

Development of a weighted means-based ranking tool for graded approach in the regulation of radioactive sources in the Philippines

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ABSTRACT

In the nuclear regulatory process, the application of graded approach is a recommended measure to ensure resources are allocated based on the associated risks. Despite comprehensive discussions on the use of graded approach in the nuclear and radiological regulatory paradigm, there are still challenges in terms of the approach regarding its utilization given the numerous criteria necessary for consideration. As for the Philippine regulations and processes, issues persist in harmonizing the application of graded approach during review, evaluation, authorization, and inspection activities. The study aims to conduct a review of existing frameworks and practices on the conduct of graded approach in the regulation of radioactive sources and equipment in the Philippines and worldwide. Based on the results, decision tool is proposed that combines a comparative analysis of criteria with a weighted-means formula to rank risks. There are specific criteria for consideration especially when considering risks from potential radiological emergencies. The utilization of weighted means also provides a practical and simple yet effective tool for prioritization of various graded approach criteria which can make decision-making easier. The developed tool contributes to a more structured, objective, and practical approach in making crucial decisions in the prioritization of risk criteria for graded approach. The tool can be refined and used in future reviews and as a reference for developing a graded approach regulation or guideline in the Philippines, as well as in nuclear installations where a more comprehensive regulation is necessary.

INTRODUCTION

Graded approach is a method applied to any process or product which might require a certain level of control, as defined by the International Atomic Energy Agency (IAEA 2014a). It ensures resources are allocated based on the associated risks. Consideration of risk pertains to the stringency of regulatory requirements that need to be applied to a particular facility or activity to ensure effective regulatory control.

Graded approach can be generally applied through a three-step method which is broadly applicable to all core regulatory functions (IAEA 2014a). As seen in Figure 1, the first step is to identify the decision that needs to be made in the regulatory process, or in the applicable regulatory function. The second step is to identify and rank the factors. Based on the results in ranking, the third step is to decide on an important regulatory concern or proper resource allocation.

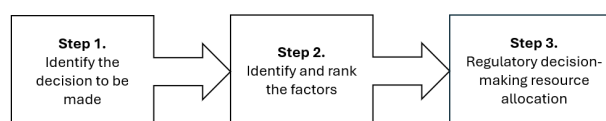


Figure 1: The Three-Step Approach in the Application of Graded Approach in the Regulatory Process or Function (IAEA 2014a)

Recent studies and documents have shown the initiative of creating a unified document or method in the use of graded approach in the nuclear and radiological regulatory realm (Lee, 2025; IAEA 2021). In the Philippines, the Nuclear Regulatory Division of the Philippine Nuclear Research Institute regulates the use of radioactive sources and nuclear installations through the Code of PNRI Regulations (CPRs). The CPRs cover various practices, including medical, industrial, research, and nuclear facilities addressing key safety and security infrastructures such as radiation protection, safety assessment, transport, emergency preparedness,

KEYWORDS

graded approach, regulation, radioactive

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Email Address: ljccobar@pnri.dost.gov.ph
Date received: 02 April 2026
Dates revised: 03 May 2026; 02 August 2026
Date accepted: 05 October 2026
DOI: <https://doi.org/10.54645/202619SupHMT-59>

and waste management. Despite the comprehensive scope of the CPRs in the regulatory process, challenges persist in harmonizing the application of graded approach during review, evaluation, authorization, and inspection activities. The absence of a particular regulation or guide for graded approach may lead to inconsistent interpretations or utilization of its application.

In addition, there are also instances where numerous categories for consideration may hinder in regulatory decision-making, particularly on the subjectivity of judgment of involved stakeholders in the regulatory process. Addressing these challenges is essential for effective regulatory control.

In various studies, decision-making from various criteria by assignment of weights has been widely utilized, particularly via the Multi-Criteria Decision Making Approach or MCDM/MCDA (Ensslin et al, 2000; Giove et al 2008; Takhar et al 2024; Analysis Function, 2024). In nuclear science and safety, the application covers the fields of nuclear waste (Schwenk-Ferrero and Andrianov 2017), sustainable energy resource (Gao et al 2017; Almonte et al 2026), and nuclear accidents (van Asselt et al 2021). Amidst the wide usage of weighted means, this application has not been fully utilized yet in the field of nuclear regulatory framework, specifically in graded approach.

This study aims to conduct a review of existing frameworks and practices on the conduct of graded approach in the regulation of radioactive sources and equipment in the Philippines and worldwide. The specific objectives for the study are:

1. To identify generic criteria for graded approach based on the existing international standards, literature, and practices;
2. To analyze, enhance, and supplement existing available criteria which are important for risk assessment; and
3. To provide a graded approach-based ranking tool through weighted means method.

REVIEW OF RELATED LITERATURE

Regulatory Framework and Practices of Radioactive Sources

The IAEA, the International Commission on Radiological Protection (ICRP) and the United Nations Scientific Committee on the Effects of Atomic Radiation are the recognized international agencies which formulates, develops and updates nuclear and radiological regulatory safety standards for the Member States' consideration (Joksic et al 2025). IAEA develops various general and specific safety standards and guides to cover various aspects of the nuclear regulatory framework on a global scale through its three tiers : (1) Safety Fundamentals; (2) Safety Requirements; and (3) Safety Guides (IAEA 2015a). Apart from the IAEA recommendatory standards, there are also national regulations set by countries in order to provide policies in the regulation of their respective nuclear and radioactive facilities. Given the existence of these global and national regulatory frameworks, it is useful to compare and learn from best practices for application in respective regulatory bodies (Bredimas and Nuttall 2008).

In the Philippine setting, the country regulates the use of radioactive sources and nuclear installations as set by its own legal and regulatory framework, mainly through the Code of PNRI Regulations (CPRs). The CPRs cover various practices, including medical, industrial, research, and nuclear facilities addressing key safety and security infrastructures such as radiation protection, safety assessment, transport, emergency preparedness, and waste management (Borras et al 2001). As of this writing, there are twenty-nine (29) CPRs available in the Philippines.

Graded Approach

As required by IAEA General Safety Requirement Part 1 (IAEA 2016), in order to ensure safety, security and proper control, regulators must perform their functions in a manner commensurate with the radiation risks associated with facilities and activities. This is the essence of applying graded approach in regulatory frameworks and processes of countries. The concept of graded approach is not only limited to the field of nuclear safety and security. Several graded methods have also been utilized for analysis mostly in clinical and medical fields where strengths and weaknesses are analyzed and rated to assess the effectiveness of healthcare guidelines (Brozek et al. 2021; Bezerra et al 2022; Prasad 2024). Graded approach in specific nuclear regulatory activities has also been applied such as in safety culture and regulatory oversight (Ahn et al 2022; Holmberg and Julin 2024), management systems (IAEA 2014a; Salama et al 2025), and decommissioning (Kudo and Sugihara 2021; IAEA 2026). In addition, graded approach has also been utilized in assessment involving specific source categories and facilities such as research reactors (IAEA 2012; Suha et al 2012), small modular reactors (Alamsyah et al 2023), HTGRs (Ngarayana and Murakami 2022) and NORM (Woo et al 2026).

For regulation of radioactive sources and equipment, the IAEA published in 2021 its technical guideline TECDOC 1974, which enumerates all the practices and industries and how graded approach is applied by assigning risk-level scores of experts or stakeholders using the following three criteria for evaluation: 1.) Level of exposure; 2.) Factors specific to radiation source; and 3.) Factors specific to facility and activity.

While IAEA TECDOC 1974 provides a comprehensive approach on graded approach for the regulation of radioactive sources and equipment, assignment of scores is disadvantaged by subjective prioritization of criteria and by contradictory perspectives on perceived risks by each stakeholder or expert. As for the graded approach methods in the nuclear regulatory field in general, while objective methods have been presented, the demonstration in the available literature focused only on the technical, probabilistic safety assessments, and criticality analyses of facilities and installations. These did not cover other external socio-economic and environmental criteria in the analysis which are critical parameters in radiological impact and risk assessments.

Weighted Means Approach in Multi-Criteria Decision Analysis

Decision-making analysis based on a multitude of criteria through the weights approach has been widely explored, particularly via the Multi-Criteria Decision Making Approach or MCDM/MCDA (Ensslin et al, 2000; Giove et al 2008; Takhar et al 2024; Analysis Function, 2024). Specifically in the field of nuclear science and safety, the application covers the field of nuclear energy systems (IAEA 2019), nuclear waste (Schwenk-Ferrero and Andrianov 2017), sustainable energy resource (Gao et al 2017; Almonte et al 2026), safety culture (Ahn 2022; Pei et al 2023), and Nuclear Accidents (van Asselt et al 2021).

While the assignment of weights depends on human judgment, the method relies on technical and mathematical techniques to enhance the objectivity of decision-making (Liu et al 2020, Wolny 2025). Since graded approach relies on ranking based on multiple factors depending on expert judgments, the use of weights approach can be explored to provide a more objective strategy resulting in enhanced results for risk consideration and control in the nuclear regulatory process.

MATERIALS AND METHODS

Practices and Regulatory Process for Decision-Making

This study covered twenty-five (25) industries with radioactive sources, or equipment and facilities using radiation energy in medical, industrial, and research sectors. The industries were selected from the IAEA Categorization (IAEA 2005). A comprehensive literature review was performed to formulate the criteria and sub-criteria which served as the basis for the ranking approach. The literature review was performed by desk research covering several studies and practices wherein graded approach was applied in the whole regulatory process (Adams et al 2002; IAEA TECDOC 1740 2014; IAEA TECDOC 1974 2021; Immonen 2023). IAEA publications, academic databases, and country reports were the key documents used in the review. The use of graded approach in specific sources and facilities, as well as emerging technologies, was also included in the research. Some countries wherein graded approach has been applied in a specific concern or phase of the regulatory process, such as safety culture (Ahn et al 2022), regulation, licensing or authorization, review and assessment and inspection were also considered. Specific safety standards and reviews focusing on radiation impact assessments and emergency preparedness were also selected as these provide further perspectives on risks and impacts of radiation to life and property (Linsley 1997; Mousseau and Møller 2020; Committee on Lessons Learned from the Fukushima Nuclear Accident for Improving Safety and Security of U.S. Nuclear Plants 2014; IAEA 2015b; Liu et al 2026; Yamamura et al, 2024).

For this study, only the industries utilizing radioactive sources and equipment will be covered as inclusion of nuclear installations may require specific criteria and complexities in the regulatory process.

Analysis of Factors or Criteria

The factors or criteria for ranking were listed and consolidated based on the surveyed literature on graded approach. Comparison of existing criteria with those integral in risk assessment in the field of nuclear safety was performed. Comparative analysis methods have been commonly used in research in various fields of studies especially in the social sciences (Mills & Rihoux 2012).

In the consolidation and analysis, six (6) criteria were developed to guide the categorization of practices based on risk:

- 1. Category based on activity ratio (A/D) formula by the IAEA (IAEA 2005; IAEA 2021)

- 2. Type of Facility (Adams et al 2002, IAEA 2021)
- 3. Location (Linsley 1997; Mousseau and Møller 2020; Committee on Lessons Learned - Fukushima 2014; IAEA 2015b; Liu et al 2026; Yamamura et al, 2024).
- 4. Risks to humans and environment (Linsley 1997; Mousseau and Møller 2020; Committee on Lessons - Fukushima 2014; IAEA 2014b, IAEA 2015b; Liu et al 2026; Yamamura et al, 2024).
- 5. Application requirements for review and evaluation (IAEA 2014b; IAEA 2021; Immonen 2023; IAEA 2025; Salama et al 2025)
- 6. Evaluation, inspection, and enforcement areas (IAEA 2014b; IAEA 2021; Immonen 2023)
- 7. Other criteria for consideration, i.e. other criteria which the evaluators may decide or prioritize as important for analysis (see example in Annex I)

Upon analysis of the factors in comparison with the initially surveyed literature, 3. *Location* and 4. *Risks to humans and environment* were explicitly stated and enumerated since these aspects are deemed very crucial in risk assessment (Linsley 1997; Mousseau and Møller 2020; Committee on Lessons Learned - Fukushima 2014; IAEA 2014b, IAEA 2015b; Liu et al 2026; Yamamura et al, 2024). Elaboration of such factors include considerations of meteorological and topographical conditions, on-site and off-site impacts of potential emergencies, radiation risk and exposure of plants and animals, and financial costs of mitigation, recovery, and rehabilitation.

Each criterion was divided into sub-criteria to be considered and assessed for ranking. As the sub-criteria can be added depending on the assessor, the sub-category ‘Others’ was listed as an additional category (Table 1). A reference guide explaining the description of each criterion can be seen in Annex I.

Scoring Based on Risk Categorization

The description on each criterion for graded approach ranking can be seen in Table 2. The lowest score or point assigned equates to *very low risk*, while 5 is assigned as *very high risk*.

Each criterion was scored from 1 (Very Low) to 5 (Very High). In each practice, a corresponding score was determined by the assessors based on their assessments from regulations and experiences.

Table 1: Criteria and Sub-Criteria for Graded Approach

CRITERIA	SUB-CRITERIA
1. <i>Category (based on the Activity ratio (A/D) computation of the IAEA’s Categorization of Radioactive Sources)</i>	1.1 Category I (Activity ratio is greater than or equal to 1000) 1.2. Category II (Activity ratio is less than 1000 but greater than or equal to 10) 1.3. Category III (Activity ratio is less than 10 but greater than or equal to 1) 1.4. Category IV (Activity ratio is less than 1 but greater than or equal to 0.01) 1.5. Category V (Activity ratio is less than 0.01 and greater than the exempted value)

2. Type of Facility	2.1.Source/Equipment operation process 2.2.Generation/Emission characteristics 2.3. Containment & shielding requirements 2.4. Complexity 2.5. Technology requirements 2.6. Utilization 2.7. Waste storage and disposal requirements
3. Location	3.1. On- and off-site impacts 3.2. Population density 3.3. Topographical conditions
4. Risks to humans and environment	4.1. Health and life impacts on flora and fauna 4.2. Damage to property 4.3. Costs for rehabilitation
5. Application requirements for review and evaluation <i>(e.g. documents/proof for safety)</i>	5.1. Application documents (plans, dose monitoring, calibration, inventory reports, etc.) 5.2. Safety assessment results 5.3. Training requirements
6. Evaluation, Inspection, and Enforcement Areas	6.1. Requirements for the conduct of inspection 6.2. Inspection areas 6.3. Potential severity of inspection findings
7. Others	-Additional sub-criteria for consideration-

Table 2: Criteria Ranking Description for Graded Approach (Adopted from IAEA 2021)

SCORE	CATEGORY	DESCRIPTION
5	Very High	Significant risk requiring stringent oversight and control
4	High	Moderate to high risk requiring regular monitoring
3	Medium	Manageable risk with routine oversight
2	Low	Minor risk with minimal regulatory requirements
1	Very Low	Negligible risk, minimal oversight required

Weighted Means Calculation

The graded approach weighted means model (Equation 1) for the calculation of ranking of criteria was formulated below:

Equation 1...

$$Wga = \sum wi(ri) / \sum W$$

Where:

Wga = Total weighted score for graded approach
wi = Assigned weights for each criterion

ri = score from 1-5 (wherein 5 - highest and 1- lowest)
W = sum of weights

To illustrate the graded approach ranking using this model, a hypothetical scenario wherein a regulatory body must decide whether to prioritize an Iodine 125 (I125) brachytherapy facility or a company that uses a Cesium 137 (Cs137) density gauge in the renewal of its license. The rankings and weights are assigned in each category for consideration based on the judgment of a regulator. The calculation was performed via the simple functions in Microsoft Excel (<https://tinyurl.com/SIonNST35>).

The total weighted score for each practice determined its risk level and priority as categorized into five levels, where Level V is identified as ‘Very High’ and Level I as ‘Very Low’ (Table 3).

Table 3: Category and level for Risk Prioritization

TOTAL WEIIGHTED SCORE	RISK LEVEL	DESCRIPTION
4.1-5.0	V	Very High
3.1-4.0	IV	High
2.1-3.0	III	Moderate
1.1-2.0	II	Low
≤1.0	I	Very Low

The steps on the conduct of methodology for this review is illustrated in Figure 2. below:

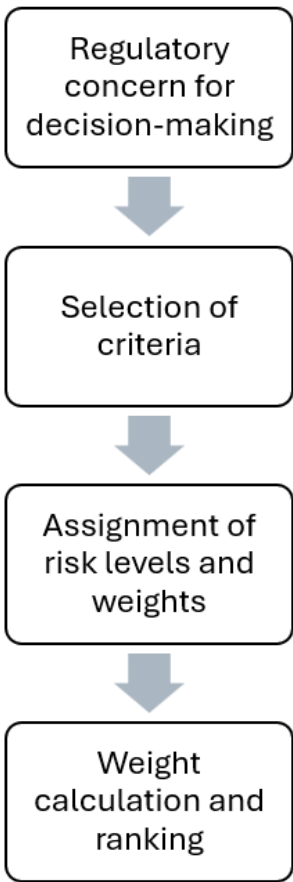


Figure 2: Step-by-step methodology for weighted means ranking for graded approach

Table 4: Criteria and Sub-Criteria for Graded Approach Analysis on Brachytherapy and Density Gauge Licensing Scenario

CRITERIA	SUB-CRITERIA
1. <i>Category (based on the Activity ratio (A/D) computation of the IAEA’s Categorization of Radioactive Sources)</i>	Category II - Category V for Cesium137 (Cs137) & Iodine125 (I125)
2. <i>Type of Facility</i>	- Energy/Radioactivity emitted by the two sources - Containment & shielding comparison between Cs137 and I125 - Technology requirements and utilization complexity of sources depending on the facility type (industry vs. hospital or medical use) - Waste storage and disposal requirements

The assignment of scores and weights from the hypothetical case study is for illustration purposes only. The utilization of this method can be improved through peer review or expert assessment, for example by the IAEA or other experts

RESULTS AND DISCUSSION

Determination of Criteria

From the generic list, the five (5) criteria were selected for the graded approach analysis of the hypothetical brachytherapy and density gauge licensing comparison scenario. The criteria concentrated on 1.) Categorization/Source of Equipment; 2.) Type/Complexity of Facility; 3.) Location Characteristics; 4.) Risks to Human Health and Environment; and 5.) Application Requirements for Review and Evaluation. Evaluation, Inspection and Enforcement was not included to focus the prioritization on the solely on the licensing process from the submission of application to review and granting of license. In Table 4, a corresponding sub-criteria or description for consideration in scoring and assignment of weights was provided for each criterion.

3. Location	- Emergencies in the two facilities together with on- and off-site impacts of accidents involving the two sources - Depending on scope and scenario, possible number of persons to be affected in case of occurrences of emergencies - Effect of topographical conditions on emergencies, if any, which may worsen the safety situation
4. Risks to humans and environment	- Possible moderate to high effects on health and life impacts on flora and fauna of Cs137 and I125 - Scope of effects of contamination on-site and off-site when an emergency occurs - Possible medium-high costs for decontamination and suspension of operations
5. Application requirements for review and evaluation (e.g. documents/proof for safety)	- Application documents (plans, dose monitoring, calibration, inventory reports, etc.) - Safety assessment results of the two industries - Training requirements of radiation protection officers, QA analysts, and medical personnel

Weighted Means Calculation

The results of the calculation for prioritization of license renewal application for both industries can be seen in Tables 5 and 6. Based on the results, the Cs-137 density gauge company can be selected as a priority in the review of license application renewal as it had a total of 3.9 out of 5, compared to the brachytherapy facility with a total of 3.4 out of 5. Given the risk category of density gauge source and its risks to humans and environment, especially the mobility in the use of gauge in the field and different locations, the gauge company scored higher for these categories than in a brachytherapy facility.

Table 5: Weighted Means Graded Approach Ranking for Evaluation of License Renewal Application: Brachytherapy

CRITERIA	WEIGHTED MEANS CALCULATION		
	Score	Weight	Total
1. Categorization of Source/Equipment	2	20%	0.4
2. Type/Complexity of Facility	3	10%	0.3
3. Location Characteristics	3	10%	0.3
4. Risks to Humans and the Environment	4	30%	1.2
5. Application Requirements for Review and Evaluation	4	30%	1.2
TOTAL	16	100%	3.4

Table 6: Weighted Means Graded Approach Ranking for Evaluation of License Renewal Application: Density Gauge

CRITERIA	WEIGHTED MEANS CALCULATION		
	Score	Weight	Total
1. Categorization of Source/Equipment	3	20%	0.6
2. Type/Complexity of Facility	3	10%	0.3
3. Location Characteristics	3	10%	0.3
4. Risks to Humans and the Environment	5	30%	1.5
5. Application Requirements for Review and Evaluation	4	30%	1.2
TOTAL	18	100%	3.9

The addition of criteria on location characteristics and risks to humans and environment, together with the assignment of risk level via the scoring system, and lastly, the addition of weight assignments in assessing the ranking of each criterion provide a feasible solution in terms of determining the importance or value in the graded approach of regulating radioactive sources. The practicality of assigning weights in ranking categories demonstrates that making crucial yet effective decisions can be performed amid limited resources (Tholaka 2011, Tholaka and Duenas 2012, Sussex et al 2013, Endrei et al 2014). Even though there are challenges in the subjectivity on scoring assignments, this method is an easy-to-follow procedure based on technical, more objective technique for regulators in the application of graded approach in the regulatory process.

The tool can be used as a starting point for the application of graded approach in the regulatory process of the Philippines in a systematic manner. As there is currently no available regulation, guide, or bulletin specifically for graded approach, the tool can be used as the basis. Development of regulations for pressing concerns is crucial amid the institutionalization of an independent Philippine nuclear regulatory body in the country. Strengthening the regulatory framework is crucial as the Philippines has been exploring nuclear energy to be a permanent part of the energy mix with the emergence of new technologies ahead.

In the international context, the tool contributes to the existing practices of nuclear regulatory graded approach worldwide. Due to its simplicity and practicability, the developed tool can also be easily applied by emerging countries, which are on the verge of discovering or expanding their respective radiological or nuclear technologies and energy resources (Petri and Vikas 2026).

As graded approach emphasizes the consideration and reduction of potential greatest risks, the developed tool can be a strategy for reducing possible high risks in order to focus on safety as an end goal, as well as more efficient and economical implementation of regulatory activities both in the national and global scales.

The analysis was conducted using a single case comparison with random assignment of weights based on assumption and general knowledge. Expert validation of the tool is also crucial to further analyze the accuracy of the model for application in the regulatory process.

CONCLUSION AND FUTURE WORKS

This study developed a structured framework and method for the application of graded approach using weighted means. A review of the existing framework and practices on graded approach in the

regulation of radioactive sources was performed, mainly focusing on the practices stated in the IAEA TECDOC 1974. The criteria stated in IAEA TECDOC 1974 and other key relevant literature were supplemented through the analysis from other literature, making six (6) criteria for consideration in graded approach ranking. Through demonstration of a brachytherapy vis-à-vis density gauge licensing scenario, decision-making of priorities via scoring of each criterion based on the IAEA approach was shown through the utilization of a weighted-means calculation. The developed tool provides a practical application in ranking and determining the importance of risk assessment in the regulatory process of radioactive practices.

This framework illustrates its applicability to regulatory functions and processes. The risk-based assessment manifested the prioritization of regulatory efforts by focusing on higher-risk practices while streamlining oversight of lower-risk activities and assigning weights to provide subjectivity in the given scores for each factor.

To enhance the reliability of this framework, it is recommended that expert regulators and safety officers of regulated facilities be involved in future assessments to further minimize subjectivity in scoring. Peer reviews by international organizations like the IAEA can validate and refine the methodology. Future studies should also explore the application of this tool in the development of a specific regulation or regulatory guide for the application of graded approach, as well as in regulation of nuclear installations especially in an emerging nuclear resource country like the Philippines.

ACKNOWLEDGMENTS

The author acknowledges the support of the Radiological Impact Assessment Section and the Nuclear Regulatory Division of the PNRI in conducting this study.

CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

CONTRIBUTIONS OF INDIVIDUAL AUTHORS

LJC: Study conceptualization, literature review, analysis, article-writing, revision, and finalization.

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SUPPLEMENTAL INFORMATION

Annex I: Ranking Per Criteria and Corresponding Description

CRITERIA	RANKING	DESCRIPTION
A. ACTIVITY RATIO (based on the IAEA)	5 – Very High	RTGs, Irradiators, Teletherapy, Gamma knife
	4 - High	Industrial radiography, high/medium brachytherapy, thickness gauges, research reactors
	3 – Medium	Industrial gauges, well logging
	2 – Low	Low dose brachytherapy, portable gauges, densitometer, static eliminators, radiotherapy
	1 – Very Low	Devices, check sources
B. TYPE OF FACILITY		
	5 – Very High	Very high energy production, fuel type, complexity, shielding/containment, utilization, waste requirements, etc.
	4 - High	High energy production, fuel type, complexity, shielding/containment, utilization, waste requirements, etc.
	3 – Medium	Medium energy production, fuel type, complexity, shielding/containment, utilization, waste requirements, etc.
	2 – Low	Low energy production, fuel type, complexity, shielding/containment, utilization, waste requirements, etc.
	1 – Very Low	Very low energy production, fuel type, complexity, shielding/containment, utilization, waste requirements, etc.
C. LOCATION		
	5 – Very High	High impact on site and moderate impact off site of the facility/place where source is being utilized
	4 - High	High impact on the specific location/place where source is being utilized, and low impact off site
	3 – Medium	Moderate impact on site and off site of the facility
	2 – Low	Moderate impact on site and low/no impact off-site
	1 – Very Low	Low impact both on and off site
D. RISKS TO HUMANS AND THE ENVIRONMENT		
	5 – Very High	Very high risks to humans and environment during accidents and threats
	4 - High	High risks to humans and environment during accidents and threats
	3 – Medium	Medium risks to humans and environment during accidents and threats
	2 – Low	Low risks to humans and environment during accidents and threats
	1 – Very Low	Very low risks to humans and environment during accidents and threats
E. APPLICATION REQUIREMENTS FOR REVIEW AND EVALUATION		
	5 – Very High	High level of review and assessment efforts & moderately high quality & quantity of licensing/safety & security requirements are required
	4 - High	Moderate level of review and assessment efforts & high quality & quantity of licensing/safety & security requirements are required
	3 – Medium	Moderate level of review and assessment efforts & moderate quality & quantity of licensing/safety & security requirements are required
	2 – Low	Low level of review and assessment efforts & moderate quality & quantity of licensing/safety & security requirements are required
	1 – Very Low	Low level of review and assessment efforts & low quality & quantity of licensing/safety & security requirements are required

CRITERIA	RANKING	DESCRIPTION
F. EVALUATION, INSPECTION, AND ENFORCEMENT AREAS		
	5 – Very High	High level of inspection & enforcement efforts, and potentially moderately high impact/remedial actions & quantity of findings can be found
	4 - High	Moderate level of inspection and enforcement efforts, and potentially high impact/remedial actions & quantity of findings can be found
	3 – Medium	Moderate level of inspection and enforcement efforts, and potentially moderate impact/remedial actions & quantity of findings can be found
	2 – Low	Low level of inspection & enforcement efforts, and potentially moderate impact/remedial actions & quantity of findings can be found
	1 – Very Low	Low level of inspection & enforcement efforts, and potentially low impact/remedial actions & quantity of findings can be found
G. OTHER CRITERIA FOR CONSIDERATION (e.g. FINANCIAL REQUIREMENTS FOR THE CONDUCT OF REGULATORY REVIEW)	5 – Very High	Very high level of financial requirements for the conduct of review and inspection before licensing
	4 - High	High level of financial requirements for the conduct of review and inspection before licensing
	3 – Medium	Moderate level of financial requirements for the conduct of review and inspection before licensing
	2 – Low	Low level of financial requirements for the conduct of review and inspection before licensing
	1 – Very Low	Very low level of financial requirements for the conduct of review and inspection before licensing

Recommended Guidelines for Conducting Graded Approach in the Regulatory Process

- Draft -

I. Purpose

This guide is provided to assist the licensees and regulators in the whole nuclear and radiological regulatory process in the Philippines. The development of this guide was based on the review of the standards prescribed by the International Atomic Energy Agency (IAEA), applications and implemented practices of other regulatory bodies, and internal ranking by and discussions with the local regulators in the country.

II. Applicable Regulations

The main regulations applicable to this guideline are the following:

- Code of PNRI Regulations (CPR) Part 3: Standards for Radiation Protection
- Code of PNRI Regulations (CPR) Part 6: Requirements for Leadership and Management Safety

In addition, all the other CPRs have provisions on the application of Graded Approach in each activity or concern in regulating nuclear installations and/or radiological practices.

III. Graded Approach

Based on Section 11 of CPRs Part 3 and 6, each management system shall be developed and applied using a graded approach. The criteria used to grade the development and application of the management system shall be documented, considering the following concerns:

- The safety significance and complexity of the organization, operation of the facility or conduct of the activity involving a radioactive material;
- The hazards and the magnitude of the potential impacts and risks associated with the safety, health, environmental, security, quality and economic elements of each facility or activity; and
- The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.

The IAEA also identified the three-step approach in the application of Graded Approach in the regulatory process or function:

- Identify the decision to be made
- Identify and rank the factors or criteria
- Decision-making and/or resource allocation

IV. Criteria for Graded Approach

As prescribed by the IAEA and mentioned in Part III of this guideline, a set of criteria must be established by the regulatory bodies which will serve as the basis for applying and implementing the Graded Approach in the regulatory process. The criteria should consider the safety significance, complexity and applicable hazards, risks, and possible consequences for safety. Thus, six (6) criteria were developed for the application of graded approach in the Philippines:

- a. Categorization based on activity ratio (A/D)
- b. Type and complexity of practice or facility
- c. Characteristics of location
- d. Risks to humans and the environment
- e. Application requirements for review and evaluation
- f. Evaluation, inspection, and enforcement areas

V. Graded Approach for Nuclear Installations

The abovementioned criteria and guidelines are applicable for both nuclear installations and industries or practices using radioactive sources. However, additional criteria must be considered in implementing the Graded Approach for nuclear installations since these are more complex and require rigorous evaluation and safety assessment.

VI. Categorization-based on Activity Ratio (A/D)

The IAEA method of categorization of radioactive sources based on the calculation of activity ratio must be considered in the application of Graded Approach (Table A1).

Table A1. IAEA Categorization Based on Activity Ratio (A/D)

RISK LEVEL	SOURCES/PRACTICES
Very high risk	Accelerators, Radioisotope Thermoelectric Generators (RTGs), Irradiators, Teletherapy, Gamma Knife
High risk	Industrial Radiography, High/Medium Brachytherapy, Research reactors
Medium risk	Industrial gauges, well logging, in vivo diagnosis
Low risk	Low dose brachytherapy, portable gauges, densitometers, static eliminators, radiotherapy
Very low risk	XRF devices, check & calibration sources, consumer products, implant sources, electron capture devices

VII. Type and Complexity of Practice or Facility

The complexity and type of each practice or facility that uses a radioactive source must be considered in the application of Graded Approach. These include the magnitude or level of energy or power production of each source or facility, and utilization process, type of fuel, shielding and containment requirements, protection equipment, waste storage and disposal, and decommissioning requirements. The more complex characteristics and sophisticated type of the facility or practice, the higher the requirements and evaluation procedures necessary for consideration of safety and security in the regulatory process.

VIII. Location Characteristics

Apart from the complexity and type of each practice or facility that uses a radioactive source, the characteristics of the location must be considered in the application of Graded Approach. These include the magnitude of potential impacts of incidents on- and off-site of the facility, population density, land cover and topography, and availability of road or transportation networks for accessibility.

IX. Risks to Humans and the Environment

The potential risks to humans and the environment must also be considered in the application of Graded Approach in the regulatory process. These include assessment of deterministic and stochastic effects per type of source, health and life impacts of flora and fauna, damage to property, economic and social costs for recovery and rehabilitation.

X. Application Requirements for Review and Evaluation

The requirements for the application, review and evaluation of licenses and permits for the operation of radioactive source utilization and facilities must also be considered for Graded Approach application. These include the quantity of application documents (i.e. plans, dose monitoring, calibration, training and registration certification, inventory reports, etc.), level (i.e. duration and effort)

of pre-licensing, review and assessment, safety assessment results, training requirements, and quality of safety and security regulations applicable.

XI. Evaluation, Inspection, and Enforcement Areas

Similar to review and evaluation, inspection and enforcement efforts must also be considered in the application of Graded Approach. Factors to be considered must include duration and effort for inspection, potential severity of inspection findings, required remedial action and consideration for suspension of operations. The reputation and history of licensees in terms of repeated or unresolved audit findings must also be considered.

Other factors which the stakeholders may consider as relevant may be included as long as they are justifiable.

XII. Ranking of Factors

For the conduct of Graded Approach in each regulatory process, the licensee and regulator may consider a category- or point-based ranking each of the abovementioned criteria from 'high level' to 'low level' to aid in the decision-making and resource allocation in each regulatory function or the whole process itself. The highest level of ranking means the risk is significant and may require a stringent oversight and regulatory control, and the lowest level means there is a minor or negligible level of risk which means a minimal oversight and regulatory control is required.

XIII. Additional Criteria and Factors

As needed, additional criteria and factors for Graded Approach may be utilized by the licensees and regulators as long as justification and proper documentation on their utilization are provided. In addition, the lead regulator or expert may determine and apply weighing factors for each criterion to determine which aspects may be prioritized in the scoring and ranking.

Weighted-Means Ranking for Graded Approach

A weighted-means approach in ranking and prioritization of factors for graded approach may be utilized through the following equation:

Equation 1.

$$Wga = \sum wi(ri) / \sum W$$

Where:

Wga = Overall ranking for graded approach

wi = Assigned weights for each criterion

ri = score from 1-5 (wherein 5 - highest and 1- lowest)

W = sum of weights