# Approaches and Methods to Conduct Regulatory Safety Review and Assessment

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IAEA
International Atomic Energy Agency

# Learning Objectives

After going through this presentation the participants are expected to be familiar with:

- Different regulatory approaches used for the development of safety regulations
- Advantages and Disadvantages of a particular approach or a combination of regulatory approaches

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# References


1. Safety Fundamental Principle SF-1
2. Governmental, Legal and Regulatory Framework for Safety, GSR Part 1
3. Safety Assessment for Facilities and Activities, GSR Part 4
4. Establishing the Safety Infrastructure for a Nuclear Power Programme, SSG-16


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# Contents



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# 1. Introduction

- The size, structure and resources of the regulatory body should be consistent with the regulatory approach to be adopted
- The size of the regulatory body depends upon whether the regulatory approach is “Prescriptive” or “Non Prescriptive”
- A prescriptive approach requires comprehensive regulatory guides prescribing detailed acceptance criteria to meet the regulatory requirements
- Ideally the regulatory approach should be decided in the early stages of planning

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# 1. Introduction

- Embarking country to make a conscious decision about the type of regulatory system that best suit its political, legal and industrial culture
- Ideally, the regulatory approach of an embarking country should be “design neutral”
- May have to be tailored to deal with:
  - the type of NPP chosen and
  - the regulatory approach in the Country of Origin.

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# 1. Introduction

- Key Considerations
  - Regulations are obligations on licensee to fulfill in order to get an Authorization
  - Embarking countries to take few fundamental initiatives in order to develop the regulations.
  - Developing regulatory framework involves maintaining a balance between prescriptive approaches and more flexible goal setting approaches
  - Expected top management  of the regulatory body should start developing awareness about the regulatory approaches in Phase-1

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# 1. Introduction

- **SSG-16 is the best "one stop" IAEA resource currently for regulatory body development, including regulatory approaches.**
- **Action 29, addressed in Phase 2, covers the regulatory approach to be considered by the regulatory body.**

*" the regulatory body should consider the various regulatory approaches that are applied for nuclear power programs of the same size, and should tentatively plan its approach, taking into account the State's legal and industrial practices and the guidance provided in the IAEA safety standards".*

- ***Prescriptive Approach***
- ***Performance Based Approach***

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# 2. Regulatory Approaches (1)

- What do we mean by regulatory approaches?
  - ✓ The way in which the regulatory responsibilities are discharged
- The main regulatory responsibilities as set out in IAEA GSR Part 1 are:
  - ✓ Licensing
  - ✓ Review and Assessment
  - ✓ Inspection
  - ✓ Enforcement
  - ✓ Production of Regulations and Guides
  - ✓ Communication with Interested Parties

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# Regulatory approaches (2)

- The Regulatory Approach used must be consistent and coherent across all the regulatory responsibilities

- For example: the approach to review and assessment must fit the licensing approach: inspection and enforcement must be allied to review and assessment.

- Though the functions are different, there must be close liaison between those personnel performing them: regulators have to assess the plant, assessors have to inspect the safety analyses!

**And similarly for the other functions**

# Implications of Regulatory Approaches (1)

Three basic regulatory approaches are **"Prescriptive", "Performance Based"** and **"Goal-setting"**

**What do they mean in practice?**

- The concept of "acceptance criteria" helps to understand the differences in these approaches

- Acceptance criteria are used in judging whether the results of safety analysis (in its widest meaning) demonstrate adequate safety: they can be;
  - numerical (quantitative) values,
  - set performance requirements (qualitative) or
  - demonstrate overarching goals (comparative criteria)

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# Implications of Regulatory Approaches (2)

***Types of acceptance criteria***:

a. Basic (high level) acceptance criteria (usually defined as limits by a regulatory body).
b. Specific acceptance criteria (chosen to be sufficient but not necessary to meet the basic acceptance criteria)
c. Licensee derived criteria to meet overarching goals

*NB Acceptance Criteria may be based on* "best estimate" *and/or* "conservative" assumptions

# Regulatory Approaches Basics (1)

*Prescriptive Regulatory Approach*

The regulatory body prescribes or approve the whole set of acceptance criteria (basic acceptance criteria, specific acceptance criteria and sometimes even analysis targets).

In this approach the regulator defines a series of safety requirements that the licensee must demonstrate are met

# Regulatory Approaches Basics (2)

## *Performance Based Regulatory Approach*

The regulatory body sets or formally approves the general (or basic high level) acceptance criteria and leave it to the licensee to set its own specific acceptance criteria in order to meet the high level acceptance criteria. This is an example of “Performance Based Regulatory Approach”.

In this approach the regulator requires the licensee to provide a demonstration that specified safety-related aspects are satisfactorily met

# Regulatory Approaches Basics (3)

## *Goal-setting Regulatory Approach*

The law sets safety goals and it is the responsibility of the licensee to demonstrate compliance to the regulatory body by justifying any design code or specific acceptance criteria or safety measure that it uses.

In this approach the regulator sets safety outcomes and the licensee must provide a suitable demonstration of adequate safety

# Examples of Regulatory Approaches

- US – NRC's Prescriptive Approach
- Finland - STUK's Performance-Based Approach
- UK – ONR's Goal-setting approach

# USNRC (NRC) Regulatory Framework (1)

NRC has developed its regulatory infrastructure in detail, particularly, regulatory requirements for commercial nuclear power plants keeping in view deterministic considerations.

In USA the safety regulations governing light water reactors are the most developed of all nuclear safety requirements, as they are formulated in terms of required systems and plant features

- e.g. a containment building, a redundant reactor shut-down system, and on-site electrical system, which are required to either prevent or mitigate a spectrum of prescribed accidents;
- e.g. specifications regarding spatial separation of redundant and component quality.

# NRC Regulatory Framework (2)

The existing regulatory literature is large and complex, consisting effectively of a long, fragmented checklist of requirements that safety-related systems in a plant must satisfy

At the top of pyramid, there is 10CFR (Code of Federal Regulations) which describes mandatory requirements

The regulations are sufficiently detailed to provide the licensee with enough information on the general safety objectives

eg The safety system design requirements, largely associated with the General Design Criteria of 10 CFR Part 50 Appendix A; design basis accident analysis guidance of 10 CFR Part 50.46 and Appendix K, directed towards demonstration of adequate design margins based upon defined acceptance criteria.

# NRC Regulatory Framework (3)

- The requirements lead to the imposition of special treatment requirements on key systems, structures, and components (SSCs) relied upon to satisfy requirements and/or mitigate postulated challenges to plant safety functions.
- In addition to special treatment requirements, numerous other prescriptive requirements are imposed on these SSCs in the areas of testing, inspection, and technical specifications governing operations.

**The key aspect is that:**

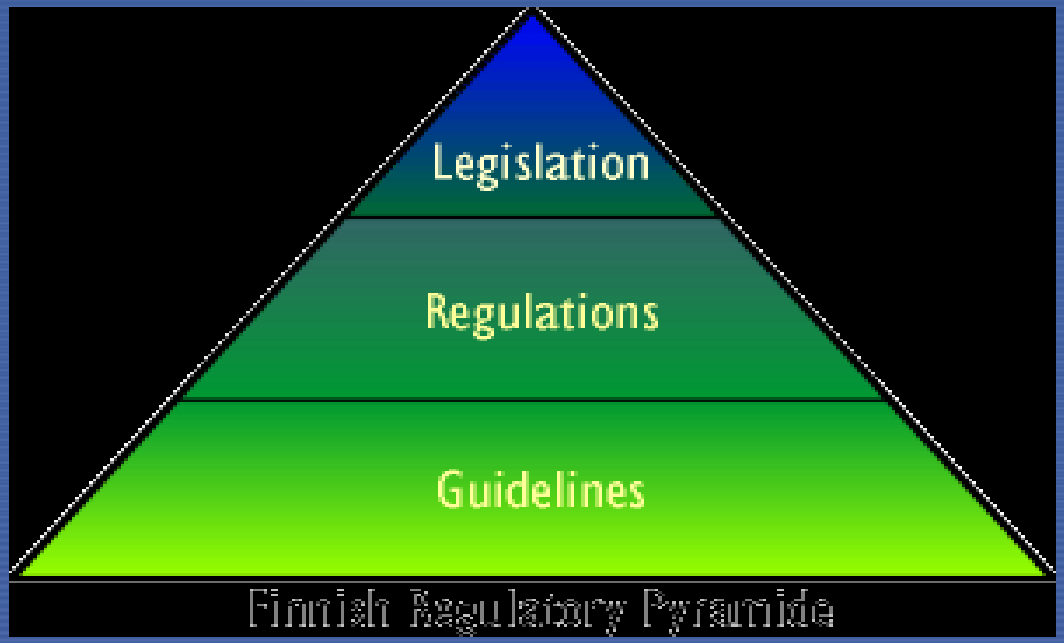
**compliance with regulatory requirements is deemed to provide reasonable assurance of adequate protection.**

# NRC Regulatory Framework (4)

- NRC regulations are supported by a complete set of regulatory guides which are well established and provide detail guidance on each specific requirement.
- NRC guides are not only useful for the regulators but also provide equal support to the applicant/licensee in order to meet the specific requirements.
- NRC RGs (Regulatory Guides) develop link with the industrial codes and standards which delineate the criteria minimally acceptable to NRC.
- In addition to NRC RGs, NRC also publish NUREG documents which provide further detail and guidance in order to implement certain requirements. These NUREGs are very helpful in understanding the complete requirement.

# STUK's Regulatory Framework (1)

STUK is the nuclear regulatory body of Finland
Its regulatory infra-structure can be viewed as a regulatory pyramid: at the top is legislation, then the regulations and then the regulatory guides.

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# STUK's Regulatory Framework (2)

- In Finland the regulatory guides (i.e. YVL) are also considered as mandatory and hence are treated equivalent to regulations.
- STUK's regulatory framework does not define a specific method to achieve any set goal by regulatory body.
- STUK provide full flexibility to the licensee to present its case on how the specific requirements will be met.

# Nuclear Regulatory Framework in UK (1)

**The fundamental law in the UK on Health and Safety in the UK is subject to the Health and Safety at Work etc Act 1974 (HSWA) and the overarching body is the Health and Safety Executive (HSE)**

**The Nuclear Installations Act (1965) [as amended] (NIA) covers Safety and Insurance aspects: the Safety part is a Statutory Provision of HSWA**

**NIA gives powers to HSE to add conditions to the licence**

**The Office for Nuclear Regulation [ONR] is the nuclear saf ety regulatory body of the UK and is an agency of HSE**

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# Nuclear Regulatory Framework in UK (2)

The HSWA requires:

- Employers to ensure the health, safety and welfare of employees;
- Risks to the health and safety of those not in their employ to be controlled;
- Designers, importers, manufacturers to ensure that use of their equipment will not cause risks to the health and safety to the users;

all these duties must be met

**So Far As Is Reasonably Practicable**

**(often the term used is ALARP)**

Licensees must demonstrate that they meet this goal

**The approach of HSE and hence ONR is "Goal-setting"**

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# Requirements for Demonstrating Reasonable Practicability

The fundamental test is to compare the sacrifice (money, time and trouble) of implementing a safety measure with the risk that would be averted by so doing. If the sacrifice is grossly disproportionate (ie much higher) than the risk averted, then implementation is not required.

Note that in the UK risk is defined as “the possibility of danger”, so does not rely on PSA. Indeed the main focus is on controlling the hazard.

The first stage is to consider whether there is “relevant good practice” that can be applied: if this not the case, or the system is complex with several overlapping “good practices”, a Cost Benefit Analysis is performed which may involve the use of PSA. To do this the consequences of an accident must be measured in monetary form, to compare with the sacrifice which must also be in the same form.

# 3. Prescriptive Approach

General Considerations:

- includes the detail specific requirements with acceptance criteria and spells out clear regulatory requirements.
- provides licensee a roadmap to comply the regulatory requirement and establishes detailed requirements for conducting specific activity.
- enables licensee to foresee that what is acceptable to regulatory body in order to get specific authorization.
- establish clear requirements and expectations for the regulatory body as well as for the operating organization
- use specific technical requirements which can be taken from relevant international industrial standards or industrial standards of other States

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# Prescriptive Approach

ADVANTAGES:

- provides both the regulatory body and the operator with clearly defined provisions for a particular activity or situation.
- prescribe the means and methods to be used in order to comply with regulatory requirements for achieving an adequate level of protection and safety.
- reduce the time and skills necessary to perform a licensing review or conduct an inspection.
- is also beneficial to regulatory inspectors for assessing the compliance
- can be used to promote systematic interaction between the regulatory body and other parties

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# Prescriptive Approach

DISADVANTAGES:

- More difficult to prepare and require detailed technical knowledge and expertise of the regulatory staff
- places a high demand on the regulatory body's resources for their development and updating, which adds to administrative burden
- leads to inflexibility which limits initiative in the licensee to strive for better performance;
- are based on vast industrial experience and are not easy to modify or replace
- May not be very helpful in developing and promoting safety culture
- Regulator can be seen as taking responsibility for the safety of NPP away from licensee

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# Prescriptive Approach

DISADVANTAGES:

- Narrowly applicable to a specific activity/situation and need to be regularly reviewed and amended as necessary to keep pace with technological changes
- Discourages other equal possible safer means to conduct a task and

***as a result***

- alter the attitude of licensee from ensuring safety to adhere safety requirements

*There is also a perception that such kind of approach shifts extra burden on the regulator regarding safety of installation*

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# 4. Performance Based Approach

- Specify primarily the overall safety objectives
- Allows for more flexibility in meeting safety goals
- Allowing fewer and less detailed regulations
- Would require high levels of professional competence of RB, TSO and operating organization to ensure that safety goals are adequately met
- Regulations need greater involvement by the operator in determining how objectives are to be met.

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# Performance Based Approach

ADVANTAGES:

- Comparatively easy to develop and are focused on what is to be achieved in terms of protection and safety
- Such regulations will not need to be changed so frequently to reflect changing technology or new knowledge
- Use of objectives will tend to promote continual safety related improvements and the search for better approaches by the operator
- Need greater involvement by the operator in determining how objectives are to be met *(safety is overall responsibility of Licensee)*
- Lesser administrative burden on the Regulatory body in assessing fulfillment of regulations.

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# Performance Based Approach

DISADVANTAGES:

- Can lead to inconsistency and sometimes wasted efforts
- Licensee is seen as clearly responsible for producing the safety arguments
- Required highly competent regulatory staff
- Verification that appropriate measures to ensure safety have been identified by the operating organization may be difficult unless the regulatory body's staff have a high level of professional competence
- Regulatory intervention is considered appropriate when these goals are not met rather than on degradation of safety

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# 5. Graded Approach

- SF-1, Principle 3: ‘ Leadership and management for safety’ states that ‘Safety has to be assessed for all facilities and activities, consistent with a graded approach.’
- GSR Part 4, Requirement 1: ‘Graded approach’ states that ‘A graded approach shall be used in determining the scope, extent, level of detail of the safety assessment consistent with the magnitude of the possible radiation risks arising from the facility or activity.’
  - And in determining the effort that needs to be devoted to the safety assessment carried out for any particular facility or activity.’

# Graded Approach

- SF-1, Principle 5: 'Optimization of protection' states that 'Resources devoted to safety and the scope and stringency of regulations have to be commensurate with the magnitude of the radiation risks.'
  - A graded approach needs to be applied in carrying out the safety assessments for the wide range of facilities and activities due to the very different levels of risk that they pose.'
- A graded approach is to be used the regulatory body in determining the scope, extent and level of detail of and the effort to be devoted to review and assessment with the resources that need to be directed to it.

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# Graded Approach

- GSR Part-1, Requirement 26: 'Graded approach to review and assessment of a facility or an activity.' states that

  'Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.'

  - The depth and scope of the review and assessment by the regulatory body shall be commensurate with the radiation risks, in accordance with a graded approach.
- The regulatory body shall assess all radiation risks associated with normal operation, AOOs and accident conditions, to determine whether radiation risks are as low as reasonably achievable.

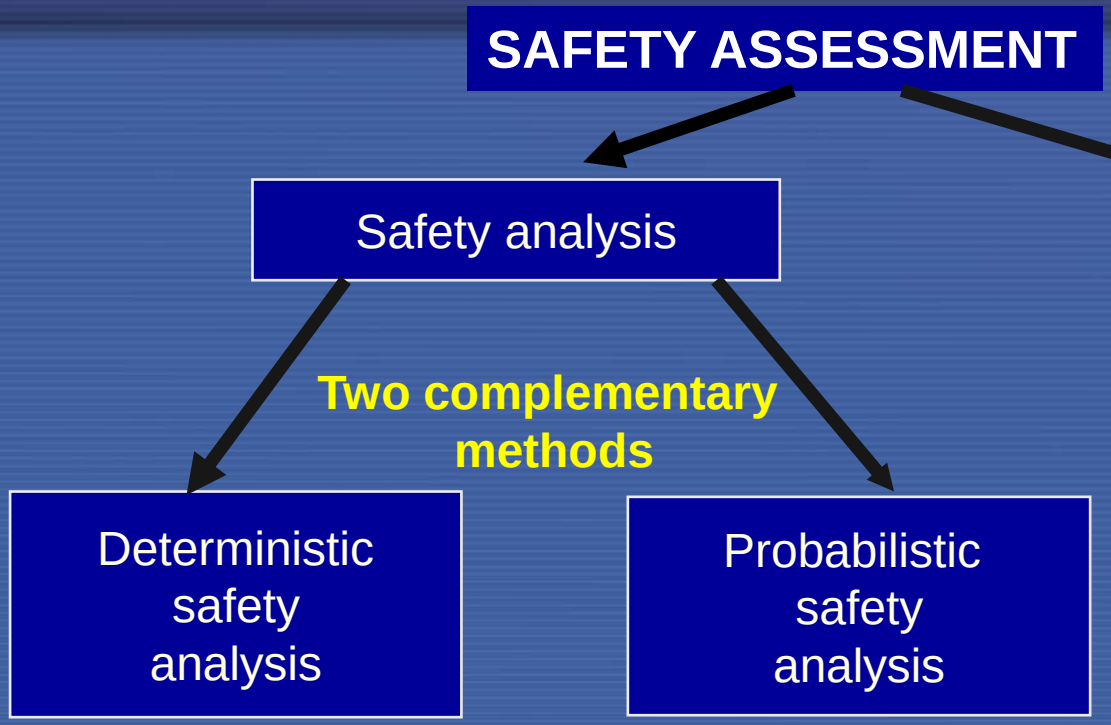
# Graded Approach

- The main factor in the application of the graded approach is the safety assessment has to be consistent with the magnitude of the radiation risks, to workers, members of the public and the environment, arising from the facility or activity.
- The approach also takes into account any releases of radioactive material in Normal Operation, AOOs, DBAs, BDBAs and Severe Accidents.
- A judgment then needs to be made as to the scope, extent, level of detail of the safety assessment, and the resources that need to be directed to the facility or activity. This should be agreed with the regulatory body.

# Graded Approach

- The graded approach to safety assessment shall also take into account other relevant factors such as the maturity or complexity of the facility or activity.
- The application of the graded approach shall be reviewed as the safety assessment progresses and a better understanding is obtained of the level of risk arising from the facility or activity, and the scope, extent, level of detail and the effort applied adjusted accordingly.
- The graded approach shall also be applied to the requirements for updating the safety assessment.

# 6. Deterministic and Probabilistic Approaches




- Proven engineering practices
- Defense in depth
- Radiation protection
- Protection against external hazards
- Selection of materials
- Single failure criterion
- Redundancy, diversity
- Equipment qualification
- Ageing
- Man-machine interface
- …..

**Predicts the response to postulated events with predetermined assumptions; checks fulfilment of acceptance criteria**

**Combines the likelihood of initiating events, potential scenarios and their consequences into estimation of CDF, Source term or overall risk**

# 7. Summary

- Prescriptive Approach
- Performance Based Approach
- Graded Approach
- Deterministic Approach
- Probabilistic Approach

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