Approaches and Methods to conduct Regulatory Safety Review & Assessment

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□ Fundamental safety objective (SF -1)

Protect people and the environment from harmful effects of ionizing radiation

- Achieved without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks
- So as to achieve the highest standards of safety that can be reasonably achieved
  - Control the radiation exposure and the release of radioactive material, restrict the likelihood of events that may lead to a loss of control, and mitigate the consequences
- Apply, the objective, for all facilities and activities, and for all stages over the lifetime

✓ *Balance between risks and benefits*

- Risk
  - Measure of the probability and severity of an adverse effect to life, health, property, or the environment

□ Conceptual criteria for balancing

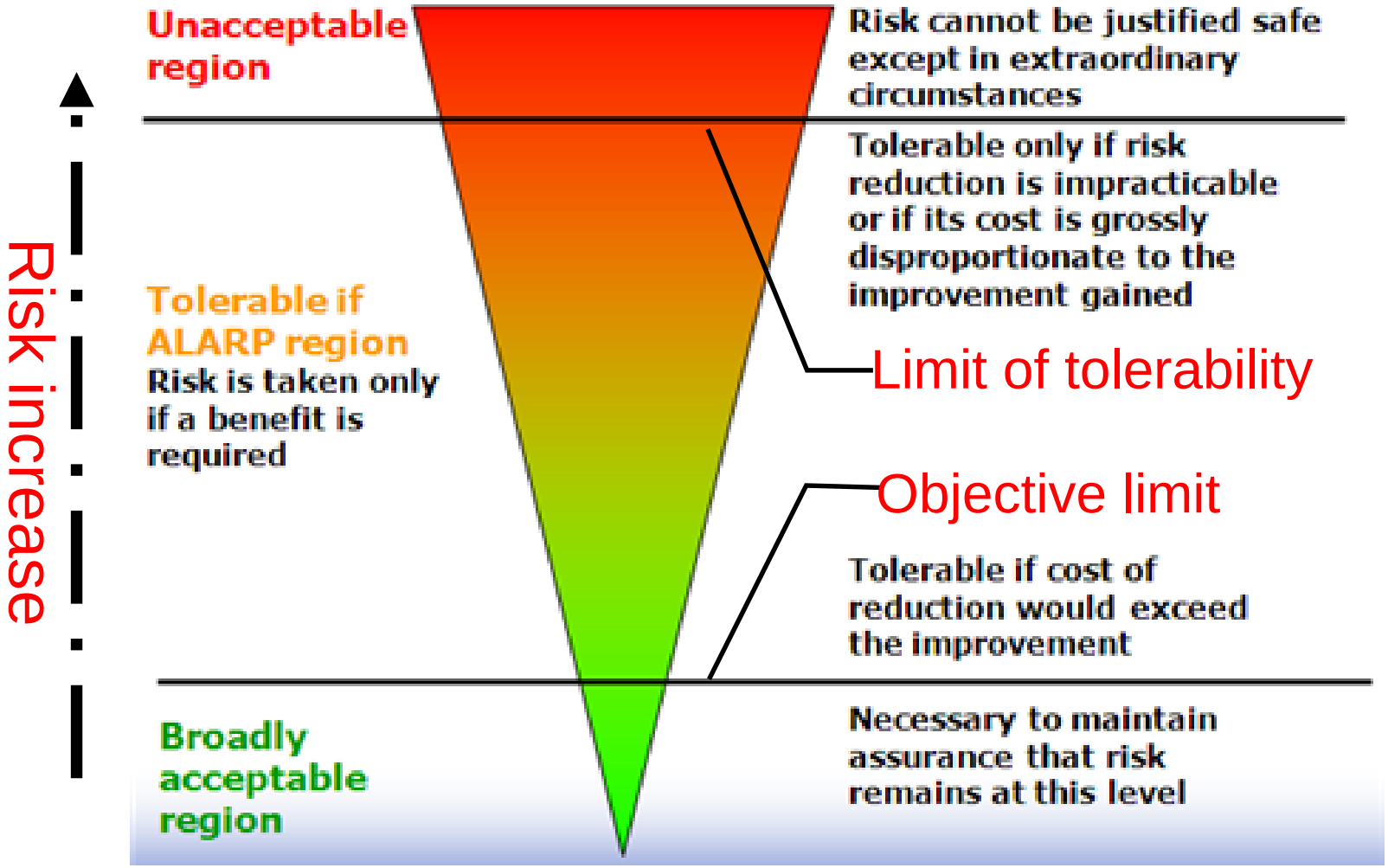
✓ *De minimis non curat lex*

- *Rule that the law will not remedy an injury that is minimal*

✓ De minimis risks

- Those judged to be too small to be of social concern, or too small to justify the use of risk-management resources
  - Those of too low a priority to regulate rather than the acceptable low risks
- Help set priorities for bringing regulatory attention to risk in a socially beneficial way
  - Further reduction of risks is a waste of public resource

□ Risk framework



- Unacceptable risks
  - Unacceptable whatever the benefits, unless they are reduced or there are exceptional reasons

- Broadly acceptable risks
  - Risks, which for the purposes of life or work, everyone who might be impacted is prepared to accept assuming no changes in risk control mechanisms
    - Regarded as insignificant and adequately controlled, and would not usually require further reduction
  - Individual risk of death of one (1) in a million per annum (10^{-6})
    - Boundary between broadly acceptable and tolerable regions

✓ Comparable to everyday risks faced by the general public

- Tolerable risks between the 2 regions
  - Risks within a range that society can live with (1) so as to secure certain net benefits
  - It is (2) a range of risk that we do not regard as negligible or as something we might ignore, but rather as something we need to (3) keep under review and (4) reduce it still further if and as we can
  - People tolerate for benefits, in the expectation that:
    - Nature and level of the risks are properly assessed and the results are used properly to determine control measures
    - Residual risks are not unduly high and kept **as low as reasonably practicable** (the ALARP principle)
      - ✓ The risk of harm has to be balanced against the cost of preventive measure, until the costs are grossly disproportionate to the safety benefits
    - Risks are periodically reviewed to ensure that they still meet the ALARP principle

□ Risks in legal systems

- Have implications for the significance of the limit of tolerability and objective limit

- Civil law based system (e.g. Netherlands)
  - Risk assessment is to demonstrate risk reduction to meet the **objective limit** with a high level of confidence
  - Give confidence the owner of risk that he met legal obligations to reduce the risk
    - If reduced risk to barely meet an objective limit and convince the regulator that has been done so

- Common law based system (e.g. UK, US, Australia)
  - Generally, tolerable risk as a goal for risk management
    - Ensure safety **so far as is reasonably practicable** (SFAIRP), to be as low as reasonably practicable (ALARP) or as low as reasonably achievable (ALARA)
    - Secure residual risk so that additional measures to reduce risk further are grossly disproportionate to the reduction
  - Limit of tolerability is a necessary but not necessarily a sufficient condition
    - ALARP is only defined retroactively as the result of a court judgement that considers whether or not the owner acted reasonably in all respects in a particular situation, and typically after a failure has occurred

✓ SFAIRP, ALARP, or ALARA as the conceptual tool for achieving nuclear safety
  - *Interpretation in each legal background?*

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1. Regulatory approaches (UK, BEIS R. Paper # 8)

□ Implications of regulatory approach

- Allocation of the responsibilities for risk
  - Goals-based regulatory (GBR) approach
    - Responsibilities of regulated parties (RPs) to ensure their actions in a way consistent with regulatory objectives
  - Rules-based regulatory (RBR) approach
    - Greater responsibility on regulator and policy makers to develop and enforce appropriate rules
- Impact on the incentives, and therefore behavior, of RPs, and ultimately on the achievement of regulatory objectives
- Enforcement approach and style of regulator, and the type of expertise and knowledge

□ Types of regulatory approach

- Principles-based and standards-based approaches
  - Involve behavioral principles: focus on moral or ethical values vs. measuring performance or conduct
- Performance-based and outcomes-based regulations
  - PBR, approach where RPs are directed to achieve, or avoid, a specific outcome related to a regulatory goal, or where a regulator sets performance goals for the outcome of behavior
  - OBR, focus on the achievement of specific regulatory outcomes
- Goals-based regulatory approach
  - Regulator sets out an objective rather than specifying precise rules
- Prescriptive regulatory approach
  - Traditional and based on compliance with specific and prescriptive rules

□ Shift away towards a more flexible GBR

- ✓ Different regulatory approaches and strategies create different incentives for RPs to act efficiently and to innovate
- ✓ Commonly require RPs to behave in ways consistent with open-textured & less precise regulatory directives
  - Goals, outcomes, targets or performance standards
- Incentive effects, allowing greater flexibilities for RPs
  - Result in beneficial innovation and more efficient outcomes
- Growing interest in alternative approaches
  - New governance, smart or meta-regulation, leading to a shift in regulatory responsibility from governmental actors to the non-governmental
  - Replace the traditional and rigid 'command and control' approach and fit the contextual circumstances

- Intuition behind GBR
  - Simple, compelling and unarguable in many ways
  - RPs should focus on complying with regulatory objectives and goals rather than on simply ticking off rules
- Political factors
  - Use GBR as a point of regulatory differentiation
  - Show signal that a regulatory system is mature, and works on the basis of principles, rather than applying a bureaucratic, one-size-fits-all prescriptive approach
  - Involve devolving responsibility for regulatory failures onto RPs

□ Conceptual differences between GBR & RBR

Factor	Goals-based	Rules-based
Degree of particularity or precision	Directives are generally imprecise and open-textured, leaving scope for interpretation	Specific and precise prescriptions for behavior
Who decides on content of provision	RPs interpret the goal and make judgments as to how best to comply with the goal	Those drafting the rule, such as a regulator
When is content determined	At the time the RPs interprets the goal and takes action	At the time of the drafting of the rule

Factor	Goals-based	Rules-based
Congruence with a regulatory objective	Encourages RPs to take actions and exercise judgements directly consistent with the regulatory objective	Assumed that the rule is congruent with the objective, and so if RPs comply with the rule the objective will be achieved
Enforcement approach	Investigate whether the RPs' actions are in consistent with the goal	Investigate whether the RPs has complied with the rule

□ Management-based regulation (MBR)

- Similarity with GBR
  - Shift away from prescriptive RBR-type strategy, towards a more flexible approach
  - RPs take more responsibility for ensuring that their actions are consistent with wider regulatory objectives
- Differences from GBR
  - Focus on the process, GBR on the achievement of goals or outcomes
  - Require RPs to engage in planning and internal rule making efforts to achieve regulatory goals
    - Focus regulatory attention on the planning stage
    - Direct RPs to engage in a planning process to be congruent with the regulatory objective
    - Place regulator as a ‘meta manager’ role that guides RPs towards actions for regulatory objectives

- Effective in circumstances
  - Where it is not possible to determine or monitor performance and achievement of outcomes or goals
  - where RPs are heterogeneous
  - ✓ Employed in the areas of food safety, environmental regulation, occupational health and safety, mine safety and railway regulation
- Application
  - Vary from minimal requirements on RPs to simply develop a plan
  - To more specific forms of oversight that require to develop plans according to various specific criteria as set out by regulator, or to submit plans to regulator for approval
- Enforcement
  - Regulator assesses whether RPs have prepared adequate plans and systems and are complying with them
  - No assessment of the outcomes of those plans or processes

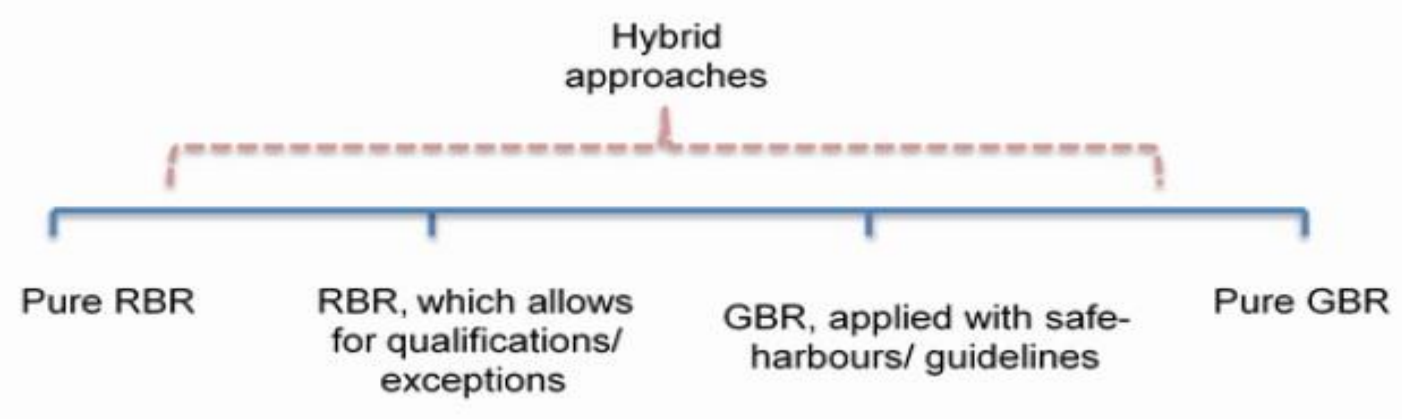
□ Relative advantages and disadvantages

Factor	Goals-based	Rules-based
Flexibility	Seen as more flexible	Less flexible
Predictability and certainty	More imprecise, and potentially less certain	More precise and therefore potentially more certain
Promotion of innovation	Seen to encourage experimentation and alternative approaches to compliance	Limited incentives to innovate in compliance
Equality	Seen to promote *substantive* equality	Seen to promote *formal* equality
Impact on approach and mindset of RPs	Requires RPs to be forward-looking and think through consequences of actions	Can result in a tick-box mentality developing

Factor	Goals-based	Rules-based
Uniform or differential treatment of RPs	Can allow for differential treatment of RPs based on compliance history or other characteristics	Formally treats all RPs the same
Ability to adapt to changes in environment/ market	More open-textured and therefore can be more adaptive to changes in the environment	Less adaptive to changes, rules can tend towards obsolescence, and require more rules to be introduced
Scope for regulatory discretion	Potentially significant scope for the exercise of regulatory discretion	Typically constrains the discretion of the regulator
Accountability	Devolves some responsibility to firms, and can create an accountability gap	Regulator is ultimately accountable for failures
Incentives for compliance	Can lead to over- or under-compliance depending on level of precision of regulation, and the risk profile of RPs	Can create incentives to 'game the rules' and engage in creative compliance

□ Various hybrid approaches, in practice

- Either more GBR-like or more RBR-like
- Spectrum between RBR and GBR
  - The distinctions are less clear cut, and the elements of each approach are combined



Approaches	Binding elements	Non-binding elements
Hybrid RBR	Rules	Regulatory goals statement, exceptions, qualifications to rules
Hybrid GBR	Goals	Guidance, safe-harbors, prior decisions, best practice requirements

- Benefits
  - Combine the positive attributes of each approach within a single regulatory strategy
    - Bring benefits by allowing for the limitations of each approach to be compensated by the benefits of the other approach
- Risks
  - Resultant combination of approaches risks being neither efficient nor optimal
    - Combination of approaches may not fully reap the benefits of either approach
- Good combination to yield the potential benefits
  - Depend on a range of contextual factors
  - **Balance may need to be refined over time**

✓ Refinements from RBR-based or GBR-based?

2. OECD principles of good regulation

- Serve clearly identified policy goals, and be effective in achieving those goals
- Have a sound legal and empirical basis
- Produce benefits that justify costs, considering the distribution of effects across society and taking economic, environmental & social effects into account
- Minimize costs and market distortions
- Promote innovation through market incentives and goal-based approaches
- Be clear, simple, and practical for users
- Be consistent with other regulations and policies
- Be compatible as far as possible with competition, trade and investment-facilitating principles at domestic and international levels

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□ Regulatory approach, in general

- The way in which RB performs their work
  - Fit into a legal system, customs and practices of the state
- Consistent with the size, structure and resources of RB, and the size and complexity of the projected nuclear programme
  - Approaches in states with large NPP may differ from those in sates with small programme
  - Approaches in states with a NPP vendor may differ from those in states that import NPPs
- Size of RB depends on the extent to which the regulatory approach will be “prescriptive” or “non-prescriptive”
  - Benefits and disadvantages of each approach
- Ideally, desirable to decide in the early stages of planning and in the form of “design neutral”
  - Tailor to deal with the type of NPP chosen and the regulatory approach in the country of origin

□ Prescriptive approach

- Analogous to the Civil Law System where cases are determined by reference to the books of code
- Expected standards from actual cases, experiments & simulations
  - What is "**reasonably practicable**" is decided for each situation beforehand, thus there is less need for expertise when applying standards
- Need expertise when standards are made in the first place

- General considerations
  - Include the detail specific requirements with acceptance criteria and spell out clear regulatory requirements
  - Provide licensee a roadmap to comply regulatory requirement and establish detailed requirements for specific activity
  - Enable licensee to foresee what is acceptable to RB in order to get specific authorization
  - Establish clear requirements and expectations for RB as well as for operating organization
  - Use specific technical requirements which can be taken from relevant international industrial standards

- Advantages
  - Provide both RB and 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
  - Beneficial to regulatory inspectors for assessing the compliance
  - Used to promote systematic interaction between RB and other parties
- Disadvantages
  - More difficult to prepare and require detailed technical knowledge and expertise of regulatory staff
  - Place a high demand on RB's resources for their development and updating, which adds administrative burden

- Lead to inflexibility which limits the initiative by licensee to strive for better performance
- Based on vast industrial experience and are not easy to modify or replace
- Not very helpful in developing and promoting safety culture
- Seen regulator takes responsibility for the safety of NPP away from licensee
- Narrowly applicable to a specific activity/situation and need to be regularly reviewed and amended to keep pace with technological changes
- Discourage other equally possible safer means to conduct a task
- Thus, **alter the attitude of licensee** from ensuring safety to adhere safety requirements

✓ Perception that shifts an extra burden on regulator regarding safety

□ Performance based approach

- Analogous to the Common Law System
  - What is "reasonably practicable" is decided for each situation on a case-by-case basis using the expertise and experience of specialists
- Determine the cases, based on previous cases, experiments and simulations
- General considerations
  - Specify primarily the overall safety objectives
  - Allow for more flexibility in meeting safety goals
  - Fewer and less detailed regulations
  - Require high levels of professional competence of RB, TSO and operating organization to ensure that safety goals are adequately met
  - Need greater involvement by operator in determining how objectives are to be met

- Advantages
  - Comparatively easy to develop and focus on what is to be achieved in terms of protection and safety
  - No need to change regulations so frequently to reflect changing technology or new knowledge
  - Tend to promote continual safety related improvements and search for better approaches by operator to meet objectives
  - Need greater involvement by operator in determining how objectives are to be met
    - Safety is overall responsibility of licensee
  - Lesser administrative burden on RB in assessing fulfillment of regulations

- Disadvantages
  - Lead to inconsistency and sometimes wasted efforts
  - Seen licensee is clearly responsible for producing the safety arguments
  - Require operating organization to identify appropriate measures to ensure safety
  - Require relevant organizations a high level of professional competence and interactions to determine whether established safety objectives for each topic are met
    - RB's staff, staff of its external support organization and staff of the operating organization
  - Regulatory intervention is considered appropriate when these goals are not met rather than on degradation of safety

□ Approaches with respect to the scope and depth of safety review & assessment

- Scope of issues under regulatory control
  - Include all structures, systems and components classified as safety relevant, or
  - Limited to the most safety relevant parts only
- Targets of comprehensive and systematic regulatory control
  - Specified in a deterministic manner, on the basis of a safety classification, or
  - Chosen on the basis of a probabilistic assessment of risks
- Depth of regulatory review
  - In some states, RB puts the main emphasis on the assessment and auditing of management system and the operations of operating organizations and their suppliers
  - In other States, RB prefers to make comprehensive independent analyses and inspections of its own

□ Use of the technical standards of vendor state

- Useful to learn from the earlier independent analyses and assessments of the technology in other States
- Give insights into the levels of quality achieved by key manufacturers and other suppliers
- Allow for better focusing of the auditing and evaluation of these organizations

□ Use of the regulations & standards of supplier state

- Used commonly in the past for the first NPP imported
- Advantage because the supplier knew in detail the requirements it had to meet
- Easy because of the criterion that such a plant was licensed in supplier state
- Disadvantage because regulatory approach should be aligned with the approach of the regulations adopted, and keeping abreast of all changes is difficult

□ Graded approach

- Leadership and management for safety (SF-1, P. 3)
  - Effective leadership - - - must be established - - - in - - - facilities and activities that give rise to, radiation risks
    - Safety has to be assessed for all facilities and activities, consistent with a graded approach
- Optimization of protection (SF-1. P. 5)
  - Protection must be optimized to provide the highest level of safety that can reasonably be achieved
    - Resources devoted to safety, - - - have to be commensurate with the magnitude of the radiation risks
- Graded approach to review and assessment of a facility or an activity (GSR P 1, R 26)
  - Review and assessment - - - shall be commensurate with the radiation risks - - -, in accordance with a graded approach
    - Depth and scope of the review and assessment - - - by RB shall be commensurate with the radiation risks

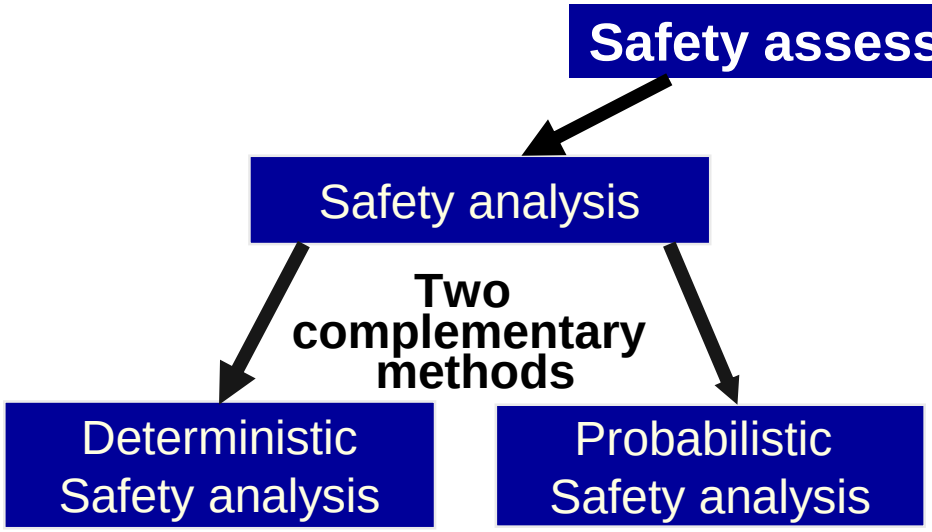
- Graded approach to safety assessment (GSR P 4, R1)
  - A graded approach shall be used in determining the scope and level of detail of the safety assessment - - - , consistent with the magnitude of the possible radiation risks - - -
    - Allow flexibility in the way that the possible radiation risks are assessed and controlled without unduly limiting the operation of facilities or the conduct of activities
    - Used in determining the scope and level of detail of the safety assessment - - -, and the resources that need to be directed to it
    - Items to be taken into account
      - Any releases of radioactive material in normal operation, the potential consequences of AOOs and accident conditions
      - Possibility of the occurrence of very low probability events with potentially high consequences
      - Maturity or complexity of the facility or activity
    - Reassess the application of graded approach as the safety assessment progresses and a better understanding is obtained of the radiation risks

□ Deterministic and probabilistic approaches

- Safety assessment
  - Assessment of all aspects of a practice related to protection and safety
  - Systematic process carried out throughout the lifetime of facility or activity to ensure that all the safety requirements are met
  - Include, but not limited to, the formal safety analysis

  ✓ *Safety analysis*
  - *The process and results of a study aimed at understanding the subject of the analysis*

  ✓ *Safety assessment*
  - *Distinguished from analysis, and include determinations or judgements of acceptability*



- While the assessment of engineering aspects important to safety may not be explicitly addressed in the safety analysis, it constitutes a relevant part of the safety assessment
- For some of these aspects, no well-defined acceptance criteria are available and therefore the assessment of the compliance with the safety requirements is based on good engineering judgement

- 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
- - - -

- Deterministic and probabilistic approaches (GSR P 4, R 15)
  - Both deterministic and probabilistic approaches shall be included in the safety analysis
    - Complement one another and can be used together to provide input into an integrated decision making process
    - The extent of the deterministic and probabilistic analyses - - - shall be consistent with the graded approach
- Deterministic approach
  - Specify and apply a set of deterministic rules and requirements for the design and operation of facilities or for the planning and conduct of activities
  - Provide a high degree of confidence that the level of radiation arising from the facility or activity will be acceptably low
  - Compensate conservatively for uncertainties in the performance of equipment and in the performance of personnel, by providing a sufficient safety margin

- Probabilistic safety analysis
  - Determine all significant contributing factors to the radiation risks arising from a facility or activity
  - Evaluate the extent to which the overall design is well balanced and meets probabilistic safety criteria
  - Use a comprehensive, structured approach to identify failure scenarios, in the area of reactor safety
  - Use realistic assumptions whenever possible and provide a framework for addressing many of the uncertainties explicitly
  - Provide insights into system performance, reliability, interactions and weaknesses in the design, the application of defense in depth, and risks
- Increased quality of models and data allows:
  - Develop more realistic deterministic analysis
  - Make use of information from probabilistic analysis in selecting accident scenarios

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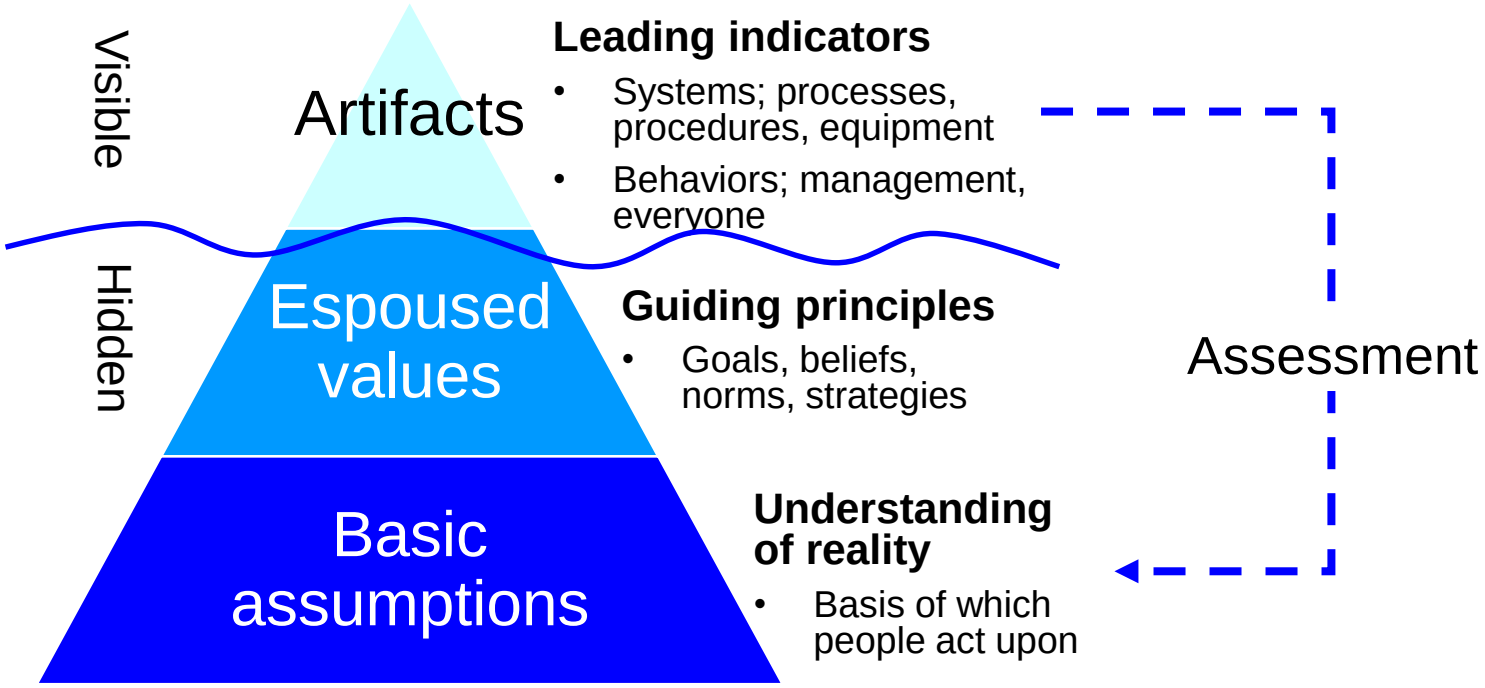
- **More GBR-like regulatory approach**
  - Provide a better conceptual background, given the nuclear safety standards well-developed
  - Create an environment emphasizing continuously the concept of balance between risks & benefits

✓ *Culture is a pattern of basic assumptions*

  - *Govern the visible artifacts*



Always we keep watching our Atomic Power

Thank You

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