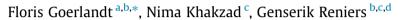
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# Validity and validation of safety-related quantitative risk analysis: A review



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## ABSTRACT

Quantitative risk analysis (QRA) is widely applied in several industries as a tool to improve safety, as part of design, licensing or operational processes. Nevertheless, there is much less academic research on the validity and validation of QRA, despite their importance both for the science of risk analysis and with respect to its practical implication for decision-making and improving system safety. In light of this, this paper presents a review focusing on the validity and validation of QRA in a safety context. Theoretical, methodological and empirical contributions in the scientific literature are reviewed, focusing on three questions. Which theoretical views on validity and validation of QRA can be found? Which features of QRA are useful to validate a particular QRA, and which frameworks are proposed to this effect? What kinds of claims are made about QRA, and what evidence is available for QRA being valid for the stated purposes? A discussion follows the review, focusing on the available evidence for the validity of QRA and the effectiveness of validation methods.

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# 1. Introduction

Risk analyses are used in many application areas, and many frameworks, models and specific applications have been presented in the scientific literature. Quantitative risk analysis (QRA)<sup>1</sup> is included in many textbooks (Aven, 2008; Bedford and Cooke, 2001; Meyer and Reniers, 2013), is considered an important topic to teach engineering students and health and safety professionals (Saleh and Pendley, 2012; Wybo and Van Wassenhove, 2016), and is used in many application areas (Marhavilas et al., 2011). Reviews of risk analysis methods in specific application areas indicate that QRA is applied, inter alia, for 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) and related land use planning (Pasman and Reniers, 2014), in the construction industry (Taroun, 2014) and for cyber security (Cherdantseva et al., 2016).

On a more fundamental level, some authors have raised the issue about the general lack of attention to validation in risk research. In an early commentary, Cumming (1981) points out that quality control procedures for risk analysis methods are not well developed, while this is an important problem which must be dealt with. Aven and Heide (2009) and Rosqvist (2010) also note the limited attention to validity and validation in risk analysis, whereas Pasman et al. (2009) find that quality criteria for QRA shall be internationally established. More recently, Rae et al. (2014) formulate the issue as follows "[...] the combination of little empirical study with little natural feedback [...] leaves us in almost total darkness as to the validity and efficacy of QRA". To the best of the authors' knowledge, the only comprehensive review made regarding risk analysis validation dates from almost three decades ago, by Suokas and Rouhiainen (1989).

If, as argued by Hansson and Aven (2014), risk analysis is a discipline in its own right rather than a trans-scientific, interdisciplinary practice as interpreted by Weinberg (1981) or a "scientistic" approach<sup>2</sup> as suggested by Reid (2009), there should be warrants about the scientific validity of QRA. In the understanding

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<sup>&</sup>lt;sup>1</sup> In different industries, other terminology is applied, including PRA (probabilistic risk assessment), PSA (probabilistic safety assessment) and FSA (formal safety assessment). All these are referred to as QRA in this paper.

<sup>&</sup>lt;sup>2</sup> According to Reid (2009), a scientistic approach is "an approach that makes use of scientific notions, images and methods, not only for the purposes of scientific enquiry, but also for the purpose of invoking the credibility, prestige and authority of 'scientific' knowledge to support an argument or to promote a point of view".

of foundational issues in risk analysis by Aven and Zio (2014), concepts and principles for establishing validity, and frameworks and methods for validating risk analysis methods and their results are important elements for strengthening the scientific foundations of the discipline. Irrespective of whether or not risk analysis is a science, considering QRA as an engineering method, the validity of the method with respect to its purpose, as well as procedures for establishing this, are important issues, both for system designers (Rae et al., 2014) and for regulators (Kirchsteiger, 1999). Nonetheless, e.g. in important regulatory documents concerning risk analysis, like the Seveso Directive (Seveso III, 2012), no specific requirements are stated concerning risk analysis quality control procedures.

In light of the above, the purpose of this paper is to make a review of the state of the art concerning the validity and validation of QRA. Focus is on QRA in a safety context, i.e. where QRA is used in a context of major accidents, engineering design for safety, or personal safety. More specifically, focus is on contributions in the scientific literature where validity or validation is considered as a research topic in itself, or is dealt with as part of a proposed framework for performing quantitative risk analysis. Hence, validation exercises of specific applications are outside the current scope. This scope limitation is made for practical reasons because risk analysis is a very wide research area, and for methodological reasons as it is important to delineate the scope of work, as found also e.g. by Li and Hale (2015). Nonetheless, it is noted that work has recently also been dedicated to validation of security risk models (Zhuang et al., 2016) and occupational safety risk assessment (Pinto et al., 2013), showing the relevance of validation in risk analysis as a topic for research and discussion.

The main questions addressed in this review are as follows:

- Which theoretical views on validity and validation of QRA can be found?
- Which features of QRA are necessary to distinguish a "good" from a "bad" QRA?
- What frameworks or methods have been proposed to validate a particular QRA?
- What kinds of claims are made about QRA, and what evidence is available for QRA being valid for the stated purposes?

A note on terminology is in place, distinguishing two uses of the term "validity" and the related term "validation". Conceptual validity is understood here as the condition where an operationalisation of a concept measures what it intends to measure. This understanding is in line with validity e.g. in social sciences, see Trochim and Donnely (2008), and is applied e.g. by Aven and Heide (2009) in questioning whether QRA fulfils the scientific criteria of reliability and validity. Pragmatic validity is the condition where a method meets its intended requirements in terms of the results obtained, as understood e.g. by Rae et al. (2014) in questioning the efficacy of QRA. Validation is understood here as the process by which validity is established, noting that different authors apply different terminology for this process, e.g. verification (Graham, 1995), quality control/qualification (Rosqvist and Tuominen, 2004; Suokas and Rouhiainen, 1989), credibility assessment (Busby and Hughes, 2006) and evaluation (Goerlandt and Montewka, 2015).

The review method is first described in Section 2, listing the materials considered relevant for the purposes of the paper. Subsequently, theoretical contributions are outlined in Section 3, and methodological and empirical contributions addressing different approaches to validation in Section 4. Section 5 describes a number of other contributions related to validation of QRA. In Section 6, a discussion is made, focusing on the effectiveness of the different approaches to validation and on the evidence for the claims made about QRA. Section 7 concludes.

### 2. Review method

In traditional indexing systems such as Scopus and Web of Science, risk analysis is not considered as a separate category in the scientific research areas. Instead, contributions related to risk are typically listed under "mathematics", "social sciences" or "engineering". Hence, general searches in those systems on terms like "risk analysis", "validation" and "QRA" results in very many hits, with low relevance to the above stated aims. Therefore, another review method has been applied, focusing on specific journals publishing papers on risk analysis methods, quantitative risk analysis and the foundations of risk analysis.

To identify these journals, a comparable method was used as in Reniers and Anthone (2012): an internet search was performed for journals based on the keywords "risk", "risk analysis", "risk assessment", "risk management" and "safety". In addition, an online journal ranking tool (SIR, 2016) was used to identify possibly relevant journals, based on a search for the keywords "risk" and "safety" in the journal title. In addition, a list of the top 35 safety-related journals in a world-wide ranking reported by Reniers and Anthone (2012), was considered to contain possibly relevant journals. Together, these searches resulted in a draft list of journals, of which, based on a description of the aims and scope on the journal websites, only journals covering safety-related risk analysis were retained. A double-check was performed using an analysis by Li and Hale (2016), ensuring that safety-related journals containing risk assessment clusters, were included. Table 1 shows the final list of considered journals.

Subsequently, acknowledging the different terminologies used in risk research for key concepts, articles were searched in these

#### Table 1

Journals considered in the literature review.

Journal title	Abbr.
Accident Analysis and Prevention	AAP
ASCE-ASME Journal of Risk and Uncertainty in Engineering Systems, Part A: Civil Engineering	AJRUA
ASCE-ASME Journal of Risk and Uncertainty in Engineering Systems, Part B: Mechanical Engineering	AJRUB
Disaster Prevention and Management	DPM
Fire Safety Journal	FSI
Georisk: Assessment and Management of Risk for Engineered Systems and Geohazards	GR
Human and Ecological Risk Assessment: An International Journal Injury Prevention	HERA IJ
International Journal of Business Continuity and Risk Management International Journal of Disaster Risk Reduction	IJBCRM IJDDR
International Journal of Disaster Resilience in the Built Environment	IJDRBE
International Journal of Reliability, Quality and Safety Engineering	IJRQSE
International Journal of Risk Assessment and Management	IJRAM
Japanese Journal of Risk Analysis	JJRA
Journal of Contingencies and Crisis Management	JCCM
Journal of Flood Risk Management	JFRM
Journal of Hazardous Materials	JHM
Journal of Loss Prevention in the Process Industries	JLPPI
Journal of Occupational Safety and Ergonomics	JOSE
Journal of Risk & Reliability: Proceedings of the Institution of	PIMEPO
Mechanical Engineers Part O Journal of Risk Analysis and Crisis Response	IRARC
Journal of Risk Research	JRR
Journal of Safety Research	JSR
Open Occupational Health and Safety Journal	OOHSI
Process Safety and Environmental Protection	PSEP
Process Safety Progress	PSP
Reliability Engineering and System Safety	RESS
Reliability: Theory & Applications	RTA
Risk Analysis	RA
Risk and Decision Analysis	RDA
Safety Science	SS
Stochastic Environmental Research and Risk Assessment	SERRA
Structural Safety	STS

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