European Nuclear Installations Safety Standard

POSITION PAPER

3 Concepts:

Cost Benefit Analysis

Reasonably Practicable

Risk Informed

ENISS Common Licensee Understanding and Principles for a Successful Approach

October 2018

Introduction

In the design, construction, operation and decommissioning of nuclear installations clear communication and understanding of scientific and technical concepts and terms are essential. This document gives an overview about the ENISS common licensee understanding of the terms cost benefit analysis, reasonably practicable (as in "reducing risk as low as reasonably practicable"), risk informed, and related principles for application and improvement.

The IAEA Fundamental Safety Principles SF-1 states "The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation". To reach this general objective, ten fundamental principles have been formulated. The fifth principle states that "Protection must be optimized to provide the highest level of safety that can reasonably be achieved". Internal events or external hazards (associated with human activities or natural phenomena) present risks and are possible sources of harm to people and the environment. The term 'risk' needs to be considered in both the magnitude of possible harms and likelihood of occurrence. Safety is achieved by ensuring that risks are maintained as low as reasonably achievable. This means that measures to reduce risks should be applied unless there is a disproportion between the level of risk reduction and the effort needed to reduce it.

There is a wide range of ways in which national legislations describe, licensees apply and regulators accept these concepts and their associated methodologies. While in some countries risk informed, cost benefit analysis and/or reasonably practicable approaches are a legal and natural part of processes exercised by both licensees and regulators, in other countries these concepts are currently not promoted, supported or transferred in national regulations.

Sections 1, 2 and 3 describe the general understanding on the three concepts: (1) Cost Benefit Analysis, (2) Reasonably Practicable and (3) Risk Informed, while section 4 provides principles for a successful approach.

1. Cost Benefit Analyses (CBA)

Cost benefit analysis can be used to support projects at every step of their lifecycle, e.g. new build design, modifications, fuel management, life extension, decommissioning and waste disposal. By evaluating the safety benefit provided by a particular measure and its cost, this can verify the non-disproportionality of safety improvements in relation to the associated costs.

When evaluating different options for solutions or assessing a set of modifications in order to achieve a general goal, such an analysis can contribute to identifying the best options or prioritising proposals for safety improvements.

Cost benefit analysis is defined in several documents e.g. the IAEA Nuclear Safety Glossary as *"A systematic technical and economic evaluation of the positive effects (benefits) and negative effects (disbenefits, including monetary costs) of undertaking an action"*/1/. Numerous documents which describe methodologies and experience are available.

While in a minor number of the European countries cost benefit analysis is used or accepted by the regulator in the licensing process, in the majority of the European countries neither regulatory guidance nor comparable standards exist. Several licensees have developed and discussed internal guidance with their regulators, but no formal approval has been given so far. Cost benefit analysis is not continuously or consistently applied in the licensing processes, e.g. when considering modifications and during periodic safety review.

In principle, if a plant requires a design change in order to fulfil a certain safety requirement or if it is shown that a modification would provide a significant reduction in the overall risk then the cost would not be a sensible argument. However, the current safety level and the remaining lifetime of the plant are parameters to be considered in the assessment. Thus, cost benefit analyses are increasingly conducted to concentrate resources essentially on issues at stake, taking particular account of the safety level in place and the expected lifespan.

CBA approaches are also relevant for decommissioning where the risks can be much different from what they are during operation, and as they are evolving, often decreasing, all along the decommissioning process. Especially in some phases the activity at stake has a low radiological risk and the costs can rapidly become disproportionate.

As part of a continuous improvement in safety, modifications can be studied to reduce the gaps with safety objectives that apply to new reactors. A cost benefit analysis approach makes it possible to highlight those which will maximise the safety gains while controlling the cost of these developments (i.e. the most efficient safety improvements). In decommissioning the choice of a preferred scenario should be based on a multi-parameter approach involving safety and radioprotection but also waste management optimisation, industrial safety, stakeholders' acceptance and costs.

ENISS licensees support the need to create common principles and guidance that would be widely accepted by the European regulators.

2. Reasonably Practicable

"ALARA" is a familiar term in relation to the ICRP principle of optimisation of radiation protection: "all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account", ICRP 26. The following prime principle is also recalled in this publication: "most decisions about human activities are based on an implicit form of balancing of costs and benefits leading to the conclusion that the conduct of a chosen practice is "worthwhile". Less generally, it is also recognised that the conduct of the chosen practice should be adjusted to maximise the benefit to the individual or to society".

Normally the term ALARA is used in relation to radiological exposure.

In some countries, the term ALARP (as low as reasonably practicable) is used and the principle of reducing risk as much as it is reasonably practicable is applied to a wide range of plants or processes of potential harm. Similarly to the ALARA optimisation process, the ALARP approach can be based on a balance between costs and benefits, in order to characterise whether an evolution can be considered as "reasonably practicable" or not.

In several documents, e.g. from EU (Nuclear Safety Directive, article 8a) and IAEA (Vienna Declaration on Nuclear Safety, SSR-2/1 and 2/2) and WENRA (Safety Objectives for New Nuclear Power Plants and Safety Reference Levels for existing NPPs), the term "reasonably practicable" is used, but no explicit harmonised definition or interpretation is provided. In the EU Nuclear Safety Directive this term is used for the definition of improvements to existing nuclear power plants. It should also apply to decommissioning activities.

WENRA guidance paper on "Timely Implementation of Reasonably Practicable Safety Improvements to Existing Nuclear Power Plants"/2/, published in June 2017, proposes an understanding of reasonably practicable safety improvements. However, objectives, rules and criteria should be introduced in order to be more explicit and facilitate the applicability of this concept.

In the WENRA guidance paper mentioned above, the term "grossly disproportionate" used when determining whether a proposed measure is not reasonably practicable would require further explanations. It is commonly considered that measures enabling to avoid large releases should be prioritised. As such, the concept of "gross disproportionality" between the measures taken and the associated safety benefits depends on the type of releases that is involved.

While in some countries "reasonably practicable" is a regulatory term which serves a special purpose in the licensing process, in other countries regulators currently do not use, promote or transfer this term in their regulatory processes or documents.

In the UK, health and safety laws are all based on the principle that an employer must protect both its workers and the public from any harmful effects that the business may cause. Operators of nuclear facilities in the UK are required to comply with the Health and Safety at Work (HSW) Act and its relevant statutory provisions. The requirement for risks to be reduced as low as is reasonably practicable (ALARP) is fundamental and applies to all activities within the scope of the HSW Act. "So Far As Is Reasonably Practicable" (SFAIRP) and ALARP are regarded as being equivalent.

A phrase translated as “as far as is reasonable and possible” is present in the Swedish regulations which roughly means the same thing as “reasonably practicable”. In addition, before deciding to introduce a new modification requirement, the regulator assesses that its implementation is “reasonable and possible” in line with the proportionality principle.

From a regulatory perspective “unreasonable costs” are not an applicable argument for not applying a regulatory safety requirement with no further analysis. Even if a case of “not reasonably practicable” is called upon it is still necessary to show that a comparable level of safety is achieved although the requirement may not be strictly fulfilled in all its parts. It is equivalent of saying that the associated “safety benefits” would be small and thus strict fulfilment would not provide any measurable safety improvement.

From ENISS point of view reasonably practicable is interpreted in a way that improvements (to fulfil a certain requirement) should be taken unless the licensee is able to demonstrate that the implementation of the improvements is unreasonable and/or provide only small safety benefits.

This may be supported by quantitative data in terms of PSA/PRA results, and by qualitative arguments involving engineering judgment and sound reasoning. The claim for an “equivalent level of safety” should include the use of realistic analysis assumptions and acceptance criteria. The balance between qualitative and quantitative criteria in the decision-making process depends on many factors and is thus to be set on a case by case basis.

As a consequence, ENISS licensees take the view that acceptance rules should be developed in a constructive manner that could be integrated into the European legislation. The acceptance rules would be applied and then acceptance criteria would be determined on a case by case basis accounting for all the applicable requirements.

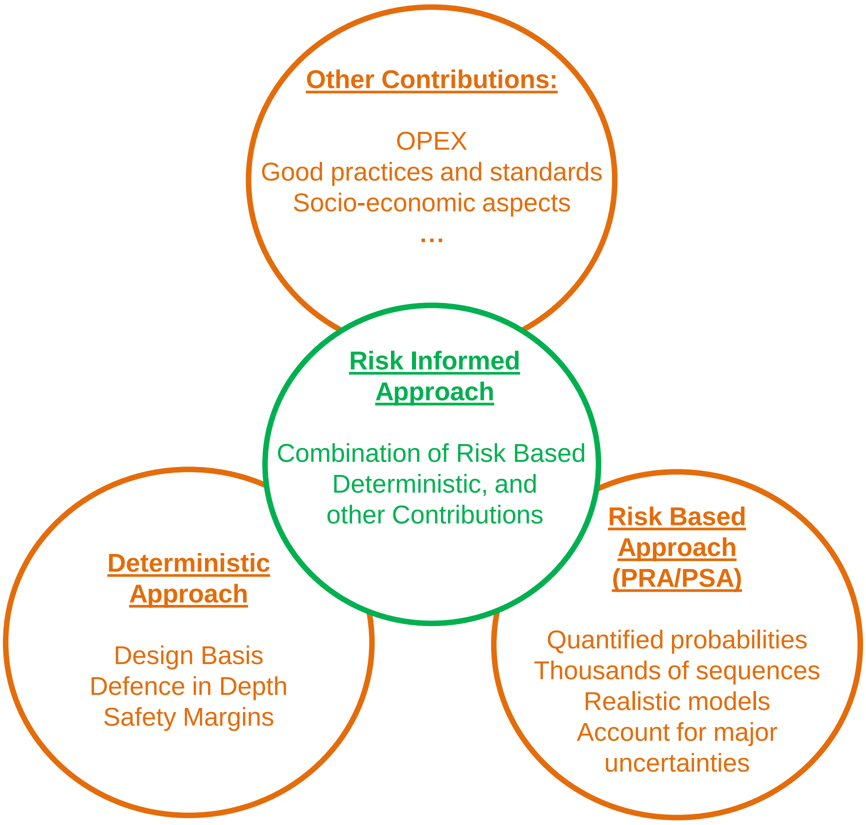
3. Risk Informed

The principles underlying risk informed applications are quite basic and they have been employed for decades, predating nuclear power by some time. When applied to nuclear power they have often been redefined and given specific meanings, and particularly linked to regulatory practices.

The term “risk informed” is widely used but is formally defined only by a minor number of organisations in relation to their processes. Risk informed approaches aim at integrating different risk assessment concepts with other factors so that solving a problem is proportionate to the risk significance of the issue. This proportion is clearly found in concepts like “reducing risk ALARP”. Application of risk informed approaches does not mean that deterministic safety principles would be abandoned, but rather that deterministic, probabilistic and other reasoning are combined in a complementary way recognising the strength and limitations of each approach.

ENISS licensees’ common view of the principles for the application of risk informed approaches is to combine risk analysis results or insights from probabilistic results together with inputs from deterministic analysis and other contributions like operational experience feedback and results (OPEX), good practices and standards, economic analysis…

The risk informed approach process involves the integration of these elements in a way that the overall resolution of the issue under consideration is commensurate with its risk significance and the efforts needed to implement it. The figure below shows the basic structure of the risk informed approach.



The IAEA INSAG-25 /3/ provide a comprehensive description on how the concept of risk can be used in making nuclear safety decisions, introducing principles and key elements and their integration (IRIDM: Integrated Risk Informed Decision Making). Several organisations (IAEA, USNRC, INPO, WANO) have produced guides relating to application of IRIDM. References /4/ and /5/ provide overviews on risk-informed decision making with insights on actual applications.

In some countries risk informed approaches and programmes have been initiated. An example is the Risk-Informed Completion Times (RICTs) Initiative by the USNRC and US licensees /6/. This initiative allows the extension of OTS completion times based on the assessment of the actual conditions. Benefits are in avoiding unnecessary plant mode changes and providing a better work management practices based on plant risk. A comparable programme was implemented for Sizewell B in the UK. The USNRC and US licensees have made a clear commitment to move towards risk informed and performance-based regulation. European regulators may follow this development, but so far there have not been similar commitments.

The IAEA is in the process of revising eight closely interrelated Safety Guides as a set of publications (DPP DS497 Nuclear Power Plants Operation). In this context, it is required to include “Risk-informed approaches to support operational safety of NPPs” as a crosscutting issue. Risk-informed operational strategies should be included in several Safety Guides on operational safety of NPPs, i.e. the Safety Guides for “Modifications to Nuclear Power Plants” and “Maintenance, Surveillance and In-service Inspection in Nuclear Power Plants”.

A similar approach should be applied to the Safety Guides WS-G-2.1 “Decommissioning of Nuclear Power Plants and Research Reactors”, WS-G-2.4 “Decommissioning of Fuel Cycle Facilities” and WS-G-5.1 “Release of Sites from Regulatory Control on Termination of Practices”. These guides include recommendations for cost-benefit analysis, optimisation of both safety and resources, integrated multi-attribute approach, graded or proportionate approach. However, they contain rather vague mentions such as “appropriate protective measures”, “acceptable confinement”, “adequate containment”, “adequate systems”, “appropriate technique”. The introduction of Risk-informed approach would help to clarify and support the recommendations.

ENISS licensees endorse a European approach that would integrate well proven and accepted risk informed methodologies taking full benefit of operating or decommissioning experience. It should allow the licensees to make a balance between the investment for safety and the safety improvements provided.

4. Principles for a successful approach

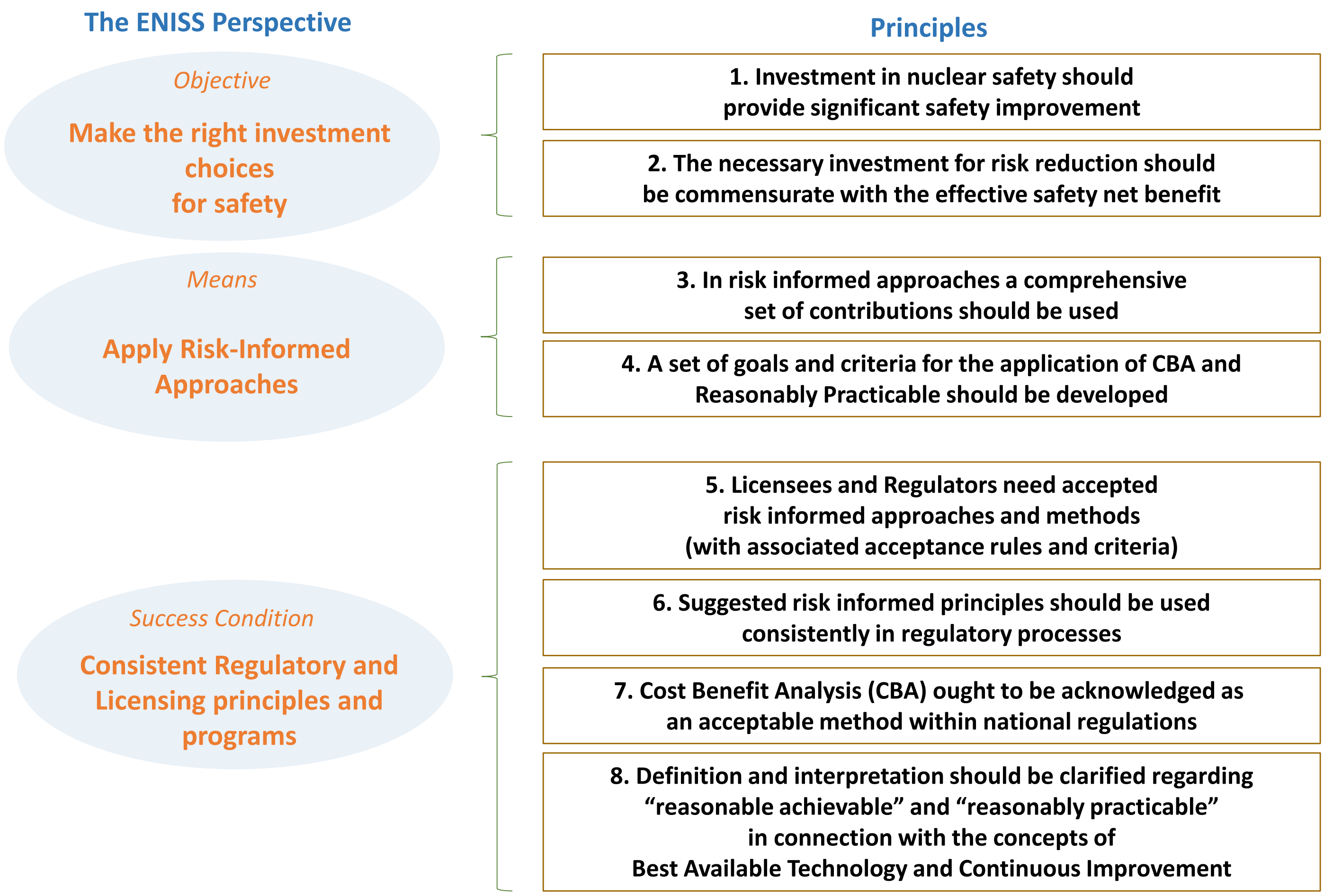
The ENISS perspective can be summarised through:

Objective =======> make the right investment choice

Means =======> apply Risk-Informed approaches

Success Condition =======> consistent regulatory and licensing principles

Eight principles are associated to this perspective as represented in the following figure.



1. Investment in nuclear safety should provide significant safety improvements

As a result of a Periodic Safety Review, the optimal safety improvements (i.e. reasonably practicable, supported by a cost-benefit analysis) among those evaluated should be selected, and they should primarily provide a significant safety increment.

Progress towards accepted approaches is needed to facilitate the overall process which leads to the decision making and optimise the resources.

For example, it is observed that risk informed approaches, in general, require high level expertise on a large range of competencies, and often lead to more extensive analyses and calculations and an increased involvement of regulators and TSOs. In addition and in most cases this is a long lead time process.

In some instances, there might be disproportionality between the engaged resources and the actual benefits of the envisioned modifications – i.e. significant effort could be needed to provide technical justifications to support the arguments that a modification involving a low safety benefit can be discarded.

Safety significance should then be factored at the first step before deciding to engage in the application of a fully developed risk-informed methodology – because the full development of risk-informed methodologies has a significant cost.

The option of no modification should always be considered with arguments and justifications based on experience feedback. The accumulation of operating experience on a stable and non-modified installation can result, in itself, in a continuous improvement of safety.

One of the possible end points should be “modification leading to no or low safety net benefit”, and the route to this end should be appropriately justified by technical arguments and evidences.

2. The investment required for introducing risk reduction measures should be commensurate with effective safety net benefit

The process should therefore include an application of the proportionality principle.

The notion of Safety Net Benefit is introduced:

- Along with safety improvements, changes generally introduce by themselves new risks, at each step of their development such as design, implementation or operation, for instance by introducing additional complexity. Safety impacts of the changes have to be evaluated (spurious events, human and organisational factors…).
- Those new risks or safety disbenefits should be identified, evaluated and minimised, and then taken into account in the net benefit evaluation.
  - Safety Net Benefit is evaluated accounting for Safety Benefit and Safety Disbenefit
  - The net benefit evaluation may include positive and negative impacts on radiation protection, security, waste management, …

  A study “Modifications to nuclear power plants: a benefit which is at risk - an extensive analysis of the operating experience” performed in 2011 by JRC, GRS and IRSN /7/ summarises and evaluates more than 700 modification related events and shows clearly the potential for risk increase.

Uncertainties have to be evaluated and, if not negligible, taken into account in the decision-making.

3. In risk informed approaches a comprehensive set of contributions should be used

Probabilistic studies provide a sound basis, but some limitations such as uncertainties, or limitation in scope or level of detail imply that they cannot be the sole means of providing inputs into the decision-making process. Hence risk-informed approaches should be based on several complementary types of analyses:

- Probabilistic Risk Analysis (Level 1, 2 and 3 PSA) – PRA (or other risk analysis, probability-based analysis)
- Deterministic Analysis (DBA events, DiD, safety margins)
- Other contributions (not exhaustive):
  - Experience feedback
  - Good practices and standards
  - Socio-economic aspects
  - Radiation Protection
  - Waste impact assessment
  - Impact on other stages of the lifecycle
  - Environmental impact
  - …

All these contributions can then be processed towards decision-making, through the application of engineering judgments, “reasonably practicable” principles, Cost-Benefit Analyses, …

4. A set of goals and criteria should be developed to support the application of cost benefit analysis and reasonably practicable,

such as or in relation with:

- Remaining operational life of the plant
- Goals or criteria representative of the safety level
- Available equipment
- Timely implementation of modifications
- Economic analysis
- Application of proportionality principle
- Optimisation of protection against radiation exposure (Doses to workers)
- Minimisation of risks

- Avoiding unnecessary changes in plant operation mode (reduce risk and system loads)
- Waste management (volume and transport minimisation)
- Provide better work management practices based on the plant risk
- Site re-use strategy after decommissioning and de-licensing

5. Licensees and regulators need accepted risk-informed approaches and methods

Risk-informed applications should allow the licensees to focus on measures which provide the most effective means of controlling the risk and to reduce conservatisms without compromising nuclear safety.

Guidance associated to risk-informed approaches and methods should include acceptance rules and criteria.

Licensees' approaches and performance based on good operating experience are results from the safe operation and should be accepted and used.

Without accepted approaches there might be additional/unplanned justifications required in the course of the Authority's assessment – for example extra peer reviews of the PSA or additional independent reviews on other parts of the justifications.

Improved methodologies in risk informed applications could lead to the revision of conservative assumptions and less strict maintenance rules, consequently allowing optimisation of maintenance activities, which is a positive factor to reduce risk.

6. Suggested risk informed principles should be used consistently in regulatory processes

ENISS licensees observed that regulators aim to apply Risk-Informed approaches when it prioritises additional plant measures, e.g. actions in relation to the stress-tests.

There is some positive trend to introduce goal-setting or performance-based aspects in regulatory frameworks. The focus should then be on objectives and measurable outcomes rather than prescribed solutions and techniques.

Performance-based methods can be devised for evaluating plant configurations that would not meet the conservative deterministic requirements, allowing engineering analyses to demonstrate that the changes in overall plant risk that result from these plant configurations is acceptably small and that defence-in-depth is maintained.

Deterministic and prescriptive approaches can limit the flexibility of both the regulated industries and the regulators to respond to lessons learned from operating experience and to adopt improved designs or processes.

Conservatisms, which were introduced into the process to simplify it or aid agreement, often proved difficult to be removed at a later date. Care should be taken when conservatisms are introduced at some point because they could lead to misrepresentations (of where are the real safety margins, where are the possible safety improvements which are not necessarily hardware changes…)

Introduction of risk-informed or performance-based principles and approaches have an impact on regulatory requirements. Such approaches can only be effective with an overall consistency of requirements. Implementing new regulatory requirements should be accompanied by reviewing and removing outdated requirements.

7. Cost benefit analysis is one natural element to justify reasonable practicability and ought to be acknowledged as an acceptable method within national regulations.

Common principles and guidance should be created and should be widely accepted by the European regulators. Existing good practices in Cost Benefit Analyses should be promoted to support this goal, as well as good practices in regards to the meaning and interpretation of reasonable practicability.

8. The definition and interpretation of the terms reasonably achievable and reasonably practicable in connection with implementation of Best Available Technology (BAT) and continuous improvement should be clarified.

The expectations associated to the application of Best Available Technology (BAT) and the principle of continuous improvement are to be fulfilled as far as the relating design/operation provisions are reasonably practicable/achievable, considering the need to include proven engineering practices and taking into account potential adverse effects associated with extensive modifications.

Reasonably practicable/achievable in connection with implementation of Best Available Technology (BAT) and continuous improvement should be clarified and the use of the Best Available Technique Not Entailing Excessive Costs (BATNEEC) concept promoted.

References

/1/ IAEA Safety Glossary, terminology used in Nuclear Safety and Radiation Protection, 2016 Revision

/2/ WENRA Guidance paper on "Timely Implementation of Reasonably Practicable Safety Improvements to Existing Nuclear Power Plants", June 2017

/3/ A framework for an integrated risk-informed decision making process. INSAG-25, / IAEA Vienna; 2011

/4/ Risk-informed decision making processes – An overview, Foundation for an industrial safety culture (FONCSI), 2012

/5/ Risk-informed decision making: A survey of United States Experience; The B. John Garrick Institute for Risk Sciences, University of California, Los Angeles - The Nuclear Risk Research Center, Central Research Institute of the Electric Power Industry, Tokyo; 2017

/6/ NEI 06-09 (Revision 0) – A; Risk-Informed Technical Specifications Initiative 4b; 2006

/7/ Nuclear Engineering and Design 256 (2013) 141-147 – Modifications to nuclear power plants: a benefit which is at risk. An extensive analysis of the operating experience, B.Zerger et al.