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Graded Approach: Not just Why and When, but How

Summary / Objectives:

Standards and regulations in many countries discuss **graded approach; some even require it**. Criteria or justifications for grading are commonly addressed. Not much, however, is discussed about the methods that can be used to grade a process once the criteria are met.
This webinar will remove any mystery associated with graded approach. Mr. Chermak asserts there are only two ways to grade one's approach to Quality Assurance — and they are very simple.
We look forward to your company while we learn about and delve into graded approach.

Meet the Presenter:

Mr. Vince Chermak is **the Assurance Director for the Versatile Test Reactor (VTR) Project based at Idaho National Laboratory**. He has enjoyed more than 20 years in Nuclear Quality Assurance that spans the U.S. Department of Energy, Naval Nuclear Propulsion Program, U.S. Commercial Nuclear, ISO, and Nuclear Waste Management industries. He is the INL representative to the IAEA for Supply Chain Management Toolkit development initiative. He also serves as a member of the ASME NQA-1 Subcommittee on International Activities.
Mr. Chermak firmly believes that one manages things and leads people. Leadership is not a position, it is a decision. Each of us has the responsibility to employ everything in our capacity to bring one another together and walk toward excellence. The most important things we as Leaders can do are recognize and leverage one another's strengths, rather than categorize each other by our differences.

Definitions of graded approach

Several documents, including ASME NAQ-1-2015, DOE O 414.1D, IAEA WS-G.5.2 etc., provide different definitions of graded approach. These definitions all have in common that when grading the approaches of the organization's activity, it considers **the application and the characteristics** of facilities or items, **the significance** to nuclear safety, and **the probability of failure** and the consequence. All of these things feed to 'risk'. **The graded approach can balance risks with any efficiency that would be gained.**

Example of the definition

- **NQA-1:2015*:** The process employed, once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:
  - a) the relative importance to nuclear safety
  - b) the magnitude of any hazard involved
  - c) the life-cycle stage of a facility or item
  - d) the mission of a facility
  - e) the particular characteristics of a facility or item
  - f) the relative importance to radiological and nonradiological hazards
  - g) any other relevant factors

*Most recent edition identified in NRC RG 1.28 Rev 5.

Risk informed approach

In order to implement the graded approach, it is necessary to promote a common understanding among the nuclear community on how the concept of risk can be used in grading one's approach. The ''Farmer curve'' can represent a starting point for arriving at a shared vision of the approach in terms of risk management. The integration of deterministic considerations, probabilistic considerations and consideration of other contributors serves to help balance risks with efficiencies.

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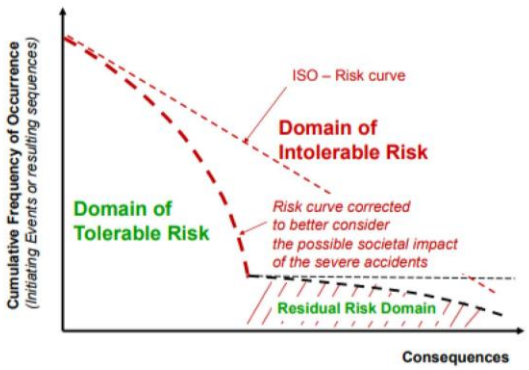
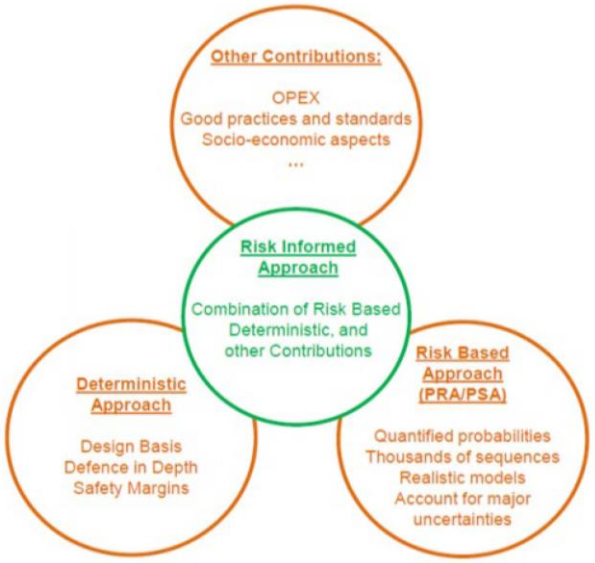
Risk Informed Approach

Schematic representation of the Risk domain (the so-called Farmer Curve and the needed evolution)



The principles of the Farmer curve



Components of the Risk Informed Approach

How to grade one's approach

It could be said that the purpose of the graded approach is to provide an efficient and compliant work process by balancing the application of process controls with business needs. Improper gradings result in imposing excessive requirements and not imposing applicable requirements. There are only two methods to grade our approach properly:

(1) Change the level of rigor for regulated activities

The level of rigor for controlling a particular item or facility depends on the application for what it is used. For example, if the micrometer is used for an inspection whose results is going to be documented in an inspection report by an inspector, it does need to be calibrated and controlled as M&TE (Measuring and Test Equipment). If this micrometer is used by an engineer to get a rough idea, then it may not need to be.

(2) Change the level of rigor for regulated personnel

The level of rigor for regulated personnel depends on where it is in the process and what the application is. If a person is just someone who checks someone else's work before it goes on to the next process, that is not a regulated activity. Therefore, this person doesn't have to be a certified inspector. If this is an inspection required, that person has to be an inspector who is fully qualified to perform that activity.

Examples of graded approach taken in a commercial nuclear plant

(1) Eliminating an inspection and replacing it with a peer check

Redundant QC (Quality Control) inspections, which were also performed at the final inspection in the process of a regulatory activity, were replaced with peer checks. This approach decreased the cost of the performance (e.g., wait-time for an inspection) because it did not require certified QC inspectors at that point.

(2) Certifying receiving personnel as receipt inspectors

A limited number of fully-qualified QC inspectors had performed all receipt inspections. However, the truth was only specific measurements in the process of those inspections needed to be fully qualified. It decreased the level of rigor for qualification and allows to certify receiving personnel as receipt inspectors. This approach not only decreased the cost, but also had a positive impact on the performance of the QC inspectors because they could spend more time on the required tasks.

(3) Eliminating QA signature from particular design documents

Quality Assurance (QA) signatures, which had been performed on individual documents throughout the whole process of the design, were changed to be performed only on the final package of these design documents. This approach did not impact the quality of the final package, but really shortened the amount of time that it took to put together that package because other persons in the process did not need to wait until all these design documents accumulated.

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Examples:

- Eliminating an inspection and replacing it with a peer check.
  - Eliminated the need for fully qualified QCIs
  - Decreased wait time
  - Decreased COPP
- Certifying receiving personnel as receipt inspectors.
  - Decreased the level of rigor for certification
  - Decreased wait time
- Eliminating QA signature from particular design documents
  - Moved to final design package for those documents

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