IAEA
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Webinar

Application of a Graded Approach in Regulating Nuclear Facilities

Wednesday 16 September 2020
15:00 – 16:15 Vienna Time

Regulatory Activities Section
Nuclear Safety and Security Department

Logistics

- Microphones and cameras will be turned off for all attendees
- Short poll on the right-hand side of the screen
- Please write all questions to the panellists in the “Q&A” section
- The presentations will be uploaded to the IAEA webpage:
  https://www.iaea.org/nuclear-safety-and-security/department-of-nuclear-safety-and-security-webinars/application-of-a-graded-approach-in-regulating-nuclear-facilities
- The event is being recorded and will be uploaded to the same page

Agenda

	Presentation	Presenter	
5’	Opening remarks	Greg Rzentkowski	Director, Division of Nuclear Installations Safety (IAEA)
10’	Generic methodology	Miguel Santini/ Sergio Miranda	Regulatory Activities Section (IAEA)
10’	Use of a graded approach for Authorization	Doug Miller	Canadian Nuclear Regulatory Commission (CNSC)
10’	Use of a graded approach for Review and Assessment	Muhammad Qayyum	Pakistan Nuclear Regulatory Authority (PNRA)
10’	Use of a graded approach for Inspection	Daniel Merzke	Nuclear Regulatory Commission (NRC, USA)
10’	Use of a graded approach for Enforcement	Ryan Maitland	Office for Nuclear Regulation (ONR, UK)
10’	Questions and Answers		
10’	Future work and concluding remarks	Miguel Santini	Regulatory Activities Section (IAEA)

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Opening Remarks

Greg Rzentkowski
Director, Division of Nuclear Installations Safety

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Generic Methodology to Apply a Graded Approach

Miguel Santini / Sergio Miranda
Regulatory Activities Section
Nuclear Safety and Security Department
IAEA

Outline

- Status of guidance on graded approach
- Regulatory decision-making commensurate with the risk
- Graded approach methodology

Current Status of IAEA Guidance on the Application on Graded Approach by Regulators

- Present guidance on application of a graded approach by regulators is sparse, lacking generic guidance for prioritization of regulatory work and oversight, and with limited focus on the various regulatory functions.
  - Most IAEA Safety Standards require the application of a graded approach when performing regulatory functions

- Lessons learnt from IRRS and Advisory missions highlight that the understanding and application of a graded approach in the regulatory functions differ between Member States

- Member States express to IAEA continuously their need for further and specific guidance for regulating nuclear installations and radiation sources facilities and activities in accordance with a graded approach

Core Regulatory Functions

GSR Part 1 (Rev. 1) requirements

1. **Development of regulations and guides** – Req. 32, 33 and 34 - §4.62
2. **Authorization of facilities and activities** – Req. 23 and 24 - §4.33
3. **Review and assessment of facilities and activities** – Req. 25 and 26 - §4.40
4. **Inspection of facilities and activities** – Req. 27, 28 and 29 - §4.52
5. **Enforcement** – Req. 30 and 32 - §4.54
6. **Communication and consultation with interested parties** – Req. 36 - §4.69

Regulatory Decision Making
Commensurate with the Risk

- Risk posed by the facilities or the activities conducted within should drive the regulatory attention
- The ‘regulatory attention’ impacts on the level of oversight and effort allocation
- A means for consistent regulatory decision making commensurate with the risk posed by the facilities or the activities conducted within.
  - Proportional application of requirements

Reaching decisions based on the application of GA

Decisions may be grouped into two types:

- Allocation of resources/effort
  - To balance resources amongst its regulatory activities based on the priorities
  - To maximize regulatory impact on higher priority areas

- Other regulatory decisions
  - The safety significance of different decisions determines their impact
  - The decision must be compared to other decisions of equivalent safety significance

Uses of a Graded Approach

Where to Use

- For each of the Regulatory Functions
  - ✓ Different examples in Member States will be presented by experts that contributed to the development of the TECDOC.

Holistic approach for different functions and nuclear facilities

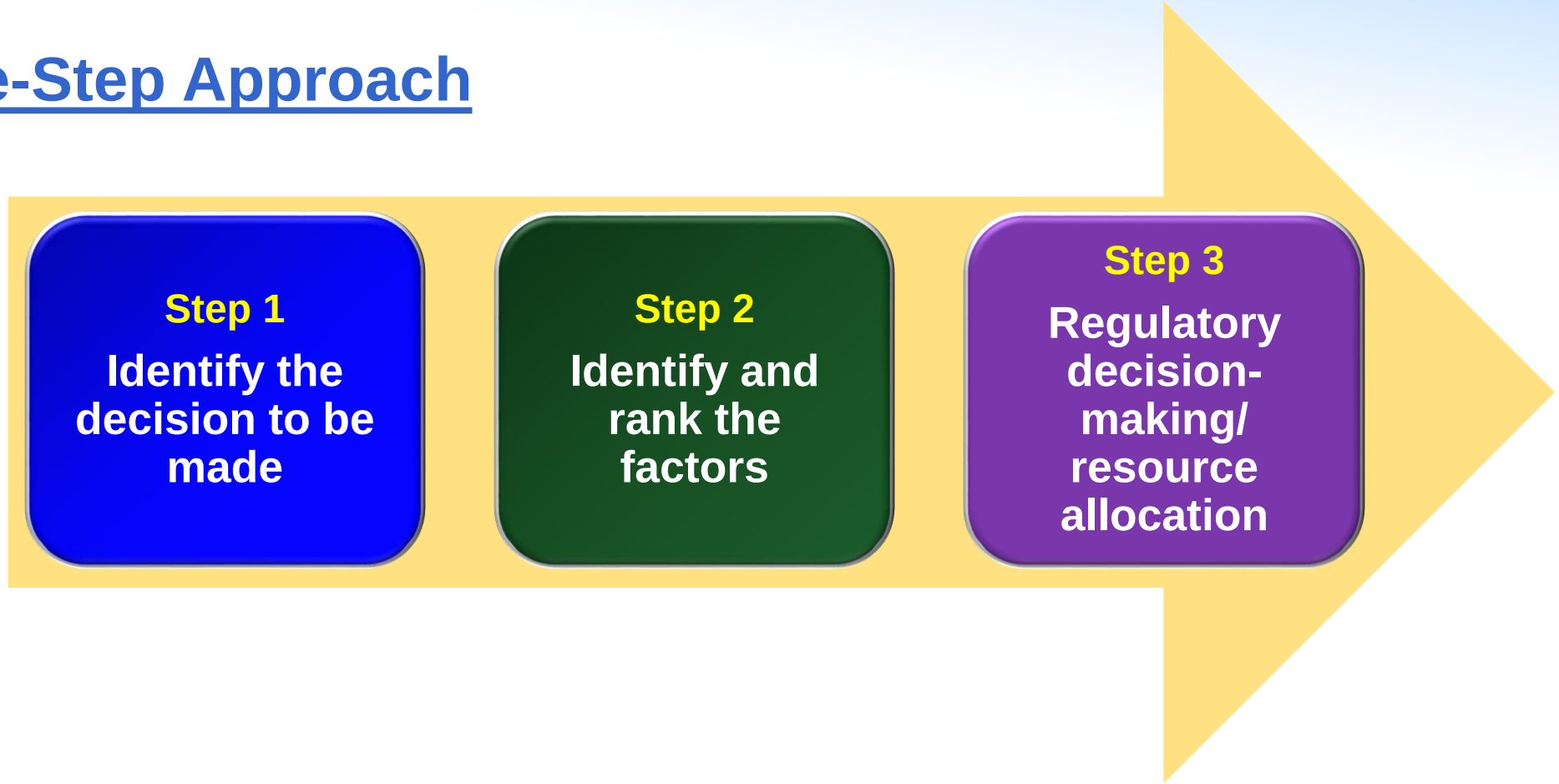
- Simultaneous Regulatory Functions performed – comparison of risks
  - ✓ Support regulatory bodies on making decisions on resource allocation to ensure regulatory effectiveness:
    - Regulatory oversight to some facilities to be prioritized
    - Where to focus regulatory attention in a nuclear facility
    - Regulatory functions to be prioritized

Grading by Comparison

- Often absolute level of risk and safety significance are difficult to estimate
  - Tools might not be available. Integrating factors that contribute to the risk is a challenge.
  - Importance of expert judgement.
- Rely on risk perception: relative and subjective – may not be realistic
  - Lack consistency and objectivity
- Comparative risks can be applied to rank level of risk for:
  - Same facility
  - Group of facilities

Graded Approach Methodology

- **Three-Step Approach**



- **Broadly applicable to all core regulatory functions**

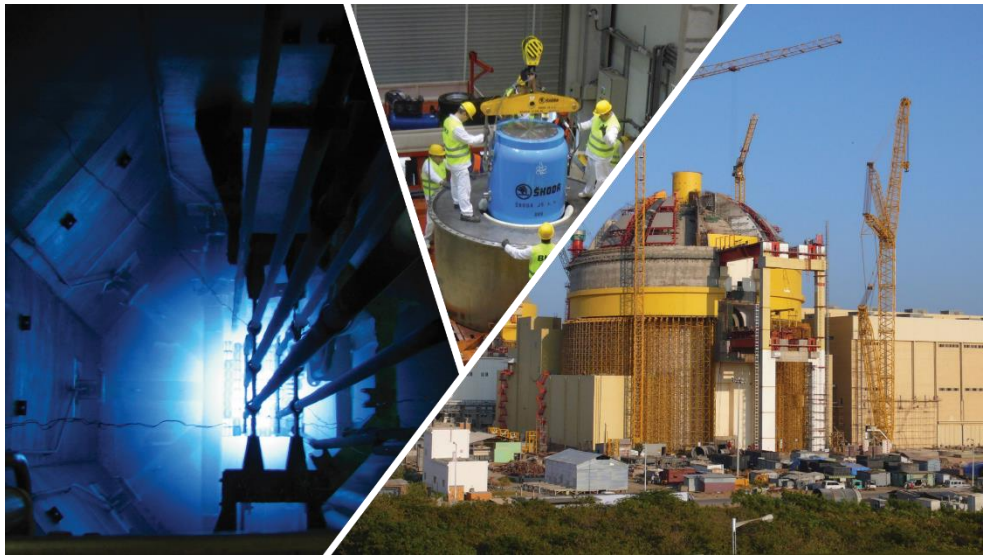
Graded Approach Methodology: Step 1

Regulatory Function	Considerations when applying a graded approach
Regulatory Framework	• Are regulations and guidance adequate/commesurate to control the risk associated with the facility?
Authorization	• Is the level of authorization (approval, consent) commensurate with the risk of the regulated facility? • Are the licences/conditions established for a facility of activity set to control the risk of the regulated facility?
Review and Assessment	• Is regulatory effort allocated for the review/assessment commensurate with the risk (potential safety significance) of the item being assessed? • Is there a systematic way of determining safety significance of review issues from a review/assessment?
Inspection	• Is regulatory effort allocated for the inspection programme commensurate with the risk of the item being assessed?
Enforcement	• Is there a systematic way of determining safety significance of findings resulting from an inspection? • Is the enforcement action commensurate with the safety significance of the non-compliance?
Communication	• Are resources allocated for communication activities commensurate with the safety significance and level of stakeholder interest?

Graded Approach Methodology: Step 2

Factors to be considered

- ***Generic Factors: independent of the regulatory function***
- ***Specific Factors: specific to each regulatory function***



Graded Approach Methodology: Step 2

Examples of **Generic Factors** to be considered

– ***Associated with type of facility, including many characteristics and utilization mode:***

- Reactor power
- Characteristics of the fuel
- Containment structure
- Complexity of the nuclear facility
- Chemical hazards
- Proveness of the technology
- Utilization of the nuclear facility

– ***Related to the location of the facility***

- Location of the site
- Population in the surrounding areas

Graded Approach Methodology: Step 2

Each Regulatory Function may have **Specific Factors** to be considered

Some examples are:

- ***Available regulatory instruments*** *– for developing rules and regulations*
- ***Number of nuclear facilities*** *– for authorization*
- ***Novel design features*** *– for review and assessment*
- ***Licensee performance*** *– for inspection*
- ***Frequency of violations or non-compliances*** *– for enforcement*
- ***"Perceived" Safety Significance*** *– for communication and consultation with interested parties*

Graded Approach Methodology: Step 2

Ranking process

- Objective criteria for selecting and analysing the safety aspects are defined - documented beforehand
- Analyse and compare all factors in respect of their safety significance: create a rank
- The rank of the factors delineate a risk profile for the installation

The comparative process could be extended to a number of installations

- Objective criteria for selecting and analysing should be the same for all installations
- This could support a more holistic allocation of resources for the oversight function

The ranking process should be clearly defined and documented

Graded Approach Methodology: Step 2

Methods for Ranking Factors

- *Panel of experts*
- *Algorithms/numerical methods*
- *Senior manager decision*
- *Other*

Need to consider

- *What impact each factor has in the final decision*
- *Use own or international experience if applicable*
- *Consultation with stakeholders*

Graded Approach Methodology: Step 3

Reaching decisions based on the application of GA

- In general, all the fundamental information required for the decision is gathered during Step 2
- Specific considerations
  - ✓ Flexibility
  - ✓ Timeliness
  - ✓ Consistency and Transparency
  - ✓ Differing opinions amongst the expert team or the regulatory staff
  - ✓ Monitoring and feedback programmes

Summary

- The process must be systematic and consistent: apply the same in all cases and for all installations

- The process must be repeatable: A different set of experts and decision makers should arrive to the same conclusion

As a general principle, it is essential that the methodology, the process and the assumptions are **properly documented** in the management system.

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Thank you!

M.Santini@iaea.org

S.Miranda@iaea.org

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Canada

Application of the Graded Approach on Regulating Nuclear Installations: Authorization

September 16, 2020
Vienna, Austria

nuclearsafety.gc.ca

e-docs
6364553

Outline

Application of the Graded Approach to Authorizations

Step 1: What authorizations are designated and delegated in Canada, and to whom?

Step 2: Factors to Consider in Delegation of Authorizations

Step 3: Delegation of Authorizations in Canada

Step One
Delegation of Authorizations?

Step 1:

What authorizations are designated and delegated in Canada, and to whom?

In general, the regulatory body is given statutory authority, and it may delegate certain authorizations to lower levels of the organization

Authorizations

The CNSC's Commission tribunal may issue, renew, suspend in whole or in part, amend, revoke or replace a licence, or authorize its transfer for the following activities:

- Possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information
- Mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance
- Produce or service prescribed equipment
- Operate a dosimetry service for the purposes of this Act
- Prepare a site for, construct, operate, modify, decommission or abandon a nuclear facility
- Construct, operate, decommission or abandon a nuclear-powered vehicle or bring a nuclear-powered vehicle into Canada

Step Two
Factors to Consider in Delegation of Authorizations

Step 2:

Factors applicable to the decision

1. **Statutory requirements** – requirements established by legal framework of member state
2. **Risk posed by the facility** – the radiological hazards and operational complexity
3. **The number of nuclear installations to be regulated** – large numbers of applicants and licensees may influence the necessity for delegation of authority

Step Two
Factors to Consider in Delegation of Authorizations

Step 2 (con't):

4. **Types of authorization to be issued at various stages** - permits and licenses, and the safety significance of changes requiring authorization
5. **Mode of operation and utilization of the facility** – authorization should address expected modes of operation for a facility, and to account for the overall purpose of the facility.
6. **Level of stakeholder involvement** – increased stakeholder interest will sometimes drive the perceived significance of an issue higher, resulting in increased authorization levels

Step Three
Delegation of Authorizations in Canada

Step 3:

Integrate the applicable factors into the decision-making process

- CNSC staff considered the factors described in step 2, and divided the authorizations into 2 groups:
  - ones that needed to be approved by the Commission and the ones that the Commission may delegate

- The results of these discussions were documented and presented to the commission for final approval

Step Three

Delegation of Authorizations in Canada

Step 3:

The following authorizations may be carried out by CNSC staff:

A. Authorizations maybe granted by the Commission or a person designated by the commission, referred to as ***Designated Officers*** (DO)

B. **Delegation** of the administration of licence conditions

A. Designated Officers

A DO may:

- Issue, renew, suspend in whole or in part, amend, revoke or replace, or authorize the transfer of the following licences:
  - **Nuclear Substances, Prescribed Equipment and Prescribed Information**
  - **Dosimetry Services**
  - **Particle Accelerators, Irradiators, Teletherapy Machines, Brachytherapy Machines**
- Certify and decertify prescribed equipment for the purposes of the NSCA
- Certify and decertify persons as qualified to carry out their duties under this Act or the duties of their employment
- Confirm, amend, revoke or replace any order made by an inspector
- Authorize the return to work of persons whose dose of radiation has or may have exceeded the prescribed radiation dose limits

A. Designated Officers

CNSC staff and managers in specific positions are designated as DOs and include:

- Senior staff
- Regulatory Program Directors
- Director Generals
- Vice-President, Technical Support Branch
- Executive Vice-president and Chief Regulatory Operations Officer, Regulatory Operations Branch

B. Delegation of Authorizations in Canada

Delegations to CNSC staff include verification that specific licence conditions are met:

i. Removal of hold points following major maintenance outages such as refurbishments, or implementation of improvements identified in periodic safety reviews

ii. Changes proposed by licensees to documents or facility operations are within the licensing basis

Demonstration that all safety-related requirements have been met
Large number of decisions pertaining to administration of licence conditions

i. Regulatory Hold Points

The Commission has delegated the authority for the removal of key regulatory hold points for the return to service of each unit undergoing a major outage to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

For each of the regulatory hold points, the licensee shall submit:

- Completion Assurance Documents (CADs) that present evidence that all pre-established conditions for removal have been met.
- Details on the pre-established conditions are documented in facility-specific licence condition handbooks.
- Any actions to be taken following removal of the hold point

ii. Authorization of changes

Authorization of changes to documents or operations proposed by licensees.

Licensees shall conduct the activities described in their licence in accordance with the licensing basis, defined as:

- The regulatory requirements set out in the applicable laws and regulations
- The conditions and safety control measures described in the facilities' licence and the documents directly referenced in that licence
- The safety and control measures described in the licence applications and the documents needed to support those licence applications

Unless otherwise approved in writing by the Commission

ii. Authorization of changes

Authorization of changes to documents or operations proposed by licensees.

Licensees:

- Assess changes to confirm that operations remain in accordance with the licensing basis
- Provide written notification of changes to the facilities or their operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis

CNSC staff verify that changes to licensee documents or facility design to verify that the changes are in the safe direction and within the licensing basis. This consent is communicated to licensees by the Regulatory Program Director

If the proposed change is **not in the safe direction**, the licensee will have to obtain approval from the Commission Tribunal

ii. Authorization of changes

Not in the safe direction means:

- A reduction in safety margins
- A breakdown of barrier
- An increase (in certain parameters) above accepted limits
- Impairment(s) of special safety systems
- An increase in the risk of radioactive releases or spills of hazardous substances
- Injuries to workers or members of the public
- Introduction of a new hazard
- A reduction of the defense-in-depth provisions
- Reducing the capability to control, cool and contain the reactor while retaining the adequacy thereof
- Causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility

Overview of Graded Approach used for Review and Assessment in Pakistan

MOHAMMAD QAYYUM

Webinar - Application of a Graded Approach in Regulating Nuclear Facilities 16 September 2020

Presentation Layout

- Objective of Review & Assessment
- Basis of Review and Assessment(R & A)
- Areas for consideration of Graded Approach(GA)
- Application of GA in the scope and detail of information in the SARs
- GA in resources for R & A of different types of NIs
- GA in allocation of resources for R & A of similar types of NIs

Objective of Review & Assessment

- Review and assessment (R&A) is one of the Regulatory body's core functions
- A R&A of licensee's submissions is performed in order to:
  - determine whether the facility or activity complies with the regulatory requirements, safety objective, principles and criteria;
  - satisfy itself that the activity/facility is within the safe envelop and
  - permit to construct, operate or decommission a facility

Basis of R & A

- PNRA regulations
- USNRC and IAEA safety standards
- Industrial standards (ASME, RCC, IEC, IEEE, etc.)
- National & International NPPs operating experience feedback

Areas for consideration of GA

- scope and detail of information in the SARs
- allocation of resources (manpower and duration) for review and assessment of;
  - ➢ different types of NIs
  - ➢ similar types of NIs with difference in design or power level

Application of GA in the Scope and Detail of Information in the SARs

Considerations for Application of GA

- Categorization of different NIs is performed on the basis of potential radiological hazard, such as;
  - on-site and off-site (in case of NPPs)
  - in case of RRs, it depends upon power of the reactor
  - on-site radiological hazard potential (in case of other NIs)
- The radiological risks associated with reactor power, radiological source term, etc.
- Document submission requirements based on associated radiological hazards, complexity of the design, etc.

Considerations for application of GA

- Based on these considerations, different reference documents for defining the scope and detail of information in SARs with safety criteria are finalized after site registration

Type of Nuclear Installations	Reference Document for SARs
NPPs	RG 1.70/1.206 (Format and Contents), NUREG-0800 (Standard Review Plan) and IAEA safety standards
RRs	SSG-20, NUREG-1537 and IAEA safety standards
Dry fuel storage facility	NUREG-1520

Chapters of SARs

No	Titles (NPPs)	Titles(RRs(SSG-20))
1	Introduction and General Description of the Plant	Introduction and general description of the facility
2	Site Characteristics	Safety objectives and engineering design requirements (**NR for NPPs**)
3	Design of Structures, Components, Equipment and Systems	Site characteristics
4	Reactor	Building and structures
5	Reactor Coolant System and Connected Systems	Reactor
6	Engineered Safety Features	Reactor coolant system and connected systems
7	Instrumentation and Controls	Engineered safety features
8	Electric Power	Instrumentation and control
9	Auxiliary Systems	Electric power
10	Steam and Power Conversion System (**NR for RRs and NFCF**)	Auxiliary systems
11	Radioactive Waste Management	Reactor utilization (**NR for NPPs**)
12	Radiation Protection	Operational radiological safety
13	Conduct of Operations(EPP and PPP) (**on-site EPP for NFCF, RRs(LP)**)	Conduct of operations
14	Initial Test Program	Environmental Assessment
15	Accident Analysis	Commissioning
16	Technical Specifications	Safety analysis
17	Quality Assurance Program	Operational limits and conditions
18	Human Factors Engineering (NR for RRs and NFCF)	Management system
19	Probabilistic Safety Assessment and Severe Accident Analysis (NR for RRs and NFCF)	Decommissioning(Submitted as a separate document for NPPs)
20		Emergency planning and preparedness (Merged with chapter 13 in case of NPP)

GA in Resources for R & A of Different types of NIs

Considerations for application of GA

- GA in allocation of resources for R & A of different types of NIs are based on;
  - facility characterization,
  - associated radiological hazards,
  - document submission requirements and
  - scope & detail of information in SARs
- Some additional considerations are;
  - experience from previous reviews and
  - availability of expertise in specific areas

Rationale for GA in resource allocation

Resource allocation for R & A of different types of NIs;

- More resources for R & A of a facility with;
  - off-site hazard potential
  - Complex design as more safety assessments and analyses are required to qualify the design for safe operation
- Resource allocation for R & A also depends upon the document submission requirements and detail of information to be included in the SARs as these varies for different types of NIs
- Availability of relevant expertise in specific areas can also reduce the allocation of resources for R & A

Practical Examples

GA in allocation of resources for R & A of different types of NIs

Activities	Facility	Number of Experts	Time in months
Review of Revised FSAR	K-1 (scope of the revision was to include PSR-2 commitments and design modifications made)	31	6.25
	PARR-I (scope of the revision was to modify the FSAR according to format of SSG-20)	17	6.5

GA in Allocation of Resources for R & A of Similar types of NIs

Considerations for application of GA

- Although, the submission requirements are almost the same, however, in case of similar type of NIs, the resource allocation for review and assessment of these submissions also varies for similar NIs as compared to different NIs
- Complexity of design and operation
- Relevant expertise and their availability, experience of previous reviews of existing facilities
- New or already approved design, novel design and analysis methods and same or new site

Rationale for GA in resource allocation

Resource allocation for R & A of the similar types of NIs depends upon;

- New or already approved design, novel design and analysis methods and same or new site
- review and assessment of a specific type of facility is already carried out by regulatory body,
- design changes or additional systems incorporated in the design of the reference plant as a result of emerging technologies and advancement
- previous experience or facility performance
- Availability of previous review experts

Practical Examples

GA in Resource allocation for R & A of similar types of NIs

Activities	Facility	Number of Experts	Time in months
Site Evaluation Report	C-3 (Already approved site)	08	03
	K-2 (New site)	10	6.25
Review of PSAR	C-3/4 PSAR (Proven technology and already reviewed plant)	59	06
	K-2 PSAR (New design)	68	16
Review of FSAR	C-3 (Proven technology and already reviewed plant)	62	10
	K-2 FSAR (New design)	80	12

THANK YOU

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Protecting People and the Environment

Graded Approach in Inspection

Dan Merzke

U.S. Nuclear Regulatory Commission

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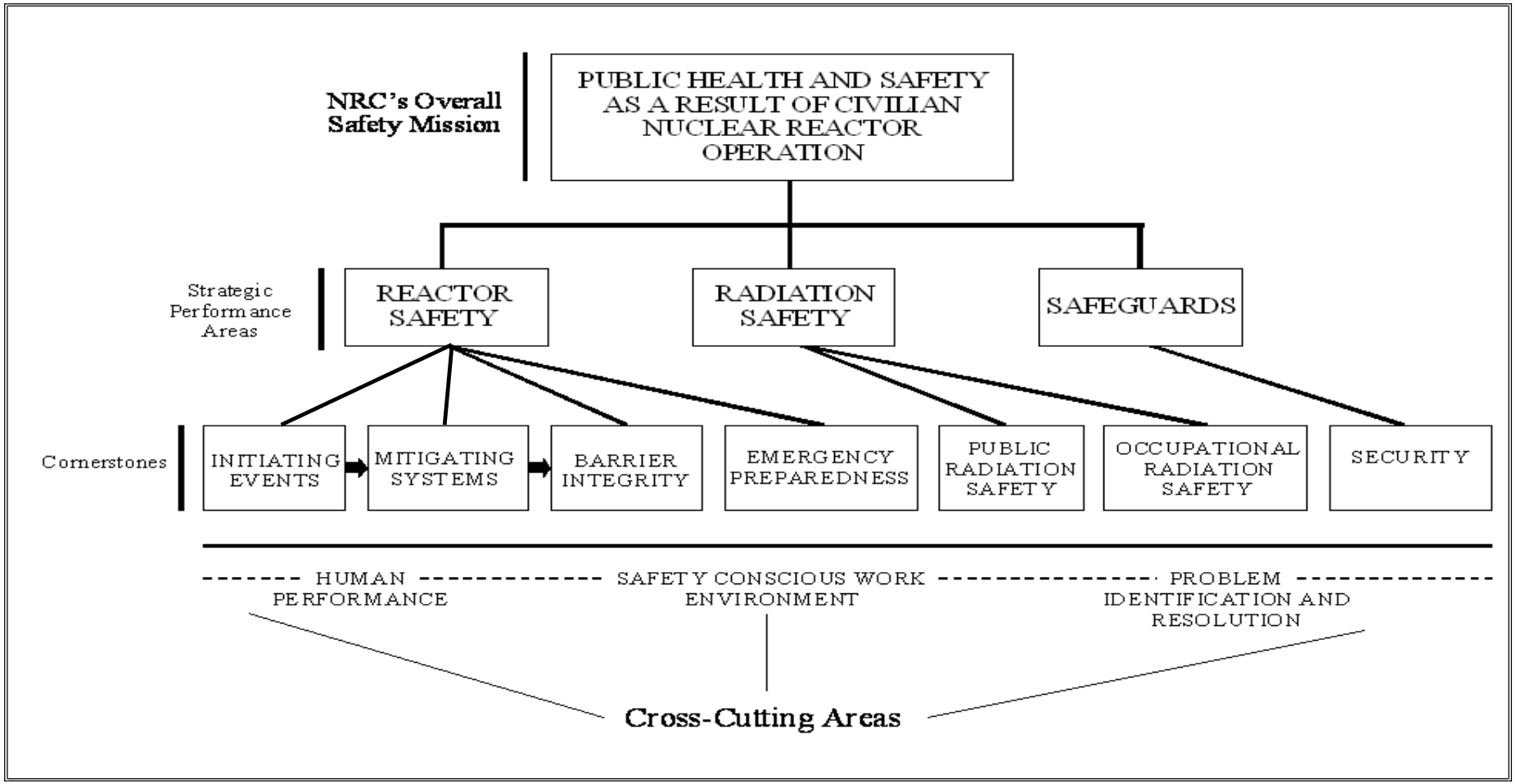
Inspection

Oversight framework



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Inspection

- Step 1- Identify activities, structures, systems, and components (SSCs) that are important to safety.
  - License application
  - FSAR
  - Probabilistic Safety Analyses (NPPs)
  - Inspection experience
  - Operating experience – historical problems

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Inspection

- Step 2 - Determine which factors are applicable to the decision
  - type of facility (PWRs have different ISI requirements)
  - Stage in life cycle (construction inspection requirements differ from operations inspections
  - Operating experience - focus inspections on areas where safety-significant SSCs have a higher failure probability, informing the sample size requirements for inspections of licensee surveillances.
  - Inspector experience
  - Special and infrequently performed activities

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Inspection

- Step 3 - Integrate the applicable factors into the determining the optimal resource effort required to ensure licensees are operating their facilities in a manner that protects public health and safety, and the environment. Regulator determines the appropriate inspection sample size and frequency.
  - Baseline inspection program – minimum inspection to assure licensee performance satisfies cornerstone objectives. (What to inspect, frequency of inspection, how to inspect)

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Inspection

- Process described in SECY-99-007.
- Risk Information Matrices (RIMs) developed in determining which activities, systems, or components are to be inspected in the baseline inspection program.
- Each cornerstone has several attributes from which the inspectable areas are derived. These inspectable areas were selected based on their risk significance

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Inspection

- RIM

CORNERSTONE			INSPECTABLE AREA	PERFORMANCE INDICATOR	FREQUENCY	HOURS FOR 2-UNIT SITE PER YEAR	LEVEL OF EFFORT	BASES
I 30	M 60	B 10	Equipment Alignment	None	Semiannual and as required by maintenance	76 hrs/yr	One system walkdown every 6 months. If available system success criteria from the site specific risk study, and the system design basis should be reviewed to focus the inspection. RIM2 should be used for system selection if plant specific information has not yet been developed. In conjunction with maintenance on higher risk systems, validate critical features on lineup of the train or system providing the backup function. Hours based on 8 hrs semiannually for a complete risk important system walkdown; 4 hrs/month in walkdowns to support verification of operable system train because other train is OOS, and 1 hr/month for Identification and Resolution of Problems/Issues.	High risk configurations may occur during normal operations and on- line maintenance activities due to multiple out-of-service SSCs, and such configurations can lead to high Core Damage Probability.
I 10	M 90	B	Fire Protection	None	Triennial	36 hours/3 yrs 12 hr/yr Residents	Selection of areas inspected should consider insights from the plant specific fire risk analysis. Regional SRA to provide input. Walkdown all accessible areas of high significance. Hours are based on a regional based Program Implementation Review, and 4 hours of Identification and Resolution of Problems/Issues. Residents should perform a monthly walkdown of high fire risk areas (hours based on One hr/walkdown) to verify transient combustible loading and fire doors/barriers.	Estimated fire risk is comparable to many internal initiating events. If potential fire initiators, aids to propagation, or fire barrier breaches exist, safe shutdown of the plant may not be possible due to the failures of the inspectable features and areas.

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Inspection

- Sample size and number of hours were developed based on expert judgement and relevant risk information on how much inspection activities would be sufficient to ensure verification that the licensee was meeting the objectives of all seven cornerstones.
- IMC 0308, Attachment 2, “Technical Basis for Inspection Program,” documents scope and basis for each inspectable area.

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Inspection Based on Performance

- Graded approach to inspection based on performance
  - As performance declines, inspection increases
- Described by Action Matrix

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Action Matrix Concept

Licensee Response	Regulatory Response	Degraded Performance	Multiple/Repetitive Degraded Cornerstone	Unacceptable Performance

Column 1 Column 2 Column 3 Column 4 Column 5

- Increasing safety significance
- Increasing NRC inspection efforts
- Increasing NRC/licensee management involvement
- Increasing regulatory actions

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Inspection Based on Performance

- Step 1 – identify SSCs important to safety
  - Focus on activity or SSC where performance is deficient
- Step 2 – determine which factors applicable
  - Safety significance of deficiency
  - Isolated vs site-wide (extent of condition)
- Step 3 – integrate factors to determine optimal resource effort
  - Scope of inspection effort described in supplemental inspection procedures based on number and/or safety significance of performance deficiencies and performance indicators

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Inspection Based on Performance

- Supplemental Inspections
  - Column 2 – IP 95001 supplemental inspection (40-120 hours)
  - Column 3 – IP 95002 supplemental inspection (200 hours)
  - Column 4 – IP 95003 supplemental inspection (3000 hours) – diagnostic inspection

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References

- IMC 0305, “Operating Reactor Assessment Program”
- IMC 0308, Attachment 2, “Technical Basis for Inspection Program”
- IMC 2515, “Light-Water Reactor Inspection Program”
- Inspection Procedure 95001, “Supplemental Inspection Response to Action Matrix Column 2 Inputs
- Inspection Procedure 95002, “Supplemental Inspection for One Degraded Cornerstone or Any Three White Inputs in a Strategic Performance Area
- Inspection Procedure 95003, “Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs or One Red Input

Office for Nuclear Regulation

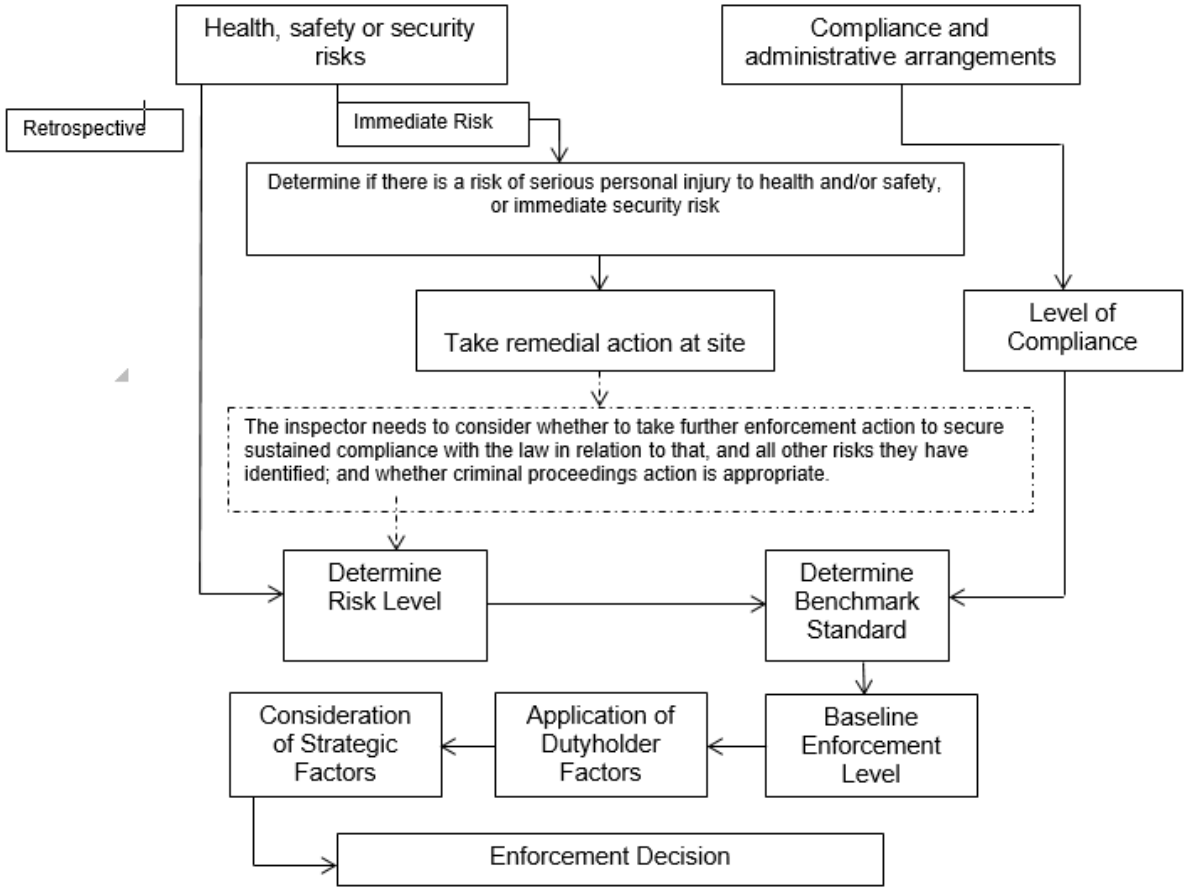
Graded approach to Enforcement in the UK

Ryan Maitland – Principal Inspector

Office for Nuclear Regulation

Graded approach to Enforcement

Step 1 – Identify the non-compliance



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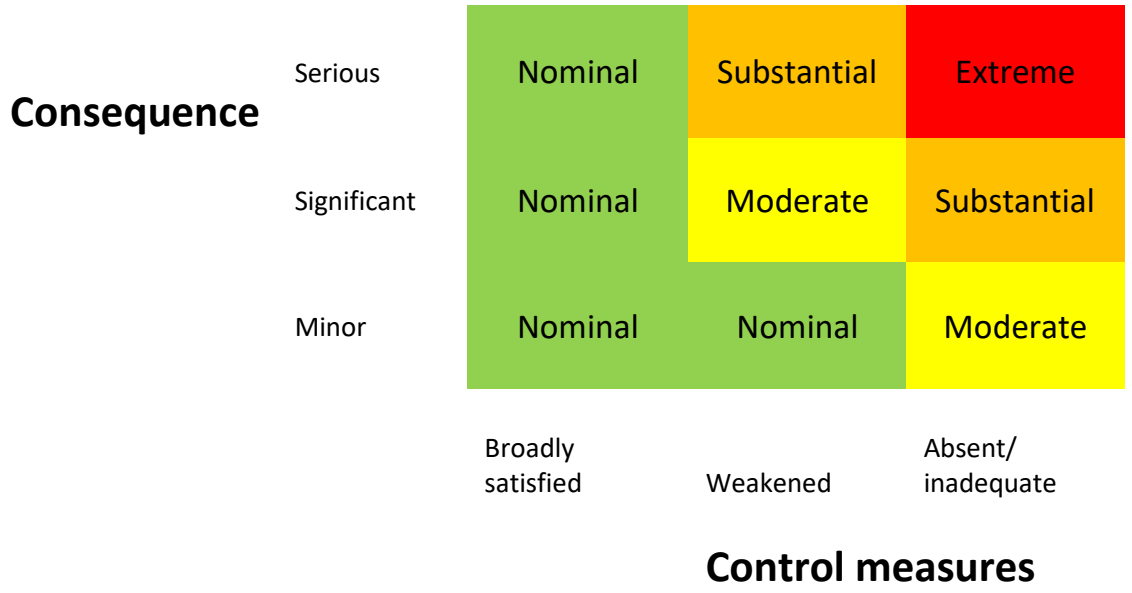
Step 2: Determine which factors are applicable to the enforcement decision

Determine Risk Level



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Step 2: Determine which factors are applicable to the enforcement decision

Evaluate benchmark standard

BENCHMARK STANDARDS	
WHAT IS THE AUTHORITY OF THE APPROPRIATE STANDARD?	
Descriptor	**Definition**
Defined Standard	Minimum standard specified by Acts, Regulations, Orders and ACoPs. For example, Regulatory Reform (Fire Safety) Order 2005, The Fire (Scotland) Act, Management of Health and Safety at Work Regulations 1999, Health and Safety at Work Act 1974, Nuclear Industries Security Regulations 2003, Control of Asbestos Regulations 2012, Working at Height Regulations 2005, Confined Spaces Regulations 1997 ACoP, Ionising Radiations Regulations, Carriage of Dangerous Goods and Use of Transportable Pressure Equipment 2009.
Established Standard	Codes of Practice and other standards linked to legislation, published or commonly known standards of performance interpreted by regulators or other specialists, industry or other organisations. For example, British Standards, Licence Conditions, Security and Safety Assessment Principles, Cabinet Office Security Policy Framework, TIGs, TAGs and IAEA Standards.
Interpretative Standard	Standards which are not published or available generally, but are examples of the performance needed to meet a general or qualified duty.

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Step 2: Determine which factors are applicable to the enforcement decision

Determine baseline enforcement level

BASELINE ENFORCEMENT LEVEL (BEL)			
		Baseline Enforcement Level (to secure compliance with the law)	**Consider Prosecution**
Risk Level	**Benchmark Standard**		
Extreme	Defined	Notice / Direction / LC Powers	Yes
	Established	Notice / Direction / LC Powers	Yes
	Interpretative	Notice / Direction / LC Powers	
Substantial	Defined	Notice / Direction / LC Powers	
	Established	Enforcement Letter	
	Interpretative	Enforcement Letter	
Moderate	Defined	Enforcement Letter	
	Established	Regulatory Advice	
	Interpretative	Regulatory Advice	
Nominal	Defined	Regulatory Advice	
	Established	No Action	
	Interpretative	No Action	

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Step 3: Implementing enforcement decision

Modify decision against dutyholder or strategic factors

The baseline enforcement level may then be **increased** depending on the outcome of other **dutyholder and strategic factors**

e.g. improvement notice may become a prosecution

Dutyholder Factor to consider
What is the inspection history of the dutyholder?
What is the level of confidence in the dutyholder?
Does the dutyholder have a history of relevant, formal enforcement being taken or relevant advice being given?
Is there a relevant incident history?
Is the dutyholder deliberately seeking economic advantage?
What is the standard of general compliance which is relative?

Factor to consider
Does the action coincide with the Public Interest?
Are vulnerable groups protected?
What is the long-term impact of the action?
What is the effect of action?
What is the functional impact of the action?

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Webinar

IAEA Main Activities on the Application of a Graded Approach in Regulating Nuclear Facilities

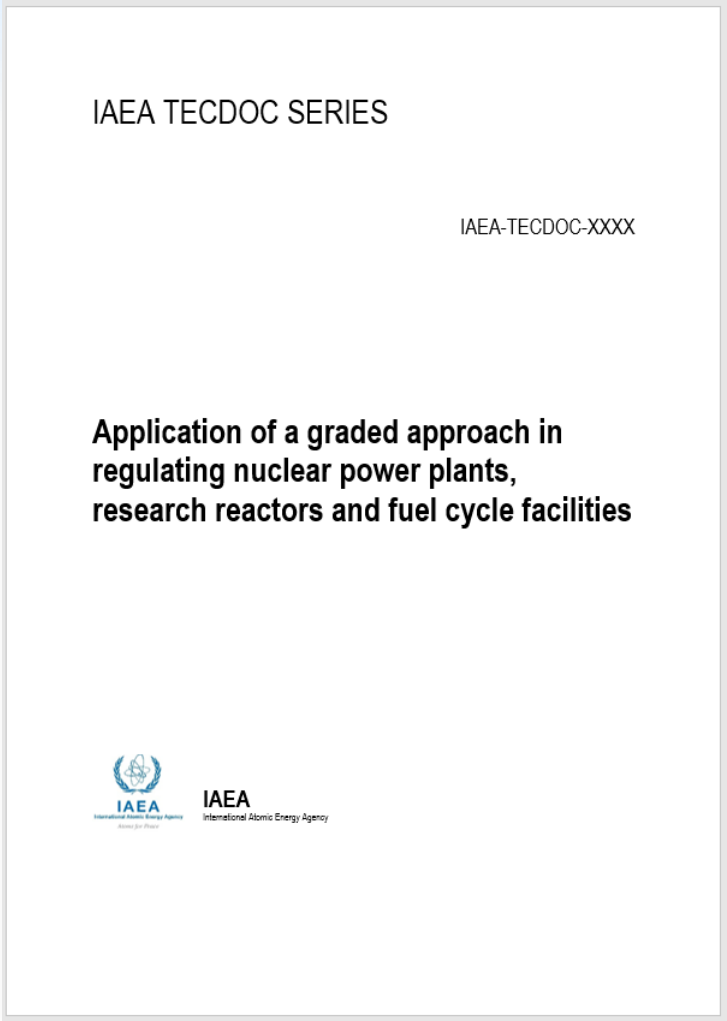
Wednesday 16 September 2020

15:00 – 16:15 Vienna Time

Regulatory Activities Section
Nuclear Safety and Security Department

TECDOC on Graded Approach for Regulation of Nuclear Installations

- Draft produced with contributions from the regulatory bodies of Canada, Pakistan, Russian Federation, UK and US
- 3 Consultancy meetings, starting in 2018
- Basis for the Summary Document distributed for the Technical Meeting
- To be sent for publication in October 2020



Technical Meeting on the Use of the Graded Approach for Regulatory Body Oversight of Nuclear Installations

- Dates: 1 to 4 February 2021
- Venue: VIC, Vienna (Contingency plan: virtual meeting)
- Papers and Presentations deadline: 02 October 2020
- The paper should contain:
  - a comprehensive description of the methodology, including factors considered in the reasoning, the prioritization approach, limitations to the approach and aspects of the decision-making process.
  - a practical example applying the graded approach methodology described
  - references to publicly available documents (regulation, guideline, procedure, policy etc.).

Safety Guide the Use of the Graded Approach for Regulatory Body Oversight of Nuclear Installations

- A proposal of a Safety Guide on the topic will be sent for Nuclear Safety Standards Committee (NUSSC) early on 2021

- Sources of information for the Safety Guide:

  – The TECDOC and feedback from Member States on its use
  – The contributions from the Technical Meeting (examples and suggested methodologies)
  – Other feedback from MSs

Training on the use of a graded approach

- A training package was developed to support Member States to apply a graded approach to core regulatory functions.
  - Methodology presented in the TECDOC
  - Practical examples provided by Member States that supported the development of the TECDOC.
- National or regional workshops

TECDOC on GA for Radiation Sources

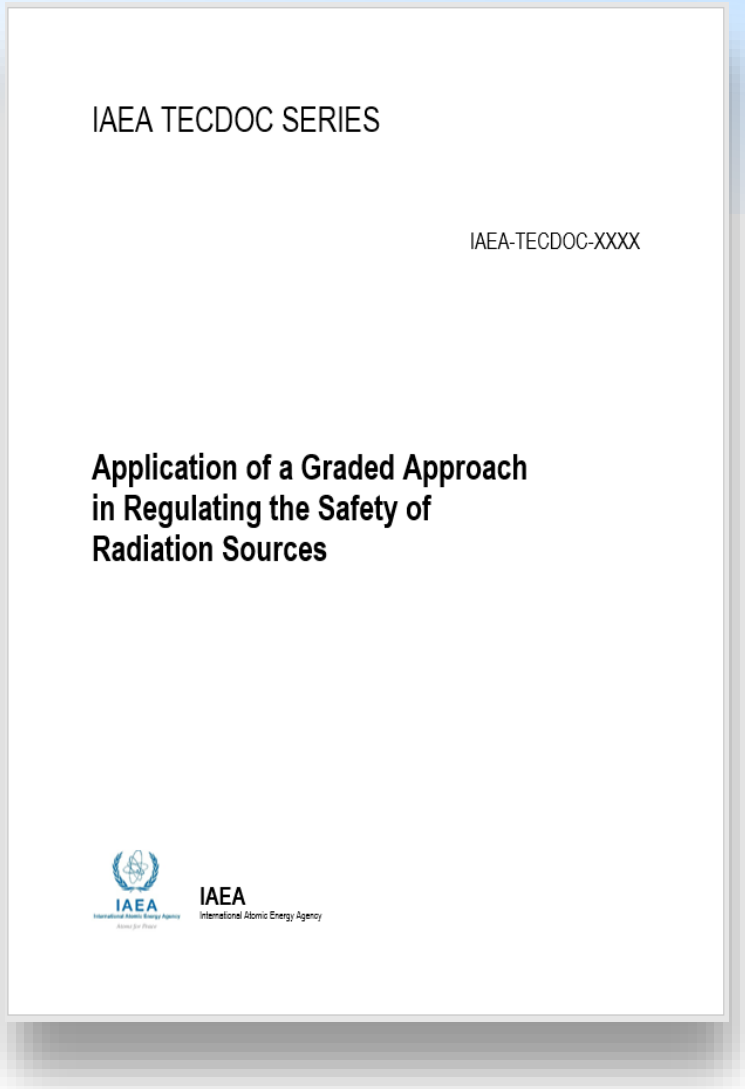
- Draft produced in parallel with the same TECDOC for Nuclear Installations

- Contact - Technical Officer:

Jovica Bosnjak

J.Bosnjak@iaea.org

+43-1-2600-26559



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Thank you!

M.Santini@iaea.org

S.Miranda@iaea.org

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Questions and Answers

Please continue submitting questions in the Q&A box

Unanswered questions will be answered later through email