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The strong power of standards in the safety and risk fields: A threat to proper developments of these fields?

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ABSTRACT

Standards like ISO 31000 on risk management are increasingly influencing the risk and safety fields, despite rather strong criticism concerning their quality. In this paper, we perform a thorough discussion of the application of standards in the risk and safety fields, using ISO 31000 as a case to illustrate the argumentation. The aim is to structure and summarise some key knowledge on the role of such standards in the progress and practice of these fields. The discussion addresses the scientific basis, the level of consistency, as well as the processes for developing and improving the standards. We conclude that the current trend of using standards represents a serious threat to the advancement of the risk and safety fields, and measures need to be taken to create broader and more scientifically based arenas for guiding risk and safety analysis and management practices.

1. Introduction

This paper discusses standards in the safety and risk fields. Our main focus is on standards published by the international standard organisations, like ISO (International Organization for Standardization). For some types of activities, a standard can be seen as a framework or structure to follow when setting up and operating these activities, whether it concerns risk management for all the activities in an enterprise or a specific risk assessment to be conducted for a critical operation. There are many types of standards in the risk and safety fields, some linked to specific applications, like safety in the nuclear industry or the oil & gas industry, others are more generic, as ISO 31000 on risk management, which provides general principles and guidelines on risk management for use by any public, private or community enterprise, association, group or individual. The present paper is mainly concerned with the general standards that apply to a broad range of applications.

According to the standardisation organisations, the use of these standards will result in increased likelihood of identifying threats and opportunities, and achieving desirable outcomes, as well as more effective allocation and use of resources [18,27,35]. They also point to the benefit for organisations of being able to compare their practices with internationally recognised benchmarks [28,35]. ISO is a global standard-setting body, a kind of roof organisation, consisting of national standards bodies. ISO defines a standard as a "document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context" [37]. The development of an ISO standard is based on market needs. Independent technical experts nominated by the respective national committees will form a technical committee that is responsible for a specific subject area, such as risk management. Based on the market needs, these experts start drafting a standard proposal that is shared for comments. The standards are developed through a multi-stakeholder process; all stakeholders, whether consumers or business people, can participate in commenting on the draft proposal. There is a voting process that indicates whether consensus is achieved. If there is a disagreement, the draft will be modified further, until it is accepted [35,36]. The main opportunity for those who do not participate actively in the standardisation work is to make comments, through their national committee, on the committee draft when it is circulated. After that, it is possible to vote against the text if the answers to the comments are not acceptable.

In general, standards are said to contribute to uniformity and coherent coordination of performance [19,52]. They represent a key element in current regulation schemes, which state functional requirements, allowing for alternative arrangements and solutions to meet these requirements. The standards constitute one way of meeting the requirements. In this way, the standards can be seen as a system of compliance [19,26]. In addition, it is stated that standards increase the safety of products, safety for humans and the environment, and enhance innovation and economic growth by providing similar codes of conduct for all stakeholders [18,27,35].

There is considerable use of standards in industry and in practical safety and risk related work today. Although these standards are

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voluntary in use – they are just to be considered as guidance documents that offer advice, suggestions and recommendations – they are strongly influencing the practice of risk analysis and management. As commented above, regulations today are to large extent based on functional requirements which require detailed examples on how to meet these requirements. For the regulator, the standards serve this purpose. As a concrete example we point to the oil and gas industry in Norway where standards (in particular ISO) is used as a key reference for how to fulfil these functional requirements, see PSA-N [44].

It is thus in place to critically examine the role of these standards in risk and safety management: Do the standards actually enhance the risk and safety field, or are they in fact leading to the cementation of inadequate principles and methods? The literature covers many scientific works pointing to strong limitations and weaknesses in current standards [21,45,50–52,55], and experience indicates that it is difficult to influence the thinking supporting the standards. The processes involved in developing and maintaining standards like ISO 31000 are comprehensive; a result of international expert consensus and as formulated by ISO, "therefore offer the benefit of global management experience and good practice" [35,36]. However, is this consensus-driven approach actually delivering high quality guidance, according to the best of the risk and safety fields and sciences? Are the standards favour compromise and the lowest common denominator of available options, at the expense of scientific quality?

The current paper aims at researching these questions by looking at both the approach and the results it produces. As a case, we compare the ISO 31000 standard with the insights provided by the risk field and science. A framework is developed for looking at the pros and cons of standardisation for risk analysis and management. This framework is partly based on 'institutional isomorphism', which refers to increasing similarities between organisations in terms of structures and practices [24], and hypotheses derived from it are exploited as we look specifically for cases characterised by contradictions and lack of consistency – these aspects are rarely addressed in the discussion on standardisation. ISO 31000 is chosen as it is a generic standard for the risk field, applicable for all types of applications. In industry and related risk and safety regulations it is commonly referred to and used as basis for recommended terminology and principles, see for example the guidance provided by the Petroleum Safety Authority Norway [43,44]. For the study of the approach itself, we highlight issues linked to power and institutional structures that maintain the current practice of using standards. The paper also raises the issue of encouraging professional organisations like the Society for Risk Analysis (SRA) and the European Safety and Reliability Association (ESRA) to initiate work, to provide alternatives to the standardisation organisations, which is based on scientific pillars and recommendations rather than on broad international consensus approaches outside the scientific environment.

The paper is a 'conceptual research paper' – a 'perceptive paper' as explained in Aven [13]. A main type of activity of the risk science is the development of suitable concepts, principles, approaches, methods and models for understanding, assessing, characterizing, communicating and managing (in a wide sense) risk. The risk science generates scientific knowledge through this type of activity, as well as through applications aiming at generating risk knowledge of specific systems and situations (an investment, the operation of a process plant, etc.) and tackling specific risk problems. The means are research, papers, work in scientific societies, etc. The present paper aims at contributing to such knowledge generation by thoroughly examining how standardization can hamper this development. By reasoning it is shown that for example the ISO 31000 recommendations on the risk concept is not meaningful and could seriously misguide decision-makers by not revealing important aspects of risk. The paper provides arguments for the statements and conclusions made, which can be scrutinized by others and lead to further insights and improvements. The conceptual research makes use of various 'approaches', such as 'identification' (for example, the paper points to some problems with the ISO definition of risk), 'revision' (for example the paper refers to adjusted definitions), 'differentiation' (for example, the paper highlights the importance of distinguishing between different types of probabilities), 'advocating' (for example, the paper argues that the strength of knowledge should be added to probabilistic risk characterisations), and 'refuting' (for example, the paper shows that the ISO 31000 definition of risk is not meaningful) (see [41] for further details on these and related 'approaches').

The paper is organised as follows. Firstly, in Section 2, we introduce a framework for understanding standards and their related development processes, with a focus on the ISO standards. The framework is inspired by insights from: risk and safety studies, and different fields of sociology, such as organisational studies [24] helping to understand drivers for standard development and mechanisms for their spread; science and technology studies (STS) [56,57] showing different ways of excluding stakeholders via inclusion; and studies on collective action and power [22,31,32] showing how to gain stakeholders' acceptance even when they may disagree [1]. These aspects contribute to a deeper and wider understanding of standardisation processes and standards. Then, in Section 3, we look in greater detail into the ISO 31000 standards for Risk Management [36], to study their content and quality, and compare them with what is considered the scientific knowledge of the risk field. Section 4 discusses the findings of the previous sections. We argue why standardisation today represents a threat to the development of the risk and safety fields. Finally, Section 5 provides some conclusions.

2. A framework for understanding standards and related development processes

The main features of the framework are presented in Fig. 1. It visualises the relevant aspects necessary to understand the standardisation process and the factors influencing it. The framework takes into account societal, economic and cultural pressures, which function as drivers for the standardisation process, to be discussed in greater detail below. The framework highlights the relevance of the identification of interests and the combination of these into nodes of interests when searching for consensus. The framework shows that there are different forms of consent or acceptance: normative and pragmatic. Normative acceptance refers to the fact that stakeholders regard standards as right, good, beneficial, whereas pragmatic acceptance suggests that standards are accepted because there are no other choices or better alternatives available. Pragmatic acceptance is also exploited by companies, which require that all project partners follow similar standards.

A key feature of the framework is different forms of 'exclusion via inclusion' [56,57]. According to ISO principles, a standardisation process is a multi-stakeholder process, which is said to include, for example, business people and consumers, in addition to experts. In this way, the process of standardisation is inclusive [55]. In practice, however, there are constraints as regards the possibility and willingness to include the opinions of all stakeholders [19,55,56]. Leading scientists, for example, are often not included in these processes. Research on public participation in science and technology has provided thorough discussions on this form of exclusion via inclusion [38,54,56]. This apparently democratic way of organising discussion can turn into the opposite when restricting participants to focus on specific themes and not letting them discuss others. Similarly, new categories such as disabled people can be included in the conversation, but they are only allowed to say something concerning their own group. By the same token, restricting the conversation functionally, so that business people talk about market needs, and customers comment on the need to protect products and humans, can weaken the possibility of different stakeholders having their voices heard. Sometimes even broadening the discussion to include several themes, while retaining the old division of labour between experts and non-experts, is a form of exclusion via inclusion [57]. Hence, even the most inclusive participation processes embrace exclusion. Furthermore, the framework addresses the outcome

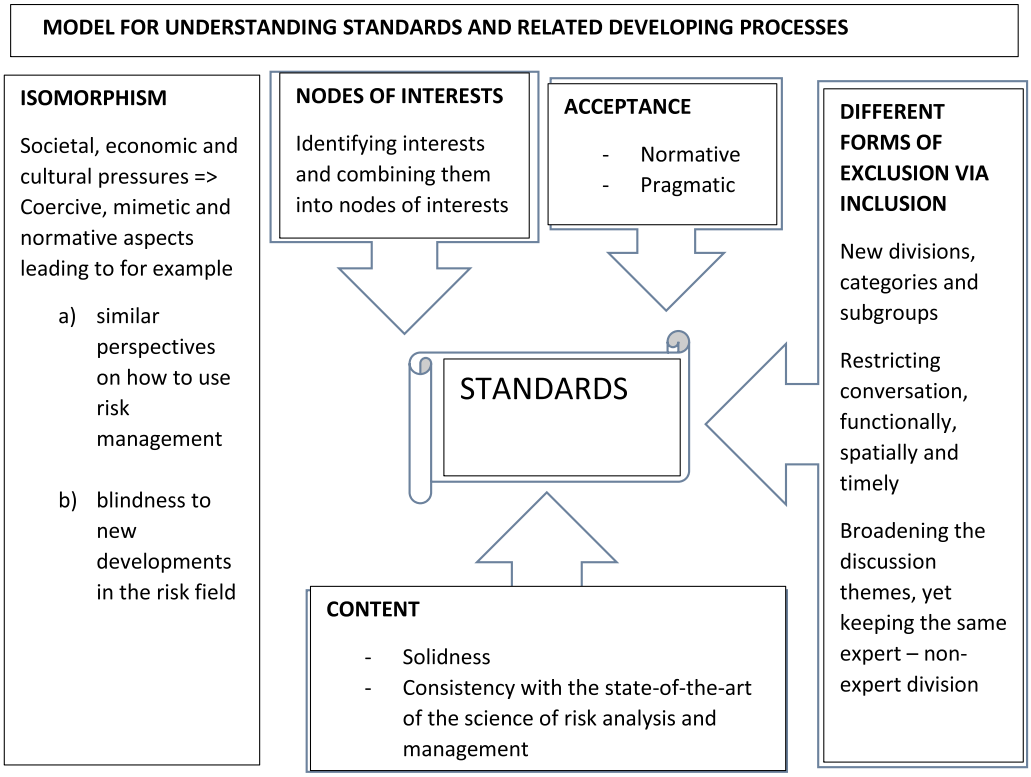

Fig. 1. Framework for understanding standards and related development processes.

of the standards by looking at the content based on criteria like solidness and consistency, as well as scientific knowledge from the related risk sciences.

The exclusion via inclusion of participants signifies the relationships of power between the stakeholders. Relationships between stakeholders in the standardisation process are affected by stakeholders' networks and their knowledge and position in the market [19]. Standardisation can be seen as a field where strong stakeholders dominate and define the rules of the field [20,30]. However, the field is under constant change, due to digitalisation and other trends, introducing new stakeholders and changes in power configurations. Also, the current standardisation forms, which incorporate elements from committee-based, market-based and government-based standards, may change the power relationships [55].

Institutional isomorphism, which refers to the phenomenon by which organisations tend to become structurally or strategically more similar [24], is also a key feature of the framework. There are several societal, economic and cultural pressures that make organisations adopt structures and practices from each other. DiMaggio and Powell have identified three mechanisms – coercive, mimetic and normative – through which the organisations become more homogeneous.

Coercive isomorphism refers to factors that force organisations to adopt standards. Examples of such organisations include national standardisation bodies or international commercial projects, which force all organisations involved in the project to adopt similar risk management practices, such as ISO 31000. *Mimetic* isomorphism derives from an uncertain environment that creates pressures to imitate other organisations, which are considered successful. This imitation can include the adoption of similar risk management practices. *Normative* isomorphism refers to the need to create a cognitive basis through standards and related training courses and networks. Normative isomorphism in the risk area creates similar understanding of and orientations to risk analysis and management among certain professions and experts. These mechanisms show different ways through which the adoption of standards is enhanced, and risk analysis and management become more homogeneous. In this way, some specific understandings of, and approaches to, risk analysis and management can effectively be spread. Thus, institutional isomorphism can lead to consensus concerning relevant understanding of standards and means to deal with risk management. This may mean enhanced awareness of risks and strengthened risk management practices.

On the other hand, the standards can be an obstacle to incorporating new needs, ideas and developments. Specifically, the framework points to the fact that the standards may demonstrate blindness in acknowledging new research findings. The standards may also hamper the adaptions to specific needs that some organisations may have in relation to the risk management. This can be understood by regarding standards as institutionalised schemes and practices, which become powerful and not easily refuted once they have been taken into use. Standards as institutionalised schemes and practices do not allow the adoption of other schemes and practices and, thus, can lead to blindness.

It may be commented that the aim of the standards is to standardize well established technologies, not new ideas. The standards are regularly reviewed and updated, which provide opportunities to introduce recent developments. Yet, experience shows – and the discussion in Sections 3 clearly demonstrates this – that such developments are not easily included. Blindness is an issue that needs attention.

The framework provides insights into critical factors of the standards and the related development processes. It is applicable to all standards and standardisation processes. It can be complemented with a discussion of power relationships that is now implicitly included.

3. Evaluation of the ISO 31000 risk management guidelines

This section performs an evaluation of the content of the ISO 31000 Risk Management Guidelines [36], which replace the first edition from 2009 [34]. The main changes made in the new version are summarised in its foreword: A review is performed of the principles of risk management; the leadership by top management and the integration of risk

management are highlighted, starting with the governance of the organisation; and the iterative nature of risk management is given more attention [36].

The evaluation in this section is based on two overall criteria:

(a) *solidness*, meaning that concepts are well-defined and coherent.
(b) scientific knowledge of the risk analysis and management field.

What the scientific knowledge refers to will be clarified and discussed throughout the evaluation. Five main points will be highlighted in the following:

(1) Overall positive features of the standard: non-controversial issues
(2) Overall ideas linked to risk and risk characterisation
(3) Fundamental principles of risk management
(4) The link between uncertainty, knowledge and information
(5) Other examples showing lack of solidness

The evaluation builds on and extends earlier discussion of the ISO 31000 standard, including that of Aven [6,10] for the first edition of the standard.

3.1. Overall positive features of the standard, non-controversial guidance

Many features of the standard are non-controversial, and risk scientists would agree that they represent current knowledge of the field. On an overall level, the changes referred to above for the 2018 edition are unproblematic. For example, there is broad support for highlighting leadership and commitment in risk management. Again, on an overall level, there is broad agreement in the risk field that risk assessment provides a useful tool for informing decision-makers and other stakeholders about risk, and that there is a need for a structure and process for how to use risk assessments in the risk management. There are many ways of describing this process, but they will all have features similar to those outlined in the standard. On a more detailed level, there are, however, many issues that could be discussed; see the coming evaluation. Also, the role of this process in risk management is a topic for debate; see Section 3.3.

The standard has a focus on objectives and meeting these, in line with the management by objectives philosophy. It is a strongly debated philosophy. It has some obvious strengths but also some severe weaknesses, as thoroughly discussed in the literature, particularly in the quality management discourse (e.g. [15,23]). Although the standard highlights continual improvement, the focus on objectives easily leads to a compliance regime, in which the main driver becomes task achievements, without really improving overall performance [5].

The standard has a focus on organisations and their risk management. Surely aspects of the standard can be useful also for broader risk problems, such as global risks, but the scope of the standard is organisations (commercial, public sector and non-governmental) and their risk handling.

3.2. Overall ideas linked to risk and risk characterisation

The standard defines risk as “the effect of uncertainties on objectives”. Compared to many other definitions of risk, uncertainty has replaced probability. The idea is in line with a recommendation made by the Society for Risk Analysis [47]: We should not define the concept of risk using one specific measurement tool (probability). This is a basic principle of measurement theory: the concept should be distinguished from how it is measured. The idea is that we face risk when we operate a process plant or make an investment, independently of whether this risk has been measured or not. Certainly, probability is a main instrument for measuring or describing the uncertainties, but it has some weaknesses and there are also other approaches that can be used for this purpose. This idea is reflected in the ISO 31000 standard. Unfortunately, the standard is poorly formulated, as will be discussed in the following.

Firstly, it is problematic that the risk concept is so tied up to formulations of objectives. We can question: Does not risk exist if objectives are not defined? Following Aven [10], think of some researchers who explore an unknown substance. Would it not be reasonable to say that they face risk? Yes, it would, despite the fact that an investigation objective has not been formulated. As another example, consider a case with many stakeholders having different interests and objectives. Some of these may be reluctant to express their preferences and goals. Yet, it should be possible to conceptualise and describe risk. Using the ISO definition, this is, however, problematic. In practice, risk assessment is commonly used as to a means to develop formulations of objectives, by, for example, identifying factors contributing strongly to risk. However, the ISO conceptualisation makes this impossible, as the objectives are incorporated in the risk term. Finally, think of an investor who invests an amount of money in a specific project. The investor adopts a strategy in which he/she seeks to obtain as high a benefit as possible. He/she rejects the idea of formulating a specific objective. Then, risk as defined by ISO has no meaning, although intuition and common understanding of the risk concept would surely point to its existence.

Secondly, it is a problem that the ISO definition is so poorly formulated. To illustrate – and again following Aven's [10] ideas – consider the future realisation of a specific activity. The outcome of the activity is either 1 or 0, corresponding to one fatal accident and no fatal accidents, respectively. We have formulated an objective as “no fatal accidents”. Now, what is “the effect of uncertainties on objectives”? This is not clear. One possibility is that the statement expresses that the activity leads to a fatal accident and in this way does not meet the objective. However, such an outcome is not an effect of uncertainty but an effect (consequence) of the activity, and this effect (consequence) is uncertain prior to the realisation of the activity. A note to the ISO definition of risk states that an effect is a deviation from the expected – positive, negative or both. Also, this is unclear: “the expected” – what does that mean? Think again about the 0 – 1 example. Suppose probabilities of 0.7 and 0.3 are specified for the outcomes 0 and 1, respectively. What, then, is the deviation from the expected – is it from 0 or 0.3? The latter number is the statistical expected value of the probability distribution – the centre of gravity of the distribution. As a consequence, deviations from the expected thus could mean either 1 or 0.7. The main point being made, however, is not this lack of clarity related to the term ‘expected’ but that the deviation is not an effect of uncertainty – it is an effect (consequence) of the activity, and this effect (consequence) is uncertain prior to the realisation of the activity [10].

Thirdly, it is a problem that the uncertainty characterisations pointed to in the standard are not really updated on current knowledge of the risk science. It is stated that risk is usually expressed in terms of risk sources, potential events, their consequences and their likelihood. Likelihood is then defined as the chance of something happening, “whether defined, measured or determined objectively or subjectively, quantitatively or qualitatively, and described using general terms or mathematically (such as a probability or a frequency over a given time period)” [36]. Likelihood is meant to be interpreted broadly, in contrast to a more narrowly interpreted mathematically-based probability concept. The logic is difficult to understand, as neither ‘probability’ nor ‘chance’ is defined. Likelihood is explained by introducing a new term, namely chance, but what does chance mean in a risk context? The scientific literature provides clear definitions with interpretations; see, for example, Lindley [39,40], Aven [8] and SRA [47]. Why are these not used? The ISO text mixes underlying theoretical concepts – like frequentist probabilities – with estimates, as well as assignments of subjective (knowledge-based, judgemental) probabilities. To characterise risk, it matters greatly whether we refer to an underlying ‘true’ probability, an estimate of this probability, or a subjective probability, which is conditional on a knowledge base.

Certainly, likelihood (probability) is the most common tool for

representing and expressing uncertainty, but the risk characterisation should not be restricted to this measure alone. In relation to subjective probabilities, there is, for example, a need to reflect the knowledge and the strength of knowledge on which the probabilities are founded. The ISO standard completely ignores this important aspect of a risk characterisation. A considerable body of scientific literature argues for extended risk characterisation, highlighting knowledge aspects beyond likelihood judgements (see e.g. [47,11]), but ISO 31000 is not updated on this matter. It refers to basically the same approach for characterising risk as that in the 1970s and 1980s. The risk field has made many advancements, also related to interval (imprecise) probabilities (see e.g. [25,29]), but this is not reflected.

It is not realistic for us all to agree on one definition of risk. It is not needed. Nonetheless, it is both realistic and meaningful to seek broad agreement among risk assessment and management researchers and analysts, when it comes to the basic ideas of the risk concept and its characterisation: Risk captures two essential dimensions: (1) something is at stake – the activity considered results in some consequences with respect to something that humans value (including health and lives, the environment and material assets) and (2) uncertainties [10,14,47]. There are different ways of (a) conceptualising this idea and (b) measuring or describing the risk and uncertainties, as shown in the SRA [47] glossary.

To characterise the uncertainty component, we are led to likelihood considerations (including intervals or imprecise likelihood judgements), knowledge characterisations, including judgements of the knowledge strength, and, finally, surprises relative to this knowledge. For the last element, the point is that there could be knowledge gaps, where we know little or nothing, or the justified beliefs that form the knowledge could actually be wrong. Potential surprises are, per definition, difficult to include in risk characterisations, but they need to be acknowledged as a risk source. Measures of different types can be implemented to meet this risk, for example implementing a qualitative analysis addressing such questions as [12]:

1 Has a risk assessment of the deviations from assumptions been conducted (an assumption deviation risk assessment)?
2 Have attempts been made to reduce the risk contributions from the assumptions that have the highest deviation risk?
3 Is the strength of knowledge, on which the assigned probabilities are based, assessed? Is this strength included in the risk description?
4 Have attempts been made to strengthen the knowledge where it is not considered strong?
5 Have special efforts been made to uncover potential surprises of the type, unknown knowns?
6 Have special efforts been made to uncover any weaknesses or holes in the knowledge on which the analysis group has built their analysis?
7 Have special efforts been made to assess the validity of the judgements made where events are considered not to occur due to negligible probability?
8 Have people and expertise, not belonging to the initial analysis group, been used to detect such conditions?

It is a research topic to improve current risk assessment practice to meet this challenge. We refer to Aven [9,12]; see also Section 3.3.

The ISO 31000 standard provides no discussion of issues like this. It is based on a traditional likelihood perspective on risk characterisation, which has been shown to be inadequate for capturing all aspects of risk and uncertainties. As formulated by one of the reviewers of the original version of this paper, the people that has developed the ISO 31000 have well identified the problem (define the concept and not its measure) but have not been able to translate that into a relevant definition.

Risk assessments inform decisions makers, they do not prescribe what to do [3]. It is however obvious that the way risk is conceptualized and described can strongly influence the decision-making in practice. If risk is seen as properly characterised by risk sources, potential events, their consequences and their likelihood as in ISO 31,000, differences in the strength of knowledge supporting the likelihood judgments will not be revealed. The result could be that the wrong decision alternative is chosen. For some examples discussing this issue, see Bjerga and Aven [16,17], Veland and Aven [53] and NOG [42].

3.3. Fundamental principles of risk management

The ISO 31000 standard highlights eight principles which are to be considered as the foundation for the risk management processes and frameworks. These principles are referred to as: integrated, structured and comprehensive, customised, inclusive, dynamic, best available information, human and cultural factors, and continual improvement. These all seem reasonable, but there is no reference to a rationale or argumentation for the selection of these principles. What is the scientific basis for the choices made? Many other principles could have been included. We would, for example, have given priority to a principle with a heading saying something like ‘Risk science based’ (refer to Section 1), expressing that the risk management should aim to follow the guidance provided by the risk science. There could be ambiguity in relation to what this science states in some cases, as for all types of sciences, but the statement is still relevant as a principle. It demonstrates a standard for the work: that it aims to follow the scientific knowledge of the risk science. This knowledge represents the most warranted (justified) statements and beliefs of the risk field and community [33]. There is a continuous ‘battle’ on what these beliefs and statements are – it is about institutions and power. Different directions and schools of thought provide argumentation for their beliefs, trying to obtain control over the field [20].

In addition to stating principles for the risk management process and framework, it would have been useful to formulate key principles for the risk management per se. It should be equally important to state what is good risk management, as well as good risk management processes and frameworks. The risk management process could be judged to be strong by reference to the ISO standard, but it completely fails if the reference is the risk science. Examples of such principles have been developed by the Society for Risk Analysis [48]. As an example, SRA [48] points to the need for using the following three main strategies for managing risk: “risk-informed strategies (I), cautionary/precautionary/robustness/resilience strategies (meeting uncertainties and potential surprises) (II), and discursive (III) strategies. In most cases the appropriate strategy would be a mixture of these three types of strategies. The higher stakes involved and larger uncertainties, the more weight on the second category and the more of interpretative ambiguity and normative ambiguity (different views related to the relevant values) the more weight on category III” [48]. ISO has published a guidance document on risk assessment techniques, but the point made here relates to the overall principles for how to scientifically best manage risk. The SRA principles guide users to seek the proper balance between strategies I-III. Such type of guidance helps users to conduct good risk management, which is ultimately the aim of the standard. Such guidance should be essential for risk analysts and managers in their work, but the current version of the ISO documents lack this type of support.

3.4. The link between uncertainty, knowledge and information

The concepts of uncertainty, knowledge and information are all referred to in many places in the ISO 31000 standard. They are all key terms in relation to this standard and risk management in general. However, none of them is defined or explained. Their interrelationship is not addressed or discussed. It seems that ‘information’ is more central than ‘knowledge’, at least if we are to give weight to the number of times these words are referred to in the standard.

As an example, the standard refers to “Best available information” as one of the risk management process principles, with the explanation:

"The inputs to risk management are based on historical and current information, as well as on future expectations. Risk management explicitly takes into account any limitations and uncertainties associated with such information and expectations. Information should be timely, clear and available to relevant stakeholders" [36]. Why not, instead, refer to 'knowledge' – and 'Best available knowledge'? Data and information provide input to the knowledge generation, and, by focusing on knowledge, a stronger statement is, in fact, obtained. Knowledge also captures beliefs justified according to scientific processes, using analysis, models, testing and argumentation. We refer to the well-established DIK (Data, Information, Knowledge) hierarchy (see e.g. [2,7,8,46,58]).

The standard does not define or explain the uncertainty concept. The literature provides a huge number of definitions and classification systems for understanding uncertainty, and it is unfortunate that the standard does not contribute to a clarification. Again, we refer to the Society for Risk Analysis and its Glossary [47]. As for risk, the Glossary distinguishes between the concept and how it is measured or described. The qualitative concept captures the idea that a person does not know the true value of a quantity or the future consequences of an activity, for example to what degree an objective is met – that there is imperfect information and knowledge about the quantity or consequences. Different methods can be used to represent and express the uncertainties, including knowledge-based (subjective) probability (probability intervals) with related strength of knowledge judgements. The ISO standard provides no guidance on the issue whatsoever. In fact, it contributes to confusion with its notes on likelihood, which are inaccurate, and mixes underlying unknown quantities and the measurement of these quantities.

3.5. Other examples showing lack of solidness

Here are two examples to further demonstrate the lack of solidness in the standard. The first example is from Section 6.4.3 on risk analysis, where it is stated: "Highly uncertain events can be difficult to quantify" [36]. Yes, it is difficult to quantify events. Probably it was meant to say that it is difficult to quantify the risk associated with such events.

The second example is taken from Section 6.5.3 on preparing and implementing risk treatment plans. It is stated that the "information provided in the treatment plan should include: — the rationale for selection of the treatment options, including the expected benefits to be gained …" [36]. But why only *expected* benefits? Restricting attention to expectation could seriously mislead decision-makers. Uncertainty does not seem to be an issue. But it definitely is and should have been addressed in the text.

4. Discussion

In this section, the following statements are discussed:

- The ISO's marketing argument that its standards are consensus-based can be questioned
- Regulators need to take responsibility and promote scientific-based alternatives to ISO
- Scientific societies have to confront the standards and provide alternative guidance, because standards are predominantly market-based rather than science-based.

4.1. The ISO's marketing argument that its standards are consensus-based can be questioned

As discussed in Section 2, the ISO standards are developed through a multi-stakeholder process, and ISO highlights that they are established by consensus. We argue, however, that this selling point is problematic. It may mislead potential users. It indicates that all relevant parties find the standard acceptable. This is not the case. As demonstrated by the case of Section 3, the risk science has raised serious concerns about some main aspects of ISO 31000. As risk experts, the authors of the present paper do not find the ISO 31000 standard acceptable from a scientific point of view, and many of our arguments have been presented to ISO but not taken into account. The critique has been addressed in scientific papers and also through the Norwegian standardization organization (Standards Norway). However, the specific comments made to ISO 31000 through Standards Norway were just ignored ('not accepted'), no argumentation, discussion or follow up to clarify issues and search for improvements. The process was disappointing and demotivating for further participation of the risk experts.

Leading scientists may to varying degree have interest in standardization work, and the lack of real influence would certainly discourage many to get involved. Working as experts in a committee their voices can be heard, but to obtain changes is difficult when the rest of the committee is hostile to the ideas and suggestions put forward. The time and costs involved are considerable, and as a scientist standardization work will not normally be prioritized.

The ISO 31000 has largely been based on ideas from Australia and New Zealand through the standard AS/NZS [4]. As commented by a reviewer of the present paper, since then, it has been difficult to change the content in depth.

If we compare the ISO 31000 standard with the SRA Glossary and guidelines developed by the Society for Risk Analysis (SRA), there are several conflicting perspectives. Consensus is thus not established, if the reference is the broader community of professional societies and organisations working with risk. Within the formal processes of ISO, it can be argued that the processes are consensus-based, but consensus is only obtained because the processes are limited to some stakeholders and power is exercised.

Of course, achieving consensus is difficult in multi-stakeholder processes. Power relationships are critical, as discussed in Section 2. There are actors (for example technical committees), who have the power to decide how to include relevant stakeholders in the development processes and what aspects to take into account or to leave out. As underlined in Section 2, there are many means to exclude stakeholders, even via inclusion.

Even if consent on the content of a standard is achieved, it is relevant to look at how the consent is gained, to what degree it is based on real acceptance as right, beneficial, and good for the business, health, environment and society (normative acceptance) or if the acceptance is more pragmatically driven. The ISO approach surely has a basis in both types of acceptance, but we will argue that the pragmatic dimension is the dominant one. If the normative acceptance had been the most important perspective, more weight would have had to be given to, for example, the scientific quality of the standards. The world-leading experts in the field should necessarily have been a part of the stakeholders involved in the process. However, such a process would have been very difficult to carry out in practice, if consensus is seen as an overriding principle for the development of the standards.

4.2. Regulators need to take responsibility and promote scientific-based alternatives to ISO

As mentioned in the introduction section, standards represent a cornerstone of modern safety and risk regulations, in the sense that the regulators specify functional requirements, and the standards are referred to as ways of meeting these requirements. Hence, standards form a system of compliance [26]. For the regulator, the quality of these standards is important, but in practice pragmatic considerations can easily lead to acceptance of these standards, without really evaluating the scientific quality, as the regulation regime requires the availability of some references for the system to be working.

However, if the regulators aim to ensure excellence, the concerns raised here should be taken seriously. Different measures should be

considered. One approach is to stimulate improved processes in ISO to ensure the quality of the standards; an alternative is to promote scientific-based alternatives to ISO. There are a number of professional societies and organisations that aim to provide guidance on how to conduct risk management and related risk types of activities, for example SRA and ESRA. These societies and organisations have historically to a rather limited degree acted as knowledge institutions of this type, but there are indications that this is changing (see e.g. [49]). Regulators can influence this development by supporting these institutions and their work. We argue that further advancement of the risk field requires more scientific-based practical guidance to be produced than is the case today. Currently, the risk field lacks authoritative guidance which has a broad scientific foundation, derived on the basis of normative acceptance and not pragmatic acceptance. In our view, regulators have a responsibility to promote such guidance. The regulations' regimes require it, and the current state is not acceptable.

4.3. Scientific societies have to confront the standards and provide alternative guidance, because standards are predominantly market-based rather than science-based

The development of an ISO standard is based on the market needs rather than the latest knowledge from the risk science field. Market- and commercial-based needs and interests cannot ensure that relevant risks and uncertainties concerning the protection of humans, health and the environment are given the value that they deserve. There are NGOs with experts participating in standards' development, but they are not necessarily experts on risk and uncertainties-related issues. Therefore, we argue that scientific societies need to confront the standards and provide alternative guidance.

Challenging standards and influencing them is not an easy task, if we think of standardisation development as a social field, where strong actors, such as business enterprises and national and international standardisation bodies, bargain and fight over the control of the field. Power in the field of standard development is also linked to actors' ability to establish themselves as spokespersons of a network, by presenting their own interests as necessary passage points for other participants to reach their goals [19,22]. In relation to scientific societies this means that if they are to be successful in providing alternative guidance, they need to tie different interests, - the market-based aspects, the protection of values (in particular related to human, health and the environment) and the scientific requirements - into nodes of interests, and to show that all stakeholders benefit from the integration, with risk science in a leading role. In this regard, surely scientific risk and safety organisations today have a long way to go. Alternative strategies should be pursed, as well as building liaisons with ISO, to influence the content and quality of the standards.

5. Conclusions

In this paper, we have discussed the thesis that the strong power of standards in the safety and risk fields represents a threat to the proper developments of these fields. We provided strong arguments for the support of this thesis. The example of ISO 31000 is used to illustrate the problems that the standards have in producing high-quality scientific content. We make the following conclusions for how to confront this situation and improve the risk and safety fields:

(1) The ideal of consensus-building processes in standard developing needs to be challenged. Rather, the ideal should be high quality, as judged by the scientific risk analysis community.
(2) The scientific risk and safety organisations need to take greater responsibility as knowledge organisations and seek to influence the risk and safety fields on what represents high quality risk analysis and management.
(3) Regulators for different areas should give increased support to scientific organisations to build the organisational capacity to meet such a responsibility.
(4) At the same time, the risk science community should increase its participation in standardization activities like ISO. It should build liaisons with the standardization organizations to influence the content and quality of the standards.

There is an urgent need for the risk and safety fields to address these issues. The leaders of the scientific organisations have a special responsibility to see to it that we move in the right directions.

One of the reviewer's of the original version of the present paper disagrees with our conclusions (1–3) and commented that as a risk expert one should get involved in the development of these standards: - If you have not participated you cannot really complain. And if you have been involved you share the faults and weaknesses of the standards. If you have raised some critical issues and suggested some changes but these are not accepted, the reviewer refers to your country's view and related voting: If it has voted for acceptance, then you have to begin by convincing your country first.

As a response to these comments, we agree that it is important to encourage the risk science community to increase its involvement in standardization work as highlighted by item 4 above. However, the issue we raise is not limited to the individual expert's stand on this. Our perspective and discussion are wider. Real changes and improvements cannot be made without involving relevant organizations. We argue that we need alternative guidance to what is produced by ISO as the scientific quality is not good enough. The Society for Risk Analysis (SRA) has taken this challenge seriously and has developed several documents providing guidance on risk terminology and fundamental principles [47,48]. SRA's vision is to be the world leading authority on risk science and have impact globally. We welcome this development, as the risk analysis and management applications need stronger scientific-based guidance, as clearly shown by the ISO 31000 example. At the same time liaison should be built with the standardization organizations. There is no contraction in that. We need different means to enhance the risk field and science.

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