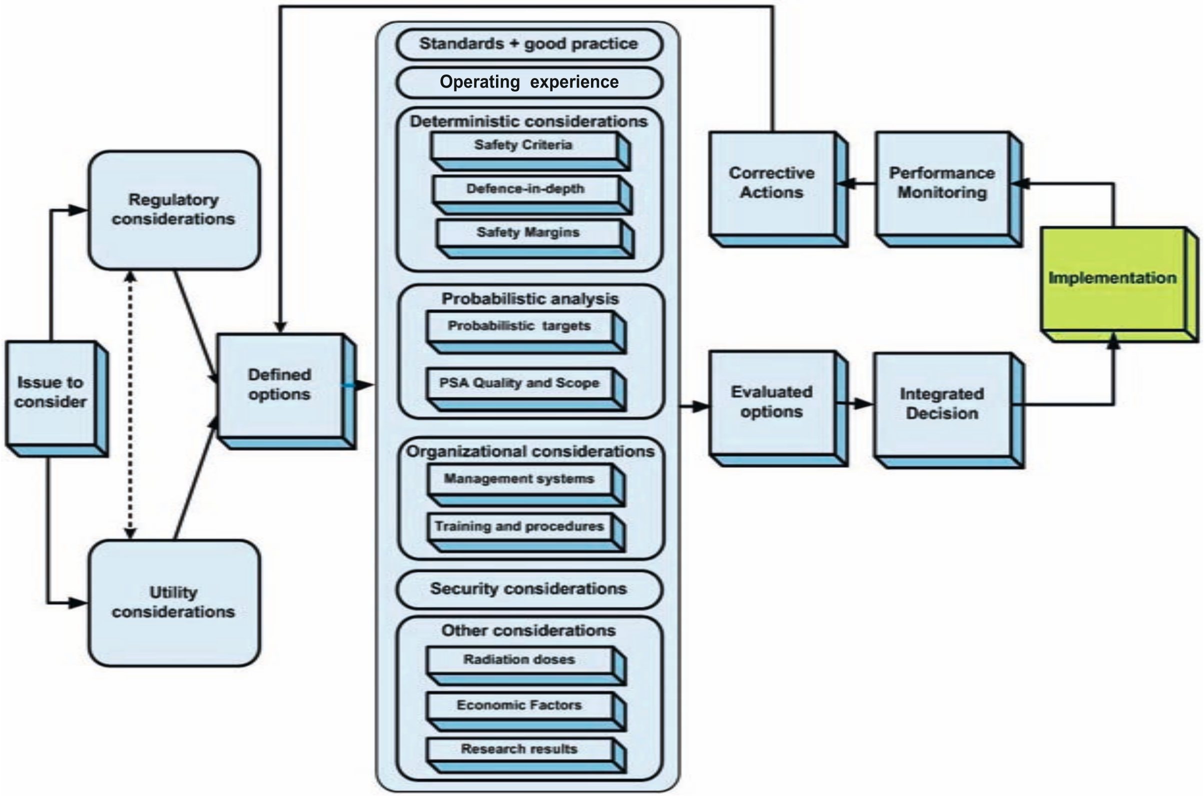

FIG. 1. Key elements of the integrated risk informed decision making process.

process of integrating them in a systematic manner that is not widely practised. In the following sections a brief review is given of the key elements and more detail is given in Ref. [2].

3.1. STANDARDS AND GOOD PRACTICES

23. The bedrock of any design and operational activity is good engineering and sound managerial procedures. These are often exemplified by standards and codes produced by professional bodies, ranging from government agencies, engineering organizations, national and international standards groups to quality assurance bodies and many others. Sound procedures of course may also be derived from, and in any event must also be consistent with, regulatory requirements identified by Member States. Engineering safety margins, based on experience and research, are important aspects of these standards and should be maintained in the IRIDM process. There are, however, a much wider set of engineering and managerial practices, which fall under the general title of good practices. Some of these are highlighted in IAEA Safety Standards, IAEA mission reports, etc. It is expected that operators and regulators will be aware of and consider these good practices for application to specific nuclear power plants. It is necessary, therefore, to establish a systematic process for capturing good practices from the nuclear power plant itself, from other similar plants, and from industry more generally. Consideration of these good practices is likely to be a major factor in many IRIDM activities.

3.2. OPERATING EXPERIENCE

24. A major factor in improving the operation and design of a nuclear power plant is learning from the events that have occurred at the plant itself, at similar plants and at other industrial complexes.[1] The IRIDM process should include a means for reviewing such events and using the analysis of them, particularly root causes, in making decisions on the adequacy of safety measures or on additional measures that may be needed [2, 4, 15].

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[1] It is good practice to include operating experience into PSA updates and other evaluations and activities (for instance, analysis of the behaviour of components and materials, in-service inspection planning).

3.3. DETERMINISTIC CONSIDERATIONS

25. IRIDM must be consistent with the basic deterministic safety principles that underlie the design and operation of the nuclear power plant. These include the requirements that serve to reduce the identified potential hazards as far as practicable, to ensure that the design is fault tolerant, to adequately meet a defence in depth philosophy, to emphasize compliance with deterministic safety acceptance criteria, to further prevent and mitigate accidents, and to maintain adequate safety margins.

26. Design basis accident analysis is guided by deterministic considerations. It is undertaken by postulating a set of initiating events and scenarios and verifying that the design is capable of protecting against such events within the limits of specified acceptance criteria. Conservative assumptions are made and scenarios bounding other potential accidents of a similar nature are considered to ensure that the design provides generally robust protection against radiation hazards and other harmful consequences. A fundamental principle in design basis analysis is to postulate single or multiple failures in safety systems, depending on the purpose of each system and its design requirements, and to demonstrate that the related safety function can be provided despite the postulated failure(s).

27. Defence in depth is a cornerstone of the design of nuclear power plants. It is aimed at ensuring design basis safety and the prevention of accidents. First, it provides for a series of successive barriers between the source containing radioactive material and the harmful effects of radiation on people or the environment. Second, the defence in depth concept [5] provides safety assurance through a series of consecutive levels to protect the integrity of the barriers and to achieve other related objectives. Independence of the successive barriers provides protection against the risk of random failures of separate barriers, although several barriers can be endangered in more serious accidents at the same time. As a whole, the set of barriers is supported by independent reliable safety systems designed to protect the integrity of barriers and thereby to ensure reliable containment of all radioactive material within the nuclear power plant. The consecutive levels of defence in depth are aimed to minimize the frequency of challenges to barrier integrity by fulfilling key safety functions through the reliable performance of systems and high quality structures and components. The IRIDM process should ensure compliance with the defence in depth concept. More information can be found in INSAG-10 [5] and INSAG-12 [6], and IAEA-TECDOC-1436 [7].

28. Safety margins are developed from design basis analysis to ensure that operation of a nuclear power plant can be carried out with adequate levels of safety in all modes of operation and at all times. The basic concept is to determine limiting values, which, if exceeded, could lead to an undesirable state. Operating parameters are then derived to ensure that these values are not exceeded in normal operation nor in any design basis accident. Although the limiting values are derived conservatively, the operating parameters are set taking into account uncertainties in phenomenological understanding, modelling, assumptions, analyses, data, equipment performance and human performance. Further details can be found in the OECD Nuclear Energy Agency's Safety Margin Action Plan report [8]. Any proposals that would lead to changing safety margins through the IRIDM process should be subject to detailed scrutiny to ensure that adequate safety is maintained.

29. Safety margins also have a role in mitigating the consequences of design basis accidents and of low frequency events, such as beyond design basis accidents and security concerns.[2]

30. Other deterministic considerations, which are part of a nuclear power plant's design and are important to successful application of IRIDM, include requirements for equipment qualification, physical and material analysis and non-destructive examinations, prevention of common cause failure, fail-safe design, provision of adequate redundancy and diversity for safety functions and systems, and physical separation of redundant systems.

3.4 PROBABILISTIC CONSIDERATIONS

31. Probabilistic analysis is intended to complement deterministic and other previously defined considerations by identifying failure sequences that otherwise may be overlooked. It also serves to help develop designs and operating practices that provide an enhanced level of safety with reasonable efforts as compared with the investigated alternatives, bearing in mind the ALARP principle. Probabilistic considerations can range from the collection and evaluation of data on simple events, such as failures in maintenance, through analysis of system reliability, to complex analyses by means of a formal PSA.

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[2] An example is the capability of the containment to withstand a beyond design basis accident.

32. PSA methodology is a structured approach to describe the logical connections between physical phenomena. It integrates information about plant design, operating practices, operating history, component reliability, human behaviour, accident phenomena and (in its widest application) potential radiological consequences. The approach aims at achieving completeness in identifying possible faults, deficiencies and plant vulnerabilities, and providing a balanced picture of the safety significance of a broad spectrum of issues, including the uncertainties of the numerical results.

33. A PSA is an essential element of IRIDM in that it aims at identifying and delineating the combinations of events that may lead to an accident. The PSA is also used to assess the expected probability of occurrence for each event combination, to evaluate the consequences [6], and to estimate quantitatively the effectiveness of measures to prevent accidents or mitigate their consequences. Accordingly, the PSA should use state of the art methodologies and be based on best-estimate inputs in order to assess the actual plant performance realistically. It is aimed at providing a realistic assessment of risk and associated vulnerabilities and at facilitating the estimation of the uncertainties in the analysis.

34. In circumstances when failure sequences identified by PSA lead to consideration of a situation for which a system has not been designed and for which the system performance cannot be predicted in the PSA in a meaningful manner, such as performance of instrumentation and control systems in conditions of high temperature, humidity or radiation, the appropriate response is to improve the design or operation so as to make such sequences of extremely low probability.

35. PSA studies are typically undertaken at three different levels. A Level 1 PSA provides information on reactor core damage frequency; a Level 2 PSA provides insights on radioactive releases to the environment; and a Level 3 PSA estimates the radiological risks to the public and the environment around the facility. At each level the PSA provides estimates of the probabilities (frequencies) of adverse consequences and information on the dependence of these values on various factors, such as technical design features, potential human errors, or weather conditions. Level 1 and Level 2 PSAs can provide useful information for decisions influencing the safety of the nuclear power plant, while a Level 3 PSA is particularly useful in decisions relating to the siting of nuclear power plants and to emergency planning.

36. Significant advances in PSA methodologies have been achieved in the past three decades, largely as a result of improved databases and more comprehensive

systems analysis and phenomenological models. Progress in PSA methodology is being made so as to include organizational factors, passive system reliability, external hazards, and failures in digital system software. Any incompleteness in the PSA can add uncertainty to the quantified results.

37. The qualitative outputs from a PSA should also be considered within IRIDM, as information from the logic structure can show weaknesses and lack of balance in the design or operation. Excessive reliance on the reliability of particular systems, structures or components (SSCs) or on operator actions can be identified in this way. Moreover, a PSA can help to demonstrate compliance with deterministic principles (e.g. single failure criteria, the fail-safe design principle) and, through the feedback process involved in integrating probabilistic and deterministic considerations, can result in modification of deterministic requirements, such as design basis events and the classification of SSCs.

38. A PSA also provides a number of quantitative measures that can be particularly useful in IRIDM as they allow the effects of changes to be evaluated, as well as comparison with safety targets. These safety targets may be expressed as frequencies for specific consequences, such as plant damage states or releases to the environment. The PSA results should be expressed as mean estimates with associated uncertainty distributions. The analysis of uncertainty is an integral part of a PSA and the careful consideration of uncertainty can greatly enhance any decision derived through the IRIDM process. In addition, estimates of the frequency or probability of specific consequences and measures of importance (e.g. of given SSCs) can be derived that can supplement the qualitative and quantitative considerations.

39. PSA is a powerful technique, but it has limitations. In using the output from a PSA in the IRIDM process it is important to consider PSA quality. The quality of the PSA is dependent on modelling scope, the choices made by the analysts and the design and operational information available. Further details can be found in the relevant IAEA Safety Guides [9, 10] and in an IAEA technical document related to PSA quality [11]. The United States Nuclear Regulatory Commission’s Regulatory Guide 1.200 [12] also provides guidance on PSA quality.

3.5. ORGANIZATIONAL CONSIDERATIONS

40. Management for safety covers a wide range of aspects, including leadership, control, competence, communication and cooperation between staff. Such management should include a clear planning function, with a system of

review and audit to ensure that such matters as maintenance, inspection and testing of equipment, staffing levels, training and managerial oversight are properly conducted and corrected if necessary. Within any IRIDM process it is essential that organizational and management issues be given proper and adequate consideration in order to maintain and improve the human input to safety. Further details can be found in the IAEA Safety Requirements publication on management systems [13].

41. Structures, systems and components are designed to fulfil their safety functions and are qualified and maintained to ensure that they will operate on demand, under specified service and environmental conditions. In developing a design, the necessary qualification, maintenance, inspection and testing procedures should also be established. IRIDM should also consider the adequacy of these procedures and how they may impact other safety aspects of the nuclear power plant, such as doses to workers. The IRIDM process should take into account whether specific training of the staff and/or additional procedures need to be incorporated in the management system.

3.6. SECURITY CONSIDERATIONS

42. Security, or physical protection, of a nuclear power plant and the nuclear material on the site is an important issue which needs to be considered when making a decision within the IRIDM process. It is important that IRIDM provides a measured decision which ensures proper integration of the safety and security requirements [14].

43. It should be recognized that security measures can in some instances support safety, while in other instances they may have a negative safety impact. For example, the robust structures required for security purposes could also provide improved protection against certain environmental hazards. Alternatively, security measures may hinder or delay safety actions that should be taken promptly to respond to some abnormal situations. Such considerations should be taken into account in an integrated way during the design, in developing operating and security procedures, and in the regulatory process [14].

44. Security measures required for different plant operating modes and configurations may require adjustment to accommodate changes in an SSC’s operability and importance. These adjustments may include increased surveillance or protection in certain areas and reductions in others (e.g. for

equipment out of service). Situations involving additional activity on-site (e.g. for plant modifications, outages) may also require adjustments in the security plan.

3.7. OTHER CONSIDERATIONS

45. During normal operations there are risks, albeit small, to workers and the public from radiation doses [15]. As part of the IRIDM process, the effect of plant or operational changes on the normal operational doses, doses during maintenance or plant modification, requirements to minimize radioactive waste and discharges to the environment, and efforts to reduce them, should be considered.

46. All safety measures have costs and the economic effects of a decision should be part of the IRIDM process. The process for such consideration should be consistent with the legal basis for decisions in each country.

4. INTEGRATION OF THE KEY ELEMENTS OF IRIDM

47. The process of making a decision relating to safety should be logical, comprehensive, transparent, reproducible and verifiable. These qualities should be preserved in the associated documentation and reporting so that it is clear how the decision was reached, as well as the factors that were taken into account and their relative importance. In this way, all stakeholders can understand why and how a decision was made. The approach should be such that any decision can be put into proper perspective with other similar decisions.

48. For the IRIDM process to be credible, there should be no bias in the final decision. Obviously, the decision should lead to implementation of the requirements defined by the decision.

49. An important element of any IRIDM process should be the explicit consideration of all effects because improvements in one area may adversely affect another area. Likewise, the IRIDM process should aim at achieving balance in the overall safety measures to ensure there are no weaknesses or over-reliance on specific features. A careful consideration of risk can be a useful tool in assuring a balanced view.

50. Decision making using the IRIDM process described here can often be difficult because the requirements and insights from different IRIDM inputs are not expressed in the same form. For example, quantitative output is available from a PSA, but only qualitative output may be available from some other elements of the process. It is a good practice to involve multidisciplinary teams in the decision process. Each member would be expected to have a high level of expertise in at least one of the areas that provide a significant input into the decision making process and to be able to deal with the diverse inputs with different measures. The team should cover all the disciplines required by the issue being addressed, and should be familiar with the plant (this should include design, operation, operating experience, etc.).

4.1. GENERAL CONCEPT OF THE INTEGRATION PROCESS

51. IRIDM decisions should be formed by the integration of results and insights from various elements and assessments as depicted in Fig. 1. Many of the inputs in the IRIDM process are numerical, but there are usually qualitative considerations as well. These quantitative and qualitative aspects are equally important and should be considered holistically.

52. As discussed in Section 2.5, the precise process will depend on the issue under consideration and there must be a clear relationship between the elements and their importance. IRIDM is not simply a process of considering several inputs at the same level, but must have a structure (see para. 10). However, due to the large number of applications of IRIDM, it is not feasible to depict a general process. For example, in the design of a nuclear power plant, the starting point is the defence in depth principle and engineering standards, which provide the safety classification of SSCs; these resulting SSCs are checked by deterministic assessment for their ability to execute the required safety functions by required margins, both in normal operation and accidents; and then the PSA looks for balance and weaknesses and, on occasion, can result in adjustment of the deterministic requirements through the feedback process described below. Quantitative risk targets should be achieved or, if not, the design should be improved by removing the highest risk weaknesses identified in the PSA.

53. The integration process is an iterative one. For each safety measure under consideration, checks should be made to justify that the requirements of each element depicted in Fig. 1 are satisfied. If a safety measure does not satisfy an essential requirement or increases another risk unacceptably, consideration should be given to its possible refinement. In the design example above

(para. 52), it is unlikely that a maintenance requirement will be changed, but the way it is done might be modified so that doses to workers are reduced, for example by going from hands-on maintenance to remote maintenance. After the refinement, the assessment should be repeated to ensure that other considerations are satisfied.

54. Where alternative safety measures being considered satisfy all the relevant requirements, the integration process should include comparison of them to arrive at a sound and balanced decision. Additional considerations could be also applied at this stage. For example, when time is a limiting factor, a safety measure that allows fast implementation may be selected.

55. Reporting on the output of an IRIDM process should show how each element has been addressed and accounted for in the final decision.

56. IRIDM boundary conditions, assumptions, uncertainties, compensatory measures or actions, and other risk reducing efforts (prevention or mitigation) need to be understood and considered. Results and insights from deterministic analyses along with risk information are combined to ensure that all important and relevant factors are adequately and appropriately evaluated.

57. When combining separate inputs, it is important to consider for each applicable element the approach, its strengths, its limitations, and any associated insights. These considerations should be clearly conveyed to the analysts and decision makers.

58. A major challenge in integrating various elements arises from the fact that a nuclear power plant does not pose only one risk; it poses several risks from a range of hazards to a range of people in a range of situations.[3] Any decision making process should be clear on how the balancing of different risks is achieved, bearing in mind that measures to reduce one risk may raise others.

59. Figure 2 depicts the integration of the deterministic and probabilistic elements of the IRIDM process to ensure a high level of safety. As shown in the

[3] Risks for workers and the public can arise from normal operation and abnormal operation (faults and hazards leading to accidents of all levels). They may result from nuclear/radiation hazards and more conventional hazards (e.g. chemicals, tripping and falling); and they may be ‘continuous’ or short term, which in themselves may be planned (e.g. refuelling outages, regular maintenance) or unplanned (e.g. repair, modification).

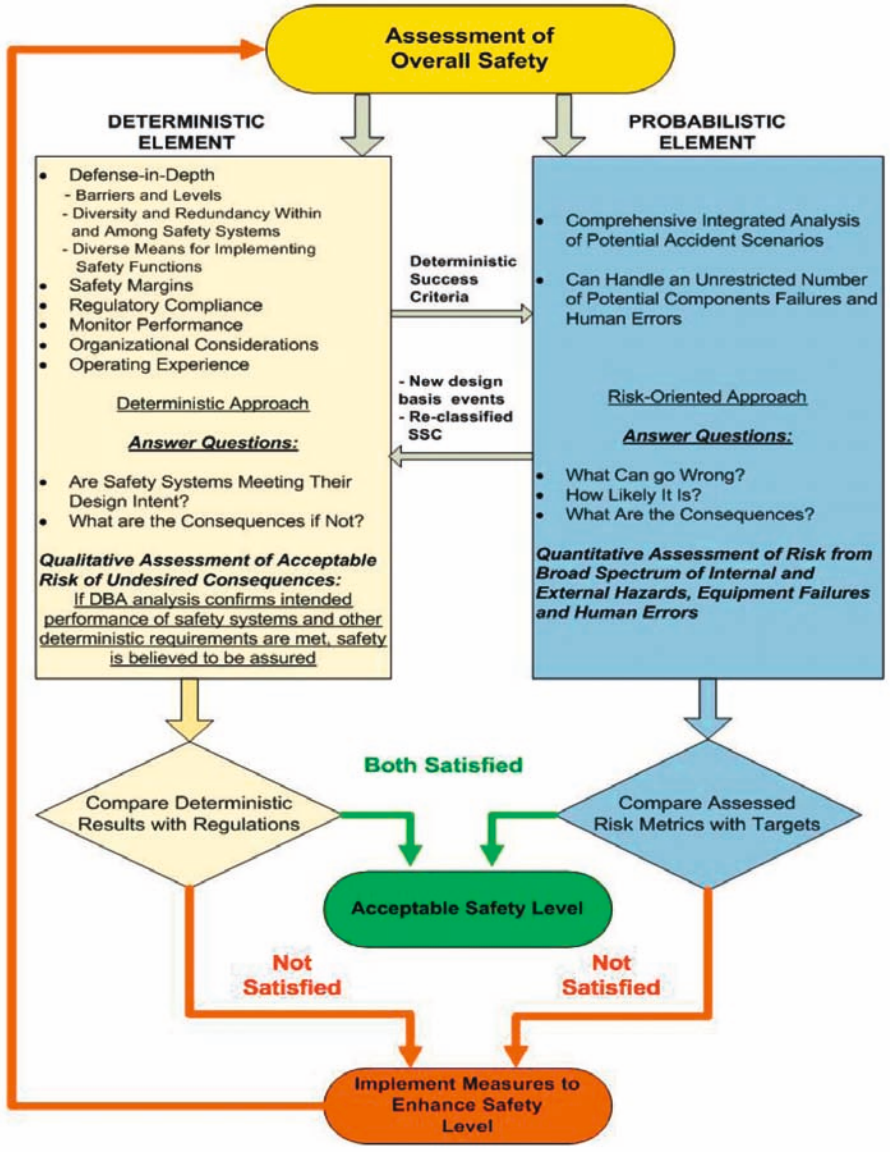

FIG. 2. Integration of deterministic and probabilistic elements.

figure, the integration of the probabilistic and deterministic elements is part of an iterative process in arriving at final safety decisions. The process can result in the identification of new design basis events and new criteria for deterministic safety classification of SSCs[4].

4.2. UNCERTAINTIES

60. The uncertainties of the numerical results of analyses, deterministic and probabilistic, are influenced by assumptions, boundary conditions, the availability of reliable data and other limitations. Uncertainties could also be affected by natural phenomena, ageing, expert judgement, analytical models and parameter uncertainties. Accordingly, while numbers are often calculated and reported as a point value, it is preferable to consider the numerical results as distributions when practical. In addition, the more qualitative inputs will also have uncertainties associated with them, due in part to how they have been derived.

61. The analysis of uncertainty is an integral part of a PSA and best estimate analysis. Taking account of this information greatly enhances the soundness of any decision derived through the IRIDM process. How uncertainties have been dealt with should be part of the IRIDM reporting structure.

62. Some of the serious abnormal observations and events that have actually taken place were not predicted by existing analyses. It is thus necessary to recognize the uncertainties resulting from the incompleteness of the risk model. Scenarios might be left out because the analysts are not able to identify them or do not regard them as conceivable. Therefore, a PSA is only one input in coming to a design, operational, or regulatory judgement. Accordingly, one should weigh engineering and operational considerations, including operating experiences, along with the predicted dominating risk factors.

[4] The weight of the elements depends on the issue being addressed and on the regulatory approaches in Member States. In particular, in some Member States the regulations are more prescriptive, while in others the regulations may establish goals.

5. IRIDM PROCESS MANAGEMENT

5.1. PERFORMANCE MONITORING

63. It is a fundamental aspect of IRDIM that the consequences of decisions affecting safety should be monitored and feedback provided on their effectiveness. Performance measures should be developed and monitored. Such measures should be measurable, observable, or calculable and should be sufficiently comprehensive as to provide the capability to assess safety in a comprehensive and complete fashion. If a performance measure is not satisfied, there should be a process in place that will result in immediate and heightened safety awareness.

5.2. FEEDBACK

64. Feedback on the effectiveness of IRIDM decisions should be documented and communicated in a clear and consistent manner to all relevant stakeholders at the earliest opportunity. The information supplied to the relevant stakeholders should enable them to understand the feedback and to make a judgement as to the effectiveness of the decisions, or, if necessary, to determine whether to require corrective or remedial measures.

65. A systematic reassessment of the safety of an existing nuclear power plant, such as a periodic safety review (PSR) [16], can be useful in checking and confirming the long term success of the IRIDM process.

6. TRAINING IN IRIDM

66. There must be a clear commitment by the licensee and the regulator to the IRIDM process in order to obtain its benefits. Sufficient budget and staff need to be allocated to the various tasks and staff need to be trained in the process so they can fulfil the IRIDM tasks. This may require that a number of staff receive specific training in IRIDM techniques and evaluation. All staff should be made aware of the enhancement to safety culture that IRIDM provides. It is important that experience be fed back into the programme, both in the use of the elements of the risk informed decision making process and in training.

67. It is important to ensure that training in IRIDM is compatible among all parties involved in the decision making process (e.g. operator, designer and regulator).[5]

7. DOCUMENTATION AND COMMUNICATION

68. IRIDM decisions should be documented, reviewed, approved and communicated in a clear and consistent manner. The documentation and reporting method used by different stakeholders, internal and external, contributing to the safety of nuclear installations should be compatible. The reporting method should clearly articulate the issue to be addressed, the decision, and the key attributes which contributed to the decision [17]. The reporting method should also present limitations, uncertainties and sensitivity analyses where pertinent.

69. The methodology, including the way the results of the process are obtained and presented, should be discussed among all parties involved in IRIDM. Even when the IRIDM process has provided the basis for design changes that have been accepted by the regulator, the integrated approach is new and should be developed in a close relation among different stakeholders.

70. At least a summary of the main issues and results should be made available to non-specialists (e.g. the public).

[5] Normally the need for IRIDM may come from the in-plant oversight, a regulatory requirement, or the need to improve safety or economics. It will normally be conducted by the utility central engineering group, with or without outside contractors, be approved by the regulator and by the licensee, and be implemented in the plant and monitored by plant personnel. All parties involved will likely need specific training in the IRIDM process.

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