Abstract

This paper outlines a strategic risk based approach to regulation based on the generic regulatory system developed with the participation of nine of Australia’s premier regulatory organisations. The result is a generic strategic management paradigm of regulation and the various behavioural interactions that regulatory systems may utilize. It includes regulatory strategies that may be employed to influence how organisations and people behave, as well as other aspects of regulating, including regulatory metrics, regulatory types, and the mechanisms of regulation. The generic nature of the framework provides for its application in almost any context and to any objective. It also provides for a top-down strategic approach to risk management, an unfortunately all too rare occurrence.

1. Introduction

In 2003, the Royal Australian Navy (RAN) commissioned the two authors to develop an intellectually robust and defendable regulatory framework based on a strategic risk management approach that would accommodate the operational exigencies of a military environment. To achieve this, the team reviewed over 300 articles, papers, instructions and policies and engaged the most significant regulatory agencies in Australia in a study and workshop to firstly define a “generic” regulatory framework considered to be best practice. This “generic” framework formed the basis upon which the RAN tailored and refined its own framework to meet its operational and “duty of care” requirements.

During the conduct of this assignment, all participants believed that regulation was conducted in an identical if not similar way. However, it soon became apparent that this was not the case. Although the reasons for regulation were generally consistent – to modify or control behaviours in people or organisations to reduce and/or manage risk of some sort – the frameworks and methods were very different. One organisation would regulate outcomes to ensure the service provided to the public was achieved, another was regulating the materiel artefacts or technologies to ensure safety was not compromised, another was regulating compliance to black letter and grey letter law, and yet another was looking at the deficiencies in process and how that might compromise the outcomes required. The challenge was to develop a generic regulatory framework that encompassed all approaches.

This was achieved by the weaving of regulatory strategies, regulatory interactions, regulatory types, and regulatory mechanisms into a coherent system wrapped within a three dimensional risk management cube. The result is a comprehensive but generic risk based regulatory system that can be used in any context and has provided a number of new concepts to the regulatory body of knowledge.

The strength of the approach is the comprehensive coverage of all elements of a system no matter the technology, the size and regardless of context. A further strength is the ease with which it can be developed within a software database application to provide the robustness of action and collaboration required of a comprehensive and systematic approach.

An illustration of this strength is that the framework can be applied in almost any context where risk exists and regulation of that risk is required:

- regulating vulnerabilities of infrastructure to terrorist attack;
- regulating opportunities for corruption in policing organisations such as law enforcement, customs, quarantine, and sports drug testing;
- regulating research institution compliance to standards and laws (for example the biotech industry);
- regulating pollution outputs and compliance to environmental requirements by industrial processes and organisations; and
- regulating water flows and restrictions in drought prone areas.
2. The Risk Context

Risk is an intrinsic feature of normal military or industrial/business operations. Accordingly, good leadership and management practices should incorporate ways of eliminating, reducing, or otherwise mitigating against those risks when identified and considered appropriate. Moreover, if systemic failure is considered a result of risk being out of control, then to reduce systemic failure there needs to be a systematic and robust framework in place to ensure that risks are identified and dealt with in a consistent and comprehensive manner throughout the life cycle of any form of system or operation, military or civilian.

The start point is to identify, or where necessary build, the rules to which the organisation and its operations must comply, as well as selecting the systems (or elements of a system) that are to be subject to the rules.

These rules may be implicit (unwritten but understood) or explicit (written and unequivocal). In either case they are the principles that govern conduct, actions, procedures, and arrangements, and determine what is, and is not, acceptable practice or standards. They may be customary, embodied as a code, or prescribed in law, but in the end analysis, they are put in place to modify or control the behaviour of an individual, group or organisation to achieve the aims of the individual, group or organisation or a regulatory authority of some sort such as the industry body or a government department.

A further matter is that once a system sets some rules, or has some rules imposed on it, it should then be subject to regulation of one form or another, if these rules are to be effective. It follows then that regulation may be defined as the embodiment of implicit or explicit laws, rules, codes of practice, and advisory notices by government or other agencies such as the organisation’s OH&S section or an industry association that influence the way organisations, and the people internal and external to those organisations, behave.

Quite plainly, the regulatory body cannot monitor and/or enforce the compliance to every single implicit or explicit rule, nor subject every system within its purview to all the rules. The key questions then are ‘which rules to enforce?’, and ‘which elements of the system should be made to comply?’. Accordingly, a key activity of the regulatory system will be to allocate its limited resources against the areas that pose the most risk to the successful achievement of the required outcomes including the constraints within which it must operate.

The crucial issue is to identify and articulate how the regulatory system might identify all the risks then allocate limited resources to achieve the best overall outcome in support of the regulatory system’s obligations or objectives. In the first instance, an understanding of the

how the Risk, Rules and Regulation might interrelate is useful. Figure 1 illustrates the point that the more risk there is across the three axes, the more rules there perhaps should be and the more regulation there might be.

![Figure 1: Risk, rules and regulation](image)

Of particular note are the three axes, specifically:

- The x-axis indicates the probability of an adverse occurrence with high risk at the top of the axis.
- The y-axis shows the impact of the adverse advent.
- The z-axis shows the risk factor being considered of the system being regulated from high/low to low/high depending on the circumstance. For instance if it is infrastructure vulnerability to terrorist attack being regulated then the z axis would be from low to high. If it was regulating opportunities for corruption it would also be low to high. But if it was the maturity of an industry in terms of industry bodies and industry standards, then it would be from high to low implying less regulation is required when industry maturity is high.

The risk profile of a system or industry is what is likely to, or perhaps more pragmatically should, determine the degree of regulation to be imposed. The higher the risk profile, the more likely regulation is to apply and the more rules there are likely to be to better manage the risk. The notion of a risk profile is illustrated with an expanded diagram of the Three R's in Figure 2 below – the Regulatory Cube. This illustrates that the further into the red a system gets the higher the risk and the higher the risk profile is considered to be, the more rules and regulation there are likely to be. Conversely, the more into the green, the better the risk profile the less rules and regulation there are likely to be.
Therefore, the Three Rs - risk, rules, and regulation embodied in the Regulatory Cube - are the cornerstones to a regulatory framework.

3. **A Regulatory Framework**

However, the question remains “what does a regulatory framework comprise?”. Regulatory Systems or Organisations are not dissimilar to any other form of system of organisation. Ultimately, the organisation has to have a robust strategy for how it intends to achieve its desired outcomes together with all the other aspects of good planning.

To answer the question completely it should first be noted that one of the primary functions of a regulatory body is to permission¹ something (for example an organisation, a ship, an aircraft, a person) against a set of implicit or explicit rules. The amount of rules and the stringency of the permissioning are balanced against the risk the thing poses. Therefore, Regulatory Systems employ regulatory strategies, which are the overarching construct for conducting the necessary functions and tasks to achieve regulatory outcomes aimed at reducing the risk and hence leading to less rules and regulation.

The broad framework construct comprises four different aspects to a Regulatory System. These are illustrated at Figure 3 below.

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¹ Permission means to ‘allow a person or organisation to do something, or to allow something to occur... It is act of permitting... the formal or express allowance or consent... the liberty or licence granted to do something.’ (Macquarie Dictionary 2002) We use the term ‘permissioning’ as the verb.
5. Regulatory Interactions

As stated at the beginning of this paper, it might be considered that the primary purpose of regulation is to influence the behaviour of people and the organisations within which they work. If this is indeed the case, then the primary method of influencing behaviours is through interactions between the various players or participants within the regulatory system. Therefore, in the first instance identifying who those players may be is the key to determining those interactions.

When conducting this analysis and examining the literature, a consistent theme seems to be that there are three primary players in any regulatory system. These are:

- The system conducting the regulation either on its own initiative or on behalf of another body, generally a government body if the focus is on an industry or perhaps a section of an entity if the focus is on an organisation. This we have called the “System Regulating” (SR) or more commonly it is called the “Regulator”.
- Then there is the organisation or system that is the focus of the Regulator’s activities. This we have called the “System Being Regulated” (SBR) because this is exactly what it is when viewed from the Regulators’ perspective. However, from the perspective of the customer that uses or receives the SBR’s products or services, the same organisation the SR calls the SBR is viewed as the “Owner” of the organisation that provides those products and services. Accordingly this body is known as both the SBR and Owner.
- The last player in this system is the “Customer”, “receiver” or the “User” of goods and services provided by the SBR or Owner.

Accordingly, we consider the prime interactions are between Customers (Users), the SBR (Owners), and the SR (Regulator). We have identified nine behavioural interactions and these are:

- complaint
- grievance
- whistleblowing
- illustrative
- rationale
- publicity
- coaching
- challenging, and
- authoritarian.

These interactions are discussed below, with the issue of “primacy of action” being a necessary notion. “Primacy of Action” is best understood when answering
the question “whose responsibility is it to advise the other elements of the issues involved in this regulation?”.

We believe the following exists:

- In some cases it is the Customer who is generally informing one of the others that the system has failed them to some degree.
- In other cases the primacy is with the SBR who is trying to tell the others that they do comply, and perhaps how they comply, with the regulations (no matter what form those regulations take).
- If the SR has primacy, then generally it is educating the others on the compliance issues or insisting that the SBR does comply.

The issue of “primacy of action” may be better understood when these same interactions are illustrated in an “entity/relationship” manner.

Complaint Interaction. The complaint interaction puts the primary onus on the customer or user, with a response from the SBR or owner. This type of approach does not have legally binding rules, and is a very mature system where the SBR accepts that it has moral obligations to the customer or user. The complaint interaction is probably most appropriate where any problem is likely to be a low risk event, with low impact or significance.

Grievance Interaction. The grievance interaction puts the primary onus on the customer or user, with a response from the SR. The grievance interaction is a higher level of the complaint interaction and probably would not work without a complaint system existing at the SBR and owner level. The grievance interaction is probably most appropriate where any problem is likely to be a low risk event, with low impact or significance, and where the industry or organisation is cohesive.

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Whistleblowing Interaction. The whistleblowing interaction is entirely dependent on an operator within the SBR identifying a problem within the SBR and exposing it directly to the SR. The key is that whistleblowing bypasses the SBR and the owner. This interaction might exist where there is mistrust between the operators within the SBR (and perhaps the customers) and the SBR itself. It is likely premised on the existence of black-letter law or mandated codes and standards. The whistleblowing interaction is most likely to occur where the industry or organisation participants do not have a strong regulatory commitment, and the problem has the potential for high impact.

Illustrative Interaction. In this approach, the SBR or owner provides information to the customer or user that informs them in order to inspire confidence in the products or services being sold or used by the Customer. Such information might include quality accreditation, or other industry endorsement. The SBR or owner accepts that it has moral obligations to the customer or user. The illustrative interaction is probably appropriate where any problem is likely to be a low risk event, with low impact or significance. Regulation is possibly achieved through ‘third party’ endorsement, with the implicit threat that this
endorsement may be removed if the industry or organisation is not compliant.

**Rationale Interaction.** The rationale interaction requires the SBR or owner to provide the SR with a logical and thorough body of evidence that inspires confidence that the SBR complies with the rules. The ‘Safety Case’ process is a very good example of a rationale interaction. The rationale interaction is probably particularly appropriate where the problem is high risk and has the potential for high impact, such as a major public health or safety issue.

**Publicity Interaction.** In this approach, the SR or regulator provides information to the customer or user that informs them of the risks associated with various behaviours. This interaction seeks to alleviate the problem by changing the quality of the information available, or by changing its distribution. It achieves improvements by allowing people or organisations to make better-informed decisions. This type of approach does not set legally binding rules on behaviour. Instead, objectives are reached through education and persuasion, and the implicit threat that sanctions might be imposed. The publicity interaction is characterised by the provision of advisory services to achieve policy objectives, targeted individual and collective training, and advertising campaigns. It is probably most appropriate as an adjunct to any strategy.

**Coaching Interaction.** The coaching interaction is a variation of the publicity interaction except that the focus of the information campaign is on the SBR rather than the customer or the user. In addition, there are likely to be formal instruction systems in place. Once again, objectives are reached through education and persuasion, and the implicit threat that sanctions will be imposed. A coaching interaction is probably most appropriate where the organisations and systems are relatively cohesive and mature. It should be noted that some risk is taken on board by the SR in this case.

**Challenging Interaction.** A challenging interaction occurs where the regulator reviews and provides an expert question or test to the SBR or owner, in order to prove risk has been minimised in an acceptable way. A challenging interaction would be appropriate where the problem is high risk and has the potential for high impact, such as a major public health or safety issue. This interaction maintains an arm’s length relationship between the SBR and SR.

**Authoritarian Interaction.** An authoritarian interaction is the traditional approach to regulation – which is sometimes known as ‘command and control’ regulation. This approach is highly prescriptive and has an enforcement component that is backed up by black-letter law and mandated codes and standards. An authoritarian interaction is particularly appropriate where the problem is high risk and has the potential for high impact, such as a major public health or safety issue.

In practice, most regulatory systems are likely to employ combinations of interactions. Which interactions are employed is likely to be largely based on the risk profile. For example, a whistleblowing method is likely to be appropriate where the risk profile is medium to bad. It should not be necessary in an environment where the risk profile is good. Similarly, an authoritarian approach is appropriate where the risk profile is bad, and conversely, it is unlikely to be used where the risk profile is minimal.

This concept is illustrated at Figure 8 below. The X-axis shows the risk profile, and the Y-axis the regulatory interaction. It is evident from the diagram that if the risk profile is low then the complaint, illustrative and publicity regulatory interactions could be used in conjunction with each other to provide regulatory coverage across the totality of the system. Similarly, if the risk profile is bad the regulatory interactions used to complement each other might be, whistleblowing, rationale, challenging, and authoritarian. Indeed the SR may decide to use all the interactions available to it in order to mitigate risk in various parts of the system, and permission something against a set of rules.
6. Regulatory Types

Given that one of the primary functions of a regulatory body is to check and permission something against a set of implicit or explicit rules, we will turn the discussion from Regulatory Strategies and Regulatory Interactions to the types of regulation that may be utilised by a Regulator. Just as Regulatory Strategies use one or more Regulatory Interactions, Regulatory Interactions make use of one or more Regulatory Types. We have defined Regulatory Types by the element of the SBR that is actually being checked and permissioned.

However, to understand this section, it is necessary to first understand the generic construct of a system regardless of what that system comprises or does. This is where our Regulatory Types Model is useful.

The heart of the model is illustrated in Figure 9. The model provides for a cascade of information leading from a conceptual System Statement through Objectives, into the real cost drivers of any system, the Solution Space. In addition to many other utilities, it provides auditable traceability from organisational goals and objectives to be achieved in selected environments, to the actual real objects or artefacts in the real world that produce the required outputs.

Accordingly, when these concepts are integrated, we can identify six Regulating Types.

**Outcome Regulating.** Outcome or Objective Regulating checks and permissions outcomes or objectives alone. Therefore, this Regulatory Type is a test of the complete system’s capability to achieve mission success in the context of the total operational environment. It answers the question ‘does the SBR meet all objectives or outcomes required of it?’ Outcome or Objectives Regulating primarily tests effectiveness.

**Operational Outcome Regulating.** Operational Outcome Regulating checks and permissions solutions against outcomes to establish whether the SBR is ‘doing the right thing.’ An alternative name might “operational test and evaluation”. Operational Outcome Regulating is a test of effectiveness.
“Check” and “permission” the Solutions against what Outcomes they are achieving and whether the Technical Performance Measures of the Solutions when performing the required Tasks or Functions matches or exceeds the Measures of Effectiveness of the required Outcomes. This is “doing the right thing” or Operational Test and Evaluation.

**Functional Regulating**. Functional Regulating checks and permissions processes or tasks and functions alone. It is confirming that the system is ‘doing the tasks it is supposed to do.’ Functional Regulating primarily tests the SBRs effectiveness in performing its agreed role.

**Operational Functional and Performance Regulating**. Operational Functional and Performance Regulating checks and permissions solutions against functions and tasks, to establish whether the SBR is ‘doing it right’ as opposed to ‘doing the right thing’. Operational Functional and Performance Regulating might be considered a test of efficiency.

**Technical Regulating**. Technical Regulating checks and permissions solutions against materiel specifications to establish specification or materiel compliance. It answers the question “does the solution meet or exceed its technical or materiel specifications?”. Technical Regulating is more complex than simply looking at the materiel compliance of a materiel item. Technical Regulating could for example, include checking and permissioning a person’s educational and workplace experience against the criteria of their job description. In this example, the individual’s technical specification is being examined for compliance against the rules that determine the parameters of his/her job. Traditional technical regulation, with its focus on engineering compliance, may therefore be better described as “Materiel Regulation” or “Solution Regulation”.

**Constraint Regulating**. Constraint Regulating checks and permissions solutions against constraints, to establish
the solutions ability to satisfy those constraints. Constraint Regulating is primarily testing effectiveness.

Figure 15: Constraint regulating

Although we might acknowledge that Regulatory Types are required, the case for why they are important has not necessarily been made.

One reason is that Regulatory Types help determine the resources a Regulatory System requires to conduct its business. For example, a regulatory system focusing solely on Functional Regulating need only check that the SBR is doing the things it is supposed to be doing. No measures of quality or consumer satisfaction are required, and the personnel doing the checking do not need or require an intimate understanding of the SBR. Similarly, if the regulatory system focuses solely on Technical (or Material) Regulating then only people who can assess technical material compliance are required.

On the other hand, if the regulatory system intent is to focus on both Operational Outcome Regulating and Operational Functional and Performance Regulating, then a mix of technical and general ‘checkers’ are required. Some of those ‘checkers’ must have a sound knowledge of the SBR and the industry within which it operates.

However, just as importantly, Regulatory Types permit the SR to really focus its efforts into those areas that have the best chance of achieving the regulatory intent, whatever that intent may be.

Therefore, Regulatory Types are important because they give focus to the regulatory system, and help to determine the type and quantity of resources required. Moreover, what Regulatory Types are used is primarily dependant on the SRs strategic intent and what behaviours it wishes to change in response to the risks it has identified within the SBR.

7. Regulatory Mechanisms

Given that there are different types of regulation and different interactions that can be utilised by a Regulator, it stands to reason that the Regulator should also have a series of tools and artefacts by which it authenticates or grants compliance. These we have called Regulating Mechanisms and they remain consistent with the literature on the same subject.

The Regulating Mechanisms are the tools, techniques and artefacts that a Regulator can use to permission something. A non-exhaustive list includes:

- demonstrative devices like, labels, advertisements, notices, annual reports, and safety cases;
- licensing methods like, permits, orders, and certificates;
- policing tools like, investigations, surveys, audits and warrants;
- monetary inducements like, tax incentives, compliance subsidies, fines, entry fees, and taxes;
- disincentives like market quotas; and
- grey letter law like codes and standards.

The Regulating Mechanisms to be used are determined by the Regulatory Strategy, Regulatory Interactions and Regulatory Types employed, as well as the type and quantity of resources that are available.

For example, the warrant is a tool that might be employed within a Mandated Regulation Strategy, the Regulatory Interaction is Authoritarian, and the Regulatory Type might be Technical (or Material) Regulating. A warrant might be used in this context to forcibly check, for example, that a foreign owned aircraft operating in your country meets your country’s technical airworthiness standards.

8. Bringing It Together

It should be considered that there are at least five Regulatory Strategies, nine Regulatory Interactions, six Regulatory Types, and six groups of Regulatory Mechanisms that might be employed in any regulatory system. This gives in excess of 1,297 component permutations available for the design and build of a Regulatory System.

As an example (see Figure 16: Example 1 – co-regulation), a Co-Regulation Strategy, using a Rationale Regulatory Interaction, could focus on Operational Outcomes Regulating, Functional Regulating, and Technical Regulating. Safety Case might be the primary Regulatory Mechanism however, the other Regulatory

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2 Nil Regulation is an option, but is mutually exclusive from the others, hence the figure of 1,297 (4 x 9 x 6 x 6 + 1) instead of 1,620.
Mechanisms employed in conjunction with Safety Case may include:
- a system of external business compliance audits (policing tool);
- a system of internal materiel specification surveys (policing tool);
- orders issued by the owner (grey letter law),
- certificates issued by the regulator (licensing methods); and
- industry developed codes and standards (grey letter law).

In a low risk situation the owner or SBR may elect to implement a Self-Regulation Strategy administered by itself within its own organisation because of the benefits that might accrue from this approach (see Figure 17: Example 2 – self-regulation). The benefits may include greater customer and public confidence in the SBR, increased acceptance of the SBR’s products or services, improved productivity, a safer working environment and perhaps even greater market share.

To support this strategy the SBR might use an Illustrative Regulatory Interaction, supported by Customer Complaint and Grievance Regulatory Interactions. The permissioning focus may be solely on Functional Regulating, and the Regulatory Mechanisms utilised could include demonstrative devices like, labels, advertisements, notices, and self developed grey letter law.

Figure 16: Example 1 – co-regulation

Figure 17: Example 2 – self-regulation

Just as equally, multiple strategies could be in place across the totality of the regulatory system. For example, the SR might choose to use the Co-Regulation Strategy outlined above. The SBR or owner may choose to impose a Mandated Strategy built on black and grey letter law, on its own organisation and people. Alternatively, the SBR might also use a Co-Regulation Strategy within its own organisation, between its corporate headquarters and its various business units.

Plainly this leaves many options for any organisation, body or industry to determine the best balance for its regulatory system.

9. Conclusion

From the forgoing discussion, it is evident that regulation is the embodiment of implicit or explicit laws, rules, codes of practice, and advisory notices by government and other agencies that influence the way an organisation, and the people internal and external to that organisation, behave. We have introduced the concept of the Three R’s - risk, rules, and regulation - and suggested that they are intrinsically related and intertwined as shown in the Regulatory Cube.

We have identified that establishing a risk profile is a seminal step in determining which regulatory strategy and behavioural interaction should be employed.

Finally, regulation should only be used to achieve social, political, and economic objectives that cannot be delivered by other means. If regulation must be used then there are at least 1,297 component permutations available for system design and to achieve the outcomes required of the regulatory system. The determination of which component permutations are to be used is based, in the first instance, on a risk assessment that weighs up the hazard or event likelihood, hazard or event severity, and the risk factor being considered.
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- the Australian Maritime Safety Authority;
- the Civil Aviation Safety Authority;
- the Department of Industry, Tourism and Resources;
- the Det Norske Veritas; and

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11. References

The list of references to this paper number over 300 and runs to over 50 pages. The list is available at http://www.durantlaw.info/presentations_papers/Regulatory_Bibliography.pdf and soon to be available on www.holistech.com.au.