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The Role of the Regulator in SMS

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Abstract

In almost all cases, the transport industry has adopted safety management systems (SMS) in response to a regulatory initiative. SMS vary dramatically across transport modes and jurisdictions – often because of the influence of different legacy regulatory programmes, and the attendant cultures. Consequently, there is no single path to guarantee a regulatory authority success in designing and implementing SMS regulations. For many, SMS has become a voyage of discovery, an experiment in proactive safety management that is being conducted in real time.

SMS has been a "step change" that has challenged industries in all modes of transport. It has severely taxed the capabilities of many regulatory authorities. It is arguably the most significant regulatory change that has occurred in the transportation industry in recent times.

Regulating SMS has often led to revised legislation, regulations or standards; whole scale restructuring of the regulatory agency; new or revised regulatory protocols, processes, activities, and tools; and new information technology (IT) and new processes for information management (IM).

SMS will continue to evolve in the coming decades. The paper draws on lessons learned to explore strategies that can be used to design, implement and operate the related regulatory programmes. Observations are provided to help decision makers manage the challenges they will predictably face. The critical role of dynamic, wide-reaching communications and strategic planning, with industry and within the regulatory organisation, is underlined.

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1. Introduction

Late in the twentieth century, a small number of companies in the transport industry introduced safety management systems (SMS) on their own initiative. Some were the vision of an executive team; others the results of an anxious Board of Directors. The goal – sometimes stated, sometimes not – was to explicitly and purposefully improve safety performance. A few adapted the features of a quality management system (QMS), while others introduced advanced safety programmes.

For a number of reasons including a series of catastrophic, high profile accidents,[1] regulatory authorities began to encourage, then require, safety-critical industries to operate SMS. The evolution of systematic, proactive safety management in transport is described in Maurino (2016). Additionally, Lappalainen (2016) presents a thorough overview of SMS regulatory regimes in transport. Consequently, the current paper is written on the foundation of these complementary works, and provides little detail about the underlying principles and components of safety management systems, or of specific regulatory requirements.

The industry has faced numerous challenges when implementing SMS. So have the regulators. Arguably, the diverse nature of regulatory programmes – which vary from domain to domain and jurisdiction to jurisdiction – has taxed regulatory authorities even more than the industries they oversee (Kelly, 2007).

There is universal agreement that SMS will continue to evolve for decades to come. Consequently, the paper examines past and present developments with a view to informing current and future policy-makers and regulatory decision-makers. With the exception of a short diversion into the theories of accident causation, it is intended to be practical. The paper presents the "lessons learned" by the author while working with companies and regulatory authorities in various transport sectors, as well as such other safety-critical industries as the offshore oil and gas industry. The "hands-on" information has been supplemented and validated by interviews with SMS regulators and practitioners.

Readers are encouraged to identify their particular circumstances in the continuum of existing SMS and SMS regulatory programmes, so they can draw from the experience of others to shape strategies that will suit the readers' specific operating or regulatory environments.

The paper examines the role of safety regulatory authorities in SMS across the air, marine and railroad modes. It examines various strategies that senior managers have employed to design, implement and operate an SMS-directed regulatory programme. It assesses the impact of regulating SMS, which in many cases has required, *inter alia*:

- Revisions to legislation, regulation or standards.

- A shift in regulatory direction, which in some cases has led to the whole scale restructuring of the regulatory agency.
- The development of new or revised regulatory protocols, processes, activities, and tools
- The collection and analysis of hazard and risk-based information, and the supporting infrastructure.

Such change has been challenging. Seldom have regulators had access to the resources they needed to carry out the day-to-day activities while designing and implementing a new regulatory programme. The paper assesses the various strategies they have employed.

2. Background

The paper is based on the premise that a safety regulator's role is to directly or indirectly aid in reducing loss of public life and property. The provider of the transportation service is directly responsible for managing risk. The regulatory authority, on the other hand, is responsible for providing feedback (often in the form of information about compliance with safety regulations or standards) and guidance on areas requiring improvement. The complementary roles are expected to prevent accidents.

As Maurino (2016) notes, accident prevention activities are shaped by the way an industry understands the causes of accidents. The understanding is a subjective, often experience-based, global view of the world. It shapes behaviours and activities, even if it is not explicitly articulated. Changes in this world view cause changes in understanding. Changes that are dramatically different results in a "step change" – a radical review and redirection of policy. Expectations, especially those of the regulator, change. Revisions to behaviours and activities are directed, usually from the top-down. Such changes often occur after the investigation of one or more high profile accidents.[2]

The emergence of safety management systems has in part resulted from an evolved understanding of accident causation in safety-critical industries, industries where humans operate increasingly complicated equipment in a resource-driven, complex environment.

2.1. In the beginning

In the recent past, accident prevention focused on optimising the reliability of equipment, and the dependability of the persons who operated the equipment. Services were reliably−hence safely−designed and delivered. The more critical the consequences of an unwanted failure (of equipment, or persons), the stronger or more redundant the defences needed to be to reduce the likelihood of the failure, or to minimise the consequences if it occurred. Reliability, whether technical, operational or organisational, were engineered and achieved. Regulations, standards and rules codified the defences, and formalised mitigation.

Given this "world view", it is not surprising that "failure analysis" was equated with "safety analysis".[3]

In more recent years, the work of a wide group of practitioners and theorists significantly changed this understanding of accident causation, and accident prevention. The diversity of their backgrounds is truly remarkable.[4]

Their growing body of work migrated attention towards the influence of organisational decisions and cultures on day-to-day operations. From their diverse vantages, they collectively recognised that conditions inherent in operating and managing tightly-coupled, complex systems had the potential to create fissures in the defences. Significantly, many of the conditions that could lead to "breaches in the defences" were not technical. Rather, they were based in the "soft sciences" of management and human behaviour. Nor were the circumstances always visible, yet they were common-place, even predictable. Viewed through this new world vision, managers and regulators of safety critical industries could no longer depend on the long-respected reliability model to prevent accidents. Reliability, for all its strengths, had shortcomings, some of which are briefly described below.[5]

The development or modification of safety regulations, system requirements and regulatory standards take time−so much so they can sometimes be all but obsolete before they are implemented. Furthermore, regulations almost always are the result of compromise between interested parties with different perspectives and interests. And they are usually "add-ons" that sometimes do not fit well with existing safety standards and requirements.

Furthermore, the "real world" machinations of providing commercial services do not align with the theoretical assumptions that underlie the reliability model. Corporate and operational decisions regularly have to be made without the benefit of complete information. Additionally, it is natural for decisions to be silently (and sometimes not so silently) influenced by interacting personalities and organisations. Procurement and human resource policies and processes are driven by economic exigencies, and by past, sometimes ineffective, practices. Organisational and operational changes−sometimes small, sometimes large− occur all the time, and unknowingly distribute hazards throughout a company, and sometimes throughout an industry. Changes to operational procedures are often misunderstood or misapplied. "Work-arounds" exist. Processes "creep" from their intended direction.

And it is not uncommon for regulatory and operational managers and staff, as well as system designers – professionals who are completely immersed in the "reliability world view" – to hold unrealistic expectations about the dependability of humans.

In summary, the current understanding of accident causation has changed. Past assumptions about regulations, organisational decision-making and human performance are unrealistic. As a stand-alone concept to reduce risks and prevent accidents, the reliability model is no longer adequate. However it continues to shape present-day safety management principles and techniques.

2.2. Making the case for SMS

The interaction between people, equipment and organisations in a dynamic operating and commercial environment is extremely complex. There is no such thing as "complete reliability", no matter how

rigorously functional specialists identify and mitigate hazards, or dedicated and well-trained individuals adhere to processes and procedures. Of course, it is true that standards and rules continue to form the foundation for managing technical and operational hazards and risks, but deficiencies (in reliability and performance) cannot be treated solely as "failures". Rather, they are often indicators of complex operational and organisational environment that at any moment are not completely understood by engineers, managers, even operational staff. Nor are they fully understood by the regulator.

To many, this change in "world view" is captured in the now-famous "swiss cheese model" of accident causation (Reason 1990, 1997). It is employed in this paper to assess the strengths and weaknesses of the various features of regulated SMS. Very few SMS address the conditions described by Reason.

There has been progress: accident prevention programmes, techniques and activities *have* changed. *Failure* analysis is still a critical part of designing reliable equipment and technical systems, but attention also focuses on hazards based in human and organisational factors. For instance, operationally-oriented accident prevention programmes (e.g., fatigue management) are increasingly based on formal human factors analyses.

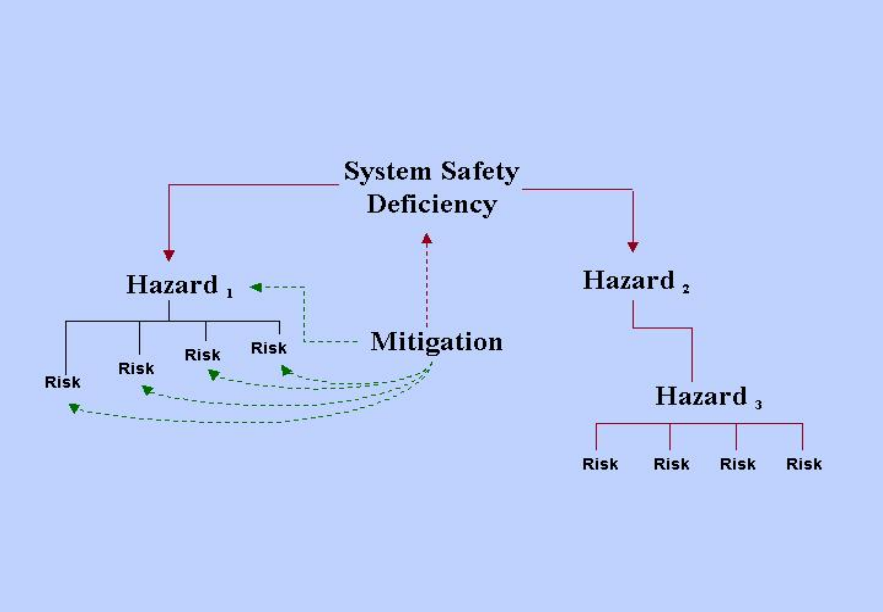
Safety management systems have the potential to more fully integrate proactive safety management into all aspects of service delivery (Mein and Kelly, 2006; Kelly, 1999; Kelly, 2002). This can be done by adapting methods from system safety engineering, safety-risk management and business management so that companies consistently identify and manage system safety deficiencies (Figure 1).

After all, optimum reliability of people, equipment and organisations still needs to be "engineered". But there also needs to be new mechanisms to identify and address the "holes in the defences" that continuously arise or diminish in every company, every jurisdiction, and every industry. Hazards – the conditions that can lead to loss, whether they are based in the human condition, the equipment, the operational setting or the organisational context – are predictable. They need to be identified and managed proactively. Therefore, transport industries must have the capability to:

- Consistently identify the key hazards that are characteristic of an operation, as well as those that are distinctive to an individual service provider;
- Assess the relative significance of hazards (or their combination), so that defences appropriate to the operating environment and the resultant risk can be developed and implemented;
- Manage these defences (usually by means of policies, procedures and practices) to obtain maximum reliability from people, equipment and the organisation;
- Obtain feedback on and assess the significance of the "breaches in the defences" that inevitably occur; and
- Continuously measure the results of risk mitigation strategies and activities, whether they relate to the day-to-day operation, or to the strategic risk management of the company.

Well-designed SMS must be comprehensive, and deal with all the business, human and organisational aspects of providing a service, not just those that are technical and operational.

Figure 1. **Putting the "reason" into safety-risk management:**



Note: By the mid-1990s, some safety management practitioners recognised the need to align safety-risk management terms with the concepts underlying Reason's model of accident causation. They defined a new term - system safety deficiency - as "the condition or circumstance that enables hazards of a like-nature to exist". Operational safety analysts conducting safety reviews, hazard analyses and accident investigations could identify what Reason called "latent conditions". Importantly, they could assess the significance of an SSD in terms of the related hazard exposure, and consequent risk. By identifying and mitigating an SSD, a company's exposure to numerous hazards could be significantly reduced.

System safety deficiencies that cause hazards-in-the defences are often rooted in the development or implementation of rules, policies and procedures, far removed from the day-to-day operation. They also emerge when a company experiences change, of any nature. A well-designed SMS has the potential to explicitly anticipate their existence. Such proactivity enables companies to consistently design safety into their future operations (or reorganisations). With time, the accumulative effect of such techniques – the successes and the "mis-starts" – enable companies to see trends, and better understand their own operation, their organisation, their management. Properly analysed, companies can improve their safety management and safety performance in ways that enhance both operational and business efficiencies.

Techniques embedded in such SMS enable a company to "customise" mitigation to address the hazards and risks they actually experience, rather than just rigidly – and blindly – complying with standards. A company's safety management activities and priorities can be explained – to clients, stakeholders, shareholders, board members, unions, and regulators – even the public. Customised safety management produces the "safety case" that can reinforce the "business case" to exceed regulated minima, or to justify an exemption from one or more rule or standard. Importantly, it can introduce policies or procedures to address the deficiencies in performance where there are gaps between co-existing rules, regulations and standards.

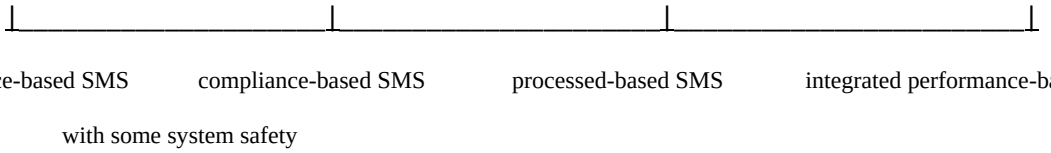
3. SMS in the transport industry

In most cases, transport service providers operate SMS that have been shaped by specific regulatory requirements. Therefore, differences in content and functionality of an SMS often reflect differences in the regulatory regimes and cultures that "sired" the SMS, or in which the SMS currently functions.

An examination of safety management systems in the transportation industry and other safety critical industries reveals a broad range of features and functions. Similar characteristics have been clustered and described as SMS typologies in a continuum, where each category displayed from left to right in Figure 2 exhibits progressively more:

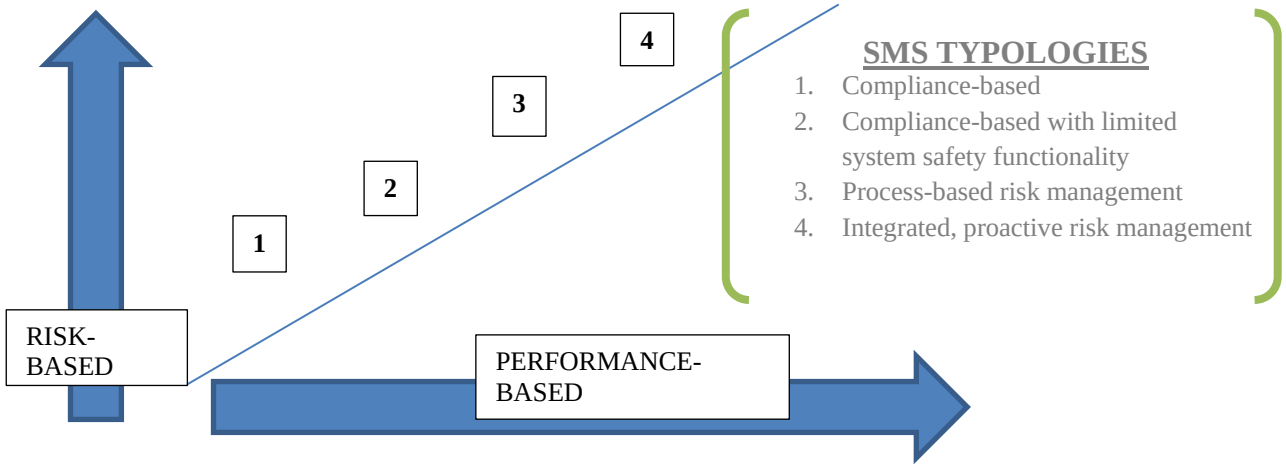
- focus on hazards and safety risk management,
- application to the whole company as an operational *and* a commercial system, and
- focus on measureable performance.

Figure 2. **Continuum of SMS typologies**



A descriptive label has been attached to each. However, readers are cautioned that the boundary between each category is arbitrary. They should not expect a single, existing SMS to fall neatly and completely into a single category. Most SMS possess characteristics and functionality described in two or more typologies.

Figure 3. **Generally, the SMS typologies are increasingly risk-based and performance-based**



Industry and regulatory policy-makers may wish to use the continuum to determine the approximate level of SMS development in their industry or jurisdiction. With this context, they may see features from other domains or jurisdictions that could guide future improvements in SMS or SMS regulations. Information from this section and section 4 (which describes SMS-regulatory-types) enables policy-makers to anticipate and prepare for predictable challenges they may encounter in the future, as discussed in section 5.

Despite the considerable variation from industry to industry, as well as across geopolitical systems, most (regulated) SMS share key components, including:

- some form of senior management or executive accountability for the SMS,
- a safety policy that explicitly commits the company to safety,
- documented safety responsibilities within the company,
- procedures for reporting and managing occurrences,
- processes for conducting risk assessments, developing risk control strategies, and monitoring mitigation strategies or activities,[6] and
- safety documentation.

3.1. Compliance-based,[7] standalone SMS

The number of companies that operate these types of SMS is decreasing. Generally, they are legacy safety management systems, operating in jurisdictions with strong, prescriptive regulations. They usually comprise minimal SMS components.[8] They are often viewed by the industry, and even by seasoned regulatory staff, as a necessary "burden".

Consequently, companies pay lip service to the SMS, which plays little or no part in safety management. SMS-related activities have the appearance of a well-rehearsed dance that has been completely choreographed by the regulator and the industry. The parties know the dance steps, but in the absence of music, activities are mechanistic, and provide no satisfaction.

The regulated company demonstrates the documented components of an SMS. In many cases, the company need not provide proof to the regulator that the components are consistently employed. Inspectors complete their checklists to document the degree of compliance with requirements. The SMS is peripheral to the traditional operating and engineering aspects of the company.

3.2. Compliance-based SMS with limited system safety functionality

These types of SMS are often found in industries governed by detailed, prescriptive operational and technical standards and procedures. The overall regulatory programme is compliance-based. In some cases, companies may be required to demonstrate they use the SMS components. Companies employing such SMS usually operate quality assurance programmes, particularly in the company's technical departments. Although safety is equated with reliability, the companies employ several features of system safety so that hazards related to the design and maintenance of select technical systems can be identified, the associated risks assessed, and mitigation strategies developed. However, these technical

analyses are not generally integrated with the SMS, which is operated as a stand-alone management device "added-on" to other, regulated company programmes.

Hazard analyses seldom include operational matters. Nor do they examine the man machine interface (MMI) between individuals and the equipment they operate. Where they do, they seek to optimise safety by "engineered" human reliability. Processes for reporting hazards or safety concerns may exist. However, staff seldom submit reports, sometimes because they consider the error they should report to be a sign of "unprofessional" behaviour, and sometimes because they don't want to be seen as a "complainer".

The understanding of accident causation and prevention is grounded in the reliability model. Consequently, safety is measured by auditing and by investigating occurrences to identify human or equipment failures, or instances of non-compliance.

3.3. Process-based SMS

Many, perhaps most safety management systems employed in transport industries today are represented in this category. The focus is on adherence to processes. The SMS is more than just an assembly of semi- or completely-autonomous parts. The SMS of such companies share many of the features of a quality management system (QMS), most notably processes for continuous improvement,[9] and voluntary reporting.[10] Reporting programmes are supported by non-punitive reporting policies. A small safety office may be responsible for administering the SMS.

Voluntary reporting programmes enable safety-related information to be collected across the company (laterally and vertically). However, hazards and safety concerns are generally under-reported compared with the mandatory reporting of incidents or events. Complete sectors of the company (functionally or hierarchically) may not submit reports at all.

Regulatory requirements usually determine the procedures a company uses to manage the SMS. However, adherence to SMS processes does not necessarily indicate that SMS components are achieving their intended purpose–which in some cases are not explicitly documented.

These SMS feature the *explicit* identification of hazards and assessment of risks, although frequently, only in prescribed areas.[11] In those companies with comprehensive change management policies, hazard analyses of engineered or operational systems beyond the regulated requirement may be conducted. The effectiveness of the analyses and assessments will depend on the nature of the company's change management policies. For example, a hazard analysis can be costly. Therefore, the conduct of a hazard analysis in some companies is triggered by the project's monetary value, not by the degree to which the project could embed hazards in the company's future operation.

A few companies may explicitly apply human factors in hazard analyses and safety studies. Most often, the focus remains on human error (i.e., failures of anticipated human performance). The "analysis" of human error (i.e., the prevailing perspective of human factors) is descriptive, and based on assumptions of human "unreliability".

Some safety data may be hazard-based, but more often, data are event-based. Frequently, SMS-related software is used to track findings or observations regarding adherence to SMS processes. Almost always, the management of other safety information is distributed across the company.

A considerable amount of data (e.g., quality assurance and failure-based data) is not analysed to explicitly identify hazards and SSDs. Neither is information regarding operational or technical systems, which is collected by individual programme managers. Deficiencies identified in the SMS are seldom assessed to reflect the potential significance on the company's safety performance

The SMS may include a process to select company safety goals or targets. The processes may result from a regulated requirement, or from a company policy. In practice, the safety goals may not target the company's most critical safety vulnerabilities, in part because the areas *within the* company most needing improvement have not been identified or prioritised. Instead, safety targets are frequently chosen because they are "do-able". Company executives hesitate to commit to far-reaching or high-risk safety-management projects[12] for fear that failure to achieve the goal will result in criticism by the regulator, and by the Board of Directors. Executives reason "it is better to surpass low expectations than …".

The determination of corporate safety priorities differs from company-to-company. In the absence of comprehensive, system-wide hazard-based information, decisions are often driven by past practices, "favoured projects", or the influence of assertive senior managers or executives.

In some cases, safety targets focus on the SMS. This approach is often endorsed and sometimes demanded by a regulatory agency that requires the company to demonstrate it is improving the *quality of the SMS*. Consequently, the company focuses on improving SMS processes. It is assumed that improvements to SMS, and particularly to SMS processes, improves the company's safety performance.[13]

The understanding of accident causation and prevention in companies with these types of SMS includes supplementing reliable technical and operational systems with reliable SMS processes.

3.4. Integrated, performance-based and risk-based SMS

Very few (if any) companies operate SMS that fall into this category, although some feature aspects of the functionality described in section 2.2. This SMS ideal type is described below in some detail because it may represent the future of SMS. Regulators will be challenged in directing, guiding and encouraging industry to achieve the functionality described below.

The leadership of companies with such SMS understand the dynamic nature of managing safety risk in complex environments, depicted in Reason's swiss cheese model. The company's strategic safety goal explicitly enshrines measureable safety-risk management throughout the company.[14] SMS processes explicitly sustain and measure safety-management functionality. Consequently, processes are recognised to be the means, not the ends of system-wide, proactive safety management. In some cases, this perspective can cause "functional tension" with process-focused regulatory requirements.[15]

In some companies, an independent "system safety" office reports to the executive in an advisory capacity. The office has no responsibility for managing safety-risks. Rather, the office guides senior

managers and staff throughout the company to make well-informed, resource-based decisions that have safety-risk implications. It is management and staff who manage safety-risks. The safety advisory office advises executives (both operational and support) on the company's safety management performance, and on the company's safety performance. In other words: on system safety. The role and activities of the office extend well beyond the administration of the regulated SMS.

To varying degrees, hazard-related data are collected and used in the operational, engineering and maintenance departments, along with more traditional data. Often the departments retain the data, but the centralised safety advisory office manages (i.e., collects, analyses and reports) information regarding system safety deficiencies, the scope of which may apply to a single department, several departments, or to the complete company.

The analysis of system safety deficiencies frequently employs formal techniques to identify and understand human or organisational factors. SSDs that are company-wide are frequently rooted in company policy and practice – including those related to the management of humans, finances and change. In some companies, staff from operationally-oriented departments as well as the corporate safety office systematically examine the findings of audits, inspections, occurrence investigations and technical failures to identify hazards and SSDs.

Change management employing proactive hazard analyses applies to organisational changes as well as operational or technical changes. Change management processes may be triggered by external change, originating from suppliers, stakeholders, and even regulatory bodies. Hazard analyses are scoped and customised to suit the complexity or safety significance of the proposed change. In recognition that corporate decisions significantly shape the change, some analyses explicitly seek potential SSDs. The principles of system safety, originally applied solely to engineering, are employed to design optimum safety performance in all aspects of the company's future operation.

Internal departmental or corporate self-assessments (i.e., performance-based audits, and in some cases, evaluations) are conducted to confirm compliance with internal or regulatory standards, but also to identify SSDs in the content or application of operational or technical policies, or of the SMS. Safety studies are initiated when new information or understanding is required.

Companies often employ a Safety Plan to help achieve their strategic safety goal on an ongoing basis. Such Safety Plans usually contain multi-year objectives that require multi-department participation and cross-department coordination. Explicit safety planning is embedded in the company's strategic and business planning.

Safety objectives extend beyond merely technical or operational matters. Some companies employ information from centralised SSD data bases to guide the determination and prioritisation of safety objectives. Other, usually smaller companies employ qualitative and quantitative data to determine safety objectives.

The understanding of accident causation and risk reduction is framed in the context of organisational factors.[16]

There are very few companies that are pushing the boundaries of integrated, performance-based safety management, described above.

Those that do employ SSD information to map and prioritise critical safety and safety-risk management vulnerabilities. The information populates the company's safety-risk profile, which, among other things, is applied to the business plan to predict systemic, future vulnerabilities. This information goes a long way to informing decisions to select multi-year safety goals in the corporate Safety Plan. The Safety Plan (and subsequent reports of achievements) is shared with stakeholders, including the regulatory authority.[17]

Often a department within the company is identified as the lead for each safety goal, and other departments (including those from HR and finance, if applicable) determine their contribution. Activities within each department are identified, and the human and financial costs are forecast with sufficient time to be included in the annual budget. The annual performance objectives of managers and supervisors within each department include activities related to the goals and objectives in the Safety Plan.

As subsequent activities are completed, and success in mitigating risk assessed, the company's safety-risk profile is updated to take account of diminished as well as emergent SSDs. The information guides decisions to modify activities to achieve existing safety goals, and to determine the nature of "new" safety targets.

SMS self-assessment tools are employed to measure the necessary functionality to achieve the company's overarching, strategic safety goal. Because performance can be measured on a scale of, for example 1 (functionality does not exist) to 7 (where complete functionality is identified), positive and negative indicators of performance are obtained. This allows for lateral comparative analysis within the company and for comparative analysis over time. A description of such a performance-based evaluation tool is found in Appendix A.

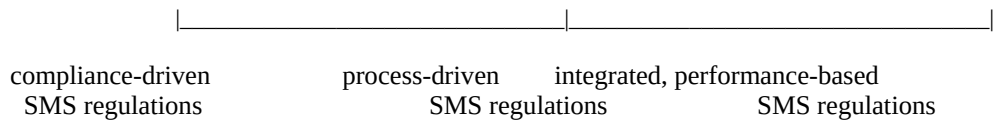
Such SMS have moved completely away from fixating on compliance, to identifying trends in safety management performance. The various characteristics of the four SMS types are presented in tabular form in Appendix B.

4. Regulating SMS

This section provides just an overview of generic types of SMS regulations. It provides the context for the discussions in the section that follows on the challenges of regulating SMS.

The reader is once again cautioned against "forcing" an existing regulatory programme into one of the three categories described below. It is unlikely that the features of a single set of SMS requirements are completely captured in just one of the ideal types depicted in Figure 4.

Figure 4. **Continuum of SMS regulatory typologies**



4.1. Prescribed and compliance-driven SMS regulations

Regulatory authorities often employ prescribed requirements to introduce SMS regulations, particularly if the existing regulatory programme is strongly prescriptive. SMS requirements are usually an "add-on" to the existing regulatory programme, and administered separately by a small office at headquarters, sometimes comprising just one person.

The regulatory objective is to measure compliance with SMS regulations. Regulatory expectations may vary from jurisdiction to jurisdiction. They may be minimal, where a company need only demonstrate that the SMS components are documented,[18] and that mandatory reports have been submitted to the Authority. Or they may be more detailed, where a company must follow the Authority's direction on documenting the SMS and conducting and reporting SMS-related activities.

Often, the SMS is not perceived as a regulatory priority – by the industry, or by the regulatory agency. Technical or operational Inspectors in the field normally include the SMS components on their technical or operational inspection checklist.

This type of programme can be appealing because:

- It aligns with an existing compliance-base, regulatory culture;
- It can usually be introduced relatively easily, and once the inevitable administrative glitches have been worked out, the industry and the regulatory body are able to get back to "business as usual"; and
- It may reflect as much change as the industry or the regulatory body has the wherewithal to absorb.

However, there are obvious shortcomings.

- The SMS regulations do not introduce new functionality. Systemic safety vulnerabilities−often unidentified−persist because of continued reliance on non-integrated, technical and operational standards.
- The prevailing mindset that equates compliance and reliability with safety continues.
- Particularly in the case of a minimalist approach, industry and regulatory staff often are confused and frustrated when there are differences in the interpretation of guidelines.
- In the case of very detailed, prescribed requirements, the industry and the regulatory agency experience considerable additional costs.
- Perhaps, most significantly, this artifact-based approach to system safety may become institutionalised. In such cases, change seldom occurs except as the result of an investigation or commission of inquiry into a high profile accident, or a high level regulatory review.[19]

The resulting changes are often perceived by industry representatives, as well as by the senior managers and staff of the regulator agency, as impositions by "outsiders".

4.2. Process-driven SMS regulations

This type of SMS regulation is often found in jurisdictions that have revised or completely rewritten previous SMS regulations, or are relative newcomers to SMS. They often draw heavily on the principles or components of quality management systems (QMS) or, to a lesser degree, on quality assurance (QA) programmes. Many SMS regulations in transportation are found in this category.

The regulatory objectives vary, but frequently continue to focus on regulatory compliance – either compliance with SMS requirements, or with SMS and other regulatory requirements. For instance, the objective of the 2015 Canadian Rail SMS regulations in Canada – regulations that completely overhauled earlier SMS regulations that had been in force since 2001 – was to "… improve compliance and contribute to more effective enforcement …." (Canada Gazette, 2015).

Process-driven regulations focus on the company's management of its SMS. They often dictate the procedures, plans and methods to support the SMS components. The intent is to formalise a systems approach by regulating processes.

Elements of the reliability model persist. For instance, with the exception of specific issues such as human fatigue, human factors often continue to be viewed from the perspective of human error (i.e., an absence of human reliability) – something to be eradicated by additional procedures or training, or by improving a person's professionalism.

SMS regulations in this category contain at least some elements of explicit safety risk management and safety assurance. For example, risk assessments are required for certain types of change, particularly technical or operational. Voluntary hazard reporting is emphasised.

The SMS regulatory programme focusses on adherence to SMS processes. The principal tool is an SMS audit. The audit team normally comprises persons with expertise in SMS requirements, supported by inspectors or surveyors with technical or operational expertise. Some regulatory authorities have experimented with performance-oriented tools to measure the effectiveness of the SMS, but with little success. The measurement of SMS performance is discussed on pages 40-45.

Increasingly, regulatory authorities in this category employ risk-based protocols to determine the scope and frequency of SMS audits. They consider such factors as the company's compliance history, the occurrence record, SMS deficiencies and inspection reports. However, individual company profiles are usually not analysed collectively to determine higher-level, perhaps industry-wide, deficiencies in safety or SMS performance.

Managers and staff who administer these types of regulatory programmes emphasise the following strengths compared to a compliance-based approach:

- The focus on processes creates better balance between prescriptive and performance-based requirements;
- Audits of SMS processes enhance consistency in the application and oversight of SMS;

- SMS audits provide a mechanism to dismantle the vertical silos that traditionally exist in regulatory organisations; and
- There are explicit requirements for elements of safety-risk management and safety assurance.

However, there are shortcomings in their current application.

- By targeting compliance with SMS processes, the reliability model of safety persists, although in more subtle form. The focus on safety assurance using reliable technical and operational systems shifts to safety assurance using reliable processes in the company's safety management system.
- Safety Improvement (SI) targets are required. But SIs often center on SMS *processes*.
- Many SMS audit tools do not enable the consistent measurement of the processes' effectiveness.
- The focus on system-wide SMS processes detracts from the collection, analysis and mitigation of hazards and SSDs – a critical function of an effective SMS.
- Where there are requirements for hazard identification, analysis and mitigation, they are not applied comprehensively throughout the company.
- Human factors are not systematically employed to explicitly identify hazards, or to determine the organisational or operational context for their existence.

4.3. Integrated, performance- and risk-based SMS regulations

Very few regulatory authorities have designed SMS regulations that are both performance-based and risk-based. Some have tried, but to my knowledge, none has been fully implemented. The information in this section draws heavily on the experience of two Authorities – one that was under close public scrutiny after a high profile fatal accident; and the other that was straining under pressures caused by an unprecedented growth of commercially-operated, passenger-carrying aircraft on its aircraft registry.[20] Conflicting demands and expectations by governments, stakeholders, clients and the public caused the leadership to examine ways to efficiently allocate resources, based on their industry's exposure to hazards and safety-risks. This led to instituting performance-based, risk-based SMS requirements.

The objective of such regulatory programmes is to effectively oversee the industry's management of safety-risks to a level as low as reasonably practicable.[21] The requirements focus squarely on the company proactively and systematically identifying and effectively managing the hazards associated with the delivery of transport services. The safety management framework is top-down, and knits all components of service delivery together, including the services provided by contractors and sub-contractors.

It employs common definitions of a hazard, system safety deficiency and risk. It requires companies to conduct hazard analyses and risk assessments during organisational and commercial changes, as well as during operational or technical change. Hazards and SSDs that account for human and organisational factors are identified, assessed and mitigated. Information is managed and analysed so SSDs are assessed in terms of safety significance.

Companies are required to determine, prioritise and manage areas of systemic safety vulnerability. Company Safety Plans containing risk-based goals and objectives are required, as well as periodic reports of achievement. Such Safety Plans are integrated with the company's processes for strategic and business planning.[22]

Companies are expected to measure the ongoing effectiveness of their SMS. The company is encouraged to conduct self-assessments using performance evaluation mechanisms that are similar to those used by the regulator.

There are a number of strengths.

- The regulatory framework aligns with contemporary understanding of accident causation and prevention, transcending, though not replacing, compliance with technical and operational standards.
- Safety management is explicitly integrated with other resource-driven decision-making by the service provider.
- The regulatory authority and industry share common definitions, mechanisms, data and performance measures.
- There is potential for long-term cost reductions to industry, and to the regulatory authority.

There are also a number of challenges.

- Because SMS regulatory programmes are compliance- or process-based, the regulatory programme needs to be completely redesigned. It may be another generation before the results are fully realised.
- Very few regulatory environments support the transparent exchange of such safety-related information.
- There is a dearth of persons with the skills to design, implement and operate such a programme.
- Such programmes rely on performance-based evaluation tools, which are in their infancy in the transportation industry.

5. The challenge of regulating SMS

This section examines the challenges that many regulatory authorities experience when regulating SMS. I describe general challenges that apply to most regulatory agencies of safety-critical industries (i.e., not just transportation industries), then discuss those that are often encountered during the design and implementation stages. Strategies to address the challenges are explored. I conclude by examining frequently encountered challenges that are experienced as the SMS programme matures.

5.1. General challenges

Regulatory authorities face a number of high-level challenges when introducing SMS requirements. Some occur because of SMS-specific circumstances. Others are more cultural.

Political and economic pressures

Regulating SMS significantly alters the way an industry is regulated, and therefore operates. The SMS regulatory programme takes many years to design, develop and implement. During this time, senior management of the Authority may be pressured to modify and even halt the introduction of SMS.

Pressure is often exerted early-on by a variety of stakeholders, including, among others:

- industry associations, which express concern that SMS are not necessary, perhaps counter-productive, and possibly a threat to the economic viability of their constituents;
- advocacy groups that perceive SMS as an example of government intrusion into the sanctity of company boardrooms;
- interest groups that are fearful SMS will dismantle society's "tried-and-proven" safety nets; and
- representatives of regulatory staff who fear SMS will lead to the long-term loss of jobs.

The concerns are commonly championed by the media, and may cause political anxiety.[23]

Even when ongoing consultation between the regulator and industry is effective, it only takes one high profile fatal accident, or a series of smaller accidents to pepper the nation's headlines, and ignite (or reignite) concerns about SMS.

Experience and skills

Most managers and staff from regulatory organisations and industry have little or no experience in SMS. Additionally, they often lack experience in conducting hazard analyses and risk assessments, and in applying human factors to safety management, particularly in the context of organisational factors. Therefore, after new roles, responsibilities and activities have been determined, the regulatory authority must determine the competencies and skills they need. They also need to adapt or create new regulatory tools that will function effectively in the transport environment.

Some Authorities consider contracting third parties organisations to perform future SMS-related regulatory activities, as illustrated in Appendix C.

Embracing regulatory change

Culturally, the industry may not be motivated to undertake such radical change. Transport sectors, like most others that include techno-centric industries, are experienced-based. The managers and staff, even the regulators, have a collective, unspoken comfort with the way things have been done−in the past and in the present. Their confidence has been acquired by hands-on experience. They are not easily swayed by policy papers on the *concepts* of safety management and *theories* of accident causation. As professionals, they understandably react to suggestions that they lack the skills to effectively manage

risk; especially if the assertions originate from the very authority that until now, has stamped their past activities as "safe".

The regulator-industry relationship

The relationship between the regulator and the service provider is often characterised by an inherent, often ideological tension.[24] Service providers of course focus on commercial objectives. They see themselves as practical entrepreneurs, driven by day-to-day exigencies. Many view their safety processes (including those required by regulation) as an important part of doing business – but nothing more, or less. They often perceive regulatory managers as being driven by administrative goals and processes, some of whom appear insensitive to the costs in time and money of introducing initiatives such as SMS.

Perceived grievances vary from jurisdiction to jurisdiction. Some wonder whether SMS will suffer the same fate of past initiatives that ultimately failed, and will be withdrawn. Others express concern that SMS is just another "flavour of the month", destined to wither when a new initiative appears over the horizon and captures the regulatory authority's attention.

Yet others worry that their business and operational activities will be inappropriately scrutinised by the regulator, that in the future, they will experience insidious "regulatory creep", where more and more is asked of them with no apparent gain in safety.

Some anticipate that they will be the guinea pigs as eager inspectors learn to regulate SMS− at industry's expense.

The nature of the existing regulator-industry relationship will determine the degree of distrust or anxiety that cloaks the SMS initiative. Even solid, trusting relationships will be taxed in the years that follow, as the industry and the regulator embark on what many consider to be a massive regulatory experiment, conducted in real time. In a safety-critical industry.

Risk aversion in regulatory agencies

Most regulatory organisations tend to be risk averse. Mandates, roles and responsibilities are framed by legislation. Regulatory programmes develop incrementally, usually over many decades. Senior managers favour tried and proven methods – methods that have been tested in the field and in the courts – over intellectually stimulating but unproven concepts. Regulatory change is usually purposeful, iterative and slow.

Such risk-aversion is completely understandable. Senior managers are accountable to politically elected representatives, and to the administration's executive cadre. They are accountable to the industry they regulate; and they are responsible for the activities of the agency's managers and staff. They almost always function with limited resources, be it time, money or personnel. When things are seen to go wrong in a regulatory programme, the media is there to explore, very publically, the weakness in the way the safety agency fulfils its mandate.

Into this environment SMS has arrived. Traditionally, wholescale changes to regulatory programmes most frequently occur after a commission of inquiry is convened to explore the causes of a catastrophic loss. The findings almost always implicate the regulatory programme. It is not surprising that the first

SMS regulations in marine and rail resulted from high profile accidents. The initiative in aviation was more conceptual, more strategic. It emerged from a growing recognition that existing regulatory programmes were stove-piped and did not take adequate account of changing perspectives of accident causation. There were underlying murmurs that the ongoing increase in commercial air traffic would lead to a frequency of accidents that the fare-paying public (and governments) would judge unacceptable. Something had to be done to reduce the rate of aviation accidents, and improvements had to be more than just technical.

Senior managers of regulatory authorities in all modes of transport have been thrust into leading what is arguably the singular, most significant initiative in safety regulation in the past fifty years, perhaps more. They are doing so while economic, political, societal, technical, organisational and cultural circumstances are arrayed to threaten the long-term success of the initiative. As Reason said in a slightly different context: such is "the regulator's unhappy lot" (Reason, 1997).

Addressing the general challenges

Regulatory authorities often employ two strategies to address the general, high level challenges described above.

Some employ comprehensive strategic and communications plans to actively engage stakeholders in the design and implementation of SMS.[25] Customised communication strategies, plans, activities and feedback loops support their decisions.

The composition of management teams is often adjusted. Consequently, managers with decades of experience in the existing regulatory programme work side-by-side with managers who are adept at managing long-term change in dynamic, sometimes adversarial circumstances.

5.2. Challenges of designing an SMS regulatory programme

The principal challenges that regulatory authorities face when designing the SMS regulatory framework are examined in this sub-section.

Scope, focus and activities of the SMS regulatory programme

For optimal performance, an SMS should draw on information from all parts of the company so that managers can explicitly, systematically and proactively manage the hazards to which the service provider is exposed.

Most regulatory designers find it difficult to introduce such radically different requirements. They recognise that for the regulations to be successfully implemented, they must:

- meet the regulatory objectives,
- be compatible with the existing regulatory framework and programmes,
- be accepted by the industry, and
- be understood by managers and staff in the industry, and within the regulatory authority.

Consequently, they usually opt for less rather than more. The objectives of the SMS regulations seldom differ remarkably from those of traditional, compliance-based regulations. The goal, often

unstated, remains to "help minimise the likelihood of accidents". The underlying assumption is that the goal will be achieved by adhering to technical and operational standards. The SMS requirements may include additional components such as a Safety Policy, management responsibilities regarding safety management, and safety documentation. But SMS requirements merely supplement the compliance-based approach with the intent – sometimes stated, sometimes not – that the SMS will facilitate "industry's ability to comply with regulations and other requirements".

This is not surprising. SMS requirements are usually tacked on to the existing regulatory programme. SMS schema emphasise the reporting and analysis of "non-conformities, accidents and hazardous *occurrences*", not the proactive identification of hazards.

Because SMS regulations intend that the industry reduce the likelihood of accidents by complying with regulations,[26] the *primacy* of stove-piped technical standards persists. The attention is on very (sometimes very, very) granular activities at the "pointy end" of the operation. SMS designers inherit a "bottom-up" regulatory framework that is divided into rigorously protected functional silos. To this they add the SMS requirements. Frequently, SMS is administered as a completely separate sub-component of the larger regulatory programme.

Addressing the challenge of integrating SMS requirements

Regulatory authorities frequently need to overhaul or rewrite the SMS requirements. Some take this opportunity to create a safety management framework to systematically collect information on hazards and SSDs from numerous sources. This is discussed more fully in the sub-section on proactive safety management, which follows directly.

Other regulatory authorities institute formal mechanisms to exchange information between regulatory branches. Some findings of SMS audits are provided to technical or operational inspectors in the field for follow-up; and inspection findings may shape the scope or direction of a future SMS audit.

In some organisations, comprehensive audits are led by staff with SMS expertise, supported by specialists with technical or operational expertise.

Proactive safety management

As Maurino (2016) notes, an essential component of an SMS is the explicit and comprehensive identification and management of hazards. Yet very few regulations call for or enable the comprehensive collection and analysis of hazard-related information. In fact, the word "hazard" is sometimes not even mentioned in the requirements.

This could be in-part the result of conceptual and definitional confusion regarding hazards on the one hand, and incidents or occurrences on the other. Regulatory programmes traditionally require the reporting of occurrences (i.e., accidents, incidents, and in some cases, specific events). Most SMS requirements add a provision for the voluntary reporting of hazards, and in some cases safety concerns. However, regulatory staff and industry representatives seldom differentiate between reporting a hazard and an occurrence. Consequently, very few hazards are reported during the early stages of an SMS. Frequently what is submitted under the guise of a hazard describes an occurrence.[27]

This is important for a number of reasons. An occurrence is normally investigated to determine cause. Aggregate causal information is frequently analysed to identify descriptive trends. Information regarding the presence of hazards is not systematically collected, nor indicators of underlying system safety deficiencies sought. Occurrence databases, even those with taxonomies, contort "causal" findings with descriptors, and obscure and conflate SSDs, hazards and risks.[28] A lot of time and effort goes into an incident investigation to collect very little useful information *vis-à-vis* explicit safety-risk management.

Furthermore, regulators and industry seldom recognise that hazard information can be derived from numerous and diverse sources of information that already exist. In fact, a voluntary hazard reporting programme—frequently included as a regulated SMS requirement—is one of the most expensive yet least effective mechanisms to collect information on hazards.

Addressing the need for proactive safety management in SMS

Some authorities recognise the need to clarify safety-risk management terms (e.g., hazard, risk, mitigation), as well as to introduce terms that enable the identification and analysis of organisational factors (e.g., system safety deficiency) (Figure 1).

A few companies and regulatory bodies take available safety-related information and, by using definitions of a hazard and system safety deficiency, convert the information into safety-risk management terms. This enables managers to understand, analyse and assess very different forms of information. The information provide multiple lines of evidence to precisely define an SSD. Managers use the information in the day-to-day management of hazards and risks, and in the identification and prioritisation of systemic risk management issues. It is a major factor in actively and explicitly managing safety-risks to a level as low as reasonably practicable.

And they can demonstrate this capability, this safety performance.

Table 1 illustrates the type of safety-risk management information that can be obtained from readily accessible sources. In those instances where the source generally yields hazards and SSDs, that which is most frequently obtained has been highlighted.[29] Similar processes employed by regulators are discussed on pages 47-50.

Most regulators do not require companies to proactively identify hazards before implementing technical and operational, let alone organisational, change. Consequently, most change occurs without a systematic and comprehensive examination of the hazards, and potential SSDs that predictably could exist when the change is implemented.[30] This is understandable because of the specialist nature of traditionalist system safety methodologies that are employed to proactively design safety into new or revised engineered systems. (System Safety Society, 1999.)

Nevertheless, several small organisations have developed practical, easy-to-use guidelines for conducting and documenting a hazard analysis, so appropriate mitigation strategies can be developed when introducing change (IBAC, 2003).

Table 1. **Sources of safety-risk management information**

Information source	Hazard	System safety deficiency (SSD)
Safety inspection (regulatory, internal, other 3rd party)	√	–
Safety audit (regulatory, internal, other 3rd party)	√	√
Operational occurrence investigation report	√	√
Occupational health and safety occurrence report	√	√
Hazard or safety concern report	√	√
Quality management system (QMS) report	√	√
Quality assurance (QA) report	√	–
Dangerous goods (DG) report	√	–
Operations meeting	√	√
Stakeholder communication	√	√
Decision record - Operational managers meeting	√	√
Decision record - Operational executive meeting	–	√
Decision record - Executive Team meeting	–	√
Decision record - Safety committee meeting	√	√
Decision record – stakeholder meeting	–	√
Industry associations	–	√
Safety study, safety analysis (internal and external)	–	√
Conferences (safety, operational, technical)	–	√

The temptation of changing the "Q" in QMS to an "S"

Numerous regulatory authorities have considered adopting or adapting quality management systems (QMS) when designing SMS requirements. QMS is defined as "a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organisation's purpose and strategic direction" (ISO9001:2015). Adapting a QMS is attractive for several reasons.

Many regulatory bodies already operate at least some aspects of a QMS. As staff start to research future regulatory requirements, they recognise similarities between QMS and SMS, including the requirement for policies, processes and procedures to plan and deliver services, as well as mechanisms for continuous improvement. Their familiarity with, and often strong support for QMS encourages designers to frame the SMS requirements around quality management.

Additionally, industry representatives who already operate QMS may lobby regulators during the consultation process. In such cases, it is eminently sensible for a regulatory body to obtain industry buy-in by adapting SMS to become what some must perceive to be a QMS on safety steroids.

It may also be argued that a QMS/SMS framework can bridge the functional silos that characterise most transport companies and industries. Adapting QMS, the argument goes, will result in SMS processes that cross the internal boundaries of the company, thereby institutionalising a systems approach. After all,

> "…a QMS integrates the various internal processes within the organisation and intends to provide a process approach for project execution. [In particular]… a process-based QMS enables … organisations to identify measure, control and improve the various core business processes that will ultimately lead to improved

business performance". (http://the9000store.com/what-is-iso-9001-quality-management-system/)

SMS, it is reasoned, will improve core safety processes and safety performance, just as QMS improves business processes and performance.

The problem as noted by Maurino (2016) is that too often SMS designers forget–or do not realise that– a QMS does not have the functionality of an SMS.

Of course, both management systems appear similar because they both are just that, management systems. But an SMS has a different objective than a QMS, and to achieve the objective, it needs to incorporate explicit mechanisms such as hazard analyses and risk assessments to consistently identify, prioritise and manage hazards. Not only are the objectives different, but so are the outputs, and the outcomes.

SMS regulations that have been adapted from QMS often focus on the processes, and on continuously improving the SMS processes. In this way, they risk confounding means with ends, and instill confidence that improved management processes will assuredly result in improved safety performance. In these cases, SMS regulations focus on artifacts.[31]

Taking this logic to the next step, there are cases where regulated SMS are nothing more than mechanisms to assure or facilitate regulatory compliance. SMS reinforce and promote a traditional mindset that equates compliance with reliability, and reliability with safety. There is danger that compliance-based SMS become institutionalised. The primacy of processes causes rigidity, and constrains the growth of mechanisms to understand the dynamic context in which hazards and system safety deficiencies exist, and need to be managed.

Such regulations have the potential to become a barrier to achieving the full benefits of an SMS.

Addressing the challenge of designing the management aspects of the SMS

It is suggested that when designing, reviewing or revising SMS regulations:

- Ensure the regulatory goal is based on optimal hazard identification and risk management throughout the company.
- Keep the hazard-related objectives top-of-mind, determine the functionality to achieve the objectives, and base the requirements and the resulting regulatory programme on measuring this functionality.
- Integrate compliance with existing technical and operational standards as measures of safety performance, where non-conformities are understood to be, and are managed as indicators of hazards or SSDs.
- Resist the temptation and apparent logic of adapting QMS, or worse, of absorbing SMS requirements into requirements for a QMS.

In parting, it should be remembered that data from QMS (and such other management systems as HR and financial systems) and programmes such as Quality Assurance or Quality Control programmes) can provide important information about hazards and SSDs. As discussed on pages 29 and 47 to 50, some

companies and regulatory authorities periodically review information from quality management systems, quality assurance programmes, and other sources of company-related information, with the purpose of identifying hazards and SSDs. The information is verified, then validated, then input into the SMS so that the company's exposure to SSDs and hazards can be determined, and the risk assessed.

To conclude: QMS processes can provide important safety information. However, a QMS cannot replace or function as an SMS.[32]

Regulating small service providers

Most SMS regulatory programmes initially focus on larger service providers. For instance, Canadian SMS Marine regulations currently apply to just a handful of Canadian registered vessels that are subject to the SOLAS convention. Transport Canada Civil Aviation's focus initially was on large commercially-operated aircraft, followed later by large airports, and then other domains within aviation (e.g., air navigation service providers). Canadian rail regulations, initially introduced in 2001, only applied to three Class 1 Railroads.

With time, regulatory authorities gain confidence from regulating the larger operators, and consider requiring smaller service providers to employ SMS. This generally presents significant challenge.

First and foremost is the problem of aligning SMS requirements with the limited capacity of smaller operators. The term "scalable SMS" is frequently heard across jurisdictions and domains. As a minimum, a small company will need to design and integrate new functionality into the management of its operation; determine new roles and responsibilities; document SMS-related policies, processes and procedures; develop and deliver appropriate training; and importantly, encourage company staff, and perhaps stakeholders, to actively participate in the SMS. All this must be done while the company continues to provide commercial services and remain economically viable. It is usually done by people who have little or no experience in SMS or formal safety management.

The challenge is made more difficult if the requirements replicate QMS, with the associated heavy workload to document and "feed" the SMS processes.

Addressing the challenge of SMS for small service providers

Some Authorities reduce the requirements. For instance, since 2015, Canadian Class 1 railroads must operate SMS comprising 12 processes, but the SMS of smaller local railway companies need only include eight processes, and in some cases, just five.

A number of regulatory authorities go to considerable length to support smaller operators. They prepare guidance material, as well as develop and deliver training that emphasises hands-on, practical activities. In aviation, a number of jurisdictions have hosted one-off or recurring seminars and workshops that target SMS for small helicopter operators, maintenance facilities, or on-demand charters operators (FOCA, 2009).

The Rail Safety Directorate of Transport Canada has created a branch, the principal purpose of which is to communicate the Department's expectations, as well as facilitate, educate and promote safety management and SMS in the industry.

Some regulatory bodies and industry associations promote the benefits of SMS that are less prescribed−SMS that are designed on risk-based and performance-based constructs. Conceptually, this approach suits smaller companies, which can design the SMS to proactively manage the hazards inherent in their operating conditions. It works as follows.

The Authority provides a performance-based, risk-based strategic safety goal that the company is expected to achieve.[33] It also provides the company with minimum SMS components, and importantly, the expected functionality (and therefore performance) of each component. The Authority provides guidance to companies on customising an SMS to achieve the desired performance. One technique enables a small company to conduct a functional gap analysis. Current safety management is compared with that which is required. When the gap analysis is completed, there is sufficient information to develop an implementation plan and schedule. Another technique involves the preparation of a company risk profile to determine and assess critical hazards, so that mitigation strategies can be developed, documented and applied. These strategies always extend beyond minimum technical and operational standards. The guidance may include:

- practical ways by which a small company of several persons can conduct and document a hazard analysis prior to implementing change;
- practical self-assessment tools; or
- techniques to set risk-based priorities−sometimes tactical, other times strategic−to improve the company's safety performance.

The gap analysis and risk profile are included with other SMS documents, which the Authority reviews. If accepted, the company is expected to demonstrate that the SMS achieves the desired performance, that it is periodically reviewed, updated and upgraded to improve its management of safety risks to a level as low as reasonably practicable.

Although some companies thrive in customising, developing and operating such an SMS, many do not. Most operators do not have the time, the understanding or the skill to design, operate and monitor such a risk-based SMS. They prefer the regulator to prescribe the requirements, so they can do what they have to do to comply, and then get back to the "business of doing business".

Which puts the challenge right back to the regulator, who needs to design a single set of SMS requirements for all small service providers – requirements that the industry will not find excessive or onerous.

A number of jurisdictions are revisiting plans to require small transport service providers to operate SMS. They are examining different ways to achieve the same regulatory objective.[34] In some cases, the regulator is considering enhanced safety programmes or accident prevention programmes. In other cases they are examining ways that a service provider can demonstrate proactive safety management without specifying minimum SMS components. In either case, regulatory authorities are considering calling it

something other than a regulated SMS, so there will be no confusion between those who are required to operate SMS, and those who achieve the same objective through other means.

5.3. Challenges of implementing SMS regulations

This sub-section describes two types of challenges regulatory authorities often face when implementing SMS regulations. One relates to the support tools and administrative infrastructure to oversee industry's SMS. It is brief, because the subject is examined more thoroughly on pages 40-45 and 47-50. The second relates to the organisational (i.e., the internal) challenges senior regulatory managers frequently face when implementing SMS.

Misperceptions about SMS

The introduction of SMS has been interpreted by some as a migration to industry self-regulation that runs the risk of regulatory capture.

As noted earlier, a safety management system is intended to formalise a company's responsibility for managing the safety risks of the services it provides. Although this may seem obvious to most, it runs counter to traditional practices that have led regulators to "own" their industry's risk by demanding compliance with detailed safety regulations. For years, inspectors have told companies what they have to do and how they have to demonstrate compliance. Companies for their part have done what they have been told: they comply. The regulator is in the driver's seat.

Societal expectations have reinforced this persistent contradiction. The public is assured that commercial operators are safe because regulators impose comprehensive regulations and standards, and conduct audits and inspections. When things go awry, and for instance, there is a fatal accident, there are loud public demands for more regulations, more inspectors, or both. Accident investigation agencies habitually prepare recommendations that focus on deficiencies in regulations or regulatory programmes.

With the advent of SMS, companies have been encouraged to develop their own safety management processes. Increasingly, they conduct internal audits and self-assessments, sometimes providing the results to the Authority. Regulatory audits are conducted less frequently. Inspectors are no longer nearly as "hands-on" as in the past. They now spend much of the time in their office, reviewing documents and documentation.

It is not surprising, therefore, that the change in roles can be construed as "less regulation", and by some as "self-regulation". Inspectors voice concern that industry is not capable of managing safety-risks well, or of balancing commercial objectives with safety objectives. They can be quite vocal in the halls of the regulatory authority, and sometimes in public venues−particularly in jurisdictions where there is industry/regulatory mistrust.

Consequently, SMS has been seen by some to be a form of regulatory capture. The public becomes concerned that governments consider their interests to be subservient to those of industry. In some jurisdictions these perceptions are exacerbated by media coverage of regulatory policies that restrict auditors from copying and removing company documentation because the information could be made public.

Addressing misperceptions

The potential for misperceptions about SMS were not evident to most of those who originally designed SMS regulations.

Different jurisdictions have responded with different strategies. Some recognise the importance of effectively communicating the weaknesses of past regulatory programmes and practices. They explain that SMS appropriately places the responsibility for managing safety-risk with the industry, guided by the regulator. Others acknowledge (at least internally) that they have spent excessive time (and human resources) reviewing industry SMS submissions. Many now use risk-based decision aids to set priorities, target companies for quality control inspections, and establish audit schedules. Some conduct limited audits to verify information provided by the company.

Some regulators encourage companies to voluntarily provide vital, safety performance information to the regulator and mark it "proprietary". This ensures the company "owns" and controls the information, and can prohibit it from being provided to a third party or released publicly. The regulator has access to safety-related information that otherwise would not be usable, and that might not be uncovered using traditional regulatory techniques.

Regulatory tools

Traditional audit and inspection tools are used to determine whether a company *complies with prescribed* SMS requirements. However, most regulatory bodies are unable to assess the effectiveness of a company's SMS. Those that do, usually supplement audit and inspection processes by applying *practices* to subjectively assess the "quality" of SMS activities or products.[35]

Some Authorities employ system audits (commonly called "value-added assessments" or "management audits") to examine organisational performance. When employed correctly, they can assess the effectiveness of processes.[36] Very few Authorities consider measuring the effectiveness by which a company manages the hazards and risks to which it is exposed, despite the critical nature of such SMS functionality. This is examined on pages 40-45 in the discussion about evaluation tools and techniques.

Associated challenges for most regulatory authorities include:

- determining the frequency with which a comprehensive SMS audit should be conducted
- the composition of an SMS audit team
- determining criteria to consistently judge the pass or fail of an SMS.

SMS-related data

Most regulatory authorities are not wanting for data. In fact, senior managers and safety analysts frequently despair of drowning in data. However, most regulatory safety-related data:

- have been collected to support specific components or aspects of past and present regulatory programmes
- are usually dispersed throughout the organisation

- are contextual and assumption-laden
- do not explicitly or directly relate to hazards and system safety deficiencies.

Sometimes these weaknesses are recognised when the SMS regulatory programme is being developed and implemented. Often they are not. In either case, regulatory authorities are usually hard-pressed to develop and implement suitable IT management to support SMS regulations. This subject is discussed on pages 47-50.

The transition to SMS

As noted earlier, few staff in transport companies and the regulatory body have experience in SMS. Consequently, senior regulatory managers need to motivate the industry to embrace the initiative, and to develop strategies to acquire SMS-related skills. They also need to develop the skills of their own managers and staff. See Box 1 for a description of one such project. Most often, the regulatory authority develops the regulations and standards, then prepares guidance materials that are used in workshops and training courses delivered to industry and regulatory staff.

Phasing-in SMS

The most successful regulatory authorities start the dialogue with their industries long before the implementation stage. For example, the Swiss Federal Office of Civil Aviation (FOCA) began to host annual safety conferences (called SASCONs, or Swiss Aviation Safety Conferences) years before ICAO took actions to require SMS. The first several events were structured around themes that reinforced the proactive principles of safety-risk management. The national conference in 2009, when SMS was being introduced, featured practical presentations for conducting operational hazard analyses, and workshops for the smallest of operators and maintenance facilities.

Most authorities develop a transition strategy to phase-in the regulations. Some require the certificate holder to implement SMS components incrementally over a period of several years. Ongoing regulatory follow-up may take the form of periodic reviews of documents submitted by the certificate holder. Or, in the case of performance-oriented SMS, progressive performance may be evaluated using performance assessment techniques such as those described on pages 41-43.

Some regulatory agencies allow a company one or more years to implement SMS before enforcing the requirements. During this period, the regulator normally hosts information sessions, and is otherwise available to explain its expectations and share best practices. In almost all cases the company must submit periodic progress reports.

Box 1. **LEARNING SAFETY RISK MANAGEMENT TOGETHER: A CASE STUDY OF REGULATORY-INDUSTRY COLLABORATION**

Bermuda is an Overseas Territory of the United Kingdom, with a small on-island civil aviation system that traditionally services commercial passenger-carrying operations to and from North America and the United Kingdom. In 2003, the then-Director of the Bermuda Department of Civil Aviation (BDCA) hosted a multi-day workshop to create a risk profile of aviation operations on or around the Island. Only the most credible representatives were selected from key stakeholders, including among others, air navigation service providers (Bermudian and the U.S. FAA), the Department of Airport Operations, the airlines, the Airport Fire Fighting Department, and of course, BDCA.

In the ensuing days, this group of professionals who had known each other for years, proceeded to uncover and discuss a wide variety of system hazards, some of which were known to all, and some of which were new to many. They grew to understand the interactive nature of hazards, and the need for different stakeholders to mitigate the associated risks. During breaks, they reflected that over the years they had grown complacent about longstanding hazards. The resulting document became the foundation for BDCA and the Island's aviation stakeholders to set priorities to address the more safety-critical hazards they individually or collectively faced.

Perhaps more importantly, participants acknowledged that their perspective on safety had changed, and changed radically. They now shared a common language when talking about hazards, risks and system safety deficiencies. They openly conceded the pitfalls of complete reliance on prescriptive regulations to assure safety. They saw the world differently, and they could talk about it in ways they never envisaged just days before – literally.

They took their stories back to their parent companies and organisations. The change in culture – driven by language, understanding, modified behaviours, and ultimately by principles and values – had started. This took place years before SMS was introduced by the BDCA.

Change management within the regulatory agency

SMS is almost always a headquarters' initiative. Traditionally, change that originates from "HQ" is challenged by regional managers and staff, whose perspectives are formed by their proximity to the industry's day-to-day operations. The radical, comprehensive nature of SMS regulations, in particular with the focus on management policies and processes, may significantly strain relationships that under the best of circumstances can be periodically tested.

There is often "push back" during the design phase. But it seems to be more significant during the implementation phase, when the ramifications of the headquarters' initiative are realised.

As noted earlier, inspectors can sometime be defiant, and challenge the wisdom of this latest HQ brainchild, the competency of industry to manage its own safety, and the motives of companies that appear just a little too willing to embrace a change that may reduce regulatory surveillance. In a number of jurisdictions, inspectors are convinced that SMS will lead directly to a reduction in their workforce.

Managing change in the regulatory authority

Most regulatory agencies address this internal cultural issue by involving regional managers and staff in the design, development, and ultimately in the implementation of SMS regulations. Working groups from across the agency are struck, and report to steering committees comprising HQ and regional managers. Workshops are developed to exchange information and resolve controversial issues. Regional staff are actively engaged in shaping the guidance and training materials that will be delivered to the industry, and to their own regional staff. The technical content is of course important. But even more important is how information about SMS is conveyed to those on the front line.

Of course, such collaboration builds networks, and nurtures understanding and common perspectives. There is buy-in, which aids the discussion of controversial issues in the regions. Importantly, such working relationships engender a healthy culture within parts of the agency, a culture that better prepares everyone to embrace and manage change over what is sure to be a long time.

After-all, these relationships will be challenged during the implementation phase and the years that follow – when many will be under pressure to respond to the demands of regulatory executives and senior representatives from industry.

Ongoing regulatory activity

Throughout the years it takes to design, develop and implement SMS regulations, the regulator continues to conduct the day-to-day activities that previously comprised its "full time job". Supervisors and managers are invariably taxed, sometimes beyond their capacity.

Addressing regulatory under-capacity

Some organisations balance the conflicting objectives by:

- Ensuring executives of the safety authority and government central agencies remain aware of the long-term demands on managers and staff, and of the possibility that industry and others may exert pressure to slowdown or halt the introduction of SMS;
- Obtaining additional resources, particularly managers experienced in project management, change management and communications with external and internal stakeholders;
- Establishing risk-based priorities during the transition to SMS to ensure regulatory activities remain appropriate.

5.4. Sustaining the SMS-focused regulatory programme

This sub-section examines key issues that emerge after industries start operating SMS.

Regulatory tools

In jurisdictions structured on reliability-based regulations, Authorities recognise the need to refine, overhaul or totally replace the regulatory tools they have employed over the years. As noted earlier, traditional audit and inspection processes only verify compliance or conformance with prescribed requirements. They neither measure the effectiveness of SMS processes, nor evaluate SMS performance.

Redesigning regulatory tools

SMS System audits

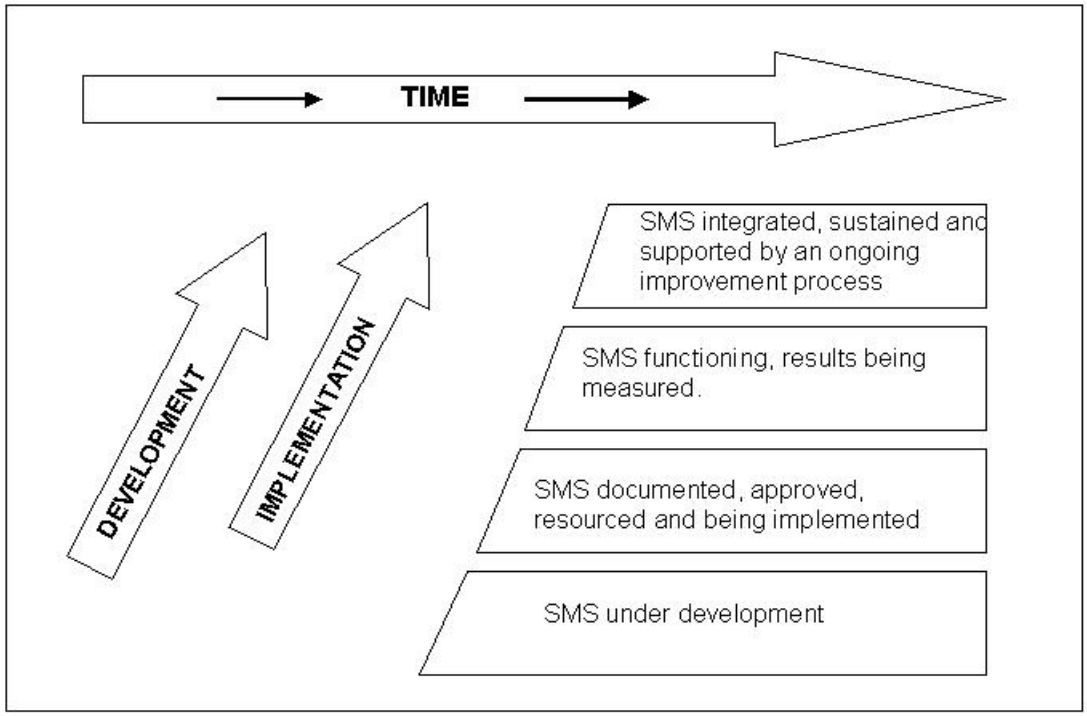
Regulators that oversee process-based SMS often employ system audits to determine whether the SMS processes are effective. Some Authorities measure the processes supporting each component of the SMS. Others measure the company's SMS in its entirety.

Most auditors and inspectors have no experience in leading system audits. Consequently, some agencies train a small cadre of well-respected, experienced inspectors to lead system audits. In others, persons with the appropriate skills are brought in from other parts of the organisation, or are hired from outside. The remainder of the system audit team usually comprises inspectors with expertise in the technical or operational aspects of the services the company provides.

SMS evaluations

A major weakness of a traditional audit is that it measures safety binomially: if the company complies, it "passes" the regulatory safety test.[37] The same test is applied to all service providers, whether it is the twentieth audit of a company that has been in operation for decades, or whether it is the second of a company starting-up. Regulatory expectations do not change. The safety bar is never raised.

Figure 5. **SMS maturation**[38]



Most evaluation tools are designed for an SMS that is structured around a risk-based strategic safety goal (e.g., reducing safety-risks to a level as low as reasonably practicable). As demonstrated in Appendix D, such evaluation tools measure the SMS functionality necessary to achieve the goal. SMS performance is measured by sampling key indicators of functionality, which, when aggregated, measure a company's safety performance. Importantly, the tools identify areas of healthy, positive safety performance, as well as areas requiring improvement.

A well designed performance evaluation tool provides more discerning feedback. However, designing and employing SMS evaluation tools is challenging, which explains in part why few regulators (or companies) currently use performance-based techniques to measure SMS effectiveness.

The logic underlying an SMS evaluation is as follows. The regulator recognises that for very practical reasons, when a company starts to implement an SMS, the SMS has little impact on the company's management of safety-risks. Although the company may be achieving its strategic safety goal of reducing safety-risks to a level as low as reasonably practicable, the contribution of the SMS is minimal. Without the system-wide, proactive safety management enabled by an SMS, risks are not being reduced "to a very low level". However, as the SMS matures and safety management improves, the company's capability to effectively manage safety-risks improves.

The regulator's expectations change accordingly. What initially constituted a regulatory "pass" early in the life of an SMS does not meet the regulator's expectations of acceptable performance as time goes on. Unlike a compliance-based audit, the bar is raised. Lower levels of risk are practicable, and are expected. In the short and middle term, an evaluation tool provides evidence that the company's safety management is more proactive, and more comprehensive and systematic: that the SMS is indeed functioning. In the longer term, the evaluation measures the degree to which the company is consistently managing safety-risks in a dynamic environment: that the functionality of the SMS is embedded in the company's business principles, values and activities.

These changing expectations are depicted in Figure 5**.** As a company starts to implement the SMS, the regulator uses an evaluation tool to gather evidence that the SMS is well designed, and that the implementation plan is sound. The regulator is evaluating the foundation of the future SMS. Later, the regulator uses the same evaluation tool to determine the appropriateness of the company's safety management activities, and to measure the functionality of the SMS. When the SMS is mature and fully functional, the same evaluation tool measures the extent to which proactive safety management is consistently embraced and employed throughout the company.

Furthermore, the regulator's feedback *assists* the company to set priorities for systemic improvements in safety performance, whether the SMS is just being planned, or is fully functional. This is a radical change in the way a regulated entity's safety performance is measured. It has been attempted by very few regulatory bodies.[39] The tools are based in the principles and techniques of formal evaluation.[40]

SMS evaluation tools present other challenges. SMS evaluations must accurately measure a company's capability to proactively manage hazards and safety-risks in a truly dynamic, complex environment. The factors that influence safety-risk management are ever-changing. They can include changes in technology; changes in the expectations of clients, shareholder, stakeholders, even regulatory authorities; fluctuating cash flow; changes in management and the workforce; and changes in company priorities, to list just a few. A successful evaluation tool must be capable first of all of measuring performance, then identifying the (often simultaneous) circumstances that may be influencing the changed or changing performance.

As a regulatory tool, it must provide consistent measures of a single SMS, as well as multiple, diverse SMS. It must measure performance consistently over time. The same protocol is used to measure the safety performance of small and large companies – companies that differ in size and complexity, operate

different equipment in very different physical and operating environments, and are managed by person employing a wide variety of business methods. Even though safety management varies from company to company, the evaluation tool must in all circumstances provide accurate and useful feedback to each service provider.

Despite these challenges, evaluation methodologies offer considerable promise in the future regulation of SMS.

Safety culture assessment tools

There is growing interest amongst rail and aviation regulatory authorities to assess a company's safety culture. This comes from the recognition that an:

> "SMS will not assure safety if it is not used properly, i.e. all staff ... need to be properly aware of its existence, understand its basis, and be motivated to use it…. It is not enough for an organisation to have a good safety management system, because performance is determined by how organisations actually "live" or "act out" their systems. Thus, …[a service provider]… needs both a[n] SMS and a positive Safety Culture in order to be safe." (Skybrary: Interdependence)[41]

Most tools that measure safety culture in transport are under development. The underlying assumptions and methodologies vary considerably. A case study is demonstrated in Box 2.

Box 2. **SAFETY CULTURE ASSESSMENT PROCESS: A EUROPEAN CASE STUDY**

EUROCONTROL has developed a safety culture assessment tool for air navigation service providers (ANSP). The objective is to establish "a widely shared understanding of the organisation's safety culture" and to identify strengths and weaknesses, so that if change is desirable, a way ahead can be planned.

The process employs qualitative and quantitative techniques, and involves:

- a pre-launch phase to prepare the ANSP senior managers and personnel for the assessment and obtain their support
- data collection phases, involving both quantitative processes (questionnaire survey) and qualitative processes (interviews, workshops / focus groups, site visits, reviews of historical information and contextual data analysis, etc.)
- Safety Culture analysis
- Diagnosis, feedback and the way ahead.

ANSP members are encouraged to collaborate with an independent safety culture assessment team (comprising external experts) to facilitate collecting information, analysing the findings, and drawing conclusions for planning and implementing improvements.

The assessment generally includes representatives of the management group and operational staff from each site (e.g., headquarters, regional centres, operational units). A wide, representative range of views is collected from all areas and levels of the ANSP to:

- ensure that the assessment reflects all aspects of the organization's safety culture;
- enable the assessment team to compare and contrast the perceptions of different groups or sub-cultures (e.g., to test whether managers do what they say they do, in the eyes of air traffic controllers); and
- minimise the potential effect of biases that may result from the sample of individuals who interact with the assessment team.

Three to five major areas for improvement are generally identified during a single assessment. Typically, some improvements are easily attained in such areas as communication and safety strategy. Others require considerably more effort.
Because of the time it takes to implement improvement strategies that can be far-reaching as well as far-ranging, and the time it takes to see early outcomes of any improvements, a re-assessment campaign is not usually recommended for at least two to three years.

Source: http://www.skybrary.aero/index.php/Assessing_Safety_Culture_in_ATM

Hybrid assessment tools

Some organisations have experimented with evaluation tools that measure SMS performance as well as safety culture. One such organisation that provides air navigation services and airport management services in numerous jurisdictions globally, created a self-assessment protocol to determine, on an ongoing basis, the degree to which the SMS (at a field unit or regional office) reduces safety-risks to a

level as low as reasonably practicable (Serco, 2006). The tool is described in Appendix D. Similar hybrid tools could be developed and employed by regulatory bodies.

In summary, each type of tool that measures SMS performance has challenges.

- *System audits*
  - They do not measure SMS functionality well, particularly those functions that relate to system safety and safety-risk management.
  - Many regulatory staff lack experience in system audits.
- *Evaluation tools*
  - They are considered experimental by most regulatory bodies and industries.
  - Regulatory staff lack experience in evaluation tools. Many are uncomfortable in their use.
  - At this stage of their development, companies are not likely to understand, value or use the information obtained in an evaluation.
  - Because performance expectations change as an SMS matures, the objective of each assessment must be determined and agreed to. This can confuse expectations.
  - Some organisations have difficulty in providing guidance regarding a pass and a fail.
- *Safety culture assessment tools*
  - Most tools are still under development in transport.
  - There is no universal agreement on methodologies, assumptions, and applicability within and across domains and national cultures.
  - Many appear to be labour intensive and are potentially expensive to administer.
- *Hybrid assessment tools*
  - Like the evaluation and culture tools, they are considered experimental and are not widely embraced by many.

Regulatory focus and priority setting

Many Authorities set regulatory priorities by examining the hazards to which each company is exposed. To aid consistency, some develop a “risk profile” for each company. The profile reflects such factors as the company’s compliance and occurrence record, the hazards associated with its operating environment, the maturity of the company’s SMS, and the degree of change (technical, operational or organisational) that the company is experiencing. In some cases, the profile takes account of financial or other potential organisational stressors (e.g., management turnover). It is periodically updated so managers can adjust the company’s audit cycle, or target the specifics of audits, evaluations or inspections.

Some regulators analyse a sample of company risk profiles to identify weaknesses in the industry’s overall management of safety risks (i.e., system safety deficiencies), or potential deficiencies in the regulatory programme or its application. This information can be used to develop or revise the regulatory agency’s own strategic plan (Figure 6).

Competencies of regulatory managers and staff

Regulatory authorities are generally staffed by inspectors who have decades of experience in their specialised fields. Their professional competencies derive from hands-on experience in managing, operating or maintaining technical systems– far removed from the theories of accident causation or concepts of safety management. We can all envisage that stereotype of the professional inspector: "crusty", "hard-nosed", "long-in-the-tooth, and very, very credible.

We should not be surprised, then, that despite the guidance and training they receive, many experienced inspectors find it difficult to transition to new, SMS-related responsibilities and activities. New competencies are being grafted onto professionals with a very different tradition and skill set.

Addressing gaps in competencies

Some regulatory agencies anticipated the need for different competencies. For example, in 2005 Transport Canada Civil Aviation (TCCA) commissioned a study "to examine the ways by which organisations and regulatory agencies oversee or evaluate the management of safety-risks in safety-critical industries, so the requisite knowledge, skills and competencies could be identified". The report contained information that regulatory managers were subsequently able to use to develop competency models for the workforce, as well as prepare job definitions and work descriptions (SMS Aviation Safety, 2006).

Generally, regulators of transportation industries need persons skilled in process management and application, safety-risk management, audit or evaluation, risk assessments and safety-risk analysis. There remains a strong need for a core of persons with functionally specialised operational expertise – the crusty inspector[42].

Consistency in regulatory oversight

Historically, regulatory authorities encounter difficulties in the consistent delivery of national regulatory programmes. Such difficulties may be exacerbated when introducing SMS.

The SMS regulatory programme is usually developed at HQ with varying degrees of regional input. Despite the development of national guidance material and the delivery of training during the implementation phase, differences in understanding and application often emerge not long after the programme is rolled out. It is true that the differences may reflect longstanding cultural variances that can exist between headquarters and regions, as well as personal rivalries or "turf-related" issues amongst senior managers. But it may also result from misunderstandings of policy or procedure, or from well-intended "workarounds" that individuals or regional offices introduce to achieve the programme's objectives.

Furthermore, there may be weaknesses in the documentation or training of the SMS requirements, regulatory expectations, processes and procedures, as well as in data collection, analysis and management. Such extensive change presents considerable opportunity for managers and staff to misunderstand or misinterpret details relating to new SMS regulatory programme.

Addressing potential inconsistencies in regulatory oversight

The best defence is to anticipate inconsistencies, and develop mechanisms to easily communicate, discuss and address anomalies as they are identified. A well-publicised internal reporting programme can be very useful, especially if the reports are reviewed by a working group comprising persons with different expertise and perspectives. Early days are filled with challenges and surprises. Discrepancies or inconsistencies provide the opportunity to engage many people in improving the new regulatory programme.

Most organisations wait until the programme has stabilised before updating the tools and guidance material, and delivering new training and workshops.

Information management and SSD management

With the SMS regulatory programme in-place, the Authority collects increasing amounts of information from numerous sources.

Most regulatory bodies traditionally operate numerous, dispersed data-bases to administer specific components of the regulatory programme. Among other things, the stand-alone databases often run on different software to: record occurrence information; track audit, inspection and investigation activities, findings and corrective measures; and record and track company-specific data regarding equipment, personnel, certification, and documents. In some organisations, information relating to SMS may be collected in a discreet data base (if the SMS is being managed as a separate regulatory programme), or it may be distributed amongst several systems.

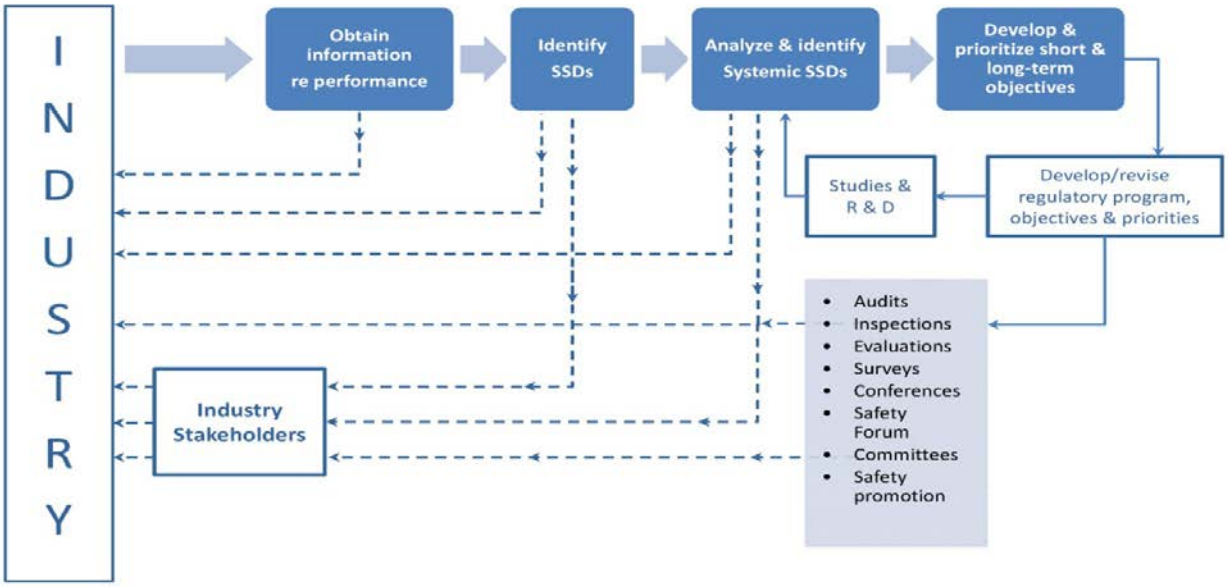
Very seldom do these administrative tools contain explicit information regarding hazards or system safety deficiencies. When they do, the information can only be manipulated to produce descriptive comparisons of data by category or field. The information does not support the analysis or assessment of system safety deficiencies, hazards or risks. In short, managers cannot access or fully understand the plethora of SMS-generated or SMS-relevant information. Consequently, they cannot employ the information to determine system-wide priorities.

Seldom (if ever) do regulatory bodies possess specific repositories of information relating to hazards or system safety deficiencies. In the very few cases they exist, they are almost always programme- or issue-specific (e.g., relating to one or more hazard analysis, risk assessment or safety study), and are not designed for the information to be further analysed.

Consequently, many authorities implementing SMS find themselves drowning in data, but unable to conduct meaningful safety analysis.

A few organisations consider developing processes to systematically translate various forms of information into safety risk management terms (e.g., system safety deficiencies, hazards, risks and mitigation). Using the concept described on pages 28–30, and depicted in Figure 6.

Figure 6. **Obtaining and using SSD information**



regulatory authorities identify SSDs (that exist within the industry they regulate), and trends in SSDs (often originating from their own regulatory programmes). Regulatory managers provide industry with information on systemic strengths and weaknesses in their management of safety risks that otherwise would be unavailable. They also use the information to guide their regulatory priorities, strategies and activities. The creation of a repository for hazard- and SSD-specific information enables existing, programme-specific IM to continue, at least in the short or middle term.

The information enables an A*uthority* to:

- target issues for national accident reduction plans;
- identify operators or areas of functional expertise within the industry that require increased or decreased regulatory oversight;
- identify issues requiring additional study, investigation or data; and
- guide policy- or rule-making initiatives.

The information also enables:

- *industry associations* to aid in setting priorities for improvements in the safety management and performance of their members and constituents; and
- *individual companies* to improve their safety performance by gaining insight from other companies or sectors of the aviation industry.

Addressing safety IT and IM issues

Regulatory authorities need to determine the short-, medium- and long-term information management requirements during the design of the SMS regulatory programme, as solutions will need to be phased-in over time.

A regulatory body should determine as soon as possible the performance requirements for hazard and SSD information management; survey existing data bases and perform a functional gap analysis; develop a viable means to efficiently collect and analyse SSD and hazard-related information; then develop a strategy to design and phase-in the new system or systems.

Organisations should be cautious about merging existing programme-specific databases with a new database for system-wide SSDs. Regulatory managers of existing programmes need stand-alone systems to support their work. But processes can be developed to regularly assess or analyse the contents to identify indicators of hazards or system safety deficiencies, which can then be validated and entered into the SSD database.[43]

Other promising initiatives are underway to employ existing safety information. See for example the multi-tiered safety performance measurement matrix developed by a group of aviation regulatory agencies (SMICG, 2014).

Revisions to regulations and standards

Many of the jurisdictions that first introduced SMS regulations found it necessary to significantly modify their regulations and standards. For example, Canadian Railway Safety Management System Regulations came into force in 2001 as a complement to Transport Canada's rail safety legislative framework. After significant feedback from the industry, and the Department's inspectors in the field,[44] Transport Canada completely overhauled the objective, scope, content and processes. The changes were so comprehensive that the 2001 regulations were repealed and replaced in 2015. Similarly, the European Railway Safety Directive has been recently revised (Directive (EU), 2016/798) to include, among other things, provisions for the application of human factors.

These examples illustrate the challenge of "getting it right" when regulating SMS. Transportation service providers and regulatory agencies should anticipate that requirements will change as the industry and the regulator agency gain experience in operating and overseeing SMS, respectively. By anticipating this need, effective change management strategies and processes can be employed, so that industry and regulatory representatives can identify and report deficiencies as they are uncovered, and remedial strategies or activities can be implemented.

Harmonising SMS regulations nationally

SMS regulations in most jurisdictions have been introduced separately for each mode of transport. In aviation, separate requirements govern different domains (e.g., commercial airlines, airports, air navigation service providers, aircraft maintenance facilities).

Recently, there has been growing interest by State policy makers to harmonise SMS regulations across transport modes. Policy-makers are likely to face challenges in doing so.

As noted throughout this paper, the nature and maturity of SMS in different modes – even in different domains in a single mode – vary considerably. A change in regulatory requirements or in the way a regulatory programme is administered, could endanger achievements to date. Additionally, regulators of the aviation and marine industries have obligations to align their programmes with guidance or criteria

developed by extra-national organisations (i.e., ICAO and IMO in the case of aviation and marine, respectively).

Addressing issues relating to regulatory harmonisation

It is not believed that any state has yet harmonised its SMS regulations for all transport domains. Consequently, there are no direct lessons to be learned.

However, it is still early in the world of regulating SMS in transport. Even those Authorities that were early adopters concede that there is much yet to learn. Unless there are unequivocal gains to be made, policy-makers may wish to delay harmonisation − especially when considering the large commitment of time, energy and money expended by industries and regulatory agencies to-date.

Regulatory fatigue

Regulatory bodies and the industries they regulate commonly experience chronic regulatory fatigue when introducing SMS. As indicated throughout this paper, each stage in the design, implementation and management of the SMS regulatory programme presents numerous challenges to the regulator, and to the industry. The challenges often demand considerable consultation, assessment, study, multi-faceted and iterative decision-making, planning and communication. This all occurs while the day-to-day business of providing and regulating transportation services goes on.

Representatives of regulatory authorities and industry agree that designing, implementing and modifying the legislative framework and regulatory processes can take decades.

6. Summary conclusions and observations

SMS have in all cases been a “step change” in transport safety regulations.

Different legacy regulatory programmes and cultures have strongly influenced the content of SMS regulations, and the way they have been implemented. Consequently, SMS vary significantly across transport domains and jurisdictions. As time goes on, the regulatory environment continues to affect the way novel features of SMS– those relating to system safety, explicit and proactive safety management, and the measurement of SMS performance — are considered.

Consequently, the paper has been structured so that policy makers can identify their location on the regulatory spectrum, and use the experience of others to inform their decisions when designing or modifying SMS requirements. The paper aims to help them anticipate and manage the challenges they are likely to experience.

When designing and implementing an SMS or SMS regulations, I have learned that each project demands a unique approach. Historic or contextual circumstances that cannot be changed are at play. The path to the future needs circumspection, reflection, communication and planning. Seldom does taking the shortest route between two points succeed. To overlook this, to be purely logical and impose significant change on an industry and a regulatory agency because the benefits are so clear, so self-evident, is to create an environment fraught with confusion, frustration and ultimately, resistance. Success will almost certainly be jeopardised, or at best delayed - perhaps for many years.

Consequently, I believe it inappropriate to prepare a long list of recommendations that policy-makers rigidly adopt and implement when designing, adapting or implementing SMS regulations. Rather, I offer a few general suggestions, then conclude with observations for consideration by regulatory policy-makers.

Recommendations

1. *Managing the introduction of SMS regulations*. When preparing to introduce or revise SMS regulations, policy-makers need to carefully consider the industry *and* regulatory objectives of SMS, and then engage representatives from industry and the regulatory authority to actively participate in the design and implementation of the requirements. Wide-reaching, effective communications and strategic planning are necessary, and will require continuous revision in the years that follow. Introducing SMS necessitates commitment, leadership, patience, planning, collaboration, and dynamic, ongoing communications.

2. *Extending system safety concepts beyond the operational delivery of transport services.* Current regulated SMS do not provide the necessary safety management functionality to consistently address the commercial, management and regulatory factors that impede proactive management of safety risks in complex operating environments. At best, a few jurisdictions require companies to set strategic safety targets, or to apply proactive safety management when initiating certain types of commercial, organisational or operational initiatives.

   Each jurisdiction needs to determine the best way to achieve enhanced system safety in their sector. Because of jurisdictional differences, it might be best to:

   - Describe the necessary functionality of a re-scoped SMS, and the current regulatory framework.
   - Conduct a gap analysis to identify areas that need to be addressed, as well as possible mechanisms to address the gaps, which could extend to legislative as well as regulatory changes.
   - Develop strategies for approval, and implementation.

   In the interim, regulatory authorities should actively engage leaders of the financial and insurance industries to encourage the transport industry to adopt system safety concepts and proactively manage safety risks.

3. *Adapting safety risk management terms and techniques to manage organisational factors.* A major shortcoming of all regulated SMS is the absence of mechanisms to explicitly and comprehensively identify, analyse and apply information about hazards, and in particular, system safety deficiencies. Only by using such mechanisms will service providers be able to systematically reduce safety-risks that relate to *all* aspects of the services they provide. The absence of such functionality means that safety management activities do not align with the current understanding of accident causation.

   Each transport sector and each jurisdiction needs to determine the best way to achieve this functionality. It will likely take many years. But it will enable transport industries to understand, analyse, manage and communicate the organisational and operational context that underlie hazards: the presence of system safety deficiencies. It will provide direction, as well as flesh and muscle to existing process-driven SMS. It may cause a step change within a step change, but it will yield considerable value.

Observations

1. *Compliance-based SMS.* Safety regulations traditionally describe minimum criteria that regulatory authorities expect service providers to exceed. In the past, there have been few regulatory incentives for service providers to do so. SMS requirements that are compliance-based perpetuate longstanding industry practices to meet the regulatory minima. The rigidity of many compliance-based SMS requirements can impede industry from enhancing SMS functionality, especially if they wish to introduce performance-based features.

2. *Understanding and measuring SMS and safety performance.* In many cases, the introduction of SMS is causing transport industries and regulatory bodies to move from legacy safety programmes and practices to the management of system performance. The understanding of system performance varies from industry to industry, and jurisdiction to jurisdiction. The differences can have a profound effect on the management of safety-risks. In some cases, performance only takes account of regulatory compliance (i.e., a good SMS is a compliant SMS). In other cases, the focus is on adherence to SMS processes (i.e., a good SMS is one with SMS processes that are demonstrably being employed). In a few, the focus is on a company's integrated safety outputs and outcomes (i.e., a good SMS is an SMS that demonstrates proactive safety management *and* safety performance, company-wide).

3. *Employing readily available information to identify hazards and system safety deficiencies.* Very few regulatory bodies, or for that matter service providers, use the vast amount of available safety-related information to identify hazards and system safety deficiencies. Audits, inspections, occurrence investigations, event reports, operational meetings, management meetings, industry meetings, surveys, and QA findings, to name a few, yield real-time, explicit information about a company's strengths and weaknesses in managing safety-risks.

4. *Regulatory tools.* Most regulatory authorities have adopted new ways to measure a service provider's SMS. If the reasons for the change are not well communicated – to the industry as well as to regulatory staff – the initiative to introduce SMS can be jeopardised.

System audits are frequently employed to determine the effectiveness of SMS *processes*. Additionally, there is growing interest in tools to assess a company's safety culture. A small number of regulators have adapted or are developing evaluation tools to measure the safety performance of a company. The information obtained from these different tools, when analysed, can to varying degrees identify strong and weak safety-risk management, as well as the presence of SSDs.

Regulatory authorities would benefit by drawing on persons with expertise in formal evaluation to guide the development of protocols for measuring SMS and safety performance.

In all cases, regulators have been challenged to:

- develop easy to use, yet rigorous tools
- instill new skills in regulatory staff
- effectively communicate the reasons for adopting new tools, so that the results are understood, and importantly, respected.

5. *SMS-related information management (IM).* Recommendation 3 and observation 3 highlight the importance of *explicitly* identifying and managing hazards and SSDs. Regulatory authorities need to determine the short-, medium- and long-term requirements for information management early in the design phase of the initiative to regulate SMS. Some organisations may need to develop comprehensive systems that can be phased-in over time.
   Furthermore, a forward-thinking regulatory body would be well-served to determine the IM performance requirements for hazard and SSD information; survey existing data bases and perform a functional gap analysis; develop a viable means to efficiently collect and analyse SSD and hazard-related information; then develop a strategy to phase in the new IT system or systems.

   Organisations should be cautious about merging existing programme-specific databases with a new database for system-wide SSDs. Managers of existing operationally-oriented programmes need easily accessible data and information to efficiently administer their programmes. Processes can be developed to regularly access and analyse programme-specific data so that hazards and system safety deficiencies across the company can be identified, validated and managed.

6. *Risk-based decision-making.* In the past, regulatory authorities have been criticised for regulating by rote, implementing audit and inspection programmes on a rigid schedule. Regulatory priorities have not taken account of the degree of risk to which individual companies are exposed (Moshansky, 1992).

   Regulatory organisations are increasingly adopting risk-based decision-making protocols – an evolution that in some cases has coincided with SMS regulations. Some protocols are more formal and comprehensive than others. Some authorities develop risk profiles of individual companies, and use them to plan the scope and frequency of their oversight activities. Others have gone the next step, aggregating and analysing information to determine industry-wide

vulnerabilities in safety-risk management and safety management. The resulting risk-based information is used to establish high-level strategic priorities – for the industry, and for the regulatory authority.

7. *SMS as a long-term initiative.* Many believe that the shift to system-wide, safety-risk management will take at least one generation. Therefore, the transition needs to be managed effectively. Neither the regulatory agency nor the industry can afford to be frustrated or blinded by unrealistic expectations. It will take time. Furthermore, SMS requirements and implementation strategies will almost certainly be revised. There will likely be regulatory, possibly even legislative change, and it may occur more than once. Consequently, there must be long-term, dynamic, two-way communications that is open, respectful and de-politicised.

   Some provide the following advice.

   - Manage political, administrative and industry expectations. Resist resorting to political or administrative expediencies, especially since a government's long-term vision can, for understandable reasons, be remarkably short − more tactical than strategic.
   - Respect and manage industry pressures that are driven by the perceived financial costs of SMS.
   - Anticipate and manage inevitable pressures from various workforces, the media, and advocacy groups that represent interested parties, or society at large. For example, there is bound to be at least one high-profile accident during the many years it takes to introduce and implement SMS regulations. Media coverage is bound to highlight perceived regulatory weaknesses.
   - Develop or promote partnerships that encourage stakeholders such as the insurance and financial industries to promote the benefits of SMS. Also consider developing networks with other jurisdictions or domains to share regulatory experience.

8. *SMS for small service providers.* Most Authorities face numerous challenges when they attempt to regulate SMS for small operators. Some initiatives have been put on hold for a decade or more.
   Regulators might benefit by "going back to the drawing board" to consider ways by which small service providers could achieve the performance that larger service providers obtain through SMS. For instance, they could determine:

   - the desired safety management objectives for small operators, and the regulatory objectives of the Authority;
   - the necessary functionality to achieve the objectives;
   - the mechanisms the regulator would need to oversee the service provider; and
   - the most effective way to transition to the new regulatory programme, including ways by which the regulatory authority could support the industry during the transition.

   Because the SMS of larger organisations would likely differ considerably from that of a small service provider, some regulators are considering a term other than SMS to describe the

requirements for small service providers. They reason that the important thing is to improve and sustain proactive safety management by *all* service providers, not obsessively impose SMS on all and sundry.

9. *Harmonising SMS regulations.* Recently, some regulatory bodies have considered harmonising national SMS requirements for all transport modes (e.g., standardised requirements for railway, marine and aviation, and where appropriate, ground transport).
   Before proceeding, policy-makers may wish to reflect on the influence that past regulatory regimes and industry cultures have had in shaping current SMS requirements. As demonstrated throughout the paper, there are good reasons for the wide range of requirements across jurisdictions. Imposing a regulatory programme that has been successful in one domain does not guarantee success in others.

   Furthermore, changing the requirements for one or more industries may lead to considerable resistance, particularly in light of the large investment some industries have already made to implement SMS.

   Rather than standardising requirements, there may be benefit in focusing on common definitions and risk-based principles. Furthermore, the modal regulatory bodies might wish to develop a common, SSD-focused data warehouse to enable political leaders and executive teams to identify areas of safety-risk vulnerability, as well as areas where one mode could benefit from the experience of others.

Appendix A. SMS evaluation tool

An SMS evaluation protocol was designed by the Bermuda Department of Civil Aviation (BDCA) to measure the SMS of organisations that conduct maintenance on Bermuda-registered, large commercial passenger-carrying aircraft in Eurasia and Asia, and business aircraft operators world-wide. It was also planned that the measurement tool be used to assess the SMS of Bermuda's international airport and the Island's air navigation service provider (BDCA, 2011).

The goal of the evaluation tool is to measure the degree to which the SMS contributes to the company's management of safety-risks to a level as low as reasonably practicable. It is structured on a measurement framework with five areas of functionality. Performance standards for each of the five functions have been written as statements of ideal functionality – narratives that describe excellent performance for each function.

1. *Proactive and comprehensive safety management*. All components of the organisation are actively engaged in and support the proactive management of safety-risks (e.g., operational, technical, financial and HR). Safety-risk management is top-down, and integrated with strategic, business and HR planning and performance measurement. The SMS is aligned with other management systems (e.g., financial, HR and quality). Safety-risk management by contracted service providers, partners and stakeholders (e.g., the certificate holder) is aligned with and contributes to the SMS.

2. *Individual and organisational reliability*. The company's accountable manager is responsible for safety performance, and formally delegates responsibility for specific functions and tasks that are clearly articulated in up-to-date job descriptions. There are neither gaps nor overlaps, and spheres of influence are respected. Managers and staff are qualified and proficient. Procedures are documented, up-to-date and employed by all. Regulatory requirements and other standards are met. Processes to improve organisational and human performance are embraced and valued.

3. *Explicit safety-risk management (SRM)*. Mechanisms are in-place and used to identify, analyse, assess and manage hazards and risks, with a focus on their organisational roots: system safety deficiencies. SRM is conducted in all components of the organisation. Hazard analyses are employed proactively during the development and deployment of technical systems, and during operational and organisational changes. Hazards and SSDs are identified from numerous sources, including reporting programmes, audits and inspections, (operational, safety, management, and executive) committee meetings, evaluations and surveys, contracts, regulatory requirements, etc.). Information is employed in day-to-day and long-term decision-making to improve or sustain safety performance.

4. *Safety Culture*. Everyone in the company understands their role and is committed to sharing information so that the risks related to organisational, human and operational factors are actively managed. Proactive safety management is embraced throughout the organisation. There is free-flow of safety-related information vertically and laterally within and outside the organisation. The positive safety culture provides organisational resiliency, which enables the SMS to remain appropriate and effective, especially during times of change.

5. *Safety measurement*. The organisation seeks and employs feedback regarding the effectiveness of its safety management activities (e.g., internal audits, self-assessments, meeting debriefing, focus groups, safety studies, etc.). The information is used to improve the SMS, the company's other management systems, and the company's safety performance. Measures are used to modify day-to-day activities and priorities, and to influence strategic initiatives.

Each area of functionality is divided into sub-functions to guide the evaluation team in collecting and assessing information. The number of sub-functions varies from four in safety measurement to ten for "explicit SRM".

The evaluator or evaluation team uses these performance statements and the sub-functions to develop a plan to efficiently collect the necessary information, which comprises quantitative, qualitative, objective and subjective information. Multiple lines of evidence are employed to validate and verify the information.

The evaluation team consolidates and assesses the information they collect in the context of each performance standard described above. A rating of 1 (no evidence of, nor plans to institute, the functionality) to 7 (excellent functionality in every regard, across the organisation) is assigned to each function, and supporting evidence documented. This enables a significant amount of complicated and sometimes complex information to be explained and understood by the company and the regulator. Areas of strong and weak performance are readily identified and improvement strategies developed, so that progress can be measured and tracked in subsequent assessments.

By charting the results numerically, variations in performance within different branches or departments of the company can be identified, as can changes in company-wide performance over time.

Information from the evaluation is also assessed to identify system safety deficiencies. Each SSD is assigned a rating of significance (comprising a category of importance and a category of urgency) so the evaluation team can communicate its perception of the risk significance of each SSD.

Appendix B. Summarised characteristics of SMS Types

	SMS Type			
Characteristic	*Compliance-based*	*Compliance with some system safety functionality*	*Process-based*	*Integrated risk- and performance-based*
The accident model on which it is based	none	Reliability model	Model of managing technical and operational systems	Organisational model
The focus of the SMS	Compliance with regulatory requirements	Regulated technical /operational systems	SMS processes	Corporate safety performance
The degree that SMS is integrated with other regulatory requirements	None – stands alone from regulatory requirements	Limited – varies by domain and jurisdiction	Generally – varies by domain and jurisdiction	Completely – SMS acts as regulatory umbrella
The degree that SMS is integrated with company management systems	No integration	At best, restricted to technical systems	Varies by jurisdiction, domain and company	Completely – the strategic safety goal is integrated with enterprise management
The degree of proactive hazard management	none	Hazard Analyses limited to technical systems	Hazard analyses, risk assessments, hazard reports	Hazard analyses and risk assessments that employ human factors
How the SMS is measured	Determine whether components are documented	Determine whether components are used	Audit SMS processes	Evaluate effectiveness of safety-risk management of corporate-wide activities
Miscellaneous features		Quality assurance, engineered human factors[1], investigations seek technical and human failures	Voluntary reports, limited human factors, SMS Office	SMS influences executive planning and decision-making, change management, applied human factors

[1] Behavioural-based approach designed to maximize the reliability of human activities.

Appendix C. Third party auditors

Very few safety regulators of transport industries employ third-party auditors or surveyors[1].One exception is the Marine industry, which has a longstanding tradition around the world of delegating surveyors, certified by a classification society[2], to conduct audits and inspections on behalf of a regulatory authority.

Delegated SMS audits: A case study

Canadian Marine SMS regulations are based on the ISM Code, and have been enabled through Canadian legislation. The SMS regulations came into force in 1998. The *Canada Shipping Act* permits the Minister of Transport to delegate the conduct of SMS audits to organizations and individuals such as classifications societies. Consequently, Transport Canada Marine Safety and Security (TCMSS) oversees the implementation of SMS regulations by contracting *Recognized Organizations* (ROs), as described below.

Transport Canada's oversight of Marine SMS is framed by a comprehensive and long-established network of international conventions, codes and protocols.

The International Marine Organization (IMO), which issued the ISM code, also publishes guidelines for the conduct of an SMS audit. A non-governmental organization− the International Association of Classification Societies (IACS)− is represented in the IMO, and each of the twelve IACS member societies apply IMO-approved interpretations of international statutory regulations when certifying compliance with the regulations on behalf of authorizing flag States, including Canada.

Each classification society:

- Develops minimum experience and other requirements for a surveyor of an SMS;
- Publishes procedures and delivers training based on the guidelines for auditing SMS; and
- Certifies surveyors, and manages the certification process.

TCMSS contracts ROs that are members of a classification society, and oversees the SMS audits they conduct. It periodically audits the RO to ensure compliance with the delegation agreement, and with the RO code issued by IMO.

TCMSS follows a risk-based approach to determine which SMS audits its inspectors will observe as part of its oversight activities of ROs.

The RO issues most statutory certificates on behalf of the Minister.

1 The Aviation Departments from several United Kingdom Overseas Territories (e.g., Bermuda and the Cayman Islands) contract third-party aircraft maintenance surveyors to inspect aircraft on their registry and to audit Maintenance Units located significant distances from the island of registry.

2 A classification society is an organization that establishes and maintains technical standards relating to the construction and operation of ships. The society also, among other things, carries out surveys to ensure compliance with standards.

Appendix D. SMS “hybrid” measurement tool

The protocol evaluates 10 safety management elements or criteria that influence proactive safety management. These include: leadership, safety policy and planning, organisation and responsibilities, standards, documentation and document control, safety-risk management, system safety, change management and abnormal operations, resiliency, audit and evaluation, and safety measurement. Each element has from two to four sub-elements, which provide the evaluator differing lines-of-inquiry to collect and assess information. The evaluator assigns a value of 1 to 4 to reflect increasing degrees of SMS functionality. Scores of 3 and particularly 4 also indicate outcome measures of a positive safety culture.

Charting the results for each of the ten elements (displayed clockwise around a “compass” or “spider web”) enables:

- measures of SMS performance and safety culture to be graphically depicted, with weak performance charted closest to the center, and strong performance charted at the periphery of the circular graph
- comparisons to be made between operational units, or within different branches or functions of the same unit or regional office, so that lessons-learned and best practices can be shared
- performance to be measured over time.

The protocol is simple to understand and use, can be completed by one person or a team, and generates a narrative report that supports the numeric performance measures that are charted and graphed in the appendix.

It was successfully tested on very small units with approximately ten persons, and a medium-sized facility with several hundred managers and staff. It is believed that an unrelated re-organisation and change of management led to the tool being put aside before it could be brought into day-to-day use.

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Notes

[1] Particularly in such non-transport industries as the oil and gas, and petro-chemical industries.

[2] For example, there was a series of aviation accidents in the 1970s in which experienced aircrew flew airworthy aircraft into the ground – or in the case of an accident involving two B747 aircraft at the Tenerife airport, into each other. The investigations did not describe the cause of the accident as "poor airmanship", as had often been done in past investigations. Instead, the findings caused the aviation industry to more comprehensively understand and manage the role of human factors.

[3] In fact, for many years system safety professionals defined "hazards" as technical failures. The first hazard analysis methodologies such as *failure* modes effect analysis (FMEA) focussed exclusively on forecasting the manner and frequency that technical sub-components, components or systems could fail. The definition of a hazard only considered a technical fault or a failure. Dealing with the cause or consequence of a technical failure equated with safety. When new hazard analysis techniques [e.g., *fault* tree analysis (FTA)] were developed to deal with more complicated technology, the focus remained on identifying the causes and consequences of failed components or sub-components.

[4] To illustrate, they included not only safety engineers but ecologists (Kenneth Watt), sociologists (Barry Turner, Dianne Vaughan, Ron Westrum), organisational theorists (Charles Perrow, Karl Weick), political scientists (Scott Sagan), software engineers (Nancy Leveson) and psychologists (James Reason, Nick Pidgeon) to name just a few.

[5] The examples in the paragraph that follows are by no means all-inclusive.

[6] Even if such terms are not always employed.

[7] The following definitions are used. A "non-compliance" is the failure to adhere to an Act or its Regulations. A "non-conformance" is the failure to comply with a requirement, standard, or procedure. See: http://www.qualitygurus.net/Non-conformance+vs+Non-compliance

[8] In some cases, they do not include the designation of an accountable executive, a system for reporting hazards or safety concerns, or the establishment of safety targets.

[9] Continuous improvement is often limited to the SMS, rather than the company's overall safety performance.

[10] In the case of SMS, the programs are for reporting events, hazards and safety concerns.

[11] For instance, the Canadian Rail SMS regulations require "where certain operational changes are proposed, the … [service provider is required to notify the Minister] … in advance of the change being made, and at the request of the Minister, the related risk assessment must be filed with the Minister". Canada Gazette (2015).

[12] "High risk" from the perspective of project management.

[13] Seldom is this articulated as explicitly as it was when the Canadian SMS Rail regulations were gazetted in 2015: regulations that were "*expected to improve the quality of safety management systems in general*, by improving the implementation by the rail industry and enhancing Transport Canada's oversight, *consequently, leading to the improved safety* of Canada's rail transportation sector" [emphasis added]. (Canada Gazette, 2015)

[14] For instance: a company's strategic safety goal may be "to reduce safety risks to a level as low as reasonably practicable". Such a goal when viewed through the "James Reason lens" embeds the understanding that system safety deficiencies and hazards continuously exist in flux. It is a normal state of being. Therefore, SMS polices, processes and activities need to be applied company-wide, including in human and financial resource management. Risk-related data must be understood in terms of system safety deficiencies and hazards. Predictive mechanisms need to be consistently employed to anticipate systemic hazards that continuously emerge because of changing interactions within (and outside) the organisation, the operation and technical systems. Patterns need to be measured and employed to guide tactical and strategic decision. These are the minimum requirements that derive from a strategic, performance-based safety goal comprising just twelve words.

[15] To the extent the process-focussed regulatory requirements impede a company's introduction or operation of a performance-based SMS.

[16] For example, there are some companies that investigate an occurrence not to "find the cause and contributing factors", but to identify potential system safety deficiencies evidenced by the circumstances leading up to, during and recovering from the event. Each SSD is assessed to determine the company's exposure to the associated hazards, so the significance is not limited to the event being investigated, but is understood in terms of the potential present and future safety risk to the company.

[17] To illustrate, stakeholders for an airport would include airport tenants, sub-contracted service providers, airlines, air navigation service providers, municipalities, selected commercial and private property owners in the vicinity of the airport, and many more.

[18] For example, a signed safety policy exists, SMS responsibilities are documented, a procedure for reporting safety concerns exists, etc.

[19] For instance, the inquiry into the fatal accident of an S-92A in 2009 off the shores of Newfoundland (Wells, 2011, v.1); and the Review of the Railway Safety Act (2007).

[20] The fatal accident involved an S-92A, Cougar Flt 491, in March 2009 off the coast of Newfoundland Canada. Although Transport Canada Civil Aviation (TCCA) was responsible for the safety oversight of Cougar Helicopters, the Canada-Newfoundland and Labrador Offshore Petroleum Board (C-NLOPB) was responsible for overseeing the offshore oil industry, including the interface between the petroleum companies and the companies that had been contracted for passenger transportation. Initially, the Bermuda Department of Civil Aviation (BDCA) was neither staffed nor organized to effectively oversee the dramatically increased number of business and commercially-operated aircraft on its aircraft registry.

[21] To emphasise: it is the industry's responsibility to *manage* safety-risks; and the regulatory authority's responsibility to *oversee the industry's management* of safety-risks.

[22] That is not to say that the scope of the SMS regulatory requirements includes a company's Strategic or Business Plan. However, the Safety Plan needs to be aligned with the company's documented vision, and its planned commercial objectives, activities and planned allocation of resources. The focus is squarely on the Safety Plan, and the regulator seeks confidence that the company will support the Safety Plan.

[23] See for instance: http://o.canada.com/uncategorized/are-big-jets-as-safe-as-we-think-some-canadian-experts-say-no

[24] For examples of the wide-range of regulatory-industry relationships, see Fisher (2005).

[25] Stakeholders from industry and the regulatory agency, as well as government support service groups.

[26] Rather than requiring the operator to manage a system that explicitly aims, for instance, to reduce safety risks to a level as low as reasonably practicable.

[27] This confusion frequently exists in the industry, as well as in the regulatory agency. It may be caused by imprecise, circular or contradictory definitions, or by the use of the terms hazard, risk and event interchangeably.

[28] I am always pleasantly surprised by the wealth of valuable safety-risk management information that is collected when conducting an incident investigation with an objective of "identifying potential SSDs evidenced by the circumstances of the occurrence", rather than "determining cause". The same processes for collecting and validating information are employed. However, information about systemic weaknesses in safety-risk management is obtained, even though the SSDs may not have played a significant role in the causal chain of the specific incident that occurred on that particular day.

[29] Of course, the analysis of hazards obtained from these different sources often results in the identification of SSDs.

[30] Or when the change is being implemented during transition.

[31] To be clear: there is benefit in improving SMS processes. However, the regulations should not be constrained to processes, especially at the expense of addressing areas of safety vulnerability.

[32] I am indebted to Bob Dodd, previously of *Qantas Airways* and currently of *The Aloft Group* for drawing my attention to some QMS that have as their goal the management of all types of enterprise risk. He noted that with such QMS, differences between QMS and SMS diminish if not disappear. He highlighted several potential benefits of a risk-based corporate-wide QMS over an SMS. Dodd (2017)

[33] Such as "Company X reduces the safety-risks of its operations to a level as low as reasonably practicable". To achieve this goal, the company must demonstrate that it "knows" and manages the hazards and associated risks to which it is exposed, in current operations, and before changes to the operation or the organization are introduced. The hazards are based in the operating, airspace and natural environment, the equipment it operates, and the organizational context (including financial and HR management, as well as relationships with clients and regulatory agencies). The resulting mitigation strategies are documented, implemented, and evaluated. When SSDs are identified, they guide changes to policies and procedures, both to the operation and to the company's SMS.

[34] Some are aware of techniques that were developed specifically for small operations. For instance, the International Business Aviation Council (IBAC) has provided guidance to its members – many of which operate only one, or just several (often) small, aircraft – to "risk profile" their operations and to conduct and document hazard analyses in several hours. See SMS Aviation Safety (2003c).

[35] Some examples of SMS performance indicators include: attendance at safety meetings; the quality of a risk assessment; the timeliness and nature of follow-up activities to hazard reports; the degree to which safety targets are employed; and the appropriateness of the safety targets in the context of the company's overall safety or regulatory performance.

[36] An audit is defined as a "systematic, independent and documented process for obtaining audit evidence [records, statements of fact or other information which are relevant and verifiable] and evaluating it objectively to determine the extent to which the audit criteria [set of policies, procedures or requirements] are fulfilled." A system audit is normally conducted on a management system. It can be described as a documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the system are appropriate and effective and have been developed, documented, and implemented in accordance and in conjunction with specified requirements. *ISO 19011:2011—Guidelines for auditing management systems*.

[37] I have simplified the characteristics of traditional audits to emphasise the potential strengths of evaluation tools.

[38] Adapted from Fröhlich (1996).

[39] More often it has been implemented by companies, and not shared with regulators.

[40] Formal evaluation methodologies and techniques have almost completely been overlooked in measuring transportation safety. For a general overview, see: http://www.socialresearchmethods.net/kb/intreval.php, and http://www.eval.org/

[41] Similar thinking occurred decades ago in the nuclear energy industry, when safety culture was formally examined after the Chernobyl accident. Subsequently, in the 1990s a number of studies examined the interrelationship between safety management, human factors and safety culture. The nuclear energy industry started promoting integrated management systems by the turn of the century. The International Atomic Energy Association (IAEA) continues to lead the development of safety culture assessment tools in the atomic energy industry. (Haber and Barriere, 1998; IAEA, 1998; Rollenhagen and Wahlstrom, 2007).

[42] The experience obtained in regulating SMS aligns with the results of the 2006 TCCA study, which concluded that "managers and staff … will need strong competencies associated with teamwork, communications, results-management, analysis and judgement and decision-making. It is highly likely that that there will be need for core staff who are specialised in human and organizational factors, risk analysis, the framing of methodologies and measurement of safety performance, as well as those with traditional experience in regulating the technical and operational aspects of aviation" (SMS Aviation Safety, 2006).

[43] For example, a company periodically reviews its QA data base. A QA finding regarding similar errors in the documentation of dangerous goods at a specific field unit is recognized to be a hazard, and is reported in the SMS. Subsequent analysis identifies an SSD regarding a "work around" that has been developed at the Unit, and which has started to become a practice at other units. The scope of the SSD (i.e., system-wide hazard exposure) and the associated risks are assessed, and a mitigating strategy implemented. Similar processes can be employed with operational regulatory information. For instance, a solitary observation of foreign object debris (FOD) by an airport inspector only indicates a one-of hazard. However, other information in the FOD-programme database indicates an SSD relating to the procedures employed by a company providing ground airport services.

[44] As well as observations and recommendations from a Review of the Railway Safety Act (2007).

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