

Technical Note

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Assessing Vulnerabilities in Laboratory Reference Material Production: A Framework for Exposure, Sensitivity, and Adaptive Capacity

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Abstract

The production of laboratory reference materials (RMs) is fundamental to maintaining precision and reliability in scientific and industrial measurements. Despite their critical importance, RM production systems are increasingly vulnerable to a range of stressors, including environmental fluctuations, operational disruptions, and socio-economic challenges. This study presents a comprehensive framework for assessing these vulnerabilities through three key dimensions: exposure, sensitivity, and adaptive capacity. Exposure measures the extent to which RM systems are subjected to external risks such as temperature variations, humidity changes, and geopolitical uncertainties affecting supply chains. Sensitivity identifies internal vulnerabilities, including the fragility of materials, infrastructural weaknesses, and reliance on stringent environmental conditions. Adaptive capacity evaluates the system's ability to anticipate, respond to, and recover from disruptions through strategies such as quality assurance, resource diversification, and institutional resilience. The framework leverages 45 indicators grounded in internationally recognized international standards. These indicators were systematically weighted and analyzed to pinpoint critical vulnerabilities in RM production systems. Based on the findings, this study provides actionable recommendations, including implementing advanced monitoring technologies, enhancing storage conditions, and adopting robust risk management strategies. This research underscores the urgent need to address vulnerabilities in RM production to ensure their reliability amid evolving global challenges. It also highlights the significance of integrating standardized approaches to develop resilient and sustainable production systems. Future research should expand on this work by refining data collection methods, applying dynamic assessments to capture temporal and spatial variability, and addressing emerging stressors such as climate change and global supply chain volatility.

Keywords Reference Materials, Vulnerability Assessment, ISO Standards, Laboratory Systems, Risk Management.

Introduction

The production of laboratory reference materials (RMs) is critical for ensuring the accuracy, reliability, and consistency of scientific measurements across various sec-

tors such as environmental monitoring, pharmaceuticals, and industrial manufacturing [1]. These materials serve as standards to calibrate instruments and validate analytical methods, ensuring traceability and reproducibility in



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scientific results. However, RM production systems face vulnerabilities that can compromise their stability and reliability. In the context of this study, vulnerability is defined as the susceptibility of RM production systems to disruptions that impair their ability to deliver high-quality, consistent reference materials. This vulnerability arises from the interplay of external stressors, internal system characteristics, and the capacity to adapt to challenges. For example, a laboratory producing RMs for environmental testing may face disruptions if extreme weather events damage facilities or if geopolitical tensions restrict access to critical raw materials, such as high-purity silica used in reference standards [2]. Understanding and addressing this vulnerability is essential to maintain the integrity of global scientific and industrial standards. With the increasing global challenges posed by climate change, environmental degradation, and socio-economic disruptions, it is essential to assess the vulnerability of RM production systems [2]. This vulnerability can be analyzed through three key dimensions: exposure, sensitivity, and adaptive capacity [3]. These dimensions help in understanding how external pressures, internal capabilities, and system resilience contribute to the overall stability of RM production. Exposure refers to the degree to which the RM production system is subjected to various environmental and stressors. These include climate-related risks such as extreme weather events, temperature fluctuations, and changes in precipitation patterns, all of which can disrupt supply chains, production processes, and laboratory operations. Additionally, geopolitical factors like trade barriers or political instability in regions that supply critical raw materials can increase exposure and lead to instability in the RM supply chain. For example, rare earth elements, crucial for the production of certain reference materials, are concentrated in specific regions, making them vulnerable to trade restrictions or geopolitical conflicts [4]. These factors can significantly impact the availability and quality of RMs, posing risks to global scientific and industrial standards. Sensitivity is the degree to which the RM production system is affected by exposure to these stressors. The sensitivity of RM production can vary across different stages, from raw material sourcing to the final certification and distribution. Materials that are more sensitive to environmental or political factors, such as rare metals or minerals, are at higher risk of supply disruptions. Moreover, RM production processes often require strict environmental conditions, precision equipment, and a skilled workforce, all of which make the system highly sensitive to small disturbances [5]. Even minor disruptions, such as power outages, equipment failure, or shifts in labor availability, can result in delays or compromises in the quality of RMs. The production of RMs is also

sensitive to the increasing volatility in the global supply of critical materials, making it crucial to identify and address these vulnerabilities. Adaptive capacity refers to the system's ability to anticipate, respond to, and recover from exposure and sensitivity to stressors. A production system with high adaptive capacity can implement strategies to reduce risks and mitigate the negative impacts of climate change, geopolitical instability, and other disruptions. Such strategies may include diversifying suppliers, optimizing production methods, improving logistical systems, or establishing contingency plans for extreme weather events [5]. Enhancing adaptive capacity is key to ensuring the continuous availability of high-quality reference materials, despite the growing uncertainties posed by global environmental and socio-economic changes. By investing in adaptive measures, RM producers can maintain the reliability of laboratory materials that are essential for scientific research and quality control.

In this paper, we aim to introduce a set of indicators in the dimensions of exposure, sensitivity, and adaptive capacity to assess the vulnerability of laboratory reference material production systems, based on existing international standards. These indicators will be developed using frameworks from several internationally recognized standards [6-14]. By integrating these standards, we aim to develop a comprehensive framework for assessing the vulnerability of RM production systems. This approach ensures that the evaluation is robust, aligned with global best practices, and contributes to the resilience and sustainability of the production process in the face of environmental and socio-economic challenges. In conclusion, assessing the vulnerability of RM production through exposure, sensitivity, and adaptive capacity is vital to ensure the continued availability and reliability of laboratory reference materials. Understanding and addressing these dimensions enables producers to develop strategies to reduce risks and enhance resilience, ensuring that high-quality RMs remain available for use in scientific and industrial applications globally.

This research aims to identify the vulnerabilities in the production of laboratory reference materials (RMs) and to develop a comprehensive framework for assessing and mitigating these vulnerabilities through the dimensions of exposure, sensitivity, and adaptive capacity. The primary research question is: What are the vulnerabilities in the production of laboratory reference materials, and how can these vulnerabilities be assessed and mitigated through the dimensions of exposure, sensitivity, and adaptive capacity? To address this question, the study pursues several objectives. First, it seeks to evaluate the exposure of RM production systems to environmental, socio-economic, and geopolitical stressors that threaten

their stability. Second, it aims to analyze the sensitivity of RM production processes to such disruptions, identifying critical points of vulnerability within the production chain. Third, the research explores strategies for enhancing the adaptive capacity of RM production systems, focusing on methods to reduce risks and improve overall resilience. Finally, the study intends to provide actionable recommendations for improving the sustainability and reliability of RM production, enabling these systems to meet global challenges effectively.

2. Material and method

2.1. Vulnerability Assessment Framework

The vulnerability assessment framework employed in this study conceptualizes vulnerability as the extent to which a system is susceptible to or incapable of managing adverse effects of external stressors, including environmental variability and operational disruptions. In this research, vulnerability is defined as a function of three interconnected dimensions: the nature and magnitude of stressors to which a system is exposed, the sensitivity of the system to these stressors, and its adaptive capacity to mitigate or recover from their impacts. In the context of laboratory reference material (RM) systems, vulnerability encapsulates the risks associated with maintaining the stability, usability, and reliability of these critical materials under varying environmental and operational conditions. The dimension of exposure captures the degree to which reference materials are subjected to environmental and operational stressors. These include fluctuations in temperature, humidity, and exposure to light or radiation, as well as risks arising from contamination, improper transportation, and storage conditions. The frequency, intensity, and likelihood of these factors significantly influence the system's overall risk profile. Sensitivity highlights intrinsic vulnerabilities within the system that amplify the potential for damage or degradation. These factors include the physical and chemical properties of the reference materials that render them prone to instability, fragility of packaging systems, and limitations in storage and handling infrastructure. Sensitivity further encompasses the dependency of analytical processes on the accuracy and integrity of these materials, which makes even minor degradations impactful. Adaptive capacity reflects the ability of the system to withstand, recover from, or adapt to external stressors. It is underpinned by robust quality assurance practices, advanced storage monitoring technologies, and the resilience of institutional and infrastructural frameworks. Adaptive capacity also involves the availability of alternative preservation methods, staff expertise and training, and adherence to international standards. Social and collaborative assets, such

as partnerships with external laboratories and emergency response protocols, further enhance the system's capacity to cope with challenges.

The interaction between exposure, sensitivity, and adaptive capacity shapes the overall vulnerability of RM production systems. High exposure, such as frequent temperature fluctuations or contamination risks, can increase vulnerability when combined with high sensitivity, for example, due to chemically unstable reference materials or inadequate packaging. However, strong adaptive capacity—through measures like real-time environmental monitoring or robust contingency plans—can reduce vulnerability by mitigating the effects of exposure and sensitivity. Conversely, limited adaptive capacity, such as outdated storage systems or lack of trained personnel, can exacerbate vulnerability even under moderate exposure, particularly if the system is highly sensitive. For instance, a laboratory producing RMs with strict temperature requirements may face significant disruptions during power outages if it lacks backup power systems, amplifying the impact of environmental stressors. These dynamic interactions underscore the importance of assessing all three dimensions holistically to identify critical vulnerabilities and prioritize resilience-building measures. To clarify these relationships, Figure 1 presents a schematic diagram of the vulnerability assessment framework. The diagram illustrates exposure as external stressors acting on the RM system, sensitivity as internal characteristics that amplify or moderate these impacts, and adaptive capacity as the system's ability to counteract or recover from disruptions. Arrows between these components highlight their interconnections, with vulnerability emerging as the net outcome of their interplay. This visual aid demonstrates how high adaptive capacity can offset the risks posed by exposure and sensitivity, while deficiencies in adaptive capacity can heighten vulnerability. This holistic approach to vulnerability assessment provides a structured means of identifying and addressing weaknesses within laboratory reference material systems. By analyzing the interplay between exposure, sensitivity, and adaptive capacity, stakeholders can develop targeted strategies to enhance system resilience, ensuring the continued reliability of reference materials in diverse operational contexts (Figure 1).

2.2. Selection of Vulnerability Assessment Indicators

The vulnerability assessment framework adopted in this study identifies 45 key indicators to comprehensively evaluate the risks faced by laboratory reference material systems (Table 1). These indicators are categorized based on three interconnected dimensions of vulnerability: ex-

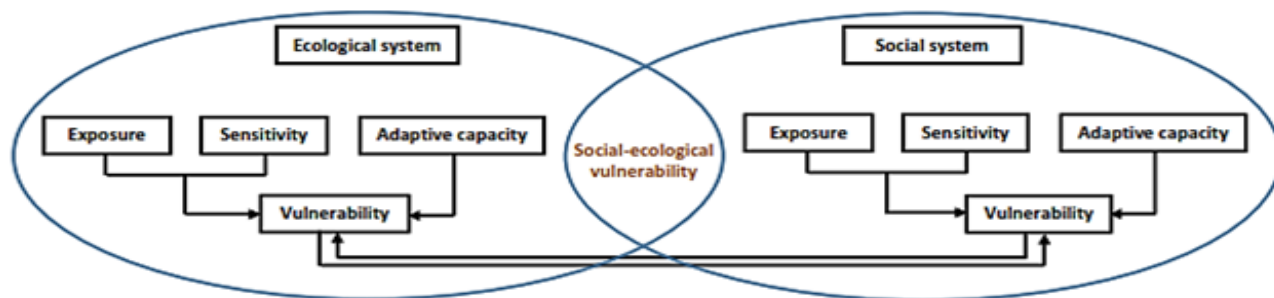


Figure 1. The framework of the vulnerability assessment framework (Description: The diagram features three inter-connected circles labeled “Exposure,” “Sensitivity,” and “Adaptive Capacity.” Exposure is depicted with icons representing external stressors (e.g., temperature fluctuations, contamination risks). Sensitivity is shown with icons for internal factors (e.g., unstable material properties, fragile packaging). Adaptive Capacity is illustrated with icons for resilience measures (e.g., monitoring technologies, quality assurance protocols). Bidirectional arrows connect the circles, indicating interactions, and converge at a central node labeled “Vulnerability,” which reflects the combined effect of these dimensions. The diagram emphasizes that high adaptive capacity can reduce vulnerability, while high exposure and sensitivity, coupled with low adaptive capacity, increase it.)

posure, sensitivity, and adaptive capacity, as conceptualized by Parry et al. (2007), Birkmann (2006) and Eakin & Luers (2006). Vulnerability is defined as the extent to which a system is susceptible to or incapable of managing adverse external stressors, such as environmental variability and operational challenges. Each dimension contributes uniquely to the overall risk profile and resilience of the system. The exposure dimension includes indicators that quantify the degree to which reference materials are subjected to environmental and operational stressors. These factors encompass fluctuations in temperature, humidity, and light exposure, as well as risks associated with contamination, improper storage, and transportation. Indicators such as the frequency and severity of stressors, along with their likelihood of occurrence, are critical in evaluating the direct impact of external conditions on material stability and usability. Sensitivity indicators focus on the inherent characteristics of the system that increase its vulnerability to stressors. These include the physical and chemical properties of reference materials, the robustness of packaging, and the capacity of storage and handling facilities. Sensitivity also accounts for the system’s reliance on the integrity of these materials in analytical processes, where even minor degradations can

compromise precision and reliability. Indicators in this category reflect the fragility of the materials and their infrastructure under adverse conditions. The adaptive capacity dimension comprises indicators that evaluate the system’s ability to mitigate, adapt to, or recover from external stressors. These include the presence of advanced monitoring and control technologies, the effectiveness of quality assurance protocols, and the resilience of institutional and infrastructural frameworks. Adaptive capacity also considers the availability of alternative preservation methods, the level of staff training, and adherence to international standards. Social and collaborative factors, such as partnerships with external laboratories and emergency response mechanisms, further strengthen the system’s ability to cope with challenges. These indicators are developed using frameworks from several internationally recognized standards [6-14]. By incorporating these standards, the framework ensures a robust, internationally aligned approach to vulnerability assessment. This structured methodology enables stakeholders to identify critical weaknesses and implement targeted strategies, ensuring the stability, reliability, and usability of laboratory reference materials across diverse environmental and operational conditions.

Table 1. Indicators for vulnerability assessment of laboratory reference material production systems across three dimensions (exposure, sensitivity, and adaptive capacity)

Dimension	Indicator	Source (Standard)
Exposure	Storage temperature: The environmental temperature in which the RM is stored.	ISO 17034:2016;
	Relative humidity: Humidity levels that might alter the RM's properties.	ISO Guide 35:2017;
	Storage duration: Period RM can be maintained without quality loss.	ISO Guide 31:2015;
	Direct light/UV exposure: Impact of UV rays on RM stability.	ISO Guide 34:2009;
	Environmental contaminants: Effects of surrounding chemical or particulate pollutants.	ISO/IEC 27001:2022
	Transport conditions: Temperature, humidity, and vibration effects during RM transport.	BS ISO 33405:2024;
	Atmospheric pressure: Variations affecting RM, especially in high-altitude storage or transport.	ISO 31000:2018;
	Mechanical vibrations: Impact of physical shocks during handling.	ISO 14001:2015;
	Microbial contamination: Influence of biological agents, particularly for biological RMs.	ISO 22301:2019;
	Electromagnetic fields: Effects of magnetic/electrical fields on sensitive RMs.	ISO/IEC 17025:2017;
	Proximity to reactive materials: Interaction risks with nearby materials.	ISO/IEC Guide
	Stability in freezing conditions: RM stability at low temperatures.	99:2007
	Chemical alterations: Changes caused by varying environmental factors.	
	Packaging quality: Efficacy of packaging in protecting RM from environmental stressors.	
	Storage facility conditions: Ventilation, lighting, and environmental controls.	
Sensitivity	Sensitivity to temperature changes: RM's reaction to temperature fluctuations.	
	Sensitivity to humidity: Stability under varying moisture conditions.	
	Sensitivity to light: Impact of visible or UV light on RM properties.	
	Sensitivity to chemical variations: RM's response to chemical exposure.	
	Sensitivity to physical changes: Alterations in structure, color, or particle size.	
	Sensitivity to contaminants: Impact of environmental pollutants.	
	Sensitivity over time: Degradations in long-term storage.	
	Oxidation sensitivity: RM's reaction to oxygen exposure.	
	Mechanical sensitivity: Reaction to physical shocks or vibrations.	
	Sensitivity to pH changes: Effects of acidic or basic environments.	
	Sensitivity to biological factors: Susceptibility to microbial activity.	
	Sensitivity to high temperatures: Stability in elevated heat.	
	Sensitivity to ionizing radiation: Effects of radioactive exposure.	
Adaptive Capacity	Particle size changes: Variations in particle distribution due to external factors.	
	Changes in color or odor: Signs of degradation or chemical alteration.	
	Flexibility in varying conditions: Ability to withstand environmental changes.	
	Chemical resistance: Capacity to avoid undesirable chemical reactions.	
	Stability during transport: Ability to maintain integrity under transport stressors.	
	Continuous quality monitoring: Maintaining compliance with standards over time.	
	Light resistance: Ability to resist visible/UV light damage.	
	Long-term stability: Resilience in prolonged storage under varied conditions.	
	Packaging innovation: Use of advanced protective materials.	
	Biological resistance: Ability to withstand microbial attacks.	
	Continuous environmental monitoring: Real-time tracking of critical parameters.	
	Recovery from adverse conditions: Ability to return to stability after disruption.	
	Resistance to contaminants: Ability to mitigate the effects of pollutants.	
	High-temperature tolerance: Maintaining stability under heat stress.	
	Physical integrity: Ability to resist mechanical stresses.	
	Adaptation to rapid changes: Resilience in handling sudden environmental shifts.	
	Support for experimental processes: Compatibility with evolving laboratory needs.	

2.3. Weighting the Indicators

The weighting of indicators is a critical step in the vulnerability assessment process, as it determines the relative importance of each indicator in evaluating the overall vulnerability of laboratory reference material systems. This process involves applying decision-making methodologies such as Analytic Hierarchy Process (AHP), Analytical Network Process (ANP), or Fuzzy Logic to assign appropriate weights to the indicators. The choice of the weighting method should align with the objectives of the study and the nature of the available data. The assigned weights reflect the contribution of each indicator to the dimensions of exposure, sensitivity, and adaptive capacity. This approach ensures that highly impactful indicators receive greater emphasis in the analysis, while less significant factors contribute proportionally. Sensitivity analysis should also be conducted to evaluate the robustness of the weighting scheme and its influence on the final vulnerability scores. By incorporating a systematic weighting approach, the assessment achieves a balanced and comprehensive evaluation of the system's vulnerabilities.

2.4. Data Collection for Indicators

Data collection is a pivotal stage in the vulnerability assessment framework, as it provides the foundational input for evaluating the indicators across the three dimensions. This step involves sourcing reliable and relevant data from a combination of primary and secondary sources, such as field measurements, laboratory experiments, and existing databases. For exposure indicators, environmental monitoring data, such as temperature and humidity records, are critical. Sensitivity indicators require detailed information about material properties, packaging robustness, and infrastructure resilience, often obtained through material testing or manufacturer documentation. Adaptive capacity indicators draw on organizational data, such as quality assurance protocols, staff training records, and emergency response systems. The data collection process must ensure accuracy, consistency, and representativeness to maintain the reliability of the assessment. Addressing potential data gaps or limitations through alternative methodologies, such as expert judgment or model-based approximations, further enhances the comprehensiveness of this stage.

2.5. Testing the Framework on a Case Study

Applying the vulnerability assessment framework to a real-world case study is essential for validating its practicality and robustness. This step involves selecting a representative laboratory reference material system and implementing the framework using actual data for the identified indicators. The case study should encompass a

detailed evaluation of exposure, sensitivity, and adaptive capacity indicators, allowing for a comprehensive assessment of the system's vulnerability. The results provide insights into the strengths and weaknesses of the framework by comparing calculated vulnerability scores with observed system performance. This analysis helps identify potential gaps in the framework and refine its components for broader applicability. Furthermore, the case study serves as a practical demonstration of the framework's utility, offering stakeholders actionable findings and recommendations for enhancing system resilience. By testing the framework in a real-world scenario, the study bridges the gap between theoretical development and practical implementation.

3. Discussion and Practical Recommendations

The discussion of results and formulation of practical recommendations are integral to translating the vulnerability assessment findings into actionable insights. This stage begins with an in-depth analysis of the calculated vulnerability scores for the three dimensions—exposure, sensitivity, and adaptive capacity—highlighting critical weaknesses and areas requiring immediate attention. The results are contextualized by comparing them with real-world system performance, identifying systemic patterns, and exploring the implications of specific indicators on the overall vulnerability. Building on these insights, practical recommendations are developed to address identified vulnerabilities and enhance system resilience. For instance, exposure-related risks can be mitigated through improved storage and transportation protocols, such as climate-controlled environments. Sensitivity reductions may involve adopting more robust packaging materials or upgrading infrastructure to withstand environmental stressors. Adaptive capacity can be strengthened by implementing advanced monitoring technologies, enhancing quality assurance processes, and providing targeted training for personnel.

To operationalize this framework across different sectors, laboratories can adopt sector-specific strategies tailored to their unique operational needs and regulatory environments. In the pharmaceutical sector, where reference materials are critical for drug quality control and regulatory compliance, laboratories can enhance adaptive capacity by deploying automated, real-time stability monitoring systems to detect deviations in temperature, humidity, or other environmental conditions that could compromise material integrity. These systems can be integrated with data analytics platforms to predict potential risks, ensuring compliance with stringent standards such as those set by the FDA, EMA, or ICH guidelines.

To address sensitivity, pharmaceutical laboratories can invest in advanced packaging solutions, such as vacuum-sealed, temperature-resistant containers, to protect reference materials during transportation and storage. Exposure risks can be mitigated by diversifying supplier networks to reduce dependency on single-source raw materials, which is particularly critical given the global supply chain disruptions observed in recent years. For environmental analysis laboratories, which rely on reference materials for accurate pollutant detection and ecological monitoring, reducing sensitivity involves selecting chemically stable reference compounds that resist degradation under variable field conditions, such as exposure to moisture, UV radiation, or extreme temperatures. These laboratories can also implement robust, tamper-proof packaging systems to ensure material integrity during transport to remote testing sites. To mitigate exposure, environmental laboratories can establish regional partnerships with other facilities to secure alternative supply chains, minimizing disruptions caused by climate-related events or geopolitical instability. Additionally, these laboratories can adopt mobile storage units with built-in environmental controls to maintain reference material stability during fieldwork. In the industrial manufacturing sector, where reference materials are used for quality assurance in production processes, laboratories can focus on adaptive capacity by implementing predictive maintenance for storage infrastructure, such as refrigeration units, to prevent equipment failures that could expose materials to adverse conditions. Sensitivity can be reduced by using reference materials with broader stability ranges, while exposure risks can be addressed through redundant storage facilities to ensure continuity during extreme weather events. Across all sectors, implementing the framework requires alignment with ISO 17034:2016 standards to ensure consistency in vulnerability assessments. Laboratories can further benefit from cross-sector collaboration, such as participating in industry consortia to share best practices, develop standardized contingency protocols, and conduct joint training programs on vulnerability management. For example, a pharmaceutical laboratory might collaborate with an environmental laboratory to adapt field-tested packaging solutions, while an industrial laboratory could share predictive maintenance strategies to enhance storage reliability. These collaborative efforts can be supported by international organizations, such as the BIPM or ILAC, to establish global benchmarks for resilient RM production systems.

By integrating detailed discussion and actionable strategies, this section bridges the analytical findings with practical improvements, offering a roadmap for stakeholders to safeguard the reliability and stability of lab-

oratory reference material systems. To achieve a more precise evaluation of the vulnerability of reference material production systems, future research should focus on addressing current limitations and expanding the scope of assessment methodologies. One key limitation lies in the availability and accuracy of data for certain indicators, particularly those related to sensitivity and adaptive capacity, which necessitates the development of advanced data collection methods and predictive models. Future studies should also explore dynamic vulnerability assessments that account for temporal and spatial variability in environmental and operational conditions. For sector-specific applications, future research could develop tailored indicator sets to address unique challenges, such as regulatory compliance and material stability for pharmaceuticals, environmental stressors and field conditions for ecological monitoring, or scalability and cost-efficiency for industrial manufacturing. For instance, pharmaceutical-focused studies could prioritize indicators related to compliance with Good Manufacturing Practices (GMP), while environmental studies could emphasize resilience to climate-induced stressors like flooding or heatwaves. Industrial manufacturing research could explore cost-benefit analyses of adaptive measures to ensure scalability across large production facilities. Additionally, future work should investigate the integration of digital tools, such as blockchain for supply chain transparency or IoT for real-time environmental monitoring, to enhance adaptive capacity across sectors.

Additionally, the inclusion of emerging stressors, such as climate change impacts or supply chain disruptions, can provide a more comprehensive understanding of system vulnerabilities. Refining the weighting schemes for indicators and incorporating machine learning or artificial intelligence tools could enhance the robustness of vulnerability models. Expanding the framework to include economic and social dimensions of vulnerability may also yield a more holistic assessment. By addressing these areas, future research can strengthen the resilience of reference material systems and ensure their continued reliability under evolving challenges.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Received: Jan. 2025 Accepted: Apr. 2025

Published online: Apr. 2025

DOI: 10.22034/ASAS.2025.498036.1073

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