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► **To cite this version:**

Enrico Zio. The future of risk assessment. Reliability Engineering and System Safety, 2018, 177, pp.176-190. 10.1016/j.ress.2018.04.020 . hal-01988966

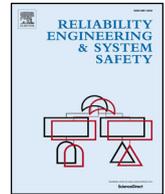
**HAL Id: hal-01988966**

**<https://hal.science/hal-01988966>**

Submitted on 8 Feb 2019

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## The future of risk assessment

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### ARTICLE INFO

#### Keyword:

Risk assessment  
Simulation  
Business continuity  
Resilience  
Condition monitoring-based risk assessment  
Dynamic risk assessment  
Cyber-physical systems  
Safety and security assessment

### ABSTRACT

Risk assessment must evolve for addressing the existing and future challenges, and considering the new systems and innovations that have already arrived in our lives and that are coming ahead. In this paper, I swing on the rapid changes and innovations that the World that we live in is experiencing, and analyze them with respect to the challenges that these pose to the field of risk assessment. Digitalization brings opportunities but with it comes also the complexity of cyber-physical systems. Climate change and extreme natural events are increasingly threatening our infrastructures; terrorist and malevolent threats are posing severe concerns for the security of our systems and lives. These sources of hazard are extremely uncertain and, thus, difficult to describe and model quantitatively.

Some research and development directions that are emerging are presented and discussed, also considering the ever increasing computational capabilities and data availability. These include the use of simulation for accident scenario identification and exploration, the extension of risk assessment into the framework of resilience and business continuity, the reliance on data for dynamic and condition monitoring-based risk assessment, the safety and security assessment of cyber-physical systems.

The paper is not a research work and not exactly a review or a state of the art work, but rather it offers a lookout on risk assessment, open to consideration and discussion, as it cannot pretend to give an absolute point of view nor to be complete in the issues addressed (and the related literature referenced to).

### 1. Introduction

Safety is freedom, freedom from unaffordable harm, and, thus, a human right. Risk assessment has been the dominant paradigm for ensuring this right in the design and operation of industrial systems. Examples of areas of applications include the chemical process industry, the nuclear industry, the transportation sectors, the aerospace industry etc.

Risk assessment is a mature discipline. The structured performance of a risk assessment guides analysts to identify possible hazards/threats, analyze their causes and consequences, and describe risk, typically quantitatively and with a proper representation of uncertainties. In the assessment, the analysts make assumptions and simplifications, collect and analyze data, and develop and use models to represent the phenomena studied. For example, the failure modes of components due to a given earthquake, the heat fluxes on a structure due to a fire, the response of operators to an accident are all the results of conceptual models that attempt to mimic how a real accident would proceed, based on the knowledge available. The risk assessment of a system requires the consideration of a possibly very large number of scenarios with multiple failures of its components and, by so doing, provides an in-depth understanding and knowledge of the system failure modes with

consequent increase of the awareness on risk and the attention to safety, which typically leads to an overall improvement of the safety of the system.

The World we live in is rapidly changing in many ways. Digitalization is bringing new opportunities of connectivity, monitoring and awareness, and is changing the way we communicate and socially behave. Mobility and social pressure are changing the landscape in which we live and operate. Continuous advancements in technical knowledge and technology are improving our production processes, products and services, as well as our environments, while changing the business and work/job scenarios. As the digital, physical and human worlds continue to integrate, we experience a deep transformation in industry, which far-reaches into our lives. The 4th industrial revolution, the internet of things and big data, the industrial internet, are changing the way we design, manufacture, supply products and services, the way we move and live in our environment. This is creating a complex network of things and people that are seamlessly connected and communicating. It is providing opportunities to make production systems and services more efficient and faster, and more flexible and resilient the complex supply chains and distribution networks that tie the global economy.

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<https://doi.org/10.1016/j.ress.2018.04.020>

Received 1 June 2017; Received in revised form 20 March 2018; Accepted 24 April 2018

Available online 25 April 2018

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In this fast-paced changing environment, the attributes related to the reliability of components and systems continue to play a fundamental role for industry and those of safety and security are of increasing concern, as a right to freedom. The innovations that are being developed have high potential of increased wellbeing and benefits, but also generate new failure mechanisms and hazards, and create new risks, partly due also to new and unknown functional and structural dependencies in and among the systems. On the other hand, the advancements in knowledge, methods and techniques, the increase in information sharing, data availability and computational capabilities, and the advancements in knowledge that these can bring, offer new opportunities of development for the analysis and assessment of risks. An evolution of risk assessment is in the making, or perhaps even a “revolution” that takes the form of new approaches to and methods for risk assessment.

In this paper, I consider the above context and point at some directions that are shaping the road of advancement of risk assessment. The underlying perspective taken stands on:

- the recognition that the knowledge, information and data (KID) available for analyzing and characterizing hazards, modeling and computing risk are substantially grown and continue to do so;
- the evidence that the modeling capabilities and computational power available have significantly advanced and allow unprecedented analysis with previously infeasible methods;
- the concern that the increased complexity of the systems, nowadays more and more made of heterogeneous elements (hardware, human, digital) organized in highly interconnected structures, leads to behaviors that are difficult to anticipate or predict, driven by unexpected events and corresponding emerging unknown systems responses;
- the realization that to manage risk in a systematic and effective way it is necessary to consider together all phases of the potential accident scenarios that may occur, including prevention, mitigation, emergency crisis management and restoration, and that this entails an extended vision of risk assessment for an integrated framework of business continuity (with respect to production reliability and availability) and resilience (with respect also to safety);
- the acknowledgment that risk varies significantly over time and so may also the conditions and effectiveness of the prevention, protection and mitigation measures installed;
- the consideration of the need of solid frameworks for the safety and security assessment of cyber-physical systems (CPSs).

As the future seems to have already arrived and considering that the roots of the methodologies to deal with the associated risks can be found in the past, in the following Sections some directions and challenges for risk assessment are discussed in relation to simulation for accident scenario identification and exploration, resilience and business continuity, dynamic and condition monitoring-based risk assessment, CPSs and their safety and security assessment.

## 2. Risk assessment

Industry is undergoing rapid changes in technology and business management. Competitiveness and liberalization have brought considerable advantages in the quality of products and services. On the other hand, processes and systems have seen an increase in the complexity of their operation (energy ratings have increased, pressures, temperatures, flows have increased, storages have been reduced, interdependencies among industries and technologies have increased, particularly through digitalization and information sharing, etc.). As a result, hazards have changed and risk of large scale accidents with significant losses in both human lives and economic terms has increased. This has led to growing public concern to safety and protection from industrial (and natural) disasters, with consequential increased

intensity in safety regulation and in the scrutiny of safety procedures.

In this evolving scenario, risk assessment remains a fundamental technical framework for the systemic analysis of the risk associated to an industrial activity. The aim is to acquire a proper understanding of the issues involved, so as to be able to take confident risk-informed decisions for protecting from such risk.

The underlying principles of risk assessment are captured in the National Academy of Science “Red Book”, where the two activities of assessment and decision making are kept distinct: assessment of risk is treated as a scientific activity limited by the available knowledge and the uncertainty inherent in risk, and decision making based on risk is regarded as a political activity, with the outcomes of risk assessment being one type of input but never the sole basis for decision making [132]. Risk as a numerical quantity is, then, useful for making decisions such as on risk prevention and mitigation measures, prioritizing measures on different sources of risk, regulating and accepting risk, transferring risk through insurance. Then, again, risk assessment should be considered as a tool for safety analysis that supports safety-related, rational decision making.

Risk assessment is a science that has been developed in the past 40 years to help understanding and controlling the risk of accident events. This allows the rational management of hazardous industrial activities, through their systemic understanding. The accident events for which the assessment is made are typically extreme but also very unlikely. The rarity of these events is such that there is typically very little ‘statistical’ information associated to their occurrence. The challenge is, then, to lay down all the knowledge available about these rare but potentially disastrous accident events, often coming from expert judgment supported by indirect physical observations (e.g. the measurement of the duct wall thickness in a pipeline) and model predictions (e.g. the prediction of the crack propagation in a turbine). The basic idea of risk assessment is to structure, by systematic modeling, the information and knowledge available at the detailed component/basic event level to assess the accident risk at system level. As knowledge on these events and on the system responses to them is limited, the outcomes of the assessment are uncertain. The common framework used to describe the uncertainties in the assessment stands on probability theory, and particularly on the subjectivistic (Bayesian) theory of probability, as the adequate framework within which expert opinions can be combined with statistical data to provide quantitative measures of risk [91,92]. Indeed, the common term used is Probabilistic Risk Assessment (PRA), although Probabilistic Safety Assessment (PSA) and Quantitative Risk Assessment (QRA) are also widely used.

For more than 35 years, the probabilistic analysis has provided the basis for the quantification of risk (see reviews by Rechar [161,162]), with its first application to large technological systems (specifically nuclear power plants) dating back to the early 1970s [138]. The basic principles underpinning today’s analyses have not much changed since. However, the purely probability-based approaches to risk assessment are challenged when dealing with highly unlikely industrial accidents (with extreme consequences). For these rare events, only very limited knowledge exists in support to the risk assessment and a number of alternative frameworks for uncertainty representation and treatment in risk assessment have been introduced [2,19,58,89].

From a general point of view, the concept of risk is introduced to deal with the possibility that an event or situation with undesirable consequences for some subjects may occur. The consequences are often seen in relation to some reference values (planned values, objectives, etc.) and the focus is typically on negative consequences. Correspondingly, the International Risk Governance Council (IRGC) defines risk as an uncertain (generally adverse) consequence of an event or activity with respect to something that human beings value [81]. Various similar definitions of risk can be found in the glossary of the Society for Risk Analysis (SRA) Specialty Group on foundational issues in risk analysis (<http://www.sra.org/frag>). Detailed scenarios are, then, commonly defined when involved subjects treat “a risk”, i.e. a specific risk described in

terms of originating hazardous conditions and undesirable consequences for the subjects. For the purposes of formal analysis and with the aim of quantification, formal characterizations and representations of risk are, then, adopted. One common description is [90]:

$$\text{Risk} = \{(s_i, f_i, c_i)\}, i = 1, \dots, N \quad (1)$$

where  $s_i$  represents the sequence of events of the  $i$ -th of  $N$  accident scenarios,  $f_i$  represents the frequency of occurrence of such a sequence of events and  $c_i$  is the consequence that would result if that scenario were to occur. For risk assessment in practice, this definition leads to the need of developing methods for the identification of the complete set of accident scenarios that could occur, and the accurate estimation of their frequencies of occurrence and consequences. As completeness of scenarios cannot be guaranteed and accuracy of estimation must be evaluated in the face of limited knowledge and approximated modelling, a second-level definition of risk needs to be introduced to account for the uncertainties associated to the risk assessment [90]:

$$\text{Risk} = \{(s_i, p_i(f_i, c_i))\}, i = 1, \dots, N + 1 \quad (2)$$

where,  $p_i(\cdot, \cdot)$  is a joint probability density function describing the uncertainties on the frequency of occurrence  $f_i$  and the consequences  $c_i$  of accident scenario  $s_i$ , and the  $N + 1$  scenario is added to account for the incompleteness of the set of scenarios, i.e., for those scenarios that have not been considered because unknown at the time of the analysis (i.e., the so-called “residual risk”).

As knowledge is central to the risk assessment, the definition of risk can be extended to make it explicit [17]:

$$\text{Risk} = (\mathcal{A}, \mathcal{C}, \mathcal{Q}; \mathcal{K}) \quad (3)$$

where  $\mathcal{A}$  indicates the set of accident scenarios that may occur,  $\mathcal{C}$  represents the set of consequences,  $\mathcal{Q}$  is the metric used to quantify the associated uncertainties and  $\mathcal{K}$  is the body of knowledge which the risk assessment (i.e., the identification of  $\mathcal{A}$  and the quantification of  $\mathcal{C}$  and  $\mathcal{Q}$ ) is based on. This is coherent with the model of the world introduced in [10], conditional on the entire body of knowledge and beliefs of the modeler. Note that the formulation in (3) does not restrict the representation of the uncertainty to the classical probabilistic one and alternative representations can be employed [18,22,57,70,150].

This formulation underlines explicitly the role of the background knowledge systematically incorporated in the risk assessment model; it makes it explicit that the risk assessment outcomes are functions of the current state of knowledge, and of the related assumptions made and parameter values assigned. Recognizing this simple fact has become so important that the need as arisen of explicitly specifying the concept that risk is conditioned on  $\mathcal{K}$  (Knowledge). Then, the methodologies and approaches for risk assessment are to be seen as supports for incorporating knowledge in a systematic, rigorous and transparent framework. In other (simple and crude) words, risk assessment is a way of generating, representing and presenting the knowledge about the risk issues and their future occurrence, to allow taking decisions thereupon. This requires developing models based on the available knowledge, representing and expressing the related uncertainties, propagating the uncertainties and using proper metrics (probabilities or others) to describe risk. Such description of risk is inherently conditional on the knowledge  $\mathcal{K}$ .

The relatively recent discussions on the fundamental concept of “risk” and other foundational issues related to its assessment [20,21,23,24,53] have stressed and reinforced this common understanding that the outcomes of risk assessment are conditioned on the knowledge available on the system and/or process under analysis [23,25,230]. Recognizing this, leads to accepting the inevitable existence of a residual risk related to the unknowns in the system, and/or process characteristics and behaviors.

Then, it is just as important to be aware of the (incomplete) knowledge conditioning the risk assessment outcomes, somewhat along the lines of thought of the former United State Secretary of Defense,

Donald Rumsfeld, who said the following at the press briefing on 12 February 2002, addressing the absence of evidence linking the government of Iraq with the supply of weapons of mass destruction to terrorist groups [167]:

“There are known knowns: things we know we know. We also know there are known unknowns: that is to say, we know there are some things we do not know. But there are also unknown unknowns: the ones we don't know we don't know.”

Correspondingly, accident events and scenarios in a risk assessment model have been classified according to the knowledge available at the time of the assessment [71]:

1. Unknown-unknown
2. Unknown-known
3. Known-unknown
4. Known-known

In particular: 1) identifies those events and scenarios that were unknown to everyone, at the time of the risk assessment; 2) indicates those events and scenarios unknown to the risk analysts performing the assessment, but known to someone else; 3) identifies situations of awareness where the background knowledge is weak but there are indications or justified beliefs that a new, unknown type of event or scenario (new in the context of the activity posing the risk) could occur in the future; 4) indicates events and scenarios that are known to the analysts performing the risk assessment, and for which evidence exists.

According to Flage and Aven [71], events and scenarios belonging to 1–2 and 4, and associated to negligible probabilities of occurrence, are black swans in the sense of [180], whereas category 3 is representative of emerging risks, i.e., either new risks or known risks that, however, become apparent in new or unfamiliar conditions. Note that, clearly, the concepts of “new” and “known” are dependent on the background knowledge available.

For the sake of giving an example, consider the South Australia power network, which underwent a massive blackout caused by a cascading failure triggered by a heavy storm on the 28th Sep 2016. Around 1.7 M people remained without power for 3 h and some days were necessary to restore completely the energy supply. According to the preliminary report of the Australian Energy Market Operator (AEMO), the heavy storm was a “non-credible event”, i.e., either an unknown-known or a known-known with a negligible probability associated. However, successive analyses have highlighted that the network had more vulnerabilities than expected and that many hazards were underestimated, e.g., those associated to wind and lightning: thus, a misuse or misinterpretation of knowledge available.

Yet, the issue of uncertainty and its interpretation remain difficult and somewhat controversial. In risk assessment, it is arguable that everything is unknown to a degree and the classification of the accident events and scenarios in the four categories given above could be questionable. In particular, the first category (unknown–unknown) may be used in the realm of political sciences, where everything is debatable, but may be less acceptable/defensible in the context of formal and scientific, risk-informed decision making. It may be used to defend a decision after the fact, as in the case of the former United States Secretary of Defense. On the other hand, formal Decision Analysis recognizes the fact that a decision is made in the light of the existing knowledge (formalized by the risk assessment in the context here of interest). In this view, a decision maybe “right” in the sense that it is consistent with a given theoretical framework and a given body of knowledge but it might, after the fact, prove “wrong” (in terms of the actual outcome), because there is always a possibility of a bad outcome from a decision or because the body of knowledge is incomplete to allow taking the “right” decision. This is true also for any risk model, which is built and applied on the basis of the existing information and knowledge of the developer. Then, the degree of knowledge and

information is something that indeed needs to be considered in risk assessment and management [11].

From the above, we can retain that risk assessment amounts to a systematic and structured effort to organize the knowledge available on events, processes and scenarios that affect specific decisions to be made for the management of risk. For decision making, risk assessment must provide traceable information for arguing the decisions; the risk assessment outcomes must be communicated in a way that allow the decision makers to interpret them properly for their purposes and to understand the associated uncertainty related to the available knowledge used for the assessment. Risk assessment provides the framework for organizing the knowledge available on the system of interest, with the aim of understanding how the system can fail and prioritizing the failure modes so that good decisions can be taken [71]. The value of the solutions of risk assessment and of the management decisions that depend on them, then, stands on the quality of the methodologies and approaches that constitute the framework, and on the strength of the knowledge  $\mathcal{K}$  which the framework incorporates. Whereas procedures of quality assurance have been developed for the former, it is still an open issue and a research challenge how to explicitly treat knowledge in risk assessment and management. How should it be described and evaluated in the risk assessment? How should it be reflected and taken into account in the decision-making process of risk management? The answers to these questions are critical for the validity of a risk assessment. When a risk assessment is performed to provide information that is used for making decisions, there must be a way to tell that it has been performed with adequate techniques and sufficient knowledge for making the decisions [155]. Quality review of a risk assessment is essential, as opposition to a particular decision often takes the form of raising questions to the validity of the risk assessment [11].

### 3. Simulation for risk assessment

Overall, accidents and incidents can be considered as extreme states of behavior of the systems involved [5] and from the above said, it is clear that identifying and characterizing hazardous accident and event scenarios is a fundamental task of knowledge mining for risk assessment. This task is far from trivial in practice, given the complexity of the systems and processes: a large, combinatorial set of possible scenarios, events and conditions needs to be considered, of which only few, rare ones lead to critical, unsafe situations. This makes experimentation economically unsustainable and physically infeasible.

This is why simulation has long been advocated as a way to explore and understand system behavior for knowledge retrieval [171,175], and has been used for safety assessment since the 1970s–80s. However, it is the continuous advancements in modelling techniques (including the fast-running artificial intelligence-based surrogate/meta-modeling) and the impressive increase in economical availability of computational power (including parallel computing and cloud computing) that are pushing to unprecedented levels (and benefits) the use of simulation for exploring system behavior and advancing knowledge for risk assessment.

Within a simulation-based accident scenarios exploration, a set of simulations is run with different initial configurations of the system design and operation parameters (input), and the corresponding system state is computed (output). Evaluation of the system state with respect to specified safety conditions (critical thresholds) allows identifying the input configurations leading to critical system states. These states form the so called “Critical Regions” (CRs) or “Damage Domains” (DDs) [130]. The CRs may be identified corresponding to prior knowledge and expectation of the analysts or be “discovered”, i.e., the analysts are not a priori aware of such critical configurations and mining by simulation allows identifying them.

Concurrently, simulation can also be exploited to estimate the accident scenarios probabilities, or any other measure of uncertainty adopted to describe risk in (2)–(3). For this, Monte Carlo (MC) methods

of stochastic discrete event simulation have been generally accepted as a gold standard [88,106,122,166,228]. In practice, MC simulation consists in generating a large number of samples/trials/histories of system response and counting those that reach the state of interest, i.e. that end in the CRs (DDs). For example, for estimating the reliability of a system at a given time  $t$ , i.e., the probability that the system does not fail before  $t$ , a set of life histories of the system are run and the time at which the system fails (Time To Failure, TTF) in each history is recorded. Then, the reliability of the system at time  $t$  is estimated as the fraction of simulations whose TTF is larger than  $t$ . Likewise, estimating the probability of occurrence of an event leading the system into a given CR, defined by specific thresholds of system safety parameters (e.g. limit temperatures, pressures, heat fluxes etc.), can be done by sampling realizations of the system life and counting the fraction of times that the system ends in the CR of interest [163].

Then, the two key research questions in the practice of risk assessment that can be addressed with the use of simulation models are:

- Identify hazardous conditions for the system, i.e., the pairs event-consequence ( $\mathcal{A}$ ,  $\mathcal{C}$ ;  $\mathcal{K}$ ) in Eq. (3), which represent critical states of the system (i.e., identify the CRs of the system).
- Estimate the probability of occurrence of rare critical scenarios, i.e., ( $\mathcal{L}$ ,  $\mathcal{K}$ ) in Eq. (3).

As simple and intuitive the use of simulation may seem for addressing the above two questions in the practice of risk assessment, it is actually quite demanding because the models of system behavior are:

- *High-dimensional*, i.e., with a large number of inputs and/or outputs.
- *Black box*, i.e., without an explicit Input/Output (I/O) relation (because coded in a computer program or because implicit in an empirical surrogate or meta-model, e.g. based on data and artificial intelligence).
- *Dynamic*, because the system evolves in time.
- *Computationally demanding* even for a single trial simulation, as a consequence of the above characteristics of the models and of the numerical methods employed for their solution.

The high dimensionality in the inputs implies that the system conditions and scenarios to consider for simulating the system behavior for the identification of the CRs and/or for the estimation of the probability of their realizations [14,190], increase exponentially with the input space dimensions [229]. It also renders difficult the a posteriori scenario analysis for risk understanding, due to the difficulty of visualization of the results in such large spaces; this requires the development of specialized representation tools [56,113,118,121].

Black box models, inevitably typically nonlinear, make it impossible to a priori identify the set of input configurations that lead the system into CRs. In practice, when the computational model is a black box (inherently because empirical, or because complicated even if physics-based), the only feasible way to do this is to run simulations and post-process the outcomes.

For dynamic systems, an additional dimension of complexity comes from having to deal with changes occurring to the system during its evolution in time, e.g., events that occur at different times (stochastically, e.g., components failures, or deterministically, e.g., control actions) and that affect the operation of the system [4,64,114,115,119,120,174,229].

Although computational power is continuously increasing, in many practical instances computational cost still remains an issue for simulation-based risk assessment, because in such cases the high computational cost for the simulation of even a single system life history prevents the analyst from running and exploring the large number of input configurations for mining knowledge to characterize the system CRs. This is even more of an issue when analyzing highly reliable systems, i.e., systems characterized by very small probabilities of failure, whose

CRs correspond to very small domains that are very hard to find in the large space of input configurations [34,165].

Two main strategies are currently followed to address the two research questions and related challenges above presented:

- Simulation of large sets of system life histories using the increased computational power made available through parallel computing, cloud computing etc.
- Simulation by adaptive sampling, which amounts to intelligently guiding the simulation towards the system states of interest (i.e., those belonging to the CRs). This entails that the simulation methods be capable of automatically understanding, during the simulation, which configurations are most promising to visit.

As answer to the first key research question formulated above, contributions are needed for the:

- Design and implementation of novel frameworks of adaptive simulation for discovering (unexpected) consequences associated to a known set of scenarios [183]. Methods must be found to guide the simulations towards those scenarios that are more uncertain regarding the consequences they can lead to (i.e., those scenarios about which the knowledge  $\mathcal{K}$  should be increased).
- Design and implementation of novel frameworks of adaptive simulation for the identification of CRs [42,43,49,61,102,131,185]. Benefitting from the advancements in modeling, artificial intelligence and machine learning, such frameworks can effectively combine model dimensionality reduction by feature selection/sensitivity analysis to screen important inputs, meta-modelling to reproduce the behavior of the computationally expensive model by a cheap-to-run one, efficient stochastic models for exploration of the system state space, non-supervised classification methods (i.e., clustering) and visualization techniques for high-dimensional spaces (e.g., Parallel Coordinates Plot), to retrieve and represent the information of interest (i.e., the critical/safe regions).

As answer to the second key research question formulated above, effective algorithms are needed for the simulation of rare events in hybrid models, i.e., models where variables evolve according to physical laws that can change as a consequence of discrete (stochastic) events [184,191,193].

Simulation of rare events in hybrid models has, indeed, become a fundamental issue in many applications. For example, the safety assessment of systems of autonomous cars using verification techniques entails ensuring safe trajectories from path planning of autonomous vehicles moving in dynamic environments [109]. In traffic scenarios, measurements, disturbances and decisions of traffic participants are uncertain. This leads to a set of possible initial states, disturbance trajectories and behavior predictions for each road actor, with a potentially infinite number of reachable outcome states of a traffic scenario over a given time horizon. As one cannot simulate all possible behaviors of traffic actors, effective simulation techniques for hybrid model verification are needed to probe the (rare) events of interest, i.e., typically those potentially leading to accidents [37,187]. Based on the reachable states of an autonomous car and other actors in the surrounding, a probability of crash can be obtained [7].

Simulation is also strongly advocated for the hazard analysis, and safety and resilient assessment of critical infrastructures and systems of systems [6,230]. The increasing concern on the vulnerability of critical infrastructures (see Section 5 below) and the increasing role of systems of systems in safety-critical applications has raised the need for methods to analyse their hazards, and verify their safety and resilience properties. One viable way for this is simulation of the variety of scenarios that can emerge from the response of the individual system components to different perturbations and failures, sampled over space and time. The effects of the interaction between system components can, then, be

observed together with the corresponding system behavior that emerges. The challenges for the analysis of such systems come from the fact that the system boundary is not well defined and the set of components in the system can vary over time, either as part of normal operation (e.g. a new car enters the traffic scene or a new aircraft enters a controlled airspace region) or as part of evolutionary development of the system itself (a traffic lane is interrupted because of construction work or a military unit receives a new air-defence system). In such an undefined and dynamic setting, conventional techniques of analysis may be inadequate for determining whether or not the failure of a given component may be hazardous for the system as a whole. Simulation, on the other hand, can provide a way of analysis of such systems made of multiple components that interact in complex and continually changing ways.

#### 4. Extended risk assessment: business continuity and resilience

As mentioned in the Introduction, systems are increasingly exposed to hazards of disruptive events [230], e.g., unexpected system failures [74], climate change and natural disasters [127,203,204], terrorist attacks [160]. Risk assessment is, then, applied to inform risk management on how to protect from the potential losses caused by the disruptive events [26,206,230]. As for the risk description (3), the focus is on the accident scenarios, their possible consequences and likelihoods, and the uncertainties therein [30]. The post-accident recovery process, is not considered.

Yet, given that the sources of hazard leading to disruptive events are extremely uncertain and, thus, difficult to describe and model quantitatively, and that the systems are highly connected to each other so that the impact of the disruption extends beyond the boundary of the individual systems, an extension of the framework of assessment is necessary, for an integrated management of risk and coherent use of the available resources. The framework must incorporate aspects beyond those of prevention, typical of risk assessment, in order to allow accounting for:

- the fact that the potential losses suffered from a disruptive event also depend on the after-the-fact recovery process;
- the recognition of the new World that digitalization has brought, with the new systems and services that are emerging. For example, according to a survey by IBM Global Services, in 2008, enterprises in IT sectors have been estimated to suffer from an average revenue cost of 2.8 million US dollars per hour for unplanned application outages inefficiently recovered. Another report reveals that for a company that operates data centers, the average downtime cost per minute has exceeded \$5000. An extension of the conventional risk assessment and management methods is, then, needed, so that the recovery process can be integrated.

Efforts in this direction have been made, particularly in the areas of socio-technical systems and occupational risk. As an example of a working model in which causes, effects and remedial actions are integrated can be found in [145], with the treatment of the uncertainties in and by that model as in [146]. Implementation of a model for a complex socio-technical system can be found in [233].

To proceed further into the reflections on the need and challenge of extending the framework of risk assessment to cover the pre- and post-accident scenarios analysis, the affine concepts and paradigms of business continuity and resilience are discussed from the perspective of their links to system reliability/availability and safety.

##### 4.1. Business continuity

Business continuity (BC) is defined as “the capability of an organization to continue delivery of products or services at acceptable levels following disruptive events” [80]. It measures the capability of an

organization to remain at or quickly recover to operational states after being affected by disruptive events. Business Continuity management (BCM) is a managerial framework that aims at ensuring that no disruptive events can lead to unexpected, unwanted interruptions of production or service activity. In this view, it lays down the vision of integrating the post-accident recovery process to the preventive view of risk assessment [50]. Indeed, such framework of BCM is defined by the International Organization of Standards (ISO) as “an holistic management process that identifies the potential threats to an organization and the impacts to business operations that those threats, if realized, might cause, which provides a framework for building organizational resilience with the capability of an effective response that safeguards the interests of its key stakeholders, reputation, brand and value-creating activities” [80]. From this definition, it is clear the reliability/availability perspective and the link with the resilience concept also in a safety perspective.

As an integrated management strategy aiming at reducing the technological and operational risks that threaten the recovery from disruptions and interruptions, BCM has attracted quite some attention in the last couple of decades [77]. A comprehensive approach to BCM planning is proposed in [50], with particular focus on internal and external information security threats. The necessity and benefit of implementing BCM in an organization is discussed in [232]. The application of BCM planning to achieve organizational disaster preparedness at Boeing is surveyed in [234]. An integrated framework to support BCM planning is presented in [235]. The historical evolution of BCM is reviewed in [77], with the critical events that motivated its development. In [176], BCM is compared to the conventional risk management methods and the comparison clearly shows that BCM not only focuses on the protection of the system before the crisis, but also on the recovery process during and after the crisis. A model to assess the maturity of the BCM programs is developed in [236] and applied on a case study from United Arab Emirates (UAE) banking sector. System reliability models to plan BCM are used in [63]. A framework to integrate BCM and disaster recovery planning, to ensure that the system would resume and recover its operation in an efficient and effective way is presented in [169]. Methods to ensure the business continuity of a safety-related power supply system are presented in [147]. An enhanced risk assessment framework to support business continuity management is developed in [188]. A fuzzy cost-benefit analysis method for planning BCM strategies is presented in [154].

As a holistic, integrated risk management strategy, BCM offers great potential benefits but the complexity of the systems and risk problems involved is such that most currently existing BCM strategies are based on qualitative methods only, and this limits practical and effective application. Very few works concern the quantitative modeling and analysis of BC. An approach to model the system behavior in the BC process, based on process algebra and modal logic, has been presented by Boehmer et al. [35]. Similar models have been applied in [38] to describe the BC process of a credit card company. A multi-layer model is developed in [15] to model the BC of a loan originating process. In [32], Cox's model and Bayesian networks are combined to model the BC process. A simulation model is developed in [178] to investigate the BC of a company considering the outbreak of a pandemic disease, where the BC is characterized by the operation rate and the plant-utilization rate. These models describe the post-crisis behavior of the system. However, no clearly defined business metrics have been proposed from these models, which impedes the quantitative analysis of BC and, therefore, limits application in practice.

To contribute to the advancement of BCM for its application in practice, Zeng and Zio [219] have developed an integrated, quantitative framework for modeling BC, founded on the definition of four metrics that measure the potential losses caused by the disruptive events. A simulation-based method has been presented in the paper to calculate the BC metrics based on the integrated model. To demonstrate the use of the framework, the BC of an oil storage tank farm is assessed.

The conceptual model that describes BC and identifies its major contributing factors refers to a performance indicator, denoted by PPIB (Process Performance Indicator-Business), whose value reflects the degree to which the objective of the system is satisfied. For example, for an oil refinery, the PPIB is its daily production yield; for a manufacturing factory, the PPIB is the products produced per day. The values of PPIB are determined by the operation state of the system: the PPIB remains at its nominal value when the system is under normal operation and drops to a degraded value when the normal operation of the system is disrupted. In practice, an organization is susceptible to various disruptive events, which might jeopardize its BC. As already mentioned, commonly encountered disruptive events include:

- technological disruptions, caused by components or systems failures;
- natural disruptions, caused by natural disasters, e.g., floods, earthquakes, lightning, etc.;
- social disruptions, caused by social movements, e.g., terrorist attacks, strikes, supply chain disruptions, etc.

When one or some of these disruptive events occur, the normal operation is disrupted and PPIB drops to a degraded value, because of the disruptive events. The production stakeholders, then, suffer from losses caused by the business interruption. To reduce such losses, various BC measures can be taken to guarantee the continuity of the business process. Generally speaking, those measures can be divided into four categories, i.e.,

- protection measures, for defending the system from the disruptive events and preventing them from damaging the system. If protection measures succeed, the business process is not interrupted;
- mitigation measures, which intervene when the protection measures fail and initial damage has been caused by the disruptive events. The aim of the mitigation measures is to contain the evolution of the disruptive events at the early stages of development, so that damages can be mitigated;
- emergency measures, which must come into play when the mitigation measures fail to contain the damage, and often require significant human intervention;
- recovery measures, which aim at re-establishing normal operation, ex-post.

For example, lightning is a severe threat to oil and gas systems [51]. Often, a lightning protection mast is installed at oil and gas tank farms as a protection measure against the threat of lightning [136]. If the protection mast fails to protect the system, the oil storage tank might catch fire [135]. Mitigation measures, such as the automatic fire extinguishing system, are automatically activated to fight the fire in order to prevent it from spreading to other tanks, causing a domino effect [135]. Emergency measures, e.g., the intervention of a fire brigade, are needed when the mitigation measures fail to stop the propagation of the accident [199]. Then, recovery measures, e.g., the repair and restoration of the affected tanks, are carried out to recover operation and minimize the losses caused by the business interruption.

Fig. 1 presents the conceptual model that schematically illustrates the evolution of a business process under a disruptive event [219]. The business process is divided into four phases: protection, mitigation, emergency and recovery. Each phase is associated with the corresponding business continuity measure. As shown in Fig. 1, the PPIB of an actual business process might deviate from its nominal value due to the presence of various disruptive events. The severity and duration of the business interruption caused by the disruptive event can be controlled by implementing business continuity measures in the different phases. Among them: protection measures affect the resistance of the system to disruptive events; mitigation and emergency measures determine how much system performance is degraded from the damage

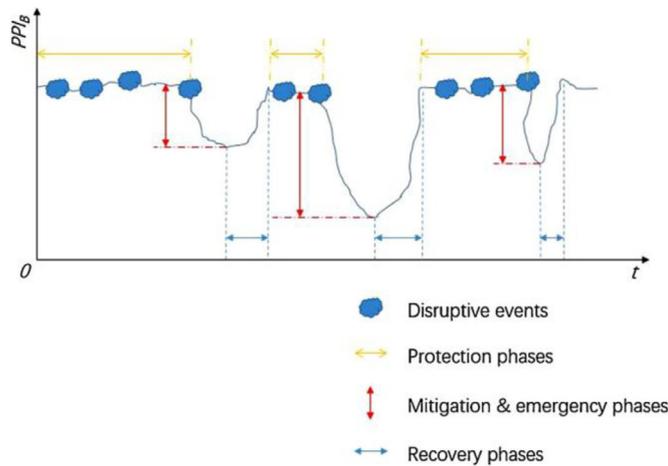


Fig. 1. A conceptual model for the business continuity process [219].

caused by the disruptive event; recovery measures influence how quickly the system can recover its performance to normal operation.

As shown in Fig. 1, the business process comprises of the protection, mitigation, emergency and recovery phases. Since each phase has its own characteristics, different modelling approaches need to be integrated to capture the phase-specific characteristics. An example of integrated modeling framework is presented in Fig. 2 [219]. The protection, mitigation and emergency phases determine the consequences of the disruptive event. Event trees can be used to model these phases [223]. In an event tree model, the probabilities of the intermediate events represent the reliabilities/uncertainties of the allocated business continuity measures. The outcomes of the protection and mitigation phases depend on the reliabilities of the protection and mitigation measures, respectively. Fault tree models can be used to calculate these intermediate probabilities [223]. The result of the emergency phase, on the other hand, involves the modeling of a sequence of activities by the emergency response team. Models capable of considering the sequential dynamics of such activities should be used for the emergency phase, e.g., the event sequence diagram [222]. The recovery process also involves the dynamics of maintenance actions, which can be effectively described in terms of the process of transitions between system states, e.g., by semi-Markovian models [52].

4.2. Resilience

Resilience is a concept closely related to BC. Here, its consideration is given particularly in relation to accidents and, thus, to its specificity with respect to safety, rather than reliability and availability of production, or other attributes of functionality for systems and critical infrastructures (CIs).

As mentioned earlier, risk-based approaches have been used to assess hazards and mitigate consequences associated with their impact.

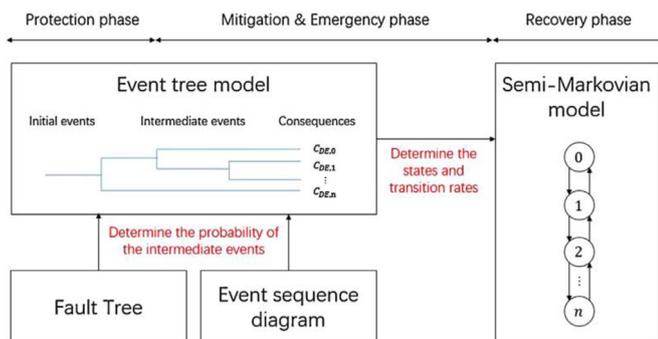


Fig. 2. An integrated model for business continuity assessment [219].

By identifying the components contribution to the overall system risk, the outcomes of risk assessment enable prioritized decisions for system improvements to buy down risk. But as already said, the rapid technological evolution, combined with the unprecedented uncertain nature and extent of emerging hazards, makes it difficult to characterize all potential hazards and estimate accurate probabilities of occurrence and magnitude of consequences, that decision makers can confidently rely on for their risk-reducing decisions. This is particularly true for the complex, interconnected systems that make up today's critical infrastructures and calls for the extension of the framework of risk assessment and management, to make these systems resilient to the wide range of hazards within specific cost and time restraints, and considering the large uncertainties. Differently from the concept of risk, resilience is focused also on the ability to prepare and recover quickly from an accident or disruptive event, which may be known or unknown. Managing for resilience, then, requires ensuring a system's ability to plan and prepare for the potential occurrence of accidents and disruptive events, and then absorb, recover, and adapt in case of occurrence.

It is the lessons learned in recent years from some catastrophic accidents that have led to the concept of resilience to ensure the ability of systems and CIs to withstand, adapt to and rapidly recover from the effects of a disruptive event [129,141,153]. The outcomes of the 2005 World Conference on Disaster Reduction (WCDR) confirmed the significance of the entrance of the term resilience into the disaster discourse and gave birth to a new culture of disaster response [48]. As a result, today's systems are not only required to be reliable but must also be able to recover from disruptions [224,230]. Government policy has also evolved to encourage efforts that would allow assets to continue operating at some level, or quickly return to full operation after the occurrence of disruptive events [129]. Consequently, resilience is nowadays considered a fundamental attribute for systems and CIs that should be guaranteed by design, operation and management.

The concept of resilience varies somewhat by discipline and application [75,133,144], and different definitions exist such as “the ability of the system to reduce the chances of shock, to absorb a shock if it occurs and to recover quickly after a shock (re-establish normal performance)” [39], “the capacity of an asset, system, or network to maintain its function during or to recover from a terrorist attack or other incident” (U.S. Department of Homeland Security 2009), the “ability of the system to withstand a major disruption within acceptable degradation parameters and to recover within an acceptable time and composite costs and risks” [73]. From these definitions, it emerges that resilience is characterized in terms of four properties, i.e. robustness, redundancy, resourcefulness, rapidity and four interrelated dimensions, i.e., technical, organizational, social, economic. It can be considered a new paradigm for risk engineering, which proactively integrates the accident preventive tasks of anticipation (imagining what to expect) and monitoring (knowing what to look for), the in-accident tasks of responding (knowing what to do and being capable of doing it) and learning (knowing what has happened), the mitigative tasks of absorbing (damping the negative impact of the adverse effect) and the recovery tasks of adaptation (making intentional adjustment to come through a disruption), restoration (returning to the normal state).

Various models, methods and frameworks for analyzing and quantifying resilience have been proposed in the literature [45,69,82,117,198], with focus on diverse fields of application such as seismic engineering and structural systems [47,48,59], ecological systems [78], economics and financial systems [9,29,168,177], service systems [164,186], telecommunication systems [142], urban infrastructures [84,13], disaster analysis for avoidance and recovery [36,181,231].

While resilience can be characterized by many system features and attributes, recovery is a vital element of strategies to improve resilience. System recovery and its role in infrastructure system resilience have attracted quite some attention. Some studies have modeled the post-

disaster restoration of various infrastructure systems in an effort to estimate the expected restoration time [68,173], and several others have compared the performance of different restoration strategies [41,44]. Other works have tackled the problem of post-disaster restoration strategy planning and optimization, for the purpose of restoring system service in a timely and efficient manner. Considering multiple types of systems simultaneously, Kozin and Zhou [103] developed a Markov process to describe the process of infrastructure system recovery; then, they used dynamic programming to estimate the repair resources required for each time step and for each system, so as to maximize the expected economic return from system functioning. In [237], a neural network was used to minimize the likelihood of post-earthquake functional loss for a telephone system. A mixed-integer programming approach was applied in [40] for selecting a set of recovery subplans giving the greatest benefit to business operation. Restoration when multiple infrastructures, operated by different firms, are involved was addressed in [46]. A case of network restoration was addressed in [108], involving the selection of the location of temporary arcs (e.g., shunts) needed to completely re-establish network services over a set of interdependent networks: a mixed-integer optimization model was proposed to minimize the operating costs involved in temporary emergency restoration. A genetic algorithm was applied in [201] to optimize the restoration of electric power after an earthquake: the objective of the optimization was the minimization of the average time that each customer stays without power. An integer programming model was proposed in [123] to restore networks where the connectivity between pairs of nodes is the driving performance metric associated with the network. The studies cited above involving the optimization of post-disaster CI restoration apply a variety of modeling approaches and focus on different aspects of the restoration strategy (e.g. the repair order of damaged components, where and how to allocate repair resources, and so on).

In more general terms, the resilience analysis of complex systems and CIs cannot be carried out only with classical methods of system decomposition and logic analysis. Furthermore, large uncertainties exist in the characterization of the failure behavior of the elements of a complex system, of their interconnections and interactions [226]. A framework is, thus, needed to integrate a number of methods capable of viewing the complexity problem from different perspectives (topological and functional, static and dynamic), under the existing uncertainties [105,143,158]:

- structural/topological methods based on system analysis, graph theory, statistical physics, etc.; these methods are capable of describing the connectivity of a complex system and analyzing its effects on the system functionality, on the cascade propagation of a failure and on its recovery (resilience), as well as identifying the elements of the system which must be most robustly controlled because of their central role in the system connectivity [65,108,137,152,227];
- logical methods based on system analysis, hierarchical logic trees, game theory, etc.; these methods are capable of capturing the logic of the functioning/dysfunctioning of a complex system due to random effects and malicious attacks, and of identifying the combinations of failures of elements (hardware, software and human) which lead to the loss of the system function [12,31,221];
- phenomenological/functional methods, based on transfer functions, state dynamic modeling, input-output modeling and control theory, agent-based modeling etc.; these methods are capable of capturing the dynamics of interrelated operation between elements (hardware, software and human) of a complex system and with the environment, from which the dynamic operation of the system itself emerges [189];
- flow methods, based on detailed, mechanistic models (and computer codes) of the processes occurring in the system; these methods are capable of describing the physics of system operation, its monitoring

and control [170].

The integration of these methods is expected to enable capturing the different relevant aspects of the complex systems [55]. For electric power grids, for example, comparisons between structural/topological and power flow methods have been made. Some studies [27] have provided qualitative comparisons between complex network theory models and power flow models, identifying similarities and differences, and evaluating advantages and disadvantages. Also, by extensive comparative simulation, Cupac et al. [54] has shown that a network-centric model exhibits ensemble properties which are consistent with the more realistic optimal power flow model. Most recently, Matisziw et al. [123] conclude on the appropriateness of graph theory techniques for the assessment of electric network vulnerability by comparison to physical power flow models. This is confirmed in [66], where the problem of searching for the most favorable pattern of link capacities allocation that makes a power transmission network resilient to cascading failures with limited investment costs is formulated within a combinatorial multi-objective optimization framework and tackled by evolutionary algorithms. Two different models of increasing complexity are used to simulate cascading failures and to quantify resilience: a complex network model, and a more detailed and computationally demanding power flow model. Both models are tested and compared on a case study involving the 400 kV French power transmission network. The results show that the optimal solutions obtained using the two different models exhibit consistent characteristics in terms of phase transitions in the Pareto fronts and link capacity allocation patterns.

## 5. Dynamic risk assessment and condition monitoring-based risk assessment

Risk assessment must account for the time-dependent variations of components and systems, as they operate, age, fail, are repaired and replaced [192]. For this, updates are performed to reflect the components and systems changes and the corresponding current overall system/plant safety state, leading to what is called Living PRA (LPRA). LPRA is a system/plant specific PRA that can be updated or modified, when necessary, to reflect the system/plant changes during its lifetime [86]. Changes can be physical (resulting from plant modifications, etc.), operational (resulting from enhanced procedures, etc.), organizational, but also changes in knowledge due to the acquisition of operational experience, field data, etc. The updated LPRA, then, reflects the current design and operational state of the system/plant, and is documented in a way that each aspect of the model can be directly related to existing system/plant information, documentation or analysts assumption [112].

Extending the concept of LPRA, Dynamic Risk Assessment (DRA) is defined as a risk assessment that updates the estimation of the risk of a deteriorating system according to the states of its components, as knowledge on them is acquired in time [95,202]. DRA is capable of capturing the time-dependent behavior of the system risk profile [76,94,192].

An early attempt of DRA was conducted in [125,126] where Bayes theorem was used to dynamically update the estimates of accident probabilities, using near misses and incident data collected from similar systems. A similar DRA method was developed in [87], where Bayes theorem is used for probability updating and Event Tree (ET) analysis is used for consequence modeling. ET was used in [159] to model the accident sequences of an ammonia storage unit and Bayes theorem for DRA. ET and Bayes theorem were used in [148] to update the risk in chemical process industries based on data from a large near-miss data base. A hierarchical Bayesian model for DRA was developed in [99] and applied to analyze the near-accident data of offshore blowouts. A similar hierarchical Bayesian model was used in [205] to dynamically assess the risk of an offshore drilling platform.

In [96], Bayes theorem was combined with a Bow-Tie (BT) model

for DRA: failure probabilities of the primary events and safety barriers in the BT were constantly revised over time and the updated BT model was used to estimate the updated risk profile. BT was used in [149] to support the DRA from metal dust accidents. (A similar method was applied in [1]) to update in real time the risk estimation of offshore drilling operations. A DRA method using a Bayesian Network (BN) model was developed in [97], where the probabilities of the basic events in the BN are updated when new accident data are collected. A comparison of the BT-based and BN-based methods were made in [98], and a procedure was given to map a BT into a BN. The DRA for assessing the risk from leakage failure of submarine oil and gas pipelines was addressed in [110] using BT and BN. In [215], BN was applied for the DRA of a natural gas station.

Most existing DRA methods, as reviewed above, only use statistical data, i.e., count data of accidents or near misses from similar systems, to update the estimated risk indexes. It should be noted that in some literature, these statistical data are also called Accident Sequence Precursor (ASP) data [126,238,239]. A drawback of using only statistical data is that one must wait until accidents or near misses (precursors) occur before updating the estimation of the risk indexes. Besides, statistical data are collected from similar systems, reflecting population characteristics but not fully accounting for the individual features of the target system.

Additional information potentially useful for the estimation of the risk indexes may come from condition-monitoring data. In practice, accident initiating events and safety barriers failures usually occur as a result of degradation mechanisms, e.g., wear [218], corrosion [217], fatigue [83], crack growth [28], oxidation [52], etc. The degradation processes can be monitored in real time and failures can be predicted and anticipated with reference to specific thresholds of the monitored variables. The condition-monitoring data give information on the individual degradation process of the target system and of the safety barriers, and provide the opportunity to update the reliability values before actual failures occur. Therefore, introducing condition-monitoring data in DRA could be a beneficial complement to the statistical data, towards a condition monitoring-based risk assessment (CMBRA).

In this direction, a few initial attempts of using condition-monitoring data in DRA have been made. Kalman filtering has been applied in [211] to estimate the true degradation states from condition-monitoring data and DRA (or CMBRA) based on a loss function associated with the degradation states has been conducted. Similar works were also conducted by the same authors using different condition-monitoring techniques, i.e., Particle Filtering (PF) [212] and Principal Component Analysis (PCA) [210]. To deal with nonlinear and non-Gaussian features, [207] developed a self-organizing map-based approach for CMBRA using condition-monitoring data. The concept of remaining time was proposed by Wang et al. [194] and used to develop a CMBRA method for multiple condition-monitoring variables. A CMBRA by monitoring sensitive variables of a passive residual heat removal system, but without considering the possible noise in the monitored data, was conducted by Kim et al. [101]. However, these existing methods consider only the condition-monitoring data, but no statistical failure data. Besides, most of the existing methods do not involve consequence analysis models, e.g., ET, BT, BN, etc., when calculating the risk indexes. Rather, the risk indexes are assessed directly from the monitored degradation variables by considering the affected performance due to the degradation.

A method for DRA that allows the joint utilization of statistical and condition-monitoring data has been proposed in [220]. Consequence analysis is also considered by means of an ET. A first step in the DRA is to online update the reliability of the safety barriers using the two types of data. For this, a hierarchical Bayesian reliability model is developed. Based on the model, an online assessment algorithm is developed for the reliability values. Statistical data refer to the count data of the consequences of accidents that occur during the operation of similar systems, thus providing “population” information, while condition-

monitoring data come from online monitoring the degradation of the specific target system of interest and describe system-specific features.

## 6. Safety and security of cyber-physical systems

With the large development of digitalization in the industrial world, nowadays, CPSs are applied in many technological areas, including aerospace, automotive, energy, chemical industry, materials, civil transportation, agriculture and healthcare. A CPS features a tight combination of (and coordination between) the system computational units and physical elements. To the benefit of safe operation, the integration of computational resources into physical processes is aimed at adding new capabilities to stand-alone physical systems, to enable functionalities of real-time monitoring, dynamic control and decision support during normal operation as well as in case of accidents. For self-adaptive properties and extensive capabilities of autonomous “decision making” and handling of uncertain operational scenarios, CPSs rely on control systems that utilize software intensive model-based paradigms. When compared with more traditional system design frameworks, model-based developments undoubtedly provide greater capability and flexibility to rapidly define, analyze and integrate different aspects of a given design. However, this expanded capability and flexibility, and the dynamic nature of the model-based design environment, also pose challenges to the execution of traditional design validation and verification (V&V) processes. It is, thus, essential that methods and tools be made available also to facilitate the task of demonstrating compliance of control systems developed in such model-based environments with safety-related requirements and any applicable certification standard [72].

In CPSs, cyber and physical processes are dependent and interact with each other through feedback control loops (e.g., embedded cyber controllers monitor and control the system physical variables, whilst physical processes affect, at the same time, the monitoring system and the computation units by wired or wireless networks [8,100,107]). The benefit of such self-adaptive capabilities is the reason why CPSs are increasingly operated in energy, transportation, medical and healthcare, and other applications [33,93,107].

In the context of CPSs, sensor measurements can be used to monitor the behavior of the systems under different operational conditions, including hazardous and malicious ones. Indeed, CPS functionality and integrity can be compromised by both hazards (safety related) and malicious threats (security related) [104,151,213]. Hazards and cyber threats originate from different sources (stochastic degradations and accidental conditions, for the former, external malevolent activities that are usually less accessible and less predictable for the latter [16,104]). Distinct properties and mechanisms between them suggest different assessment methodologies for their identification.

CPSs demand that in the risk analysis both safety and security aspects be considered [60,104,151,213]. With respect to safety, hazards relate to components failures that can result in accidental scenarios leading to unacceptable consequences on the system physical processes; as for security, malicious attacks can impair both the physical and cyber parts of the system, possibly leading to unacceptable consequences.

Failures of both hardware and software can compromise CPS integrity and functionality [134]. During operation, failures of embedded hardware components (e.g., sensors and actuators) can be induced by aging, degradation, and process and operational conditions, which modify the way components work and interact with each other, generating multiple failure modes [195]. For example, sensors can degrade and fail in different modes such as bias, drift and freezing [195]; actuators can fail stuck, accidentally driving the physical process to be isolated from the controlling units of the cyber domain [216,225].

Components failures can lead to two types of misoperations: (1) failure on-demand, e.g., failing to trigger protections or execute proper control strategies (when demanded); (2) malfunction, e.g., spurious triggering of protections (e.g., unintentional shutdown) or incorrect

execution of control actions. Failures on-demand and malfunctions of both hardware and software components have gained increasing attention in the risk community [3,124].

Resilience of CPS to failures can be granted by self-adaptiveness of control decisions on actuators, resorting to intelligent control systems that properly manipulate sensors measurements [116]. For example, Proportional-Integral-Derivative (PID) controllers, typically used as feedback controller in CPS to retroact to actuators the actions to be undertaken for responding to changes of physical parameters, may suffer of software failures/errors (generated from inadequate specification, incomplete testing scope and algorithm/logic failures) that are latent and triggered only when context modifications are to be met [3,85]. In these situations, control rules adaptability to variable physical conditions is a fundamental requirement to the robustness of CPS for resilience during CPS operation.

CPSs reliance on digitalization and remote control systems increases their exposure to cyber attacks to controllers, databases, networks and human-system interfaces, that can result in the loss of system integrity and/or functionality. Malicious activities can be manifested as Denial of Service (DoS) attacks [156,208,214], False Data Injection (FDI) attacks (e.g., packet/data modification) [111,128,179], network scan and sniffing attacks [156,182], integrity attacks (e.g., through malware contagion) [139,140] and, illegal command executions [172]. They can be initiated in the cyber domain through local or remote accesses, mimicking the components failures but isolating the connectivity between cyber and physical systems, leaving the physical process uncontrolled and possibly drifting towards severe consequences.

Cyber attacks can cause serious security and privacy issues [200]. Under cyber attacks, e.g., by contagion of malware, security-related system features may result to be compromised and, the system safety and security potentially endangered. The identification of the cyber threats most affecting the system response is quite important for decision-making on optimal protection and resilience, as prevention and mitigation of malicious attacks contribute to guaranteeing CPS integrity and functionality [67,79,196,209].

From the perspective of integrated safety and security of CPSs, distinguishing cyber attacks from component failures is important for evaluating the potential impacts on the system integrity and defining proper protection and mitigation actions for resilience. To make CPSs resilient, it is necessary to integrate the knowledge on cyber security, human interactions and complex networks, to address all possible failure and threats in a comprehensive and holistic way. For this, frameworks are still needed.

## 7. Conclusions

Risk assessment is a mature discipline, widely applied in practice for the design and operation of safe systems. The assessment involves a structured analysis of the system of interest to qualitatively and quantitatively describe risk, based on the available knowledge. The quantitative analysis is often criticized in view of the difficulty of assigning probabilities (e.g., to human errors or software failures), the difficulty of verifying the assumptions behind the models at the basis of the assessment, the inherent uncertainty involved in the phenomena of interest. However, the use of quantitative measures remains essential for rational, effective decision making combining evidential knowledge and subjective beliefs. The decisions that need to be made will be better if quantitative (and peer reviewed) information is available. For this, we need to provide risk outcomes that are either certain (a given accident scenario would indeed definitely occur) or of quantified uncertainty (there is a given probability that the accident may occur), and can, thus, be compared for risk prioritization and resource allocation. By engaging in quantifying the uncertainties and identifying the risk contributors, risk assessment contributes to the understanding of the risk and provides information useful for its regulation and management. For this, the quantitative measures must express to what degree we

know about the event and, thus, how much we believe in its assessment. In this sense, they are an argument tool in support of the decision making. It is the duty of the risk analysts to make transparent the way the quantitative measures have been calculated. The risk assessment must, thus, provide an argument that it must be possible to scrutinize and not a formalized demonstration of an objective truth. The argument stands on the knowledge available and the related modeling assumptions made to formalize the assessment.

In this view, the increasing modeling and computational capabilities and data availability open great opportunities for mining knowledge and improving models for use in risk assessment. In this respect, we have discussed and analyzed some research and development directions with regards to the use of simulation for accident scenario identification and exploration, and the reliance on data for condition monitoring-based, dynamic risk assessment.

As for simulation, although it has long been thought has a fundamental asset for the future development of risk assessment, it is the advancement in modeling and computing capabilities that is nowadays making it actually feasible. Yet, for taking full use of simulation, and for taking the related benefits, trust must be put in the fast-running artificial intelligence-based techniques of surrogate/meta-modeling for their controlled application in exploring system behavior and risk assessment, with adequate treatment of the errors and uncertainties introduced by the associated approximations.

Regarding condition monitoring-based, dynamic risk assessment, the increased availability of sensors-monitored condition data is indeed opening new horizons to develop condition-informed risk assessment that can be more representative of the actual state of the components and systems. There, frameworks of integration of the condition data-driven predictive models into the risk assessment model must be soundly developed and practically implemented, for actual industrial benefit.

The changes and innovations that the World is experiencing, with digitalization and the complexity of cyber-physical systems (CPSs), climate change and extreme natural events, terrorist and malevolent threats, challenge the existing methods to describe and model quantitatively risk. In this respect, we have discussed and analyzed some research and development directions with regards to the extension of risk assessment into the framework of resilience and business continuity, and the safety and security assessment of CPSs.

As for resilience and business continuity, they are indeed offering integrated paradigms that extend the risk one, and provide frameworks for more effectively coping with the uncertain nature and extent of emerging hazards, and their impacts on today's complex, interconnected systems. Several concepts, definitions, models and techniques are emerging, all contributing insights into this difficult problem. Still advancements are needed, also with respect to how to manage resilience and business continuity from a design, normative and operational viewpoint, setting resilience goals, regulating resilience within a defence-in-depth safety approach and maintaining resilience margins during operation.

As for the safety and security of CPSs, the problem is of great relevance since these systems are applied everywhere, at every scale and every area, including aerospace, automotive, energy, chemical industry, materials, civil transportation, agriculture and healthcare. Examples are micro- and nano-scale cyber and physical materials, controlled components, cooperating medical devices and systems, next-generation power grids, future defense systems, next-generation automobiles and intelligent highways, flexible robotic manufacturing, next-generation air vehicles and airspace management, and so on. CPS integrate computing and communication capabilities with the monitoring and control of entities in the physical world, building a bridge between the cyber space and the physical space. A CPS is, then, a system of systems where there is a tight coupling between the computing components and the physical components, the underlying processes and the policies governing all this. The cyber part of the system demands

security as one of its requirements; the physical part of the system requires safety. The system of systems combining the two parts requires both security and safety, and functional dependability. In CPSs, components are networked at every scale and each physical component has cyber capability. Computing is deeply embedded into every physical component. The behavior of a CPS is a fully integrated hybridization of computational (logical) and physical actions. Moreover, the complete system has an excellent adaptability to the uncertain environment. While it is undoubtful that the new technologies will improve our lives, we must not underestimate the risks and neglect the additional requirements that these bring. The high integration in the CPS has brought new risks as the physical components and systems can be malevolently accessed from the cyber space. With the integration of the cyber and physical spaces, the use of the general software, hardware, interfaces and protocols, the access to the internet etc., bring additional risks that must be considered. If the physical environment under control can be taken over by malicious entities, serious damage can occur. Besides the physical interferences, attacks, destructions to the physical components, what can be attacked is the information flow that runs them. An attacker could eavesdrop and tamper the sensor information, store information, control information, and even modify the logic of control algorithms. These can cause delays of the system, and even denial of service (DOS), which can pause the system operation. For instance, brief outages of critical infrastructures like the power grid may cause immeasurable losses and impacts. The suspension of a medical CPS may even be fatal. Therefore, we have to assess and demonstrate that our CPSs are dependable, safe, secure, besides being functional and efficient. To make CPSs resilient, it is necessary to integrate the knowledge on cyber-security, human interactions and complex networks, to address all possible failure and threats in a comprehensive and holistic way. The aim is to design CPSs with the capabilities needed to operate safely and to survive the impacts of natural disasters, human errors, or intentional cyber attacks, with no loss of critical functions. For this, frameworks are needed that can combine simulation to recreate the physical components and processes, and emulation to recreate the cyber components and processes of networked industrial control systems such as SCADA servers and corporate networks. The framework should be flexible and adaptive to enable modifications, given that malevolent attacks and cyber threats keep changing to defeat the installed protections.

Other emergent topical aspects intertwine with the discussions made in the paper. Some are worth at least a mention, because of their expected growing role in the development of the future of risk assessment and the bigger picture of future safety.

A first relevant topic is the growing awareness of the need for a concrete and practical method for accounting of safety mindfulness in operational situations [197]. If the operators are aware of the potential threats that can occur during system operation, they can recognize and anticipate them. The challenge is in the management of the variety of risk information that can be utilized to the scope, including that coming from outside the local environment, e.g. across the industry. Some relevant information may take a long time to reach operators or concern new risks that may have been identified only by few involved parties, and formal processes of transmission are missing so that the needed information may not reach in time the operators who really need it: an incident could occur before existing processes have identified, analysed and processed such information, and disseminated it to the concerned operators. Fundamentally, safety mindfulness leads to being proactive, based on the best and most up-to-date information needed for carrying out the tasks related to the situation. It relies on the proper perception of the risk-relevant elements in the environment of interest, within a specified time and space domain, the correct comprehension of their meaning and the adequate projection of their status in the near future, to guide proper safety actions [62]. Mindfulness has become a quite popular concept for safety but has been difficult to implement, and so far there is no accepted measure of organizational mindfulness [157].

Concrete proposals on how to engineer mindfulness into organisations and processes are still needed.

Shifting along the risk profile from operational situations, and the need to recognize and anticipate risks, to emergency situations, the lessons learned from recent industrial accidents have confirmed the need to focus not only on the preventive measures that need to be designed for protection and on crisis management plans for mitigation, but also on the capacity to adapt in extreme situations that far exceed the scope of safety standards based on probabilistic risk assessment and on the comprehensive analysis of disaster scenarios. Crises in which conventional resources are lacking, but societal expectations are high, call for "engineering thinking in emergency situations". This is a new concept that emphasizes adaptability and resilience within organizations—such as the ability to create temporary new organizational structures, to quickly switch from a normal state to an innovative mode and to integrate the social dimension into engineering activities. Future risk and resilience assessments will need to assess and demonstrate also the ability to create and implement effective engineering strategies on the fly, and the capability for resilience in the aftermath of accidents beyond design basis (those which defeat the designed protections and crisis management plans).

A last topic which seems worth mentioning, because emerging and expected to emerge even more in the developing "smart" technological World, is the social pressure and related behavioral influence that can be expected to affect the demand-response behavior of socio-technical systems. More and more attention will need to be paid in risk (and resilience) assessments to the effects of the intertwining of social media communication onto the operation of technical systems, with phenomena (e.g. of alert (positive effect) or fake news (negative effect) on hazards, dangers and opportunities, and others), which can deviate mass behavior of demand in operational and emergency situations, with effects on the operation and challenges to the capacity of response of the technical systems. Integration of these aspects in the risk and resilience assessment and management frameworks will become more and more necessary, and will require effective integration of different disciplines and competences.

In conclusion, the directions discussed in this paper are some relevant ones in which risk assessment is evolving and must continue to evolve for addressing the existing and future challenges, considering the new systems and innovations that are coming ahead. These directions all revolve around the knowledge at the basis of risk assessment and the modeling for organizing it in a structured, meaningful way. This involves the development of new methods and approaches, for which additional competences are required, e.g. in simulation and data analytics but also in social sciences. This is likely to change the framework of risk assessment and the related educational curricula for the preparation of the risk professionals of the future. In this view, the Society for Risk Analysis (SRA) Specialty Group on foundational issues in risk analysis and the SRA Committee for Specialty Groups have established a group of risk analysis experts with the mandate of producing a list of core subjects for the field (<http://www.sra.org/frag>).

## Acknowledgments

I am deeply grateful to Dr. Francesco Di Maio and Wei Wang of Politecnico di Milano, and Drs. Yiping Fang, Pietro Turati and Zhiguo Zeng of CentraleSupélec, Paris, and Nicola Pedroni of Politecnico di Torino, for their work that has greatly contributed to the substance of this paper. I am also grateful to the four anonymous reviewers, whose comments have allowed improving the paper significantly.

## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.res.2018.04.020.

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