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| cetlogo ***CHEMICAL ENGINEERING TRANSACTIONS***  ***VOL. xxx, 2025*** | A publication of  aidiclogo_grande |
| The Italian Association  of Chemical Engineering  Online at www.cetjournal.it |
| Guest Editors: Bruno Fabiano, Valerio Cozzani  Copyright © 2025, AIDIC Servizi S.r.l. **ISBN** 979-12-81206-xx-y; **ISSN** 2283-9216 | |

Uncertainty Assessment in Validating a Risk Study

Nazmul Rahmani\*, and Hans Pasman

Mary Kay O’Connor Process Safety Center, Texas A&M University, College Station, TX 77843, USA

[Nazmul.rahmani@tamu.edu](mailto:Nazmul.rahmani@tamu.edu), hjpasman@gmail.com

Risk assessment outcomes inherently carry a degree of uncertainty. This uncertainty arises from several factors, such as incomplete evidence, overlooked hazards, insufficient or non-existent data, and the inherent limitations of analytical models. This raises a critical question: How much confidence can decision-makers reasonably have in these results?

Traditionally, risk communication has often relied on single-point estimates, yet presenting only such values fails to capture the full scope of uncertainty. For decision-makers, risk assessments are essential but not the sole basis for decisions. Recognizing the range of possible risk outcomes through confidence intervals is crucial. Depending on the context and other influencing factors, a decision-maker might prefer to consider either an average risk value or a probability distribution that reflects the inherent uncertainty in the risk estimates.

This paper first explores the diverse application areas of risk assessment and emphasizes the importance of these analyses. It then introduces a validation procedure aimed at bolstering confidence in risk outcomes. Finally, it explores several approaches aimed at improving the reliability of these studies. Among the most notable is the maturity proposal put forth by Rae et al. (2014), which involves a rigorous examination of a large body of risk assessment outcomes to identify and understand the flaws that render certain studies less reliable.

* 1. Introduction to Risk Study

A risk study, often referred to as a risk assessment or risk analysis, is a meticulous and structured process aimed at identifying, evaluating, and analyzing the potential risks associated with a specific activity, project, or decision. The overarching goal of such a study is to estimate the likelihood and impact of possible hazards, enabling informed decision-making and the formulation of effective strategies for risk mitigation or management.

Risk studies are essential across many sectors, each facing unique challenges. In financial services, they address credit risks, market fluctuations, and regulatory compliance to ensure stability. The energy sector uses risk analysis to manage price volatility, supply chain issues, and environmental concerns. Healthcare relies on it for patient safety, clinical trials, and regulatory adherence. Construction preempts hazards, delays, and cost overruns through risk management. Manufacturing tackles supply chain disruptions and quality control, while aerospace and defense handle safety, security, and geopolitical risks. IT companies safeguard against cyber threats, and pharmaceuticals assess drug safety. Transportation sector must manage risks related to accidents, regulatory compliance, supply chain challenges, and evolving market demands. Industries like mining, forestry, agriculture, and conservation depend on risk analysis to evaluate environmental impacts, sustainability concerns, and regulatory adherence. These are just a few examples, and risk analysis is applicable across various other industries.

The risk study process begins with the systematic identification and documentation of risks, both internal and external, whether predictable or unforeseen. Sources of risk can include technological failures, equipment malfunctions, natural disasters, regulatory shifts, or human errors. Following identification, risks are assessed based on the probability of occurrence and the severity of their consequences. Using both qualitative and quantitative methodologies, risks are prioritized according to their potential impact on project objectives. High-priority risks receive focused attention, prompting risk treatment measures such as prevention, control, transfer, or mitigation strategies. Implementing these measures involves preventive actions, contingency planning, insurance procurement, and resource allocation. Ongoing monitoring and review of risks are crucial to ensure the continued efficacy of these measures. This involves evaluating the performance of risk mitigation strategies, tracking emerging risks, and refining processes as needed. Ultimately, a comprehensive risk study enables organizations to anticipate challenges, make well-informed decisions, and minimize financial, operational, and safety risks. It fosters resilience, enhances safety, and contributes to the successful execution of projects.

* 1. Importance/Value of Risk Study in Decision Making

A comprehensive risk study is crucial for informed decision-making. First, risk assessment identifies potential hazards and uncertainties across financial, operational, legal, environmental, reputational, and strategic areas. By analyzing the likelihood and impact of these risks, decision-makers can develop informed strategies and implement measures to manage exposure effectively. This approach ensures a deeper understanding of trade-offs, enhancing decision quality. Evaluating possible risks allows for a balance between benefits and consequences, resulting in decisions that are both comprehensive and sustainable.

Moreover, proactively identifying risks helps organizations mitigate potential losses through contingency plans, preventive measures, or insurance. These strategies protect financial and operational stability, minimizing the impact of adverse events. Additionally, risk studies aid in resource allocation by prioritizing areas with the most significant impact, ensuring efficient use of resources and reducing waste. Incorporating risk assessment into decision-making also strengthens stakeholder confidence. Transparent risk management builds trust among employees, customers, investors, and the public, demonstrating the organization’s proactive and responsible approach. This trust fosters long-term success and solidifies key relationships. Overall, a well-conducted risk study enhances decision-making quality, minimizes potential losses, optimizes resource allocation, and reinforces stakeholder trust. Effective risk analysis enables organizations to make balanced, well-informed choices, driving sustainable and successful outcomes.

A risk study essentially predicts potential adverse events in the future. Beyond the uncertainty of when these events might occur, there is significant uncertainty in the failure data and models used to predict their impact. This challenge has been acknowledged since the early days of risk analysis. Apostolakis (1990) highlighted that analyst often reported risk as a single-point value, even when a range of values would be more appropriate. Scholars like Paté-Cornell (1996) and Winkler (1996) have consistently underscored the considerable uncertainty inherent in risk calculations. Despite rigorous arguments aimed at enhancing confidence in risk results—by emphasizing data quality, methodological robustness, and domain expertise—Graydon and Holloway (2017) demonstrated that claims about minimal fatal risk probabilities (e.g., lower than 10-6 per year) can be deeply uncertain.

Researchers such as Aven (2012) have written extensively on the topic of risk and uncertainty. Innovative proposals for improvement have emerged. For instance, Johansen and Rausand (2014) introduced indicators to account for the subjective complexity perceived by analysts, which inform decision-makers about confidence limitations. In 2015, they addressed ambiguity in risk expressions to prevent multiple interpretations. Fortunately, thanks to scholarly efforts, uncertainty has become a central topic in risk assessment, and it is now more accurately described and bounded.

* 1. Validation of Risk Study

Validation of risk analysis is an essential step in the risk management process to ensure the accuracy and reliability of the results obtained. It involves reviewing and assessing the methodologies, assumptions, data sources, and calculations used in the analysis to identify any potential errors, biases, or inconsistencies. The validation process aims to enhance the credibility of the risk analysis and increase confidence in the results.

Lathrop and Ezell (2017) introduced a systems perspective for validating risk analysis in the context of risk management. The authors argue that the effectiveness of risk analysis in supporting risk management should be evaluated based on its alignment with real-world decision-making processes, considering factors such as trust, third-party review, and stakeholder acceptance. The underlying idea is that validation should assess how effectively a risk analysis supports real-world risk management implementation (Rae et al., 2014). The authors propose a logical sequence based on this perspective, which is presented in Figure 1. This figure presents sixteen elements of risk analysis in its Analyst’s Domain section. Those sixteen elements are the five boxes on the left (Scope Judgments, Assumptions, Data, SMEs and Elicitation), then the five dash-list elements under Risk Analysis (scenario initiation, scenario unfolding, completeness, adversary decisions and uncertainty), the four dash-list elements under Report, Communication with metrics (metrically valid, meaningful, caveated and full disclosure) and the two dash-list elements under Transparency, Documentation (analytic, narrative). These sixteen elements are represented with a distinctive green colour in Fig. 1. A risk analysis validation at the system level should be conducted by critically posing and investigating sixteen questions, one for each of the sixteen elements. Each question is a validation test and discusses shortfalls related to the issues associated with each test. The authors (Lathrop and Ezell, 2017) introduce three domains within the system: the Analysts' Domain, Users' Domain, and Analysis Community Domain. The Analysts' Domain is commonly considered in discussions

A diagram of a computer program

Description automatically generated

Figure 1. Risk analysis validation – a systems perspective. Green font denotes the sixteen analysts’-domain elements (Lathrop and Ezell, 2017)

of risk analysis validation. The paper extends this perspective by introducing the Users' Domain, which represents the separation between risk analysis and its final consequences and residual risk. This domain encompasses the risk management decision process, the desired implementation of risk management actions, and the actual actions taken based on acceptance or denial. Acceptance or denial is influenced by the acceptance of implementers and stakeholders, which, in turn, is influenced by the transparency and documentation provided in the risk analysis report. Encompassing both the Analysts' and Users' Domains is the Analysis Community Domain, which has the potential to establish a "Culture of Analysis Quality." In this domain, both risk analysts and commissioners of risk analyses enforce the sixteen validation tests outlined in the paper. However, the authors acknowledge the difficulty in creating such a culture.

In summary, this paper (Lathrop & Ezell, 2017) introduces a logical framework that connects risk analysis, risk reporting, risk management decision making, third-party and stakeholder reviews. It outlines sixteen critical elements and corresponding validation tests to evaluate the effectiveness of risk analysis in supporting real-world risk management. The proposed structure also emphasizes the role of the Analysts' Domain, Users' Domain, and Analysis Community Domain in fostering a culture of analysis quality.

In the review paper by Goerlandt et al. (2016), the authors examine the validity and validation of quantitative risk analysis (QRA) in the context of safety. While QRA is commonly used in various industries to enhance safety measures during design, licensing, and operational processes, there is limited academic research on the subject. The paper aims to address this gap by analyzing theoretical, methodological, and empirical contributions found in the scientific literature. The review focuses on three main questions. Firstly, it explores the different theoretical perspectives on the validity and validation of QRA. Secondly, it investigates the features of QRA that are valuable for validating a specific QRA and examines the proposed frameworks for this purpose. Lastly, it assesses the claims made about QRA and the available evidence regarding its validity for its intended purposes.

Reviews of risk analysis methods illustrate that QRA is employed in various industries, such as nuclear installations (Garrick and Christie, 2002), offshore oil and gas platforms (Vinnem, 1998), maritime transportation in waterways (Li et al., 2012), chemical installations (Khan et al., 2015), land use planning (Pasman and Reniers, 2014), construction (Taroun, 2014) and cyber security (Cherdantseva et al., 2016). Despite its widespread use, there's a general lack of attention to validation in risk research. Authors have pointed out the deficiency in quality control procedures for risk analysis methods. Several authors (Cumming (1981), Aven and Heide (2009), and Rosqvist (2010)) have noted the limited attention given to validity and validation in risk analysis. There is a call for internationally established quality criteria for QRA (Pasman et al. (2009)). The lack of empirical study and natural feedback leaves uncertainty about the validity and efficacy of QRA (Rae et al. (2014)). The last comprehensive review regarding risk analysis validation dates back almost three decades ago, by Suokas and Rouhiainen (1989), suggesting a gap in current understanding. There's a debate about whether risk analysis should be considered a discipline on its own or as a trans-scientific, interdisciplinary practice (Hansson and Aven (2014), Weinberg (1981), Reid (2009), and Aven (2018)). Regardless, there's a need to establish the scientific validity of QRA. Concepts, principles, frameworks, and methods for validating risk analysis and results are essential for strengthening the scientific foundations of the discipline. Validity of the method and procedures for establishing it are crucial for both system designers (Rae et al., 2014) and regulators (Kirchsteiger, 1999), emphasizing its significance in ensuring safety and compliance. Despite the importance of quality control procedures in risk analysis, some regulatory documents such as the Seveso Directive (Seveso III, 2012) do not specify requirements concerning them. In a nutshell, this paragraph underscores the importance of validation and quality control procedures in risk analysis methods, particularly in ensuring the scientific validity and efficacy of QRA across various industries and regulatory frameworks.

Goerlandt et al. (2016) explored the theoretical perspectives on validity and validation, emphasizing the significance of a realist or constructivist foundation when conducting and validating risk analysis. Then the article discusses about the pragmatic validity of QRA, focusing on various methods used to establish validity. These methods included benchmark exercises, reality checks, procedures for independent peer review, and quality assurance. Each of these approaches was found to provide valuable insights into the validity of a specific QRA. However, further research is required to evaluate the effectiveness of these proposed methods for different applications of QRA. Additionally, investigations are needed to determine which processes, techniques, and social structures support the successful implementation of these methods. Lastly, the review examines the claims made about QRA in relation to the available evidence. While rejecting the assertion that accurate risk estimation is possible, this paper considers the claim of cost-effective usefulness to be plausible. However, it should be noted that there is a lack of substantial evidence supporting this claim, highlighting the need for further research in this area.

Validation of quantitative risk assessment involves verifying the accuracy and reliability of the risk assessment processes and the results obtained. To validate a risk study, one should follow a systematic approach that involves several steps. A general outline exhibiting some key steps and considerations for validating a risk study is presented below.

• Define the Objectives: Clearly define the objectives of the risk study. What specific risks are being analyzed, and what outcomes are expected to achieve? This step ensures that the validation process is focused and targeted.

• Review Methodology: Evaluate the overall methodology used in the risk study. Examine the data collection methods, and understand the approach, techniques, assumptions, and models used to assess and manage risk. Ensure that the methodology is scientifically sound and appropriate for the objectives of the study.

• Data Evaluation: Assess the quality and reliability of the data used in the risk study. Verify the sources of the data and assess their relevance, accuracy, completeness, and consistency. Check for any gaps, biases, or limitations in the data that may affect the accuracy of the risk analysis. If necessary, conduct data audits or perform additional data gathering to address any data gaps or uncertainties.

• Verify Assumptions: Examine the assumptions made during the analysis. Assess their reasonableness and determine if they are supported by relevant evidence or expert judgment. Identify any critical assumptions that may significantly influence the results and ensure they are well-documented and justifiable.

• Sensitivity Analysis: Conduct a sensitivity analysis to assess the robustness of the risk study. Vary the inputs, assumptions, and models within reasonable ranges to determine the impact on the study's findings. This analysis helps identify the key drivers of risk and uncertainties in the study's results.

• Comparison to Existing Literature: Compare the findings of the risk study with existing literature, similar studies, or industry standards. Conduct cross-validation to check for consistency or discrepancies in the results and conclusions. Inconsistencies should be investigated and resolved. This step helps ensure that the risk study aligns with established knowledge and practices.

• Peer Review: Engage subject matter experts or independent reviewers to evaluate the risk study. Peer review provides an external validation of the study's methodology, assumptions, and conclusions. Experts with relevant knowledge and experience can provide valuable insights and identify potential errors, biases, or limitations in the analysis.

• Stakeholder Engagement: Engage relevant stakeholders, such as decision-makers, industry professionals, or affected communities, in the validation process. Seek their input and feedback on the risk study to address any concerns or discrepancies. This step enhances the transparency and credibility of the study.

• Documentation and Transparency: Ensure that the risk study is well-documented, transparent, and reproducible. Provide detailed information on the methodology, data sources, assumptions, and calculations used in the study. This documentation should be readily available for review and audit purposes.

• Iterative Improvement: Consider the feedback received during the validation process and incorporate any necessary revisions or improvements into the risk study. Validate the updated version of the study to ensure that it addresses previous concerns or issues.

• External Audit: In some cases, it may be beneficial to seek an external audit of the risk study. Independent auditors can assess the study's compliance with relevant standards, regulations, or guidelines. This audit provides an additional layer of validation and confidence in the study's findings.

By following these steps, one can validate the quantitative risk assessment process and ensure that it provides reliable insights for decision-making and risk management. It is important to ensure that the assessment reflects a realistic representation of the risks involved and that the methodology used is sound.

* 1. Quality of Risk Study

Under the sweeping title “Fixing the cracks in the crystal ball”, Rae et al. (2014) discusses the weaknesses of Quantitative Risk Assessment (QRA) in safety management and raise concerns about the lack of adequate evidence to support the claims made about QRA. The authors argue that while QRA is commonly used in systems safety, there is insufficient evidence to determine if it is generally fit for purpose. The authors do that based on a rigorous investigation of a hundred QRA reports (Rae & Hawkins, 2012). The paper addresses the argument made by proponents of QRA who distinguish between poor or misused QRAs and correct, appropriately used QRAs. However, this distinction is only valuable if there are reliable methods to identify flaws in individual QRAs. Rae et al., 2014, suggests that more skepticism about QRA is justified and calls for a more careful use of its outputs. The authors believe that a rigorous empirical study is needed to establish the scientific validity of the claims made about QRA. They emphasize the importance of evaluating individual QRAs effectively and appropriately, as they may not be amenable to direct empirical study.

Rae et al., 2014, proposes a maturity model for QRA that encompasses all potential flaws in individual QRAs, discussed in the risk assessment literature and draws from a collection of risk assessment peer reviews. The model aims to provide a comprehensive evaluation framework for QRAs, ensuring their completeness and realism. By utilizing this maturity model, organizations can prioritize process development within their own operations and facilitate empirical research within the QRA community.

The model is presented as a series of five levels: Level 1 Unrepeatable, Level 2 Invalid, Level 3 Valid but inaccurate, Level 4 Accurate but challengeable, Level Ω ideal, hence practically unachievable. The levels highlight the most significant flaws to be prioritized. By using this model, the authors aim to direct process improvement and empirical research, with the goal of advancing safety risk analysis from superstition to a more robust science. The maturity model provides a scale against which individual applications of QRA can be measured, allowing for investigation of the maturity level based on different sectors, system risk levels, or the safety experience of organizations involved. The authors suggest examining existing guidance and standards for QRA in the context of their maturity model to identify the flaws they address, which can encourage improvement and support claims about the quality of QRA. The authors acknowledge that their maturity model may not be definitive, but they believe it serves as a stepping stone to improving safety engineering practices and contributes to the maturing of the discipline. It offers a means to identify and rectify flaws in individual QRAs and enables organizations to improve their risk assessment processes. They emphasize that their work does not argue against using QRA or advocate for alternative analysis methods but rather calls for a more rigorous and critical approach to its application.

Fenner-Crisp and Dellarco (2016) address the incessant efforts to improve the quality, transparency, and utility of risk assessments conducted by U.S. federal government agencies. Numerous reports have been published, and a consensus has emerged regarding the essential characteristics that high-quality risk assessments should embody. The objective of the study was to summarize the key characteristics of a high-quality assessment as identified in the consensus-building process and integrate them into a comprehensive guide for use by decision makers, risk assessors, peer reviewers and other interested stakeholders to determine whether an assessment possesses the desired features of high quality, transparency, and usefulness. The guide emphasizes characteristics such as transparency, effectiveness, efficiency, and scientific integrity, amalgamating them under the term "quality." It underscores the importance of these traits for assessments of any type, whether qualitative or quantitative, and at any level of complexity, not only for governmental agencies but also for non-governmental entities seeking to influence regulatory decisions. Key components of a high-quality assessment include its fit-for-purpose, systematic review process, evidence integration, transparency, clarity, acknowledgment and explanation of uncertainty. Peer participation and review are highlighted as crucial for ensuring credibility and integrity in assessment processes. Overall, the guide serves as a comprehensive tool for assessing the quality and robustness of assessments. It also advocates for consistent and rigorous standards across all levels of government and for non-governmental entities seeking involvement in regulatory decision-making processes.

* 1. Conclusions

This paper highlights the essential role of risk validation and quality assessment in decision-making across various fields. By systematically identifying and analyzing potential risks, individuals and organizations can make informed choices and effectively manage risks. It underscores the significance of incorporating uncertainty into analyses and emphasizes the need for rigorous validation processes and transparency. Various validation approaches, such as systems perspectives and peer reviews, are discussed, along with challenges associated with quantitative risk assessment (QRA). Additionally, the paper promotes guides and frameworks to evaluate risk assessments by government agencies, advocating for best practices that enhance reliability and effectiveness in risk management strategies.

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