

A Graded Risk Based Framework for Inspection Planning in Radiation Regulatory Authorities

Henry Lawluvi^{1,2*}; Cyril Cyrus Arwui^{1,2}; Emmanuel Akrobortu^{1,2};
Nelson Agbemava¹; Etornam Ann Mensah¹; Sheilla Victoria Gbormitta¹

¹ Nuclear Regulatory Authority, P.O. Box AE 50, Kwabenya, Accra, Ghana

² School of Nuclear and Allied Sciences, University of Ghana, Legon, Accra, Ghana

Corresponding Author: henrylawluvi@gmail.com

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Abstract: Radiation regulatory authorities supervise highly heterogeneous facilities and activities, yet inspection resources are finite and fixed inspection periodicity rarely reflects real differences in hazard, exposure pathways and compliance performance. This paper develops a graded risk based inspection framework that translates international safety requirements into a practical decision model for routine regulatory use. The study is a methodological framework paper based on documentary synthesis and design logic rather than on a primary empirical dataset. International safety standards, technical guidance, selected national regulatory manuals and methodological literature on semi quantitative risk tools were reviewed and converted into an operational model for inspection planning. The proposed framework separates inherent risk from managed risk and integrates five scored domains: hazard tier, exposure potential and operational complexity, compliance and event history, management system maturity, and source lifecycle or safety security flags. A conservative uncertainty uplift, documented override rules, stratified sampling and reactive inspection triggers are incorporated so that low scoring populations do not disappear from regulatory view and missing data do not falsely imply low risk. The main outputs are transparent risk bands linked to inspection frequency, inspection scope, inspector competence requirements and annual portfolio composition. The framework is intended for use by authorities with limited analytics capability as well as by regulators operating structured information systems such as RAIS+. Its main contribution is a reproducible and auditable method for converting a graded regulatory philosophy into an inspection programme that is proportionate, conservative under uncertainty and capable of continuous improvement.

Keywords: Risk Based Inspection; Graded Approach; Radiation Regulation; Compliance; Inspection Planning; Radiological Protection.

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I. INTRODUCTION

Radiation regulatory authorities are expected to maintain credible oversight of facilities and activities that may expose workers, patients, members of the public or the environment to ionising radiation. In practice, this mandate extends across a diverse inventory that may include industrial radiography, diagnostic radiology, radiotherapy, nuclear medicine, research laboratories, well logging, irradiators, naturally occurring radioactive material activities, waste management practices and other source related operations. Because hazard and operational conditions differ markedly across these practices, a uniform inspection interval is rarely proportionate or efficient.

International safety standards address this problem through the graded approach, under which regulatory control is expected to be commensurate with the radiation risks associated with facilities and activities (IAEA, 2014; IAEA, 2016a; IAEA, 2021). Inspection is therefore not simply an administrative cycle linked to authorisation renewal. It is a core regulatory function that should reflect hazard, exposure potential, compliance performance and changing operational conditions. Regional regulatory instruments have reinforced the same position by requiring inspection programmes to consider both the magnitude and nature of hazards and the state of compliance of the undertaking (European Union, 2013).

Despite this broad normative consensus, inspection planning in many jurisdictions still relies on fixed periodicity, informal judgement or inherited practice specific schedules. These approaches are easy to administer, but they have important weaknesses. They can misdirect scarce inspector time, obscure the reasons why some facilities are prioritised over others, and make it difficult to demonstrate fairness or consistency when decisions are challenged. They may also fail to respond quickly when organisational performance deteriorates between routine inspections.

A second weakness is the common tendency to treat all facilities within the same practice category as if they presented the same regulatory challenge. This can lead to under inspection of moderate hazard organisations with poor controls, or over inspection of relatively well managed facilities whose residual risk is low. A robust planning method should therefore distinguish between the intrinsic hazard of the practice and the quality of the controls that are operating in the field.

This paper develops a practical framework for risk based inspection planning in radiation regulatory authorities. The aim is not to present a probabilistic risk model or to claim universal weighting values. Rather, the paper offers an auditable method for converting regulatory principles and implementation guidance into a decision structure that can be used with routine regulatory records. The specific contributions are threefold. First, the paper separates inherent risk from managed risk. Second, it translates this distinction into a scored planning model linked to frequency, scope and portfolio design. Third, it identifies the governance controls required to keep such a defensible model in real regulatory settings.

II. MATERIALS AND METHODS

A. Study Design

This study was designed as a methodological framework paper derived from documentary synthesis and design logic rather than from a primary empirical dataset. The purpose was to convert the general concept of graded or risk informed inspection planning into an operational

model that can be implemented by radiation regulatory authorities. The paper therefore emphasises conceptual clarity, implementation feasibility and legal defensibility rather than statistical prediction.

The manuscript is not presented as a systematic review. The objective was not to estimate effect sizes or to compare regulatory outcomes quantitatively, but to identify recurrent principles and decision variables that could support an inspection planning model. For that reason, sources were selected purposively based on authority, relevance and direct usefulness for framework construction.

B. Evidence Base and Sources

Four source groups informed the framework. The first group comprised international safety requirements and guidance dealing with the regulatory framework for safety, basic safety standards, graded control, source categorisation, management for safety and protection of the public and the environment (IAEA, 2005; IAEA, 2014; IAEA, 2016a; IAEA, 2016b; IAEA, 2018; IAEA, 2021; IAEA, 2022). The second group comprised implementation oriented documents and manuals from selected regulators that provide practical signals on inspection planning, inspection types, programme governance and compliance assessment (AERB, 2014; ARPANSA, 2023; CNSC, 2025). The third group comprised legal and policy instruments that explicitly connect inspection intensity to hazard and compliance status, especially Council Directive 2013/59/Euratom (European Union, 2013). The fourth group comprised methodological literature addressing the strengths and weaknesses of semi quantitative risk matrices and related oversight tools (Cox, 2008).

Sources were retained when they met at least one substantive function in framework development: defining the graded approach; clarifying the purpose and structure of inspection programmes; identifying variables useful for facility prioritisation; supporting the treatment of uncertainty, enforcement or environmental interfaces; or informing governance safeguards for model use. Publications that discussed radiation protection in general terms without operational relevance to inspection planning were not used as core design sources.

Table 1. Core Sources and their Design Implications for the Proposed Framework.

| Source | Main Inspection Relevance | Implication for the Framework |
|--------------------------|--|--|
| IAEA GSR Part 1 (Rev. 1) | Defines inspection and enforcement as core regulatory functions within the governmental, legal and regulatory framework for safety. | Provides the procedural backbone for a documented, auditable inspection programme. |
| IAEA GSR Part 3 | Requires graded regulatory control commensurate with radiation risk and the protection of workers, patients, the public and the environment. | Anchors prioritisation in proportionality rather than fixed periodicity. |
| IAEA RS G 1.9 | Provides source categorisation as a practical basis for consequence based hazard tiering. | Supports minimum oversight floors for higher hazard sources and practices. |
| IAEA TECDOC 1526 | Explains inspection types and scheduling considerations and cautions against tying inspection frequency directly | Supports dynamic scheduling, unannounced inspections and reactive |

| | to licence renewal. | oversight. |
|-----------------------------------|---|--|
| IAEA TECDOC 1974 | Provides practical guidance on applying a graded approach using systematic criteria. | Supports structured scoring, banding and transparent regulatory reasoning. |
| IAEA TRS 1002 | Links authorisation, inspection and enforcement and addresses safety and security in a harmonised regulatory context. | Supports lifecycle flags, override logic and enforcement linkage. |
| Council Directive 2013/59/Euratom | Requires inspection programmes to consider both hazard and the state of compliance. | Reinforces integration of performance indicators into scheduling. |
| Selected national manuals | Provide operational examples of inspection planning, programme governance and compliance assessment. | Support local calibration and implementation realism. |

C. Framework Development Process

Framework construction proceeded in three stages. First, recurrent planning constructs were extracted from the source material. These included hazard or source category, exposure pathway, operational complexity, compliance history, management system quality, event signals, source lifecycle issues, environmental interface, enforcement linkage and the need for both planned and reactive inspections. Second, related constructs were consolidated into broader operational domains suitable for routine scoring. Third, the domains were mapped to inspection outputs, namely risk band, inspection interval, inspection scope, required inspector competence and portfolio composition.

Candidate variables were judged against five design requirements: transparency, proportionality, conservative treatment of uncertainty, reproducibility and operational feasibility. Variables were retained only when they could be described clearly, observed from routine regulatory records or inspection findings, and interpreted consistently enough to support documented decisions. This favoured a semi quantitative design over a purely qualitative narrative approach and also avoided the false precision associated with more elaborate models that cannot be sustained by available data.

D. Model Logic and Scoring Architecture

The model separates inherent risk from managed risk. Inherent risk is driven primarily by the source or practice itself and by the plausible consequences of loss of control. Managed risk reflects the degree to which that hazard is being controlled in practice. This distinction was adopted because facilities with similar source inventories may warrant different inspection intensity if their compliance performance and management systems differ materially.

Five scored domains were retained: hazard tier (H), exposure potential and operational complexity (E), performance and compliance history (P), management system maturity (M), and lifecycle or safety security flags (S). Each domain is scored on a five point ordinal scale from 0 to 4, where higher values indicate greater regulatory concern. To prevent incomplete data from artificially lowering oversight, an uncertainty uplift (U) is added when essential information is missing, outdated or contradictory.

A suggested composite score is expressed as:

$$R = 100 * \left(\frac{0.30H + 0.20E + 0.25P + 0.15M + 0.10S}{4} \right) + U \tag{1}$$

where R is the composite score on an approximate 0 to 100 scale, and U is a conservative uplift of 0, 5 or 10 points depending on data quality. The default weights are illustrative rather than universal. Regulators may alter them under documented change control, provided that the reasons for doing so are explicit and the consequences are periodically reviewed.

The model also allows documented overrides. A facility may be moved temporarily to a higher priority band when there is a serious event, credible allegation, major modification, emerging security concern, prolonged nonresponse to regulatory correspondence or another circumstance that materially changes the need for oversight. Override rules ensure that the model structures professional judgement rather than replacing it.

III. RESULTS

A. Regulatory Synthesis for Inspection Planning

The documentary synthesis showed strong convergence across the core sources on several points. First, inspection is a core regulatory function that must be organised as a programme rather than as a sequence of ad hoc visits (IAEA, 2016a; IAEA, 2022). Second, the graded approach requires regulatory effort to be commensurate with the radiation risks and complexity of the activity (IAEA, 2014; IAEA, 2021). Third, inspection decisions should incorporate evidence of actual performance and compliance, not hazard alone (European Union, 2013). Fourth, inspection findings should inform future regulatory action, including escalation, enforcement and revised scheduling. Finally, lower risk populations should not be left entirely uninspected, because this creates blind spots and weakens deterrence (IAEA, 2007; AERB, 2014; ARPANSA, 2023).

A further recurring message is that inspection periodicity should not be linked mechanically to

authorisation renewal. Such a linkage may be administratively convenient, but it can mask deterioration in safety performance between renewal points and can also generate unnecessary effort in well controlled settings (IAEA, 2007). The synthesis therefore supports a dynamic inspection programme in which frequency is linked to risk band and updated as new information becomes available.

B. Framework Architecture

Figure 1 summarises the conceptual structure of the framework. Inherent risk is captured through hazard tier and exposure complexity, while managed risk is captured through performance history, management system maturity and lifecycle or safety security concerns. These inputs are combined within a conservative scoring engine that includes uncertainty uplift and documented override rules. The immediate outputs are a risk band, inspection interval, scope and competence requirement. These in turn shape the annual inspection portfolio, which combines planned, sampled and reactive inspections.

The framework is implemented through eight linked steps. First, the regulator defines the inspection population by consolidating the authorised inventory and checking the completeness of key fields. Second, each facility or activity is assigned a preliminary hazard tier using source category, practice type, dose potential and plausible consequences of loss of control. Third, exposure pathways and operational complexity are assessed. Fourth, performance indicators are compiled, including previous findings, repeat noncompliance, overdue corrective actions and event notifications. Fifth, management system maturity and lifecycle or safety security flags are scored. Sixth, the composite score is calculated and translated into a provisional risk band. Seventh, the annual inspection programme is constructed by combining targeted inspections for higher bands with a sampled component for lower bands and reserved capacity for reactive work. Eighth, inspection outcomes are fed back into the model so that future prioritisation reflects actual performance rather than historical assumption.

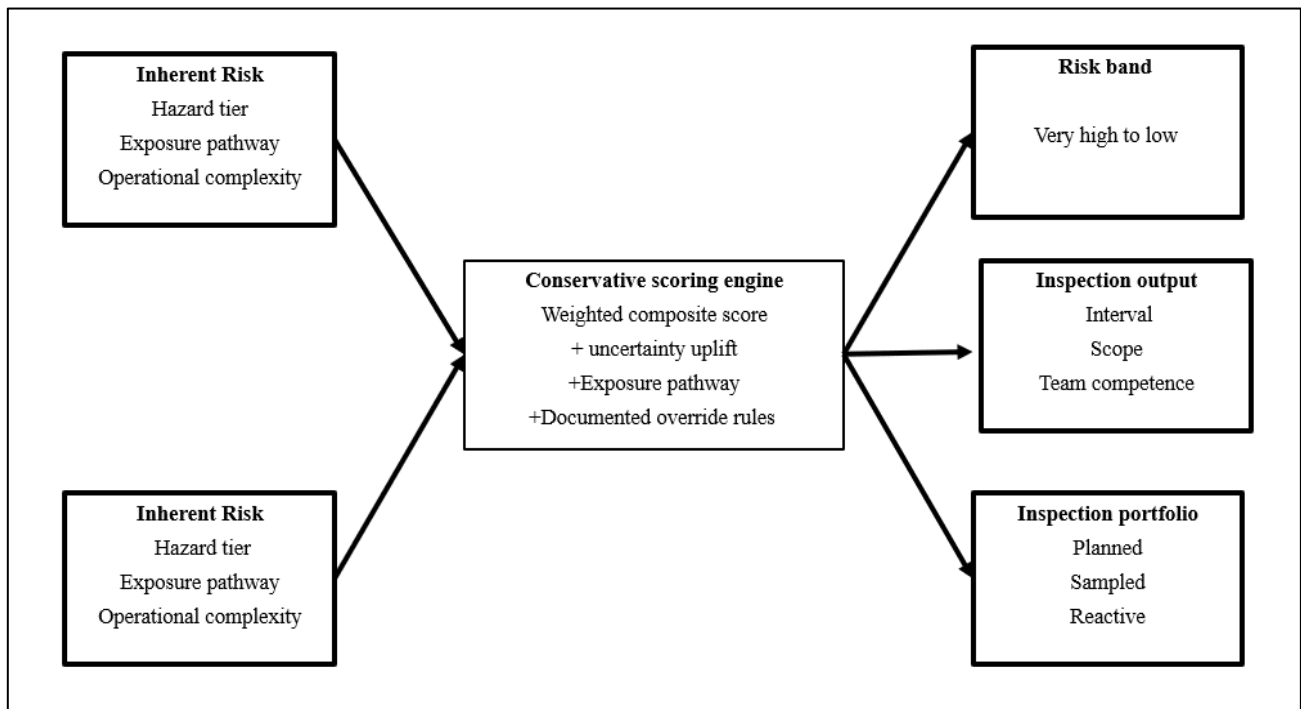


Fig. 1. Conceptual Architecture of the Proposed Risk Based Inspection Model.

C. Scoring Domains and Indicators

Hazard tier is the strongest anchor in the model because it captures the potential magnitude of harm if control is lost. In most programmes, source categorisation and practice class provide the most defensible starting point (IAEA, 2005). High category sources, radiotherapy services, industrial irradiators, dispersible radioactive material, high activity industrial radiography and waste management operations with more complex source inventories typically score higher than simple fixed diagnostic units or low activity research sources.

Exposure potential and operational complexity refine the hazard baseline by considering whether the practice

involves mobile sources, work in uncontrolled environments, public interface, frequent transport, multiple exposure pathways, clinically complex optimisation requirements, environmental discharge or other conditions that increase the probability of loss of control or complicate inspection. A moderate hazard practice may therefore move upward in priority when work is mobile, dispersed or operationally unstable.

Performance and compliance history address the likelihood that weaknesses will persist or recur. Important signals include repeated major findings, history of incidents or near misses, timeliness of corrective action closure, quality of mandatory reporting and evidence that previous

enforcement actions were ineffective. Management system maturity captures the institutional capacity that sustains good performance, including competence, staffing stability, quality assurance, maintenance, calibration, internal audit and managerial oversight (IAEA, 2016b; CNSC, 2025).

Lifecycle or safety security flags capture circumstances that are often missed when scoring is based

only on present operations. Examples include accumulation of disused sources, source transfers, import or export activity, decommissioning transition, storage of orphaned material, weak control of source movement or the need for concurrent safety and security attention (IAEA, 2022). These flags do not replace hazard tier, but they can materially affect inspection priority and scope.

Table 2. Operational Domains and Representative Indicators Used in the Scoring Model.

| Domain | Low Concern Indicators (Score 0 to 1) | Higher Concern Indicators (Score 3 to 4) | Why the Domain Matters |
|---|---|--|---|
| Hazard tier (H) | Low activity or well shielded fixed practice; limited plausible consequence of loss of control. | High activity source, high dose medical use, irradiator, dispersible material, complex waste activity or other high consequence practice. | Sets the minimum regulatory concern associated with intrinsic hazard. |
| Exposure potential and operational complexity (E) | Stable fixed installation; limited public interface; few exposure pathways; simple operating conditions. | Mobile work, uncontrolled settings, transport, public interface, discharge pathway, dispersible material or clinically complex optimisation. | Refines hazard by capturing the practical difficulty of maintaining control. |
| Performance and compliance history (P) | Recent inspections satisfactory; findings minor and corrected promptly; reliable reporting. | Repeat major findings, overdue corrective actions, poor reporting culture, event history or ineffective past enforcement. | Indicates the likelihood that noncompliance will persist or recur. |
| Management system maturity (M) | Competent staff, clear procedures, maintained equipment, calibration, quality assurance and internal oversight. | Weak staffing, poor training records, missing procedures, overdue maintenance, weak quality assurance or unstable management. | Captures the organisational capacity that sustains safe performance. |
| Lifecycle or safety security flags (S) | No unusual lifecycle concerns; source movement and storage well controlled. | Disused source accumulation, source transfer activity, storage anomalies, decommissioning transition or concurrent safety security concerns. | Ensures that overlooked but materially important conditions influence priority. |

D. Risk Bands and Portfolio Design

A practical output of the framework is a set of risk bands linked to inspection action. For illustration, facilities in the very high band may be scheduled every 6 to 9 months, high band annually, moderate band every 18 to 24 months, low band every 24 to 36 months, and very low band every 36 to 48 months with continued eligibility for sampled inspection. These intervals are examples, not universal prescriptions. They should be calibrated against national inventory size, inspector capacity, statutory expectations and the distribution of practices under regulatory control.

Hard floors should be retained for certain high consequence activities even when observed performance is good. Examples may include very high category sources, radiotherapy, industrial irradiators, major waste management installations or facilities with authorised releases to the environment. Conversely, very low hazard

activities should not disappear. The framework therefore incorporates stratified random or quota based sampling within lower bands. This preserves baseline visibility, tests whether the model is missing deteriorating sites and supports procedural fairness across the regulated population.

The portfolio should also include a reactive component. Reactive inspections are triggered by reportable events, complaints, intelligence, major modifications, unexpected exposure trends, prolonged failures to respond, suspected unauthorised practice or urgent safety security concerns. In operational terms, many regulators may reserve a defined proportion of annual capacity for such reactive work. As a starting point, a portfolio split of approximately 65 to 75 per cent targeted planned inspections, 10 to 20 per cent sampled inspections and 10 to 20 per cent reactive reserve may be workable, but the proportions should remain locally adjustable.

Table 3. Illustrative Risk Bands and Corresponding Inspection Actions.

| Risk Band | Indicative Score Range | Illustrative Interval | Typical Inspection Response | Minimum Additional Control |
|-----------|---------------------------|-----------------------|--|---|
| Very high | 85 to 100 or hard trigger | Every 6 to 9 months | Expanded scope; senior or multi inspector team; possible unannounced elements. | Immediate reactive inspection after serious event or major concern. |
| High | 70 to 84 | Every 12 months | Full scope inspection with targeted follow up on known weaknesses. | Shorten interval when corrective actions remain open. |
| Moderate | 50 to 69 | Every 18 to 24 months | Routine planned inspection with risk focused modules. | Remain eligible for sampled unannounced visits. |
| Low | 30 to 49 | Every 24 to 36 months | Reduced scope routine inspection or mixed desk and field review. | Sampled inspection to test model validity. |
| Very low | Below 30 | Every 36 to 48 months | Light touch oversight subject to legal minimums. | Retain inclusion in sampled pool and reactive triggers. |

E. Governance and Information Systems

The framework is only defensible if its use is governed. Scoring criteria, weights, band thresholds and override rules should be version controlled and approved within the regulator's management system. Inspectors should receive calibration training using historical cases and inter inspector consistency should be reviewed at defined intervals. Significant overrides should be documented with reasons and approved at an appropriate managerial level. These steps are essential for legal defensibility and organisational consistency.

Data discipline is equally important. At minimum, the regulator needs a reliable inventory, authorisation status, inspection history, severity of findings, corrective action tracking, event history and basic information on responsible

personnel and programme controls. Where applicable, environmental interfaces such as discharges or monitoring obligations should also be recorded. A structured information system such as RAIS+ can support implementation, but information technology alone does not create risk based regulation. Without agreed criteria, calibration and quality control, digitisation simply reproduces inconsistency in electronic form.

Figure 2 illustrates the implementation and feedback cycle. Inspection findings, enforcement outcomes and closure of corrective actions are fed back into the next planning cycle. This prevents inspection frequency from remaining static until licence renewal and allows the model to respond to actual changes in control performance.

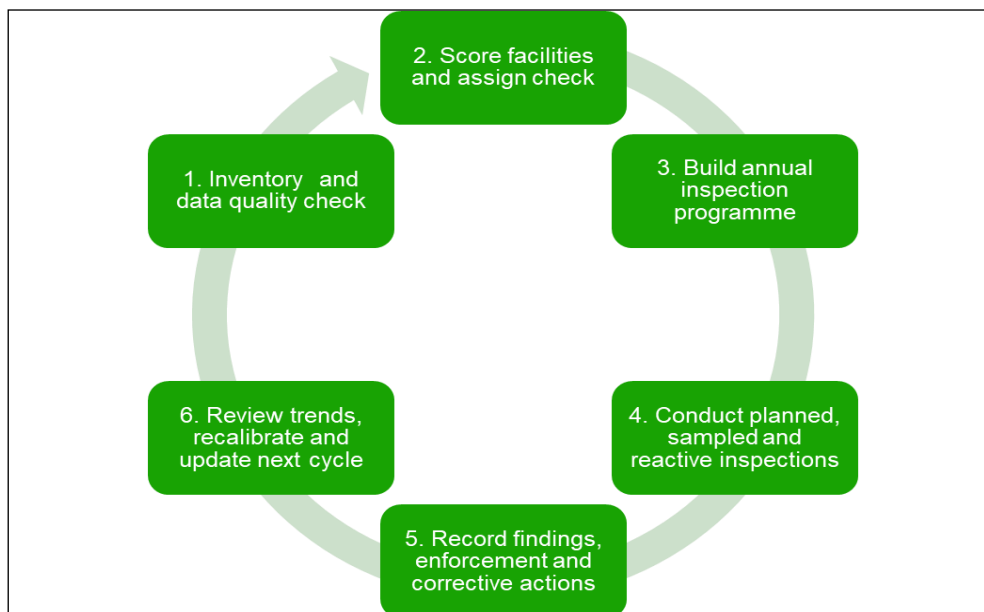


Fig. 2. Implementation and Feedback Cycle for a risk Based Inspection Programme.

IV. DISCUSSION

The framework addresses a persistent operational problem in radiological protection: how to translate the graded approach from a general principle into a defensible inspection programme. Its principal contribution is therefore methodological. It offers a structured decision architecture that can be implemented by authorities with modest data capability while remaining compatible with more mature regulators that operate integrated information systems and dashboards.

A major strength of the model is its separation of inherent risk from managed risk. This reduces two common regulatory errors. The first is under prioritising a moderate or high hazard facility because its paperwork appears complete. The second is over inspecting an entirely low hazard population without regard to actual performance. By retaining hazard based minimum oversight while allowing performance modifiers, the model preserves regulatory caution and improves the coherence of resource allocation.

A second strength is the explicit use of sampled and reactive inspection alongside targeted planning. Many ranking systems fail because they are treated as complete substitutes for professional field visibility. Once lower scoring facilities are omitted from the inspection programme, the regulator loses both deterrence and the ability to detect model failure. The sampled component therefore performs both a substantive oversight function and a quality assurance function for the framework itself.

The model also responds to known weaknesses of simple risk matrices. Ordinal matrices can be useful for communication, but they may produce unstable rankings when treated as if they were precise quantitative tools (Cox, 2008). The present framework uses structured scoring and banding for prioritisation, while reserving matrices mainly for communication and escalation transparency. This reduces the risk of false precision without abandoning the practical value of simple decision aids.

The framework is especially relevant to regulators working under resource constraints. Many authorities operate with incomplete data, uneven regional records, staff turnover and heterogeneous inventories. In such settings, the most useful model is not the most mathematically sophisticated one; it is the model that can be applied consistently, defended externally and improved incrementally. The uncertainty uplift and staged implementation pathway were included precisely for this reason.

Several limitations should be recognised. First, the weighting scheme remains partly judgement based and should not be mistaken for empirical truth. Second, some constructs, particularly management system maturity, can be difficult to score consistently without good inspection guidance and calibration exercises. Third, legal arrangements differ across jurisdictions, especially where safety and security functions are institutionally separate.

Fourth, the paper does not yet present validation against a multiyear inspection dataset. The framework should therefore be regarded as a structured management tool that requires local testing rather than as a universal standard.

Future work should concentrate on validation and learning. Regulators can test predictive usefulness by examining whether higher scored facilities are more likely to generate major findings, severe repeat noncompliance, slower corrective action closure or event recurrence. Inter rater reliability studies would help determine whether the scoring guidance is sufficiently reproducible. Comparative work across jurisdictions would also support calibration of weights, floors and sampling proportions. Finally, environmental and lifecycle dimensions deserve more empirical attention, especially in practices involving discharges, long term source storage or transitions to decommissioning.

V. CONCLUSION

Risk based inspection planning is necessary for radiation regulatory authorities that must oversee diverse practices with finite resources. The framework presented here translates graded regulatory principles into a transparent planning method that combines hazard tier, exposure complexity, compliance history, management system maturity and lifecycle or safety security flags. By linking these inputs to risk bands, interval setting, inspection scope and portfolio composition, the model supports more proportionate and reproducible oversight than fixed periodicity alone.

The framework is deliberately semi quantitative. Its purpose is not to create spurious mathematical certainty, but to make regulatory reasoning explicit, conservative under uncertainty and open to review. Used with calibration, documentation and periodic validation, it offers a credible basis for strengthening inspection planning in both data limited and digitally mature regulatory authorities.

DECLARATIONS

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➤ Conflict of Interest

The authors declare no conflict of interest.

➤ Author Contributions

Henry Lawluvi led the conceptualisation and design of the study, conducted the formal analysis and primary

investigation, prepared the original draft, coordinated manuscript development, and served as corresponding author. Cyril Cyrus Arwui contributed to conceptualisation, methodology, validation of the framework, and critical revision of the manuscript. Emmanuel Akrobortu contributed to methodology, formal analysis, validation, and critical review of the manuscript. Nelson Agbemava, Etorname Ann Mensah, and Sheilla Victoria Gbormitta contributed to investigation, data curation, validation, and manuscript review. All authors approved the final version of the manuscript.

➤ *Data Availability Statement*

No new empirical dataset was generated for this methodological study. All evidence used in framework development is derived from publicly available standards, guidance documents and published literature cited in the reference list.

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