RESEARCH REPORT

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Graded approach to nuclear safety – State of the practice

Author: Essi Immonen

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Summary

This report studies graded approach to nuclear safety from a literature perspective. The aim of the report is to obtain an overall picture of graded approach(es) and identify some of the main issues of the state-of-the-practice graded approach. The relationship of overall safety and graded approach, and future development needs for a risk-informed graded approach are studied.

Definitions and application areas of graded approach are collected from different sources to obtain an understanding of current uses of graded approach. One specific area of interest is graded approach regarding management systems. The role that management systems play for graded approach is in this report considered from what is found in literature. Literature on risk-informed decision making is presented for the background of risk-informed grading processes. The key aspects of a methodology for risk-informed grading are discussed, such as integration of qualitative and quantitative assessments.

Based on the literature review it is concluded that graded approach in nuclear safety is so far still a concept; a concept that could be developed in more detail in order to achieve an integrated framework applicable to most situations and users. Utilising an integrated collection of methods and tools in a risk-informed graded approach would require firstly integrating technical aspects with the other areas of overall safety, such as organisational factors.

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Written by	**Reviewed by**
Essi Immonen Research Scientist	Kim Björkman Research Scientist

VTT's contact address

VTT Technical Research Centre of Finland Ltd, P.O. Box 1000, FI-02044 VTT, FINLAND

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Date:	18 January 2023
Signature:	DocuSigned by: Nadezhda Gotcheva E21E683840FD424...
Name:	Nadezhda Gotcheva
Title:	Research Team Leader

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1. Introduction

Graded approach is a concept that is mentioned in many contexts in the area of nuclear safety. It can be defined as a process to ensure that the level of e.g. analyses, regulation or documentation are commensurate with the level of risk. With use of graded approach during all lifecycles of a nuclear power plant, the resources and attention could in best case be directed to the areas of greatest risk-significance.

Graded approach is also widely practiced in radiation safety in nuclear and medical applications. This report is focused on the methodology of graded approach in the safety of nuclear power plants. Section 2 lists some definitions of graded approach. Section 3 describes some national and International Atomic Energy Agency's (IAEA)'s methods of graded approach and application areas from scientific literature. Sections 4 and 5 discuss the concepts of management systems and risk-informed decision making in relation to graded approach. Section 6 discusses the findings of the literature view and section 7 concludes the report.

2. Definitions of graded approach

The IAEA Safety and Security Glossary (International Atomic Energy Agency, 2022) defines graded approach as

1. "For a system of *control*, such as a regulatory system or a *safety system*, a *process* or method in which the stringency of the *control* measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of *risk* associated with, a loss of *control*.

2. An application of *safety requirements* that is commensurate with the characteristics of the *facilities and activities* or the *source* and with the magnitude and likelihood of the *exposures*."

Graded approach should ensure that the safety functions are preserved, that operational limits and conditions are not challenged, and that there are no additional risk to the staff, public and environment (International Atomic Energy Agency, 2014).

The American Society of Mechanical Engineers (ASME) standard NQA-1-2015 (ANSI/ASME, 2015) defines graded approach as

"The process employed, once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

- the relative importance to nuclear safety
- the magnitude of any hazard involved
- the life-cycle stage of a facility or item
- the mission of a facility
- the particular characteristics of a facility or item
- the relative importance to radiological and nonradiological hazards
- any other relative factors."

The Canadian Nuclear Safety Commission's (CNSC)'s glossary (CNSC, 2022) defines graded approach as

"A method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with:

- the relative risks to health, safety, security, the environment and the implementation of international obligations to which Canada has agreed,
- the particular characteristics of a nuclear facility or licensed activity."

The three definitions have commonalities that basically describe grading the risks in relation to some advantage, such as efficiency or easier application, while staying compliant to safety requirements, i.e. ensuring that safety is not compromised due to grading. E.g. CNSC (2017) emphasizes, that grading is an application of requirements proportional to the risks, not a relaxation of requirements *per se*.

Graded approach is also alluded to in the Finnish Nuclear energy act Section 7a (The Nuclear Energy Act 990/1987, 1987), where it states: "The safety requirements and measures for ensuring safety shall be graded and targeted so as to be commensurate with the risks in the use of nuclear energy."

3. Methods of graded approach

3.1 Background

A methodology referred to as a graded approach is described across scientific literature, and is used widely in the nuclear sector. However, the graded approaches are somewhat different and do not use a formulated framework. Recently, IAEA has given guidelines on grading methodology in TECDOC-series for use of graded approach in management systems (International Atomic Energy Agency, 2014) and regulatory functions (International Atomic Energy Agency, 2021). Graded approach is closely linked to risk-informed decision making as a concept, and also the IAEA generic graded approach method briefly follows the integrated risk-informed decision making process. (International Atomic Energy Agency, 2011) Some national approaches to graded approach from the regulatory side, the IAEA graded approach, and examples of graded approaches in scientific literature are described next.

3.2 National approaches

The Canadian Nuclear Safety Commission has applied graded approach in risk-informed regulation (CNSC, 2017). CNSC applies risk-informed regulation by allowing proportionality and proposal of alternative methods to meet the regulatory requirements. The graded approach used consists of *a framework of decision-making tools and rules and is supported by an organization's management system* (CNSC, 2017), in the process, analyses that support the decision making are documented and overall the approach supports a transparent regulatory process. Outside design and safety analysis, the graded approach may also be applied to environmental characterization, elements of the management system like procurement, emergency response and planning programs, and research and development program.

When applying graded approach in design and safety analysis, there are several factors considered, such as reactor power, safety, fuel and source term characteristics, amount of fissile and fissionable material or other hazardous materials, uncertainties or lack of knowledge, or site characteristics like external hazards. The regulator in Canada considers the previous factors and technical requirements in *a risk-informed manner* to ensure the fulfilment of fundamental safety objectives. The technical assessment is carried out based on risk, complexity and novelty. According to the CNSC, the applicant or licensee may use graded approach to demonstrate that certain design or other measures are commensurate with the level of risks posed; to propose alternative methods to meeting requirements or to propose that a detailed requirement may not have to be met since an overarching fundamental safety requirement is met.

In any application of graded approach, the fundamental principles apply (CNSC, 2017):

- demonstration of defence in depth
- fulfilment of fundamental safety functions
- establishment of appropriate safety margins
- meeting the regulatory requirements.

In Finland, the Radiation and Nuclear Safety Authority (STUK) utilizes graded approach in regulation of radiation exposure (Bly, 2020), but also in oversight of nuclear safety. In general, graded approach is required in The Nuclear Energy Act, and in several regulatory guides on nuclear safety, for example in the context of management systems and security. There are also general principles STUK applies in the regulation of nuclear and radiation safety (Paajanen, 2015), that is based on the categorisation of inspection and oversight actions on the grounds of the risk-significance and safety class of the target of the inspection.

3.3 IAEA graded approach method

The IAEA methodology for applying a graded approach in regulating nuclear installations is shown in Figure 1 and has three steps (International Atomic Energy Agency, 2021):

1. Identifying the decision associated with the regulatory function,
2. Identifying and ranking the applicable factors,
3. Integrating the applicable factors into regulatory decision-making, including resource allocation.

The methodology is described in context of regulatory functions.

The first step is to identify the regulatory decision to be made. The form of the step depends on the regulatory function, which are regulations and guides, authorization, review and assessment, inspection, enforcement and communication and consultation with interested parties. For each regulatory function, key questions to identify the decision to be made are given as examples, e.g. for inspection whether the regulatory effort allocated for the inspection programme is commensurate with the risk associated with the item being assessed.

The second step is to identify and rank applicable generic and specific factors. Generic factors are typically the characteristics of the nuclear installation, such as the reactor power, radiological source term, type of fuel, the complexity of the installation, or the proven-ness of the technology. Also factors related to the location of the installation are generic factors. Specific factors depend on the decision to be made, and on the regulatory function. The ranking of the factors is based on the risk associated with the factor, and the impact of the factor. In practice the ranking is done using different qualitative and quantitative methods, like weighting factors and risk significance levels.

The factors are defined using many of the fundamental principles of nuclear safety, such as defence-in-depth, deterministic and probabilistic safety analysis, organisational considerations (management, leadership, human factors, safety culture), licensee performance history, operating experience and periodic safety reviews.

The third step is to integrate the applicable factors into regulatory decision-making. The information from the previous steps is available and usually the integration of the aspects is made by professional judgement of experts, to enable the decision-maker to make a risk-informed decision. The document

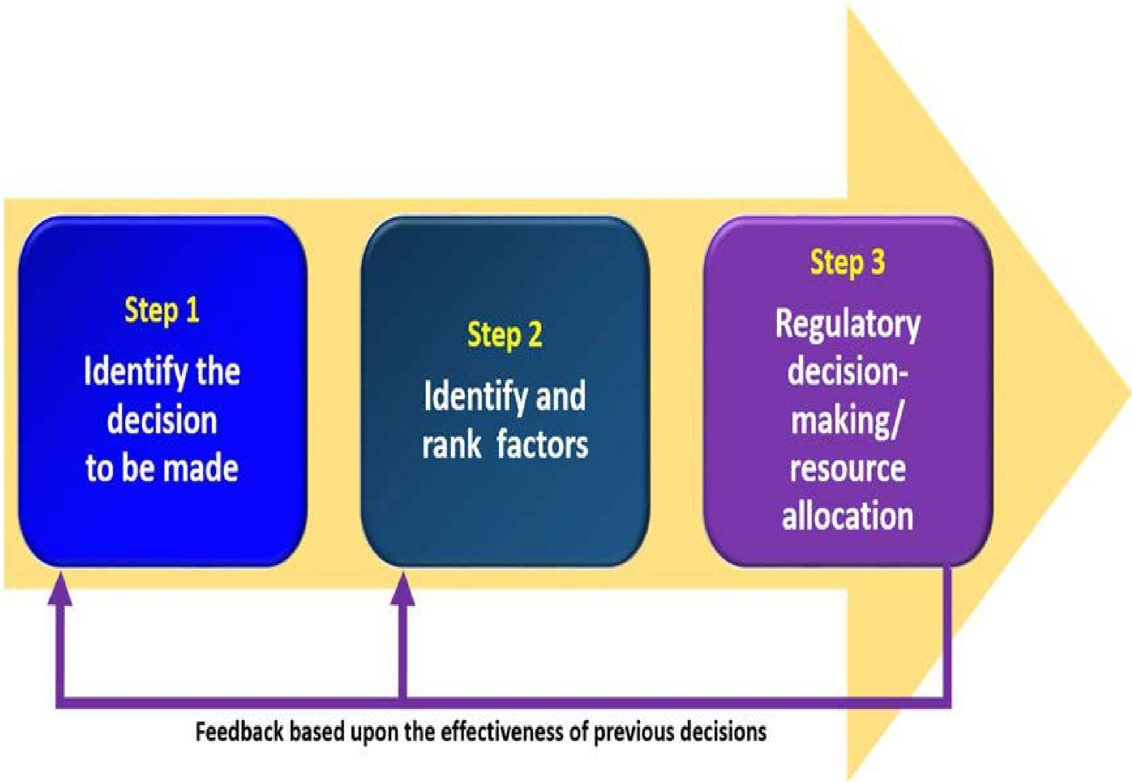

Figure 1: Steps 1-3 of the IAEA graded approach method (International Atomic Energy Agency, 2021).

(International Atomic Energy Agency, 2021) identifies, that typically the decisions to be made using graded approach are either regulatory decisions made as a result of the analysis, or decisions on allocation of resources and efforts to regulating the nuclear installation.

The IAEA approach is focused on the regulatory decision-making and does not give concrete examples of the use of graded approach in the design and operation of nuclear facilities. However, the main idea of the methodology may be well applicable also to design and operation of nuclear facilities. Some approaches in application areas extending outside regulation are described in the following section.

3.4 Application areas

Recently, use of a graded approach has made its way across different areas of nuclear safety and security. Besides nuclear power plant safety, overall safety includes other areas, such as security and radiation safety.

In terms of nuclear security, the use of graded approach is required for example by the Finnish authority STUK and in the U.S. by Nuclear Regulatory Commission (NRC). STUK defines in Guide YVL A.11 graded approach as:

> Graded approach related to nuclear security shall refer to a principle according to which the specification, planning and implementation of nuclear security takes into account the applicable threat assessment, the properties of nuclear materials and the potential consequences of unlawful action directed at nuclear materials and other action endangering nuclear or radiation safety. (Radiation and Nuclear Safety Authority, 2021)

According to YVL guide A.11, a risk-informed, graded approach is to be used to determine the need for protection at the facility and during transport. A risk-informed graded approach to security should also be used to classify the facility, as well as the nuclear material and nuclear waste. In order to utilize a graded approach for example in physical protection, the NRC requires the definition of areas with different security levels such as exclusion areas, protected area, vital areas and material access areas (United States Nuclear Regulatory Commission, 2020a).

In the area of radiation safety, graded approach is applied in categorization of radiation exposure. In Finland the exposure is categorization is 3-leveled and based on different effective dose in occupational exposure, public exposure and medical exposure. The categories are targeted with a different level of requirements, such as the necessity to use a radiation safety expert (Bly, 2020).

Recent applications of graded approach to nuclear safety include areas of safety like human factors and safety culture, decommissioning and waste management, research reactors, I&C, safety classification, radiation protection and maintenance activities. Some examples from the scientific literature are summarized next.

Ahn et al. (2022) have applied graded approach to safety culture attributes in the form of a frequency-difficulty matrix. The approach takes advantage of risk-informed grading, by weighting the difficulty of the safety culture attributes with qualitative and quantitative criteria. Braruud et al. (2019) have applied graded approach to human factors validation of control system and control room updates.

Basic concept of a safety evaluation method using graded approach is presented in (Kudo & Sugihara, 2021) in the context of decommissioning. The concept divides the severity of consequences of radiation exposure to public into three categories. Graded approach is also used to classify each object to be dismantled based on its residual radioactivity and expected accidents. The graded approach to safety assessment for decommissioning is also described in detail by IAEA (International Atomic Energy Agency, 2013).

Graded approach in waste management is described for emergency and legacy radioactive waste in (Fuzik et al., 2021). In design of radioactive waste and spent fuel facilities, a graded approach design categorization is suggested in (Stevenson, 2001).

Research reactors are one area that may benefit from a graded approach in many aspects of design and regulation, as many of the requirements of nuclear power plants are targeted to a different scale, purpose and system design (Park et al., 2013) of a facility. Suh et al. (2012) have applied graded approach in the design of I&C of a research reactor. In (Park et al., 2013), a graded approach has been applied to the cyber security of research reactor.

In management of maintenance activities (Eisa, 2021), (Ngarayana & Murakami, 2022), graded approach plays a role in the optimisation of resources, since maintenance activities often demand a lot of resources and employees. Graded approach has been utilised to assign resources commensurate with importance of the Systems, Structures and Components (SSCs). Maintenance strategies are applied based on the grade of the SSC. Also, safety classification of the SSCs is a graded approach activity.

4. Grading in management systems

Management system as a concept includes e.g. management and verification for safety, design, organisational control, training, qualification, operating procedures, records and reports. In the graded approach of management systems “the controls, measures, training, qualification, inspections, detail of procedures, etc. might be adapted to the level of risk or importance for safety, health, environmental, security, quality and economical aspects” (International Atomic Energy Agency, 2014), which in return will result in more optimally applied resources.

In Finnish YVL Guide A.3 on leadership and management of safety, there is a separate requirement of the application of a graded approach in management systems:

> The management system shall be developed and applied with consideration to the safety significance of the operation. The principles of observing risk-based decision-making and safety significance shall be described. (Radiation and Nuclear Safety Authority, 2019)

In the assessment of safety significance, complexity of the organisation and operation, uniqueness and novelty of the product or function and the resulting lack of experience and risks related to the plant or operation, including the probabilistic risk assessment (PRA), shall be taken into account. Also, the quality management procedures of products and services shall be conformed with consideration to safety significance (Radiation and Nuclear Safety Authority, 2019).

Since the graded approach is a framework of decision-making tools it is strongly supported by the organisation's management system in form of documenting the analyses that support the decision-making and supporting transparent regulatory processes (CNSC, 2017). The management system is necessary to provide instructions on when and how certain risk-informed tools are to be used, such as safety classification, safety analysis, process for review and approval of decisions, risk-informed decision-making process and work instructions. For tracing purposes, clear documentation of the decision-making process and reasoning is essential.

A graded approach could also be used as a management process, for example when grading the level of resources needed when defining a quality assurance program for example. The factors for the grading are not limited to only risks, but include aspects like cost, schedule, environment and public perception (Agarwal, 2012).

Management systems are just one example of the organisational considerations that should be accounted for in the framework of graded approach. For example, IAEA identifies organisational considerations that allow the regulatory body to analyse, identify, prioritise and select compliance verification areas and activities, when used in a risk-informed approach. The key elements include (International Atomic Energy Agency, 2021):

- programmes, processes and procedures whose failure may cause unreasonable risk to the health and safety of persons and the environment,
- individual awareness,
- knowledge and competence,
- commitment,
- motivation,
- supervision,
- responsibilities.

5. Risk-informed decision making

Risk-informed decision making (RIDM) and the principle of graded approach are closely linked, which is why RIDM is briefly covered in this section. In the early years of nuclear power plant operation, ensuring the safety of the plant was based mainly on deterministic safety analyses. Risk-informed grading takes advantage of quantitative and qualitative criteria, relying heavily on probabilistic risk assessment, see for example (International Atomic Energy Agency, 2020).

INSAG-25 (International Atomic Energy Agency, 2011), defines the goals of an integrated risk-informed decision making (IRIDM) process as a systematic process to integrate the major considerations affecting nuclear power plant safety. IRIDM should ensure all safety related decisions are optimised, without unduly limiting the operation. The process is based on similar nuclear safety considerations as the later IAEA approach to grading described in Chapter 3.3. These considerations and the flow of the IRIDM process are shown in Figure 2. The main idea of IRIDM is to provide a way to integrate the different considerations, such as deterministic and probabilistic analyses, as well as organisational and security aspects, in a single formal framework. Graded approach is used in the supporting analyses meaning 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" (International Atomic Energy Agency, 2020).

Risk-informed decision making should be based on the principles illustrated in Figure 3, i.e. meeting the current regulations, maintaining consistent defence-in-depth and safety margins, using risk-informed analysis and monitoring the performance of the risk-informed approach (United States Nuclear Regulatory Commission, 2020b).

The Finnish Radiation and Safety Authority aims for a "risk-informed and commensurable oversight" (Tiippana, 2019) and has in the recent years increased the use of risk insights in oversight activities. Risk-informed approach accounts for both deterministic and probabilistic views. For example, PRA has been used in risk-informed safety management for a long period of time. Benefits of a risk-informed approach are enhanced safety and operation, risk-informed allocation of resources, transparent support to decision making, more consistent and efficient regulatory decisions and reviews, and increased risk awareness and common risk concept for both the licensees and the regulatory body.

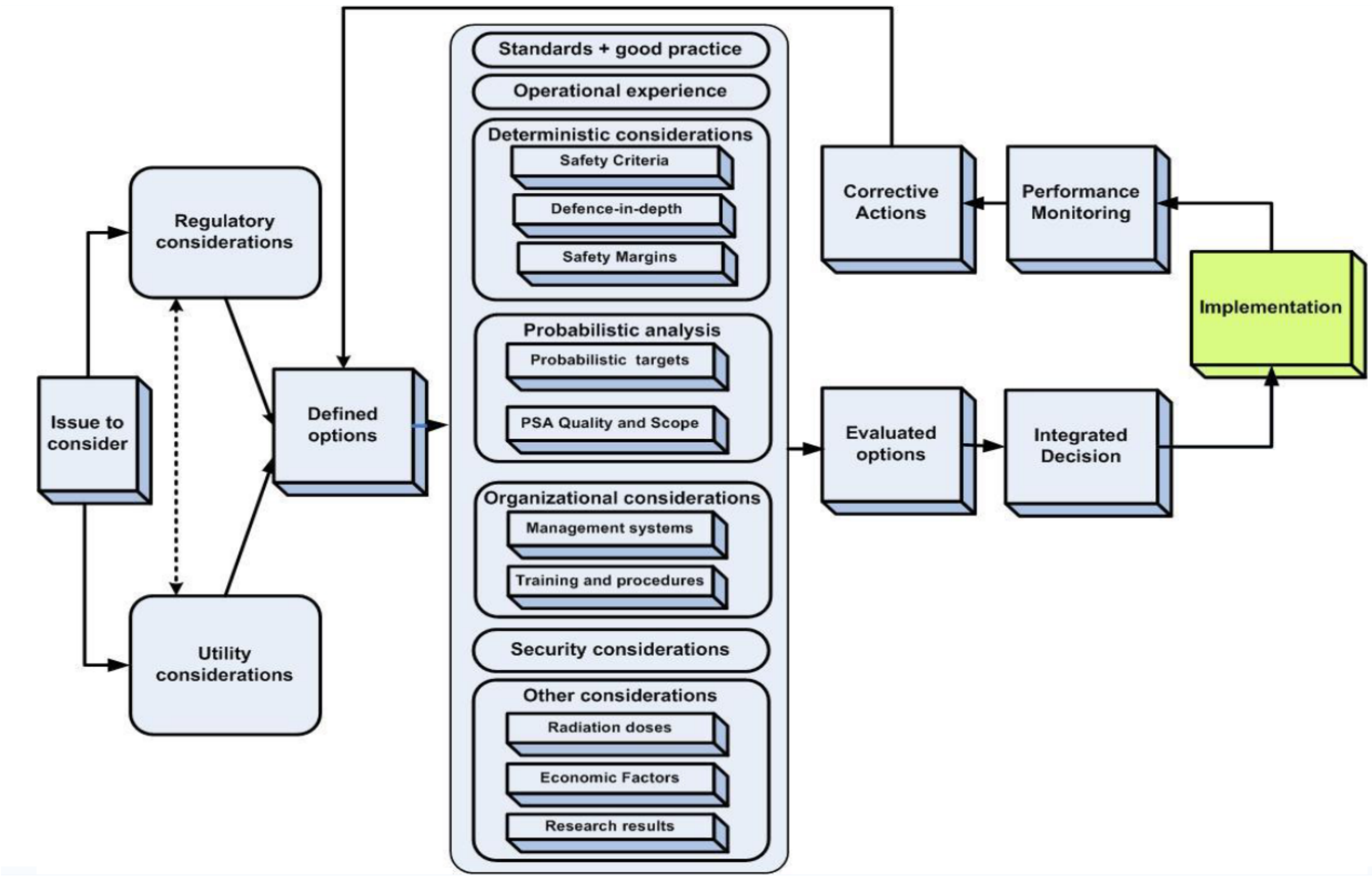

Figure 2: Integrated risk-informed decision making considerations according to INSAG-25 (International Atomic Energy Agency, 2011).

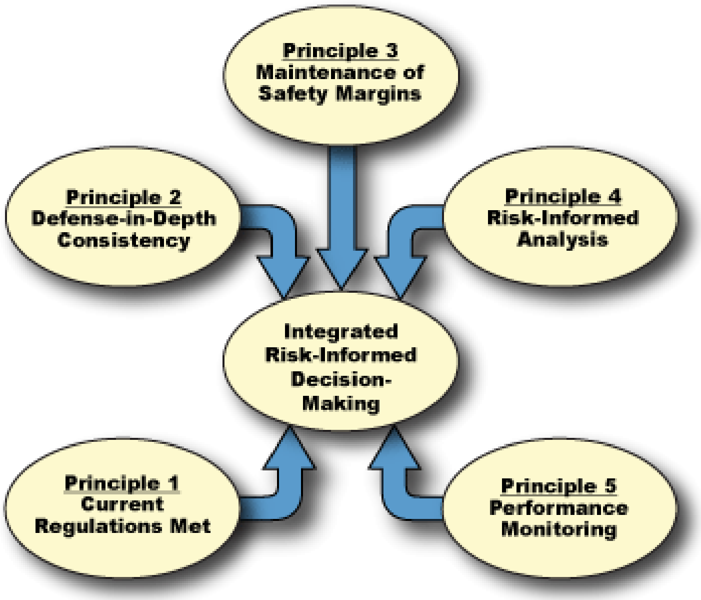

Figure 3: Key principles in implementing a risk-informed approach according to U.S. Nuclear Regulatory Commission (United States Nuclear Regulatory Commission, 2020b).

6. Discussion

Graded approach, the process of scaling actions and controls based on risk and complexity, is a way to allocate resources according to the risk-significance of different hazards. Optimally, one main benefit of graded approach is the clear and balanced use of resources while improving cost-effectiveness without negative effects in safety.

However, if the use of graded approach is inconsistent or the grading is done improperly, different issues might arise. Improper grading, such as imposing excessive requirements, or not imposing applicable requirements, can actually increase the hazard and costs (GIF Education and Training working group, 2021). Other difficulties in the use of a graded approach may be the inconsistent application of graded approach in different programs or parts of the organisation and use of different definitions, which makes communication and comparison of results more difficult (Agarwal, 2012).

The evolution of assessing nuclear safety has led from the early years of mainly using deterministic considerations to complementing the analysis with PRA and risk-informed approaches like IRIDM, and to the relying on graded approach as well. The graded approach in essence is a decision-making process that treats actions based on their risk-significance. For example the general graded approach method proposed by IAEA and the integrated risk-informed decision making process are based on the same high-level concepts.

An effective and formulated graded approach to safety eventually requires the use of multiple assessment approaches in an integrated way. If a graded approach is applied to the classification of items or activities (like classification of SSCs or selection of inspection, test and maintenance intervals), an outline of a risk-formed graded approach could be something like the schematic presented in Figure 4. Qualitative assessment of the importance of an item is based on the functional importance of an item with respect to the defence-in-depth concept (deterministic importance). Quantitative assessment of the importance of an item is basically assessed with PRA. Depending on the application there may be other criteria to be accounted for. Finally, when all items have been assessed, an overall assessment of the whole grading is needed.

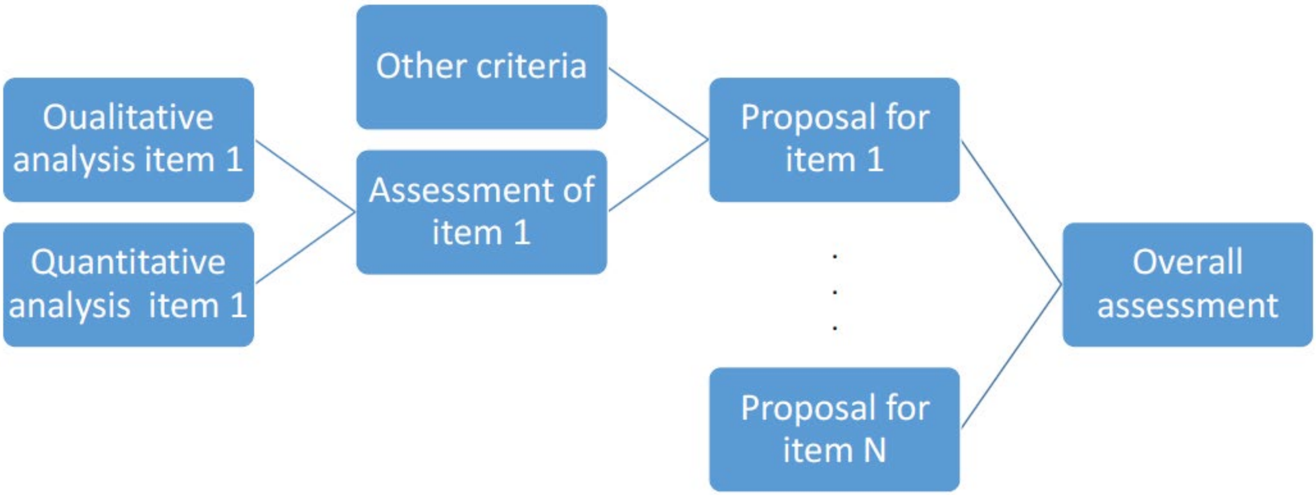

Figure 4: Risk-informed approach to grading.

The approach would need to be developed further by expanding the approach with considerations of organisational factors, e.g. management system characteristics in the first place, to achieve a better understanding of overall safety. In (Hyvärinen et al., 2022), the framework for an overall safety concept is presented. Comprehensive understanding of the factors that affect the overall safety of a nuclear power plant, including the management system characteristic and organisational factors in general, is necessary for effective safety management. Connecting the technical and organisational factors in the risk-informed approach to grading, would be one method to broaden the scope of the overall safety management. Detailed formulation of the approach to risk-informed grading and connection to the overall safety concept is one future development possibility.

7. Conclusions

This report has presented literature on graded approach to nuclear safety. The definitions, found in different sources, for the graded approach concept were found to be quite consistent. The use of graded approach is also required by multiple regulatory bodies in the nuclear industry. The methodology of using a graded approach was presented from the perspectives of Canadian and Finnish regulatory bodies and the IAEA. Examples of the application of graded approaches were listed from the scientific literature, with examples from e.g. human factors and safety culture, decommissioning and waste management, research reactors, I&C, safety classification, radiation protection and maintenance activities.

Management systems and risk-informed decision making were described and discussed in relation to graded approach. The management and verification for safety, design, organisational control, training, qualification, operating procedures, records and reports are areas of management systems that may also be graded to achieve balanced use of resources. Also, graded approach needs the support from effective management systems procedures to achieve a clear process of grading and the traceability of reasoning and decisions and documentation of analyses. Risk-informed decision making on the other hand is a process integrating different considerations, such as deterministic and probabilistic analyses, as well as organisational and security aspects, in a single formal framework. The high-level concepts of IRIDM have been the basis of the IAEA formulation of graded approach.

Graded approach in nuclear safety is so far still a concept that could be developed in more detail in order to achieve an integrated framework applicable to most situations and users. Utilising an integrated collection of methods and tools in a risk-informed graded approach would require firstly integrating technical aspects with the other areas of overall safety, such as organisational factors, first in the form of management system requirements.

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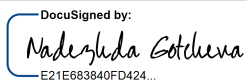
Nadezhda Gotcheva Nadezhda.Gotcheva@vtt.fi Research Team Leader Security Level: Email, Account Authentication (None), Authentication	 Signature Adoption: Pre-selected Style Using IP Address: 130.188.17.16	Sent: 18 January 2023 | 08:21 Viewed: 18 January 2023 | 10:23 Signed: 18 January 2023 | 10:23

Authentication Details

SMS Auth:

- Transaction: 66170FE5CD8019049190C879B97A15A8
- Result: passed
- Vendor ID: TeleSign
- Type: SMSAuth
- Performed: 18 January 2023 | 10:23
- Phone: +358 40 1326030

Electronic Record and Signature Disclosure:

Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	18 January 2023 | 08:21
Certified Delivered	Security Checked	18 January 2023 | 10:23
Signing Complete	Security Checked	18 January 2023 | 10:23
Completed	Security Checked	18 January 2023 | 10:23

Payment Events	Status	Timestamps