IAEA
International Atomic Energy Agency
Atoms for Peace and Development

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P17. Risk informed regulations. Risk-informed oversight and enforcement

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Outline

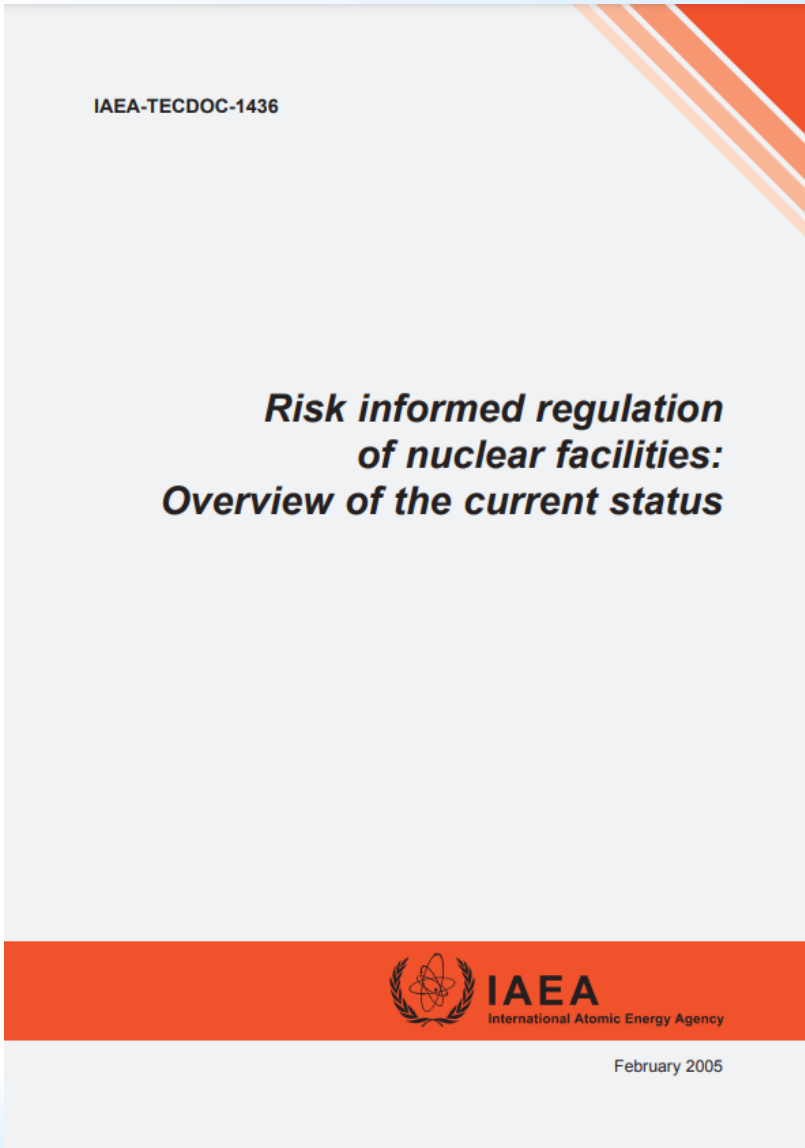
- Introduction
- Risk informed decision making
- Risk informed regulations
- Risk informed regulatory activities
  - Risk informed overtight
  - Risk informed enforcement

Intoduction

publication addresses the main elements of the risk informed, decision making process and provides guidance on how to implement the risk informed regulation concept.

The advantages and potential safety benefits from the implementation of ‘risk informed’ regulation are underlined.

The information provided could be of equal interest to utilities and regulatory bodies in IAEA Member States.



Introduction

The regulatory body is responsibility for effective control of nuclear, radiation, radioactive waste and transport safety within a country. To fulfil its obligations the regulatory bodies carry out a number of activities:

- reviewing and assessing submissions on safety
- making decisions on safety issues that arise at nuclear facilities
- establishing, promoting or adopting a regulatory documents, (e.g. regulations, guides, safety standards, etc.)
- carrying out site inspections
- issuing, amending, suspending or revoking authorizations
- carrying out enforcement activities
- reacting to incidents that occur at nuclear sites
- carrying out research and comparable activities.

The traditional approach to regulation has been based on a deterministic approach where a set of rules and requirements has been defined that is aimed at ensuring a high level of safety.

Introduction

Deterministic approach

In the early days of safety analysis the aim of the deterministic approach was to define and apply a set of conservative rules and requirements for the design and operation of a nuclear facility. If these rules and requirements are met, they are expected to provide a high degree of confidence that the level of risk to workers and members of the public from operation of the nuclear facility will be acceptably low.

The deterministic requirements are :

- Providing for defence in depth,
- Ensuring adequate safety margins,
- Applying the single failure requirement,
- Preventing common cause failure,
- Providing equipment qualification,
- Limiting the claims made on the plant operators, etc.

Introduction

Shortcomings of the deterministic approach

- deterministic approach has tended to look at infrequent, bounding fault conditions (e.g. large LOCAs vs small LOCAs)
- deterministic approach considers only approximate event frequencies and failure probabilities into account in an way so that it is not possible to show that this approach leads to a balanced design.
- For Identified shortfalls is not possible to determine which of the possible plant improvements would give the greatest reduction in risk and hence which of them need to be given the highest priority for implementation.

Although the deterministic approach has been refined over the years so that it now takes probabilistic information into account, it is widely recognized that the reliance on a deterministic approach on its own is unlikely to be sufficient to demonstrate that high levels of safety have been achieved in a way that is balanced across initiating events and safety systems. **This is done by probabilistic approach.**

Introduction

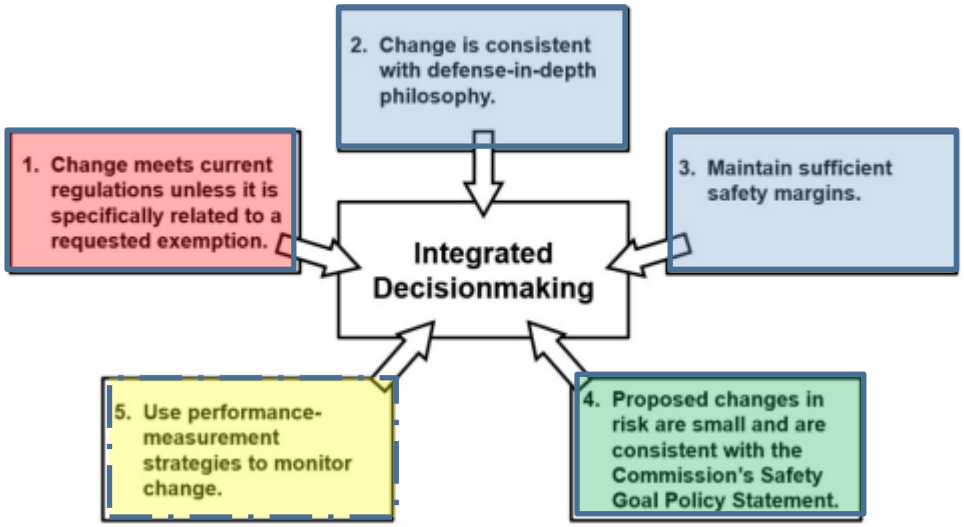
probabilistic approach

- Analyze comprehensive list of initiating events and identify all the fault sequences that could lead to core damage or a large earle release;
- The analysis determines quantitatively the level of risk from the plant;
- Provides importance of the initiating events, fault sequences and structures/systems/components included in the PSA model;
- Address parameter uncertainties;
- Perform sensitivity analysis;
- identify where improvements to the design and operation of the plant are needed to give the greatest reduction in risk
- the analysis can be used to determine the degree to which deterministic requirements such as the provision of defence in depth and the single failure criterion have been met;

Risk informed decision making

- Risk informed decision making process or integrated decision making process is a structured process in which all the insights and requirements which relating to a safety or regulatory issue that needs to be dealt with by a regulatory body are considered in reaching a decision.
- It includes the recognition of any mandatory requirements, the insights from the deterministic analysis, the insights from the probabilistic analysis and any other applicable insights.

Risk informed decision making



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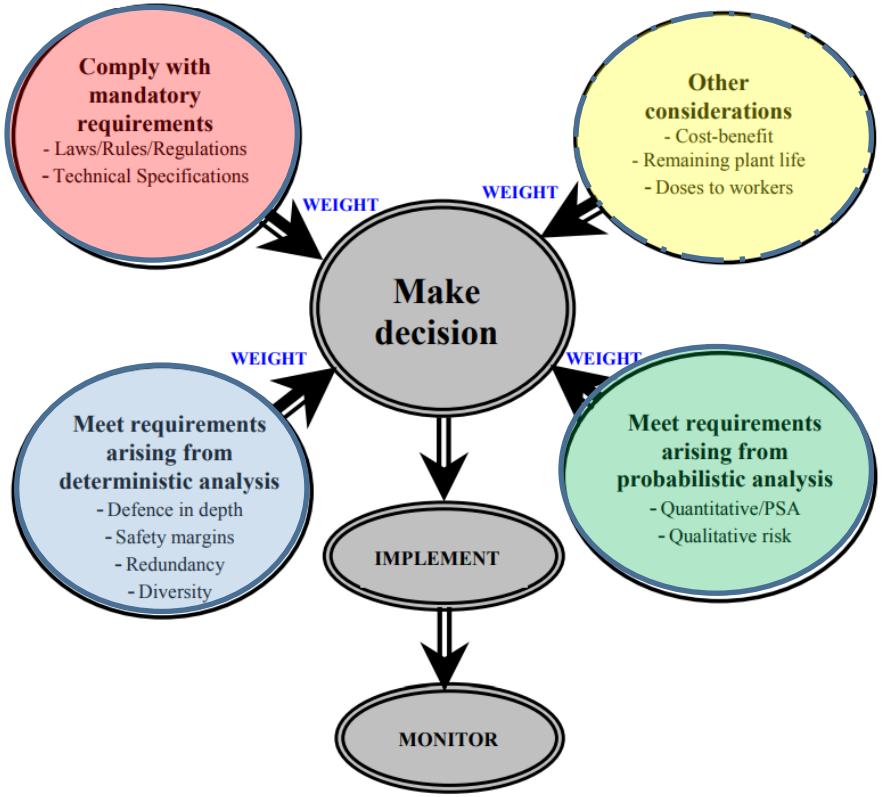

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Principles of risk-informed integrated decision making process.

Risk informed decision making

- Issues that can be addressed by an integrated decision making process related to the regulatory body activities include the following:
  - making changes to regulations;
  - planning regulatory inspections;
  - responding to incidents at a plant;
  - carrying out enforcement actions;
  - initiating and coordinating safety related research.

Risk informed decision making

- **Step 1: Defining the issue** to be addressed by the integrated decision making process.

- **Step 2: Identifying the requirements and criteria** related to the specific issue to be addressed.

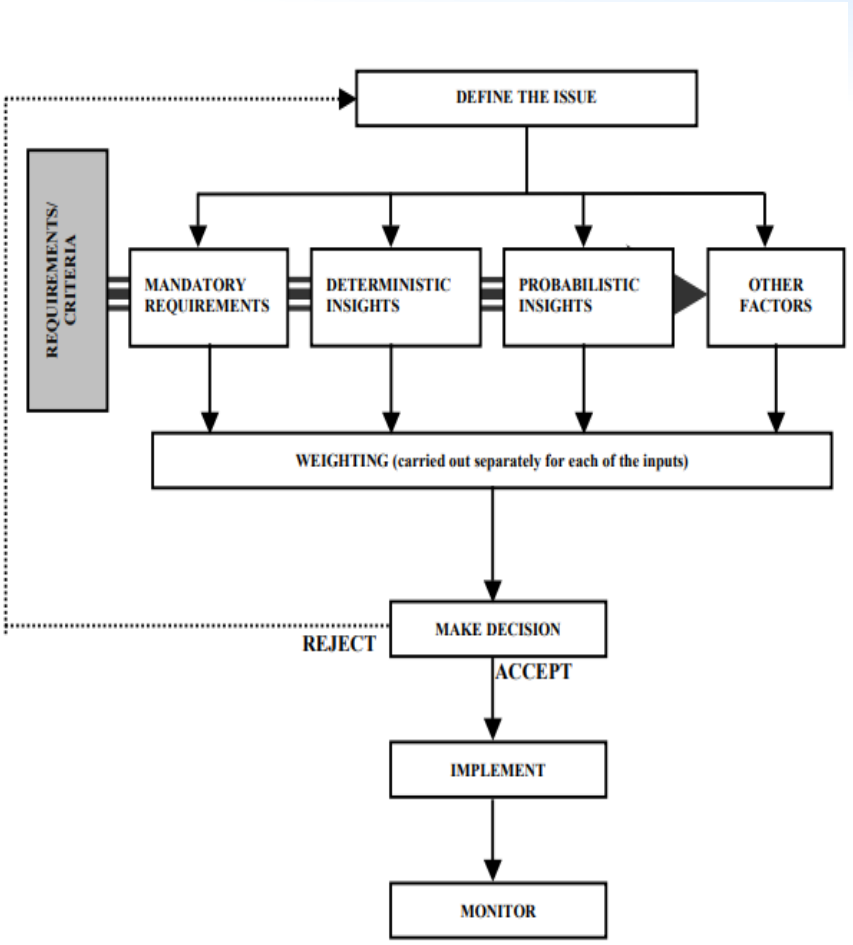
  These will usually include:

  – mandatory requirements

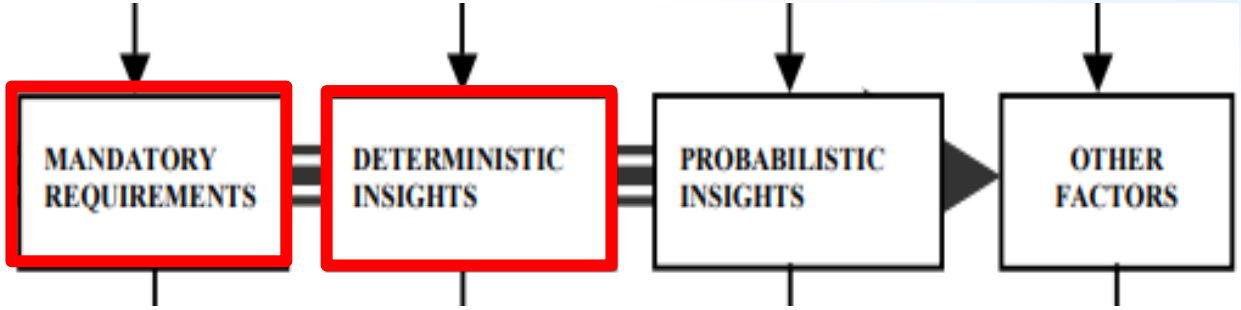
  – deterministic requirements

  – probabilistic requirements

  – other requirements



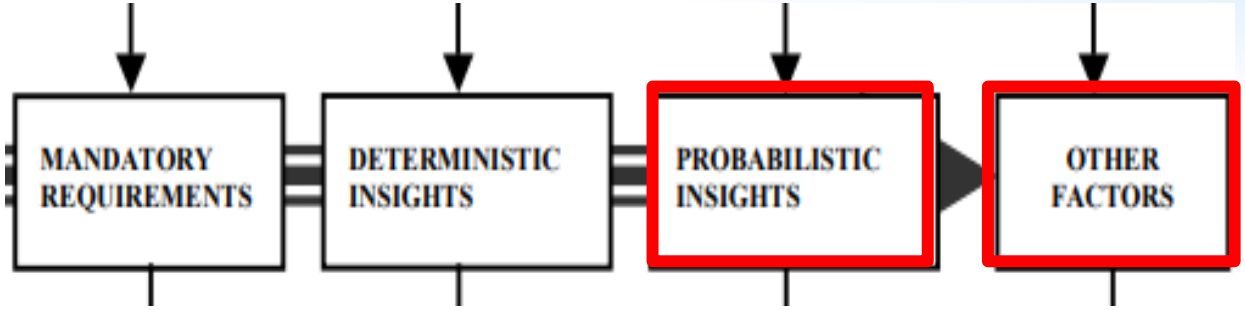
Risk informed decision making



Step 3: Determining how the proposed change affects the mandatory requirements a review is carried out to determine if there are any shortfalls in meeting any of the mandatory requirements identified in Step 2.

Step 4: Carrying out the assessment to get the deterministic insights on applicability of deterministic requirements identified in Step 2

Risk informed decision making

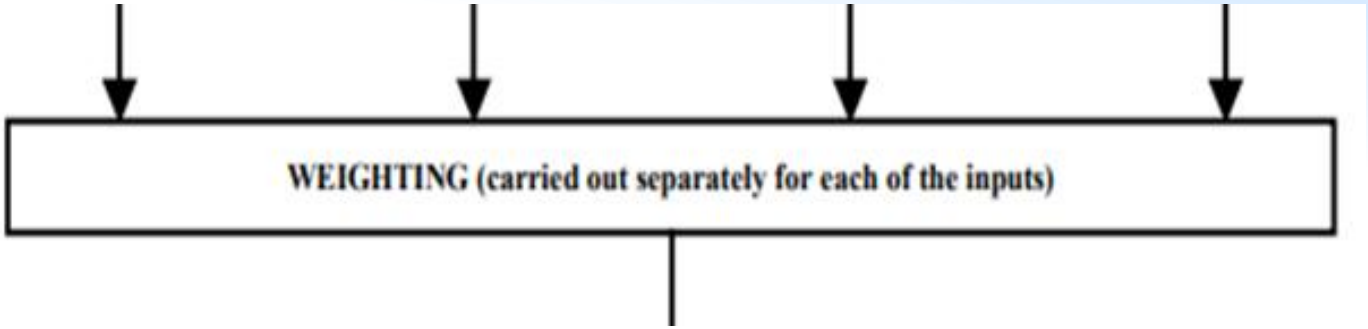


Step 5: Carrying out the assessment to get the probabilistic insights this refers to an assessment using the probabilistic criteria identified in Step 2 to determine the risk significance of the issue being addressed.

Step 6: Carrying out the assessment to gain insights from the other relevant factors the aim of this step is to generate the information required to address the other relevant considerations identified in Step 2. This could include:

- the doses to workers that would be incurred while carrying out the work to make any changes required to the design of the plant,
- the costs and timescales for carrying out the work
- Any adverse factors that could arise in making the change

Risk informed decision making



Step 7: Weighting the inputs from the assessments carried out this refers to determining the weight that needs to be assign to each input of the decision making process derived from Steps 3, 4, 5 and 6. Usually, insight relates to mandatory national legal requirements or to the need to meet established national practices, have the highest weight and will have to be observed.

If the deterministic and probabilistic insights are not in agreement, it is often the case that greater weight is given to the more conservative insight

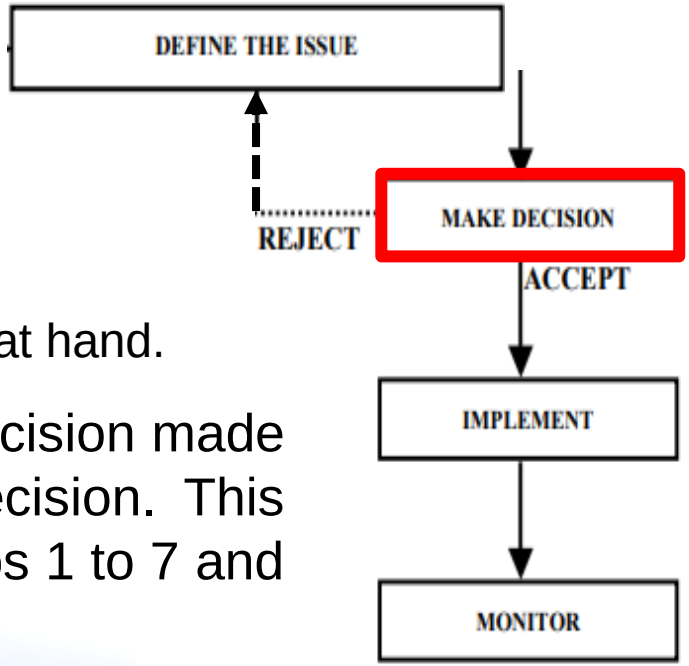
It should be recognized that there are significant national differences in the regulatory approach and the way in which plant safety issues have been resolved. In many countries, the regulatory approach has been based very strongly on the traditional deterministic approach, which would be difficult to change.

Risk informed decision making

Step 8: Making the decision refers to making a decision on whether the change (to the design or operation of the plant, the regulation under consideration, etc.) should be made. This requires consideration of individual insights and their associated weights.

It is good practice that (for major decisions at least) the decisions are made by a multidisciplinary panel. Based on the application at hand this would usually include expertise in:

- plant operation,
- maintenance,
- engineering,
- safety analysis,
- licensing and PSA, depending on the application at hand.



The final part of this step is to document the decision made along with the reasons for arriving at the decision. This needs to record all the inputs derived from Steps 1 to 7 and the weights assigned to these inputs.

Risk informed decision making

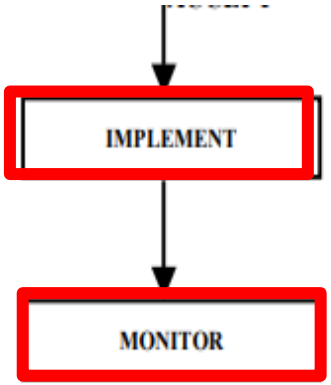
Step 9: Implementing the decision refers to implementation of the decision. For plant safety issues, this would require the regulatory body to approve the programme of work by the plant operators to make the necessary changes to the design or operation of the plant and the corresponding changes as required to items such as plant safety documentation, operating procedures and training.

Step 10: Monitoring the effect of a decision

Changes to the design or operation of a nuclear facility, a monitoring process would usually be agreed with the plant operators and this would be included in inspection activities by the regulatory body.

Changes to the way in which the regulatory body carries out its duties, a monitoring programme needs to be set up using appropriate performance indicators to determine whether the new activities are delivering more efficient and effective regulation.

changes to regulations, the performance of the regulatory body and the plant operators in implementing the new regulations needs to be monitored.



Risk informed decision making

- US CDF RISK ACCEPTANCE GUIDELINES

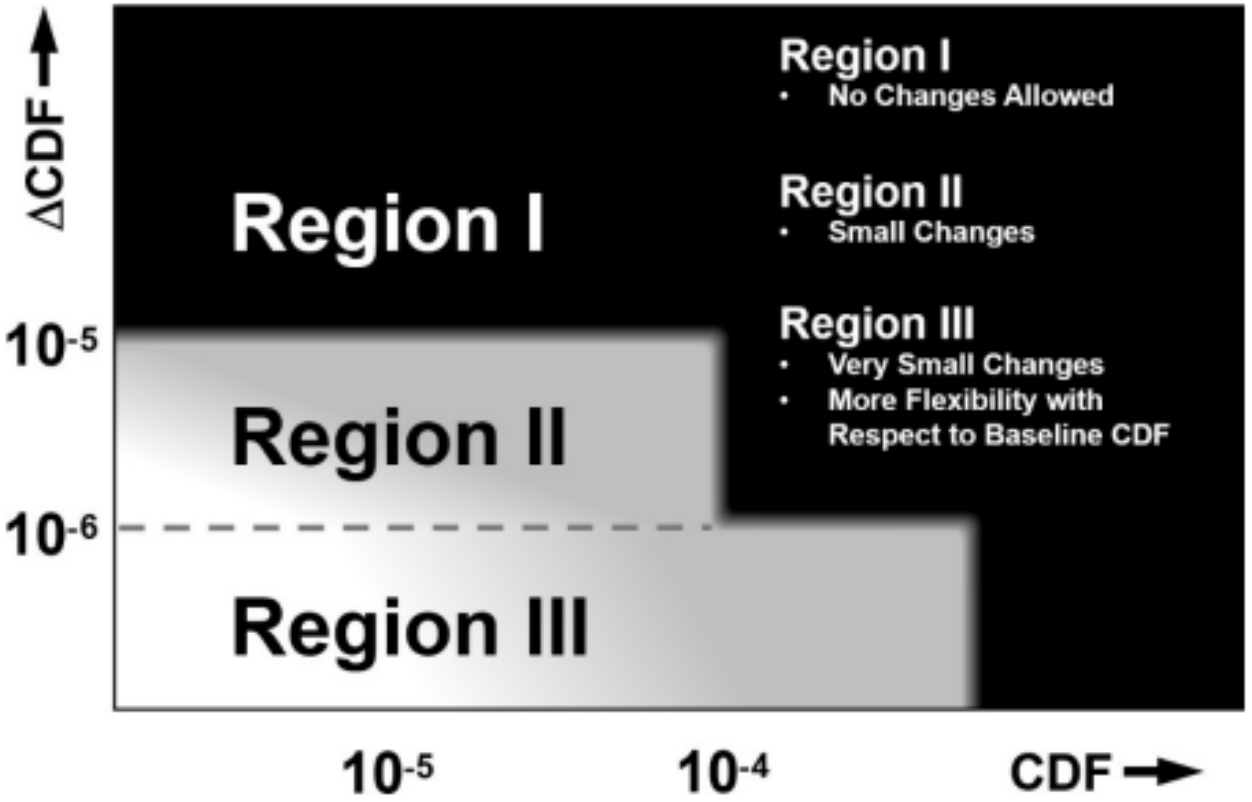


Figure 4. Acceptance guidelines* for core damage frequency

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Risk informed decision making

- US LERF RISK ACCEPTANCE GUIDELINES

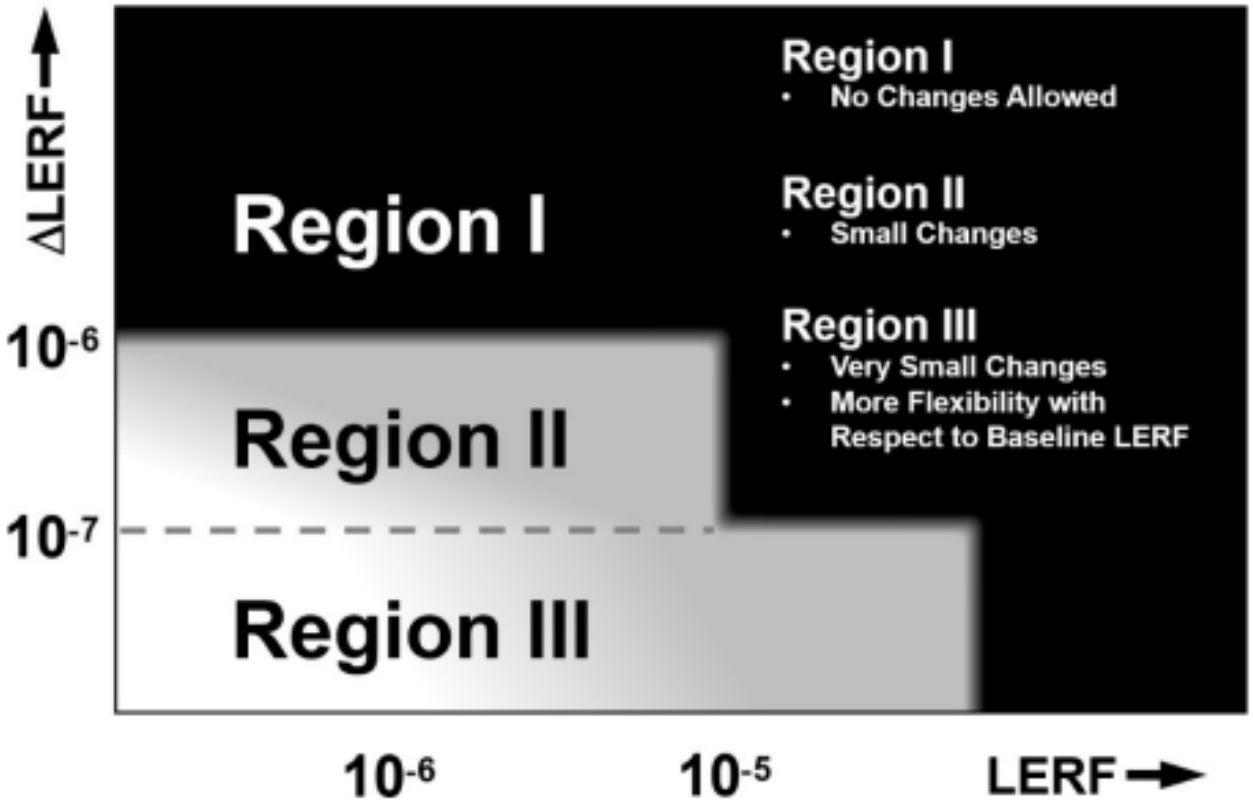

Figure 5. Acceptance guidelines* for large early release frequency

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Risk informed decision making

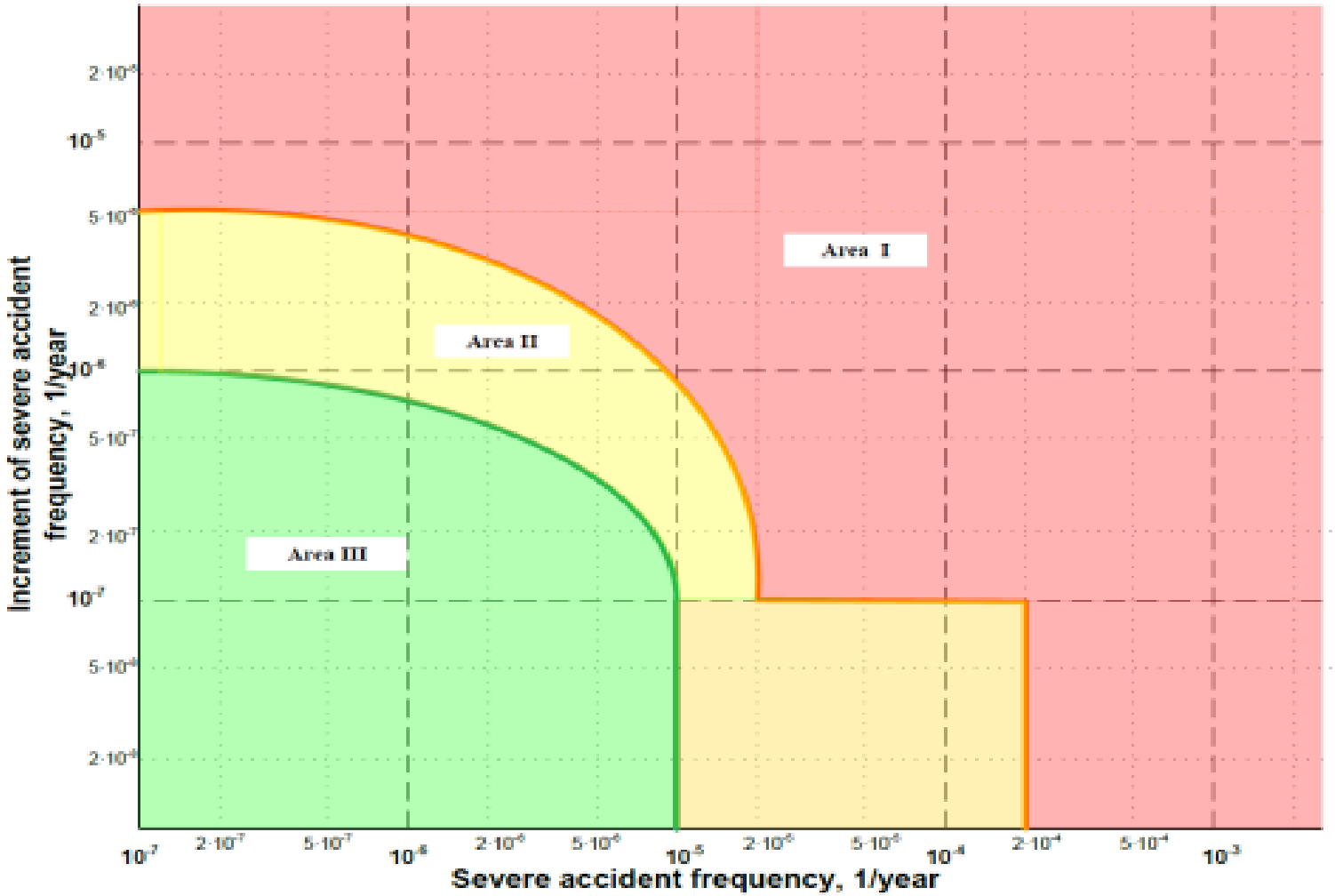


FIG. 15. Diagram of assessment of risk acceptability for a severe accident.

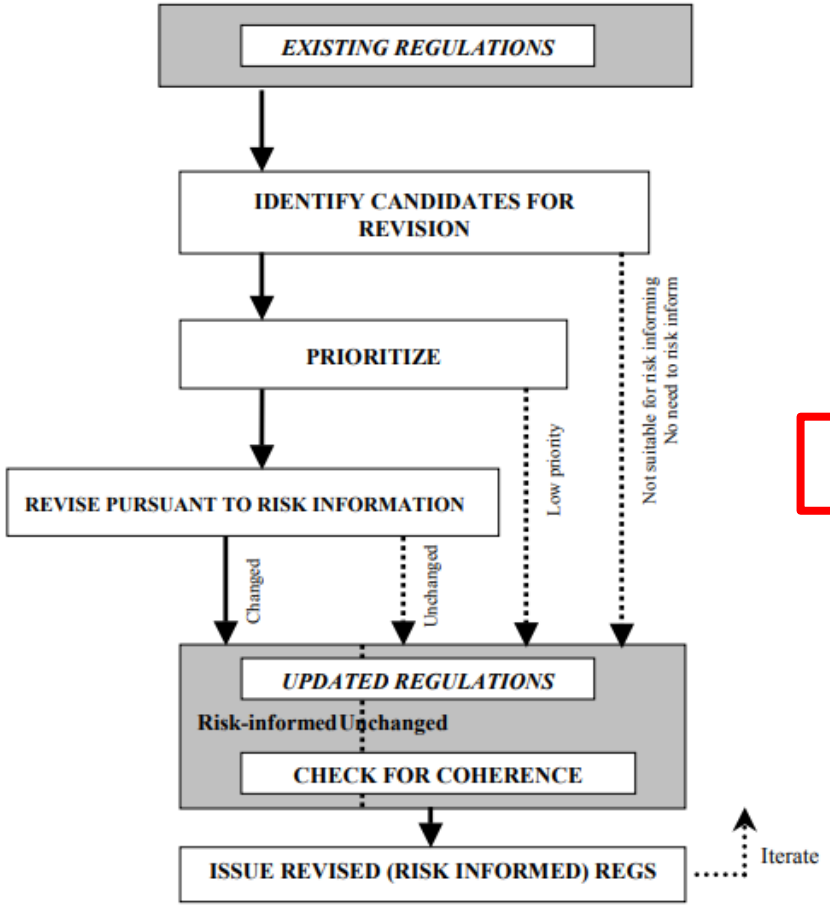
Risk informed regulations

- One of the most important responsibilities of a regulatory body is the establishment and updating of regulations and guides that form the basic structure for the regulatory process.
- that is, what benefit can we have from risk informed regulations? some of the benefits are:
  - Enhancing safety by focusing the work and the resources of the regulatory body and the operator in areas commensurate with their importance to health and safety.
  - Addressing more explicitly the broader set of challenges, as well as their associated uncertainties, identified from risk information.
  - Providing the regulatory body with a consistent structure for considering risk information when taking action in regulatory matters.
  - Etc.

Risk informed regulations

Step 1. — Identif informed”:

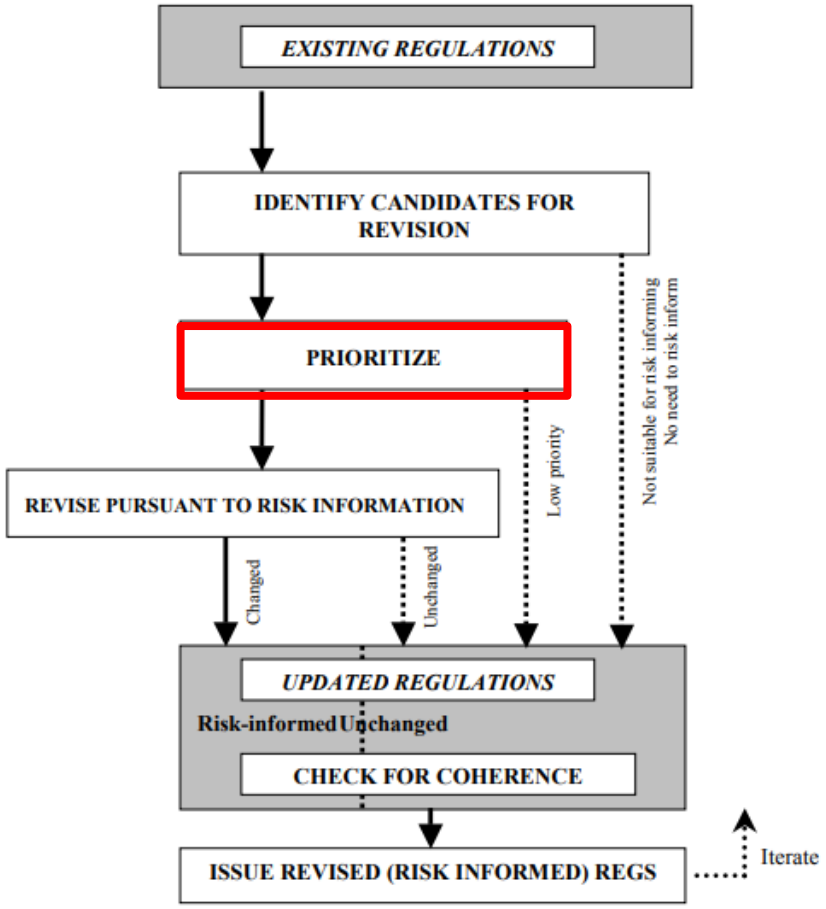
- The objective is aggregate set o for risk informe may involve requirements, or
- The identificatio regulations, that informed should such as:
  - the potential fo
  - the potential operator and/o
  - the extent to which risk information can be incorporated in the requirement



Risk informed regulations

Step 2. — Prioritizing:

- In this step, the candidate regulations and the identified requirements from the previous step are prioritized according to some criteria, such as:
  - the potential for improving safety,
  - the potential for reducing burdens for the operator and/or regulator, and
  - the expected complexity of changes
  - resources needed for putting changes in place
  - time needed for full implementation
  - application to current and/or future plants
  - the scope of the risk assessment that is required
  - Etc.



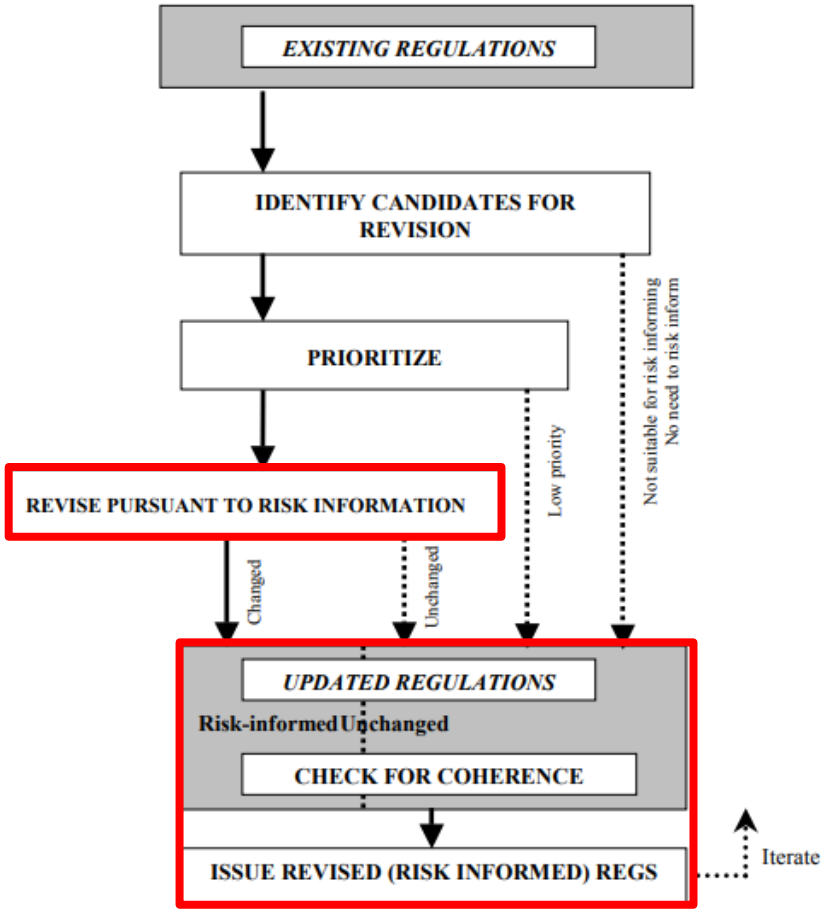
Risk informed regulations

Step 3. — Revision:

The aim is to carry out risk informed changes to individual (or a group of related) regulations.

Step 4. — Checking for coherence:

The final step when undertaking the ‘risk informing’ of the set of existing regulations is to check whether the resulting body of regulations is coherent and consistent.



Risk informed regulatory activities

Carrying out regulatory inspections

- Risk information is an obvious input to focus the emphasis of regulatory inspections on the most safety significant aspects of a plant, thereby optimizing the resources needed for the inspections.
- By using a risk informed approach is included as one of the inspection criteria, along with the usual criteria based on regulatory requirements and operational experience.

Risk informed regulatory activities

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Risk informed regulatory activities

Carrying out regulatory inspections

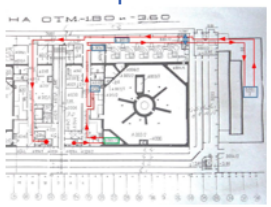
Risk-informed regulatory inspection

Implementing inspection and recording the observations:

- Communications during the inspection
- Inspector requests for additional information
- Discussion of observations with the licensee

In this process the presence of PSA specialist will be beneficial.

Updated the inspection checklists

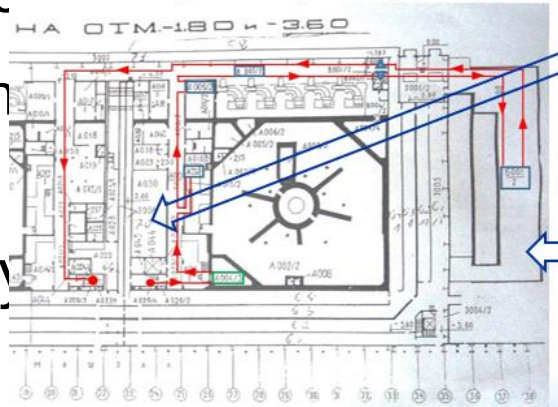


Risk-informed inspection routes

Risk-informed regulatory inspection

Inspection Planning

- Assigning components to corresponding compartments



Compartment 2

#	Component name	Importance
1	Component 1	Low
2	Component 2	Low
…	…	Low

Compartment 1

#	Component name	Importance
1	Component 1	High
2	Component 2	High
3	Component 3	High
4	Component 4	Medium
5	Component 5	Medium
6	Component 6	Low
	…	Low

may detract from the review of issues of potentially higher risk.

P10. Experience in use PSA for inspections, tests, and maintenance optimization

Risk informed regulatory activities

Corrective and enforcement actions

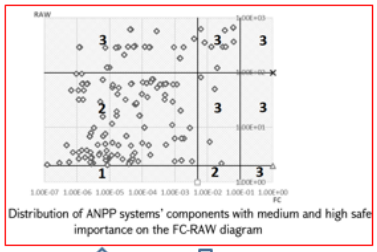
- Risk information can be a useful input for a regulatory body to determine whether corrective and enforcement actions that are proposed or implemented need to be taken and are adequate to address the concern identified.
- Using the risk informed helps the regulatory body to:
  - determine the significance of specific violations
  - provide a means of prioritizing enforcement actions,
  - Provide means of making the actions (including penalties imposed) commensurate with the seriousness of the violation.
  - determine the urgency for corrective action (based on risk significance)
  - Etc.

Risk informed regulatory activities

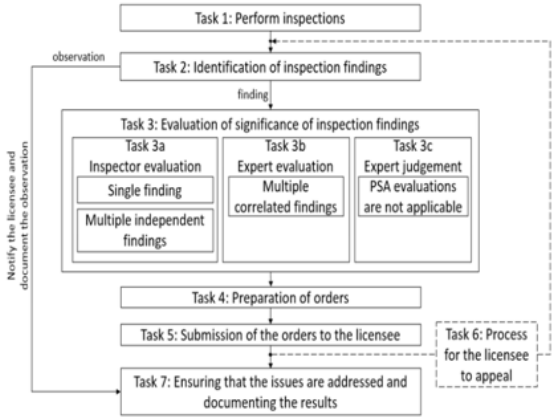
Corrective and enforcement actions

Risk-informed regulatory inspection

Finding evaluation:



Distribution of ANPP systems' components with medium and high safe importance on the FC-RAW diagram



PSA

Risk-informed regulatory inspection

- **Finding evaluation:**

Case	Hypothetic finding №	Hypothetic finding №	Hypothetic finding №	ΔCDF
1a	1	-	-	2.93E-07
1b	4	-	-	8.31E-07
1c	1	4	-	1.1E-06
2a	2	3	-	1.7E-06
2b	2	3	4	2.51E-06

Qualitative assessment is performed based on the evaluation of potential findings impact on:

- initiating event frequency;
- safety functions;
- potential consequences.

Finding significance	ΔCDF, 1/reactor×year	ΔLERF, 1/reactor×year
Very low	<1E-06	<1E-07
Low	<1E-05	<1E-06
Medium	<1E-04	<1E-05
High	>1E-04	>1E-05

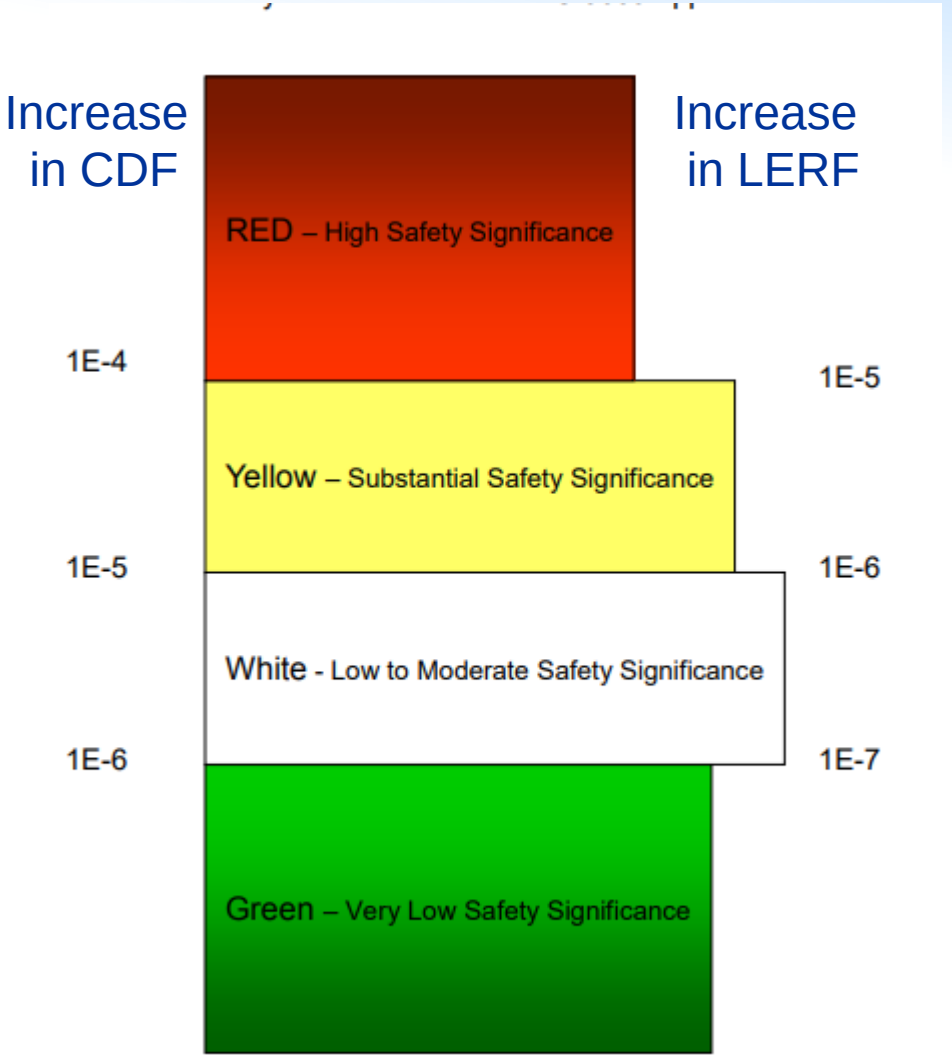
licensing conditions.

P10. Experience in use PSA for inspections, tests, and maintenance optimization

Risk informed regulatory activities

Example

- The NRC carries out independent inspections, the the violations are colour-coded based on indicators of risk. ‘Green’ is least risk significant while ‘Red’ is the most risk significant, immediate action are required.



Important !

- Importance of realistic PRA models in RIDM
  - *"… the use of best estimate models and data, as opposed to conservative assumptions, cannot be stressed enough. Conservatisms may provide a false sense of security. In fact, they are likely to distort the relative importance of accident sequences and, thereby, lead to potentially erroneous conclusions*."

    EPRI PSA Applications Guide (105396)
- PSA is about insights and knowledge, not about numbers.

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Thank you!