



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Canada

Application of a Graded Approach in Regulating the Safety of Radiation Sources: Inspection and Enforcement

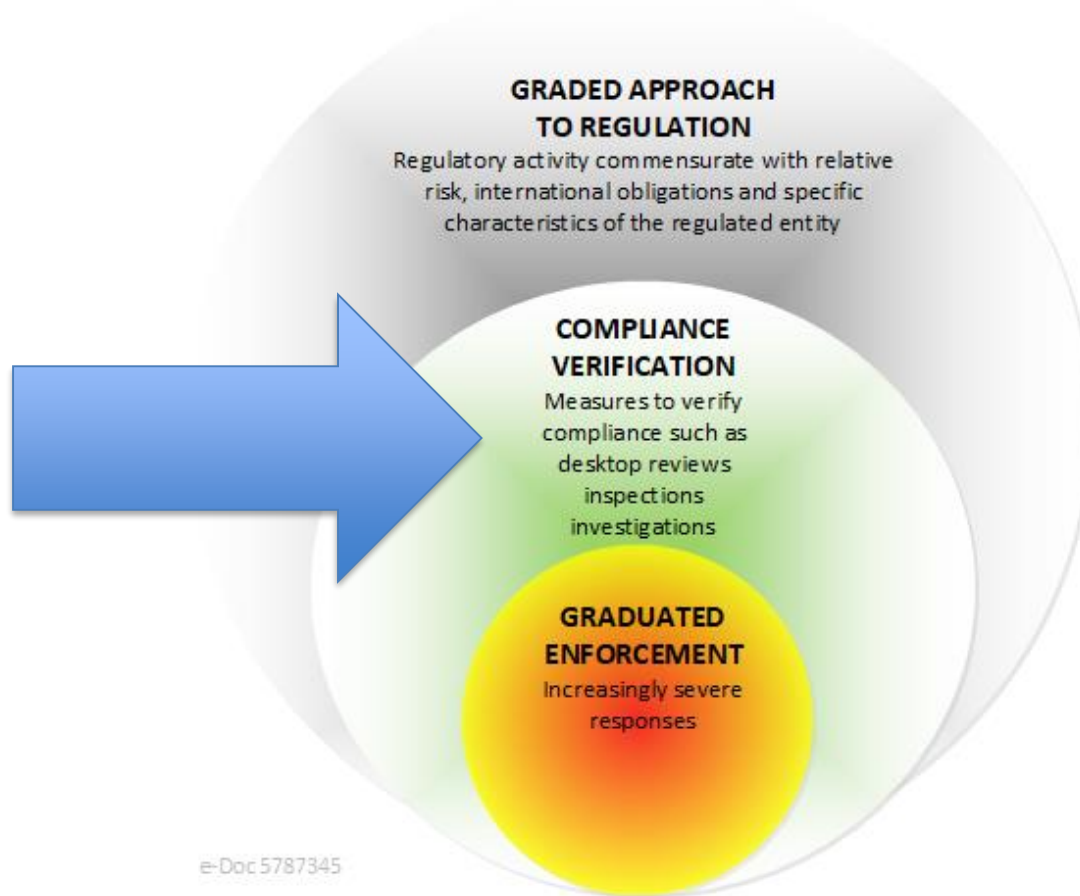
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Applying a Graded Approach to Inspection



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Risk Index Method



- In general, the higher the risk of an activity, the more effort required to regulate them
- Risk indices can be used to rate a series of risks using similar criteria so they can be compared
 - These criteria are chosen by the regulatory body in order to establish the risk index approach
- The Risk Index approach allows aggregation of a number of contributing factors to an overall risk ranking which considers the impact of an event and the probability of occurrence

Criteria Used for Ranking



- In Canada, the criteria used are called Safety and Control Areas (SCAs)
- SCAs are the technical topics used across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance

Safety and Control Areas



1. Management System
2. Human Performance Management
3. Operating Performance
4. Physical Design
5. Fitness for Service
6. Radiation Protection
7. Environmental Protection
8. Emergency Management
9. Waste Management
10. Security
11. Safeguards and Non-Proliferation
12. Packaging and Transport

Ranking Impact and Probability

Impact on H&S	Regulatory Effort Required		
Significant Impact 3	3	6	9
Moderate Impact 2	2	4	6
Minor Impact 1	1	2	3
Probability of Non-Compliance	Low 1	Moderate 2	High 3

- For each SCA, the impact of non-compliance on health and safety, and probability of non-compliance, are each assigned a corresponding ranking ordinal (3, 2, or 1)
- The product of the two determines the overall risk rank for that given SCA within that use type. The risk rankings for each of the SCAs are totalled to give an overall ranking

Example: Industrial Radiography

Management System	Human Performance Management	Operating Performance	Physical Design	Fitness for Service	Radiation Protection	Environmental Protection	Emergency Management	Waste Management	Security	Safeguards and Non-Proliferation	Packaging and Transport
9	9	9	6	9	9	0	9	0	9	6	6



Impact on H&S	Regulatory Effort Required		
	Significant Impact 3	3	6
Moderate Impact 2	2	4	6
Minor Impact 1	1	2	3
Probability of Non-Compliance	Low 1	Moderate 2	High 3

Overall Risk Score:
81

Example: Fixed Gauges

Management System	Human Performance Management	Operating Performance	Physical Design	Fitness for Service	Radiation Protection	Environmental Protection	Emergency Management	Waste Management	Security	Safeguards and Non-Proliferation	Packaging and Transport
6	4	9	2	4	4	0	6	0	3	0	2



Impact on H&S	Regulatory Effort Required		
	Significant Impact 3	3	6
Moderate Impact 2	2	4	6
Minor Impact 1	1	2	3
Probability of Non-Compliance	Low 1	Moderate 2	High 3

Overall Risk Score:
40

Example: Portable Gauges

Management System	Human Performance Management	Operating Performance	Physical Design	Fitness for Service	Radiation Protection	Environmental Protection	Emergency Management	Waste Management	Security	Safeguards and Non-Proliferation	Packaging and Transport
9	3	9	2	4	6	0	6	0	4	0	3



Impact on H&S	Regulatory Effort Required		
	Significant Impact 3	3	6
Moderate Impact 2	2	4	6
Minor Impact 1	1	2	3
Probability of Non-Compliance	Low 1	Moderate 2	High 3

Overall Risk Score:
46

Example: Overall Risk Rankings



Use Type	Overall Risk Score		
Industrial Radiography	81	More regulatory effort required	
Operate Pool Type Irradiator	55		
Portable Gauges	46		
Fixed Gauges	40		
X-ray Fluorescence	12		Less regulatory effort required

The risk ranking of each use type provides a **relative ranking of risk** compared to other use types.

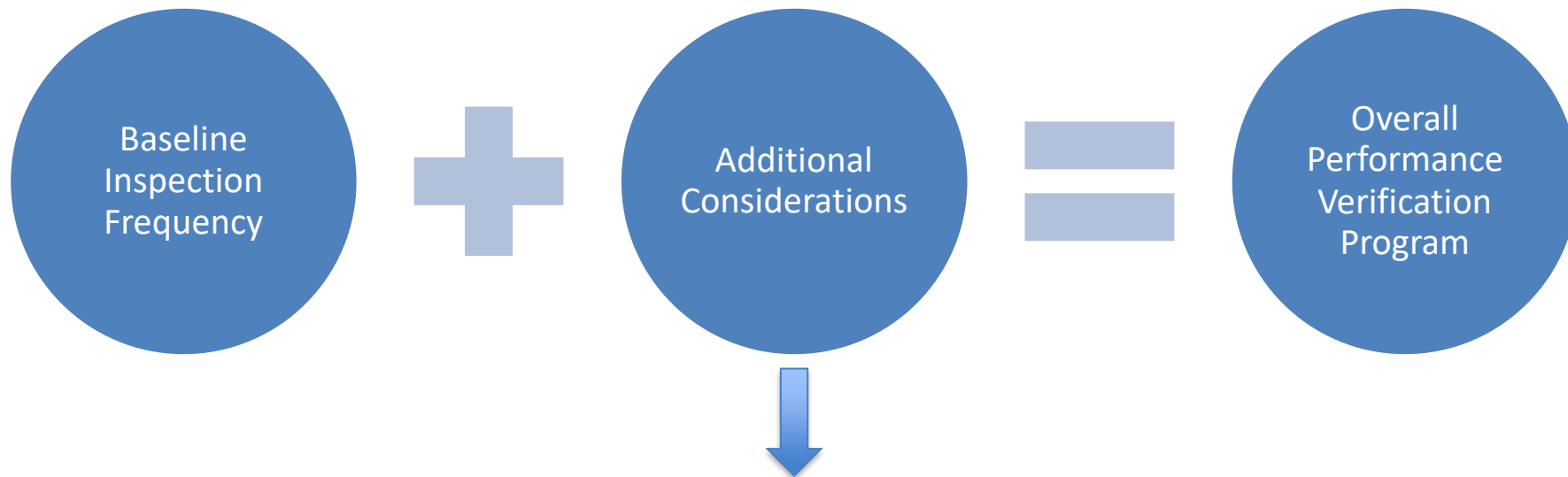
While a calculated value is used in the relative ranking, it is based on a scoring approach using ordinals and is not an absolute measure of risk.

Baseline Inspection Frequency



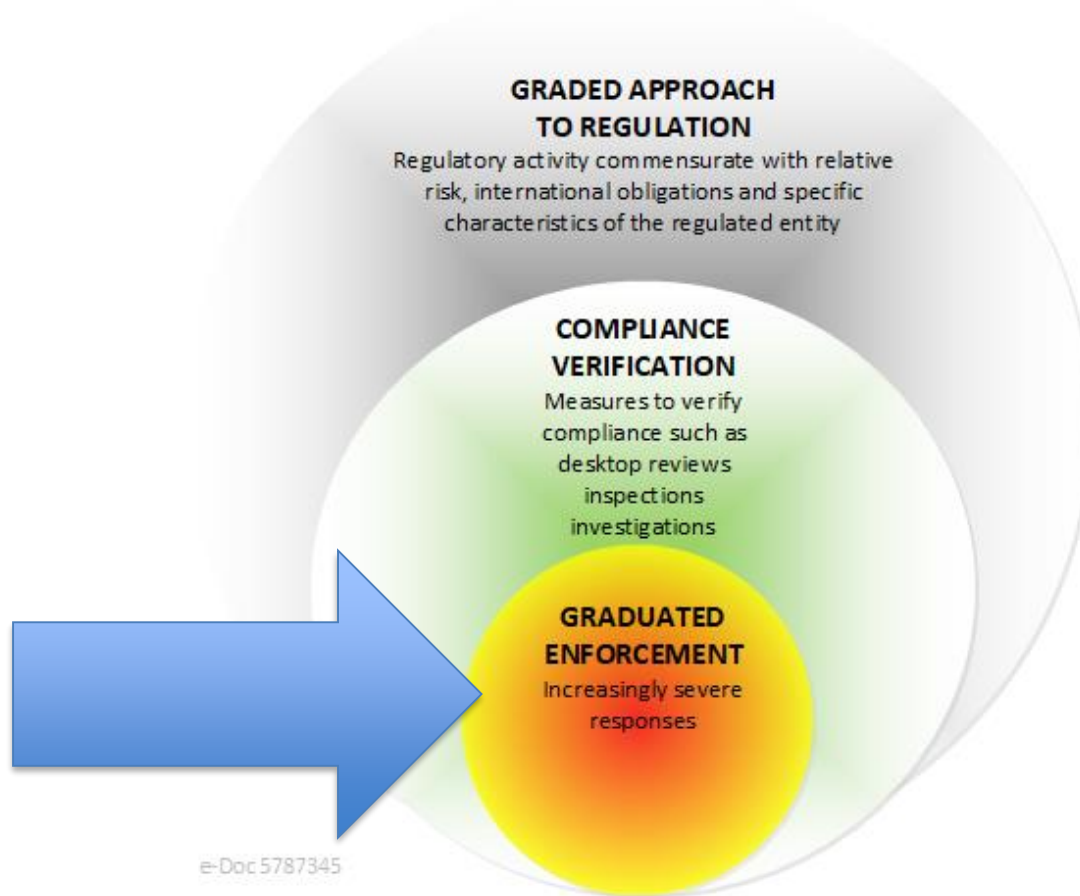
Use Type	Overall Risk Score	Risk Ranking	Baseline Inspection Frequency
Industrial Radiography	81	High (72+)	Two years.
Operate Pool Type Irradiator	55	Medium (25-71)	Two to Three Years.
Portable Gauges	46		Three Years. (Emphasis on Field inspections)
Fixed Gauges	40		Five Years.
X-ray Fluorescence	12	Low (0-24)	As needed.

Overall Performance Verification Program



Program Monitoring Results	<ul style="list-style-type: none">• Licensee and/or Sector Performance• Reported events and trends
Resources/Capacity of the Regulatory Body	<ul style="list-style-type: none">• Inspector resources and tools• Capacity for unanticipated work
Licensee Complexity	<ul style="list-style-type: none">• Large institutions, multiple locations or high-risk operations
Instigating Factors	<ul style="list-style-type: none">• Triggers such as changes to licensing basis or key personnel, major organizational changes (i.e. mergers), new regulatory requirements, etc.

Applying a Graded Approach to Enforcement



Goal of Enforcement Measures



- The goal is to determine the response(s) that would be most likely to result in restoring compliance as quickly and effectively as possible, considering:
 - the regulatory significance of the non-compliance
 - the circumstances that led to the non-compliance
 - the entire compliance history of the regulated party
 - any operational and legal constraints
 - any industry-specific factors

Enforcement Tools Available at the CNSC



AT ANY TIME

INFLUENCE COMPLIANCE AWARENESS (ongoing)

Outreach

Discussions, Meetings and Letters (DMLs)

Recommendations

AFTER NON-COMPLIANCE IS CONFIRMED

RESPOND TO NON-COMPLIANCE

Notice of Non-Compliance (NNC)

GNSCR 12(2) Request 

Licensing Action

Warning Letter

Order

Decertification

Increased Regulatory Scrutiny

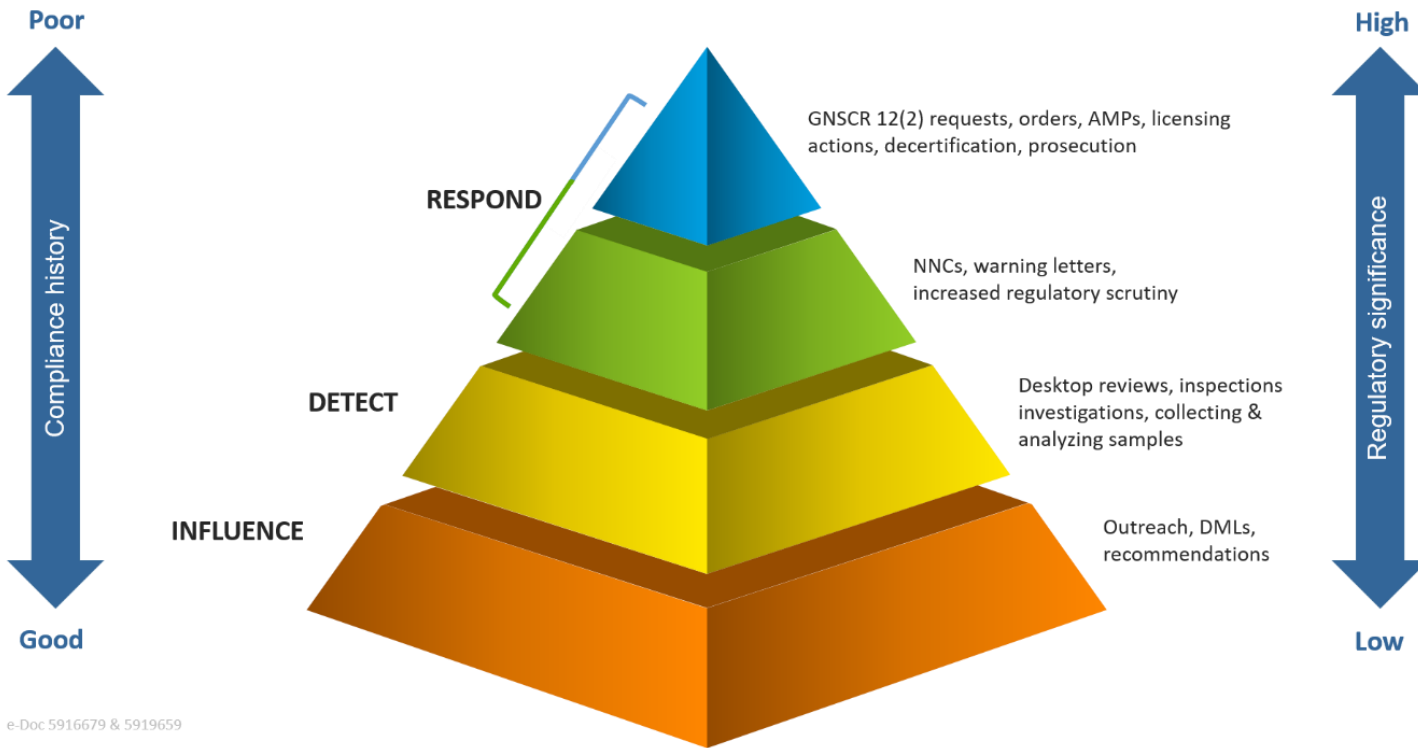
Administrative Monetary Penalty (AMP)

Prosecution

VISIO e-Doc 5772689

 A request under subsection 12(2) of the *General Nuclear Safety and Control Regulations* (GNSCR) is a legal instrument to which the licensee must respond.

Enforcement Tools Hierarchy



Conclusion



- CNSC staff apply a risk-informed approach when establishing:
 - regulatory requirements and guidance;
 - planning and conducting regulatory activities; and
 - making regulatory recommendations and decisions.
- Using a risk-informed approach, regulatory requirements and guidance may be applied in a graded manner, commensurate with the risk posed by the regulated activity included.



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Thank You !

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