A Socio-Technical System Framework for Risk-Informed Performance-Based Building Regulation[1]

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Abstract

Building regulatory systems have been evolving in recent decades, first with a transition to a functional or performance basis, and more recently with the introduction of new societal objectives, including as related to sustainability and climate change resiliency. Various policy and technical challenges have been identified with this evolution, including the lack of a common basis for establishing performance expectations, quantified performance metrics, and robust mechanisms to incorporate new objectives in a manner that effectively integrates a diversity of stakeholder input and results in regulatory requirements that do not compete with long standing objectives. Among the mechanisms being explored to facilitate a managed evolution is the use of risk as a basis for performance, and modifications within the building regulatory environment to enable this. It is posited that framing the building regulatory system as a socio-technical system (STS) will highlight the complex interactions which exist between regulators and the market, the roles stakeholders play in characterizing risk for use in building regulation, and what steps are required to shift to a risk-informed performance-based building regulatory system, taking into account different legal structures and regulatory approaches that exist between jurisdictions.

Keywords: risk-informed, performance-based, building regulation, socio-technical system

Introduction

Discussions with several governmental members of the Inter-jurisdictional Regulatory Collaboration Committee (IRCC) have indicated a strong interest among many to (a) develop clear, well-supported, and quantified performance criteria (metrics) for use in building codes, (b) explore whether a common benchmark for performance might exist, and (c) investigate the extent to which risk might serve as a common benchmark. One country in particular, Australia, is currently exploring the latter across all health and safety issues, while others, particularly in Europe, already use risk concepts as a basis for structural safety given natural hazard events (i.e., Eurocodes (EN1990, 2002)), and several countries are exploring how to incorporate risk as a basis for fire safety requirements. However, in many countries, progress has been difficult due to the complex nature of incorporating risk into regulation, and gaps in the regulatory development framework that could be helpful for facilitating this activity.

To help overcome the existing gaps and facilitate movement in all three areas, a socio-technical system (STS) framework is suggested. The framework identifies key aspects and interactions within building regulatory systems that are critical to understand and facilitate regulatory change, in particular characterizing and implementing risk metrics into building regulation. In developing this framework, a wide range of challenges associated with risk and regulation are presented, as well as how different forms of law and approaches to regulation can impact approaches to incorporating risk into regulation. It is illustrated how the STS framework can function within the differences presented by civil and common law systems, and amongst different regulatory approaches. Where common knowledge and approaches can be applied, and how different strategies may be needed

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based on the form of law, regulatory regime and regulatory development system in use, are presented. A set of eight steps to guide regulatory developers going down this path is presented.

Research Approach

The framework developed and presented below is largely a result of qualitative research, grounded in review of literature and case studies, supported by interviews with building regulatory developers, engineers and other stakeholders, and the experience of the authors working in the areas of risk assessment, building regulation and building engineering. In conducting this research, three primary focal areas were considered: assessment of the state of performance-based building regulation, use of risk as a basis for establishing quantified performance metrics, and development of a framework within which risk could be used as a basis for establishing quantified performance metrics.

Review of the situation with building regulatory systems, the need for quantified performance criteria, and use of risk as a basis of performance has been ongoing as part of the work of the IRCC (see for example Meacham et al., 2005; Meacham, 2009; 2010; 2010a). This has involved numerous discussions with representatives of lead entities responsible for research, development and implementation of performance-based building regulations in fourteen countries. In 2016, this was supplemented by targeted research in which one of the authors spent between 2 weeks and 8 weeks, for a total of 28 weeks, with seven IRCC member entities, researching these issues. As part of this research, policy makers, regulatory developers, stakeholders (engineers, designers), researchers and academics were interviewed, with questionnaires used for collecting additional information. Interviews and group discussions involved more than 200 persons. This paper reflects a small part of the body of knowledge which was developed.

Specific to the aspects of the research discussed in this paper, differences between Civil Law and Common Law systems, which may not have been appreciated previously, and the extent to which differences in regulatory approach and stakeholder engagement play critical roles in risk characterization and acceptance, are highlighted. In considering the applicability of the STS framework to building regulation, specific cases, detailed in the literature, were also considered. These included the ‘leaky building’ situation in New Zealand (e.g., see May, 2003; Mumford, 2010; Meacham, 2010) and the Aneha Scandal in Japan (e.g., see Gojo, 2011; Meacham, 2010). The situation with potential competing objectives between fire safety and sustainability requirements (e.g., see Meacham et al., 2012; Meacham, 2016) and with private certification (MFB, 2015) was also considered.

Hazard-Based Risk and Regulation

As Otway (1985) so clearly stated, “the risks to which society is, in fact, exposed are largely determined by the regulations and how effectively they are implemented and enforced.” While humans have used regulation to help prevent hazards from impacting people for centuries (e.g., Code of Hammurabi, ca 1754 BC; regulations following the Great Fire of London (see Bell, 1971; Ben-Joseph, 2005; Imrie and Street, 2011)), the explicit recognition and use of risk in regulation is a relatively new concept. The impetus to incorporate quantified values of risk in regulation resulted from health and safety concerns which became publicly intolerable in the late 19th and early 20th centuries (e.g., see Zachmann, 2014), and by the seminal work of Starr (1969), who posited that historical national accident records are adequate for revealing consistent patterns of fatalities in the public use of technologies, and that such historically revealed social preferences and associated costs are sufficiently enduring to permit their use for predictive purposes. The move to incorporate risk into regulation was further facilitated by the formalization of risk analysis as a discipline in the late 1960s and 1970s (e.g., see Covello and Mumpower, 1986; Zachmann, 2014).

Risk as a basis for regulation has worked its way into a broad range of regulated areas, including environmental protection (e.g., NRC, 2009), occupational health and safety (e.g., HSE, 2009), nuclear power (e.g., IAEA, 2005), transportation (e.g., EMSA, 2014), structural performance of buildings and physical infrastructure (e.g., Vrijling, 2001; EN1990, 2002; Ellingwood, 2015; May and Koski, 2013), hazardous facility planning (e.g., CCPS, 2007; 2009; NSW, 2011), finance (Ojo, 2010) and more. In recent years, emerging threat areas, such as climate change impacts, disaster reduction, and terrorism mitigation have seen an uptake in the use of risk concepts (Kunreuther et al., 2004; Smolka, 2006; Thompson and Bank, 2007; IPCC, 2012; UN, 2012; World Bank, 2015). The preponderance of entities seeking to use risk as a basis for or to inform regulation has triggered assessments of, and guidance for, the use of risk in regulation from a policy perspective (e.g., see Stern and Fineberg, 1996; Hutter, 2005; Meacham, 2010a; OECD, 2012; UN, 2012).

There are many ways to define risk (e.g., see Renn, 1992). In this work, the focus is on risk as a function of hazards which may impact buildings and their occupants, the potential consequences of the event occurrences, and the likelihood of unacceptable or intolerable consequences (outcomes) occurring. Thus the emphasis is on managing 'hazard-based' risk through regulation, and not managing the risk associated with design and regulatory approval, or reputational risk, such as explored by Imrie (2007; Imrie and Street, 2009; 2011), albeit these types of risk can be addressed within the socio-technical system paradigm. Also, as used here, the discussion tends toward the 'realist' view that risk is something which can be characterized and addressed. However, it is recognized that the characterization of risk occurs within a social construct, wherein factors such as experiences, emotions, attitudes, and knowledge shape one's perception of risk. This is a critical component of the risk characterization process (Stern and Fineberg, 1996), and is important to policy setting. In this light, a combined realist and constructivist approach to risk, or 'weak constructivist' approach as defined by Hurlbert and Gupta (2016), which posits that risk is both real and socially constructed, i.e., even though risks are necessarily real, they are socially selected, transformed, and debated, is the approach suggested here.

By adopting the view that risk can be characterized within a social context, a process can be designed for incorporating risk concepts into building regulation. This is especially true for characterizing 'acceptable' or 'tolerable' risk measures for individuals and societies for the hazards of concern. It is understood that developing 'acceptable' risk measures is difficult (see Annex A for more discussion on acceptable risk), and that trying to manage risks about which the uncertainty is very high can create its own problems (e.g., Beck, 1992; 2006; Funtowicz and Ravitz, 1992; Burns and Muchado, 2010). It is also understood that some have argued that the notion of 'acceptable' risk may not appropriate for regulation. May (2003), for example, in discussing earthquake hazards, questions whether the discussion should be about acceptance of risks at all, or rather, about desired levels of safety. He cites issues with framing the risk (or safety) problem, the costs for achieving desired outcomes, and the aversion in the USA of politicians to publicly state that any risk of death from a regulated activity is acceptable, regardless of the fact that zero risk is unachievable. Nonetheless, if one wants to try and establish some level of acceptable risk, May (2003) notes that "On the one hand, determining levels of acceptable risk is fundamentally a value judgment that presumably requires some form of collective decision making. On the other hand, knowledge of relevant risk considerations, technical details, and costs and benefits are important for establishing meaningful standards. The first consideration argues for public processes for establishing safety goals. The second argues for deference to technical experts. Finding the appropriate middle ground is a serious challenge." The approach identified in the following sections aims to provide a benchmark for finding this middle ground within a building regulatory system.

The terms 'risk-informed' and 'risk-based' are used throughout this paper. As used here, risk-informed reflects the perspective that risk may be quantified, but the quantified value in and of itself is not the sole determinant in assessing whether a safety target has been achieved, but is one component in the risk decision. Risk-based, by contrast, reflects the view that the quantified risk value is predominantly the decision metric. An example of risk-informed approaches is that of the U.S. Nuclear Regulatory Commission (USNRC), as described by the USNRC (2016), Saji (2003) and others (e.g., May, 2007). Two examples of risk-based design are the approach used in the chemical process industry for design of safety systems (e.g., see CCPS, 2007; 2009) and the Eurocodes (EN1990, 2002).

Building Regulation: A Socio-Technical System

In order to appropriately characterize and incorporate risk measures into building regulation, it is helpful to view building regulatory systems as complex socio-technical systems (STS). STS theory and concepts emerged from studies of organizations and the roles of social and technological components, and the realization that they are integrally linked (Trist and Murray, 1993). There are many definitions of STS, not all of which align (Majchrzak and Borys, 2001). However, most share core concepts of: understanding the component parts, and how each contributes to the performance of the enterprise and creates or meets the requirements of other parts; the interrelation of these parts, with particular reference to the problems of internal coordination and control; and the analysis of the relevant external environment of the enterprise, and the way the enterprise manages its relations to it (Emory, 1993). One representation of STS is illustrated in Figure 1 (adapted from Linstone, 1984).

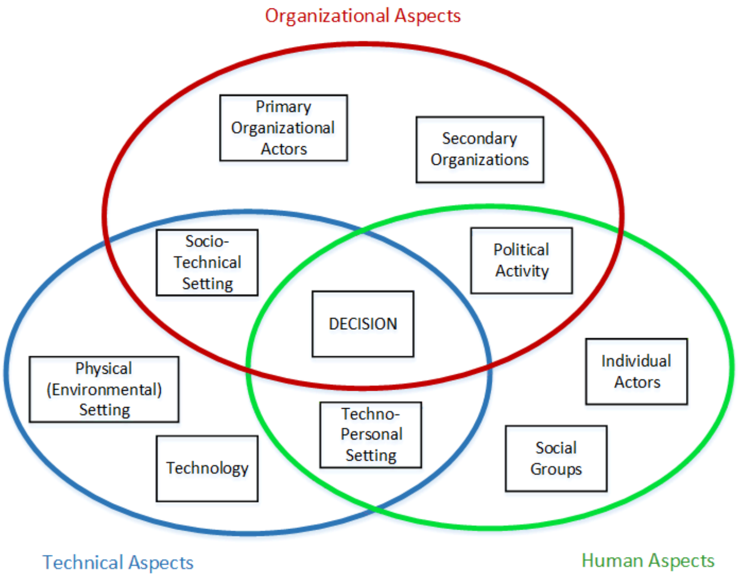

Figure 1. Framework for socio-technical decision making (adapted from Linstone, 1984).

There are three levels of STS: primary work systems, whole organization systems, and macrosocial systems, which include systems in communities and industrial sectors, and institutions operating at the overall level of society (Trist, 1993). It is noted that these concepts apply "to architectural forms and the infrastructure of the built environment" and "although these are not organizations, they are socio-technical phenomena" (Trist, 1993, p40). This has been recognized by others studying the built environment and physical infrastructure, including Harty (2005), Schweber and Harty (2010) and Guy et al. (2011). It is in from this perspective that we view the building regulatory system as a STS, and consider the interaction of actors (stakeholders), institutions and innovation in regulatory and market environments. As with Burns and Machado (2010), we suggest that consideration of both social and technical systems, and how they interact, is critical for understanding modern socio-technical systems and the associated problems of effective regulation of their risks.

This work does not look to advance STS theory. Rather, as used here, the STS framework provides a model for describing the actors and interaction is the building regulatory system. In particular, the framework presented by Petak (2002) in a lecture to the International Institute for Applied Systems Analysis, which describes an approach for building risk management and resiliency to earthquake hazards within a socio-technical framework, is used as a model. Petak's concept is adapted here to more broadly reflect the building regulatory system, as illustrated in Figure 2. In this adaption we use fire as the representative hazard.

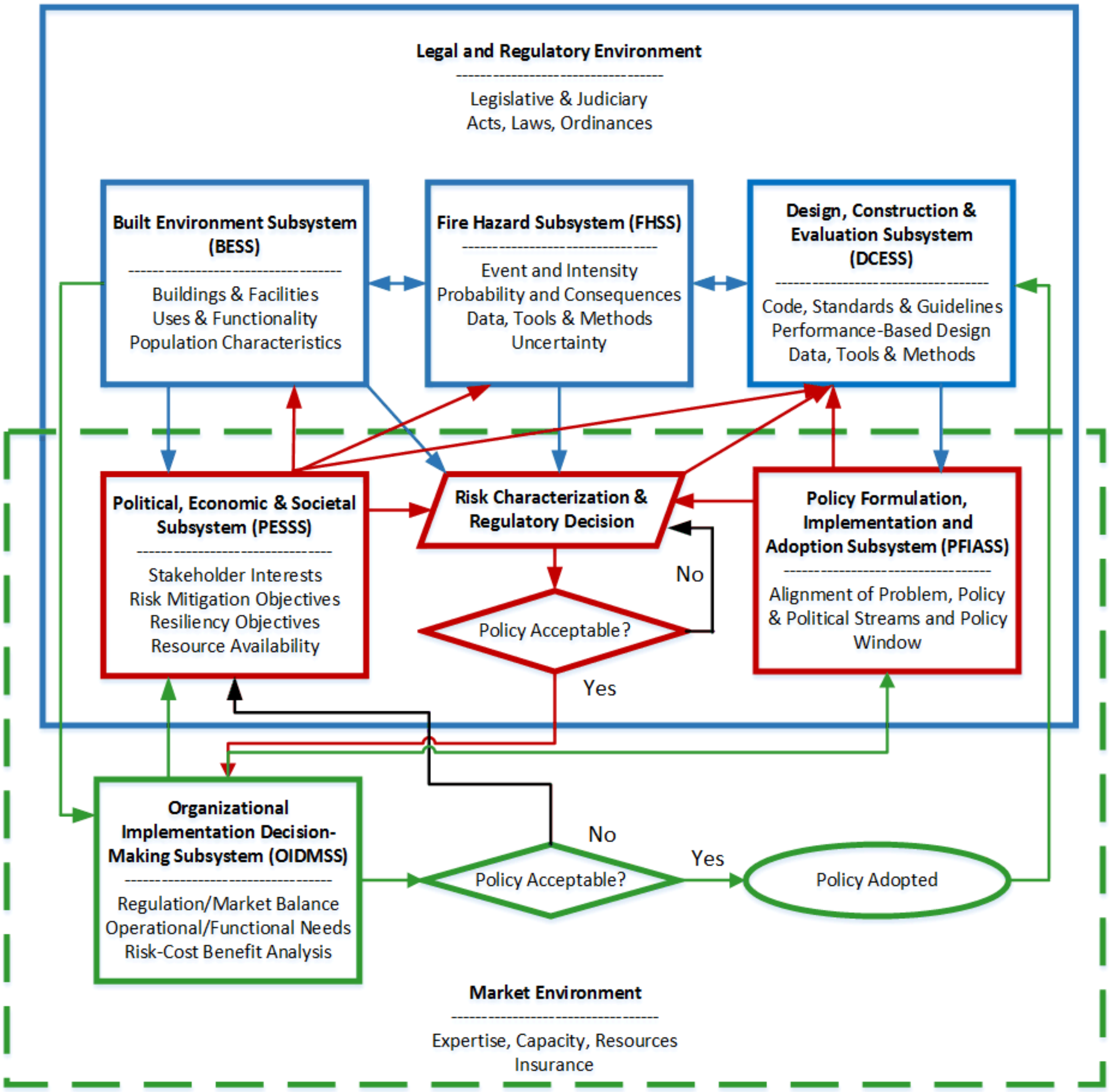

Figure 2. Building regulatory system as a socio-technical system (adapted from Petak, 2002).

In this framework there are two operational environments, 'legal and regulatory' and 'market', and an 'interactions' environment within which decisions are made. Within each environment are subsystems associated with technology (Built Environment (BESS), Fire Hazard (FHSS) and Design, Construction and Evaluation (DCESS)), policy / decision making (Political, Economic and Societal (PESSS) and Policy Formulation, Implementation and Adoption (PFIASS)), and the market (Organizational Implementation Decision-Making (OIDMSS)).

Figure 2 illustrates the high-level interactions between sub-systems. For example, the BESS, FHSS and DCESS interact with each other to describe/define the hazards, assessment approaches and mitigation options. The selection of regulated levels of performance, and tools and methods of analysis recognized for compliance with the regulations, are developed and agreed in the PESSS, PFIASS and risk characterization and decision environment. The policy suggestions are vetted and balanced with market options in the OIDMSS. It is noted that the subsystems themselves are also socio-technical systems. It is also recognized that standards are developed in the private sector, and may or may not become part of the regulatory environment, as they may be used on a voluntary basis. However, the placement of standards within the DCESS reflects the role they play within the regulatory environment.

While building regulatory systems have been identified as STS by some (e.g., Petak, 2002; Rohracher, 2001), this cannot be said to be a common perspective. Many stakeholders in the building regulatory process still view building regulations as largely technical documents, and do not always consider social and institutional infrastructure, roles and expectations, especially from the market side. Failure to appreciate the complex interactions has been cited as contributing to regulatory system failures, which often result from infrastructure-related issues and not from the technical documents (e.g., see May, 2003; Spence, 2004; Mumford, 2010; Meacham, 2010; Gojo, 2011). Failure to note the roles that various stakeholders play in the process, and the resulting narrow perspectives, has also been recognized (e.g., du Plessis and Cole, 2011; Eisenberg, 2016).

Introduction of such a STS framework is useful as it helps to place into context the major subsystems that impact policy adoption and the implementation decision-making process. This is needed given the complexity of the building regulatory system. As noted by Petak (2002) in discussing earthquake hazard mitigation: "Complex dynamic economic forces, business practices, technological options, alternative regulations, scientific understanding and public opinion influence each of the interrelated subsystems. Social values, and public perceptions and demands shape strategies designed to address public interest concerns." Being able to see how these influences interact is important in order to facilitate good outcomes. Any policy decision related to the built environment must take into account the form of law and regulatory environment of a jurisdiction, as well as the relationship and balance with market forces, whether one is operating in a more regulatory-driven or a more market-driven environment. These attributes can impact the extent to which the public and experts are involved, and when, which in turn can influence, and are influenced by, public perception of risk associated with the hazards and the acceptability of approaches to quantify and manage the hazards and risks. The perceptions and responses are influenced by whom is at risk, from what, and under what circumstances. Ultimately, the success of risk-informed policies or strategies to mitigate the risk to a tolerable level are influenced by these complex interactions.

Performance-Based Building Regulatory Structure

Within the STS structure, a building regulation (code) is a component of the Design, Construction and Evaluation Subsystem (DCESS). The basic structure behind many of the performance-based building regulations currently in use is the five-tiered hierarchy first suggested by the Nordic

Committee on Building Regulations in 1976 (NKB, 1976; 1978), as reflected in Figure 3. Since the introduction of the NKB model, it has become apparent from studying the performance-based systems in several countries that in order to assure that solutions meet the upper-level goals and objectives, more detail is required to describe the levels of performance – and in many cases the level of risk – which a particular category of buildings is intended to achieve over a wide range of hazard events. As a result, an eight-tiered performance-based hierarchy has been suggested (Meacham, 1999; 2004a; 2009; 2010a).

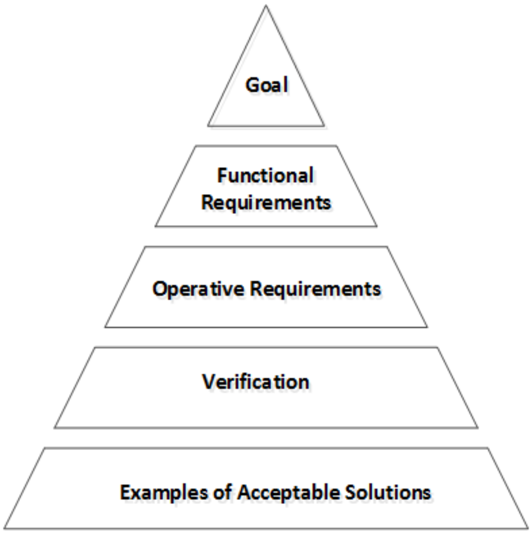

Figure 3. NKB Hierarchy (NKB, 1976)

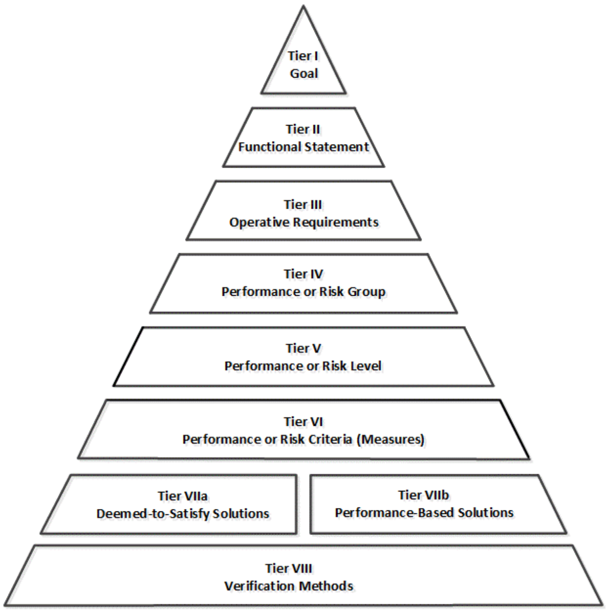

Figure 4. IRCC Hierarchy (Meacham, 2010a; 2016)

The inclusion of the risk and performance levels into the IRCC hierarchy are seen as critical to a risk-informed performance-based approach since societal and policy level goals (Tier 1), and to some extent each of the lower tiers, embody value statements regarding tolerable performance of buildings in terms of meeting risk-related expectations for issues deemed important to society (Meacham, 2010a). The STS framework is helpful to see the various interactions required to address these issues. The target performance is ultimately codified in the DCESS, which draws upon knowledge about the considered hazard / risk from the FHSS and who/what is at risk via the BESS.

The interaction between these subsystems generally exists as part of any building regulatory development system. A key addition within the legal and regulatory environment is explicit inclusion of the risk (probability, uncertainty) component of the FHSS. How the risk becomes characterized and implemented into regulation is through the interactions of the PESSS, PFIASS, and risk characterization and decision function. How the risk characterization and decision function works in any given jurisdiction will be a function of the legal and regulatory environment and the PFIASS. Once a regulatory solution is developed, it will typically be vetted in some manner by the market (OIDMSS) before it is fully implemented.

Risk Characterization

As one approach to overcoming some of the challenges in identifying, quantifying and establishing thresholds for risk, a U.S. National Research Council committee developed a risk characterization process, which envisions joining up risk data from experts with the perceptions and perspectives of other stakeholders in an analytic-deliberative process (Stern and Fineberg, 1996). This risk characterization process provides a framework for the integration of various aspects of risk, including identification, assessment, communication and analysis. It is the product of an analytic-deliberative decision-making process, wherein there is an appropriate mix of scientific information (from "traditional" risk assessment) and input from interested and affected parties throughout. It is a decision-driven activity, directed toward informing choices and solving problems. Since coping with a risk situation requires a broad understanding of the relevant losses, harms, or consequences to the interested or affected parties, significant interaction is required (see Figure 5). It is essential, therefore, that the process have an appropriately diverse participation from the spectrum of interested and affected parties, decision-makers, and specialists.

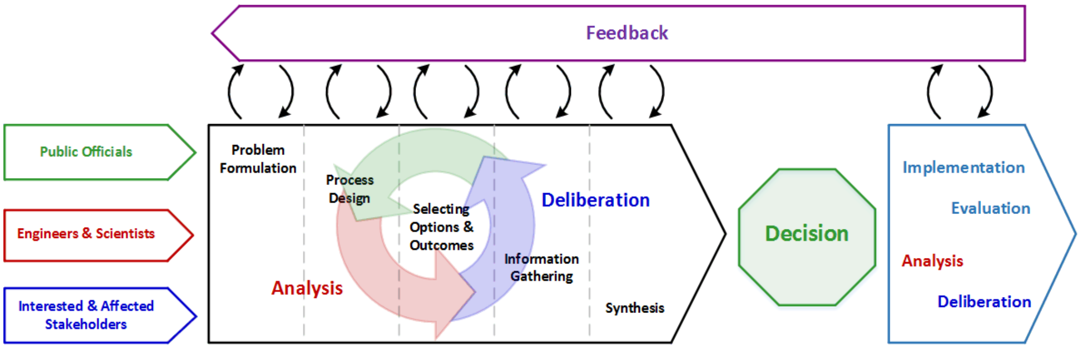

Figure 5. Risk Characterization Process (Meacham, 2010a, as adapted from Stern and Fineberg, 1996)

This risk characterization process fits well within the STS framework, as it brings together the stakeholders, data, tools and methods, to develop an agreed decision on the characterization of risk, with defined policy formulation and implementation constructs, within the legal and regulatory and market environments of a jurisdiction..

Legal and Regulatory Environment

<u>Form of Law and Impact on Risk Regulation</u>

In studying the building regulatory systems in several countries, it has been recognized that the rule of law that is applied within a country can have a significant impact of how risk levels are set in regulation. By rule of law we refer to the civil law tradition and the common law tradition. A fundamental aspect of civil law is that the law defines what are unlawful or unjust acts, and for each of these, the penalty. As such, anything not expressly forbidden is allowed. By contrast, common law is based on judicial precedent and is applicable in the absence of relevant statutory provisions. As such, it could be said that what is not explicitly allowed is forbidden, unless it can be justified where necessary in court. See Annex B for additional discussion.

In addition, it is helpful to think of law in terms of *legal cultures*: a term that denotes legal norms, rules, and institutions and the interaction between them (OECD, 2010). Legal culture determines the language, the priorities, the sites for dispute, and the remedies available. Much as with the differences in rule of law, the legal culture can significantly influence how risk may be incorporated into regulation.

Consider the establishment of 'minimum' risk criteria, or *de minimus* risk levels (see also Annex A). Within the common law system, a seminal decision regarding *de minimus* risk was rendered by the British Lord Justice Asquith in 1949 (Ale, 2005). This ruling established that a computation must be made in which some measure of risk is placed on one scale, and sacrifice, whether in terms of money, time or trouble, which is required to avert the risk, is placed on the other. If it is shown that there is a *gross disproportion* between them, i.e., the risk as compared with the sacrifice required to reduce the risk, it is not *reasonably practicable* to reduce the risk. Thus, the benchmark(s) for *de minimus* risk, for which reduction below is not *reasonably practicable*, is ultimately a legal decision and not a legislative one. By contrast, establishment of a minimum or *de minimus* level of risk in a civil law system falls within the jurisdiction of legislators, as is the case in the Netherlands (Ale, 2005). Here, establishment of *reasonably practicable* is a matter of legislation and not legal interpretation. The practical implication is that the *de minimis* risk level, while similar in concept and using the same terms, has much different implementation and enforcement attributes within civil law and common law.

The impact of differences in legal culture can be seen by considering differences between jurisdictions which operate under the same system of law. Due to how respective cultures have developed over time, there can be different interpretations and approaches. Consider a comparison between the US and England, both of which are under the common law approach. In US environmental and public health regulation, risk has played a key role since at least 1980, and has given rise to hundreds of cases in which the legitimacy of decisions about environmental and public health risks has been the subject of judicial review actions. By contrast, the incorporation of risk concepts in regulation in the England followed shortly thereafter in the mid-1990s, but has not resulted in a large body of case law (OECD, 2010). Thus, interpretations in each country could be much different based on the weight of case law and precedent – even for the same risk. One can also see examples of this in the building regulatory environment. In Europe, for example, where most governments follow the Civil Law tradition, use of risk as a basis of structural performance in the Eurocodes was accepted. In New Zealand, by contrast, there remains concern within government to adopt risk-based methods for structural design, particularly for earthquake hazards.

Regulatory Approaches

In discussing methods to regulate industrial hazards and manage risk, Otway (1985) and O'Riordan (1985) describe four fundamental approaches to regulation: the adversarial approach, regulation by consensus, regulation by centralized authority, and the corporatist approach. This taxonomy largely reflects differences observed between common law and civil law countries, reflecting as well different degrees of central government control versus distributed regulatory development, promulgation and enforcement authority, even within the same type of legal system. With respect to the STS framework, these approaches correspond to the interaction between the PESSS, PFIASS and risk characterization and decision function, in the context of the legal and regulatory environment.

An adversarial approach has developed in countries, such as the United States, where interested parties become adversaries, often arguing their cases in contentious regulatory processes and in legal battles. This is an aspect of common law systems. This approach is typified by the following characteristics:

- Constitutional separation of government powers and wide dispersal of government activity;
- Regulation framed in precise, quantitative targets, standards, and licensing procedures;
- Legally enshrined openness of procedures and public access to all relevant information;
- A society with many informed and effective interest groups, well-established in legislative and executive branches of government; and
- Political structures and attitudes geared towards issue-oriented power brokering rather than more formalized negotiations.

A regulation by consensus approach aims to achieve agreement through consensus rather than through adversarial means. This is an artefact of civil law systems, where bureaucrats play a larger role in the regulatory development process. Many western European countries, for example, use what O'Riordan (1985) classifies as an 'elite' consensual approach (typified by having participation only by civil servants, experts, and influential politicians and industrialists), characterized by the following:

- Flexibility in interpreting rules (specifics are avoided as much as possible, and standards tend to be based on best practical means);
- Confidentiality (the bias is towards secrecy rather than disclosing information);
- Stronger reliance on self-regulation (the close-knit nature of the regulatory development activity results in regulators seeing their role as police officers, stewards, helpers, and advisors to the regulatees, thus promoting self-regulation and minimizing the need for proving compliance)
- Enforcement seldom occurs through legal prosecution (as all key parties are involved in the consensus building process, there is rarely a need to take any type of legal action to resolve issues); and
- Creation of an 'elite' club (regulatory officials may tend to regard themselves as part of an elite club of professional and technical experts, sharing specialized information and advice) and a relatively closed management system.

Regulation by centralized authority is most often found in countries with a strong central government but weak legislatures, where local or regional governments are limited to executing orders issues by national bodies, and where cultural and political traditions lead to the general acceptance of such a hierarchical structure. This can be found in either civil law or common law systems. Japan and Singapore are examples, although Japan has a mix of Civil and Common Law components, with a basis in Civil Law, and a strong history of customary law (Hahn, 1983). The strong centralized authority approach is characterized by the following:

- Regulators have considerable leeway in setting standards and enforcing compliance;
- Consultations with industry and the public tend to be minimal; and
- Regulations are usually imposed and enforced with limited scope for legal redress unless the regulator can be shown to have acted arbitrarily or contrary to statutory procedures.

The corporatist approach is a combination of the above three approaches, with the unique characteristic that the outcomes of regulatory development are represented collectively in collegiate organizational forms. It has been suggested that the Netherlands operates in this manner (O'Riordan, 1985)

The various regulatory approaches tend to encourage public participation to different extents. In an adversarial system, participation is not only encouraged, but it is a right, which if ignored or violated, may lead to conflict. In the 'elite' consensus and strong central government approaches, there may be limited avenues for public participation or means to elicit public expectations and perceptions (until widespread dissatisfaction results in enough political pressure to effect change), and no requirement to specifically act on any input received.

Being able to characterize appropriately the regulatory approach within a jurisdiction is important, as it may influence methods or approaches related to policy formulation, stakeholder engagement, risk characterization, and policy decisions (the PFIASS, PESSS, and risk characterization and decision functions within the STS framework). For example, the analytic-deliberative process described by

Stern and Fineberg (1996) has its basis in the adversarial, common law system of the U.S., and may not be directly transferable into a civil law legal and cultural environment, or at least not seen as being necessary, since bureaucrats have more independent decision-making authority. Likewise, an approach where civil servants identify and characterize the risks of concern, and establish quantitative targets, will minimal public consultation, may not play well in an adversarial, common law system, such as the U.S. In much the same way that a particular building regulatory system cannot be taken from one country and adopted into another due to myriad legal, social and cultural reasons, particular approaches to characterizing or quantifying risks have the same limitation. The STS framework helps identify regulatory system differences that matter in this regard.

Trust and Credibility

There is broad agreement that trust in risk management institutions is an important factor in risk perception and acceptance of risk (Poortinga and Pidgeon, 2003). At a fundamental level, the acceptance by the lay public of risk quantification / characterization, and management through regulation or other means, is significantly dependent upon the trust that relevant stakeholders have in those assessing, characterizing and managing (regulating) the risk.

With respect to risk regulation, the issue of trust is tied in many ways to the form of law within a jurisdiction as well as the regulatory approach. In a civil law system, where it is generally accepted that bureaucrats and their contractors have the expertise to undertake the risk assessment, and integrate the risk measures appropriately into regulation, the path to acceptance can be straightforward (e.g., see O'Riordan, 1985; Vrijling van Gelder, 1997; Ale, 2005). In a common law, adversarial system, where there is distrust of the government and the experts for whatever reason, the path can be much more difficult (e.g., see Wynne, 1980; 1992; Slovic, 1993; Kasperson et al., 1992; Poortinga and Pidgeon, 2003).

The perception of credibility in institutions and actors is also a key concern (e.g., Kasperson et al., 1992; Peters et al., 1997; Pidgeon et al., 2003; Lachapelle, 2014). As with trust, if credibility is low, than acceptance of risk assessment and management is low. Here the credibility of experts - those quantifying risk – and the credibility of bureaucrats who implement risk measures into regulation – are of concern. (See Annex A.)

Accountability in the Verification and Enforcement of Risk-Informed Design

May (2007) has previously argued that a requirement for a performance-based regulatory regime is accountability - the obligation or willingness to accept responsibility or to account for one's actions. This is supported by Mumford (2010) and others. Accountability likewise plays a critical role in risk-informed performance-based regulation. It is inherently built into the STS framework through the accountability of institutions, organizations and stakeholders involved.

May (2007) suggests that there are four levels of accountability within a regulatory regime. The most basic level is 'legal accountability,' which is the accountability of those who promulgate regulations with respect to the content of regulatory provisions. The second level is 'bureaucratic accountability,' which reflects accountability of regulators and regulated entities in terms of answerability in the implementation of regulatory provisions. Recognition of the limits of bureaucratic accountability has led to the importance of greater reliance on 'professional accountability,' as supported by standards, codes of practice and the like, to enhance the appropriate exercise of professional judgment. 'Political accountability' reflects the accountability in the responsiveness of elected officials to shortfalls in regulatory regimes. See Annex C for additional discussion.

Drawing from May, and focusing on incorporation of risk into a performance-based building regulatory system, it is suggested that there is need for transparency in establishing performance goals, as well as objectives and criteria, especially those which are based on risk characterization activities (FHSS, PESSS, PFIASS and risk characterization and decision interaction within the STS framework). In addition, there is need for monitoring adherence to performance goals, which can become a joint regulatory and market (DCESS and OIDMSS) function in a performance system, especially where deregulation is a driver for the implementation of a performance-based building regulatory system. In these systems, adherence to performance goals by regulated entities (the market and actors in the market) becomes critical, as poor performance by actors can lead to loss of confidence and systemic failure (e.g., see May, 2002; Lundin, 2005, 2007; Meacham, 2010; Mumford, 2010; Bjelland et al., 2012, 2015).

Ways in which to help avoid such failures include having robust standards to be available for professionals to apply, along with a strong sense of professional ethics and standards of practice (see Annex C). These are issues which need to be addressed within the interfaces between the legal and regulatory environment and the market environment, specifically via interaction between the OIDMSS and the DCESS. As enforcement by government (DCESS) decreases, responsibility by the market increases (OIDMSS). In some cases, additional regulation, such as professional licensing and certification, or market instruments, such as insurance, may be needed as well.

Practical Implications for Implementing Risk Criteria in Building Regulation

There are a number of complicated factors which materially affect the identification, implementation and certainty of quantified risk criteria for use in regulation, and the application of risk-informed and risk-based design respectively. Risk is not uniformly understood and characterized within or across disciplines, large differences in perception can exist between experts and the lay public, and implementation into law can vary widely by jurisdiction. As such, even if a common characterization of risk can be developed within a specific area and methods of quantification and assessment are agreed by experts, the acceptance by the public and politicians may vary widely between jurisdictions, and the practical implementation may be significantly affected by the rule of law. These issues become clear, and can therefore get resolved, within a STS framework.

Supporting steps

Based on the research discussed above, the following is posited as a set of steps which can facilitate incorporation and acceptance of risk criteria and methods in a broadly universal manner within the context of the STS framework for risk-informed performance-based building regulatory development, implementation and adoption. The steps are framed within three fundamental areas: Technical and Legal Basis (Legal and Regulatory Environment), Acceptance and Implementation (Market Environment), and Decision-Making (Interaction Environment).

<u>Technical and Legal Basis</u>

Step 1 – Understand the Legal Culture (Civil/Common Law, Regulatory Approach)

To begin, one must clearly understand the legal culture and associated factors which can influence the characterization of risk, use of quantified measures and associated methods of assessment, and enforcement of risk-informed design within a jurisdiction. This starts with whether one is in a civil or common law system, and the impacts that has on characterizing, implementing and enforcing risk criteria. Risk and regulatory issues to be considered are summarized in Table 1.

Table 1. Overview of Risk and Regulatory issues within Civil and Common Law Structures

	Civil Law System	**Common Law System**
Public Perception of Risk	Important, but not as much as in common law system, since public is less involved in regulatory decisions and challenges.	Very important, since public is less involved in regulatory decisions and challenges.
Trust in Regulatory System and Institutions	Very important, since critical decisions made within the institutional systems.	Important, but not as much as in civil law system, since public is participant in regulatory development, so their involvement is more critical.
Aspects of Approach(es) to Quantify Risk	Can be quantified by institutions within the regulatory system (e.g., research institutes), and if trust exists in institutions, can expect acceptance of risk criteria and approaches. Benchmarking to historically accepted (tolerated) risk is recommended, and may be an acceptable basis (as implemented in an F-N curve, for example).	Approaches can be suggested by institutions within system, academia, the market, and/or the public. Participation by the public in agreeing risks to whom, from what, how to characterize, how to assess, etc. is imperative. Benchmarking to historically accepted (tolerated) risk is recommended (revealed risk), but is not likely to be accepted without also actively interrogating perception of risk (expressed preference) and its influence on target risk level(s).
Types of Quantified Values Which May be Acceptable	Almost any, which are based on sound scientific knowledge, and for which appropriate data and methods of assessment and estimation exist. Can be single values of individual risk, F-N curves, or economic approaches. Focus is more on the legitimization of the risk target and approaches through trust in institutions and legislative process than in public participation.	To be acceptable, metrics must reflect social, cultural and economic perspectives, as well as technical bases. Vulnerable populations, social equity, and related issues at least as important as technical issues. Public participation essential to bound values of acceptability. Availability and confidence in data, assessment and estimation methods (including identification and treatment of uncertainty and variability) critical. May be easier to use objective data from past history, as it is difficult to argue against, as compared with estimated values, for which lack of understanding about probability, or lack of trust, may negatively impact acceptance. Even so, may have to accept subjective input to gain acceptance.

‘Public’ Involvement in Agreeing Risk Level(s)	Public involvement not critical in development of law, if there exists trust in the institutions, but is helpful and necessary for law to be appropriately used / enforced.	Participation by the public in agreeing risks to whom, from what, how to characterize, how to assess, etc. is imperative. Essential for helping to manage legal accountability.
Certainty of Public Accepting Risk Level(s)	Public acceptance not as big an issue as with common law systems, if there exists trust in the institutions.	Not likely to gain public acceptance without public participation. Participation has to be seen as accurately reflecting those impacted by risk decisions.
Certainty of Legislated Risk Level(s) as ‘Fixed’	By nature of civil law, likely to be accepted, once legislated, with little challenge.	By nature of common law system, likely to be challenged by anyone who disagrees or perceives to be ‘damaged’ by risk allocation.
Need for Agreed Risk-Based (RB) Design Approach	Critical.	Critical.
Benefits of RB Design Approach being Standardized	Desirable, but less required than in common law system, especially if trust in institutions and market.	Essential, not only to guide practice, but to establish ‘standard of care’ for professional accountability.
Need for Qualified / Competent Authorities	Desirable, but less required than in common law system, especially if trust in institutions and market.	Essential to establish ‘standard of care’ for bureaucratic accountability.
Need for Qualified / Competent Practitioners	Desirable, but less required than in common law system, especially if trust in institutions and market.	Essential, not only to guide practice, but to establish ‘standard of care’ for professional accountability.
Need for Clear Approvals Process	Desirable, but less required than in common law system, especially if trust in institutions and market.	Essential to establish ‘standard of care’ for bureaucratic accountability.
Need for Clear Approvals Guidance (Standards)	Desirable, but less required than in common law system, especially if trust in institutions and market.	Essential to establish ‘standard of care’ for bureaucratic accountability.
Need for Clear Accountability / Liability Regime	Desirable.	Essential.
Factors to Reduce Legal Challenges	Consideration of implementing special courts, special review bodies, appeals bodies or the like with required expertise and legitimacy to make ‘good’ decisions.	Sound justification that risk is properly characterized (analytic-deliberative process). Using ‘right’ data, which is agreed by ‘all’. Having ‘right’ mix of people in deliberations. Properly treating uncertainty and variability. Using standards which establish duty of care. Having appropriate accountability measures in system.

This step also includes consideration for public trust in regulatory institutions and the ability of the institution to balance quantitative data and approaches with public perceptions. These issues are a function of the regulatory approach, which in turn are related to the form of law, but can vary even within the same legal framework. Review of case law in common law systems will give insight into realms of acceptability and standard of care required in establishing, enforcing and designing to quantified risk targets. Likewise, consideration of bureaucratic expertise is risk identification and quantification is an important consideration in civil law systems.

This step is important also for jurisdictions undertaking benchmarking efforts, as it is critical that the differences in form of law and regulatory approaches between jurisdictions are well-understood, as a solution which works in one jurisdiction may not work in another because of these factors.[i]

Step 2 – Understand the State of Knowledge (BESS, FHSS, DCESS)

In order to incorporate risk concepts into building regulation, significant knowledge about the hazards / risks of concern, to whom or what, and under what conditions or situations, needs to be assembled. While decisions on characterizing the risk come in the interaction phase, this step is needed to benchmark the situation. It will likely require consideration of how one characterizes buildings and occupants, including uses, associated hazards, occupant characteristics, etc. (BESS), whether physical location matters and if so how, what data, tools and methods for risk analysis and risk-informed design (FHSS), and the extent to which the concepts are compatible with existing codes and standards of design, and where new technology is needed (DCESS). This is the 'analytic' phase of the analytic-deliberative risk characterization process of Stern and Fineberg (1996).

The level of knowledge needed to implement an effective risk-informed or risk-based approach can be directly related to the legal culture and regulatory approach. In particular, it is feasible within a civil law system for government to determine which data, tools and methods are appropriate. In a common law system, this will likely need to come from stakeholders via the risk characterization process. In either case, the potential exists that data which are acceptable within one jurisdiction / system may not be acceptable within another.

Acceptance and Implementation – Phase I

Step 3 – Understand the Market (OIDMSS)

While one often thinks of acceptance and implementation of policy as an end component, it is imperative to understand how likely the market is to accept the concepts. This again starts with a benchmarking exercise. It is important to assess whether the market is open to using risk-informed tools, if sufficient data exist to apply the tools with confidence, whether the education, competency assessment, and professional qualifications systems in place, if the lines between what is regulated and what is market driven are well characterized and agreed, and whether supporting market instruments are in place, such as liability covers for engineers and loss protection for consumers. As discussed by Lundin, (2005), May (2007) and others (e.g., Meacham, 2010), if decisions are made by regulators that assume certain practices in the market (e.g., competence in new tools and methods), yet the market is unprepared, system failure can result.

Consider the interaction of professional qualifications and liability scheme on market willingness to embrace more or less flexibility, and as would be required in a risk-informed or risk-based system. If there are legal requirements for professional licensure, and appropriate insurance instruments in place, one can arguably feel comfortable with innovative design, since these forms of 'risk management' help spread the risk and facilitate close attention to operating within clearly defined ethical boundaries. By contrast, if no form of licensing is required, and the liability culture is to place all the burden on 'the last person standing,' there may be more opportunity for taking 'shortcuts' within the system, since the risk associated with poor decisions can be small.[ii] The work by Imrie (2009) and Imrie and Street (2011) speaks to similar issues with respect to architects in the design process, and their perception of risk within the regulatory system.

Understanding the market is also the stage at which to identify stakeholders who are critical to the risk characterization and decision activities – a cornerstone of the PESSS. To conduct a thorough risk characterization process, and agree how to incorporate risk into building regulation, getting the right stakeholders involved is essential. Otherwise, lack of trust, differing perceptions about who is at risk, under what conditions, and the extent to which 'liability avoidance' is desired may result. Furthermore, without this component, it will be difficult to establish agreed risk-cost-benefit tradeoffs, which will ultimately be required.

<u>Decision-Making</u>

Step 4 – Identify Appropriate Risk Characterization Method (PFIASS, PESSS, Risk Characterization)

This will vary by civil or common law system, and even by jurisdiction within each type of system. In a civil law system, where there is significant trust in the regulatory institutions (including legislative and supportive, such as research institutions), risk-informed / risk-based design approaches can be largely developed by those with expertise, with a reasonable likelihood of acceptance by the public and the market once legitimized through the legislative process. Experience in the Netherlands with acceptance of F-N curves developed for environmental and/or infrastructure planning, or individual risk targets for structural performance, are examples of this (e.g., Vrijling, 2001; Ale, 2005). In a common law system, it is likely that an analytic-deliberative process will be needed (e.g., see Stern and Fineburg, 1996; Kunreuther and Slovic, 1996; Meacham, 2004). To gain acceptance, it will be necessary to have an interplay between experts and the public (or those representing the public) so as to come to agreement on who is at risk, from what, how to quantify, what data are acceptable, what methods of assessment or estimation are acceptable, and how the resulting risk estimates are to be used. Historical data, perceptions of risk, social equity, vulnerable populations, reliability of technology, and related issues are likely to play a role in the process.

Step 5 – Select Criteria and Methodology Pairing(s) (FHSS, BESS, PESSS, Risk Characterization)

In any regulatory system, how likely it is that a risk criterion will be accepted depends on confidence that the targets utilize sound data and methods, appropriately treat uncertainty and variability, and can be readily and consistently applied. In common law systems, it will also matter how well the criteria and methods reflect / incorporation public perceptions, input and expectations. In a civil law system, it is likely that a risk target, developed by a trusted institution and legitimized through the regulatory process, will be accepted. In a common law system, it is unlikely that this will be sufficient on its own. Input from the public will be needed, and ultimately the courts may rule on the target. This not only makes for a more complex risk regulatory development process, but a more time consuming one.

Step 6 – Undertake Risk Characterization / Quantification (Risk Characterization)

In order to develop an integrally linked hierarchical construct such as envisioned in the IRCC Hierarchy, which links concepts of tolerable risk to tolerable levels of building performance, a well-defined and transparent process is needed

In a civil law country, it may be acceptable to have a respected institution select a criterion, with appropriate justification, as the target risk level, and implement it into legislation. For example, it has been accepted in the Netherlands that the target individual risk to life with respect to several hazards is 10^{-5} (e.g., Vrijling, 2001; Vrijling and van Gelder, 1997; Jonkman et al., 2003; Ale, 2005).

In a common law country, such as the USA, it is not likely acceptable to have any singular institution select a criterion in isolation, but rather, to engage in an analytic-deliberative process, where a target and associated evidence is presented, and deliberation with the public and other interested and affected parties, will be undertaken until agreement is reached on how the risk is characterized and represented (Stern and Fineberg, 1996).

Step 7 – Identify or Develop Risk-Informed Design Methods (FHSS, Risk Characterization, DCESS)

If the information benchmarking (Step 2) identifies a lack of appropriate risk-informed design approaches, then new guides or standards may need to be developed. Even if methods already exist, it is likely that they will need to be modified to accommodate regulatory agreements on issues such as the risk metrics, how the risk is to be assessed, and how risk mitigation designs will be evaluated. Various efforts are underway in this regard (e.g., van Straalen, 2014; Meacham and van Straalen, 2017; Meacham and Ashe, 2017; ISO, 2016). As part of the step, study cases, educational materials and programs, and other supporting infrastructure may be required to be developed as well.

Acceptance and Implementation – Phase II

Step 8 – Evaluation and Implementation

As would be expected in any policy development activity, iteration will be required to assure a balance has been achieved between regulatory and market objectives, and that the market is able and willing to implement the policy, and that the right enforcement mechanisms are in place (regulatory, market, or both). Consideration of economic impact will be important, including benefit-cost assessments by the market of the benefit of the regulation and associated risk mitigation strategy (e.g., see Ramachandran, 2002; Kunreuther et al., 2004).

Engage Appropriate Stakeholders Appropriately

This is not a step, but a cross-cutting requirement. Stakeholder involvement is a key component of the STS framework, and a foundation of the PESSS. Discussion regarding the need to get the right stakeholders involved in risk policy decisions is widely agreed, as articulated well by Kasperson and Kasperson (1982), Stern and Fineberg (1996) and others. Likewise, the dangers of not engaging the right stakeholders has been well articulated (e.g., Cole, 2011; du Plessis and Cole, 2011; Lutzkendorf et al., 2011; Eisenberg, 2016). Without appropriate representation of the diversity of stakeholder interests, key issues can be missed, inadequate regulations can be enacted, or other unfortunate outcomes may occur.

Although stakeholders interact across market and regulatory boundaries, as illustrated in the STS framework, they largely interact within specific stakeholder domains. Stakeholder domains are characterized as including three primary segments: (1) all actors who have some stake in the regulatory decision from whom input is solicited (stakeholder domain), (2) a subgroup that contains stakeholder representatives who are designated by members of the stakeholder domain to play an active role in the decision process (active group, participating in DCESS, BESS, FHSS (and other hazard areas)), and (3) a smaller subset who are identified and empowered as the principally responsible parties in the regulatory development decision-making process (decision arena, risk characterization and decision component of the STS framework).

While more categories can be considered, it is suggested that the key stakeholder domains for building regulatory development must at a minimum contain representation from the following stakeholder groups:[iii]

- Authorities. Those with ultimate responsibility to support societal needs by developing, implementing and maintaining building regulations (legal and regulatory environment).
- Building owners and users. Those which have to live with and within the building environment (market environment).
- Special experts. Professional parties involved in building and material design, construction and monitoring (e.g. manufacturers, design offices, housing corporations, etc.).

With respect to special experts, it is important that they understand their role in the regulatory development process, and how they can best inform and influence decisions (e.g., see Kasperson and Kasperson, 1982; Stern and Fineberg, 1996; Meacham, 1999). The specifics of how the stakeholder interactions will play out, and the extent of influence, will be a function of the legal and regulatory environment and the regulatory approach in any given jurisdiction, in particular common law / adversarial approach as compared with civil law / elite consensus approach. Recognizing this and establishing appropriate mechanisms is important.

Conclusions and Recommendations

Several governments have indicated an interest to better incorporate risk concepts into performance-based building regulations, and are actively pursuing efforts in this regard. However, progress has been difficult due to the complex nature of incorporating risk into regulation, and the lack of a regulatory development framework for facilitating the activity. To help overcome the existing barriers and facilitate movement in this direction, a STS framework has been presented which identifies key aspects and interactions within building regulatory systems that are critical to understand in facilitating regulatory change, with a focus on characterizing and implementing risk metrics into building regulation. A wide range of challenges associated with risk and regulation are presented, as well as how different forms of law and approaches to regulation can impact approaches to incorporating risk into regulation. It is illustrated how the STS framework can function within the differences presented by civil and common law systems, and amongst different regulatory approaches. It highlights where common knowledge and approaches can be applied, and how different strategies may be needed based on the form of law, regulatory regime and regulatory development system in use. A set of eight steps is provided as guidance to regulatory developers going down this path.

The framework and steps are applicable to all hazards addressed by building regulations, including: fire safety, health risks associated with indoor air quality, sanitation, heating and cooling; personal safety issues, such as slips, trips and falls; as well as safety from natural hazards, including earthquake, wind, snow and other. This is because the STS framework is agnostic when it comes to hazards – the issues which need to be addressed are largely the same, what changes are the specifics within the Hazard Subsystem. The risk characterization issues, in the context of the legal, regulatory and market environments, do not radically change, albeit some might be more readily agreed than others. Factors which influence this are the data, uncertainty around the data and predictions, and perception of the risks, as outlined herein. As such, while the details, emphasis and ease of incorporation may change, the framework and steps are valid across all hazards. This was intentional, as a critical ultimate aim is to characterize risk in such a way that it can be used as the basis for quantifying performance requirements across the regulations.

The benefits of adopting the STS framework and the associated steps are many, with the principal being that a mechanism for incorporating risk will be provided: one in which the challenges and opportunities are more transparent that in current approaches. It also helps jurisdictions assess the value of approaches taken in other countries, in the context of differences in structure of law, regulatory development approach, stakeholder interaction, availability of data and more. It can also help those countries just embarking on risk-informed building regulation development do so from a more complete foundation than might otherwise exist.

There are some risks with going down this path, of course, the primary being that the political risk of establishing quantified risk criteria is unacceptable, and therefore the approach will not be adopted. It is also possible that an established risk target may change with time. However, the STS framework and associated steps help identify where such roadblocks might exist and give insight as to how to overcome them.

Overall, the STS framework and associated steps provide a more transparent representation of the building regulatory process and what is needed to incorporate risk into building regulation. It is planned that the STS framework and steps will be further tested with a selection of building regulatory entities over the coming years.

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Annex A: Supporting Discussion on Risk Concepts

The Notion of Acceptable Risk

Investigation into 'acceptable' risk, particularly as a concept for use in regulation, was triggered by Starr (1969) when he proposed that societal risk acceptability could be determined by reviewing the level(s) of risk that society "accepted" in the past. His 'revealed preference' concept suggested 1) that the public accepts voluntary risks on the order of 1000 times greater than involuntary risks, 2) that statistical risk of death from disease is a psychological yardstick for establishing a level of risk acceptability, 3) that acceptability is proportional to the third power of the benefits, and 4) that social acceptance of risk is influenced by public awareness as determined by advertising, usefulness, and number of people participating.

This work triggered interest across a wide range of disciplines, including economics, psychology, sociology, and geography, as well as engineering (e.g., see Lowrance, 1976; Fischhoff et al., 1978; 1979; 1981; Kahneman and Tversky, 1974; 1982; Litai, 1980; Litai and Rassmussen, 1983; Kasperson; 1983; Kasperson et al., 1988; Otway and von Winterfeldt, 1982; Rasbash, 1985; Slovic, 1987). The focus of much of this work was to help understand how lay persons and experts view risk and its acceptability or tolerability, what data, tools and methods would be useful in characterizing risk and informing decisions on acceptable or tolerable risk levels.

It was quickly determined that establishing acceptable or tolerable levels of risk requires not only judgments regarding the risk, but in the case of regulation, also about acceptable or tolerable distribution of risks across various populations. This requires value judgments, and various ethical issues enter into the decision-making process, including valuing consequences, paternalism versus autonomy, equity considerations, and a responsible decision process (e.g., see Keeney, 1980; Kasperson and Kasperson, 1983; Kunreuther and Slovic, 1996). There are a variety of issues to consider, such as whether the hazard posing the risk is known or unknown, controllable or not by the target (e.g., driver of a car versus passenger in an airplane), 'normal' or catastrophic, temporary or intergenerational, and so forth. One aspect that most people will be familiar with is that we generally are more tolerant of deaths which occur one at a time (e.g., due to car crashes, or fires in the home), as compared with large life-loss events (e.g., aircraft crash, fire in a nightclub).

Taking these various issues into account, leading risk scholar Baruch Fischhoff and his colleagues (1978; 1981) suggested that acceptable risk problems be viewed as decision problems, where different solutions to a risk problem provide different benefits, and acceptability is a function of the options available and the option(s) selected. They argued that because values, perceptions, and available information may affect evaluation of the options, there are no universally accepted or acceptable risks. Rather, they argue that the acceptability of risk should be viewed as an attempt to solve or manage a problem, and whether the risk is acceptable will be dependent on whether the approach to managing the risk problem is acceptable. Furthermore, weighing costs and benefits becomes a key part of the decision problem: for an individual, regulation or within an entity. Wolski et al. (2000) explored these concepts as part of formulating performance-based codes for fire.

De Minimus Risk

In brief, the concept of *de minimis* risk is based on the premise that there is some level of risk below which one does not need to be concerned. For example, some regulations reflect the position that a risk of less than a 10^{-6} probability of developing cancer is a *de minimis* threshold, and as such, no mitigation is required to lower the risk below that value (see Whipple, 1987). However, there can be difficulties in gaining agreement on *de minimis* levels given differences in perceptions and values, and uncertainties in scientific assessment and quantification methods, and ultimately the courts make the decision (e.g., see Breyer, 1993). An example is the difficulty in trying to regulate for "safe" levels of carcinogens, where there can be scientific disagreement on whether thresholds exist or if the effects are cumulative, and even where clear thresholds can be determined, the "safe" threshold varies for each individual.

Societal Risk / F-N Curves

In much of the literature, societal risk is represented by an F-N curve,[2] where generally F is the frequency of a particular hazard, event or type of event, and N is the number of fatalities, given that hazard, event or type of event (see for example, CCPS 2009; Ale, 2005; HSE, 2009; Jonkman et al., 2003; EMSA, 2013). The seminal paper by Starr (1969) laid the foundation for the concept of the F-N curve, specifically the historical representation of frequency of events which result in certain numbers of fatalities. However, the of risk analysis allowed for F-N curves to be constructed using quantitative risk assessment (QRA) as a predictive tool as well (e.g., see CCPS 2009).

In several countries a F-N criterion line is used to reflect the target level of 'acceptable' risk of various hazardous activities. These F-N criterion lines can be described with the following general formula: $1 - F_N(x) < C/x^n$, where n is the steepness of the limit line and C the constant that determines the position of the limit line (Jonkman et al., 2003). A line with a steepness of n = 1 is called risk neutral. If the steepness n = 2, the standard is called risk averse (Vrijling and van Gelder, 1997). In this case larger accidents are weighted more heavily and are thus only accepted with a relatively lower probability.

In many cases, F-N curves are used with set boundary conditions of 'intolerable' (or 'unacceptable') risk on the one side, and 'negligible' ('broadly acceptable / tolerable') risk on the other side, with the region in between being deemed as 'tolerable.' The lower bound – the 'negligible' bound – can be determined based on agreement by parties involved, but may also be set by legal ruling, typically by the concept of *de minimus* risk (see above). However, the use of F-N curves is not universally agreed (e.g., see Evans and Verlander, 1997). The key concern is that while F-N curves can be used to describe historical or even predicted losses, they alone do not establish 'acceptable' or tolerable levels. Rather, such limits must still be set by policy makers.

Trust and Credibility in Risk Regulation

An aspect of risk regulation that has garnered much attention is that of trust, or perceived trust, in the institutions and organizations responsible for risk regulation, assessment and management (e.g., see Wynne, 1980; Slovic, 1993; Kasperson et al., 1992; Peters et al., 1997; Pidgeon et al., 2003; Poortinga and Pidgeon, 2003; Walls et al., 2004; Chryssochoidis et al., 2009; Lopez-Navarro, 2013). This area of study is attributed to work by Wynne (1980), who argued that differences between expert and lay perspectives on technological risk were founded in the differing evaluation of the trustworthiness of risk managing institutions between the experts and the lay public.

Early concerns were raised when the nuclear accident at Three Mile Island in the USA occurred, which was not long after a probabilistic risk assessment approach had indicated that the risk of such

[2] With respect to representing 'societal risks,' the CCPS (2009a) notes that frequency and fatality curves may be plotted in either of two fashions: non-cumulative frequency basis, called f-N curves, where the value plotted on the y-axis is the discrete frequency of experiencing exactly N fatalities, or cumulative frequency basis. For these graphs, called F-N curves, the value plotted on the y-axis is the cumulative frequency of experiencing N or more fatalities. Since 'societal risk' data and criteria are more commonly expressed in terms of cumulative frequency, F-N representations are most often used.

an event was negligible. Concerns were also raised by people who lived in the neighborhood of a hazardous facility, where experts deemed the risk low, but that is not how it was perceived by the local inhabitants (e.g., see Kasperson et at., 1992; Stern and Fineberg, 1996; Pidgeon et al., 2003; Lopez-Navarro, 2013; Lachapelle, 2014).

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Annex B: Supporting Discussion on Form of Law and Impact on Risk Regulation

The issue of what rule of law is applied within a country and how it impacts the 'acceptable' risk issue does not appear to be well-treated in the literature, yet can have a significant influence on the practicality of adopting qualitative or quantitative risk criteria into legislation. By rule of law we refer to the civil law tradition and the common law tradition.

The civil law is often defined as a law which derives its source and inspiration from Roman law (Canada, 2016), but is also often referred to as Napoleonic law, as it was introduced in all countries that were part of the French Empire under Napoleon Bonaparte (Ale, 2005). Most European countries, for example, other than the UK, are civil law countries. Many civil law countries have also generally canonical rules or rules of customary law (Canada, 2016). A fundamental aspect of civil law is that the law defines what are unlawful or unjust acts, and for each of these, the penalty. As such, anything not expressly forbidden is allowed (Ale, 2005).

Dating back to 1066, the common law was gradually developed by the Royal Courts in England, which sought to standardize the law, contrary to local custom, on the basis of a general custom applicable throughout the kingdom (Canada, 2016). England and its former colonies, including the USA, are generally common law countries, as well as some others (note: the USA and Canada have both, wherein the US State of Louisiana and the Canadian province of Quebec follow civil law, and all others common law). The form of reasoning in common law is known as causitry or case-based reasoning (Ale, 2005). Common law may be unwritten, or written in statutes or codes. The common law, as applied in civil cases, was devised as a means of compensating someone for wrongful acts, known as torts, including both intentional torts and torts caused by negligence, and as a way of developing the body of law recognizing and regulating contracts. The common law thus derives from the activity of the courts: it is the work of judges. In this sense, the common law must be understood as unwritten law based on judicial precedent (as opposed to statutory law which derives from legislative sources) and are applicable in the absence of relevant statutory provisions (Canada, 2016). As such, it could be said that what is not explicitly allowed is forbidden, unless it can be justified where necessary in court (Ale, 2005).

In comparing the two approaches, common law is distinguished by its method and inductive reasoning, which consists of generalizing from precedents and observing similarities. Civil law, on the other hand, is characterized by its deductive method, high degree of abstraction and generalization. In other words, the method of the civil law is rational, that of the common law empirical (Canada, 2016). On the implementation side, civil law can establish clear targets for compliance, with little concern of intervention by the courts, whereas in common law a legislated target may be open to interpretation by the courts. Because of the nature of common law as a mechanism which embodies the concept of compensation for wrongful acts (torts), this leads to consideration of what is a reasonable effort to avoid causing harm. This can lead to differences in interpretation and use of common terms and concepts between civil and common law systems.

In considering how to implement risk concepts into regulation, it is helpful to think of law in terms of *legal cultures*: a term that denotes legal norms, rules, and institutions and the interaction between them (OECD, 2010). Legal culture determines the language, the priorities, the sites for dispute, and the remedies available. The fact that law is a form of culture has four implications with respect to risk and regulation:

- Risk regulatory concepts are embedded in complex cultures, which will shape how such concepts operate and are defined.

- Legal cultures vary significantly between jurisdictions, which means that risk regulatory concepts cannot be transplanted between legal cultures and operate in the same manner.
- Globalization has led simultaneously to a proliferation of legal cultures and to a demand for greater uniformity.
- The complexity of legal cultures means that unambiguous legal interpretations of concepts will often not exist.

To the first point, the operation of any risk regulatory concepts will be embedded in, and interact with, a complex legal culture: risk regulatory concepts are not just rules that operate in isolation and how they are interpreted and operate will primarily be influenced by the institutions, laws, and ethos that surround them (OECD, 2010). This is reflected in the STS framework.

To the second point, differences between jurisdictions can be significant. An inquisitorial civil law operates in a very different way from an adversarial common law system, perhaps most significantly in that case law does not have the legal authority in civil law system that it has in a common law system (OECD, 2010). Furthermore, even between common law systems there are often significant differences. The US legal culture, particularly in relation to administrative law, is often said to be dominated by adversarial legalism in that many disputes are litigated in the courts, whereas the UK administrative law has been dominated by negotiation and informal agreements.

Closely related to the above discussion is the fact that there is not always one agreed interpretation of the law within a jurisdiction, let alone between jurisdictions. A law may apply differently in different factual contexts: establishing a “significant risk” in relation to occupational risks from electrocution is different from establishing a “significant risk” from occupational HIV infection and is different again from establishing a “significant risk” from air particulates (OECD, 2010). Furthermore, language, is ambiguous, and how it is interpreted will depend on context: the concept of “risk” can validly have a number of different definitions, and risk in an economics sense for example means something different from risk in an engineering sense. Even in the same discipline, a risk concept can be validly interpreted two different ways.

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Annex C: Supporting Discussion on Accountability within Regulatory Regimes

The different levels of accountability for different types of regulatory regimes are characterized by May (2007), along with an assessment of accountability issues with examples of the difference regulatory regimes. The regulatory regimes are prescriptive, system-based, and performance-based regulation. As defined by May, prescriptive regulation tends to be highly particularistic in specifying required actions and standards for adherence to them, performance-based approaches emphasize regulation for results rather than specification of specific actions or technologies, and system-based regimes (which have also been labeled as process-based or management-based) aim to achieve regulatory goals by instituting appropriate systems for monitoring production and processes by system actors (somewhat like a quality management approach).

A matrix of the accountability levels for these three regimes is presented in Table 1 below.

Table 1. Accountability structures (May, 2007)

	Regulatory regime		
Accountability levels	Prescriptive regulation	System-based regulation	Performance-based regulation
Legal	Transparency in setting rules and standards	Transparency in establishing features of desired systems	Transparency in establishing performance goals
Bureaucratic	Monitoring for adherence to prescribed rules	Monitoring for adequacy of management system	Monitoring for adherence to performance goals
Professional	Enforcement decisions by regulatory inspectors	Systems design decisions by regulated entities	Adherence to performance goals by regulated entities
Political	Triggered by complaints about regulatory process	Triggered by multiple system breakdowns	Triggered by systemic undesired outcomes

A number of study cases, where accountability concerns have arisen, including in performance-based building regulatory systems, fire safety engineering and risk-informed regulation, are discussed by May (2007).

Irrespective of the accountability level, it is suggested that there are four major elements which help define and assess accountability: the setting of standards; the obtaining of an account; the judging of such an account; and finally a decision about the consequences that arise from such a judgment (Davies, 2001, p. 81, as cited in OECD, 2010). A fundamental element is the standard by which a decision maker will be held, that is, what is a "good" decision and how is it judged. Items such as well-defined approaches, standards or codes of practice are very important for this.

For example, requiring a decision maker to carry out a risk assessment as part of a regulatory impact assessment is setting a standard that the quality of a decision will then be judged by (OECD, 2010). Likewise, having clear standards and codes of practice, which help define the duty of care for an engineer undertaking and interpreting a risk analysis is essential. It is suggested that much of judicial review litigation is essentially challenges to the criteria of "good decision making" and litigants in judicial review are often arguing that a decision should have been based on different standards, perhaps for example, comparative risk analysis, the precautionary principle, or cost/benefit analysis instead of some other quantitative approach (OECD, 2010). In a common law system, lacking consensus around professional standards it can become the role of the court to determine the standards by which a risk decision should be judged.

This second point reflects the fact that there are many different means of holding decision makers to account. In many cases, the judge presiding over a case is making this decision, in large part on the weight of evidence admitted. However, legislation sometimes provides for particular or specific review mechanisms for certain types of decisions involving risk regulatory concepts. In Australia and New Zealand, for example, there exists a series of different specialist environmental courts that review planning and environmental decisions on their merits and which have developed special procedures for hearing expert evidence (Edmond, 2008; Fisher, 2008, as cited in OECD, 2010). This is not the case in the USA, although Breyer (1993) has argued the need for such a 'science court.'

Judging of the account can likewise be accomplished in many ways, including by assessment of the analytical rigor and methodological quality of a decision, as in the case of specialist peer review or in relation to impact assessments, by political actors in a political or legislative forum, or by vesting an appeal body with the power to overturn the decision and replace it with a decision they deem "correct" in a process commonly described as merits review (OECD, 2010). The approach taken is generally dependent upon legal culture and historical and legal context.

With respect to the consequences that arise from a decision being judged as not meeting a certain standard, these too can vary significantly, ranging from a decision being struck down, remanded for reconsideration or replaced, to instigation of widespread political or institutional change, such as administrative or legal reform (OECD, 2010). The latter was clearly seen in the response to the 'leaky building' situation in New Zealand, which resulting in changes to the Building Act, Building Code, oversight of Building Consent Authorities, licensing of practitioners, and more (e.g., May, 2003; Mumford, 2010; Meacham, 2010).

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Endnotes

[i] For example, consider differences between Australia and New Zealand. New Zealand introduced a performance building code in 1992. Australia followed shortly thereafter in 1996. In order to jumpstart the process, the basic structure used in New Zealand and elsewhere was adopted (the NKB (1978) hierarchy). While the NKB structure on its own is transferrable, and both countries are common law countries, the New Zealand building regulatory approach can be considered centralized, while the Australian functions more as adversarial. This in part is due to Australia being a federation of states and territories and New Zealand not. In New Zealand, the national government sets building regulatory policy and develops the code (administrative and technical roles) within the Ministry of Business, Innovation and Employment (MBIE). Stakeholders are consulted, but not necessarily at all stages of regulatory development. In principle, implementation is nationally consistent. In Australia, the Australian Building Codes Board (ABCB) develops the building code (now the National Construction Code), but the states and territories have flexibility with administrative provisions. Code development is largely through the ABCB Board (established under an Inter-Governmental Agreement) (, which has representatives from the state, territories and commonwealth governments, as well as industry groups (see the ABCB website for more details).

In recent years each country has looked to incorporate risk concepts into building regulation (see Meacham, 2010). In principle, MBIE can mandate risk criteria / levels in New Zealand, but has not yet done so explicitly. However, the ABCB can do so directly, as the decisions flow through the ABCB Board, and ultimately the states and territories have to agree. The approach to defining risk criteria / levels therefore differs considerably, as does the socialization of the ideas and ultimate acceptance by the market. These issues will be explored for these two countries in more detail in a future publication.

[ii] As used here, a qualifications system reflects a means by which professionals are deemed qualified to practice in a jurisdiction. In some countries, such as the USA, there are requirements to be a licensed Professional Engineer, which generally requires an engineering degree from an accredited university program, some period of professional practice under the mentorship of a licensed professional engineer, and successful completion of a Fundamentals of Engineering (FE) exam and a Principles and Practices of Engineering (PE) exam, which is in the area of specialty (e.g., fire protection engineering). In the USA it is required by law to be a licensed engineer before one can practice engineering, in particular undertake and be responsible (accountable) for engineering designs, in the built environment. In addition, the title of engineer is protected: you cannot call yourself an engineer unless you are licensed. In other countries, the qualification of an engineer might be through a professional body, such as the Institution of Fire Engineers (IFE) in the UK, which registers Chartered Engineers through the Engineering Council. The Engineering Council has requirements for education and demonstration of knowledge (as determined from the professional body, in this case IFE), but not through examination, and there is no legal requirement to be a Chartered Engineer in order to practice engineering – it is strictly a market decision.

In New Zealand there is no legal requirement to have any particular engineering qualification to practice and titles are not protected. The Institution of Professional Engineers New Zealand (IPENZ) maintains a register of engineers, and looks to specialty groups / societies, such as the Society of Fire Protection Engineers (SFPE) New Zealand Chapter, to define competencies. However, it is not legally required that one be a member of IPENZ to practice engineering. In principle, anyone can call themselves a fire engineer (fire safety engineer, fire protection engineer), for example, and this can result in work being conducted by unqualified persons, with the market left to sort who is qualified and how. This places a burden on the market and on the regulatory system. In Australia, there is a similar registration through Engineers Australia (EA), and no national requirement to be on the register, but registration is required to practice in some states. In the Netherlands no legal registration system exist and only rely on private initiatives.

With respect to liability schemes, if a jurisdiction operates under joint and several liability, the approach often taken is to seek damages from everyone, especially targeting those with 'deep pockets,' with the aim to recover damages from any one party, leaving it to them to then seek damages from the others. In some cases, many of the potential contributors to the damage go out of business, and the 'last person standing' is required to pay. Under a proportionate liability scheme, damages are still sought from all involved, but the courts determine the percentage contribution of the involved parties to the damage, and it is argued that having a potentially large number of entities paying small percentages of the damages means it is less likely for entities to simply go away. Depending on how insurance is structured, the joint and several liability approach could mean a significant risk of losses for a single insurer or small number of insurers. This might still occur under proportionate liability, but is less likely (less likely that all parties have the same insurer(s)). Thus, the strength of the insurance sector can play a significant role in how well a liability scheme in practice (e.g., see Macaulay, 2010).

In New Zealand, there is a joint and several liability scheme in place for the building sector. When the 'leaky building' disaster hit, the 'last person standing' was the government – in many cases local government. As a result, local government has become averse to approaches in which there is uncertainty in decision-making. This has played out in terms of reducing the appeal of performance-based solutions, for which government determines compliance. There is even less desire for 'risk-informed' approaches, especially in the absence of clear and agreed risk criteria. A net result of the lack of required qualifications in a joint and several liability market is that engineered solutions have become more conservative than envisioned within a performance-based regulatory system. A 'prescribed performance' approach for verifying fire engineered solutions was promulgated, and many have claimed innovation was stifled. While the government has in the past considered moving to a proportionate liability approach, the insurance sector was not supportive, since it was expected that they would end up paying more (e.g., their insured entities having some proportion of the damage, and not just expecting local government to pay). They have also been reluctant to mandate engineering qualifications. The combination is not conducive to a risk-informed regulatory approach.

[iii] It is suggested that representatives in the active group should be assigned as appropriate to a specific decision area (e.g., aging, sustainability, fire safety), depending upon the topic under consideration. The selection of representatives should be based on a mix of four qualities. It is noted that not each individual has to match with all four qualities, but the decision area in total should have the right mix of these qualities:

- Committed. He or she is concerned about the considered topic and feels a strong need to go forward.
- Competent. He or she should be competent in the area of which he or she represents.
- Involved. He or she should be active within the domain.
- Accountable. He or she should not focus on his or her individual interest, but must be able to act based on common needs of the stakeholder group.