Questions and Answers

Question on general methodology

1. **If you use the Graded Approach (GA) methodology to determine resource allocation for the whole regulatory programme, how often this should be redone?**

The better approach would be to align it with the budget/resource planning cycle; however, many of the aspects of the holistic GA approach would be repetitive, as the proportion of the resources among regulated facilities or regulatory functions will only change for some circumstances, such as big changes in the status of the facilities, significant events, new facilities to be licensed, etc.

2. **Is there any caution to be kept in mind when applying graded approach i.e. can there be a scenario when applying graded approach, we may grade wrongly an activity or facility?**

The application of a graded approach involves a great deal of expert judgement. This is true even for the development of numerical methods and its input parameters. To minimize the risk of wrongly grading, the regulatory body (RB) should use the most qualified experts at hand, lessons learned and international experience. If the process and methodology, including assumptions are properly documented, a different set of equally qualified experts should arrive to the similar results. This could be used as a confirmation of the correct application of a graded approach.

A useful verification whenever applying a graded approach would involve confirming that applicable safety requirements are met, and that safety margins and defence-in-depth are maintained.

3. **Q: Safety analysis for independent verification and anticiaptory research is performed by AERB. How do we apply the graded approach to these activities?. Any specific**

guidance other than it is based on risk/importance etc? Any IAEA documents available on this?

The proposed methodology in the TECDOC does not address the specifics of application of graded approach to anticipatory research by regulatory bodies. Presently, the IAEA is working on a TECDOC to provide information on processes and methods to assist regulatory bodies in utilizing research results, i.e. planning and utilization of its own research as well as monitoring and utilization of external research. This document will include examples from various Member States on implementation and use of processes and methodologies for utilizing research results. It is planned to start with the activities related to this TECDOC later in 2020.

4. **I come from aerospace and defence sectors. It would be appreciated to find a comparative overview of methods and criteria in these (of chemical industries , for Gen IV reactors)**

This may be an interesting topic for a second tier TECDOC on graded approach on the overarching methodology. It should be noted, however, that the TECDOC discusses graded approach applied to the nuclear regulatory functions and these may differ from the regulatory functions of other industries (chemical, defense, aerospace, etc.). If the common denominator is risk to workers, public and the environment, it would be expected that the overarching methodology would be similar, provided that the functions are defined similarly, although then factors to consider would clearly be different.

5. **How IRIDM - Integrated Risk Informed Decision Making can be used in graded approach as overall?**

INSAG-25, "A Framework for an IRIDM", describes how the concept of risk can be used in making safety decisions relating to nuclear installations. The overarching methodology proposed in the TECDOC is largely based on the high-level principles described in INSAG 25.
INSAG-25 states that a comprehensive and balanced understanding of an installation's risk spectrum allows effective use of resources to address the more risk significant aspects while conserving resources that would otherwise be applied to less risk significant aspects. The overarching methodology proposed in the TECDOC goes beyond a single installation but may be extended it to the whole regulatory programme for allocation of resources, using the IRIDM principles.

6. **We know that each country has hierarchy regulatory system theirself. In another side, the radiation utilization also very diverse from simple and low risk into complex with high risk. How to implement graded approach in this conditions?**

Regulatory bodies need to consider the context of their whole regulatory programme when applying the graded approach for allocation of resources. It is noted that the best practice methodologies for nuclear installations may differ from the best practice methodologies for radiation sources. The IAEA is developing 2 separate TECDOCs for that reason. Senior managers

of the RBs should consider the integration of both approaches for the application of graded approach to whole regulatory programme.

Question on Authorization for the CNSC

1. **How is the safety significance of a regulated activity, for the purposes of authorization, determined in Canada?"**

The CNSC has methodologies for assessing the safety significance of regulated activities, broadly speaking it is based on the consequences to persons and the environment from exposure to nuclear and hazardous substances, and the complexity of the activity, it is applied to reactor facilities, fuel cycle facilities and nuclear substances and radiation devices

Questions on Inspection for NRC

1. **How does the NRC determine the appropriate resource effort for the inspectable areas? What factors influence the resource effort?**

For developing the initial baseline inspection program resource effort, expert judgment and inspector experience were used to determine the appropriate effort. The inspection program should have constant feedback so that it evolves with changing conditions and operating experience. The NRC inspection program has a biennial realignment of inspection resources in order to optimize inspection in areas considered most safety significant.
Another factor is reactor design. The new AP1000 design relies on passive safety systems to prevent core damage. There are approximately 60% fewer components in the design that need to be inspected, as well as a significantly lower risk profile. This necessitated a thorough review of all inspectable areas to reduce sample sizes and resource efforts to reflect the lower risk.

2. **Are there other inspection activities where the graded approach can be applied?**

The graded approach can also be used for inspection response to events that occur at reactor plants. "Incident investigation" is a formal process conducted for the purpose of accident prevention. The process includes gathering and analyzing information; determining findings and conclusions, including the cause(s) of a significant event; and disseminating the investigation results. The NRC uses a graded approach based on the risk or safety significance of the incident; it is described in Management Directive 8.3. A Special Inspection is initiated for incidents with lower safety significance. An Augmented Inspection Team is a larger team effort to inspect the circumstances surrounding more significant events. An Incident Investigation Team is assembled to investigate the most significant events based on deterministic and risk levels.

3. **Are there any specific requirements to the quality of PRA models used for risk-informed inspections. Requirements in terms of the scope of coverage (external hazards? spent fuel pools? etc.)**

The NRC requirements for the quality of PRA models is described in Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," which describes the technical elements required for levels of PRA. There are other Regulatory Guides for specific applications that describe PRA technical adequacy. The Regulatory Guides that address specific applications, such as Regulatory Guide 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," allow for the use of PRAs that are not full-scope (e.g., they do not include contributions from external initiating events.) Those regulatory guides do, however, state that the missing scope items are to be addressed in some way, such as by using bounding analyses, or by limiting the scope of the application.
Reg Guide 1.200 does address external hazards. There are no PRA quality requirements for spent fuel pools (SFPs). NRC uses already performed SFP PRAs to consider and appropriately incorporate risks associated with SFPs in risk-informed decision making. This is reflected in agency decisions following Fukushima and how we developed the regulatory analysis for the Decommissioning rule.

4. **How do you take into account the risk of reputation of NRC (which may not be related to safety significance, but rather to public acceptance of risk...) ?**

Regulators will always have detractors who mistrust them, who think that any risk is unacceptable. Very often risk, in the eyes of the public, is more perception than reality. Tritium contamination of groundwater is an example where tritium levels may be significantly lower than EPA regulatory requirements and not necessarily risk-significant, but for most of the public, any contamination is unacceptable. There is a chapter in the TECDOC on Communications and Interactions with Stakeholders that discusses a graded approach. Risk of reputation can be mitigated by being open and transparent with stakeholders and the public in all decision-making activities. The regulator cannot over-communicate with the public, and there needs to be consistent key messaging that is honest and objective. Ensuring technical competency when engaging with the public is another factor that builds trust.

Questions on Enforcement for ONR

1. **Your enforcement model does not take explicitly into account any increased risk of NPP core damage frequency following an incident which appears to be the case for other nuclear regulatory authorities. How does the ONR model consider enhanced risk to the public?**

The ONR enforcement management model considers the enhanced risk arising from an accident or non-compliance, based on actual (or potential) consequences and the extent to which defence in depth has been eroded. For higher hazard facilities such as NPPs, application of the model may lead to high risk gaps depending on the extent to which defence in depth is eroded. For lower hazard facilities where the actual risk gap is likely to be lower in many instances, the extent of enforcement may be influenced by other dutyholder and strategic factors that could escalate the level of enforcement; for example previous compliance history; whether enforcement is in the public interest. So in summary, the framework is versatile and can be applied in all risk settings.

2. **How do you ensure that your framework ensures consistency of enforcement across the different sectors of the industry – i.e. NPP, fuel cycle facilities, lower risk decommissioning facilities?**

The risk gap is determined using generic criteria that is agnostic to the type of facility as previously mentioned. ONR also undertakes assurance reviews to examine consistency and proportionality of decisions across different sectors.

3. **What is a duty holder factor?**

They are factors that could lead to an escalation in enforcement outcome relative to the baseline enforcement level based on the inspection history of the licensee, our confidence that it will return to compliance and whether they were seeking advantage.